Challenging preoperative guidelines

Qualitative research and implementation studies to optimize preoperative care

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Qualitative research and implementation studies to optimize preoperative care

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Marije Marsman

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Promotor:

Prof. dr. W.A. van Klei

Copromotoren:

Dr. T.H. Kappen

Dr. J.A.R. van Waes

Beoordelingscommissie:

Prof. dr. J.P. Ruurda (voorzitter)

Prof. dr. R.J. Stolker

Prof. dr. J.J.M. van Delden

Prof. dr. F.C. Öner

Prof. dr. S. van Dulmen

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1

GENERAL INTRODUCTION

Introduction

Millions of patients receive anaesthesia for surgery or invasive procedures annually. Anaesthesiology is an unusual medical specialty, since anaesthesia is not a treatment itself, but it is provided to enable other specialties to perform their diagnostic or therapeutic procedures. However, the 'procedure' of anaesthesia delivery is complex, requiring dedicated and specially trained physicians called anaesthesiologists (USA) or anaesthetists (UK) to minimize intraoperative risks and complications.[1] In the previous century the specialty of anaesthesiology focused on preventing and reducing these intraoperative complications. This has been very successful: outcomes have improved and severe intraoperative complications, directly caused by anaesthesia, are rare.[2] Factors that contributed to this improved safety were better monitoring of vital signs, invention of devices to facilitate anaesthesiologists in intubation or locoregional anaesthesia, discovery of new drugs with a better safety profile, and improved team-work reflected in multidisciplinary care and use of practice guidelines.[2 3]

The shift towards perioperative care

Since severe anaesthesia-related intraoperative complications are becoming rare, anaesthesiologists have started to expand their care to the pre- and postoperative period with the intention to prevent postoperative complications, such as postoperative myocardial injury or pulmonary complications, leading to development of preoperative assessment clinics in the previous century.[4] At the preoperative assessment clinic elective patients visit the (nurse-) anaesthesiologist well before their procedure both to assess their health, to optimize medical diseases, to receive information about anaesthesia and to give informed consent. The field of preoperative care is still evolving and new studies aiming to improve patient outcome by optimizing preoperative care are published every day. To help anaesthesiologists in this expanding complexity of modern anaesthesia, many practice guidelines for delivering 'evidence based' perioperative care have been developed.[5 6 7]

Benefits of guidelines

Practice guidelines are intended to help physicians in delivering up-to-date evidence based care. The main objective of practice guidelines is to "systematically develop statements to assist practitioners' decisions about appropriate healthcare for specific clinical circumstances".[8] It is thought that use of practice guidelines (hereafter referred to as

guidelines) lead to more uniform care and improve quality of care, and as a consequence improve patient safety, patient outcomes and cost effectiveness.[9 10]
Currently guidelines are firmly embedded into daily practice.

Limitations in guideline recommendations

Guidelines can have limitations that need to be acknowledged. First, recommendations are preferably based on available research. Randomized controlled trials (RCT's) are regarded as evidence of the highest quality. However, since RCT's are time consuming and costly, especially when outcome parameters are rare, such as with regard to anaesthesia-related complications, adequately powered RCT's in perioperative medicine are rare. As a consequence, recommendations in anaesthesia guidelines are often based on expert opinion rather than on high-quality research findings, leading to perceived insufficient substantiation, which can make interpretation of their recommendations difficult.[11 12] Second, guidelines can base recommendations on older literature, that may no longer be fully applicable to modern anaesthesia practice, such as the value of the self-reported '4 METs' for predicting cardiac complications in combination with all other medical information that is nowadays available for anaesthesiologists.[13] Third, as society is developing, guidelines often fall behind in incorporating potential developments in recommendations. For example, guidelines still recommend in-person preoperative patient education and in-person obtained informed consent, but the use of digital applications for such purposes is becoming popular and imbedded in daily practice. However, current guidelines give no advise how to use such applications.

Limitations in guideline implementation

After publication of a guideline, its recommendations should be interpreted by the target population, i.e. health care workers, and implemented into daily practice. However, interpretation and subsequent implementation of guidelines can be difficult.[14 15] This is beautifully illustrated by the title of a study by Herztum and colleagues: "How come nothing has changed? Reflections on the Fasting-Time Project".[16] This study describes the unsuccessful implementation of a project to reduce preoperative fasting times. Several factors contributed to the failed implementation: a lack of urgency to reduce fasting times by the surgeons or ward nurses, fear of reduced flexibility in the operating schedule and no time to change behavior, because of busy daily practice. Over the years several studies have been published that describe barriers and facilitators for successful guideline implementation.[9 17 18] Barriers

can be divided into personal factors such as physicians' knowledge and attitude, guideline-related factors such as lack of evidence or complexity, and external factors such as lack of resources and social and clinical norms.[9] Facilitators can be broadly divided into workflow-focused strategies and provider-focused strategies.[9]
In this thesis various aspects of barriers and facilitators for guideline implementation in preoperative anaesthesia care will be discussed.

First, I would like to share my personal reflections based on my observations of daily perioperative care that lead to this PhD project.

My personal reflections

Preoperative fasting is required to reduce aspiration risk during anaesthesia, a rare but severe complication in planned procedures. During my residencies I observed that anaesthesiologists, surgeons and nurses dedicatedly followed the fasting guideline with regard to the two hours 'nil by mouth' for clear fluids. However, to simplify daily logistics, patients were often instructed to stop drinking after midnight of the day of surgery, leading to patient discomfort and also contributing to malnourishment in frail patients scheduled for urgent surgery.

Intriguingly, I also noticed that many, most often the more experienced anaesthesiologists and those working in smaller hospitals, had a more liberal view with regard to patients who accidentally drunk within two hours before anticipated anaesthesia induction. Apparently, these anaesthesiologists assessed the risk-benefit ratio differently, if postponing surgery would lead to rescheduling the procedure. Still, they standardly instructed their patients to fast for fluids for at least two hours, because they argued that "We have to follow the guidelines".

For children, fasting duration for fluids was reduced from two hours to one hour in Europe in 2018 after a change of perspective with regard to this risk-benefit ratio: the incidence of regurgitation and aspiration in elective procedures in modern anaesthesia is very low and the benefit with regard to well-being is high.[19]

This combination of observations of daily practice in adults and changes within pediatric literature triggered my curiosity: if we reassess the literature described in guidelines and combine this with observations of daily practice and societal developments (more focus on well-being), should this lead to a change in the fasting policy for adults as well? Can we

successfully implement a new fasting policy after decades of advocating a nil by mouth policy? And how about recommendations in other guidelines?

Case

Mrs de Wit, a frail 82-year-old lady, has broken her hip after stumbling over a carpet in the evening. She is admitted to the hospital at midnight and planned for urgent surgery the next morning. She is instructed to fast for solids, but she is allowed to drink clear fluids until 6:00 AM, because the first surgeries start at 8:00 AM. Unfortunately, that morning patients requiring more urgent surgery appear and Mrs de Wit's surgery is postponed until the evening. Mrs de Wit becomes hungry and thirsty and she feels weak. At 9:00 PM the surgeon comes by and tells her she unfortunately will not get her surgery today anymore, due to other more urgent cases. She is now allowed to eat and drink and she drinks some tea, eats a slice of bread and falls asleep. She is instructed to fast for solids again after midnight and to stop drinking after 6:00 AM. The next morning she wakes up at 7:00 AM and she feels weak, thirsty and hungry, which adds to her depressed mood. At 1:00 PM she finally gets her surgery. During the surgery the anaesthesiologist has to rehydrate her with intravenous fluids, because she is hypotensive. Her recovery is complicated by weakness due to loss of muscle mass. No access to proper drinks and nutrition for almost two days contributed to critical weakening of this frail lady.

Objectives of this thesis

In this thesis four different preoperative guidelines were studied and the following objectives were determined:

- To provide new evidence to improve recommendations of four current preoperative guidelines.
- To study why some preoperative guidelines are firmly embedded in daily practice and others are not and to provide tools to increase implementation.
- To study if developments in digitization and the current focus around patient autonomy and well-being, could be incorporated in current preoperative guidelines, centralized around preoperative fasting and informed consent guidelines.

Outline of this thesis

This thesis consists of three parts.

Part I presents two studies about the use of two different perioperative guidelines in daily clinical care. In the first study (**Chapter 2**) we evaluated the added value of a patient's self-reported ability to 'climb two flights of stairs', e.g. 4 metabolic equivalents (MET), as a marker of exercise capacity. In the European guideline 'Prevention of perioperative cardiac complications in non-cardiac surgery', the assessment of exercise capacity is traditionally a very important predictor of postoperative cardiac complications.[13] It is used for recognizing patients with a potentially increased risk for cardiac complications and is also used to guide further preoperative cardiac testing. In light of the current quality of preoperative assessment, we studied the additional predictive value of the 4 MET cut off.

In the second study (**Chapter 3**) we evaluated the implementation of the Dutch guideline 'Prevention of pulmonary complications after non-pulmonary surgery'.[20] We studied how often this guideline was followed at the preoperative assessment clinic and in the operating room. Next, we qualitatively studied why anaesthesiologists and pulmonologists decided to follow or deviate from the guideline. Results from this study provide insight in why this guideline is not thoroughly implemented and offers various tools for optimization.

Part II of this thesis focuses on the preoperative fasting guideline in adults. Using an implementation study, we implemented a liberal fluid fasting policy in adults. As we were one of the first hospitals that implemented a liberal fluid fasting policy, we evaluated its effect on duration of fasting, well-being and safety (**Chapter 4**). The implementation of this new policy was successful and will be used in the general discussion of this thesis as an example how a guideline can be successfully implemented and how policy evaluation studies could be used in guideline optimization.

We hypothesized that anaesthesiologists could remain sceptic about the safety of a liberal fluid fasting protocol with regard to aspiration, as they might fear high gastric volumes in patients who have drunk within two hours before anaesthesia, because high gastric volume is associated with an increased risk of aspiration before anaesthesia induction. In **Chapter 5** we therefore evaluated the effect of a liberal fluid fasting policy on gastric volume. We measured gastric volumes in patients scheduled for gastroscopy in both the standard and in the liberal fluid fasting protocol.

Part III of this thesis challenges the value of informed consent in anaesthesia in light of advances in digitization and developments in patient autonomy. Informed consent consists of information provisioning and consent. It remains a subject of debate which anaesthetic

risks need to be discussed before obtaining informed consent and what most patients want to know.[21-23] In many countries guidelines state that 'the patient should be aware of any material risks that are involved in the treatment'.[24-27] Material risks are defined as risks that 'a reasonable person, in the patient's position, would be likely to attach significance to, or whether the doctor is or should be aware that the particular patient would be likely to attach significance to it' [Montgomery v Lanarkshire Health Board].[21-23 28 29] The guideline from the Dutch Society of Anaesthesiologists states that informed consent should be asked during an in-person consultation between patient and anaesthesiologist and is based on the Dutch law 'Wet Geneeskundige Behandelovereenkomst' (WGBO).[25 30] We observed that information provisioning has changed from oral consultation to partial or full digital information provisioning by applications in the past few years in The Netherlands. The benefits, risks, indications and limitations of this technology have not been properly studied in anaesthesia and we hypothesized that digitally provided information could replace information provisioning and/or informed consent by the anaesthesiologist. In **Chapter 6** we explored the value of digital information provisioning and e-consent from a patient's perspective in low-risk patients scheduled for minor procedures. From this study we learned that low-risk patients scheduled for minor procedures felt no need for a separate informed consent for anaesthesia. This observation was further explored in a different patient population in **Chapter 7**. In this chapter we aimed to answer several questions related to the need for information about rare but severe anaesthetic risks, the perceived value of a separate anaesthetic informed consent if surgery is perceived inevitable, and the assessment of anesthesic risks as compared to surgical risks and benefits.

The results of the two studies of part III challenge the current vision of informed consent in anaesthesia and expose discrepancies between guidelines and law on the one hand and the patient's perspective and societal developments on the other hand.

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PART I

PREVENTION OF CARDIAC AND PULMONARY COMPLICATIONS IN PATIENTS SCHEDULED FOR NON-CARDIOPULMONARY SURGERY

2

ADDED VALUE OF SUBJECTIVE ASSESSED FUNCTIONAL CAPACITY BEFORE NON-CARDIAC SURGERY IN PREDICTING POSTOPERATIVE INJURY: A COHORT STUDY.

Authors: Marije Marsman, Judith A.R. van Waes, Remco B. Grobben, Corien S.A. Weersink, Wilton A. van Klei

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Abstract

Background: Functional capacity is used as an indicator for cardiac testing before non-cardiac surgery and is often performed subjectively. However, the value of subjectively estimated functional capacity in predicting cardiac complications is under debate. We determined the predictive value of subjectively assessed functional capacity on postoperative cardiac complications and mortality.

Design: An observational cohort study in patients aged 60 years and over undergoing elective inpatient non-cardiac surgery in a tertiary referral hospital.

Methods: Subjective functional capacity was determined by anaesthesiologists. The primary outcome was postoperative myocardial injury. Secondary outcomes were postoperative inhospital myocardial infarction and one year mortality. Logistic regression analysis and area under the receiver operating curves were used to determine the added value of functional capacity.

Results: A total of 4879 patients was included; 824 (17%) patients had a poor subjective functional capacity. Postoperative myocardial injury occurred in 718 patients (15%). Poor functional capacity was associated with myocardial injury (relative risk (RR) 1.7, 95% confidence interval (CI) 1.5–2.0; $P<0.001$), postoperative myocardial infarction (RR 2.9, 95% CI 1.9–4.2; $P<0.001$) and one year mortality (RR 1.7, 95% CI 1.4–2.0; $P<0.001$). After adjustment for other predictors, functional capacity was still a significant predictor for myocardial injury (odds ratio (OR) 1.3, 95% CI 1.0–1.7; $P=0.023$), postoperative myocardial infarction (OR 2.0, 95% CI 1.3–3.0; $P=0.002$) and one year mortality (OR 1.4, 95% CI 1.1–1.8; $P=0.003$), but had no added value on top of other predictors.

Conclusions: Subjectively assessed functional capacity is a predictor of postoperative myocardial injury and death, but had no added value on top of other preoperative predictors.

Introduction

Cardiac events are among the most important complications after surgery and therefore preoperative cardiac risk assessment is essential.[1] According to current guidelines, estimation of preoperative functional capacity is a key tool in cardiac risk assessment and is used to guide the need for additional cardiac testing.[2,3] A functional capacity of less than four metabolic equivalents (MET) is associated with an increased cardiac risk.[2-5]

The gold standard to determine a patient's functional capacity is cardiopulmonary exercise testing (CPET).[6,7] Although poor functional capacity as measured by CPET is a reasonable predictor of postoperative complications, CPET testing is not widely used, because it is time consuming and expensive. Therefore, in daily practice, preoperative functional capacity is often estimated by the patient's self-reported activity, clinical observation during preoperative assessment, or a questionnaire like the Duke Activity Status Index questionnaire (DASI).[4,5,8,9] Although subjective assessment of functional capacity is an easy and widely used method, there is conflicting evidence whether it is a good predictor of postoperative cardiac complications.[4,5,8,10-17] Recently, a large study showed that preoperative subjective assessment of functional capacity neither accurately identified patients with poor cardiopulmonary fitness nor predicted postoperative morbidity and mortality.[17] The authors therefore recommended that subjective assessment should no longer be used. Despite this, subjective preoperative assessment of functional capacity is a widespread practice and changing long existing habits and incorporating new evidence into guidelines often requires several studies that confirm previous findings.

Therefore, we aimed to determine the added value of subjectively assessed functional capacity for predicting postoperative myocardial injury and infarction in elective surgical patients, on top of other preoperative predictors.

Methods

Study Population

This cohort study included patients aged 60 years and over who underwent elective non-cardiac surgery under general or spinal anaesthesia with an expected postoperative length of hospital stay of at least 24 hours. Surgery took place at the University Medical Center Utrecht, a tertiary referral hospital in The Netherlands, between 1 July 2011, and 31 December 2014. A part of this cohort was included in previous publications.[18 19] For patients who underwent surgery more than once within one year, only the first surgery was included in the analysis. The local medical ethics committee waived the need for informed consent because only routinely collected patient data were used and data were anonymized before analysis (University Medical Center Utrecht Medical Research Ethics Committee 11–120/C and 18-762/C).

Data collection

Data were obtained from electronic medical records. The Dutch municipal personal record database was consulted for mortality data.

Preoperative assessment

All patients visited the preoperative anaesthesia assessment clinic where medical history, physical examination and if indicated, further diagnostic testing was performed. Patients filled out a short questionnaire with regard to functional capacity (Supplemental Table 1). Functional capacity was estimated by anamnesis and physical examination by the attending anaesthesiologist or anaesthesia nurse. It was reported as poor (1-3 MET), moderate (4-7 MET), good (8-10 MET), high (>10 MET), or unknown in patients who were not able to perform any physical activity.

Outcomes

The primary outcome was postoperative myocardial injury, defined as a Troponin-I elevation (>60 ng/L) within the first three postoperative days. Troponin I was analyzed using the third-generation enhanced AccuTnI assay (Beckman Coulter, Brea, CA). According to our postoperative care protocol, troponin was measured routinely on these first three days after surgery. The cut-off value of 60 ng/L was the 99th percentile with a variation coefficient less than 10%, in accordance with the fourth universal definition of myocardial infarction.[20]

Secondary outcomes included postoperative inhospital myocardial infarction (POMI), defined according to the fourth universal definition of myocardial infarction, and all-cause one year mortality.[20] Clinical assessment of POMI was performed by a consultant cardiologist, in addition to retrospective adjudication by an independent cardiologist (RBG).[18,19]

Statistical analysis

Baseline characteristics were calculated as means, medians or percentages where appropriate. Data on functional capacity were missing in 7% of patients. These data were imputed using a multiple imputation model including patient characteristics, comorbidities and primary outcome data. Five data sets were imputed by the method of fully conditional specification.

Functional capacity was dichotomized into poor (<4 MET) and normal (≥4 MET), in accordance to international guidelines.[2,3] Patients in whom the functional capacity was reported as unknown were classified as having a poor functional capacity because the functional capacity in these patients is likely poor.[4]

Baseline characteristics were compared between patients with a poor and a normal functional capacity, by using the chi-square test for categorical variables and the t-test for continuous variables.

Next, the incidences of the primary and secondary outcomes were compared between patients with a poor and normal functional capacity using the chi-square test, and relative risks (RR) were calculated. Univariable logistic regression analysis was used to determine the predictive value of functional capacity on myocardial injury. Consequently two regression models were built, in order to determine the added predictive value of functional capacity on top of other known preoperative predictors of mortality or cardiac complications, including the variables from the Revised Cardiac Risk Index (RCRI).[21] The first model included the individual variables from the RCRI, and variables that were significantly associated with the outcome in the univariable analysis. In the second model, functional capacity was added to the variables from the first model. The added predictive value of functional capacity was determined by comparing the Area Under the Receiver Operating Curve (AUROC) of the two aforementioned models. Finally, the positive and negative predictive values of functional capacity were determined.

Subsequently, incidences of inhospital POMI and one year mortality were compared between patients with a poor and normal functional capacity using the chi-square test, and relative

risks were calculated. Multivariable logistic regression analysis was used to determine the added predictive value of functional capacity on top of other preoperative predictors for inhospital POMI and one year mortality. The variables used in the two regression models for one year mortality were the same as in the model for myocardial injury. Because the incidence of POMI was low, the number of variables in the two regression models for POMI was limited. Therefore only two variables were included in the first model, namely age and RCRI and in the second model age, RCRI and functional capacity.

In a post-hoc sensitivity analysis, the analysis was repeated in complete cases only, hence after excluding patients with missing data for functional capacity.

Finally, differences between the patient's self-reported functional capacity and the physician's reported functional capacity were determined.

Throughout the analysis, a p-value of less than 0.05 was considered statistically significant. The statistical analysis was performed by using SPSS (Release 25 for Windows).

Results

In total, 4,879 patients were included. Data on subjective functional capacity were missing in 357 patients (7%). Missing values were imputed and compared with the original data (Supplemental Table 2). After imputation 824 patients (17%) were classified as having poor functional capacity, and 4,055 patients (83%) as having normal functional capacity. Patients with poor functional capacity were older and had more comorbidities as compared to patients with normal functional capacity (Table 1).

Table 1. Baseline characteristics in patients with poor and normal functional capacity.

	Poor functional capacity N=824	Normal functional capacity N=4055	P-value
Mean age in years (SD)	73.6 (7.9)	70.1 (6.8)	<0.001
Sex (female/male)	424/400 (51/49)	1,905/2,150 (47/53)	0.020
Mean BMI in kg m^{-2} (SD) †	27.0 (5.5)	26.0 (4.2)	<0.001
Smoking	180 (22)	689 (17)	0.001
COPD‡	139 (17)	308 (8)	<0.001
Hypertension	547 (66)	2,089 (52)	<0.001
Diabetes	254 (33)	613 (15)	<0.001
History of ischemic heart disease	218 (26)	537 (13)	<0.001
History of chronic heart failure	57 (7)	52 (1)	<0.001
History of (paroxysmal) atrial fibrillation	128 (16)	336 (8)	<0.001
Pacemaker and/or ICD§	53 (6)	62(2)	<0.001
History of cerebrovascular disease	232 (28)	541 (13)	<0.001
History of preoperative renal failure	129 (16)	260 (6)	<0.001
History of peripheral vascular disease	164 (20)	362 (9)	<0.001
Betablocker	346 (42)	1,176 (29)	<0.001
Calciumchannel blocker	190 (23)	698 (17)	<0.001
ACE-inhibitor/Angiotensin receptorblocker	379 (46)	1,460 (36)	<0.001
Diuretics	321 (39)	1,014 (25)	<0.001
Aspirin	329 (40)	1,135 (28)	<0.001
Warfarin	140 (17)	324 (8)	<0.001
Oral antidiabetics	173 (21)	446 (11)	<0.001
Insulin	91 (11)	203 (5)	<0.001
Statins	396 (48)	1,622 (40)	<0.001
High risk surgery	273 (33)	1513 (37)	0.031
ASA classification*			<0.001
I	9 (1)	559 (14)	
II	297 (36)	2884 (71)	
≥III	518 (63)	612 (15)	

	Poor functional capacity N=824	Normal functional capacity N=4055	P-value
RCRI class||			<0.001
I	263 (32)	1911 (47)	
II	279 (34)	1404 (35)	
III	160 (19)	561 (14)	
IV	12 (15)	179 (4)	
Surgical specialty			<0.001
General	152 (19)	902 (22)	
Neurosurgery	162 (20)	808 (20)	
Ear Nose Throat	107 (13)	566 (14)	
Vascular	182 (22)	616 (15)	
Orthopedics	159 (19)	441 (11)	
Uro-genital	63 (8)	721 (18)	
Self-reported limitation in functional capacity			
Yes	636 (77)	2084 (51)	<0.001
Missing	138 (17)	552 (14)	

Figures are numbers (%) of patients, unless stated otherwise.

* ASA classification, physical status according to American Society of Anaesthesiology. † BMI, Body Mass Index. ‡ COPD, Chronic Obstructive Pulmonary Disease. § ICD, implantable cardioverter defibrillator. || RCRI, Revised Cardiac Risk Index. Diabetes included patients with oral antidiabetics and/or insulin. History of ischemic heart disease is defined as a history of previous myocardial infarction and/or previous revascularization. Heart failure is defined as a left ventricular ejection fraction (LVEF) < 40%. History of cerebrovascular disease is defined as a history of transient ischemic attack (TIA) and/or cerebrovascular accident (CVA). Renal failure is defined as a Glomular Filtration Rate (GFR) < 45 ml/min.

Primary outcome

Postoperative myocardial injury occurred in 718 patients (15%): in 184 patients (22%) with poor functional capacity as compared to 534 patients (13%) with normal functional capacity (RR 1.7; 95% CI 1.5-2.0; p<0.001). The AUROC of the model including only functional capacity was 0.55. The positive predictive value of poor functional capacity on myocardial injury was 22% and the negative predictive value was 87%. After adjustment for other preoperative predictors (age, sex, body mass index (BMI), American Society of Anaesthesiology (ASA) classification, and high risk surgery), functional capacity was an independent predictor of postoperative myocardial injury (Table 2). However, adding functional capacity to a multivariable model including these predictors, did not improve the predictive value for postoperative myocardial injury (AUROC 0.70 vs 0.70, respectively).

The post-hoc sensitivity analysis including complete cases only yielded similar results.

Table 2. Association between patient characteristics and postoperative myocardial injury.

Variable	Odds ratio (unadjusted)	95% CI	P-value	Odds ratio (adjusted)	95% CI	P-value
Poor functional capacity	1.9	1.6-2.4	< 0.001	1.3	1.0-1.7	0.023
ASA*						
II	1.9	1.3-2.6	<0.001	1.2	0.9-1.8	0.243
III-IV	3.6	2.5-5.0	<0.001	1.3	0.9-2.0	0.168
Age	1.05	1.04-1.06	<0.001	1.04	1.02-1.05	<0.001
Female sex	0.8	0.7-0.9	0.001	0.92	0.8-1.1	0.337
BMI†	0.98	0.96-0.99	0.009	0.97	0.95-0.99	0.001
Smoking	1.3	1.1-1.6	0.005	1.4	1.1-1.8	0.001
COPD‡	1.5	1.2-1.9	0.002	1.07	0.8-1.4	0.634
Diabetes	1.5	1.3-1.8	<0.001	1.2	0.99-1.5	0.056
Hypertension	1.6	1.4-1.9	<0.001	1.2	1.01-1.5	0.031
History of ischemic heart disease	2.0	1.6-2.4	<0.001	1.2	1.02-1.5	0.049
History of chronic heart failure	4.1	2.8-6.1	<0.001	2.3	1.5-3.6	0.001
History of (paroxysmal) atrial fibrillation	1.9	1.5-2.4	<0.001	1.4	1.08-1.8	0.010
Pacemaker and/or ICD§	2.4	1.6-3.7	<0.001	1.2	0.8-1.9	0.412
History of cerebrovascular disease	1.3	1.0-1.5	<0.033	0.8	0.6-0.9	0.013
History of peripheral vascular disease	2.0	1.6-2.5	<0.001	1.3	0.98-1.6	0.078
Preoperative renal failure	3.3	2.7-4.2	<0.001	2.1	1.9-2.8	<0.001
High risk surgery	2.3	1.9-2.7	<0.01	2.2	1.9-2.6	<0.0001

* ASA classification, physical status according to American Society of Anaesthesiology. † BMI, Body Mass Index. ‡ COPD, Chronic Obstructive Pulmonary Disease. § ICD, implantable cardioverter defibrillator.

Secondary outcomes

POMI was diagnosed in 39 patients (5%) with poor functional capacity as compared to 67 patients (2%) with normal functional capacity (RR 2.9; 95% CI 1.9-4.4, p<0.001). One year mortality occurred in 170 patients (21%) with poor functional capacity as compared to 499 patients (12%) with normal functional capacity (RR 1.7; 95% CI 1.4-2.0; p<0.001). After adjustment, functional capacity was an independent predictor of POMI (Table 3) and one year mortality (Table 4). The predictive value of a model for myocardial infarction, consisting of age and RCRI from the adjusted regression model, had an AUROC of 0.71. Adding functional capacity to this model did not change this (AUROC 0.71).

Table 3. Association between patient characteristics and postoperative myocardial infarction.

Variable	Odds ratio (unadjusted)	95% CI	P-value	Odds ratio (adjusted)	95% CI	P-value
Poor functional capacity RCRI ‖	2.9	1.9-4.4	<0.001	2.0	1.3-3.0	0.002
II	2.3	1.3-4.0	0.002	2.2	1.3-3.8	0.004
III	3.8	2.1-6.9	<0.001	3.2	1.8-5.8	<0.001
IV	8.1	4.3-15	<0.001	5.8	3.1-11	<0.001
ASA*	9.8	1.3-71	0.024			
II	27	3.7-194	0.001			
III-IV						
Age	1.06	1.03-1.08	<0.001	1.04	1.01-1.06	0.008
Female sex	0.8	0.5-1.2	0.272			
BMI†	0.96	0.9-1.0	0.098			
Smoking	1.6	1.0-2.5	0.039			
COPD‡	1.8	1.0-3.1	0.035			
Diabetes	1.3	0.8-2.1	0.286			
Hypertension	2.4	1.6-3.7	<0.001			
History of ischemic heart disease	3.4	2.3-5.1	<0.001			
History of chronic heart failure	3.2	1.5-7.1	0.004			
History of (paroxysmal) atrial fibrillation	3.0	1.9-4.8	<0.001			
Pacemaker and/or ICD§	2.6	1.1-6.0	0.027			
History of cerebrovascular disease	1.4	0.9-2.6	0.163			
History of peripheral vascular disease	3.1	2.0-4.8	<0.001			
Preoperative renal failure	4.4	2.8-6.8	<0.001			
High risk surgery	2.0	1.4-3.0	<0.001			

* ASA classification, physical status according to American Society of Anaesthesiology. † BMI, Body Mass Index. ‡ COPD, Chronic Obstructive Pulmonary Disease. **§** ICD, implantable cardioverter defibrillator. **‖** RCRI, Revised Cardiac Risk Index.

Table 4. Association between patient characteristics and one year mortality.

Variable	Odds ratio (unadjusted)	95% CI	P-value	Odds ratio (adjusted)	95% CI	P-value
Poor functional capacity	1.9	1.5-2.3	<0.001	1.4	1.1-1.8	0.003
ASA*						
II	1.4	1.0-1.9	0.031	1.6	1.2-2.2	0.005
III-IV	2.6	1.9-3.6	<0.001	2.7	1.8-4.0	
Age	1.04	1.02-1.05	<0.001	1.02	1.01-1.04	<0.001
Female sex	0.7	0.6-0.9	0.001	0.7	0.6-0.9	<0.001
BMI†	0.9	0.93-0.97	<0.001	0.94	0.92-0.96	<0.001
Smoking	0.9	0.7-1.2	0.483	0.9	0.7-1.1	0.364
COPD‡	1.1	0.8-1.4	0.513	0.9	0.6-1.2	0.345
Diabetes	1.3	1.1-1.6	0.013	1.3	1.0-1.6	0.045
Hypertension	0.9	0.8-1.0	0.159	0.8	0.6-0.9	0.004
History of ischemic heart disease	1.3	1.0-1.6	0.026	0.9	0.7-1.2	0.580
History of chronic heart failure	2.0	1.3-3.1	0.002	1.2	0.7-1.2	0.512
History of (paroxysmal) atrial fibrillation	1.4	1.1-1.8	0.006	1.1	0.8-1.4	0.476
Pacemaker and/or ICD§	1.2	0.7-2.0	0.522	1.1	0.4-1.2	0.157
History of cerebrovascular disease	0.8	0.7-1.1	0.131	0.6	0.5-0.8	0.001
History of peripheral vascular disease	1.0	0.7-1.3	0.860	0.7	0.5-1.0	0.032
Preoperative renal failure	2.1	1.6-2.7	<0.001	1.6	1.2-2.0	0.001
High risk surgery	1.0	0.9-1.2	0.804	1.0	0.8-1.2	0.996

*ASA classification, physical status according to American Society of Anaesthesiology. †BMI, Body Mass Index. ‡COPD, Chronic Obstructive Pulmonary Disease. § ICD, implantable cardioverter defibrillator.

The predictive value of the multivariable model for mortality (consisting of the variables age, sex, BMI, ASA classification, comorbidities, and high risk surgery) had an AUROC of 0.65. Adding functional capacity to this model did not change the predictive value (0.65).

