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Octopus follow-up: 20 year prognosis in patients randomized to on-pump CABG, off-pump CABG or PCI

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ABSTRACT

Background: The very long-term outcomes of off-pump versus on-pump Coronary Artery Bypass Grafting (CABG) and Percutaneous Coronary Intervention (PCI) are largely unclear. We linked 20-years outcomes of two randomized trials to evaluate re-intervention and mortality outcomes for on-pump CABG, off-pump CABG and PCI.
Methods: A data linkage project was performed using data as registered within the Netherlands Heart Registration (NHR), Statistics Netherlands (CBS) and the Octopus trials. Between 1998 and 2000, these trials randomized patients with coronary artery disease to on-pump versus off-pump CABG (OctoPump trial), or to PCI versus off-pump CABG (OctoStent trial). With data linkage, the original 5 years follow-up time for clinical events was extended to 20 years, including mortality and coronary reinterventions.
Results: After 20 years, in the OctoPump trial all-cause mortality was 50.0% after on-pump, and 46.5% after off-pump CABG. There was no difference in the combined outcome of mortality and re-interventions (HR 0.82, 95% CI 0.59–1.12). In the OctoStent trial, all-cause mortality was 56.7% after PCI and 52.5% after off-pump CABG. There was no difference in the combined outcome of mortality and re-interventions (HR 0.76, 95% CI 0.57–1.04). Off-pump CABG patients underwent less re-interventions than PCI patients (HR 0.52, 95% CI 0.33–0.80).
Conclusion: This study revealed no differences in 20-year survival between patients randomized to on-pump versus off-pump CABG, or to PCI versus off-pump-CABG. However, off-pump CABG patients underwent less re-interventions than PCI patients.

1. Background

Coronary artery disease (CAD) is a leading cause of death and disability worldwide and the demand for coronary revascularisation is increasing globally, due to the aging population and increasing prevalence of risk factors such as hypertension, hyperlipidaemia, and diabetes [1]. Percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) are well established treatment options in the management of patients with CAD [2]. CABG can be performed with cardiopulmonary bypass (on-pump) as well as surgery on the beating heart (off-pump) [3]. The latter may have advantages regarding fewer neurological and cognitive adverse events, but may also be associated with lower graft patency and thus a greater need for coronary re-interventions [4]. However, outcomes beyond 5 years of follow-up comparing PCI and the CABG methods have rarely been reported. This study aimed to evaluate outcomes in terms of re-interventions and

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Table 1
Baseline characteristics of included patients in the Octopus trial, specified for the Octopump and Octostent groups.

	Octopump		Octostent	
Variable	On-pump ($N = 128$)	Off-pump ($N = 129$)	PCI ($N = 134$)	Off-pump ($N = 141$)
Age in years, mean (SD)	60.6 (9.0)	61.2 (9.2)	60.9 (9.3)	59.2 (10.0)
Sex, female	35 (27.3)	40 (31.0)	38 (28.4)	39 (27.7)
Origin, Netherlands	123 (96.1)	122 (94.6)	122 (91.0)	137 (97.2)
One-vessel disease	24 (18.8)	35 (27.1)	83 (61.9)	99 (70.2)
Two-vessel disease	62 (48.4)	67 (51.9)	46 (34.3)	37 (26.2)
Three-vessel disease	42 (32.8)	27 (20.9)	<10 [a]	<10 [a]
Angina CCS class I or II	33 (31.7)	42 (40.8)	22 (16.4)	38 (27.0)
Angina CCS class III or IV	65 (62.5)	59 (57.3)	73 (54.5)	56 (39.7)
Unstable angina, Braunwald I - IIB	24 (18.8)	24 (18.6)	38 (28.4)	45 (31.9)
Previous myocardial infarction	33 (25.8)	41 (31.8)	32 (23.9)	33 (23.4)
History of coronary angioplasty	25 (19.5)	20 (15.5)	<10 [a]	<10 [a]
Smoking, Yes	18 (18.6)	19 (20.0)	33 (24.6)	27 (19.1)
Hypertension	56 (43.8)	49 (38.0)	46 (34.3)	43 (30.5)
Hypercholesterolemia	86 (67.2)	87 (67.4)	80 (59.7)	84 (59.6)
Family history of coronary disease	75 (58.6)	75 (58.1)	81 (60.4)	88 (62.4)
Obesity (Quetelet index >30 kg/m2)	19 (14.8)	17 (13.3)	23 (17.2)	17 (12.1)
Peripheral vascular disease	15 (11.7)	<10 [a]	10 (7.5)	<10 [a]
Diabetes	20 (15.6)	11 (8.5)	13 (9.7)	20 (14.2)
History of stroke	<10 [a]	<10 [a]	<10 [a]	<10 [a]
Pulmonary disease	13 (10.2)	10 (7.8)	12 (9.0)	19 (13.5)

N (%) are presented unless specified otherwise.
[a] Absolute values below 10 are not presented, in accordance with CBS privacy regulations.

mortality during 20 years of follow-up, in patients that were originally randomized to PCI, off-pump and on-pump CABG treatment.