The post-hoc analysis in patients without missing data again showed comparable results for all these outcomes.

With regard to the self-reported functional capacity, 690 patients (14%) did not report their functional capacity. Of the 4,189 patients who did report, 1,469 patients (35%) reported no limitations. The 2,720 patients with self-reported limitations, stated this was most often to be due to nerve/joint/muscular problems (N=393, 14%), low endurance (N=404, 15%), fatigue (N=262, 10%), or multiple reasons (N=1,469, 50%). When comparing patients' and

physicians' estimations in the 4,189 patients with self-reported functional capacity, we found a discrepancy in 2,134 patients (51%). Fifty patients (1%) who self-reported having 'no limitations', were classified by the physician as having poor functional capacity, and 2,084 (50%) patients who self-reported having limitations were classified by the physician as having normal functional capacity. Functional capacity was estimated by both patient and physician as poor in 636 patients (15%) and as normal in 1,419 patients (34%).

Discussion

In this cohort study including older patients undergoing elective non-cardiac surgery, subjective estimation of functional capacity before surgery was significantly associated with postoperative myocardial injury, POMI and mortality. Patients assessed as having poor functional capacity had a slightly increased risk of postoperative myocardial injury (OR 1.3), POMI (OR 1.7) and death (OR 1.4). However, in predicting these events such subjective assessment had no added value on top of other preoperative predictors.

Literature

Several other studies investigated the relationship between subjectively assessed functional capacity and postoperative (cardiac) complications, with conflicting results.

Reilly and colleagues found that self-reported poor functional capacity was an independent predictor of cardiac ischemia and cardiovascular complications on top of other patient characteristics, including age, in patients undergoing major surgery.[4] A study of Shah and colleagues in patients with pulmonary hypertension also showed that a patient's self-reported poor functional capacity was associated with longer lengths of hospital stay and major complications.[15] However, in these studies the added value of functional capacity was not determined, nor were troponin levels monitored.

The added value on top of other known information was determined in a study by Wiklund and colleagues in 5,939 patients undergoing elective non-cardiac surgery.[5] They found that subjective assessment of functional capacity predicted postoperative cardiac complications in univariable analysis, but that it had no added predictive value on top of age and ASA classification, which is in accordance with our study.[5] The METS study, a recent cohort study in 1,401 patients undergoing major non-cardiac surgery showed no added predictive value of the physician's subjective assessment of functional capacity on patient outcomes, including myocardial injury, 30 day mortality and one year mortality.[17]

The lack of additive effect of subjectively assessed functional capacity may be explained by the physicians' inability to correctly estimate functional capacity based on anamnesis and short clinical observation. This was also observed in the METS study; only 15% of patients with a low DASI were correctly assessed by physicians as having low functional capacity. However, in patients with higher DASI scores, 97% of the physicians estimated them as having moderate to good exercise capacity.[22] The DASI questionnaire is a more objective measure of functional capacity and an easier and cheaper method of estimating functional capacity as compared to CPET testing. [8-12,16,23-25] In the METS study, the DASI was significantly associated with myocardial injury and death after adjustment for other variables.[17]

Another test to determine functional capacity more objectively is the six-minute walk test (6MWT). Several studies have determined the relation between 6MWT and postoperative (cardiac) complications and mortality.[23,26-28] These studies showed conflicting results but overall no good relation between the 6MWT and postoperative complications.[25] However, some more recent studies showed a good relation between a low 6MWT and cardiopulmonary complications.[26,27] Finally, a recent study by Shulman and colleagues in patients undergoing major surgery showed that the 6MWT was predictive of death and myocardial infarction.[28]

Gait speed is another test for functional capacity and is used in elderly patients in the assessment of frailty.[29] There is a relation between low gait speed and increased mortality in elderly patients undergoing cardiac surgery.[30,31] In a study of Kamiya gait speed was comparable to the 6MWT in a subgroup of patients undergoing cardiac surgery.[31] No studies have compared gait speed with 6MWT with regard to myocardial injury and mortality in patients undergoing non-cardiac surgery.

Strengths and weaknesses

A major strength of our study is the routine postoperative assessment of myocardial injury by troponin measurements, which makes it unlikely that early postoperative cardiac events were missed. Although this clinical protocol was not always followed as troponin was not measured in 10% of the patients, these missing likely were random as reported previously in a part of this cohort.[19] This study also has some weaknesses. First, data on functional capacity were missing in 7% of patients. However, these data were imputed because these were likely not missing at random, and we also performed a post-hoc complete case analysis that did not change the results. Second, because CPET was not performed, we could not determine whether the subjectively estimated functional capacity correlated to the actual functional

capacity. Finally, as the assessment of functional capacity was not standardized, this may have varied between individual physicians, which may have influenced the results. However, this variation in assessments also reflects daily practice.

Clinical implications and addition of knowledge

Few aforementioned studies determined the added value of functional capacity tests. Our study, including a large number of patients, confirmed the results from the METS study and adds new insight in the additive effect of subjective functional capacity on other preoperative predictors.[17]

Future directions

Given the findings from these studies it could be considered to use more objective tools to assess preoperative functional capacity, such as the DASI or other structured questionnaires. Currently, the MET REPAIR study is recruiting patients to assess the value of preoperative functional capacity as assessed by a structured questionnaire in predicting (cardiac) complications and death.[32] It is of interest whether this has any added value on top of other preoperative variables to estimate functional capacity. In the light of limited (human) resources in medicine, questionnaires such as the DASI, and more objective tools to estimate functional capacity such as the 6MWT and gait speed should only be used if they have any additive value, because although these are simple to perform, still cost time and manpower.

Conclusion

In patients undergoing non-cardiac surgery, subjectively assessed preoperative functional capacity was a predictor of postoperative myocardial injury, infarction and death, but had no added value on top of other preoperative predictors.

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Supplemental Table 1. Patient questionnaire with regard to functional capacity.

'Do you experience limitations with exercising?' **(multiple answers possible)**	• No • Yes, because of fatigue • Yes, because of dyspnea • Yes, because of chest pain • Yes, because of low endurance • Yes, because of problems with nerves, joints or muscles • Yes, because of other reasons, please specify: ……

Supplemental Table 2. Original data and imputed data on functional capacity.

	Original data **N=4879 (%)**	**Imputed data** **N=4879 (%)**
Functional capacity		
Unknown	20 (0.4)	22 (0.5)
Poor	728 (14.9)	802 (16.4)
Moderate	3062 (62.8)	3292 (67.5)
Good	654 (13.4)	701 (14.4)
High	58 (1.2)	62 (1.3)
Missing	357 (7.3)	0

3

PROTOCOL TER PREVENTIE VAN PERIOPERATIEVE PULMONALE COMPLICATIES. HOE VAAK NAGELEEFD? EN WANNEER WORDT ERVAN AFGEWEKEN?

Authors: Lynn A. Miggelbrink, Marije Marsman, Jasper R. Senff, Judith A.R. van Waes, Inez Bronsveld, Wilton A. van Klei, Teus Kappen

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Abstract

Doel: Onderzoeken in hoeverre de nationale richtlijn 'Preventie van pulmonale complicaties bij niet-thoracale chirurgie' wordt toegepast bij patiënten met chronische obstructieve longziekte (COPD) of astma die een operatie ondergaan en in beeld brengen om welke redenen van deze richtlijn wordt afgeweken.

Opzet: Retrospectief cohortonderzoek, interviews en enquêtes.

Methode: Patiënten met een voorgeschiedenis van astma of COPD die in de periode januari 2017-juli 2018 een niet-thoracale operatie ondergingen werden geïncludeerd. De primaire uitkomstmaat was opvolging van de richtlijn, gedefinieerd als de aantekening in het patiëntendossier dat perioperatief intraveneus prednisolon of oraal prednison was toegediend. De redenen om de richtlijn niet op te volgen werden geïdentificeerd met interviews en enquêtes; dit was de secundaire uitkomstmaat.

Resultaten: Er kwamen 1,623 patiënten in aanmerking voor een preventieve behandeling. In totaal kregen 653 patiënten (40%) een behandeling volgens de richtlijn. De overige 970 patiënten kregen geen behandeling (79%), een ander corticosteroïd (12%) of eenmalig prednisolon op de dag van de operatie in plaats van 3 dagen preoperatief (9%). Redenen om de richtlijn niet te volgen waren: angst voor bijwerkingen van corticosteroïden, indicaties voor andere soorten corticosteroïden en gebrek aan bewijs.

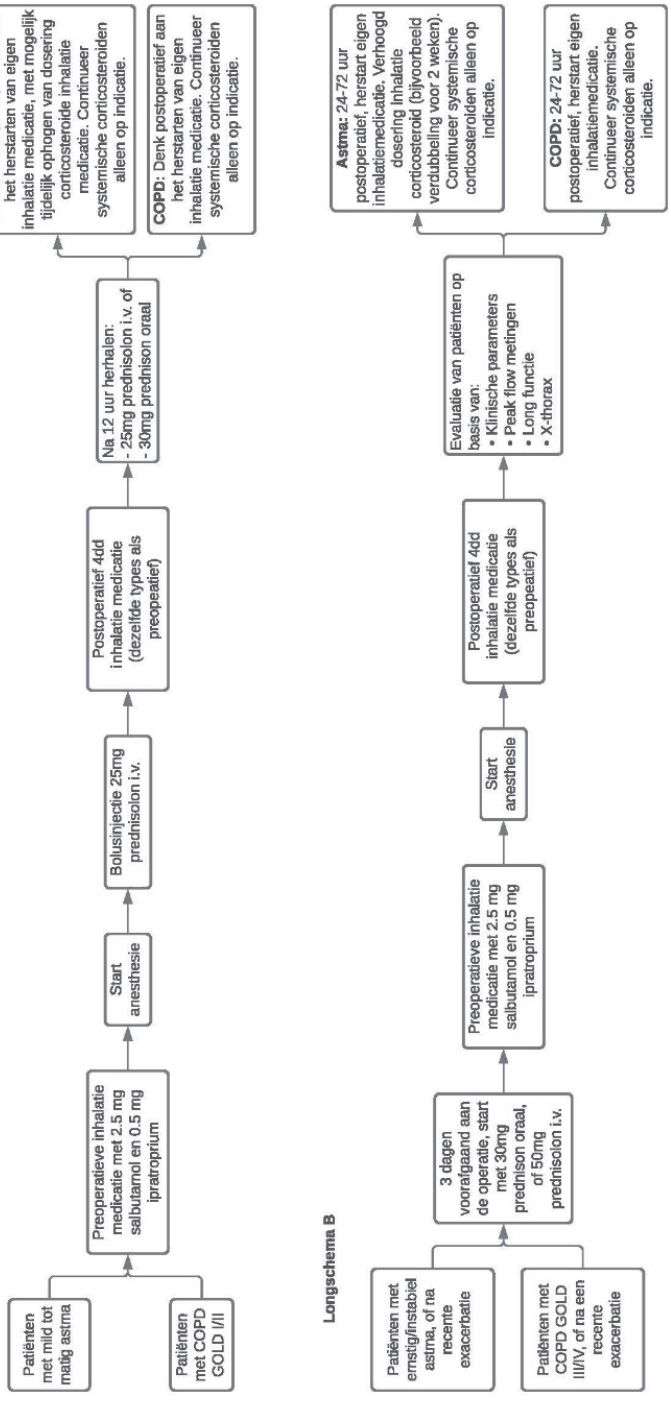
Conclusie: De huidige richtlijn is in ons ziekenhuis matig geïmplementeerd. Dit lijkt te worden veroorzaakt door gebrekkige aansluiting op de complexiteit van de praktijk, gebrek aan vertrouwen in het bewijs waarop de richtlijn is gebaseerd en angst voor bijwerkingen. Er zijn opmerkelijke verschillen tussen de visies van longartsen en anesthesiologen. Verder onderzoek is nodig om de landelijke richtlijn te verstevigen, met anticipatie op de genoemde barrières om een betere implementatie te bereiken.

Introductie

Perioperatieve pulmonale complicaties (PPCs) zoals atelectase, bronchospasme en pneumonie, zijn een veelvoorkomende oorzaak van postoperatieve morbiditeit, mortaliteit en dragen bij aan een landurige verblijfsduur en heropnames.[1-5] De incidentie van PPCs varieert en kan in sommige patiëntengroepen oplopen tot 75 procent.[1,6] Patiënten met chronische obstructieve pulmonale ziekte (COPD) of astma hebben een verhoogd risico op het ontwikkelen van PPCs, waaronder een exacerbatie van de bestaande longaandoening.[4,7,8] Andere risicofactoren zijn type chirurgie, spoedoperaties, langdurige ingrepen en algehele anesthesie.[4,9]

Verschillende onderzoeken naar preventie van PPCs lieten zien dat perioperatief toegediende systemische corticosteroïden het risico op een PPC zouden verkleinen bij patiënten met astma en/of COPD.[10-13] Deze bevindingen zijn in 2012 opgenomen in een nationale multidisciplinaire richtlijn die het gebruik van corticosteroïden voor preventie van PPCs adviseert bij patiënten.[14] De richtlijn adviseert daarnaast sympathicomimetische en anticholinerge inhalatiemedicatie. Voor patiënten met stabiele en milde longziekte, wordt intraveneuze toediening van prednisolon geadviseerd bij de inleiding van de anesthesie en 12 uur na toediening van het eerste gift ('Longschema A') (Figuur 1). Voor patiënten met een ernstigere of instabiele vorm van COPD of astma wordt geadviseerd drie dagen preoperatief te starten met oraal prednison ('longschema B') (Figuur 1).[14] Er zijn sinds de ontwikkeling van de richtlijn in 2012 géén nieuwe onderzoeken verschenen die inventariseren wat het effect is op corticosteroïden op de ontwikkeling van PPCs.

Voor zover ons bekend is Nederland het enige land dat corticosteroïden adviseert ter preventie van PPCs. In de dagelijkse praktijk merkten wij op dat er veel commentaar is op dit protocol binnen onze vakgroep anesthesiologie in een universitair medisch centrum, ondanks een lokale vertaling van het protocol. Daarom onderzochten wij de implementatiegraad van de richtlijn, door opvolging van het protocol te kwantificeren in een cohort patiënten die volgens de richtlijn een indicatie hadden voor preventieve behandeling met corticosteroïden. Vervolgens is door middel van interviews en enquêtes onder anesthesiologen en longartsen onderzocht welke barrières er bestaan voor implementatie.



Figuur 1. Longschema A en B (online supplement)

COPD chronische obstructieve pulmonale ziekten. GOLD Global Initiative for Chronic Obstructive Lung Disease.

Methoden

Studieontwerp en -populatie

Dit onderzoek bestond uit twee delen.

Allereerst is gekeken naar de opvolging van de Nederlandse richtlijn ter voorkoming van PPCs bij patiënten met astma of COPD door anesthesiologen. Dit is onderzocht met een retrospectief cohort onderzoek onder patiënten met astma of COPD die tussen januari 2017 en juli 2018 een geplande operatie ondergingen onder algehele of locoregionale anesthesie in het UMC Utrecht. Patiënten die reeds opgenomen waren op de Intensive Care (IC) of die een thoracale ingreep ondergingen werden geëxcludeerd. Alle patiënten werden voorafgaand aan de operatie gezien op de polikliniek anesthesiologie hadden volgens de richtlijn een longschema toegediend moten krijgen op de operatiekamer (longschema A), danwel zijn voorgeschreven (longschema B). Via het elektronisch patiënten dossier is gekwantificeerd bij hoeveel patiënten dit gebeurde.

Vervolgens zijn anesthesiologen geïnterviewd om de barrières voor het opvolgen van de richtlijn te identificeren. De hoofdthema's die voortvloeiden uit de interviews, werden gebruikt voor het maken van enquêtes, die gestuurd werden naar alle anesthesiologen (i.o.) en alle longartsen (i.o.) in het UMC Utrecht. Het doel van de enquêtes was om de belangrijkste bevindingen van de interviews te valideren in een grotere groep anesthesiologen en longartsen.

De medisch ethische toetsingscommissie van het UMC Utrecht heeft de studie beoordeeld als niet WMO plichtig.

Data verzameling

De voorschrijf- en toedieningsgegevens van de corticosteroïden zijn verzameld uit de elektronische registratiesystemen van het ziekenhuis (HiX, Chipsoft, Nederland en Anstat, Carepoint, Nederland). De verkregen gegevens omvatten patiëntkenmerken, het specialisme, duur van de operatie en type anesthesie. Indien de ernst van de longziekte niet was gedocumenteerd, werd de ernst beoordeeld op basis van longfunctietests en beschreven longklachten. Als deze gegevens onbekend waren, werden patiënten pragmatisch beschouwd als patiënten met een milde longziekte.

Patiënten werden onderverdeeld in twee groepen: patiënten die volgens de richtlijn longschema A zouden moeten krijgen, en patiënten die longschema B zouden moeten

krijgen. Toediening van prednisolon binnen 30 minuten na inleiding van anesthesie werd genoteerd als opvolging van de richtlijn bij patiënten met een indicatie voor longschema A (25 mg prednisolon i.v. bij inductie). Het voorschrijven van 30 mg prednison oraal vanaf 3 dagen voor de operatie, werd genoteerd als opvolging van de richtlijn bij patiënten met een indicatie voor longschema B (Figuur 1).

Uitkomst

De registratie van toegediende inhalatiemedicatie was niet betrouwbaar omdat patiënten die vaak in eigen beheer hadden. De primaire uitkomst was daarom gedefinieerd als het voorschrijven van orale corticosteroïden op de poli anesthesiologie (longschema B), of de toediening van prednisolon vlak voor de operatie (longschema A). Patiënten die geen corticosteroïden kregen volgens een longschema (A of B), werden gecategoriseerd als "niet opvolgen van de richtlijn". Wanneer patiënten een ander type corticosteroïd kregen op de operatiekamer, werd dit apart gecategoriseerd. De behandelende anesthesioloog kan een ander type corticosteroïd kan hebben overwogen als een alternatief voor prednisolon.

Statistische analyse

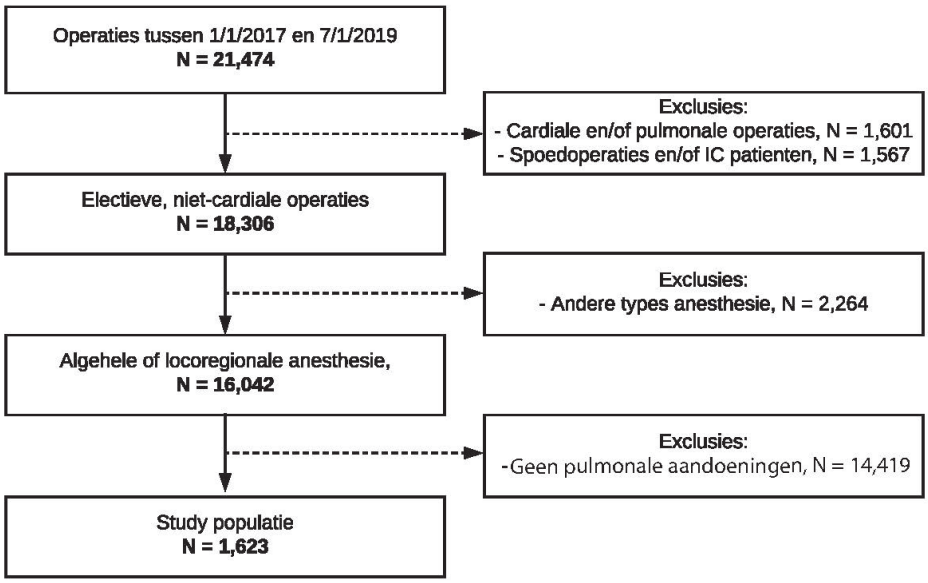
Patiënten werden geanalyseerd op basis van hun indicatie voor longschema A of B. Categorische data werden beschreven als absolute getallen (N) en frequenties (%). Continue data werden beschreven als een gemiddelde met standaarddeviatie (SD) of een mediaan met interkwartielen (IQR) indien van toepassing. De (normale) verdeling van variabelen werd getest met behulp van de Kolmogorov-Smirnov-test. Gegevens werden geanalyseerd met behulp van SPSS Statistics 25.0 software (IBM, Armonk, NY).

Implementatie barrières

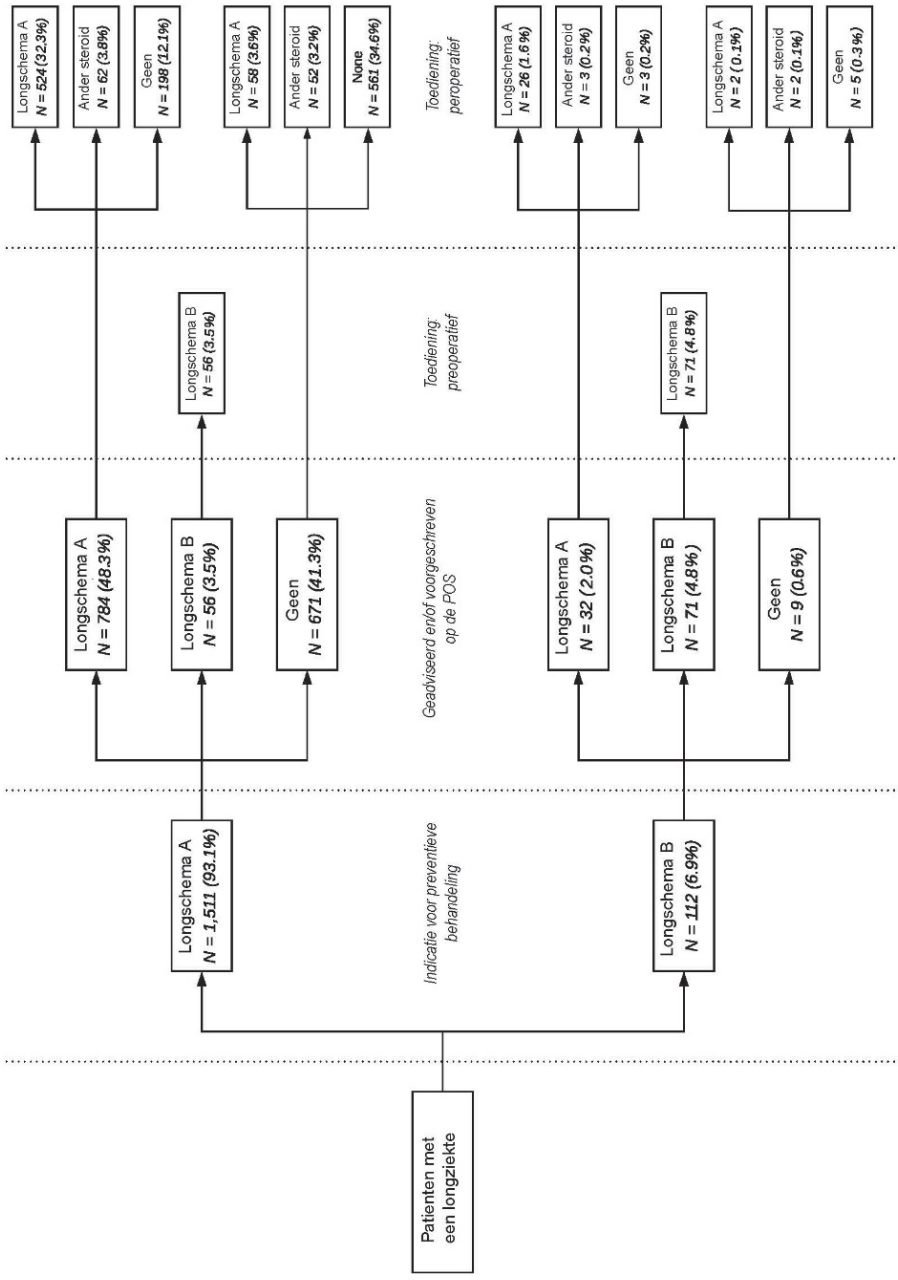
Barrières voor de implementatie van de richtlijn werden onderzocht aan de hand van semigestructureerde interviews en enquêtes. Anesthesiologen werden willekeurig gekozen en geïnterviewd (auteur LAM) over hun visie op de richtlijn en redenen voor het (niet) opvolgen van de richtlijn. Het aantal interviews werd niet vooraf bepaald, maar interviews werden voortgezet totdat de gegevensverzadiging was bereikt. Verzadigd betekende dat er gedurende twee opvolgende interviews geen nieuwe redenen voor (niet) opvolgen van de richtlijn meer benoemd werden. Interviews werden opgenomen en vervolgens getranscribeerd.

De tekst werd geanalyseerd met behulp van open codering, gevolgd door classificatie in hoofdthema's. Vervolgens werden de gevonden redenen voor het (niet) opvolgen van de richtlijn gebruikt om verschillende "voorbeeld casus" te formuleren voor de enquête. De enquête was bedoeld om te onderzoeken of behandelaars in verschillende specifieke gevallen corticosteroïden zouden adviseren en/of toedienen, en om redenen voor het (niet) opvolgen van de richtlijn te valideren die tijdens de interviews werden aangetroffen. De enquête werd naar longartsen (in opleiding) en anesthesiologen (in opleiding) gestuurd. Alle data werden anoniem geanalyseerd.

Figuur 2. Flowchart (online supplement)



IC Intensive Care. Andere types anesthesie bevat procedurele sedatie en procedures onder lokale anesthesie.



Figuur 3. Stappen voor het (niet) opvolgen van de richtlijn

Resultaten

Van de 1,623 geïncludeerde patiënten (Figuur 2) had 55% astma en 45% COPD. De mediane leeftijd was 61 jaar (IQR 49-70) en 54% was vrouw. Patiëntkarakteristieken zijn te zien in Tabel 1. Alle 1,623 patiënten zouden volgens de richtlijn een longschema (A of B) moeten krijgen, bij 943 patiënten (58%) werd op de poli anesthesiologie daadwerkelijk een longschema geadviseerd (Figuur 3). Bij 653 patiënten (40%) werden daadwerkelijk corticosteroïden toegediend. Er kwamen 1,511 patiënten (93%) in aanmerking voor longschema A, waarvan 582 patiënten (39%) de corticosteroïden passende bij longschema A kregen. Bij 112 patiënten (7%) was longschema B geïndiceerd, waarvan er 71 (63%) daadwerkelijk volgens de richtlijn werden behandeld (Figuur 3).

Implementatie barrières

Interviews

Vijf anesthesiologen en drie anesthesiologen in opleiding (AIOS) werden geïnterviewd over het gebruik en toepasbaarheid van de richtlijn. Hoewel sommigen twijfels hadden over de literatuur, de richtlijn is gebaseerd op een beperkt aantal kleine studies, zou geen van hen de richtlijn negeren. Niet iedereen vond toediening van corticosteroïden zinvol ter preventie van PPCs bij patiënten met een milde longziekte op basis van de literatuur en ervaring. Zorgen werden geuit over bijwerkingen van corticosteroïden. De belangrijkste geïdentificeerde thema's voor het niet volgen van de richtlijn staan weergegeven in bijlage 1.

Enquête

De enquête werd ingevuld door 19 AIOS en 21 anesthesiologen (54% van de 74 artsen binnen de anesthesiologie, vanaf hier de respondenten genoemd, bijlage 2). Van de respondenten gaf 95% aan dat zij longschema A zouden toedienen bij patiënten die een electieve operatie onder algehele anesthesie zouden ondergaan indien er géén (relatieve) contra-indicaties aanwezig waren. Slechts 54% van de respondenten geloofde dat corticosteroïden PPCs zou kunnen voorkomen. Desondanks zou 46% van de respondenten de corticosteroïden op de operatiekamer geven als dit op de poli anesthesiologie was geadviseerd. Daarnaast vond 44% van de respondenten in zijn algemeenheid dat het voordeel van corticosteroïden (risicoreductie op het optreden van PPCs) niet opwoog tegen de bijwerkingen. Bij een voorbeeldcasus van een patiënt met diabetes die een ingreep onder locoregionale anesthesie onderging, gaf slechts 28% van de respondenten aan zich aan de richtlijn te houden. Genoemde redenen om de richtlijn niet te volgen, waren de nadelige invloed van

corticosteroïden op glucoseregulatie en de inschatting dat de kans op PPC bij locoregionale anesthesie klein is (72%).

Dexamethason wordt vaak perioperatief gegeven bij bepaalde typen chirurgie, zoals prothese chirurgie en neurochirurgie, of ter preventie van postoperatieve misselijkheid en braken.Bij een voorbeeldcasus van een patiënt met COPD en daarnaast een indicatie voor dexamethason, meldde 63% van de anesthesiologen dat ze bij voorkeur prednisolon zouden toedienen in plaats van dexamethason. Van de anesthesiologen die dexamethason zouden geven, meende 79% dat dexamethason ook de kans op PPC zou verkleinen.

Bij de voorbeeldcasus van een patiënt die volgens de richtlijn met longschema A behandeld zou moeten worden, maar waarbij een longarts longschema B adviseerde, zou 68% van de anesthesiologen de patiënt alsnog behandelen met longschema A. Bij de voorbeeldcasus van een patiënt met een indicatie voor longschema B volgens de richtlijn, zouden de meeste anesthesiologen dit ook volgen (85%). Echter als longschema B op de polikliniek niet voorgeschreven was, zou 93% van de anesthesiologen op de dag van de operatie pragmatisch kiezen voor longschema A als alternatief.

De enquête voor longartsen werd ingevuld door 10 longartsen (63% van het totale aantal benaderde longartsen) waarvan 7 in opleiding. De resultaten hiervan worden getoond in bijlage 3. De resultaten van de enquêtes en de observaties in de dagelijkse praktijk voor zowel de anesthesiologie als de longgeneeskunde zijn te zien in tabel 2 Anesthesiologen en longartsen waren het meestal eens over de indicatie voor longschema B (respectievelijk 85% en 90%).

Tabel 1: Patiënten karakteristieken

		Longschema A		**Longschema B**	
		Geïndiceerd, behandeld volgens protocol N = 582	**Geïndiceerd, niet behandeld volgens protocol[1] N = 929**	**Geïndiceerd, behandeld volgens protocol N = 71**	**Geïndiceerd, niet behandeld volgens protocol[1] N = 41**
Astma, N (%)	Mild	220 (38)	539 (58)	0 (0.0)	0 (0.0)
	Matig	58 (10)	56 (6.0)	0 (0.0)	0 (0.0)
	Ernstig/ Instabiel	0 (0.0)	0 (0.0)	8 (10)	11 (2)
COPD, N (%)	GOLD I	140 (24)	177 (19)	0 (0.0)	0 (0.0)
	GOLD II	151 (26)	144 (16)	0 (0.0)	0 (0.0)

		Longschema A		Longschema B	
		Geïndiceerd, behandeld volgens protocol N = 582	**Geïndiceerd, niet behandeld volgens protocol[1] N = 929**	**Geïndiceerd, behandeld volgens protocol N = 71**	**Geïndiceerd, niet behandeld volgens protocol[1] N = 41**
	GOLD III	0 (0.0)	0 (0.0)	45 (63)	27 (66)
	GOLD IV	0 (0.0)	0 (0.0)	14 (10)	3 (7.3)
	Instabiel COPD	0 (0.0)	0 (0.0)	3 (4.2)	0 (0)
	Ontbrekende gegevens	*13 (2.2)*	*13 (1.4)*	*1 (1.4)*	*0 (0)*
Inhalatie medicatie, N (%)	Alle types [2]	468 (80)	569 (61)	63 (89)	36 (87)
	Steroïden [3]	331 (57)	426 (46)	47 (66)	25 (61)
ASA, N (%)	1	3 (0.5)	49 (5.3)	0 (0)	0 (0)
	2	335 (58)	576 (62)	6 (8.5)	10 (24)
	3	239 (41)	290 (31)	50 (70)	29 (71)
	4	5 (0.9)	14 (1.5)	15 (21)	2 (4.9)
Roken, N (%)	In het verleden	214 (37)	280 (30)	38 (54)	17 (42)
	Huidig	200 (34)	222 (24)	24 (34)	16 (39)
	Ontbrekende gegevens	*0 (0.0)*	*1 (0.1)*	*0 (0)*	*0 (0)*
Type opname, N (%)	Opname	490 (84)	645 (69)	67 (94)	30 (73)
Type operatie, N (%)	Orthopedisch	34 (5.8)	99 (11)	7 (9.9)	3 (7.3)
	Urogenitaal	88 (15)	166 (18)	13 (18)	5 (12)
	Vasculair	50 (8.6)	46 (5.0)	10 (14)	3 (7.3)
	Hoofd en hals	208 (36)	247 (27)	25 (35)	18 (44)
	Algemeen	98 (17)	88 (9.5)	7 (9.9)	4 (9.8)
	Overig	104 (18)	283 (31)	9 (13)	8 (20)
Type anesthesie, N (%)	Algeheel	547 (99)	807 (87)	60 (85)	40 (98)
	Spinaal	6 (1.0)	89 (9.6)	10 (14)	0 (0.0)
	Perifere zenuw blokkade	2 (0.3)	33 (3.6)	1 (1.4)	1 (2.4)
Operatieduur, N (%)	≥ 2 uur	302 (52)	363 (39)	35 (49)	15 (37)

ASA American Society of Anaesthesiologists physical status classificatie system. COPD Chronic Obstructive Lung Disease. GOLD Global Initiative for Obstructive Lung Disease. IQR Interquartile range (interkwartielafstand). [1]Inclusief patiënten die géén corticosteroïden, andere type corticosteroïden hebben gekregen, danwel het andere longschema. [2]Het percentage weergeeft de patiënten die inhalatie medicatie gebruiken, welk type dan ook. [3]Het percentage van patiënten die steroïden inhalatie medicatie gebruiken van de patiënten die inhalatiemedicatie gebruiken.

Discussie

Wij onderzochten de lokale implementatie van de landelijke richtlijn ter preventie van PPC's. Bij patiënten waarbij de richtlijn corticosteroïden aanbeveelt op de dag van operatie (longschema A), werd slechts 39% volgens protocol behandeld. Bij patiënten met een indicatie voor langduriger voorbereiding met corticosteroïden (longschema B), werd 63% volgens protocol behandeld. Een enquête onder betrokken professionals toonde aan dat de intentie om de richtlijn te volgen hoog is, maar de data uit de praktijk laat zien dat de daadwerkelijke implementatie achter blijft. Voor longschema A werd in de dagelijkse praktijk een veel lager percentage opvolging van de richtlijn gevonden dan in de enquête (39% versus 95%). De discrepantie was ook aanwezig voor longschema B, maar niet zo uitgesproken (63% versus 85%).

De gecombineerde resultaten van de daadwerkelijk geobserveerde therapietrouw, de interviews en enquêtes suggereren verschillende verklaringen voor het niet naleven van de richtlijn. Ten eerste sluit de richtlijn onvoldoende aan bij het gedachteproces van anesthesiologen om corticosteroïden toe te dienen. Geïnterviewde anesthesiologen gaven aan dat de kans op hyperglycaemie en wondgenezing hun keus beïnvloedt, vooral bij patiënten bij wie zij de kans hierop hoog achtten. Ook beïnvloedde locoregionale anesthesie de implementatie, omdat de kans op PPCs hierbij klein is. Daarnaast staat er in de richtlijn geen advies of een ander corticosteroïd, zoals bijvoorbeeld dexamethason gegeven ter preventie van misselijkheid, een gelijkwaardig alternatief zou kunnen zijn.

Ten tweede rapporteerden geïnterviewde anesthesiologen dat zij twijfelen over de effectiviteit van corticosteroïden ter preventie van PPCs, omdat deze aanbevelingen uit de richtlijn zijn gebaseerd op beperkt bewijs. Slechts een handvol kleine gerandomiseerde onderzoeken zijn uitgevoerd waarbij patiënten corticosteroïden kregen toegediend.[10,13,18,19] Ook grotere retrospectieve onderzoeken gaven geen doorslaggevend bewijs.[11,20] In een recentere een meta-analyse, worden verschillende methodes ter preventie van PPCs geïnventariseerd, waarbij corticosteroïden niet benoemd worden.[18]

Anesthesiologen dienen niet vaak twee soorten corticosteroïden toe wanneer er een indicatie is voor zowel dexamethason ter preventie van postoperatieve misselijkheid en braken, als ook prednisolon ter voorkoming van PPCs. Tevens zijn zij minder geneigd prednisolon toe te dienen bij patiënten met diabetes mellitus of een operatie onder locoregionale anesthesie. Onze resultaten suggereren daarom sterk dat de richtlijn

onvoldoende houvast biedt bij verschillende beslissingen die in de dagelijkse klinische praktijk gebruikelijk zijn. Eind 2022 volgt een revisie van het Nederlandse protocol, die mogelijk meer aansluit bij de dagelijkse praktijk.

Door het retrospectieve karakter van het onderzoek moesten een aantal aannames gedaan worden. Allereerst werd alleen de intraveneuze toediening van prednisolon beschouwd als "in overeenstemming met het protocol" voor longschema A, omdat het niet mogelijk was om de redenen voor toediening van andere corticosteroïden te achterhalen. Bovendien werd aangenomen dat deze patiënten ook hun inhalatiemedicatie kregen. Deze veronderstelling heeft mogelijk geleid tot een overschatting van de implementatie van de richtlijn. Tevens werd aangenomen dat patiënten die drie dagen voor de operatie thuis moesten starten met prednison, dit ook daadwerkelijk hadden gedaan.

De enquête was opgebouwd aan de hand van diepte interviews met anesthesiologen (i.o.). Hoewel is geprobeerd de vragen zo representatief mogelijk te maken voor klinische situaties, kan het zijn dat deze geheel overeenkomen met de werkelijkheid. De enquête liet een discrepantie zien met de observaties in het cohort. Hoewel dit (deels) mogelijk wordt veroorzaakt door sociaal wenselijke antwoorden of een overschatting van individuele prestaties, kan het ook het resultaat zijn van het verschil tussen patiënten beschreven in de enquête en de daadwerkelijke populatie van ons ziekenhuis. Dit zou tevens kunnen leiden tot een overschatting van de naleving van het protocol.

Implementatie van richtlijnen is een uitdaging.[21-23] Dit geldt zeker wanneer een richtlijn gebaseerd op consensus onder de leden van de richtlijn werkgroep in plaats van op substantieel bewijs. Verschillende studies hebben naleving van protocollen onderzocht en vergelijkbare barrières voor de implementatie van richtlijnen gemeld: een gebrek aan bewijs voor de aanbevelingen, onvoldoende specificatie van de toepassing van de richtlijn voor de complexiteit van dagelijkse praktijk, en een gebrek aan argumentatie en redenering achter de aanbevelingen.[21,22,24–26] De mate van implementatie van verschillende richtlijnen verschilt hierdoor ook aanzienlijk. Zo wordt de richtlijn voor diabetespatiënten beter opgevolgd, dan de richtlijn voor verdere preoperatieve diagnostiek bij vrouwen. Bij diabetespatiënten wordt in 71% van de gevallen preoperatief een HbA1c bepaald, waarvan het merendeel met een afwijkend HbA1c worden verwezen naar een diabetes team voor begeleiding.[23] Dit in tegenstelling tot het uitvoeren van preoperatieve diagnostiek bij vrouwen, waarbij slechts

17% van de metabole labonderzoeken, 36% van de ECGs en 29% van de volledige bloedonderzoeken volgens de richtlijn werden uitgevoerd.[22]

Katz concludeerde dat onvoldoende bewijs een belangrijke factor is bij de implementatie van richtlijnen. Echter een richtlijn op basis van literaire onderbouwing alleen zou niet voldoende zijn voor een goede implementatie.[27] Baron rapporteerde dat implementatie van richtlijnen verbetert als richtlijnen gebaseerd zijn op bewijs van hoge kwaliteit, aansluiten bij de patiënten/situaties die artsen in hun dagelijkse praktijk zien, en artsen moeten de redenering achter de aanbevelingen begrijpen.[25] Tickell vond dat het niet opvolgen van richtlijnen correleert met zorg op maat voor individuele patiënten die buiten de patiëntenpopulatie vallen zoals deze in de richtlijn wordt beschreven.[26] Volovici rapporteerde vergelijkbare bevindingen en vond de belangrijkste implementatiebarrière de unieke patiënt, waarin het protocol aanbevelingen mist.[28]

Conclusie

De lokale implementatie van de landelijke richtlijn ter preventie van PPCs is matig succesvol met betrekking tot toediening van corticosteroïden bij patiënten met astma of COPD. Anesthesiologen lijken meer bereid om corticosteroïden toe te dienen bij patiënten met een ernstigere longziekte. Het niet opvolgen van de richtlijn lijkt het gevolg van het ontbreken van duidelijk bewijs en het ontbreken van advies voor specifieke patiënten groepen.

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Bijlage 1. Thema's na kwantitatieve analyse van getranscribeerde interviews

Hoofdthema	Citatie
Redenen voor opvolgen van protocol	
Patiënten met een indicatie voor longschema A, krijgen longschema A. Echter, herhaling van toediening na 12 uur wordt vaak vergeten	"Als patiënten een laag risico operatie ondergaan, in dagbehandeling, twijfel ik aan de haalbaarheid van de herhaling van toediening van prednison."
Patiënten met een indicatie voor longschema B, krijgen vaak longschema B.	"Ik schrijf een recept, maar vaak na overleg met hun eigen longarts." "Ik schrijf bijna altijd prednison voor bij patiënten met een indicatie voor longschema B."
Redenen voor het niet opvolgen van protocol	
Milde gevallen of kleine operaties krijgen vaak geen longschema A.	"In patiënten met stabiel of mild COPD of astma die een laag risico operatie ondergaan, dien ik meestal geen prednisolon toe." "Soms vergeet ik het. Soms, vooral als ik twijfel, dien ik het niet toe bij patiënten die in dagbehandeling worden geholpen."
Bijwerkingen, vooral bij patiënten met comorbiditeiten	"Soms voelt de toediening van corticosteroïden erg overdreven. Soms is het te veel, vooral bij sommige soorten patiënten. Onze populatie bestaat uit veel diabetici. Hun glucosespiegels zullen worden beïnvloed door corticosteroïden. Het kan zelfs leiden tot problemen met de genezing van de wond." "Soms wijk ik bewust af van het protocol, bijvoorbeeld bij patiënten met diabetes of patiënten met een bekende bipolaire stoornis met een indicatie voor longschema B."
Niet overtuigd door de literatuur	"Er is weinig literatuur over de preventieve toediening en alle studies zijn klein. Er is echter veel bewijs over bijwerkingen van corticosteroïden. Dat is waarom ik altijd de toediening van steroïden kritisch zal overwegen." "Er is weinig bewijs voor preventieve longbehandelingen. De literatuur waarop het protocol is gebaseerd, is zeer beperkt... Ik denk dat het bewijs beperkt is en ik ben niet overtuigd van het effect."
Moeilijk op te volgen protocol door de ingewikkeldheid van het protocol. Niet altijd bekend dat er een indicatie aanwezig is.	"Soms is de enorme hoeveelheid protocollen, maar ook de hoeveelheid informatie in protocollen, overweldigend, en dan vergeet je het." "Ik ben niet vaak op de preoperatieve screeningspoli (POS) en dan moet ik het protocol echt nog eens bekijken. Ik vind het protocol moeilijk te volgen."

Hoofdthema	Citatie
Prednison moet niet extra worden toegediend als er al een ander type corticosteroïd is toegediend.	"Wanneer een ander type corticosteroïd is geïndiceerd op basis van het type operatie of als PONV-profylaxe, dien ik vaak een ander type corticosteroïd toe, meestal dexamethason. Ik dien geen extra prednison toe, dit zou overkill zijn." "Ik verwacht niet veel verschil tussen verschillende soorten corticosteroïden. Als ik dexamethason of hydrocortison toedien, zal dit ook als preventieve behandeling werken."
Thema's die niet in enquêtes zijn opgenomen	
Het niet voelen als een praktiserende arts als je alleen protocollen mag opvolgen.	"Soms voel je je geen dokter als je alleen de diagrammen opvolgt. Als je het als een arts bekijkt, zal je waarschijnlijk toch corticosteroïden toedienen."
Een pragmatische aanpak in patiënten die excessief roken, die vaak een longschema A toegediend krijgen.	"Soms als patiënten nog geen diagnose hebben, maar ik denk dat ze een onderliggende longziekte (zoals COPD) moeten hebben, zal ik pragmatisch longschema A adviseren."

Bijlage 2. Resultaten enquête anesthesiologie

	N AIOS	% AIOS	N staf	% staf
Reacties	19	47.5	21	52.5
Casus: patiënt met COPD GOLD 2 zonder recente exacerbaties, een laparoscopische hemicolectomie onder algehele anesthesie. Advies op de preoperatieve screeningspoli (POS):				
Preventieve behandeling longschema A	18	94.7	20	95.2
Geen preventieve behandeling	1	5.3	1	4.8
Redenen voor niet toedienen preventieve behandeling				
Niet overtuigd op basis van de huidige literatuur	0	0	1	100
Niet voldoende kennis over preventieve behandelingen	1	100.0	0	0
Casus: patiënt met COPD GOLD 1 zonder exacerbaties en insulineafhankelijke diabetes mellitus, totale knievervanging onder locoregionale anesthesie. Advies op de POS:				
Preventieve behandeling longschema A	7	36.8	4	19.0
Geen preventieve behandeling	11	57.9	15	71.4
Overig	1	5.3	2	9.5
– *LIA protocol voor versneld herstel (8 mg dexamethason)*	– *1*		– *2*	
Redenen voor niet toedienen preventieve behandeling				
Niet overtuigd op basis van de huidige literatuur	1	5.3	3	14.3
Bijwerkingen	7	36.8	6	28.6
Locoregionale anesthesie	6	31.6	11	52.4
Alleen inhalatiemedicatie	1	5.3	0	0
Onbekend	1	5.3	1	4.8
Casus: patiënt met COPD GOLD 2 zonder exacerbaties, laparoscopische hemicolectomie onder algehele anesthesie. PONV profylaxe (4mg dexamethason is ook geïndiceerd). Advies op de POS:				
Preventieve behandeling longschema A	12	63.2	13	61.9
PONV profylaxe	6	31.6	6	28.6
Beide	1	5.3	1	4.8
Geen	0	0	1	4.8
Redenen voor prednisolon als preventieve behandeling				
Voorkomt pulmonale complicaties	9	47.4	5	23.8
Prednisolon werkt ook als PONV profylaxe	4	21.1	7	33.3
Advies van de POS	2	10.5	5	23.8
Redenen voor dexamethason als PONV profylaxe				
Dexamethason werkt langer en werkt tevens als preventieve van pulmonale complicaties	6	31.6	5	23.8
Dexamethason alleen voor PONV profylaxe	0	0	1	4.8
Redenen voor geen preventieve behandeling				
Niet overtuigd op basis van de huidige literatuur	0	0	1	4.8

	N AIOS	% AIOS	N staf	% staf
Casus: patiënt met COPD GOLD 3, laatste exacerbatie 6 maanden geleden, herziening van de totale heupvervanging met LIA protocol, voor versneld herstel (8 mg dexamethason tijdens inductie) onder algehele anesthesie. Advies op de POS:				
Preventieve behandeling longschema A	2	10.5	3	14.3
Preventieve behandeling longschema B	17	89.5	17	81.0
Overig	0	0	1	4.8
– *LIA protocol voor versneld herstel (8 mg dexamethason)*	– *0*		– *1*	
Casus: patiënt met COPD GOLD 3, laatste exacerbatie 6 maanden geleden, herziening van de totale heupvervanging met LIA protocol, voor versneld herstel (8 mg dexamethason tijdens inductie) onder algehele anesthesie. Er is geen preventieve behandeling gestart op de POS. Actie op de operatiekamer (OK):				
Preventieve behandeling longschema A, want het is te laat voor longschema B	14	73.7	15	71.4
Preventieve behandeling longschema A, dit is voldoende	3	15.8	3	14.3
Niks, overig	2	10.5	3	14.3
– *LIA protocol voor versneld herstel*	– *1*		– *1*	
– *Ligt aan de pulmonale conditie op dat moment*	– *1*		– *0*	
– *Longschema A, met consult aan de longarts*	– *0*		– *1*	
– *Longschema A, en tevens terugkoppeling aan de POS*	– *0*		– *1*	
Casus: patiënt met matig astma, advies van longarts is longschema B. Wat beslis je op de POS?				
Preventieve behandeling longschema A	11	57.9%	16	76.2%
Preventieve behandeling longschema B	7	36.8%	4	19.0%
Geen preventieve behandeling	1	5.3%	1	4.8%

Bijlage 3. Resultaten enquête longgeneeskunde

	N AIOS	% AIOS	N staf	% staf
Reacties	7	70	3	30
Casus: De afdeling anesthesiologie vraagt om advies. Patiënt met COPD GOLD 2 zonder exacerbaties voor een laparoscopische hemicolectomie onder algehele anesthesie. Uw advies:				
Preventieve behandeling longschema A	7	100%	3	100%
Preventieve behandeling longschema B	0	0%	0	0%
Casus: De afdeling anesthesiologie vraagt om advies. Patiënt met COPD GOLD 3, laatste exacerbatie 6 maanden geleden. De patiënt ondergaat een revisie van een heupprothese onder algehele anesthesie. Uw advise:				
Preventieve behandeling longschema A	1	14.3%	0	0%
Preventieve behandeling longschema B	6	85.7%	3	100%
Geen preventieve behandeling	0	0%	0	0%
Casus: De afdeling anesthesiologie vraagt om advies. Patiënt met COPD GOLD 1 en insulineafhankelijke diabetes mellitus, die een knieprothese onder locoregionale anesthesie ondergaat:				
Preventieve behandeling longschema A	4	57.1%	2	66.7%
Preventieve behandeling longschema B	0	0%	0	0%
Geen preventieve behandeling	3	42.9%	1	33.3%
– *Bij een locoregionale techniek is er geen indicatie voor een preventieve behandeling door middel van een longschema in laag risico operaties*			– *1*	
Casus: De afdeling anesthesiologie vraagt om advies. Patiënt met COPD GOLD 1 en insulineafhankelijke diabetes mellitus, die een knieprothese onder locoregionale anesthesie ondergaat. De patiënt kreeg 8 mg dexamethason aan het begin van de operatie. Moet je longschema A toedienen?				
Ja	4	57.1%	3	100%
Nee	1	14.3%	0	0%
Overig	2	28.6%	0	0%
– Ligt aan de kliniek	2		0	
Casus: De afdeling anesthesiologie vraagt om advies. Patiënt met COPD GOLD 2 onderging een hemicolectomie onder algehele anesthesie. De patiënt krijgt 4 mg dexamethason voor PONV-profylaxe. Advies longgeneeskunde:				
Preventieve behandeling longschema A	6	85.7%	2	66.7%
– *Met een consult van de longgeneeskunde bij hoog risico operatie*	– *0*		– *1*	
Preventieve behandeling longschema B	0	0%	0	0%
Geen prednison als preventieve behandeling	1	14.3%	1	33.3%%
– *Eenmalig dexamethason is voldoende*	– *1*		– *1*	
Casus: De afdeling anesthesiologie vraagt om advies. Patiënt met COPD GOLD 2 onderging een hemicolectomie onder algehele anesthesie. De patiënt kreeg dexamethason voor PONV profylaxe. U had geadviseerd om de gift prednisolon na 12 uur wel te geven. Volgens het dossier is de anesthesie afdeling niet van plan om advies op te volgen dat u eerder gaf. Wat doet u?				

	N AIOS	% AIOS	N staf	% staf
Bel de anesthesie voor overleg	3	42.9%	3	100%
– *Het moet wel worden herhaald*	– *0*		– *1*	
4 mg dexamethason is voldoende	2	28.6%	0	0%
Niks	2	28.6%	0	0%

PART II

PREOPERATIVE FASTING

4

ASSOCIATION OF A LIBERAL FASTING POLICY OF CLEAR FLUIDS BEFORE SURGERY WITH FASTING DURATION AND PATIENT WELL-BEING AND SAFETY.

Authors: Marije Marsman, Teus H. Kappen, Lisette M. Vernooij, Evelien C. van der Hout, Judith A.R. van Waes, Wilton A. van Klei

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Abstract

Importance: Current fasting guidelines for procedures under anaesthesia are poorly implemented, leading to negative metabolic sequelae. Recent studies in children showed support of liberal clear fluid intake; adult physiology can support clear fluid intake but implementation studies are lacking.

Objective: To evaluate the successfulness of implementation of a liberal clear fluid policy with regard to fasting duration, well-being and safety in adults scheduled for anaesthesia.

Design: Quality improvement study conducted between January 2016 to July 2021.

Setting: Tertiary referral hospital in The Netherlands.

Participants: Adults scheduled for nonemergency procedures under anaesthesia, excluding obstetrics or preoperatively intubated patients.

Intervention: Stepwise introduction of a liberal fluid fasting policy, allowing for ingestion of clear fluids until arrival at the operating room.

Main outcomes and measures: The primary outcome was change in fasting duration. Secondary outcomes were patient well-being, measured as preoperative thirst, amount of fluid ingested, postoperative nausea and vomiting (PONV) and administration of anti-emetics. Safety was measured as incidence of regurgitation and aspiration (pneumonia).

Results: Of the 76,451 included patients (mean [SD] age 56 [17] years; 39,530 male individuals [52%]) included in the study, 59,036 (78%) followed the standard policy and 16,815 (22%) followed the liberal policy. Time series analysis showed an estimated decrease of 3:07 hours (IQR 1:36-7:22; P < 0.001) after implementing the liberal policy. Post-implementation median (IQR) fasting duration was 1:20 (0:48-2:24) hours. The incidence of regurgitation changed from 18 (95% CI 14-21) to 24 (95% CI 17-32) in 10,000 patients and the incidence of aspiration changed from 1.7 (95% CI 0.6-2.7) to 2.4 (95% CI 0.5-4.7) in 10,000 patients. In the liberal policy thirst feelings decreased (37% [4,982 of 8,615] versus 46% [3,3373 of 7,362]; P <0.001). PONV incidence decreased from 10.6% (6,339 of 59,636) to 9.4% (1,587 of 16,815; P < 0.001) and anti-emetics administration from 11.0 (6,538 of 59,636) to 9.5% (1,592 of 16,815; P <0.001).

Conclusions and Relevance: Results of this quality improvement study suggest that a liberal preoperative fluid fasting policy was associated with a clinically relevant reduction in fasting

duration and improved patient well-being with regard to preoperative thirst and PONV. Although a slightly higher incidence of regurgitation could not be ruled out, wider implementation of such policy may be advocated as results are still within the clinically accepted risks margins. Results suggest that surgical procedures in patients who drink clear fluids within two hours before anticipated anaesthesia, should not be postponed or cancelled.

Introduction

Preoperative fasting is commonly implemented to minimize the risk of aspiration in patients undergoing elective procedures under anaesthesia. In adults, guidelines advise withholding solids six hours and clear fluids two hours before anaesthesia.[1-3] Studies have shown that guideline implementation is suboptimal: in many hospitals, patients still fast five to six hours for clear fluids, leading to negative metabolic sequelae.[2 4-10] Inadequate implementation is, among other things caused by fear of aspiration and anxiety to lose flexibility in operating room scheduling.[7] Although aspiration can lead to aspiration pneumonia and even death, its reported incidences are between 1 and 10 in 10,000 elective procedures.[11-13] Recent studies, mainly in children, have shown that reducing fluid fasting times results in flexible operating room scheduling, reduced postoperative nausea and vomiting (PONV) and better patient well-being, without increasing aspiration risk.[14-18]

In response to these studies, European pediatric fasting guidelines relaxed their recommendations to allow intake of clear fluids until one hour before anaesthesia.[19-21] An international consensus statement on procedural sedation advises liberal clear fluid intake in adults considered at low risk for regurgitation.[22 23] For adults scheduled for anaesthesia, guidelines were not relaxed further, as there is limited supportive evidence available. However, because the physiology of gastric emptying in children and adults is comparable, a liberal fluid fasting policy in adults would likely not be accompanied by an increased risk of aspiration.[18 24-27] Accordingly, recent editorials propose a liberal fasting policy for clear fluids for adults and some hospitals have started implementation.[28-32]

Based on these considerations, we implemented a liberal fasting policy for clear fluids in adults scheduled for procedures under anaesthesia. This prospective study evaluated the implementation of this liberal policy, by studying the change in fasting duration. We also aimed to assess the safety of this liberal fasting policy with regard to regurgitation and aspiration. Finally, we studied if fasting duration was related to patient well-being (thirst and PONV).

Methods

Patient selection and fasting policy

This quality improvement study conducted between Januari 2016 and Juli 2020 included patients aged 18 years and older, who were scheduled for elective or urgent procedures under anaesthesia at the University Medical Center Utrecht, a tertiary referral hospital in the Netherlands. We excluded patients scheduled for emergency surgery requiring intervention within 8 hours, those with preoperative intubation, and patients undergoing obstetric procedures.

The University Medical Center Utrecht Medical Research Ethics Committee waived the need for informed consent, because of the non-interventional nature of the study. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

In the standard fasting policy, clear fluids were allowed until two hours before the start of anaesthesia. Between 15 and 60 minutes before anaesthesia, patients received one gram of acetaminophen with sips of water. In the implemented liberal policy, intake of clear fluids was permitted until arrival in the operating room, with a maximum of one glass per hour, and it was advised that the acetaminophen was ingested with one glass of fluid. In patients with a policy of 'nothing by mouth policy' no additional fasting policy was advised. Even after implementation of the liberal policy, by protocol, we advised patients with a proven gastroparesis or previous aspiration to follow the prior, standard protocol. In both fasting policies, patients were instructed to fast for solids for six hours.

Implementation of the liberal fasting policy

Implementation of a new policy can be difficult.[6 8] We therefore used a stepwise plan at four different locations in our hospital where implementation of a new fasting policy was considered increasingly difficult (Methods 1, Table 1 in the Supplement). In June 2019, the liberal policy was implemented in the first location and other patients in the hospital still followed the old policy. Subsequent locations started implementation in November 2019, June 2020 and September 2020. After September 2020, all patients followed the liberal fasting policy.

Data collection

All data were documented as part of standard care and obtained from electronic medical records. Registration of thirst and amount of fluid intake was implemented in June 2019. Data regarding baseline characteristics, fasting duration, thirst and fluid ingestion were collected from the hospital medical records (Chipsoft). Perioperative data regarding the occurrence of regurgitation, aspiration, PONV and anti-emetics administration were obtained from an Anaesthesia Information Management System (AIMS) (Anstat [Carepoint]). The AIMS allows entering of free text, and also contains a critical incident reporting system to be filled out at the end of each case, when a pop-up offers several choices from a standardized computerized audit form, including 'aspiration' as well as a free-text box.[33] If the pop-up is ignored, a reminder email is sent. This consistently results in a 95% completion rate for incident reporting.[33] Incident reports were searched for both the standardized category – aspiration– as well as by a free text search for 'aspiration' and 'regurgitation'. Additionally, free text records within the AIMS were systematically searched for keywords as 'aspiration', 'regurgitation', 'vomiting', 'bile' and 'food'. Subsequently, two authors (MM and THK) assessed the medical records of the patients with suspected regurgitation or aspiration, to confirm the diagnosis of regurgitation or aspiration. If the diagnosis of regurgitation was unclear, this was discussed until agreement. The medical records of patients with suspected aspiration pneumonia were also assessed by an independent pulmonologist (ECH) to adjudicate the diagnosis of pneumonia.

Outcomes

The primary outcome was the fasting duration for clear fluids, which was defined as the time between the last intake of fluids (at least ½ glass or 75 mL) and the start of anaesthesia. Secondary outcomes were the incidence of regurgitation, aspiration, aspiration pneumonia, preoperative thirst, the amount of fluid ingested, the incidence of PONV and administration of anti-emetics in the recovery room. Table 2 in the Supplement describes the definitions of the outcomes of regurgitation, aspiration and aspiration pneumonia. Thirst was defined by a three point numeric rating scale (no, intermediate, very thirsty). The amount of ingested fluid was defined as less or equal to half a glass, one glass or two or more glasses. One glass contained approximately 150 mL.

Sample size

Ideally in studying implementation of an intervention with a risk for potential harm, a non-inferiority analysis on the safety outcome would be preferred. In this case, this would include regurgitation and aspiration. However, because the incidence of these safety outcomes is rare, the number of patients that would have had to be evaluated to test the non-inferiority with regard to safety was considered not feasible in terms of time and costs. Because the historical estimated incidence of regurgitation among patients scheduled in our hospital between 2013 and 2017 was 7 in 10,000, a non-inferiority study taking this incidence into account would require inclusion of more than 50,000 patients in the liberal policy and would take a total of five years. We considered an implementation and evaluation cycle of two years to be optimal for successful implementation, and this would include an estimated 15,000 patients in the liberal fluid policy. This would provide sufficient numbers for evaluation of the primary outcome, the change in fasting time, and the secondary well-being outcomes. It would also result in multiple cases of regurgitation, allowing a reasonable estimate of the incidence of safety outcomes.

Statistical analysis

Baseline characteristics are presented as means, medians or percentages, where appropriate. Patients in the standard policy group were compared with those in the new policy group, regardless of the implementation location. Normality for continuous variables was checked by visualization of QQ-plots and histograms. Fasting duration was not normally distributed and these data were presented as medians. The chi-square test for categorical variables and the t-test or Mann-Whitney U test for continuous variables were used to compare groups where appropriate.

Multiple variables showed missing data, with 26% of the data on fasting duration missing. Missing data were handled using multiple imputation using the –mice- library in R (R Foundation for Statistical Computing), creating 20 imputed datasets. All analyses were conducted in the imputed datasets and subsequently, estimates were pooled using the Rubin's rule (Table 3 in the Supplement). Missing data on registration of thirst and ingested fluids were not imputed as collection of these data started only after June 2019, resulting in missing data of 23% (thirst) and 20% (ingested fluids) after June 2019 and of 100% before June 2019. As kidney function was only measured for strict indications preoperatively,

patients with missing preoperative glomular filtration rate were assumed to be within normal ranges.

The association of the implementation of the liberal fasting policy with median monthly fasting duration was analyzed using an interrupted time series analysis. For this purpose, autoregressive integrated moving average (ARIMA) models were created, with the different implementation dates as possible outcome predictors.[34] Based on visualization of the observed and fitted models, two extra predictors were added that explained abrupt changes in fasting duration due to implementation of new registration forms in June 2016 and February 2017 (Methods 1). ARIMA (0,0,0) models were tested and the accuracies of the fitted models were checked by visual inspection of the (partial) autocorrelation function plots and were considered a good fit using the Ljung-Box Q test (test for autocorrelation applied to the residuals of the fitted model) and stationary R-squared. In addition to the ARIMA model fitted on the full dataset of combined locations, separate models were created for the different locations, as it was expected that the success of implementation would differ across locations.

Similar ARIMA models were constructed to assess the association of the implementation of the liberal policy with the secondary well-being outcomes. The incidences of regurgitation, aspiration and aspiration pneumonia were determined for both periods after either the standard or the liberal policy and confidence intervals were calculated using the one-way analysis of variance test. Adjusted analyses were not performed for the safety outcomes, as the incidences of regurgitation and aspiration were too low to make accurate ARIMA models or to make clinically accurate risk estimations.