2. Methods

A data linkage study was performed using clinical trial data from the Octopus randomized controlled trials (RCT), combined with Cause of Death Register (CDR) and Population Register (PR) from Statistics Netherlands (CBS) for mortality and population data, and Netherlands Heart Registration (NHR) for coronary revascularisation data (PCI and CABG).

2.1. Octopus trials

The study population were patients included in the Octopus RCTs. The Octopus study comprised two RCTs: 1) OctoPump trial, and 2) OctoStent trial [5–8]. Patients with an indication for first-time isolated CABG were randomized to on-pump versus off-pump surgery (OctoPump trial), and patients with an indication for PCI were randomized to PCI versus off-pump CABG (OctoStent trial). Inclusion for the Octopus trials was between march 1998 and august 2000, with initially a 1 year follow-up period for early clinical outcomes and cost effectiveness [8]. Included patients had single or multivessel disease, class I-II, B of the Braunwald classification of unstable angina and a preserved left ventricular function. Exclusion criteria were, inter alia, a previous CABG, a myocardial infarction within 6 weeks before inclusion or an elective PCI within 6 months before inclusion. The full list of all in- and exclusion criteria has been published in the design article of the Octopus trials [6]. Both Octopus trials included re-intervention data for up to 5 year of follow-up, outcomes registered during the trial follow-up were included in the analysis [9].

Table 2
Mortality and re-intervention data of included patients in the Octopus trial, specified for the Octopump and Octostent groups.

	Octopump		Octostent	
Variable	On-pump (N = 128)	Off-pump (N = 129)	PCI (N = 134)	Off-pump (N = 141)
Time until first event, in years, mean SD	16.88 (7.1)	17.44 (7.3)	14.53 (7.8)	15.51 (8.0)
Procedure data				
Total number of PCI procedures [b]	32	43	46	37
PCIs per patient, mean (SD)	1.39 (0.6)	1.79 (2.0)	1.67 (0.9)	1.46 (0.7)
Time until PCI in years, mean (SD)	13.43 (6.3)	11.33 (6.4)	8.24 (6.6)	10.27 (6.3)
Total number of CABG [b]	<10 [a]	<10 [a]	16	<10 [a]
CABG per patient	1	1	1	1
Time until CABG in years, mean (SD)	12.00 (3.6)	9.00 (1.0)	12.88 (6.1)	12.75 (7.1)
Mortality data				
Deceased	64 (50.0)	60 (46.5)	76 (56.7)	74 (52.5)
Time to death in years, mean (SD)	14.09 (6.61)	14.07 (6.80)	15.37 (5.1)	13.76 (7.1)
Mortality after:				
1 year	<10 [a]	<10 [a]	<10 [a]	<10 [a]
5 years	<10 [a]	11 (8.5)	<10 [a]	<10 [a]
10 years	16 (12.5)	16 (12.4)	15 (11.2)	24 (17.0)
15 years	33 (25.8)	28 (21.7)	31 (23.1)	38 (27.0)
20 years	47 (36.7)	45 (34.9)	57 (42.5)	56 (39.7)
Cause of death				
Cardiovascular diseases	20 (15.6)	19 (14.7)	30 (22.4)	30 (21.3)
Malignancies	26 (20.3)	18 (14.0)	24 (17.9)	20 (14.2)
Other causes:	18 (14.1)	23 (17.8)	22 (16.4)	24 (17.0)
Mental and behavioural disorders				
External causes of injury				
Respiratory diseases				
Neurological diseases				
COVID				

N (%) are presented unless specified otherwise.
[a] Absolute values below 10 are not presented, in accordance with CBS privacy regulations.
[b] Total number per patient, in case of >1 procedure per patient then both are counted.

2.2. Registry data

2.2.1. Sources

The PR is based on municipal records which provide demographic information of all Dutch citizens, from this register country of birth and date of birth data was obtained [10]. Mortality data was obtained from the national CDR, the CDR receives data from a legal reporting system regarding all deceased people in the Netherlands. Cause of death is classified using the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10) from 2013 onwards. Before 2013 ICD-9 is used for classification of causes of death and therefore we converted mortality data for the years 1998 to 2012 from ICD-9 to ICD-10.