Further, a post hoc analysis was performed for the primary and secondary outcomes, excluding patients who underwent urgent surgery or endoscopic procedures as these procedures were associated with a higher risk for regurgitation. All *P* values were 2-sided, and statistical significance was set as $P < 0.05$.

The imputation model was constructed in R, version 4.0.3 (R Core Team) and statistical analyses were performed with IBM SPSS Statistics for Windows, version 26.0 (IBM Corp).

Results

Of the 76,451 patients, mean [SD] age 56 [17] years; 39,530 male individuals [52%]); 36,921 female individuals [48%] included in the study, 59,036 (78%) followed the standard fasting policy and 16,815 (22%) followed the liberal policy (Table 1).

Table 1. Baseline characteristics comparing standard and liberal fluid policy.

	Standard policy (n=59,636)	**Liberal policy (n=16,815)**
Mean age in years (SD)	57 (17)	56 (18)
Female sex	28,449 (48)	8,472 (51)
Mean BMI in kg/m² (SD)[a]	26 (5.0)	26 (5.1)
Obesity[b]	11,103 (19)	2082 (18)
Smoking[c]	11,778 (20)	3,143 (19)
Alcohol use[d]	33,018 (55)	9,022 (54)
History of diabetes[e]	7,407 (12)	2,139 (13)
History of renal failure[f]	1,336 (2.2)	323 (0.22)
Mean GFR in mL/min (SD)	84 (26)	88 (27)
ASA classification[g]		
1	9,693 (16)	2,395 (14)
2	29,088 (49)	7,810 (46)
≥3	20,855 (35)	6,610 (40)
Urgent surgery[h]	3,699 (6.2)	1,009 (6.0)
Motion sickness/previous PONV	12,618 (21)	3,253 (19)
Apfel criteria (0-3)[i]		
0	21,986 (37)	6,003 (36)
1	23,995 (40)	7,108 (42)
2	12,115 (20)	3,350 (20)
3	1,540 (2.6)	354 (2.1)
Number of anti-emetics administered intraoperatively[j]		16815
0	1,8584 (31)	3,660 (22)
1	29,496 (49)	7,998 (47)
2	9,101 (15)	3,817 (23)
≥ 3	2,488 (4.1)	1,340 (8.0)
Anaesthesia technique		
General anaesthesia	39,769 (67)	12,299 (73)
General +locoregional anaesthesia	2,600 (4.4)	664 (3.9)
Locoregional anaesthesia only	3,224 (5.4)	841 (5.0)
Procedural sedation	13,387 (22)	2862 (17)
Monitored awake anaesthesia care	656 (1.1)	150 (0.9)

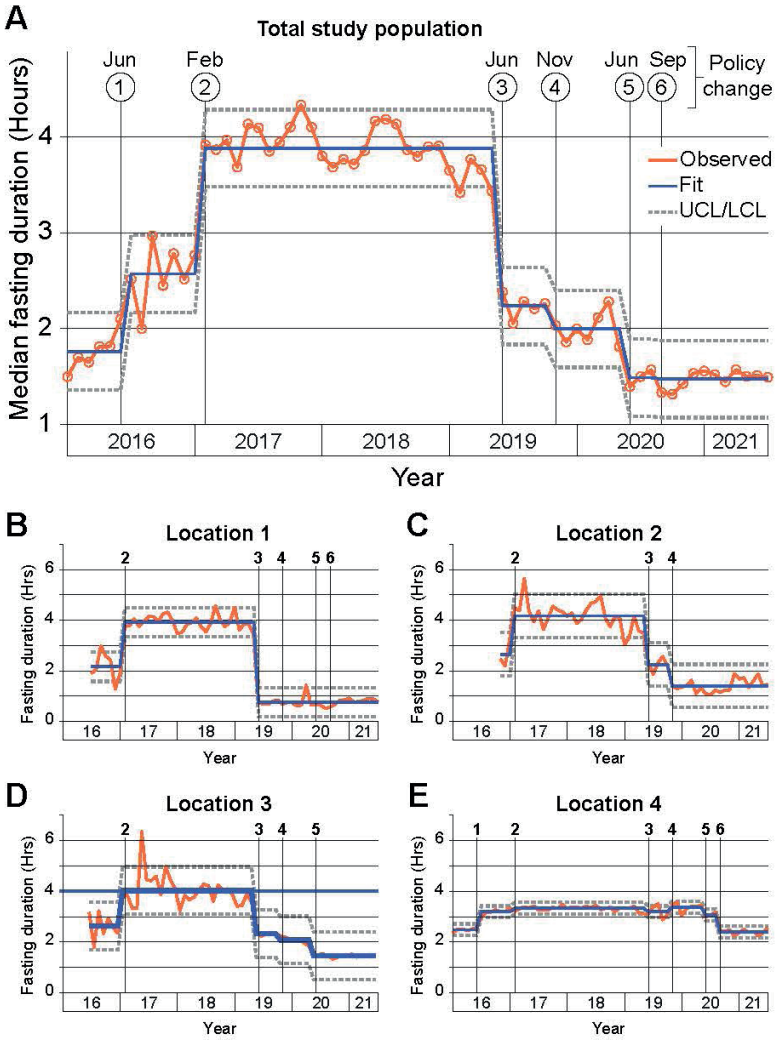
	Standard policy (n=59,636)	Liberal policy (n=16,815)
Anaesthesia depth		
General anaesthesia	42,369 (71)	12,962 (77)
Procedural sedation	13,387 (22)	2,862 (17)
Awake procedure	3,880 (6.5)	991 (5.9)
Surgical specialty[k]		
Group 1: airway manipulation without digestive tract involvement	7,621 (13)	2,529 (15)
Group 2: minor procedures without airway or digestive tract involvement	8,617 (14)	2,073 (12)
Group 3: major procedures without airway or digestive tract involvement	15,100 (25)	4,935 (29)
Group 4: major procedures with digestive tract involvement	20,567 (35)	5,803 (35)
Group 5: endoscopy of digestive tract	7,731 (13)	1,475 (8.8)

Figures are numbers (%) of patients, unless stated otherwise. [a]BMI is Body Mass Index.[b]Obesity was defined as a BMI ≥ 30 kg m^{-2}. [c]Smoking was defined as currently smoking. [d]Alcohol use was defined as drinking any alcohol daily. [e]Diabetes included patients with oral antidiabetics and/or insulin. [f]Renal failure is defined as a Glomerular Filtration Rate (GFR) < 30 mL/min. [g]ASA classification is physical status according to American Society of Anaesthesiology. [h]Urgent surgery was defined as needing surgery between 8 and 24 hours. [i]Apfel criteria included female sex, history of motion sickness or previous PONV, no history smoking (one point per criterium). [j]Included anti-emetics are ondansetron, droperidol, dexamethasone, continuous propofol infusion. [k]Surgical specialties were grouped based on potential for airway manipulation by surgeon, potential for involvement of digestive tract and as minor versus major surgery (group 1, ENT, maxillary surgery and bronchoscopy by pulmonologists; group 2, interventional cardiology, complex pain procedures, interventional radiology, electroconvulsion therapy; group 3, neurosurgery, orthopedics, plastic and reconstructive surgery and ophthalmology; group 4, cardiothoracic surgery, general surgery, gynecology, urology, vascular surgery; group 5, endoscopic procedures of digestive tract).

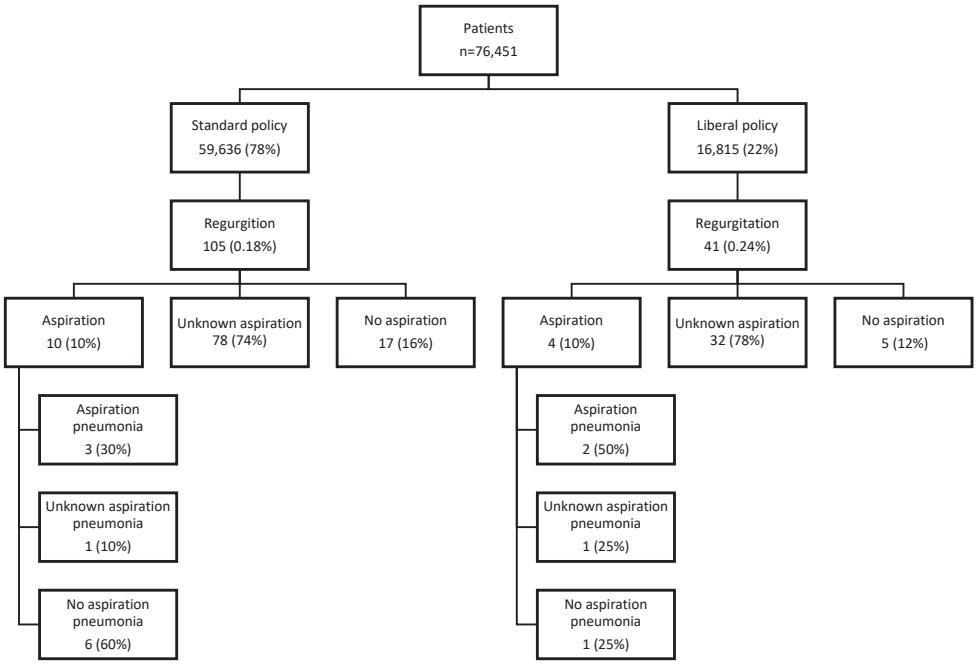
After implementation of the liberal fasting policy, overall median (IQR) fasting time decreased significantly from 3:07 (1:36-7:22) hours to 1:20 (0:48-2:24) hours (P < 0.001). The 75th percentile decreased from 7:22 hours to 2:24 hours. Implementation was most successful in ambulatory surgery patients, leading to median (IQR) fasting times of 44 (0:29- 1:35) minutes, whereas implementation was less successful in patients undergoing procedures at remote locations, with post-implementation median (IQR) fasting times of 2:24 (1:16-4:49) hours (Figure 1). The ARIMA models showed that implementation of the new fasting policy across the different locations explained the overall decrease in fasting duration (estimated change of 2:24 hours (P < 0.001), stationary R^2 0.996; LJung-Box Q 0.692) (Figure 1). Analysis per location showed that the implementation outcome was largest in ambulatory care (estimated change 3:08 hours, P < 0.001) and smallest at remote locations (estimated change of 0:41 hours, P < 0.001) (Figure 1). Implementation of the liberal fasting policy at the ambulatory

location already reduced fasting duration at the inpatient care locations before it was implemented there.

Figure 1. ARIMA models for observed and fitted median fasting duration over time.



The red dotted line denotes the observed median fasting duration. The blue line denotes the fitted median fasting duration. The dotted grey lines denote the upper and lower 95% Confidence Intervals of the fitted line. The vertical lines denote changes in policy or registration and these moments were used as predictors. Line 1 (June 2016) is the change in registration forms in the remote locations, leading to better registration of glasses of fluid ingested. Line 2 (February 2017) is the change in registration forms in the operating rooms, leading to better registration of glasses of fluid ingested. Line 3 (June 2019) denotes implementation of the liberal fluid policy in ambulatory surgery (Location 1). Line 4 (November 2019) denotes implementation of the liberal fluid policy in the inpatient minor surgery area (Location 2). Line 5 (June 2020) denotes implementation of the liberal fluid policy in the inpatient major surgery area (Location 3). Line 6 (September 2020) denotes implementation of the liberal fluid policy in the remote locations (Location 4). Figure A shows change in fasting duration over time for total study population. Figure B shows change in fasting duration over time for Location 1, the ambulatory surgery location. Figure C shows change in fasting duration over time for Location 2, the location for minor inpatient procedures. Figure D shows change in fasting duration over time for Location 3, the location for major inpatient procedures. Figure E shows change in fasting duration over time for Location 4, that include all procedures at remote locations. Figure 2. Flowchart with incidences of regurgitation, aspiration and aspiration pneumonia.



Figures are numbers (%) of patients.

Safety outcome

In total, 146 patients (0.2%) regurgitated (Figure 2). The incidence of regurgitation was 24 (95% CI 17-32) in 10,000 patients in the liberal policy group, compared with 18 (95% CI 14-21) in 10,000 patients in the standard policy group (Table 2). Patients who regurgitated were more frequently obese and more often underwent urgent surgery or endoscopy and the majority regurgitated during maintenance of anaesthesia (Table 4 in the Supplement). Of the 146 patients who regurgitated, 14 (9.6%) had a proven aspiration, 22 (15%) did not aspirate and in 110 (75%) it was unknown if they had aspirated (Figure 2). The incidence of aspiration in the liberal policy group was 2.4 (95% CI 0.5-4.7) in 10,000 patients as compared with 1.7 (95% CI 0.6-2.7) in 10,000 patients in the standard policy group (Table 2). Five of the 14 aspirating patients (36%) developed an aspiration pneumonia as adjudicated by pulmonologist ECH, and in two patients, this diagnosis was uncertain, but they were classified as having an aspiration pneumonia. Of these seven patients with aspiration pneumonia, three followed the liberal policy and four followed the standard policy resulting in an

incidence of aspiration pneumonia of 1.8 (95%-CI 0.23-3.8) and 0.7 (95%-CI 0.01-1.3) in 10,000 patients, respectively. The pneumonia contributed to a longer hospital stay in four patients and may have contributed to death in two (Table 5 in the Supplement).

Table 2. Primary and secondary outcomes as compared between the standard and liberal fasting policy.

Outcome	Standard policy (n=59,636)	Liberal policy (n=16,815)	P Value
Median fasting duration (h:min) (IQR)	3:07 (1:36-7:22)	1:14 (0:48-2:24)	< 0.001
Incidence of regurgitation	105 (0.18)	41 (0.24)	0.09
Incidence of aspiration			0.17
Yes	10 (0.017)	4 (0.024)	
Unknown	78 (0.13)	32 (0.19)	
No	59,548 (99.9)	16,779 (99.8)	
Incidence of aspiration pneumonia	4 (0.007)	3 (0.018)	0.18
Phase of anaesthesia during regurgitation[a]			0.82
Induction	27/105 (26)	12/41 (29)	
Maintenance	61/105 (58)	23/41 (56)	
Emergence	17/105 (16)	6/41 (15)	
Postoperative nausea and vomiting	6,339 (10.6)	1,587 (9.4)	<0.001
Use of anti-emetics	6,538 (11.0)	1,592 (9.5)	<0.001
Ingestion of ≥ 1 glass[b]	3,915/7,888 (50)	10,010/14,018 (71)	<0.001
Preoperative thirst[b]	3,373/7,362 (46)	4,982/8,615 (37)	<0.001

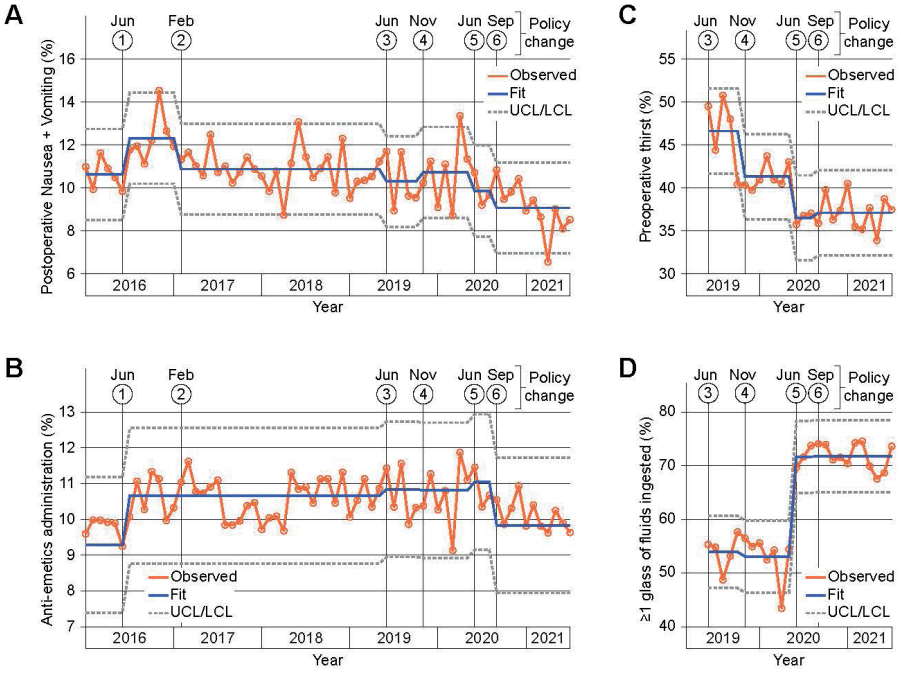
Figures are numbers (%) of patients, unless stated otherwise. A glass contains approximately 150 mL of clear fluids. [a]Percentages calculated based on number of patients who regurgitated in the standard (n=105) and liberal policy (n=41). [b]Data registration was available only for patients scheduled after June 2019 and percentages were calculated based on available number of patients.

Well-being outcome

The reported PONV incidence was lower in the liberal policy group, 9.4% (1587 of 16,815) vs 10.6% (6339 of 59,636; P < 0.001) and patients received significantly less anti-emetics in the liberal policy group (9.5% [1592 of 16,815] vs 11.0% [6538 of 59,636]; *P* < 0.001) (Table 2). The ARIMA models for PONV and administration of anti-emetics were less accurate (stationary R^2 of 0.235 and 0.43 respectively, with LJung-Box Q tests of 0.492 and 0.775), and implementation of the liberal policy did not explain decrease in PONV incidence and anti-emetics administration (Figure 3). Analysis per location showed that implementation of the liberal fasting policy decreased anti-emetic use in the ambulatory care location (estimated decrease 2.0%, P= 0.02). PONV incidence and anti-emetics administration decreased in the inpatient care location with minor surgery (estimated decrease 2.4% P = 0.01 and 2.7%, P = 0.02 respectively), but not in other locations.

Registration of thirst and amount of fluid intake started after June 2019 (n=27,284). In the liberal policy group 71% of patients (10,010 of 14,018) of patients drank 1 or more glasses of clear fluids and 37% (4, 982 of 8,615) felt thirsty before surgery as compared with 50% (3, 915 of 7888) and 46% (3,373 of 7,362), respectively, in the standard policy group (*P* < 0.001) (Table 2). The ARIMA models for thirst and fluid intake were accurate (stationary R^2 of 0.741 and 0.904 respectively, with LJung-Box Q tests of 0.001 and 0.938), and implementation of the fasting policy could explain the decrease in thirst and increase in fluid intake (Figure 3).

Figure 3. ARIMA model of observed and fitted values for secondary outcomes of well-being.



The red dotted line denotes the observed well-being values (%). The blue line denotes the fitted values. The dotted grey lines denote the upper and lower 95% Confidence Intervals of the fitted line. The vertical lines denote changes in policy or registration and these moments were used as predictors. Line 1 (June 2016) is the change in registration forms in the remote locations, leading to better registration of glasses of fluid ingested. Line 2 (February 2017) is the change in registration forms in the operating rooms, leading to better registration of glasses of fluid ingested. Line 3 (June 2019) denotes implementation of the liberal fluid policy in ambulatory surgery (Location 1). Line 4 (November 2019) denotes implementation of the liberal fluid policy in the inpatient minor surgery area (Location 2). Line 5 (June 2020) denotes implementation of the liberal fluid policy in the inpatient major surgery area (Location 3). Line 6 (September 2020) denotes implementation of the liberal fluid policy in the remote locations (Location 4). Figure A shows the change in PONV in the recovery room over time. Figure B shows change in administration of anti-emetics in the recovery room over time. Figure C shows change in preoperative thirst over time. Figure D shows change in percentages of patients who received ≥ 1 glass of fluid preoperatively over time.

Post-hoc analyses

After excluding patients scheduled for endoscopy or undergoing urgent procedures, 14,334 of the 62,561 remaining patients (23%) followed the liberal policy group (Table 6 in the Supplement). Median (IQR) fasting time in the liberal policy group was 1:14 (0:45-2:11) hours, compared with 2:54 (1:29-6:21) hours in the standard policy group and, based on the ARIMA analyses, could be explained by the stepwise implementation (Figure 1 in the Supplement). Table 6 in the Supplement describes secondary outcomes with regard to

well-being and safety. In both policies, the incidences of regurgitation, aspiration and aspiration pneumonia were lower than in the total population. The beneficial effect of the liberal policy with well-being was comparable to that of the total population.

Discussion

This was a quality improvement study of the implementation of a liberal fasting policy that allowed adults scheduled for procedures under anaesthesia to drink clear fluids until arrival in the operating room. Time series analysis showed an associated estimated decrease in fasting duration of 3:07 hours to a median post implementation duration of 1:10 hours and 75% of patients had a fasting duration of 2:24 hours or shorter, suggesting implementation success.. The liberal policy was associated with improved patient well-being as patients felt less thirsty. We also found a small decrease in PONV and antiemetics- administration in minor surgery. The incidence of regurgitation was 24 (95% CI 17-32) in 10,000 patients after implementation, compared with 18 (95% CI 14-21) in 10,000 patients before implementation. Inferiority of the liberal policy with regard to safety could not be ruled out.

Implication for current practices and future research

Current fasting policies advocated in guidelines are poorly implemented in clinical practice.[4 10] This study offers a strategy how a preoperative fasting policy can be changed with succes (Supplemental Methods 1). In addition, our results add to the available literature that a liberal fluid policy is associated with improved patient well-being. Furthermore, it suggests that the risk of regurgitation and aspiration is likely to be within clinically acceptable limits. At the very least, the results suggest that surgery in patients who (accidentally) drink clear fluids within two hours before anticipated anaesthesia induction in a standard fasting policy, should no longer have their procedures postponed or cancelled. Finally, as conducting a randomized clinical trial comparing incidences of aspiration between a standard and a liberal fasting fluid policy is challenging, we call for wider implementation of a liberal fluid policy. If fasting duration, regurgitation and aspiration are monitored adequately and the results are shared, this may result in more accurate estimates of the incidence of aspiration and regurgitation.

Regurgitation

Both in the standard and liberal policy, the incidence of regurgitation was higher than anticipated. The higher incidence could be explained by better registration, due to a Hawthorne effect. Another contributing factor could be an increase in the number of more

complex procedures under procedural sedation at the endoscopy department in our hospital. Because such procedures may be painful and require higher doses of opioids, these relatively often result in nausea with subsequent regurgitation, which was suggested by our results showing a higher incidence of regurgitation in endoscopic procedures. Although higher than anticipated, our current incidence of regurgitation matches recent literature.[12 17]

The German prospective multicenter observational (NIKS) study of 12,093 children prospectively evaluated the safety of a liberal fluid policy.[17] For children undergoing elective procedures after a fasting duration of 2.3 hours, the reported incidence of regurgitation was 32 per 10,000 patietns, which is higher than in our study. No significantly higher incidence was observed in children with a fasting duration of one to two hours. A recent retrospective record study in 155,830 adults evaluated the standard two hours of fasting for clear fluids and reported an incidence of regurgitation in elective anaesthesia of 0.6 per 10,000 patients.[12] This incidence is lower than in our population and likely to be attributed to the retrospective study design. The authors noticed that some anaesthesiologists considered regurgitation without aspiration relatively innocent and were inclined not to record this, leading to an underestimation. We used regurgitation as an outcome to evaluate the safety of our liberal policy, because its incidence is higher than aspiration and aspiration pneumonia making the safety estimates more reliable.

Aspiration

Previously, the estimated incidence of aspiration was reportedly between 1 and 10 per 10,000 patients, which was considered to be an acceptable risk.[13] In our study, the overall incidence of aspiration was 1.8 per 10,000. The incidence of aspiration was slightly higher in the liberal group compared with the standard group. More recent studies also investigated the incidence of aspiration, both in standard and liberal fasting policies. In the prospective multicenter Anaesthesia PRactice In Children Observational Trial (APRICOT) study in children, including elective and emergency procedures, the incidence of aspiration was 9 per 10,000 patients.[35] In the NIKS study the incidence of (suspected) aspiration in elective procedures was 8 per 10,000 patients, which is higher than in our study. In a prospective study by McCracken and Montgomery evaluating a liberal fasting policy in elective ambulatory surgery in adults the incidence of aspiration was 0.7 per 10,000.[36]

Strengths and limitations

The major strength of this study was the successful implementation of a liberal fasting policy and adequate recording of fasting duration, regurgitation and aspiration. In addition, to our best knowledge, this was the largest study evaluating a liberal fluid policy in adults. Our study also has some limitations. It was underpowered to conclude on safety of the liberal fasting protocol with regard to regurgitation and aspiration. In addition, because of the observational design, residual confounding could not be ruled out.

Conclusion

Results of this quality improvement study suggest that a liberal fasting policy was associated with a clinically relevant reduction in fasting duration and improved patient well-being with regard to preoperative thirst and PONV. Although a slightly higher incidence of regurgitation could not be ruled out, wider implementation of such a policy may be advocated, as results are still within the clinically accepted risks margins. Results suggest that surgical procedures in patients who drink clear fluids within 2 hours before anticipated anaesthesia should not be postponed or cancelled. To obtain definitive estimates on safety outcomes, there is a need for collaborative multicenter studies evaluating a liberal fluid fasting policy.

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Supplemental Methods. Description of implementation plan of the liberal fasting policy.

Implementation of a new liberal fasting policy in a hospital was regarded as a major culture change, requiring a careful strategy. We therefore planned a stepwise implementation based on four locations where implementation of a liberal fluid policy was thought to be increasingly difficult (Supplemental Table 1). We considered that the implementation would be more manageable if it started at a smaller scale. This way the time that was invested by the researchers could be better targeted. Moreover, if implementation in one location was successful, this location could serve as a 'champion' for subsequent locations.

Overall, the implementation plan involved oral explanation of the liberal fasting policy at the preoperative assessment clinic and adjustment of patient education material, in addition to adjustment of patient letters with preoperative instructions. Nurses and ward physicians were trained during workshops and by instruction videos to give the patients their preoperative acetaminophen with one glass of water or lemonade instead of sips of water and to advocate a liberal fluid intake at the wards. Upon arrival at the holding area, nurses were stimulated to offer a glass of water to the patients. Patients who were not thirsty usually declined this offer. Additional hospital-wide communication of changes in policy was achieved by multiple emails and leaflets, and by promotion during campaigns at the wards. The first months after implementation in a location nurses received monthly feedback about their registration rate of fluid intake and the actual duration of fasting, until no improvement could be expected. We estimated that it would take around five months per location to be reasonably successful.

No changes in the standard fasting policy were made before June 2019, but in June 2016 and February 2017 new registration forms for fasting times were implemented, which was combined with a campaign for accurate registration. This led to increased awareness of accurate registration. Before February 2017 nurses at location A and B were inclined to register the sips of water ingested with the acetaminophen as the 'last moment of fluid intake'. After this optimization campaign they were more inclined to register only the moment of last intake of ≥ ½ glass of fluid, and not to count the sips of water used to ingest the Acetaminophen as 'fluid intake'. Consequently, registered fasting durations increased after February 2017. A similar change occurred at the remote locations in June 2016.

In June 2019 we started implementing the liberal policy for ambulatory minor surgeries (operating complex A). This group was thought to be the most easy to start with, thanks to its

small group of dedicated nurses, close connection to the operating rooms and close supervision by anaesthesiologists. For five consecutive months, the nurses got monthly feedback about the fasting duration of their patients. Direct feedback encouraged the nurses to give patients one glass of water and to increase the registration rate of the fasting times. In November 2019, the liberal policy was applied to inpatients undergoing minor procedures at operating room complex A. The holding area for inpatients is separated from the holding area for ambulatory care patients. The nurses working in this area are recovery room nurses, together with some of the dedicated holding area nurses from the ambulatory care holding area. The inpatient area is both next to the ambulatory care area as well as to the operating rooms and again is supervised by anaesthesiologists, so nurses could be encouraged to follow the liberal policy by their colleagues from ambulatory care and by the anaesthesiologists. In June 2020, the liberal policy was further applied to patients who underwent procedures at operating room complex B. This started two months later than planned, due to the COVID pandemic. Complex B serves inpatients undergoing major surgery. For these patients the fasting policy had to be executed by ward nurses from more than ten different surgical wards, not supervised by anaesthesiologists. This challenged daily promotion of the liberal policy. In September 2020, the liberal policy was introduced at the endoscopy department and other remote locations were anaesthesia is provided, such as radiology and the cardiac catheterization laboratory. Especially at the endoscopy department, fasting times were already traditionally longer than in other departments, due to need of empty stomachs and intestines, resulting in longer fasting duration than even advised in endoscopy guidelines.

Supplemental Table 1. Overview of stepwise implementation of liberal fasting policy.

hospital	within-hospital sites	type of patients	type of procedures	before June 2019	step 1 June 2019	step 2 November 2019	step 3 June 2020	step 4 September 2020
UMC Utrecht	operating room complex A	outpatients	minor surgery	standard	liberal	liberal	liberal	liberal
		inpatients	minor surgery	standard	standard	liberal	liberal	liberal
	operating room complex B	inpatients	major surgery	standard	standard	standard	liberal	liberal
	remote areas	out- and inpatients	endoscopic and minimal invasive	standard	standard	standard	standard	liberal

Supplemental table 2. Definitions of secondary safety outcomes.

Secondary safety outcome	Definition
Regurgitation	Visualization of gastric content in the oral cavity or pharynx.
Aspiration	Visualization of gastric content in the tracheobronchial tree behind the vocal cords as seen by laryngoscopy, bronchoscopy and/or after tracheal/bronchial suctioning. Patients with signs of perioperative distress, such as reduced saturation, increased respiratory rate, coughing, or wheezing after a registered regurgitation. Patients developing an aspiration pneumonia after a registered regurgitation.
Aspiration unknown	Patients with observed regurgitation, but where no laryngoscopy, bronchoscopy or tracheal suctioning was performed and that had no signs of perioperative respiratory distress or pneumonia.
Aspiration pneumonia	A postoperative pneumonia based on clinical symptoms of respiratory distress, fever and if available a postoperative chest radiograph demonstrating a new infiltrate that did not exist preoperatively and that developed postoperatively within 24 hours or as diagnosed by the attending physician and adjudicated retrospectively by the independent pulmonologist.

Supplemental Table 3. Original data, data without missing primary outcomes and imputed data on baseline characteristics and fasting duration.

	Original data (n=76,451)	**Original data without missing data (n= 56,287)**	**Imputed data (n=76,451)**
Mean age in years (SD)[a]	57 (17)	56 (17)	57 (17)
Female sex[a]	36,921 (48)	27,494 (49)	36,921 (48)
Mean BMI in kg m^{-2} (SD)[b]	26.1 (5.1)	26.1 (5.0)	26.1 (5.1)
Missing	2,277 (3.0)	1,426 (2.5)	
Smoking[c]	13,402 (18)	10,146 (18)	14,921 (20)
Missing	7,071 9.2	4,505 (8)	
Alcohol use[d]	37,973 (50)	29,152 (52)	42,041 (55)
Missing	7,706 (10)	4,929 (8.8)	
History of diabetes[e]	7,833 (10)	6,050 (10)	9,546 (12)
Missing	12,185 (16)	9,524 (16)	
History of renal failure[f]	1,659 (2.2)	1,187(2.1)	1,659 (2.2)
Missing	33,035 (43)		
Mean GFR in mL min^{-1} (SD)	85 (26)	85 (26)	89 (26)
Missing	33,022 (43)	26,103 (46)	
ASA classification[g]			
1	11,066 (14)	9,578 (17)	12,088 (16)
2	33,407 (44)	24,919 (44)	36,902 (48)
≥3	24,419 (32)	16,489 (29)	27,451 (36)
Missing	7,559 (10)	5,301 (9.4)	
Urgent surgery[a,h]	4,708 (6.6)	3,851 (6.8)	4,708 (6.6)
Motion sickness/previous PONV	13,563 (18)	10,266 (18)	15,871 (21)
Missing	12,459 (16)	8,665 (15)	
Anaesthesia technique			
General anaesthesia	51,963 (68)	43,259 (78)	52,068 (68)
General + locoregional anaesthesia	3,260 (4.3)	3,064, (5.4)	3,264 (4.3)
Locoregional anaesthesia only	4,058 (5.3)	3,077 (5.5)	4,065 (5.3)
Procedural sedation	16,244 (21)	5,411 (9.6)	806 (1.1)
Monitored awake anaesthesia care	805 (1.1)121 (0.2)	647 (1.1)	16,249 (21)
Missing		91 (0.2)	
Anaesthesia depth			
General anaesthesia	55,223 (72)	47,061 (84)	55,332 (72)
Procedural sedation	16,224 (21)	5,411 (9.6)	16,249 (21)
Awake procedure	4,836 (6.4)	3,724 (6.6)	4,864 (6.4)
Missing	121 (0.2)	91 (0.2)	

	Original data (n=76,451)	Original data without missing data (n= 56,287)	Imputed data (n=76,451)
Surgical specialty[i]			
Group 1: airway manipulation, without digestive tract involvement	10,135 (13)	8,270 (15)),(13)	10,149 (13)
Group 2: minor procedures without airway or digestive tract involvement	10,676 (14)	3,155 (5.6)	10,690 (14)
Group 3: major procedures without airway or digestive tract involvement	20,026 (26)	18,270 (33)	20,035 (26)
Group 4: major procedures with digestive tract involvement	26,347 (35)	23,719 (42)	26,370 (35)
Group 5: endoscopy of digestive tract	9,133 (12)	2,835 (5.0)	9,204(12)
Missing	0.1 (74)	38 (0.1)	
Fasting policy[a]			
Standard	59,636 (78)	42,189 (75)	59,636 (78)
Liberal	16,815 (22)	14,089 (25)	16,815 (22)
Median fasting duration (h:min) (IQR)	2:30 (1:15-5:19)	2:30 (1:15-5:19)	2:36 (1:17-5:38)
Missing[j]	20,164 (26)		
Postoperative nausea and vomiting			
Yes	5,555 (7.3)	4,862 (8.6)	7,924 (10)
No	39,419 (52)	33,526 (60)	68,527 (90)
Missing	31,477 (41)	17,899 (32)	

Figures are numbers (%) of patients, unless stated otherwise. [a]Denotes data without missings and that were used as predictors only. All other variables were imputed and served also as predictors. The location were the patient had the procedure was also a predictor in the imputation model, just as intraoperative administration of anti-emetics.

[b]BMI is Body Mass Index. [c]Smoking was defined as currently smoking. [d]Alcohol use was defined as drinking any alcohol daily. [e]Diabetes included patients with oral antidiabetics and/or insulin. [f]Renal failure is defined as a Glomerular Filtration Rate (GFR) < 30 ml/min. [g]ASA classification is physical status according to American Society of Anaesthesiology. [h]Urgent surgery was defined as needing surgery between 8 and 24 hours. [i]Surgical specialties were grouped based on potential for airway manipulation by surgeon, potential for involvement of digestive tract and as minor versus major surgery (group 1, ENT, maxillary surgery and bronchoscopy by pulmonologists; group 2, interventional cardiology, complex pain procedures, interventional radiology, electroconvulsion therapy; group 3, neurosurgery, orthopedics, plastic and reconstructive surgery and ophthalmology; group 4, cardiothoracic surgery, general surgery, gynecology, urology, vascular surgery; group 5, endoscopic procedures of digestivetract). [j]Percentage of missing data with regard to fasting duration varied across the different intervention periods. In the pre-intervention period (period 1) 30% of data were missing, in period 2, 3, 4 and 5 data were missing in 28%, 17%, 19% and 18%, respectively

Supplemental Table 4. Baseline characteristics compared between patients with and without regurgitation.

	No regurgitation (n=76,305)	Regurgitation (n=146)	P Value
Mean age in years (SD)	57 (17)	56 (18)	0.58
Female sex (%)	48	48	0.87
Mean BMI in kg m^{-2} (SD)[a]	26 (5.1)	27 (5.5)	0.01
Obesity[b]	14,145 (19)	39 (27)	<0.001
Smoking[c]	14,893 (20)	118 (19)	0.90
Alcohol use[d]	41,962 (55)	79 (54)	0.80
History of diabetes[e]	9523 (12)	24 (16)	0.14
History of renal failure[f]	1,658 (2.2)	1 (0.7)	0.21
Mean GFR in ml/min (SD)	85 (26)	90 (24)	0.06
ASA classification[g]			0.02
1	12,059 (16)	29 (20)	
2	36,819 (48)	79 (54)	
≥3	27,427 (36)	38 (26)	
Semi-urgent surgery[h]	4,692 (6.1)	16 (11)	0.02
Motion sickness/previous PONV	15,845 (21)	26 (18)	0.38
Apfel criteria (0-3)[i]			0.58
0	27,936 (37)	54 (36)	
1	31,038 (41)	65 (45)	
2	15,442 (20)	23 (16)	
3	1889 (2.4)	4 (2.6)	
Number of anti-emetics administered intraoperatively[j]			<0.001
0	22,221 (29)	23 (16)	
1	37,415 (49)	79 (54)	
2	12,884 (17)	34 (23)	
≥ 3	3,785 (5.0)	10 (6.8)	
Anaesthesia technique			0.02
General anaesthesia	51,981 (68)	87 (59)	
General + locoregional anaesthesia	3,257 (4.3)	7 (4.8)	
Locoregional anaesthesia	4,062 (5.3)	3 (2.1)	
Procedural sedation	16,204 (21)	45 (31)	
Monitored awake anaesthesia care	802 (1.1)	4 (2.7)	
Anaesthesia technique related to depression of consciousness			<0.001
General anaesthesia	55,237 (72)	94 (64)	
Procedural sedation	4,864 (6.4)	7 (4.8)	
Awake procedure	16,204 (21)	45 (31)	

	No regurgitation (n=76,305)	Regurgitation (n=146)	P Value
Surgical specialty[k]			<0.001
Group 1: airway manipulation without digestive tract involvement	10,135 (13)	14 (9.6)	
Group 2: minor procedures without airway or digestive tract involvement	10,680 (14)	10 (6.8)	
Group 3: intermediate risk procedures without airway or digestive tract involvement	20,008 (26)	27 (18)	
Group 4: intermediate/high risk procedures with digestive tract involvement	26,312 (34)	59 (40)	
Group 5: endoscopy of digestive tract	9170 (12)	36 (25)	
Median fasting duration (hh:mm) (IQR)	2:36 (01:18-4:39)	2:52 (01:23-8:19)	0.50

Figures are numbers (%) of patients, unless stated otherwise. [a]BMI is Body Mass Index. [b]Obesity was defined as a BMI ≥ 30 kg m^{-2}. [c]Smoking was defined as currently smoking. [d]Alcohol use was defined as drinking any alcohol daily. [e]Diabetes included patients with oral antidiabetics and/or insulin. [f]Renal failure is defined as a Glomerular Filtration Rate (GFR) < 30 mL/min. [g]ASA classification is physical status according to American Society of Anaesthesiology. [h]Urgent surgery was defined as needing surgery between 8 and 24 hours. [i]Apfel criteria included female sex, history of motion sickness or previous PONV, no history smoking (one point per criterium). [j]Included anti-emetics are ondansetron, droperidol, dexamethasone, continuous propofol infusion. [k]Surgical specialties were grouped based on potential for airway manipulation by surgeon, potential for involvement of digestive tract and as minor versus major surgery (group 1, ENT, maxillary surgery and bronchoscopy by pulmonologists; group 2, interventional cardiology, complex pain procedures, interventional radiology, electroconvulsion therapy; group 3, neurosurgery, orthopedics, plastic and reconstructive surgery and ophthalmology; group 4, cardiothoracic surgery, general surgery, gynecology, urology, vascular surgery; group 5, endoscopic procedures of digestive tract).

Supplemental Table 5. Description of patients with an aspiration pneumonia.

No	Age (yrs)	Sex	ASA[a]	Anesthesia technique	Phase of anesthesia	Procedure	Fasting policy	Fasting duration	Amount of fluid	Comorbidities related to risk factors for regurgitation	Description event
1	51	Male	3	Procedural sedation	Induction	Urgent Gastroscopy	Standard	unknown	Unknown	History of esophagectomy and receiving palliative care. Complaints of gastroparesis. Preoperatively suspected of chronic aspiration due to gastroparesis and progressive weakness.	After introduction of endoscope patient vomited and aspirated. Patient also developed atrial fibrillation. Procedure was terminated and patient felt dyspnoeic. No X-ray. No antibiotics started. Patient returned to nursing home and died a couple of days later due to progressive weakness. Symptoms or diagnosis of pneumonia was not explicitly described in medical record, but could not be ruled out.
2	84	Male	3	Procedural sedation	Maintenance	Trans-femoral aortic valve repair	Standard	unknown	Unknown	-	During procedure patient became hypotensive and started vomiting. Postoperative hypoxia and development of clinical signs of a pneumonia, with negative X-ray. Antibiotics started based on symptoms. Longer hospital stay due to pneumonia and surgery-related complications.
3	68	Male	3	General anesthesia	Induction	Wound debridement	Liberal	0:23	½ glass	Alcohol abuse. Urgent surgery due to infection of spondylodesis with systemic infection. Preoperative (unrecognized) ileus.	Aspiration during induction. Postoperatively the diagnosis ileus was made. Postoperatively patient was detubated, but reintubated due to respiratory insufficiency and admitted to the ICU. Infiltrate on X-ray. Antibiotics started. 2 days later patient underwent emergency surgery due to progressive ileus, leading to septic shock. Patient died after 14 days due to multiorgan failure.

4	61	Male	2	General anesthesia	Induction	Fixation of acetabulum	Liberal	0:50	1 glass	Daily alcohol use Urgent trauma patient. Preoperative opioid use.Preoperative (unrecognized) gastroparesis	Regurgitation during induction and aspiration of stomach content consisting of liquids and food. Postoperative ICU admission and pulmonologist removed remaining food particles from the lungs by bronchoscopy. Infiltrate on X-ray. Antibiotics started. Discharge from ICU 2 days later and full recovery.
5	30	Male	Un-known	General anesthesia	Induction	Pelvic fixation	Liberal	2:09	½ glass	Two days after pelvic trauma and pulmonary contusion. Preoperative opioid use and nausea. Obesity.	During induction regurgitation. Suctioning of oropharynx and subsequent endotracheal intubation. Unclear if tracheal suctioning was performed. Postoperative hypoxia. Unclear, based on symptoms and CT, if this was caused by worsening of the pulmonary contusion in combination with pain and anesthesia or due to aspiration pneumonia. Antibiotics already preoperatively started because of complicated fractures.
6	58	Male	2	Awake/ general anesthesia	Maintenance	Awake craniotomy	Standard	3:07	Unknown	Previous esophagectomy.	During awake craniotomy patient developed a grand-mal insult. She regurgitated and oropharynx was suctioned. The insult was treated. Patient was intubated and postoperatively admitted to the ICU. Detubation and discharge from ICU within hours after arrival. Infiltrate on X-ray. Antibiotics started. No longer admission to hospital due to pneumonia.
7	68	Male	2	General Anesthesia	Induction	Vitrectomy	Standard	3.26	Unknown	Daily smoking. Daily alcohol use. Dysregulated diabetes type 1. Renal function unknown.	During induction vomiting with regurgitation of liquids and food. Last meal > 12 hours ago. Postoperative dyspnea with diagnosis of aspiration pneumonia and infiltrate on X-ray. No antibiotics started. Patient was admitted longer to hospital, mainly because of dysregulated diabetes.

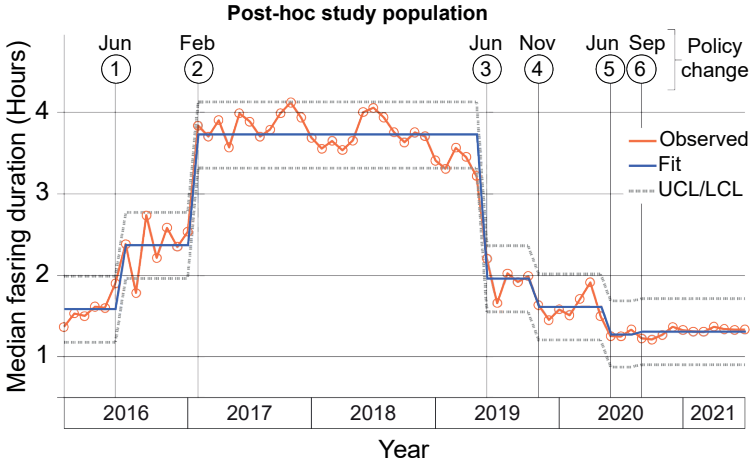
[a]ASA classification is physical status according to American Society of Anaesthesiology. The diagnosis of aspiration pneumonia was unsure in patients 1 and 5. Patients 2, 3, 4, 5 had a longer hospital stay due to their aspiration pneumonia. An aspiration pneumonia possibly contributed to death in patients 1 and 3.

Supplemental Table 6. Post-hoc analysis excluding patients for urgent surgery or endoscopy. Primary and secondary outcomes.

Outcome	Standard policy (n=48,227)	Liberal policy (n=14,334)	P Value
Median fasting duration (h:min) (IQR)	2:54 (1:30-6:20)	1:14 (0:45-2:10)	<0.01
Incidence of regurgitation (% [95% CI])	65 (0.13 [0.10-0.17])	29 (0.20 [0.13-0.28])	0.06
Incidence of aspiration			0.12
Yes (% [95% CI])	8 (0.017 [0.005-0.028])	2 (0.014 [0.005-0.033])	
Unknown	46 (0.095)	23 (0.16)	
No	48,173 (99.9)	14,309 (99.8)	
Incidence of aspiration pneumonia (% [95% CI])	3 (0.006 [0.0008-0.013])	2 (0.014 [0.005-0.033])	0.36
Postoperative nausea and vomiting	4,864 (10)	1,280 (8.9)	<0.001
Use of anti-emetics	946/7,402 (13)	1,470/14,334 (10)	<0.001
Ingestion of ≥ 1 glass[a]	2,533/5,396 (47)	8,816/12,025 (73)	<0.001
Preoperative thirst[a]	2,122/4,999 (42)	4,113/11,690 (35)	<0.001

Figures are numbers (%) of patients, unless stated otherwise. A glass contains approximately 150 mL of clear fluids.
[a]Data registration was available only for patients scheduled after June 2019.

Supplemental Figure 1. Post-hoc analysis: ARIMA model for observed and fitted fasting duration in total patient population.



The red dotted line denotes the observed median fasting duration. The blue line denotes the fitted median fasting duration. The dotted grey lines denote the upper and lower 95% Confidence Intervals of the fitted line. The vertical lines denote changes in policy or registration and these moments were used as predictors. Line 1 (June 2016) is the change in registration forms in the remote locations, leading to better registration of glasses of fluid ingested. Line 2 (February 2017) is the change in registration forms in the operating rooms, leading to better registration of glasses of fluid ingested. Line 3 (June 2019) denotes implementation of the liberal fluid policy in ambulatory care (Location 1). Line 4 (November 2019) denotes implementation of the liberal fluid policy in the inpatient minor surgery area (Location 2). Line 5 (June 2020) denotes implementation of the liberal fluid policy in the inpatient major surgery area (Location 3). Line 6 (September 2020) denotes implementation of the liberal fluid policy in the remote locations (Location 4). Figure A shows change in fasting duration over time for total study population. Figure B shows change in fasting duration over time for Location 1, the ambulatory care location. Figure C shows change in fasting duration over time for Location 2, the location for minor inpatient procedures. Figure C shows change in fasting duration over time for Location 3, the location for major inpatient procedures. Figure D shows change in fasting duration over time for Location 4, that include all procedures at remote locations.

5

GASTRIC FLUID VOLUME IN ADULTS FASTED FOR CLEAR FLUIDS AND UNFASTED PATIENTS: A PROSPECTIVE COHORT STUDY.

Authors: Marije Marsman MD, Niels Pouw MD, Leon M.G. Moons, Wilton van Klei, Teus H. Kappen

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Abstract

Background: Patients normally fast before anaesthesia to reduce aspiration risk. In children, fasting guidelines have changed, allowing liberal clear fluid intake. We hypothesised that in adults a comparable liberal fasting protocol would not increase gastric volumes beyond an upper limit of 1.5 ml kg^{-1}.

Methods: Prospective observational cohort study during a fasting policy change in adults scheduled for gastroscopy in a university hospital. The standard protocol allowed clear liquids until two hours before gastroscopy. In the liberal protocol water was offered at the holding area. During gastroscopy gastric content was suctioned and its volume measured. Gastric volumes, its content and elapsed time between last fluid intake were compared between the two patient groups as secondary outcomes.

Results: The liberal and standard groups included 45 and 44 patients, respectively. Mean gastric volume in the liberal group was 0.64 ml kg^{-1} (SD 0.54), which was below the prespecified mean upper limit (p=0.04) and higher than in the standard group (0.44 ml kg^{-1} (SD 0.64)), adjusted difference 0.15 ml kg^{-1} (95%CI -0.07-0.38). Median fasting times in the liberal and standard group were 0:39 and 6:06 hours, respectively (p<0.001). In the liberal group four patients (8%) had a stomach volume >1.5 ml kg^{-1} versus one patient (2%) in the standard group (p<0.001).

Conclusion: After introduction of a liberal fasting protocol in adults, the majority of patients had gastric volumes below the normally accepted upper limit of 1.5 ml kg^{-1}. Mean gastric volumes were within physiological range, but higher in the liberal group.

Editor, preoperative fasting for clear fluids for at least two hours is standard policy to minimise aspiration risk in adults. In children, current guidelines allow intake of clear fluids until one hour before induction of anaesthesia.[1] For procedural sedation without risk factors for aspiration, a recent international guideline advises unrestricted intake of clear liquids, and there have been calls to shorten fasting times before general anaesthesia to improve patient satisfaction.[2-4] An issue in the 'fasting debate' is the gastric fluid volume in relation to the aspiration risk. Previous studies reported mean gastric volumes in standard fasted patients of 0.4-0.6 ml kg^{-1} with reported upper limits of the normal range of 1.2-1.5 ml kg^{-1}.[5-7] Even though these studies were underpowered to assess aspiration risk, daily experience demonstrates that the standard policy is safe. As water passes the stomach within 30

minutes, we hypothesized that a liberal fluid policy would not result in gastric volumes exceeding 1.5 ml kg^{-1} for the majority of adults.

We studied the effects of implementation of a liberal fasting policy for clear fluids on gastric volumes in adults scheduled for gastroscopy. This policy allows intake of clear fluids with a maximum of one glass (± 150 ml) per hour and 150 ml of water is offered upon admission at the preoperative holding area. During the three week transition period of transition (September 2020) from old to new policy, the fasting protocol alternated per day and was applied to all patients regardless of inclusion in this study. The Medical Research Ethics Committee of the UMC Utrecht waived the need for informed consent (20-517/C). Nonetheless, all patients consented to the use of personal data for the purpose of the study under the General Data Protection Regulation.

We prospectively measured fasting times and gastric volumes according to the old (standard group) and the new policy (liberal group). Suctioning during gastroscopy resulted in precise measurements of gastric volumes. Exclusion criteria were a nil-by-mouth policy, gastroparesis (as documented in the medical history), abnormal upper gastrointestinal anatomy or inability to follow fasting guidelines. Our primary objective was to measure the mean gastric fluid volume (ml kg^{-1}) and its distribution in patients who followed the liberal fluid policy and to assess whether this mean volume was below the physiological upper limit of 1.5 ml kg^{-1}. We additionally compared the number of patients with gastric fluid volumes >1.5 ml kg^{-1} between the standard and liberal group. Assuming non-inferiority for the primary outcome, we aimed to assess whether 97.5% (+2SD) of the patients in the liberal group had a gastric volume below 1.5 ml kg^{-1}. Assuming a standard deviation (SD) of 0.35 ml kg^{-1}, the mean volume at which 97.5% (+2SD) of patients would have a gastric volume ≤1.5 ml kg^{-1} was 0.81 ml kg^{-1} (reference value). The minimum required sample size was 21 patients in the liberal fasting group. For the primary outcome a one-sample t-test was used to test the mean gastric volume of the liberal group against the reference value.

Eighty-nine patients were included: 44 in the standard group and 45 in the liberal group. The mean age of all patients was 56 years, 64% was male, mean BMI was 25.5 kg m^{-2} and 46% was classified ASA ≥3. Except for higher PPI use in the standard group, baseline characteristics were comparable between the groups. Figure 1 shows fasting times related to gastric fluid volumes (ml kg^{-1}). Mean volume was 0.64 ml kg^{-1} (SD 0.54) in the liberal group, a statistically significant difference with the reference value of 0.81 ml kg^{-1} (p=0.04, 95%CI-0.34 to-0.01).

In the standard group mean volume was 0.44 ml kg^{-1} (SD 0.64) ($p<0.01$, 95%CI-0.56 to-0.18). The adjusted mean gastric fluid volume between the two groups was 0.15 ml kg^{-1} (95% CI -0.07 to 0.38). In the liberal group four (8%) patients had a gastric fluid volume >1.5 ml kg^{-1} versus one (2%) patient in the standard group ($p<0.01$) (Figure 1).

Although the mean gastric fluid volume in the liberal group was higher than in the standard group, the mean volumes of both groups were within the range of 0.4-0.6 ml kg^{-1} as reported previously.[5] The higher mean volume in our liberal group can be explained by the short median fasting time of 39 minutes, because 34 patients (76%) drank within one hour before gastroscopy of whom 19 within 30 minutes. It may be likely that the 150 ml of water had not yet passed, resulting in higher stomach volumes. Although more patients in the liberal group had gastric fluid volumes >1,5 ml kg^{-1}, this is reasonably in line with previous studies that measured gastric fluid volumes in standard fasted adults: 3 to 6% of patients had volumes >1.5 ml kg^{-1}.[6] In one study 21% of standard fasted patients had a volume >1.5 ml kg^{-1}.[8] In a study that randomised children into standard or liberal fluid fasting policy, 1% of children in the standard group had gastric fluid volumes > 2 ml kg^{-1}, versus 15% in the liberal group, a significant difference.[9] The highest volumes were found in children who drank within 30 minutes before the procedure, comparable to our study.[9] These numbers are higher than in our liberal group. Nonetheless, in children a liberal fluid policy was accepted in an international consensus statement and a liberal fluid policy did not result in increased aspiration risk in two large studies.[1 10 11] One could speculate that if gastric fluid volumes in liberally fasted adults are comparable to such volumes in children with a comparable fluid policy, adopting a liberal fluid policy in adults may not result in increased numbers of aspiration.[9-12] The main limitations of the study were its non-blinded observational design and not having aspiration as our primary end point, which would require a substantially larger sample size.

In conclusion, after implementing a liberal fasting policy for clear fluids in adult patients undergoing gastroscopy, mean gastric fluid volume was below a pre-specified reference value based on the physiological upper limit of 1.5 ml kg^{-1}. In the liberal group more patients had a gastric fluid volume >1.5 ml kg^{-1} (8% versus 2%, respectively).

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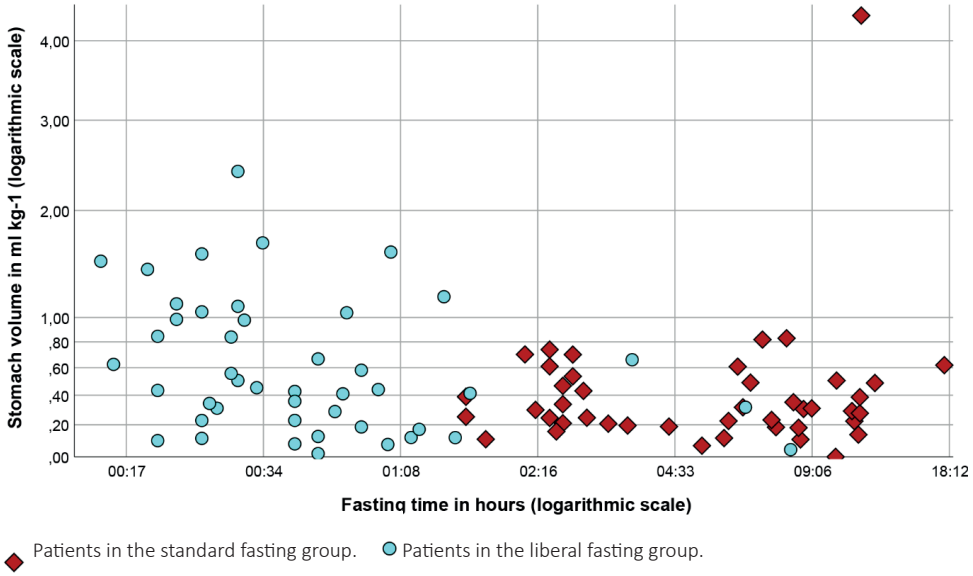
Figure 1. Scatterplot of fasting times (hh:mm) related to stomach volume (ml kg-1).



PART III

INFORMED CONSENT

6

AUTONOMOUS PATIENT CONSENT FOR ANAESTHESIA WITHOUT PREOPERATIVE CONSULTATION: A QUALITATIVE FEASIBILITY STUDY INCLUDING LOW RISK PROCEDURES.

Authors: Marije Marsman, Wisse M.F. van den Beuken, Wilton A. van Klei, Teus H. Kappen

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Abstract

Background: Informed consent for anaesthesia is mandatory and requires provision of information and subsequent consenting during consultation between anaesthesiologist and patient. Although information provisioning can be provided in a digital format, it is unknown whether this a valid substitute for a consultation. We explored whether provision of digital information is equivalent to oral consultation and whether it enables patients to give electronic informed consent (e-consent) for anaesthesia.

Methods: Qualitative feasibility study using semi-structured interviews in 20 low-risk adults scheduled for minor surgery under general anaesthesia or procedural sedation at a university hospital. Data were analysed using a thematic content analysis approach. During the interviews, patients followed an application that provides information and subsequent e-consenting.

Results: Mean age was 50 years and patients had good digital skills. Fifteen patients (75%) had previous experience of anaesthesia. The digital application provided enough information for all patients, but eight (40%) preferred consulting an anaesthesiologist, mainly for personal contact. Patients had different information needs, with previous experiences leading to lower information need. Nineteen patients had sufficient information to consent autonomously. Most patients considered a separate anaesthesia consent superfluous to the surgical consent.

Conclusion: The digital application provided sufficient information and patients valued the information offered and the advantage of processing information at their own pace. This information made patients feel empowered to autonomously consent to anaesthesia without consultation. Remarkably, consent for anaesthesia was considered unimportant, because patients felt they had ‘no choice’ if they wanted to undergo surgery.

Introduction

According to current guidelines, patients must give informed consent for anaesthesia, apart from their surgical consent.[1-5] From a medical perspective this separation of consents makes sense: anaesthesia is a procedure distinct from the surgical procedure, with its own risks and complications. Many countries require anaesthesiologists to provide information about anaesthesia, to guide patients in their deliberation about risks and benefits of anaesthesia and to obtain a consent for anaesthesia during a consultation.[1 2 5] For example in the Netherlands, verbal consent needs to be given to the anaesthesiologist and this should be noted in the medical record. However, a consent for anaesthesia is not as straightforward as it seems.

In general, consenting requires patients to weigh risks and benefits of the proposed treatment. As anaesthesia is not an isolated treatment, but an inevitable component of the main treatment, that is the surgery, patients have to weigh the risks of anaesthesia against the benefits of the surgical procedure. However, most patients will have weighed surgical risks and consented to the planned surgical procedure before they visit the anaesthesiologist. As anaesthesiologists are not fully aware of the risks and benefits of the surgical procedure this can make guidance of anaesthesia risks related to surgical risks and benefits suboptimal.

The value of anaesthesiologists as providers of information also remains uncertain, even though many authors consider information provisioning by anaesthesiologists important.[2 6-9] Patients require information that is tailored to their individual needs, which they can understand and remember, but research has shown that information offered by physicians is often too complex or biased.[9-13] Therefore, instead of relying on a verbal consultation with an physician, other ways may be more effective in informing patients, for example using multimedia. Studies have shown that multimedia-based information provisioning about a procedure is equal – or even superior – to provision of information by a physician in terms of reducing anxiety and knowledge retention.[14-20] Especially when decision-support applications guide patients in their informational needs before to the informed consent consultation with physicians, patients seem to be better informed.[12 16 21]

If anaesthesiologists cannot fully guide the informed consent process, then provision of adequate information could be sufficient for patients to provide informed consent for anaesthesia. Moreover, if information offered digitally is equivalent to information provided by an anaesthesiologist, then patients may not need a consultation. We therefore

hypothesised that an interactive web-based digital application could offer sufficient information about anaesthesia to make patients feel well informed. We additionally hypothesised that this information could empower them to give their consent digitally (e-consent) without having consulted an anaesthesiologist.

Methods

Study design and setting

This study was conducted at the pre-anaesthesia assessment clinic at the University Medical Center Utrecht, a tertiary referral hospital in The Netherlands. We used semi-structured interviews to answer four research questions:

1. Are patients able to independently select and process information about anaesthesia without consulting an anaesthesiologist (autonomous information provisioning)?
2. Can a digital application provide sufficient information for an informed consent equivalent to a verbal consultation?
3. Do patients feel empowered for autonomous consent, that is consent without consulting an anaesthesiologist, after having received that information?
4. Under what conditions could fully digital information provisioning, e-consenting or both be feasible?

After constructing our hypothesis based on literature and expert opinion, MM interviewed seven adults, not scheduled for anaesthesia, in open, exploratory interviews. The goal was to obtain information about the patient perspective regarding content of the desired application to be developed, to determine the domain in which our research questions could be explored, and to test interview questions. We concluded that provision of digital information and electronic informed consent (e-consent) could be explored in relatively healthy patients (ASA 1 and 2) scheduled for minor procedures, with a low risk for complications. A framework was constructed for the web-based digital application and for an semi-structured interview guide (Appendix A). The interview guide was subsequently pilot-tested two times in healthy adults who were not planned for surgery, and questions were refined.

Digital application with e-consent

The digital e-consent application is a prototype of an interactive web-based programme. Every web page provides basic information around a theme, such as ‘what is procedural sedation’, using both text and video (online Video 1 and Appendix A). Patients can receive additional information by selecting a subtitle on a page. Subsequently, patients can mark the checkbox if they have understood the information. The application ends with marking the informed consent checkbox. If patients feel they cannot consent or if they have questions, they mark the ‘no’ or ‘doubt’ checkbox, which results in an appointment for a consultation.

Patients

Eligible patients were low surgical-risk adults (ASA 1 and 2) scheduled for elective minor procedures under either general anaesthesia or procedural sedation and able to speak and read the Dutch language. Patients scheduled for a pre-anaesthesia consultation at the outpatient clinic were purposively screened for eligibility based on our inclusion criteria. After the interview, patients had their regular pre-anaesthesia consultation. Patients were interviewed between March and June 2020. After interviewing the fifteenth patient, five patients were included for their younger age or inexperience in anaesthesia after which no new insights were obtained regarding provision of information and consent (data saturation was achieved).