Follow-up data on all-cause and cardiovascular disease (CVD) mortality, was linked to the cohort up to 31st of December 2020. CVD was selected using the codes I00 - I99 of ICD-10 [11]. Lymphedema (I88-I89)

Table 3
Incidence rate per 1000 person-years and survival analysis for patients in the Octopus trial, specified for the Octopump and Octostent groups.

	N	Events, N (%)	Person-years	Incidence rate per 1000 person-years	Cox proportional hazard model [1], HR (95% CI)	Cox proportional hazard model [2], HR (95% CI)
Outcome: Any event						
Octopump						
On-pump	128	84 (65.6)	2160.9	38.9	1 [Ref]	1 [Ref]
Off-pump	129	76 (58.9)	2250.0	33.8	0.81 (0.59–1.10)	0.82 (0.59–1.12)
Octostent						
PCI	134	103 (76.9)	1947.0	52.9	1 [Ref]	1 [Ref]
Off-pump	141	95 (67.4)	2187.5	43.4	0.88 (0.66–1.17)	0.76 (0.57–1.04)
Outcome: Re-intervention[3]						
Octopump						
On-pump	128	25 (19.5)	2746.7	9.1	1 [Ref]	1 [Ref]
Off-pump	129	24 (18.6)	2728.2	8.8	1.00 (0.57–1.73)	1.05 (0.59–1.85)
Octostent						
PCI	134	54 (40.3)	2379.6	22.7	1 [Ref]	1 [Ref]
Off-pump	141	39 (27.7)	2799.5	13.9	0.59 (0.39–0.90)	0.52 (0.33–0.80)
Outcome: Mortality						
Octopump						
On-pump	128	64 (50.0)	2399.6	26.7	1 [Ref]	1 [Ref]
Off-pump	129	60 (46.5)	2461.2	24.4	0.81 (0.57–1.16)	0.82 (0.57–1.18)
Octostent						
PCI	134	76 (56.7)	2541.0	29.9	1 [Ref]	1 [Ref]
Off-pump	141	74 (52.5)	2600.8	28.5	1.14 (0.82–1.58)	1.00 (0.70–1.42)

[1] Corrected for sex, age and ethnicity.
[2] Corrected for sex, age, ethnicity and trial baseline (risk) factors.
[3] Corrected for competing risk mortality, Fine and Gray model.

and varicose veins (I83-I86) were not considered as CVD.

Data regarding coronary re-interventions was added with NHR data for PCI and CABG. NHR is a non-profit organisation which aims to contribute to quality improvement and safety in cardiac care by facilitating quality registries [12]. Registration committees of the NHR monitor the data registration of cardiac procedures of all hospitals in the Netherlands. NHR data includes patient characteristics, indication and procedure specific data, as well as clinical outcomes up to 5 years. NHR prepared the CABG and PCI dataset with procedures between 2000 and 2021. National coverage for both interventions within the NHR was not reached until 2007 for CABG and 2013 for PCI. All data was analysed within the secured CBS remote access environment in compliance with privacy legislation.

2.2.2. *Linkage*

Data from the PR and CDR of CBS was linked to the Octopus trial and NHR data within the CBS environment. CDR and PR were linked using a pseudonymized identification number (RIN), which is based on the national personal identification number. Octopus and NHR data were uploaded to the CBS environment, for data linkage the RIN was added to each dataset by CBS using either a citizen service number or a combination of 4- or 6-digit postal code, index date for postal code, date of birth and sex depending on the availability of linkage variables within a dataset. For the Octopus trials the citizen service number was used if available, otherwise the combination of identifiers with 6-digit postal code was used. For the NHR datasets, the combination of identifiers was used including the 4-digit postal code for the period 2000 – 2013 for PCI and 2000 – 2007 for CABG, and including the 6-digit postal code for the following years up to 2020. CDR and PR were available in the secured environment of CBS and RIN was already added based on citizen service number.

2.3. *Data analysis*

Baseline characteristics were summarized as mean (standard deviation [SD]) for continuous variables, and proportions for categorical variables. Re-intervention and mortality data was summarised with absolute values and proportions, data included number of re-interventions, time to event and specific causes of death.

For the main analysis the following selections were made for the long term outcome: 1) any event, the combined outcome of re-interventions and mortality, 2) separate analysis for re-interventions, 3) separate analysis for mortality. Re-interventions included both CABG and PCI. For each outcome the incidence rate per 1000 person-years (PY) was calculated for all trial groups, using the number of events and the total person-years. Subsequently, cox proportional hazard analysis was performed to compare on-pump versus off-pump and PCI versus off-pump, specified for each outcome. Analyses were adjusted for age, sex, country of birth and clinical data from the Octopus trial including number of lesions, angina classification, previous MI or CVA, hypertension, diabetes, PAD and family history of CAD. Survival was visualized with a Kaplan-Meier curve. For the main outcome where re-intervention was evaluated separately, we conducted survival analysis using a Fine and Gray model to account for mortality as a competing risk. In essence, this allows us to evaluate the occurrence of re-intervention while accounting for the possibility of mortality events occurring concurrently and influencing the outcome of interest. All analyses were performed using R Statistical Software (version 3.6.2., R Foundation).