Interview

One author (WB) conducted all interviews, which were recorded by video. Baseline data were obtained by a short questionnaire (Appendix B). No data were collected from the medical record. Patients followed the digital application, while the interviewer asked questions according to the interview guide (Appendix A), and observed reading behaviour. Between interviews, questions were adjusted if necessary, based on topics mentioned by previous patients and analysis of previous interviews.

Ethics

The Medical Research Ethics Committee of the UMC Utrecht waived the need for informed consent (20-117/C), but all patients consented to the use of personal data for the purpose of the study under the General Data Protection Regulation (GDPR).

Data analysis

The recorded interviews were transcribed verbatim and anonymised. We used a thematic content analysis strategy, in which data analysis is a circular process and interlinks with data collection. An initial coding framework was created, consisting of deductive and inductive codes. WB coded transcript 1 to 10 and MM 11 to 20. The coding framework was continuously adjusted with analysis of every subsequent interview by rereading, discussing and recoding previous interviews (Appendix C). MM and WB cross-checked several transcripts for the created codes, and if there were discrepancies a discussion followed until achieving agreement. Next, codes were compared, categorised and combined with patient characteristics leading to concepts around the research questions and overlapping themes

were sought. Baseline data from the short questionnaire are presented as frequencies with percentages. In addition, some (open) questions from the interview guide resulted in answers that were quantifiable, because interviewees gave comparable answers.
Nvivo 12 pro was used for coding.

Results

Twenty patients were interviewed (interviewees), of whom eighteen were interviewed before their pre-anaesthesia consultation and two immediately after, owing to logistics. The mean age was 50 years (range 20-75) and 12 were female (Table 1). All interviewees had good digital skills and 15 (75%) accessed their online electronic health records regularly. Fifteen interviewees (75%) had already undergone their planned type of anaesthesia during a previous procedure (experienced interviewees).

Table 1. Baseline characteristics.

Baseline		Number of patients (%)
Female sex (%)		12 (60)
Age categorical		
20-39 yrs		4 (20)
40-59 yrs		11 (55)
60-79 yrs		5 (25)
Highest education	High school	3 (15)
	Community college	8 (40)
	University	9 (45)
Digital skills*	<4 (low)	0
	4-8 (intermediate)	5 (25)
	>8 (good)	15 (75)
Did patient sought information before anaesthesia consultation?	Yes	5 (25)
	No	15 (75)
How much did the patient want to know about anaesthesia?	Nothing	1 (5)
	As less as possible	0
	Enough to make a decision	16 (80)
	As much as possible	3 (15)
Previous experience with anaesthesia	yes, conscious sedation	1 (5)
	yes, general anaesthesia	10 (50)
	yes, neuraxial anaesthesia	0
	yes, peripheral nerve block	1 (5)
	Yes, ≥ 2, of above	5 (25)
	No	3 (15)
Scheduled Anaesthesia technique		
	General anaesthesia	18 (90)
	Procedural sedation	2 (10)

Baseline		Number of patients (%)
Surgical speciality**	Endoscopy	1 (5)
	Cardiology	1 (5)
	General / Orthopedics	3 (15)
	Gynaecology	5 (25)
	ENT/plastic	3 (15)
	Ophtalmology	7 (35)

Figures are numbers (%) of patients, unless stated otherwise.* Digital skills included use of computer for leisure, social media, buying goods, work, email, taxes, insurance, private banking, seeking information about own health, online access to personal hospital heath record. Use of computer for <4 activities was regarded as low digital skills, 4-8 as intermediate and > 8 as good. ** Various surgeries were performed by the different specialties. For example endoscopy: esophageal dilation, cardiology: ablation for arrhythmia, general/orthopedics: knee arthroscopy and removal of plates, gynaecology: laparoscopic procedures, ENT/plastic: changing breast prosthesis, nose surgery, ophthalmology: strabismus surgery, eye lid corrections, vitrectomy.

Research questions 1 and 2: receiving adequate digital information

After finishing the application, all interviewees felt they had received sufficient information. One interviewee (no previous anaesthesia) had a remaining question for an anaesthesiologist. The interviewees reported being capable of selecting and processing the information they wanted to receive.

We observed that interviewees differed in how they processed the information offered. Most interviewees did not read all the text. A frequently reported reason for not reading information was familiarity with the topic because of previous experience with anaesthesia (Table 2, quote 1). Some did not read additional information when they considered the subject irrelevant to their situation. Others preferred not to know too many details and reported to rely on the healthcare professionals (Table 2, quote 2), especially for severe complications (Table 2, quote 3).

Contrastingly, several reasons for reading information were reported. Some interviewees indicated that knowing what might happen to them was important, even concerning rare, yet severe, complications (Table 2, quote 4). Interviewees with no previous experience of anaesthesia read more, which was acknowledged by some interviewees with previous experience who said they required more information before their first experience of anaesthesia (Table 2, quote 5). We observed that patients who read additional information often reported previous negative experiences, such as side effects or complications on that particular topic. These experiences could be their own, but also those of others, such as

family members (Table 2, quotes 4 and 6). After having read the risks most patients considered the benefits of the planned procedure to outweigh the risks (Table 2, quote 7).

Research question 3: empowered autonomous consent

We asked interviewees if they felt sufficiently informed to provide e-consent without consulting an anaesthesiologist. All interviewees felt empowered to give e-consent.

In addition, most interviewees reported that consent for anaesthesia itself was superfluous, as they felt they did not have a choice: their planned procedure would not be possible without anaesthesia (Table 2, quote 8). Several observations supported that patients had no need for a formal anaesthesia consent. Reading about side effects or rare severe complications did not make interviewees reassess their choice for anaesthesia (Table 2, quote 9). Also, we asked interviewees at different points within the application whether they could give informed consent at that point. Sixteen (80%) said they would already give consent at the first page with general information about anaesthesia, because of their previous experiences. We also observed that more than half of the interviewees thought that informed consent for surgery also included consent for anaesthesia (Table 2, quote 10). Consent for anaesthesia or consultation with an anaesthesiologist was not seen as contributory, because some interviewees regarded anaesthesia as less important than surgery (six interviewees, 30%, Table 2, quote 11). Some interviewees also reported that the (perceived) safety of anaesthesia was a reason for no need for consent, because of their good health or low-risk procedure (Table 2, quote 12).

Research question 4: feasibility of a digital application

Although all interviewees said they were well informed by the application, when offered the choice, eight interviewees (40%) preferred a consultation with an anaesthesiologist. The main reported reasons were need for personal contact (Table 2, quotes 13-16), the possibility to ask additional questions (Table 2, quote 16), and the perceived feeling that physical examination was necessary for a preoperative assessment (quote 17). Some interviewees could not explain their preference for a consultation and reported it was more about 'feeling safe' (Table 2, quotes 13 and 14). However, would the hospital ask them to only use the application, seven of the eight interviewees who preferred a consultation would accept a digital solution without a consultation, because they recognised that this could make healthcare more efficient. Only one interviewee would always choose a consultation, because of personal contact (Table 2, quotes 14 and 15).

Information provisioning by consultation versus application: overall and patient-specific indications and benefits

The social aspect of a consultation was suggested as an important benefit and was reported by 14 interviewees (70%) for reasons of personal contact, comforting, and relieving anxiety (Table 2, quote 16). The option to ask additional questions and to get information tailored to specific individual needs was deemed important (reported by eight interviewees (40%)). Therefore, a consultation was suggested as appropriate for anxious or patients with no previous experience of anaesthesia, for patients with extra questions, low digital skills or illiteracy, and for patients with comorbidities or major surgery to discuss patient- or procedure-specific risks (Table 2, quote 18) (Table 3).

Time was the most frequently reported benefit of using the digital application (Table 3). It saves traveling and waiting time (reported by 14 interviewees, 70%) and it allows patients to process the information at their own pace (11 interviewees, 55%, quote 19). Seven interviewees considered an application advantageous, because information provisioning can be tailored to their personal needs (Table 2, quotes 19 and 20). Interviewees reported that simple language and the combination of text and video made the information comprehensible. Interviewees thought that electronic provision of information and e-consenting was suitable for patients with adequate digital skills, for patients in good health or undergoing minor procedures, for patients with previous experience in anaesthesia, and also for patients who did not want to receive much information (Table 2, quote 21) (Table 3).

Age was reported by the interviewees as a potentially complicating factor. Generally, younger patients were seen as digitally skilled compared with elderly and applications were therefore regarded as suitable for younger patients and consultation for elderly. However, after asking for an age limit, interviewees reconsidered and indicated it would depend on individual digital skills.

Discussion

In this qualitative study, we investigated whether a digital application provided sufficient information to healthy adults scheduled for minor procedures under general anaesthesia or procedural sedation compared with a consultation and if so, if patients would be able to autonomously consent to anaesthesia. Patients felt well informed, valued the information offered and appreciated the autonomy provided by the application. They felt empowered to consent without consulting an anaesthesiologist. Most interestingly, consenting for anaesthesia was considered unimportant, because patients felt they had 'no choice' if they wanted to undergo surgery.

In this study the patients reported that they would give an e-informed consent. Interestingly, most patients felt no need to consent for anaesthesia at all, because they already had consented to surgery and considered this inseparable from anaesthesia. The complex relation between both consents has been discussed before.[8-10 13 22] Historically, consents were separated for medical and legal reasons, as there was need for provision of information and risk assessment about anaesthesia by anaesthesia experts.[6] Despite these reasons for a separate consent, this study shows this separation is complicated for patients. As patients have to consider risks for the whole 'perioperative package', separating anaesthesia and surgery seems artificial. From a patient perspective it seems more logical to combine surgical and anaesthesia education and risk assessment, and to give a single 'perioperative consent'. For low-risk procedures and patients a digital application about anaesthesia could be an option for timely provision of information about the anaesthetic part of this consent.

Patients valued provision of information as very important in the consent process. This has been acknowledged in a study by Fung and Cohen.[6] We observed major differences in the quantity of information patients read, but all patients were satisfied with the amount of information. In our application, patients had the autonomy to choose how much information to read, how to receive this information (text, video or both) and when to read it, which was regarded as superior to verbal information from a physician. A study of Van den Berg and colleagues on shared decision making for postoperative analgesia also showed that anaesthesiologists did not tailor information to the needs of the patient and that a decision support tool would provide added knowledge.[12] Current reviews and editorials about informed consent emphasize the importance of patient tailored information provisioning, but acknowledge that this is very difficult for physicians.[8 9 13 22] If information meets the

patient's needs this will be more likely result in a satisfied patient.[8 9 13 22] A digital application may be more likely to fulfil the informational needs of individual patients.

In this study 15 patients (75%) had previous experiences of their planned anaesthesia technique. This previous experience lowered their informational need, because patients trusted their previous experiences to be also applicable to their upcoming anaesthesia.[18 23] Patients without previous experience indeed read more information. This observation adds to the literature with conflicting results regarding the influence of experience on information need.[14 24]

This study has several strengths. The interviews offered a broad insight in patient's perceptions about information provisioning and consent. Thanks to the cyclic process of data gathering and analysis, newly evolved themes during interviews could be explored in subsequent interviews. The application gave us real-time insight in the patients' collection and processing of information, which reduced the change of a recollection bias. Our study also has some limitations. First, qualitative research can be prone to interpretation bias, during coding and analysis. We reduced this by cross-checking codes and discussing if in doubt. Also the results from the analysis were discussed with three researchers (MM, WB, TK). Second, twenty patients were interviewed. This quantity is in line with current qualitative research studies in which thoughts and perceptions from patients about a specific topic are explored. Based on our exploratory interviews we chose a restricted domain to explore our hypotheses: low-risk patients undergoing minor procedures, thus limiting the generalisability of our study.

Implications for current practice and future studies

Digital applications have the potential to replace in-person information provisioning by an anaesthesiologist for low-risk patients scheduled for minor procedures under procedural sedation or general anaesthesia. In the Netherlands all patients have a pre-anaesthesia consultation at the outpatient clinic days to weeks before their procedure, making the use of digital applications as a replacement for consultations potentially cost-effective. For healthcare systems with a pre-anaesthesia consultation at the day of the procedure, digital applications could be offered in advance, making patients better prepared to their procedures. This could replace the consultation at the day of the procedure or reduce the consultation time, making healthcare more cost-effective. It is likely that for other, more complex patients an application could add to a patient's knowledge ahead of consultation and result in a more in-depth discussion during a consultation.[12 16 17] Digital applications offer patients autonomy

in time management and acquisition of information, which will probably result in higher patient satisfaction compared to traditional consultations. Upcoming research should explore how information should be offered to patients, adjusted to individual needs.[14 16 17 19] The patient's perceptions about provision of information in other domains should be investigated, such as in those planned for major surgery or when patients have to choose between anaesthetic procedures. Lastly, a focus should be on appropriate selection of patients capable of using digital applications as our study shows that some patients need a consultation.

We also studied the concept of autonomous informed consent. Consent is an important right of patients and current laws require anaesthesiologists to be 'physically' involved in this process. However, this study has shown that some patients feel empowered to consent autonomously, provided that they received adequate information. As digitisation and autonomy are rapidly expanding in society and medicine, it is important to test if such an autonomous informed consent could be possible under certain conditions. Our 'proof-of-concept' could serve as a framework for further research on informed consent and stimulate the adaptation of guidelines and laws to societal changes.

It may also be worth to explore the possibility of a 'common informed consent' in which anaesthesiologists and surgeons work together in provision of (digital) information and subsequently obtaining one consent for the whole perioperative process.

Conclusion

A digital application provided sufficient information to healthy adults scheduled for minor procedures under general anaesthesia or procedural sedation and offers patients the advantage of processing information at their own pace and well ahead of the planned procedure. This information empowered patients to autonomously consent to anaesthesia without consulting an anaesthesiologist. From the patient's perspective, consenting for anaesthesia separately from surgery was considered complex and unnecessary, but receiving sufficient information about anaesthesia to get confidence in a good outcome was considered important.

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Table 2. Quotes from the interviews.

Quote No.	Patient	Topic	Quote
1	5	Need for information- experience	Last time I had no pain or sore throat …No I don't have this.
2	5	Need for information- trust in health care	I'm in good hands, you will do your best. I'll get anaesthesia and afterwards I wake up.
3	2	Information provisioning- severe complications	It's the same as reading a package leaflet, you already get sick just by reading it. So I just don't do it.
4	15	Information provisioning- severe complications	I have seen this [awareness] in a movie once, so you don't want this to happen to you.
5	2	Need for information- unexperienced	I have heard this 10 times before. The first time I read everything and asked questions.
6	16	Information provisioning- severe complications	My brother-in-law had complications, so I want to know what can go wrong even if it [the risk] is 1:100.
7	6	Information provisioning- severe complications – weighing information	These are just complications that can happen, but .. crossing the street, there is also a change you get hit by a bus…
8	19	Informed consent- no choice	When I want to undergo that surgical procedure, I need to have the anaesthesia. So do I have a choice? Not really.
9	7	Informed consent- influence of severe complication	I just want that surgery, so I just have to accept the consequences.
10	8	Informed consent – consent surgery includes consent anaesthesia	To my opinion, it actually belongs together
11	18	Informed consent- unimportance anaesthesia	Consultation with the surgeon: yes. [Consultation with an] anaesthesiologist? I would fill it in [online] right away. No need to come to the hospital.
12	7	Informed consent – no need because of good health	No, for me there is no special indication to speak an anaesthesiologist. Everything is normal.
13	8	e-consent vs anaesthesiologist- 'undefined feeling'	it's about your health and you get general anaesthesia, I must have the feeling I'm safe.
14	4	e-consent vs anaesthesiologist- personal contact	You can look into someone's eyes.
15	4	e-consent vs anaesthesiologist- personal contact	It's about your life and that's important enough for me to have a personal consultation.
16	13	e-consent vs anaesthesiologist- anxiety and asking questions	personal contact…, perhaps relieves anxiety, you can ask extra questions. Perhaps you can be comforted.

Quote No.	Patient	Topic	Quote
17	3	e-consent vs anaesthesiologist-medical safety	It would be strange to give informed consent … without physical examination.
18	20	e-consent versus anaesthesiologist-high risk surgery	I think that with heart surgery [the risk] is higher, so it would be great to speak to a physician to obtain more insight about [the risk] really being okay.
19	5	e-consent vs anaesthesiologist-time saving	You are at home and can take your time reading. With extra [mouse] clicks you get extra information before you give an answer.
20	15	e-consent vs anaesthesiologist-information provisioning	You have the choice: do I want more information or not.
21	13	e-consent vs anaesthesiologist-information provisioning	[People] who choose digital are like: "I'll just see what'll happen" or just don't want to give it to much attention.

Table 3. Comparison of application with consultation with anaesthesiologist.

Application with e-consent		**Consultation with anaesthesiologist**	
Benefit	**Indication**	**Benefit**	**Indication**
Time	**Social**	**Social**	**Social**
Patient perspective	Experienced	Personal contact	Unexperienced
Traveling time	Uninterested	Comforting	Anxious patients
Waiting time	No questions	Reducing anxiety	Need for personal contact
Following application any time of day	'Not wanting to know'		
Own pace	**Medical**		**Medical**
Anaesthesiologist perspective	Good health	**Medical**	High-risk procedure
More time for other duties	Low-risk procedure	Physical examination	Comorbidities
		Anamnesis	
	Communication		
	Digitally skilled		**Communication**
	Young patients	**Safety**	Low digital skills
		No data leak	Elderly
			Other language
Information provisioning		**Information provisioning**	
Video		Answering extra questions by anaesthesiologist or patient	
Simple language			
Consistency in information offered			
Autonomy what information to read			

Appendix A. Topics adressed in the web-based digital application, choices for patients and matching questions from the interview guide.

Web-page	Title (with basic information on every page)	Subtitles (after clicking additional information appears)	Choices for patients	Interview guide - main questions
1	Introduction	None	Start of e-consult or stop program and make an appointment	Do you know why you have to visit the anaesthesiologist? Wat will be discussed? You have consented for surgery, does it include anaesthesia consent? What do you want to discuss with the anaesthesiologist?
2	Login by secured access		Secured login	Do you use secured access? Is it safe? Can the anaesthesiologist trust the safety of your e-consult?
3	Conduct of anaesthesia (general anaesthesia/ sedation)	What is general anaesthesia/sedation? What happens to me during anaesthesia/sedation? What happens to me between arrival at the OR and the end of anaesthesia?	Choice for additional information in subtitles Choice for film about anaesthesia	What do you think of the information provided? Why do you (not) click for more information? If a patient had anaesthesia before: How does this information relate to your previous experiences? Do you have enough information at this moment to consent?

Web-page	Title (with basic information on every page)	Subtitles (after clicking additional information appears)	Choices for patients	Interview guide - main questions
4	Recovery ward	Am I awake at the recovery ward? Can I have visitors at the recovery ward? When can I go to the general ward or home?	Choice for additional information in subtitles Choice for film about recovery ward	What do you think of the information provided? Why do you (not) click for more information? If a patient had anaesthesia before: How does this information relate to your previous experiences? Do you have enough information at this moment consent?
5	Minor side effects	Nausea Pain Sore Throat	Choice for additional information in subtitles	What do you expect with regard to side effects? How much do you want to know about side effects? How does this information makes you feel? Why do you (not) click for more information? If a patient had anaesthesia before: How does this information relate to your previous experiences? How does this information relates to your current planned surgery? Do you have enough information at this moment consent?

Web-page	Title (with basic information on every page)	Subtitles (after clicking additional information appears)	Choices for patients	Interview guide - main questions
6	Severe but rare complications	More about rare complications Death Dementia Awareness Aspiration	Choice for additional information in subtitles	About title page: What do you think after reading the title? How much do you want to know about complications? Why do you (not) click for more information? How does this information makes you feel? If a patient had anaesthesia before: how does this information relate to your previous experiences? How does this information relates to your current planned surgery? Does this information influence your consent? Do you have enough information at this moment consent? Do we have to show this information to patients? Currently the anaesthesiologist initiates the complications to be discussed. How do you think about this?

Web-page	Title (with basic information on every page)	Subtitles (after clicking additional information appears)	Choices for patients	Interview guide - main questions
7	Preparing for anaesthesia			
8	Fasting policy		Choice for film about fasting Choice for signing if preparation is understood (yes, no, doubt)	What do you think about this topic? If you click yes, can we hold you responsible, if you do not follow the fasting preparations?
9	Continuation of medication		Choice for film about medication continuation/ cessation Choice for signing if preparation is understood (yes, no, doubt)	What do you think about this topic?
10	Getting help during the first night at home		Choice for film about help Choice for signing if preparation is understood (yes, no, doubt)	What do you think about this topic?
11	What to do if you get sick the week before your anaesthesia		Choice for film about getting sick Choice for signing if preparation is understood (yes, no, doubt)	What do you think about this topic?
12	Blood transfusion	More about transfusion Advantages Disadvantages Additional information	Choice for additional information in subtitles Choice for consent for transfusion (yes, no, doubt)	What do you think about this topic? Did you know you had to consent for transfusion? Why do you (not) click for more information?

Web-page	Title (with basic information on every page)	Subtitles (after clicking additional information appears)	Choices for patients	Interview guide - main questions
13	Informed consent	I understand what will happen to me I have gotten enough information about side effects and risks of anaesthesia I consent for anaesthesia I understand what preparations I have to do I have a question	Choice for consent (yes, no, doubt) Choice for consent (yes, no, doubt) Choice for consent (yes, no, doubt) Free text field and option to choose between: I will ask it at the day of surgery, I will send an e-consult, I want a consultation by telephone, I want a consultation in the hospital	Do you have enough information to give consent? If yes, why? If no/ doubt, why not? Do you feel barriers to ask questions? Currently a consultation with an anaesthesiologist is needed for official consent. This e-consent can be an alternative. How do you think about this? For who or under which circumstances would e-consent be suitable? When do you need an consultation with an anaesthesiologist?
14	What happens after this e-consent	Patient will receive a letter within 3 days with confirmation and approval of anaesthesiologist or appointment if necessary		What do you think of this information?

Web-page	Title (with basic information on every page)	Subtitles (after clicking additional information appears)	Choices for patients	Interview guide - main questions
15	End of program			Additional questions: What do you think of e-consenting? Would you recommend this to others? What are advantages and disadvantages of e-consenting at home? When do you want an consultation with an anaesthesiologist? Does the COVID-19 pandemic influence your choice of e-consulting versus consultation in the hospital? During consultation with an anaesthesiologist communication and consent can be at a high pace. How is this for you? Some people are afraid of anaesthesia. How is this for you? How much do you want to know about your planned anaesthesia

Appendix B. Short questionnaire.

Wat is your age?

What is your sex?

What is your highest level of education?

Digital skills: Do you use a computer/tablet/smartphone for*

- Buying goods
- Banking
- Taxes
- Insurance
- Access to personal health record
- Email
- Work
- Social media
- Leisure
- To get information about any topic of interest
- To get information about my health

Do you search for information about your own health/sickness/surgery?

How do you get this information?

- Internet
- Personal health record
- Friends/family
- Other

How much do you want to know about upcoming anaesthesia?

- Nothing
- As less as possible
- Enough to know what will happen to me and to make a decision
- As much as possible
- Other

What (surgical) procedure will you get?

Do you have previous experience with anaesthesia?

If yes, which one(s)

- General anaesthesia
- Procedural sedation
- Neuraxial anaesthesia (spinal or epidural)
- Peripheral nerve block

Have you looked for information about anaesthesia before you came to the clinic or did you already have information?

Where did you get this information from?
- Internet (google, wikipedia)
- Official website from the hospital
- Paper leaflets
- From referring physician
- My own previous experiences
- Other

Appendix C. Code book.

Codes and subcode	Description
First choice	What chooses the interviewee intuitively: application or consultation?
consultation	
application	
Recommend application to others	Would the interviewee recommend the application to others?
Yes	
No	
Doubt	
Consultation versus application	Advantages and disadvantages of application and consultation.
Consultation	Advantages and disadvantages of consultation.
Application	Advantages and disadvantages of application.
Importance of anaesthesia versus surgery	
Bloodtransfusion	Questions and answers related to the topic of blood transfusion.
Consent bloodtransfusion	Code for all reports about consent for blood transfusion.
Information bloodtransfusion	Code for all reports about information about transfusion: what did interviewees already know about transfusion, why do they read information, previous experiences.
COVID-19	All COVID-related reports.
Worries about Covid	Afraid of COVID.
No worries Covid	No fears for CoOVID.
Personal secured access system	All reports about secured access system to personal health record.
Trust in secured access	Can the anaesthesiologist entrust a patient that he does not fraud with the secured access?
Secured access safety	Is secured access safe, for example can it be hacked?
Uses secured access	Does the interviewee use secured access.
Barriers	Are there barriers that prevent interviewees from contacting an anaesthesiologist or hospital? For example: I don't want to call the hospital, because they are busy.
Emotions	All reports and observations of emotions.
Fear	
Anxiety	

Codes and subcode	Description
Experience	Previous experiences of interviewees with hospitals, surgery, other experiences that influence them in need for information and consenting.
Own experiences	Own experiences with anaesthesia.
Experiences from others	Experiences from others with anaesthesia.
Negative experiences	
Neutral experiences	
Positive experiences	
Comforting	Code for all (implicit) reports about comforting.
Informed consent	Reports from interviewees about information provisioning and consent.
Consent	Every report about consenting.
Choice	Do interviewees have the feeling that they have a choice in the decision for anaesthesia?
Timing of consent	After which web page does the interviewee report that he has enough information to consent?
Severe complications	Reports about the web page severe complications.
Reports about information provisioning	All reports about information provisioning.
Learns from new information	
Not reading additional information	
Enough information	Did interviewee have enough information?
Reading additional information	
Application	Report about how to improve the application.
Unclear	Reports about topics that an interviewee doesn't understand.
Does researcher think patient can use the application	Does the r esearcher think that the patient knows enough for a valid consent?
Personality	Reports about personality of interviewee.
Tasks of anaesthesiologist	What should an anaesthesiologist do during consultation?
Discuss the conduct of anaesthesia and discussion about risks	
Physical examination	
Being a 'figurehead of anaesthesia'	
Safety	Examine if a patient is healthy enough to survive anaesthesia.
Responsibilities patient	Every report about responsibilities of patients. Can anaesthesiologist entrust the patient to take his responsibilities?
Using secured access	
Reading the offered information	
Responsible for correct preparations for anaesthesia	
Wrongly understood by patient	Information that is misinterpreted by interviewees.

Codes and subcode	Description
Faith and trust	Where interviewees report about faith (in general, god, healthcare, etc.)
Wanting to see a familiar face	Reports about wanting to see an anaesthesiologist before the surgery, because knowing some-one gives hope and comforting
Faith that everything will be fine	'blind faith'
Faith in physicians	
Referring to other people	Reports from interviewees about other patients. For example: I could use the application, but my aged neighbor could not.
Those who consider secured access safe	
Anxious patients	
Major surgery or comorbidity	
Low digital skills	
Age	
Those who fraud with secured access	
Patients with previous experience	
Patients who want to know much	
Patients who do not speak up for themselves	
Patients who do not want to know anything	
Unexperienced patients	
Patients who do not read or speak Dutch	
Other	
Questions & answers	Do interviewees have questions after following the application? How do they want to receive their answer? How soon do they want their answer?
Answer on day of surgery, earlier not necessary	
By phone	
By email	
By consultation	
No clear answer	
As soon as possible	

7

THE PATIENT PERSPECTIVE ON INFORMED CONSENT FOR ANAESTHESIA IN PATIENTS SCHEDULED FOR CARDIAC SURGERY, AN OBSERVATIONAL STUDY.

Authors: Marije Marsman MD, Twan G. Meulenbeld, Judith A.R. van Waes, Teus H. Kappen MD PhD, Wilton A. van Klei, MD PhD

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Abstract

Background: In current practice anaesthesia and surgery require separate informed consents. It is not known, however, whether patients value a separate consent for anaesthesia, whether information about risks influences consent and how patients assess anaesthetic risks compared to surgical risks.

Methods: This cross-sectional quantitative study included patients scheduled for cardiac surgery in a tertiary referral hospital in the Netherlands between May 2021 and March 2022. Patients completed a questionnaire exploring patient perceptions about information provisioning, anaesthetic risks, informed consent and how anaesthetic risks relate to surgical risks and benefits.

Results: Of 120 patients eligible, 100 completed the questionnaire and those were analyzed. Twenty-six were female and 62 were older than 60 years. Sixty-five patients valued information about anaesthesia and 35 not. Most patients worried about surgical risks instead of anaesthetic risks. Seventy-six patients felt no need for a separate consent for anaesthesia, mainly because of the feeling of 'no choice but to undergo surgery'. Even when probabilities for severe anaesthetic complications were high, 63 patients would still be willing to undergo surgery.

Conclusion: The majority of patients scheduled for cardiac surgery reported to have no need for a separate informed consent for anaesthesia. Although most patients valued information about anaesthesia, this information was not needed, nor did it influence their consent as surgical risks and benefits outweighed any anaesthesia risk. In the future, surgeons and anaesthesiologists may offer information tailored to patients' preferences after which combined consent for the complete anaesthetic and surgical process can be obtained.

Introduction

According to current guidelines informed consent for anaesthesia is separated from surgical informed consent.[1-6] Patients typically give informed consent during a preoperative consultation with an anaesthesiologist, who offers information about anaesthesia and explains risks and benefits of the planned anaesthetic technique. Although guidelines advise that patients should be informed about any material anaesthetic risk, it remains inconclusive what patients value to give consent for. Furthermore, a separate consent is complex. Anaesthesia facilitates the surgical procedur eand contrary to surgery, anaesthesia has no direct health benefit. Patients therefore have to weigh anaesthetic risks against the risks and benefits of surgery in their consent for anaesthesia.

In a recent study in low anaesthetic risk patients scheduled for minor procedures under general anaesthesia or procedural sedation, patients reported to have no need for a separate informed consent for anaesthesia.[7] As their main reason for not requiring a separate consent, patients reported they felt 'not to have a choice'. As they had already decided to undergo the procedure – and already gave surgical informed consent – a separate anaesthetic consent felt artificial. This contrasts with guidelines on anaesthetic informed consent.[1-4 6] This previous study was performed in patients undergoing minor procedures. Therefore, we considered that the perceived significance of an anaesthetic risk and need for a separate anaesthetic informed consent may be different for patients undergoing major surgery.

Cardiac surgery is such major surgery that carries significant (surgical) risks. However, it also comes with major benefits. Therefore, cancelling the procedure when additional anaesthetic risks are identified, is often not a realistic option. We hence considered this to be a good setting for exploring how patients perceive anaesthetic risks in relation to surgical risks and benefits, and how these anaesthetic risks influence their need for a separate informed consent for anaesthesia.

Methods

Study design and setting

This cross-sectional study was conducted at the pre-anaesthesia assessment clinic at the University Medical Center Utrecht, a tertiary referral hospital in The Netherlands. We used a questionnaire to answer two objectives:

1. Do patients scheduled for cardiac surgery value a separate anaesthetic consent in addition to consent for the surgical procedure?
2. How do patients perceive risks specifically related to anaesthesia, and compared to surgical risks and benefits?

Patients

We included patients scheduled for elective Coronary Artery Bypass Grafting (CABG) or valve repair under general anaesthesia, who were not expected to have an increased risk for the complications described in the questionnaire, based on information already available from the electronic medical health record and preanaesthesia assessment questionnaire. Patients had to be able to speak and read the Dutch language and to give informed consent. They were screened for eligibility before their consultation at the pre-anaesthesia assessment clinic, based on above criteria. Patients were included between May 2021 and March 2022.

Consent was obtained verbally and no medical record data were used. The Medical Research Ethics Committee of the UMC Utrecht waived the need for written informed consent (21-312/C).

Questionnaire

We developed a digital anonymous three-part questionnaire (Appendix 1) that consisted of multiple-choice and open questions. All multiple-choice questions had to be completed before the questionnaire could be submitted, the open questions were non-mandatory. The questionnaire was sent by email. Patients were instructed to answer the questionnaire after preoperative consultations with the surgeon and anaesthesiologist, if possible. For example, patients without an email address could answer the questionnaire at a desktop at the pre-anaesthesia assessment clinic, aided by a researcher if necessary, and some of these patients had not visited the surgeon or anaesthesiologist yet.

The first section of the questionnaire questioned demographics. The second section consisted of the six questions of the Amsterdam Preoperative Anxiety and Information Scale (APAIS).

This is a standardized questionnaire to assess preoperative anxiety and information requirements.[8] Each question can be answered with a five point Likert scale from one (not at all) to five (extremely). The scores of the individual questions are added, resulting in a maximum score of 30. The APAIS can be further divided into three different subscores, related to information requirement, anxiety for surgery and anxiety for anaesthesia. The last section explored patients' attitudes towards anaesthetic informed consent, and how they perceived specific anaesthetic risks overall and compared to surgical risks and benefits. Risks were divided into severe anaesthetic complications and side effects, since clinical experience and studies show that patients attribute these risks differently.[9] Anaesthetic side effects are anaesthesia-related events that occur frequently and are of limited severity (such as postoperative nausea and vomiting (PONV), pain, sore throat). Severe intraoperative anaesthetic complications are unfavorable, rare events, that adversely affect morbidity or contribute to mortality (awareness, anaphylaxis, tooth damage, esophageal rupture and intraoperative death). Patients were asked how much they overall worried about anaesthetic side effects and complications by filling in a Numeric Rating Scale (NRS) between 0 (no worries) to 10 (very worried). Subsequently, they were asked to numerically rate their worries about surgical side effects or complications compared with worries for anaesthesia (NRS-10 to +10). We also asked if (and why) patients wanted to be informed about anaesthetic side effects or severe complications and if they felt that information was needed, before anaesthetic consent could be given. In a non-mandatory free text field, they could subsequently add their considerations.

Subsequently, we wanted to know at what probability rate of a side effect or complication patients would reconsider their consent to undergo surgery. Severe intraoperative anaesthetic complications are rare and we chose awareness as an example, because for most patients this is a known severe anaesthetic complication. If awareness would happen to them with a risk of either 100%, 10%, 1% or 0.1%, would they still undergo their surgery? This question was repeated for the side effect PONV.

Finally, we asked how patients valued the separate anaesthetic consent. In a non-mandatory free text field, they could add their considerations. We also asked whether there were certain individual complications of anaesthesia that patients always wished to be informed of before giving consent (Appendix 1).

Data analysis

Our hospital performs approximately 750 CABG or valve surgeries annually. As it was difficult to estimate an expected effect size, we considered the inclusion of at least 10% of this annual population to fairly accurate representee the target population. The aim was therefore to have 100 completed questionnaires. Unfinished questionnaires were excluded from analysis as these were incomplete.

Descriptive statistics were used to present baseline characteristics and outcomes of the questionnaire. Total APAIS scores were presented and subsequently subdivided to classify patients into high or low anxiety (anxiety score >10 points and ≤ 10 respectively), and low (2-4 points), average (5-7 points) or high information requirement (8-10 points).

For several questions patients could give multiple answers (Appendix 1) and results were grouped where relevant. For example, in the free text field answers were grouped where patients gave comparable considerations.

Statistical analyses were performed with IBM SPSS Statistics for Windows (Version 26.0, Armonk, NY: IBM Corp.).

The results from the questionnaire were discussed with a spokesman from the Dutch experience expert organization for patients with cardiac diseases during an interview.

Results

The questionnaire was sent to 120 patients and completed by 100.. Sixty-two patients were older than 60 years, 26 (26%) were females, 33 (33%) had a low level of education and 79 (79%) had undergone previous surgery (Table 1). Nineteen (19%) patients were classified by the APAIS as having a high information requirement and 31 as being highly anxious. On the APAIS the anxiety for surgery was higher than anxiety for anaesthesia with a median (IQR) surgical anxiety of 5 (4-8) compared with a median anaesthetic anxiety of 3 (2-5) (Table 1).

Need for separate informed consent

Seventy-six (76%) patients considered a separate consent for anaesthesia unnecessary, 13 (13%) reported need for a separate consent and 11 (11%) 'did not know' (Table 2). Free text comments were given by 72 (72%) patients. Answers could be summarized into 'no separation necessary, because surgery and anaesthesia belong together' (reported by 57, 79%), 'no separation necessary because surgery is more important' (reported by 2, 3%) or 'trust in healthcare workers' (reported by 3, 4%). Eight out of the 13 (62%) patients who considered a separate consent necessary, reported that anaesthesia and surgery are separate treatments, therefore requiring separate consents. A separate question asked about the need for consent for specific severe anaesthesia-related complications. Eighty-seven (87%) patients answered that a separate consent for any severe complication was not necessary. Nine patients wanted information with a subsequent deliberate consent for the complication of intraoperative death (Table 2).

Patient perceptions of anaesthetic risks versus surgical risks and benefits

With regard to worries for surgical-related side effects compared with anaesthesia-related side effects, patients rated their median (IQR) NRS 4 (0-7) (Table 3). Six patients worried more about anaesthetic side effects than surgical side effects and 72 were more worried about surgical side effects (Table 3). Similarly, with regard to worries forsurgery-related complications compared with anaesthesia-related complications, patients rated their median (IQR) NRS 5 (0-7). Four (4%) patients were more worried about anaesthesia-related complications than about surgical complications and 77 (77%) worried more about surgical complications (Table 3). Somepatients did not worry at all (22 not for side effects and 19 not for complications).

Regarding the need for information, sixty-five patients wanted to receive some information about anaesthesia, either about side effects (n=22), complications (n=1) or both (n=42) and

thirty-five did not want to receive any information (Table 3). A main reason not to need information was the feeling of 'no choice' but to undergo surgery, and a main reason to get information was 'to know what to expect' (Table 3).

Focusing on specific side effects, patients were not worried about PONV in general (NRS 2, IQR 0-4.8). Less patients were worried about PONV compared to surgical side effects (7% versus 74%). With regard to the PONV probability in relation to the benefits of the surgery, even if the probability of PONV would be 100%, 94 (94%) patients would still be willing to undergo surgery. For the remaining six (6%) patients this question was too difficult to answer. Five (5%) patients wanted to be informed about PONV before their consent. Another 59 (59%) reported they wanted information, but their consent would be independent of the information provided. The other 34 (34%) wanted no information and their consent would be independent of information (Table 2). The main considerations reported in the free text field regarding PONV, were the feeling of 'no choice', reported by 51 out of 68 patients (75%) who filled in the free text field.

Focusing on the complication awareness, patients were little worried about awareness (median NRS 1, IQR 0-4). More patients were worried about surgical complications than about awareness (68% versus 11%). With regard to the chance for awareness in relation to the benefits of the surgery, even if the probability of awareness would be 100%, 63 (63%) patients would still be willing to undergo surgery. Three (3%) patients wanted to be informed about awareness, before they could consent. Another 52 (52%) reported they wanted information about awareness, but their consent would be independent of this. Another 45 (45%) wanted no information nor would it influence their consent (Table 2). In the free text field, 57 patients reported their considerations for consent for anaesthesia with relation to awareness and 31 of these 57 (54%) mentioned 'no choice' as a reason for no need for consent.

The above observations were shared with a spokesman from the experience experts organization for cardiac diseases. The spokesman confirmed that the participating patients were representative of cardiac surgery patients in the Netherlands with regard to baseline characteristics and the results of the questionnaire were in line with perceptions observed within their patient organization.

Discussion

Before elective cardiac surgery, 76% of patients indicated they had no need to give a separate informed consent for anaesthesia. Patients felt that surgery and anaesthesia belong together and one cannot consent to surgery without consenting to anaesthesia. Risks for severe intraoperative events specifically related to anaesthesia did not influence patients in their decision to undergo surgery. Even if these risks would be very high, the patients would consider the expected surgical benefit to outweigh almost all anaesthetic risks. Regarding individual anaesthetic risks, a deliberate consent for death was reported to be important by 9% of the patients. Overall, more patients were concerned about surgical risks than about anaesthetic risks. Although not deemed required to give consent, 65% of the patients valued information about the anaesthesia and its risks. They preferred information about side effects above information about complications. Interestingly, 35% of the patients needed no information at all.

In this study patients valued information about what will happen to them during anaesthesia and some patients wanted to receive information about rare but severe complications, such as death, as well.[7 10-12] Studies that examine whether and how information about anesthestic risks influence the decision to consent for anaesthesia are rare. A study by Asehnoune showed that 63% of patients wanted to be informed of all risks of complications, but it was not studied whether knowing risks influenced patients in their decision to consent for anaesthesia and surgery. A recent study in patients scheduled for anaesthesia in Singapore examined what patients considered a material anaesthetic risk.[10] They reported that 41% wanted to know all risks, 20% only severe risks, 20% only common risks and 17% did not want to know any risks. Although this study examined how much patients wanted to be involved in the shared decision making process, it was not studied how risk information influenced patients in their decision to consent to anaesthesia.

We found that most patients value information about intraoperative risks for cardiac surgery under general anaesthesia, but this information would not change their consent for anaesthesia. A review by Sturgess about shared decision making in anaesthesia offered an explanation for this: “Anaesthesia consultations are not done to decide whether the patient will have anaesthesia; the patient is already somewhat positioned as the ‘recipient of whatever is on offer’, …because he or she has already agreed to an overarching course of care… this inflicts the preoperative consultation in complex ways”.[13] Our study objectively

confirms these observations as patients reported they feel not to have a choice but to undergo their cardiac surgery, so they accept anaesthesia risks. From a patient perspective, consenting for surgery includes consenting for anaesthesia.

This study is the first to examine the value of anaesthetic informed consent for cardiac surgery, and the first to define material anaesthetic risks for cardiac surgery. It surveyed patients' preferences and its results were further objectified by the spokesman of the expert experience organization. We have to acknowledge limitations. We used a questionnaire with multiple choice answers to examine patient perspectives. This could have introduced a bias, but free text fields offered additional information, and those answers were consistent with the multiple choice answers. Also it could be possible that the question about the probability rate for awareness was difficult to understand for patients as a low numeracy is still frequent.[14] From an anaesthesiologist's perspective it is inconceivable that 63 patients would want surgery, even if they would get awareness. However, it may be likely, that a framing bias, possibly induced by the timing of the information provisioning about anaesthesia may explain these high numbers. The perceived benefit of the surgery is so substantial, that it outweighs any other risks that are discussed afterwards, such as anaesthetic risks discussed at the preoperative outpatient clinic. Next, the patients were scheduled for surgery in a tertiary referral hospital in the Netherlands, and both the setting and the country could influence study generalizability. However, the demographics are comparable to other cardiac surgery patients. The results with regard to the need for information are fairly comparable to other studies, making generalizability to other Western-European countries likely.

Implications for current practice

This study offers various leads to optimize preoperative consultation for patients scheduled for cardiac surgery. Ideally, surgeons and anaesthesiologists should act together in obtaining informed consent for the entire 'cardiac surgery process'. If patients have an increased risk for specific (rare) anaesthetic complications, for example based on co-morbidities, they should be informed about this before the surgical consent. These risks may influence their decision for surgery and may prevent framing bias. Before offering information, patients should be asked which information they need; general information about what to expect during the perioperative process, or also information about rare complications. Subsequently, patients are informed about the perioperative period and its risks by the anaesthesiologist

and surgeon together, if possible. Thereafter, a patient can weigh all risks against the benefit of surgery, resulting in one consent.

In some countries anaesthesiologists need to discuss all material risks before obtaining consent, to prevent liability just in case a rare complication accidently occurs. This study is the first to investigate what risks patients scheduled for cardiac surgery value to know. It shows that knowing these risks does not influence their decision to consent for surgery. Our results can help define what a material risk is for patients scheduled for cardiac surgery. These results can help anaesthesiologists to gain confidence for starting a meaningful informed consent consultation. Such a meaningful informed consent, driven from patients' preferences was proposed by an editorials by Waisel and Sturgess.[13 15] Our study offers the perspective of patients and their preferences about information and consent for anaesthesia.

Future studies

There is need for additional investigations about patients' perspectives on information provisioning and consent in other domains, such as other major surgery or when patients can choose between two anaesthetic techniques. Furthermore, studies that discuss the value of informed consent or shared decision making in anaesthesia mainly focused on patients with a high complication risk, though they are not the majority of patients. In addition, a combined anaesthetic and surgical consent needs to be explored further. How to fit in such consultations into daily practice, for which patient group is this valuable, is it cost-effective and how do patients perceive this and will it lead to other choices?

Conclusion

In patients scheduled for elective cardiac surgery under general anaesthesia, 76% reported no need for a separate informed consent for anaesthesia. Most patients valued information about anaesthesia, but was not needed to consent. A minority of patients wanted information about rare severe intraoperative anaesthetic risks, but this information would not influence patients' decisions to consent, as surgical risks and benefits were considered to outweigh anaesthesia risks. In the future, information about anaesthesia should be offered together with surgical information. The information should be tailored to patient preferences after which one common consent should be obtained.

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Table 1. Baseline characteristics.

	N=100
Female sex	26
Age	
<40 yrs	5
41-50 yrs	8
51-60 yrs	25
61-70 yrs	33
71-80 yrs	26
> 80 yrs	3
Level of education[1]	
Low	33
Middle	39
High	28
Previous surgery	79
Previous surgery under general anaesthesia	73
Previous surgery considered by patient as major surgery	37
Previous experience with anaesthesia[2]	
Positive	24
Neutral	43
Negative	11
Not applicable	25
Received information about anaesthesia before consultation[3]	68
By surgeon	33
Own experiences	9
Experiences from relatives/friends	11
Searching the internet	21
Website hospital	36
Paper leaflet	2
Other	7
No information	28
Received information from ≥ 3 sources	
Questionnaire filled in	
After consultation with surgeon	86
After consultation with anaesthesiologist	85
Median APAIS total (IQR)	15 (12-18)
APAIS Information[4]	6
Low	22
Average	59
High	19

	N=100
Median APAIS Anxiety (IQR)[5]	9 (6-12)
Low Anxiety (≤10)	69
High (>10)	31
Median APAIS Anxiety surgery (IQR)[6]	5 (4-8)
Median APAIS Anxiety anaesthesia (IQR)[6]	3 (2-5)

[1] Level of education. Low level: completed only primary education. Middle level: completed secondary school and/or community college. High level: > 1 year of university. [2]Some patients had both positive and negative experiences. [3] Patients could fill in multiple answers. [4]APAIS information has a maximum score of 10 points and low information is classified as 2-4 points, average as 5-7 points and high as 8-10 points. [5]APAIS Anxiety has a maximum score of 20 and low anxiety is a score ≤10 and high anxiety > 10 points. [6]APAIS Anxiety can be subdivided into surgical anxiety and anaesthetic anxiety, each with a maximum of 10 points.

Table 2. Outcomes with regard to informed consent.

	N=100
Need for separate informed consent	13
No need for separate informed consent	76
Do not know	11
Free text comments related to previous question about need for separate consent[2]	72
No, they belong together	57
No, surgery is more important	2
No, I have trust in healthcare professionals	3
No, only relevant if options for different types of anaesthesia	2
Yes, it are separate treatments	8
Need for separate consent about specific complications[1]	
None	87
Dental damage	2
Anaphylactic reactions	1
Awareness	1
Death during procedure	7
Esophageal rupture due to intraoperative TEE[3]	3
All of above	2
Anxious about awareness median (NRS 0-10, IQR)	1 (0-4)
Anxious about awareness versus surgical related complications	
Median NRS (IQR)	2 (0-7)
Percentage with more worries about awareness	11
Percentage with more worries about surgery	68
Percentage with no worries for both (NRS 0)	21
Influence incidence of awareness on decision to proceed with surgery	
Chance 100%	63
Change 50%	7
Chance 10%	6
Chance 0.1%	1
Too difficult to answer	23
Need for information about awareness before consent	
Information needed before consent	3
Information needed, no influence of consent	52
No information needed, consent independent	45

	N=100
Free text comments related to previous question about need for information and/or consent about awareness[2]	57
No need, 'no choice' but to undergo surgery	23 (40)
No need, 'no choice' and chances are small	8 (14)
No need, faith in healthcare	10 (18)
No, because information will cause anxiety	3 (5)
Yes, because information reduces anxiety	1 (2)
Yes, wants to know as much as possible	12 (21)
Anxious about PONV (median NRS 0-10), IQR	2 (0-5)
Anxious about PONV versus surgical related side effects[4]	
Median NRS (IQR)	3 (0-7)
Percentage with more worries about PONV	7 (7)
Percentage with more worries about surgery	74 (74)
Percentage with no worries for both (NRS 0)	19 (19)
Influence incidence of PONV on decision to proceed with surgery	
Chance 100%	94
Change 50%	0
Too difficult to answer	6
Need for information about PONV before consent	
Information needed before consent	5
Information needed, no influence of consent	59
No information needed, consent independent	34
Free text comments related to previous question about need for information and/or consent about PONV[2]	**68**
No, 'no choice' but to undergo surgery	51 (75)
No, PONV cannot be influenced	6 (8.9)
No, PONV risk does not outweigh surgical benefit	13 (19)
No, during previous surgery I experienced no PONV	8 (12)
No, faith in healthcare	10 (15)
Yes, I want to know what to expect	18 (26)

[1]Patients could fill in multiple answers. [2]Comments were non-mandatory and comparable free text answers were grouped if comparable. [3]TEE Trans Esophageal Echocardiography. [4]NRS rating scale from -10 (more worries for anaesthesia) to +10 (more worries for surgery).

Table 3. Outcomes with regard to information provisioning.

Questions and outcome	N = 100
Need for information	
About side effects and complications	42
About side effects	22
About complications	1
Not any information	35
Reasons for information about side effects[1,2]	64
To know what to expect[1]	62
Wants to know as much as possible	11
Because of side effects during previous anaesthesia	5
Reasons for information about complications[1,2]	**43**
To know wat to expect	38
Wants to know as much as possible	10
Because of worries about complications of anaesthesia	7
Because of complications during previous anaesthesia	3
Reasons for no need for information about complications[1]	**67**
No choice, since surgery is needed	38
Does not want to worry unnecessary	17
Mainly interested in complications about surgery	4
No worries at all	12
Reasons for no need for information about side effects[1]	**36**
Had previous anaesthesia and knows what to expect	19
No choice, since surgery is needed	22
Does not want to worry unnecessarily	13
Mainly interested in complications about surgery	5
No worries at all	10
Worries about anaesthetic side effects versus surgical side effects	
Median worries (IQR)[3]	4 (0-7)
Percentage with more worries about anaesthesia	6
Percentage with more worries about surgery	72
Percentage with no worries for both (NRS 0)	22
Worries about anaesthetic complications versus surgical complications	
Median worries (IQR)[3]	5 (0-7)
Percentage with more worries about anaesthesia	4
Percentage with more worries about surgery	77
Percentage with no worries for both	19

Questions and outcome	N = 100
Need for information about specific complications[1]	
None	49
Dental damage	29
Anaphylactic reactions	27
Awareness	25
Death during procedure	28
Esophageal rupture due to intraoperative TEE[4]	22
Other	6

[1]Patients could fill in multiple answers.[2]Some patients filed in 'other' and used the free text field to explain themselves. Their answers could be classified into one of the statements from the primary question and therefore were scored as such in the table. [3]NRS rating scale from-10 (more worries for anaesthesia) to +10 (more worries for surgery). [4]TEE Trans Esophageal Echocardiography.

Appendix A. Questionnaire translated into English.

Part I General information

What is your sex?

Male

Female

What is your age?

< 40 years

40-50 years

51-60 years

61-70 years

71-80 Ears

> 80 years

What is your highest completed level of education?

Primary education

Lower vocational education

Secondary education – lower level

Middle vocational education

Secondary education – higher level

Higher vocational education

Higher education

Other

Have you already received information about anaesthesia? (Multiple answers possible)

Yes, through a surgeon or nurse
Yes, through my own experience
Yes, through experiences of others
Yes, through the internet
Yes, through leaflets
Yes, through the UMC Utrecht website
No
Other

Have you ever had surgery?

Yes
No
I do not know

How are your experiences with anaesthesia? (Multiple answers possible)

I have positive experiences
I have neutral experiences
I have negative experiences
Not applicable
Other

Have you already received information about side effects and complications of anaesthesia for your cardiac surgery?

Yes
No
I do not know

Have you already received information about side effects and complications of cardiac surgery?

Yes
No
I do not know

Part II APAIS

I am worried about the anaesthesia.

1 = not at all
2 = somewhat
3 = moderate
4 = moderately high
5 = extremely

The anaesthesia is on my mind continually.

1 = not at all
2 = somewhat
3 = moderate
4 = moderately high
5 = extremely

I would like to know as much as possible about anaesthesia.

1 = not at all
2 = somewhat
3 = moderate
4 = moderately high
5 = extremely

I am worried about the surgery.

1 = not at all
2 = somewhat
3 = moderate
4 = moderately high
5 = extremely

The procedure is on my mind continually.

1 = not at all
2 = somewhat
3 = moderate
4 = moderately high
5 = extremely

I would like to know as much as possible about the surgery.

1 = not at all
2 = somewhat
3 = moderate
4 = moderately high
5 = extremely

Part III information and consent

Would you like to receive information about side effects of anaesthesia (Multiple answers possible)?

Yes, because I want to know what to expect.
Yes, because I want to know as much as possible about the anaesthesia.
Yes, because I had side effects previously and want to discuss this.
No, because I don't want to worry unnecessarily.
No, because the surgery will have to be performed anyway.
No, because I had surgery before and I know what to expect
No, because I am more interested in the surgical side effects.
No, because I do not worry at all.
Yes or no, other.

Non mandatory free text field for 'other'

Which side effects are you more concerned about: anaesthetic or surgical side effects?

Numeric rating scale from-10 (anaesthesia) to 0 (indifferent) and 10 (surgery)

Would you like to receive information about complications of anaesthesia (Multiple answers possible)?

Yes, because I want to know what to expect.
Yes, because I want to know as much as possible about the anaesthesia.
Yes, because I had complications previously and want to discuss this.
No, because I don't want to worry unnecessarily.
No, because the surgery will have to be performed anyways.
No, because I had surgery before and I know what to expect
No, because I am more interested in the surgical complications.
No, because I do not worry at all.
Yes or no, other.

Non mandatory free text field for 'other'

Which complications are you more concerned about: anaesthetic or surgical complications?

Numeric rating scale from-10 (anaesthesia) to 0 (indifferent) and 10 (surgery)

The chance of experiencing nausea or vomiting after your surgery is 33%. This means that 1 in 3 people who undergo cardiac surgery, experience nausea or vomiting. This is a common side effect. The following questions concern nausea and vomiting after the surgery.

Are you worried that you will experience the side effects nausea or vomiting?

Numeric rating scale from 0 to 10

Which side effects worry you more: nausea/vomiting, or surgical side effects?

Numeric rating scale from-10 (anaesthesia) to 0 (indifferent) and 10 (surgery)

Nausea and vomiting are common after anaesthesia. Imagine that nausea and/or vomiting would be more frequent, at what point would you doubt to proceed with the surgery?
I would always proceed with the surgery, even at 100% certainty for nausea and/or vomiting.
I would not want the operation if the chance were 1 in 2 (= 50%).
I find this difficult to answer.

Before undergoing anaesthesia, you must be informed of side effects. Afterwards you must make the decision to consent for anaesthesia. What is your opinion on information and consent regarding the side effect nausea and vomiting.
I want information about nausea/vomiting. Thereafter I can decide to consent for anaesthesia.
I want information about nausea/vomiting, but my decision to consent to anaesthesia is separate from this information.
I do not want information about nausea/vomiting. My decision to consent for anaesthesia is separate from this information.

Can you explain your answer? [non-mandatory free text field]

A rare but severe complication of anaesthesia is awareness. Awareness is when a patient accidentally wakes up during surgery, and experiences part of the operation. What patients experience can vary from mild, such as hearing voices, to severe, such as feeling intense pain. As soon as awareness is noticed, patients receive extra anaesthetics. People who have experienced awareness usually are traumatized and often need psychological therapy. Awareness is rare and occurs around 1 in 10,000 operations; roughly the odds that one would win 75,000 euros in the lottery. The following questions concern awareness.

Are you worried you will experience the complication awareness?
Numeric rating scale from 0 to 10

Which complications are you more concerned about: awareness, or surgical side complications?
Numeric rating scale from-10 (anaesthesia) to 0 (indifferent) and 10 (surgery)

Now that you know more about awareness, is this a reason for you to not proceed with the surgery?
Yes
No
I do not know

Awareness is very rare. Imagine awareness was more common, at what point would you doubt to proceed with the surgery?
I would always proceed with the operation, even at 100% certainty for awareness.
I would not want the operation if the chance was 1 in 2 (= 50%).
I would not want the operation if the chance was 1 in 10 (= 10%).
I would not want the operation if the chance was 1 in 100 (= 1%).
I would not want the operation if the chance was 1 in 1000 (= 0.1%).
I find this difficult to answer.

Before undergoing anaesthesia, you must be informed of complications. Afterwards you must make the decision to consent for anaesthesia. What is your opinion on information and consent regarding the complication awareness.

I want information about awareness. Thereafter I can decide to consent for anaesthesia.
I want information about awareness, but my decision to consent to anaesthesia is separate from this information.
I do not want information about awareness. My decision to consent for anaesthesia is separate from this information.

Can you explain your answer? [non-mandatory free text field]

The last questions concern decisions and complications in general.
Do you think you should give separate consent for anaesthesia, independent of your consent for cardiac surgery?

Yes
No
I do not know

Can you explain your answer? [non-mandatory free text field]

About which of the following complications should we inform you before surgery? (Multiple answers possible)

None.
Tooth damage due to placement of breathing tube, rare (1 in 500).
Severe allergic reaction to anaesthetic drugs, rare (1 in 1000).
Awareness, extremely rare (1 in 10.000).
Death during surgery due to anaesthesia, extremely rare (1 in 10.000).
Damage to the esophagus due to insertion of ultrasound probe, extremely rare (1 in 30.000).
Other.

Are there complications of anaesthesia for which you want to give separate consent, indicating you understand and accept the risks, before undergoing anaesthesia (Multiple answers possible)?

None.
Broken tooth due placement of breathing tube, rare (1 in 500).
Severe allergic reaction to anaesthetic drugs, rare (1 in 1000).
Awareness, extremely rare (1 in 10.000).
Death during surgery due to anaesthesia, extremely rare (1 in 10.000).
Damage to the esophagus due to insertion of ultrasound probe, extremely rare (1 in 30.000).
Other.

Information can be offered through various media: orally during consultation, by paper leaflets or by websites with text and movies. How do you prefer to be informed about complications (multiple answers possible) (for every filled in complication this question appears separately)

Orally, during physical consultation with the anaesthesiologist

Orally, during physical consultation with a specialized nurse

Orally during consultation by telephone with the anaesthesiologist

Orally during consultation by telephone with a specialized nurse

By secured website with text and movies. If I have questions afterwards, I can discussed this with the anaesthesiologists.

By a paper leaflet. If I have questions afterwards, I can discussed this with the anaesthesiologists**.**

PART IV

Summary, Summary in Dutch and Curriculum Vitae

8

GENERAL DISCUSSION

General discussion

In modern medicine guidelines are a basis for many of our daily medical decisions. Implementation of guidelines contributed to the safety and cost-effectiveness of patient care. In the last decades, the quantity of guidelines has grown exponentially, making implementation in a complex hospital organization a challenging task.

In this thesis, several recommendations from four different guidelines were investigated: the preoperative fasting guideline, the guideline 'prevention of cardiac complications in non-cardiac surgery', the guideline 'prevention of pulmonary complications in non-pulmonary surgery' and the guideline 'perioperative care' with its associated position statement 'informed consent'.[1-5] We observed important discrepancies between daily practice and guideline recommendations. This led to development of hypotheses and initiated research projects on how to improve recommendations from these guidelines, how to improve guideline implementation and how to incorporate societal changes into guidelines.

This chapter discusses the overall results of these studies in relation to the objectives of this thesis. All research projects provided new evidence that can be incorporated in guideline updates. This chapter also discusses the degree of implementation of the guidelines studied (chapters 2-5), how qualitative research can be used as a starting point to study societal and work floor innovations (chapters 6 and 7) and how qualitative studies can contribute to future updates of current guidelines (chapters 3, 6 and 7). First, however, I will share personal reflections on the journey I travelled during the conduct of the studies described in this thesis.

1. Reflections on this research period

Anaesthesiologists deliver care to patients from almost every medical specialty and although some prefer to work within the boundaries of their specialty and focus on delivering high quality anaesthesia in the operating room, growing numbers of anaesthesiologists are focusing on perioperative care. These anaesthesiologists connect with other specialists, broaden their medical skills and gain more knowledge about the hospital organization. From an organizational perspective these anaesthesiologists may be used as a resource for innovation and implementation of novel care for many (surgical) patients. During this PhD project, I benefitted from my experience of the perioperative process and the local network I created in the 18 years of my career. I learned that if you want to start a change within a major organization it is very important to understand the work processes of all stakeholders

needed to execute the intended change and how this intended change can be incorporated into their daily activities. Understanding an organization and the people involved however, takes a lot of time and for healthcare workers time is unfortunately limited, so literally looking outside your own specialty remains difficult. An important point I discovered, however, is that hospital organizations are not yet fully utilizing the experience, (organizational) knowledge and networking opportunities that anaesthesiologists have to offer.

The next section discusses two guidelines, one with more successfully implemented recommendations and one that failed, giving a good example why knowledge of an organization and the people involved is important.

2. The success of one guideline versus the failure of another

Chapters 2 and 3 investigated the guideline 'Prevention of cardiac complications in non-cardiac surgery' and the guideline 'Prevention of pulmonary complications in non-pulmonary surgery'.[1 5]

The cardiac guideline (published in 2014) recommended a cut off of 4 MET to recognize patients who are at risk for cardiac complications and could have need for further preoperative cardiac testing and this cut off has a central place in the decision tree. Our study showed that a self-reported low functional capacity had no additive value compared to other predictors.[6] Our study was published in 2020 and since then other studies were published, that also challenged the additive value of a self-reported functional capacity.[7-9] As a result, in the updated guideline published in August 2022, the role of self-reported functional capacity has indeed changed: risk stratification is now primarily based upon risk factors for cardiovascular diseases instead of functional capacity and the 4 MET cut off is placed lower in the decision tree.[7 10]

Self-reported functional capacity has been used for decades by anaesthesiologists at times where there were not many predictors available and is still firmly embedded in daily practice during preoperative assessment, because of its simplicity. This was a main reason for successful implementation of self-reported functional capacity. As the role of functional capacity is less pronounced in the new guideline, it will be interesting to see if this change in approach will be implemented into daily practice. During implementation of the guideline it would be advisable to acknowledge the thoroughly embedded self-reported MET as a barrier for implementation of the new recommendation and to give education about the shift from MET to CVD risk factors, as education is an important strategy to reach a behavioral change.

It will be a major task to successfully implement the 2022 guideline since overall implementation of the 2014 guideline was only moderate.[11 12]

In contrast to the thoroughly implemented self-reported MET, the administration of corticosteroids in patients at risk for postoperative pulmonary complications (PPC) is only moderately implemented as shown in chapter 3. The perceived low quality of the available evidence was reported as a reason for non-compliance to the guideline by anaesthesiologists. Indeed, the recommendations of this section of the guideline are based on low-quality evidence, which can be a barrier for implementation.[13 14]

Interestingly, the quality of evidence that supports the use of a self-reported MET is comparable, but MET is used widely in daily practice. Therefore, the level of evidence for the benefit of the intervention to administer corticosteroids itself does not seem to be a main determinant of implementation failure. Although fear for side effects was another reported reason for non-compliance, there also is no evidence that one day of corticosteroid use results in side effects with a negative (long term) outcome for patients, but apparently some anaesthesiologists perceived it as such.[15] Thus, during development of a guideline authors should discuss evidence of potential benefit and harm of their proposed intervention and explore evidence or other arguments that fit within the mindset of the stakeholders (in this case anaesthesiologists). In this, understanding of the culture and beliefs of stakeholders is important.

We also found that administering prednisolone as a corticosteroid does not always fit in the daily anaesthesia practice where dexamethasone is the main corticosteroid used for various indications. It can be speculated that the guideline developers did not sufficiently inventoried the work process of their stakeholders (e.g. anaesthesiologists) that might hinder implementation of their guideline. We recommend that the updated guideline incorporates these intraoperative work processes, as this may result in increased guideline compliance.

Overall, it can be concluded from Chapters 2 and 3 that assessing the knowledge (gaps), attitudes, beliefs and work processes from the stakeholders that will have to execute the guideline is useful, not only during implementation of a guideline, but also during development of a guideline. A change has started and currently more guidelines are developed by specialists from different (para-)medical specialties and patient organizations are increasingly involved.[16] It has been recommended that during guideline development translating evidence into a recommendation not only involves assessing the quality of evidence, but also assessing

costs, feasibility and acceptability.[17 18] In daily practice, this ideal scenario can be limited by time, costs and the complexity of care, and such considerations are not always visualized in the recommendations that physicians read.

3. The success and failure of the current adult fasting guideline

Pulmonary aspiration of gastric content during anaesthesia is a major anaesthesia-related complication contributing to many anaesthesia-related deaths in the previous century. Fasting guidelines are one of the oldest anaesthesia-related guidelines, developed to ensure patients had an empty stomach, thereby lowering the chance of aspiration. Their implementation reduced anaesthesia-related perioperative morbidity and mortality significantly.[19] Current fasting guidelines recommend fasting for 2 hours for clear fluids and 6 hours for solid food.[2 20 21] However, most anaesthesiologists, surgeons, nurses and patients have not succeeded in implementing these guidelines correctly: many patients fast much longer than required.[22-25] This does not further decrease aspiration risk, but leads to increased risks for negative sequelae such as dehydration, induction of a catabolic state and prolonged recovery due to deprivation of fluids and nutrition. [25-28] These negative sequelae may be negligible for healthy patients undergoing minor procedures, but may be pivotal for frail patients undergoing major procedures. Also deprivation of food and drinks reduce patients' general well-being in terms of thirst, nausea and mood depression.

This raises the question why recommendations of the fasting guideline are so firmly embedded and devotedly followed, resulting in very long fasting durations. An important determinant for compliance to a guideline is the 'knowledge' why a recommendation needs to be followed.[29 30] Besides evidence from literature, most anaesthesiologists have experience with (emergency) patients aspirating, with severe instant consequences, which is a direct negative feedback/penalty for disobedience. As a result, many anaesthesiologists may feel the urgency to adhere to the fasting policy. Surgeons and nurses wish their patients to undergo their surgery and since disobeying the recommendations results in direct cancellation or postponing of the procedure, again a penalty for disobedience, there is much incentive to follow the guideline. The stricter than necessary fasting duration in many hospitals (including the UMC Utrecht) is caused by so-called 'external factors', such as time restrictions and workload: keeping all patients fasted from midnight takes less time for nurses (no need to offer drinks) and less chance for accidental miscalculation of the timeframe before surgery.[30-33] Although many nurses are directly confronted with the negative consequences of long fasting

duration as patients complain about thirst, weakness and a 'bad mood', this apparently does not outweigh the risk of cancellation. In addition, long-term metabolic effects are probably difficult to apprehend for many nurses and physicians.

The start of a change in pediatric fasting guidelines

Today, patient well-being and fast recovery from a procedure is becoming more important.[34-37] With regard to preoperative fasting, children especially suffer from the negative effects of long fasting duration as compared to adults. Therefore, pediatric anaesthesiologists felt a need to shorten fasting duration to increase well-being and recovery for their patients. Around 2015 the first (retrospective) studies appeared that assessed the current aspiration risk and concluded that this risk remained similar after introducing a liberal fluid fasting policy and that the benefits outweighed the risks. Thereafter some hospitals started to implement a liberal fluid fasting policy in children and the first prospective studies appeared. Subsequently, pediatric fasting guidelines in Europe and Australia changed. Interestingly, in North-America pediatric fasting guidelines were not liberated. The guidelines state that the metabolic and well-being benefits do not outweigh the chance that the aspiration risk might be slightly higher. It may be speculated that the active 'claiming' culture in North-America influences anaesthesiologists, making them focus on minimizing severe but extremely rare complications.

A strategy to implement a new fasting policy in adults

The changes within pediatric fluid fasting induced a discussion in adult literature as well and in editorials anaesthesiologists were challenged to adopt a liberal fluid fasting in adults, but studies assessing the positive effects and safety of a liberal fluid policy are slow to appear, so clinicians remained reluctant to deviate from guidelines. Advocates of a liberal policy focus on increased well-being, better nutritional status that may lead to better recovery and the increased flexibility of OR schedule. Opponents argue that, until there is enough evidence that aspiration risk is not increased, wellbeing, recovery and OR scheduling cannot be a reason to relax fasting guidelines. This scientific debate, the evidence in pediatric patients and our positive experiences with a liberal fasting policy in the Wilhelmina Children's Hospital, made us believe that a liberal fluid fasting protocol in adults could be beneficial and we decided to implement such a liberal protocol. To increase the chances for successful implementation a multifaceted implementation strategy was written.[29 30 38 39]

First, we inventoried possible barriers and facilitators for implementation based on aforementioned literature and based on observations of daily practice in our hospital. Second, we investigated the local willingness to change during anaesthesiology staff meetings. Though some anaesthesiologists feared the legal consequences of deviating from national fasting guidelines, some key anaesthesiologists favored a change and this resulted in a collective decision to accept the proposed change. During subsequent education sessions for anaesthesiologists and residents we acknowledged the long history of preoperative fasting, but relativized the incidence of aspiration in elective anaesthesia and focused on the benefits of shorter fasting duration. The anaesthesiologists were subsequently regarded as opinion leaders that advocated the policy change. Third, we educated holding nurses, ward nurses and surgeons that they no longer had to 'fear' that ingesting clear fluids within two hours would result in cancellation of their procedure and that it would result in more flexibility in OR schedule. We emphasized the beneficial effects of a decreased fasting duration, especially to ward nurses who had to stimulate drinking. We used different communication strategies to promote the liberal policy to these important stakeholders: education by presentations, multiple outreach visits, reminders by email and posters on floors for nurses, physicians and nutrition assistants. Different communication strategies were used at multiple time points. Fourth, a stepwise implementation strategy was used where subsequent locations could 'learn and be stimulated' from their predecessors. Successful wards were rewarded for their compliance and used as champions for others. Fifth, a key factor was embedding the liberal fasting policy within current organization of care: before implementation nurses were trained to give premedication with ½ glass of water within 1 hour before admittance to the OR. We considered changing this ½ glass into 1 glass as a relatively simple way to implement the new policy as a starting point. Sixth, after the start of the new policy, nurses received monthly feedback on performance, which also contributed to the success of implementation. Reasons for non-compliance were sought and plans were made to increase compliance subsequently. Seventh, at the preoperative assessment clinic patients were instructed to follow the liberal fasting guideline and leaflets, instruction letters and websites were adjusted.

Overall, it can be concluded that our implementation strategy was carefully planned. In a scoping review by Gagliardi trends were assessed in guideline implementation and a concomitant guideline implementation planning checklist was developed.[38 40 41] We used many of the strategies that were described in that checklist, resulting in a successful policy

change. As many authors have described how difficult it is to change a fasting policy, we have presented a strategy that can be used by others.

To securely establish this successful implementation, it remains important that the policy change will become firmly embedded into daily practice, so further dissemination strategies will remain necessary. For example, scientific publication of the results of the implementation project can serve as a trigger for a new in-hospital campaign to stimulate compliance to the protocol, but can also serve as a basis for an external campaign to stimulate further distribution of the new policy to other hospitals. If more hospitals adopt a liberal fluid fasting policy and collect results with regard to fasting duration and safety, and these safety results with remain reassuring, it is likely that this will be noticed by guideline developers and it will be incorporated into the updated guideline. In the next five years I expect more fasting policy evaluation studies will be published, which will probably result in a change in guidelines.[42] As long as the evidence is insufficient to change guidelines, it would be advisable that guidelines acknowledge the current risk-benefit debate of a liberal fasting policy in their recommendations, so that hospitals feel strengthened to make decisions to adopt a liberal fluid fasting policy based on their patient population.

4. Towards improving guidelines

Qualitative studies as a resource for identifying barriers for guideline implementation

In this thesis qualitative research strategies were used in Chapters 3 and 6 and results from Chapter 6 served as the basis for Chapter 7. Qualitative research has its origins in social sciences and is used to understand social phenomena. Qualitative research uses techniques to explore non-numerical data such as people's beliefs, behavior, experiences, interactions and culture. In the past decades, its use in health care and health services research has grown, because of increasing need to understand the complex social healthcare environment.[43] However, in anaesthesiology qualitative studies are still rare, unknown and therefore undervalued.[44 45] In preoperative care quantitative research can be valuable if one needs to understand perceptions, experiences and behavior around a complex subjective topic such as informed consent or if one wants to understand why a guideline is (sub) optimally implemented. I want to discuss two fields where qualitative research can be of a benefit for guideline developers in preoperative care.

In a review by Gisselbaek, exploring the use of qualitative research in perioperative medicine, 24 out of 107 included studies explored barriers to best care (N=9) or implementation of

changes in clinical practices (N=15). This review showed that qualitative studies can be used to assess guideline implementation in anaesthesiology. Indeed, in Chapter 3 we used a mixed-methods research strategy (using both quantitative and qualitative methods) to identify the degree of guideline compliance and to understand why anaesthesiologists did (not) adhere to the guideline. Based on the literature and the results from our study, it is useful for anaesthesia guideline developers to perform a qualitative study to assess the level of compliance by the stakeholders and to search for reasons of (non-) compliance to a current guideline and to publish these results, before updating a guideline. This can contribute to improvement of an updated version, where besides new medical content, also other deliberations and interests from stakeholders are covered. It would be advisable to include these stakeholders in the development of a guideline and not only in the comment phase, after a concept has been drafted.[16 46]

These recommendations come together in an American intensive care guideline for family-centered care. They used qualitative research methods during their guideline development to check if the suggested recommendations, which were based on qualitative studies, could be endorsed by ICU patients and their family members.[47] This is an illustrative example in an anaesthesia-related work field where results from qualitative studies were incorporated in a guideline and where recommendations were actively reflected upon by stakeholders using qualitative methods.

Using qualitative studies to identify developments and offer leads for future research

A second field in preoperative guideline development where qualitative research could be useful is in exploring what developments in society or at the work floor should be incorporated in guideline (updates), as visualized in Part III of this thesis.

Our Western European society is digitizing and people want more autonomy.[48] Hospitals have started to use digital information provisioning to inform patients about anaesthesia and in some hospitals even informed consent for anaesthesia is obtained digitally.[49 50] However, guidelines recommend that informed consent is an action that has to be executed during a consultation between physician and patient and they offer no advice how to incorporate these digital developments. Since information provisioning and informed consent is a complex interaction between patients and anaesthesiologists involving communication, behavior and culture, it is perfect to use qualitative research to understand current patient perceptions about informed consent, as shown in Chapter 6. Chapters 6 and 7 provide many

entry points for guideline developers how to value digitalized information provisioning and informed consent. This quantitative study also identified where further research is necessary to modernize informed consent.

In conclusion, quantitative research can be used to identify developments in society or within healthcare that need attention in guidelines, and it offers a framework for further research. Before updating a guideline priority setting takes place with stakeholders, but the level of formality of this process can vary and it carries the risk of introducing a bias. [51] Qualitative studies can used as a formal objective way to identify these advancements or other changes that need to be prioritized.

5. Conclusions and future perspectives

Physicians use practice guidelines. This has improved patient safety and efficacy and has reduced complications. Intriguingly, many guidelines are only moderately implemented. Poor implementation triggered the emergence of implementation science: an area of expertise that tries to increase the success of implementation.[52] Different strategies can be used to study guideline implementation, but qualitative studies are an important, yet undervalued tool. Qualitative studies can be used to examine the perceptions of stakeholders, such as patients and anaesthesiologists. They can identify if and why a guideline is (not) properly implemented and give guideline developers a good starting point for a guideline update. Qualitative studies can also reveal knowledge gaps in current guidelines or novel developments that need to be answered or given advice on in updated versions of a guideline. It can also offer a framework for further research.

Within perioperative medicine guideline (qualitative) implementation studies are relatively rare and studies published within implementation journals are not easily visible for anaesthesiologists. Therefore, I make a call to conduct studies that evaluate implementation of anaesthesia guidelines both qualitative and quantitative and for anaesthesia journals to publish such studies, so that anaesthesiologists can benefit from the results to improve implementation in their hospitals.

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SUMMARY

Anaesthesiologists work in the operating room to provide anaesthesia and analgesia (sleep and inability to feel pain) and to maintain homeostasis of the body during surgery or other invasive procedures. In the earlier days of anaesthesia, intraoperative complications were common, but during the previous century the incidence of severe intraoperative complications has decreased. Currently anaesthesiologists have started to expand their work field towards preoperative and postoperative care, making anaesthesia an even more complex specialty. To overcome the complexity of modern (anaesthesia) healthcare, practice guidelines were developed to aid physicians in delivering up-to-date evidence-based care. It is thought that use of practice guidelines (hereafter referred to as guidelines) will lead to more uniform care and improves quality of care, resulting in higher patient safety, patient outcomes and cost effectiveness.

Currently, guidelines form the basis for many of our daily medical decisions. Over the last decades, the quantity of guidelines has grown exponentially, making implementation in a complex hospital organization a challenging task. Indeed we observed important discrepancies between daily practice and guideline recommendations in preoperative care. This led to the development of hypotheses and initiation of research projects on how to improve recommendations in these guidelines, guideline implementation and incorporation of societal developments into guidelines.

In this thesis, above hypotheses were investigated in four different preoperative guidelines.

In **Part I**, consisting of Chapters 2 and 3, we explored two recommendations, one from the European guideline 'Prevention of cardiac complications in non-cardiac surgery' and one from the Dutch guideline 'Prevention of pulmonary complications in non-pulmonary surgery'.

In **Chapter 2** we evaluated the added value of a patient's self-reported ability to 'climb two flights of stairs', e.g. 4 metabolic equivalents (METs), as a marker of exercise capacity. In the cardiac guideline, the assessment of exercise capacity is recommended for recognizing patients with a potentially increased risk for cardiac complications and is also used to guide further preoperative cardiac testing. However, our study demonstrated that this had no additive value on top of other variables to predict postoperative myocardial injury. As a result of our study and others with comparable outcomes, in the updated guideline that was published in August 2022, the role of self-reported functional capacity was changed: risk stratification is now primarily based upon risk factors for cardiovascular disease instead of

functional capacity.

In **Chapter 3** we showed moderate implementation of the Dutch guideline 'Prevention of pulmonary complications after non-pulmonary surgery' by anaesthesiologists with regard to the administration of the corticosteroid prednisolone. We qualitatively explored reasons for guideline compliance. One reason for non-compliance was the work process of anaesthesiologists in the operating room: anaesthesiologists often have to administer other corticosteroids for several indications, such as prevention of edema or postoperative nausea and vomiting. A second reason was the knowledge about the benefits and risks of corticosteroids leading to low compliance, since some anaesthesiologists believed the that benefits do not outweigh the risks. To improve compliance, we recommended to involve anaesthesiologists in future guideline updates.

Part II focused on the preoperative fluid fasting guideline for adults. This guideline is under debate since fasting duration for clear fluids was decreased in pediatric guidelines. The UMC Utrecht was the first Dutch hospital that implemented a liberal fluid fasting protocol for adults. In **Chapter 4** we evaluated the implementation of this liberal protocol with regard to fasting duration, patient well-being and safety. The implementation of the liberal policy was successful and median fasting duration decreased from 3:07 hours to 1:20 hours. Safety, measured as incidence of regurgitation and aspiration, did not increase after implementation, although the sample size of this study was not sufficient to draw definite conclusions regarding the safety of this new policy. Patient well-being improved, with patients reporting less thirst and slightly less postoperative nausea and vomiting, as well as a reduced administration of anti-emetics. In the general discussion we reported why the implementation strategy was successful, where many failed before. This offers tools for other hospitals to successfully implement a (liberal) fasting policy.

In **Chapter 5** we compared the effect of this liberal fluid fasting policy on gastric volume in patients scheduled for gastroscopy to the standard protocol, and showed that gastric volumes remained within clinically accepted limits with the liberal policy.

In **Part III** we explored the patient perspective on informed consent for anaesthesia, in light of advances in digitalization and increasing patient autonomy. It remains a subject of debate which anaesthetic risks need to be discussed with patients, and what patients wish to be informed about before giving informed consent. The Dutch anaesthesiologist's guideline states that informed consent should be given during an in-person consultation between patient

and anaesthesiologist. However, we observed that in the past few years in The Netherlands, information provision has moved from in-person consultation to partial or full digital information provision using applications. However, the benefits, risks, indications and limitations of this technology had not been properly studied in anaesthesia. In **Chapter 6** we qualitatively explored the value of digital information provision and e-consent in low-risk patients scheduled for minor procedures from a patient perspective. We observed that digital information provision and e-consent fulfilled the needs of most patients. Also, patients felt no need for a separate informed consent for anaesthesia after they already had consented for surgery. This observation was further explored in patients scheduled for major surgery, e.g. cardiac surgery and presented in **Chapter 7**. This confirmed that 76% of patients scheduled for elective cardiac surgery under general anaesthesia felt no need for a separate anaesthetic informed consent. Patients valued information about anaesthesia, but felt that this information was not needed for their anaesthetic consent. A minority of patients wanted information about rare severe intraoperative anaesthetic risks, although knowledge of these risks did not influence their decision to provide consent for undergoing surgery as the surgical risks and benefits outweighed anaesthetic risks.

These two studies suggest that information about anaesthesia should be offered together with information about the surgical procedure. Depending on the complexity of the procedure, comorbidities and patient preferences, digital information may be useful in addition to in-person information by healthcare providers, or may even replace this. After information provision, clinicians may consider asking patients for one 'perioperative' consent for both surgery and anaesthesia combined. Further research is needed to explore the benefits and limitations of such consent.

In this thesis, qualitative research methods have been used to explore perceptions of patients and anaesthesiologists. Qualitative studies are undervalued, but can be useful in anaesthesiology as they can offer thorough understanding why guidelines are not properly implemented. Furthermore, qualitative methods can be used to explore advancements and changes in society or hospital workflow and thereby offer a good starting point for further research, or they can help in objectively prioritizing topics for guideline updates.

In summary, this thesis presents new evidence to optimize preoperative care with regard to guideline recommendations, guideline implementation and patient informed consent. It showed why some guidelines are (not) fully implemented into daily practice, and how ad-

vancements and innovations in society and care may be incorporated into guidelines. Both qualitative research methods and implementation studies are excellent tools to study guideline implementation and innovation, and should be used more to evaluate and optimize daily preoperative care.

NEDERLANDSE SAMENVATTING

Nederlandse samenvatting

Anesthesiologen werken op de operatiekamers, waar ze zorgen voor slaap (anesthesie) en pijnstilling (analgesie) bij patiënten die een pijnlijke ingreep ondergaan, zoals een operatie. Ook zorgen ze dat tijdens deze ingreep het lichaam goed blijft functioneren (behoud van homeostate). In de beginjaren van de anesthesie kwamen complicaties tijdens de anesthesie vaak voor, maar in de vorige eeuw is de incidentie van ernstige complicaties fors gedaald. Tegenwoordig zijn anesthesiologen hun werkgebied aan het uitbreiden naar de pre- en postoperatieve fase, om de kans op complicaties tijdens en na de ingreep verder te verkleinen. Dit maakt het werk van anesthesiologen complexer. Om anesthesiologen en andere zorgprofessionals te helpen in deze steeds complexer wordende gezondheidszorg zijn er richtlijnen ontwikkeld, zodat artsen evidence-based zorg kunnen leveren. Men denkt dat het gebruik van richtlijnen leidt tot meer uniforme zorg en betere kwaliteit van zorg. Er is bewijs dat dit de patiëntveiligheid verbetert, de uitkomst van een behandeling voor de patiënt beter wordt en de zorg kosteneffectiever wordt.

Op dit moment vormen richtlijnen de basis van veel van onze dagelijkse medische beslissingen. Echter, in de laatste decennia is het aantal richtlijnen fors toegenomen. Hierdoor is de implementatie van al deze richtlijnen in een grote complexe organisatie zoals een ziekenhuis, een uitdagende taak. Inderdaad, hebben wij verschillen geobserveerd tussen aanbevelingen van richtlijnen enerzijds en de uitvoer hiervan in de dagelijkse praktijk anderzijds. Dit heeft geleid tot de ontwikkeling van hypotheses en onderzoeksprojecten over hoe deze richtlijnaanbevelingen en richtlijnimplementatie verbeterd kan worden. Ook hebben we onderzocht hoe ontwikkelingen vanuit de maatschappij in richtlijnen verwerkt zouden kunnen worden.

In dit proefschift werden deze hypotheses getest bij vier verschillende richtlijnen over preoperatieve zorg.

In **deel I**, bestaande uit hoofdstuk 2 en 3, onderzochten we twee aanbevelingen, één uit de Europese richtlijn ‘Preventie van cardiale complicaties bij niet-cardiale chirurgie’ en één uit de Nederlandse richtlijn ‘Preventie van pulmonale complicaties bij niet-pulmonale chirurgie’.

In **hoofdstuk 2** evalueerden we de meerwaarde van de door patiënten zelf gerapporteerde mogelijkheid om twee trappen te kunnen lopen. Dit komt overeen met 4 metabolic equivalents (MET), een marker van inspanningstolerantie. Patiënten die geen twee trappen kunnen lopen, worden geclassificeerd als hebbende een ‘lage inspanningstolerantie’. Deze

patiënten hebben een verhoogde kans op complicaties na een operatie. De richtlijn beveelt daarom het bepalen van de inspanningstolerantie aan, om patiënten te herkennen die mogelijk een verhoogd risico hebben op cardiale complicaties. Ook wordt het gebruikt als een uitgangspunt voor eventueel verder onderzoek naar het hart. Echter onze studie toonde aan dat zelf gerapporteerde inspanningstolerantie geen meerwaarde had bovenop andere variabelen om postoperatieve hartschade te voorspellen. Als gevolg van deze studie en andere met gelijke uitkomsten, is de herziene versie van de richtlijn in augustus 2022 aangepast. De rol van zelf gerapporteerde inspanning is veranderd: risicostratificatie wordt nu primair gebaseerd op risicofactoren voor hart- en vaatziekten in plaats van inspanningstolerantie.

In **hoofdstuk 3** toonden we aan dat de implementatie van de Nederlandse richtlijn 'Preventie van pulmonale complicaties bij niet-pulmonale chirurgie' door anesthesiologen matig was ten aanzien van de toediening van het corticosteroïd prednison. We hebben kwalitatief onderzocht wat redenen waren voor het (niet) naleven van de richtlijn. Eén van deze redenen was het werkproces van anesthesiologen in de operatiekamers: anesthesiologen dienen vaak andere soorten corticosteroïden toe voor verschillende redenen, zoals preventie van oedeem of het voorkomen van postoperatieve misselijkheid. Een tweede reden voor het niet naleven van de richtlijn was de kennis over nadelen en voordelen van corticosteroïden, doordat sommige anesthesiologen geloofden dat de voordelen van corticosteroïden niet opwogen tegen de nadelen, waren zij minder geneigd corticosteroïden te geven. Wij adviseren dat anesthesiologen beter betrokken moeten worden bij de herziene versie van de richtlijn, wat hopelijk resulteert in beter naleving van de richtlijn.

In **deel II** werd de richtlijn voor preoperatief nuchterbeleid besproken. Deze richtlijn ligt onder vuur sinds de richtlijn voor kinderen is aangepast en kinderen nu tot aan de ingreep helder vloeibaar mogen blijven drinken. Het UMC Utrecht was het eerste ziekenhuis in Nederland dat een liberaal nuchter beleid implementeerde bij volwassenen, waarbij patiënten tot aan de ingreep helder vloeibaar mochten blijven drinken. In **hoofdstuk 4** evalueerden we de implementatie van dit liberale protocol ten aanzien van nuchterduur, patiënttevredenheid en veiligheid. De implementatie was succesvol en de mediane nuchterduur daalde van 3:07 uur naar 1:20 uur. De veiligheid, gemeten als de incidentie van regurgitatie, aspiratie en aspiratiepneumonie steeg niet na implementatie, hoewel de grootte van de studie onvoldoende was om hier definitieve uitspraken over te kunnen doen. De patiënttevredenheid steeg, want minder patiënten rapporteerden dat ze dorst hadden, er was iets minder misselijkheid en braken op de recovery en er werden minder anti-emetica toegediend. In

de algemene beschouwing van dit proefschrift beschreven we ons implementatieplan en waarom deze implementatie succesvol was, waar dit in veel eerdere onderzoeken niet lukte.

In **hoofdstuk 5** vergeleken we het effect van het liberale nuchterbeleid met het oude beleid ten aanzien van het maagvolume bij patiënten die een gastroscopie ondergingen. We toonden aan dat het maagvolume binnen klinisch geaccepteerde grenzen bleef in het liberale beleid.

In **deel III** exploreerden we het patiënt perspectief ten aanzien van informed consent met het oog op veranderingen in de maatschappij, waarin de digitalisering en wens voor autonomie de afgelopen jaren zijn toegenomen. Het blijft een onderwerp van discussie welke anesthesiologische risico's met patiënten besproken moeten worden voordat informed consent verkregen kan worden. Het beroepskader van de Nederlandse Vereniging voor Anesthesiologie vermeldt dat informed consent tijdens een fysiek gesprek met de patiënt verkregen moet worden. Echter, wij observeerden dat in Nederland informatievoorziening veranderd is van poliklinische gesprekken naar gedeeltelijke of volledige digitale voorlichting met applicaties. De voordelen, nadelen, indicaties en beperkingen van deze technologie zijn nog niet goed onderzocht binnen de anesthesiologie. In **hoofdstuk 6** exploreerden we daarom middels kwalitatief onderzoek de waarde van digitale informatie voorziening en informed consent bij laag-risico patiënten die gepland waren voor laag risico ingrepen, door het interviewen van deze patiënten. We observeerden dat digitale informatievoorziening en consent voorzag in de behoeftes van de meeste patiënten. Ook viel op dat patiënten een apart informed consent voor anesthesiologie geen (meer-)waarde vonden hebben, naast het consent voor hun operatie. Deze observatie hebben we verder onderzocht in **hoofdstuk 7** bij patiënten die een grote operatie moesten ondergaan, namelijk een hartoperatie. Dit bevestigde dat 76% van de patiënten die een hartoperatie onder algehele anesthesie (narcose) moest ondergaan geen behoefte had aan een apart informed consent, naast het chirurgisch consent. Patiënten waardeerden informatie over anesthesie, maar deze informatie was niet nodig voor het anesthesiologisch consent. Een minderheid van de patiënten wilde uitleg over zeldzame ernstige complicaties, hoewel deze kennis vervolgens niet hun keuze om geopereerd te willen worden beïnvloedde. Zij vonden dat anesthesiologische risico's niet opwogen tegen chirurgische risico's en voordelen.

Deze twee studies suggereren dat informatie over anesthesie tegelijk met de informatie over

de chirurgische ingreep aangeboden zou moeten worden. Afhankelijk van de complexiteit van de ingreep, de co-morbiditeit en de voorkeuren van de patiënt, kan digitale informatie een toevoeging zijn aan mondelinge informatie van een zorgverlener of kan dit het gesprek zelfs vervangen. Nadat gezamenlijke informatievoorziening gedaan is, zouden zorgverleners vervolgens een gezamenlijk informed consent kunnen overwegen voor zowel de anesthesie als de chirurgie. Er is meer onderzoek nodig naar de voordelen en nadelen van dit concept.

In dit proefschrift zijn kwalitatieve onderzoeksmethodes gebruikt om de visie van patiënten en anesthesiologen te onderzoeken. Kwalitatieve studies zijn ondergewaardeerd, maar kunnen nuttig zijn binnen de anesthesiologie. Ze geven bijvoorbeeld een goed inzicht waarom richtlijnen niet nageleefd worden. Ook kan kwalitatief onderzoek gebruikt worden om veranderingen en innovaties in de maatschappij of op de werkvloer aan het licht te brengen en te exploreren. Het biedt daardoor een goed uitgangspunt voor verder onderzoek of het kan helpen om bij richtlijnherzieningen onderwerpen te prioriteren.

Samengevat, in dit proefschrift zijn punten beschreven om de preoperatieve zorg op het gebied van richtlijnaanbevelingen, richtlijnimplementatie en informed consent te verbeteren. We hebben laten zien waarom sommige richtlijnen niet volledig zijn geïmplementeerd en hoe veranderingen en innovaties in de maatschappij en gezondheidszorg ingebed zouden kunnen worden in richtlijnen. Zowel kwantitatieve onderzoeksmethodes als implementatiestudies zijn goede strategieën om richtlijnimplementatie en innovatie te onderzoeken. Dit zou meer gebruikt mogen worden om de preoperatieve zorg te evalueren en optimaliseren.

LIST OF PUBLICATIONS

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DANKWOORD

'If they cannot eat, let them drink tea'. De originele versie van deze stelling leidde tot de Franse revolutie. De onderwerpen uit dit proefschrift zijn ontstaan uit een aantal observaties, die leidden tot verwondering en soms zelfs onvrede over onze zorgprocessen. We doen veel dingen in de gezondheidszorg (en in ons dagelijks leven) omdat ze ooit logisch waren en pasten bij de inzichten van weleer. Echter, inzichten en prioriteiten veranderen, dus we moeten kritisch blijven en kijken of onze processen nog klopen.

Ik kan concluderen dat ik kritisch naar enkele anesthesiologische dogma's heb gekeken en veranderingen teweeg heb gebracht.

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CURRICULUM VITAE

Marije Marsman was born on October 9th 1983 in Deventer. She grew up in Lochem, a town in the Achterhoek. After graduating from her secondary school, the Staring College, she went to Utrecht to study Medicine in 2001.

In 2007, she graduated and started her recidency in Anaesthesiology at the UMC Utrecht under supervision of prof. Dr. J.T.A. Knape. In the last year of her residency she started with a fellowship on chronic pain medicine at the UMC Utrecht with an interest in postoperative pain. After completing her residency and fellowship she started working as an anaesthesiologist in the UMC Utrecht. She became head of the preoperative assessment outpatient clinic in 2014. She has an interest in preoperative care, management and use of digitization to aid healthcare workers in patient care. These interests were the starting point for this thesis, which started in 2018.

Marije lives in Utrecht and is married to Wilco. They have three daughters, Esther, Mathilde and Nathalie.