3. Results

3.1. *Study population*

Of all 561 patients, 29 (5%) missed linkage variables (at random missingness) and could not be linked for this study, resulting in an analytical sample of 532 patients from the Octopus trials. For the OctoPump trial, 128 in the on-pump and 129 in the off-pump groups, the mean age was 60.6 ± 9.0 years and 27.3% were women in the on-pump group, for the off-pump group this was 61.2 ± 9.2 years and 31.0% respectively. For the OctoStent trial, 134 in the PCI and 141 in the off-pump groups, the mean age was 60.9 ± 9.3 years and 28.4% were women in the PCI group, for the off-pump group this was 59.2 ± 10.0 years and 27.7% respectively. Data on patients characteristics, cardiovascular risk factors and medical history are presented in Table 1.

3.2. *OctoPump*

Of the 257 OctoPump patients, 124 (48.2%) patients died during

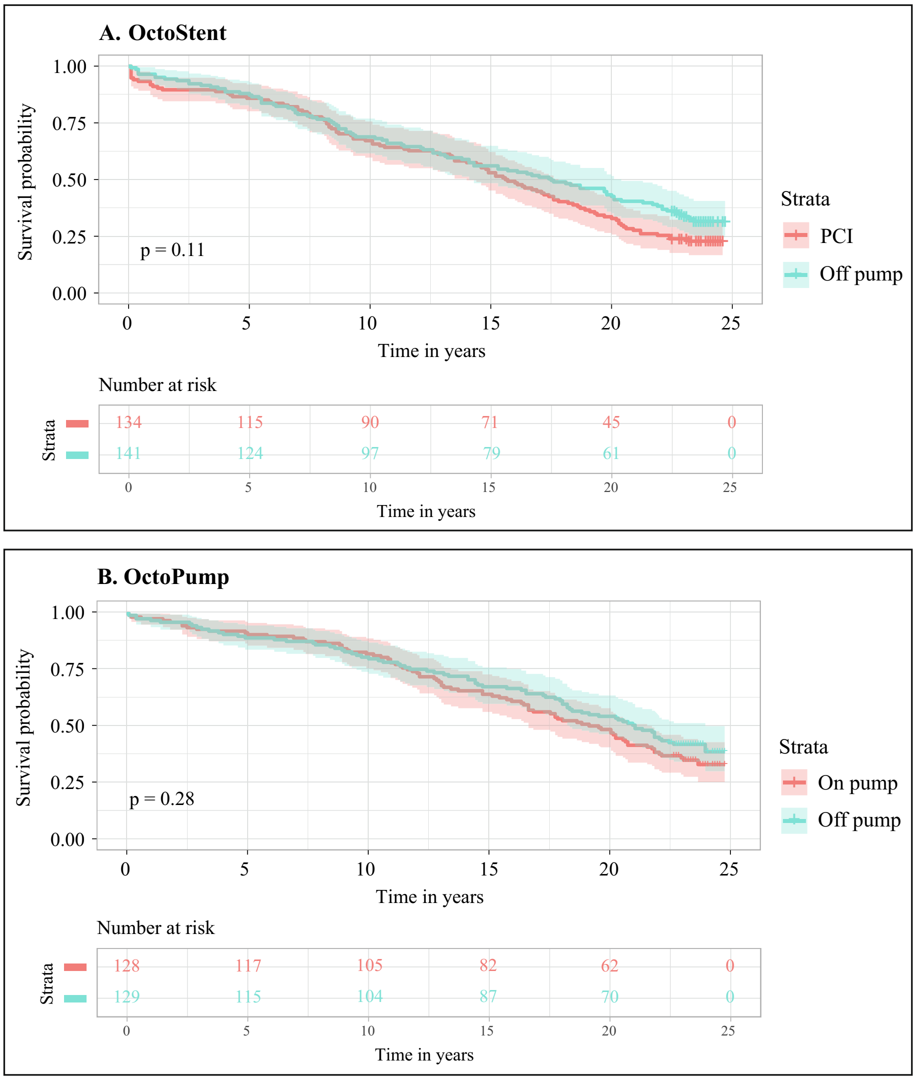

Fig. 1. Kaplan meier curves for the combined outcome of mortality and re-interventions.

follow-up. In the on-pump group 64 (50.0%) patients died and 60 (46.5%) in the off-pump group. CVD and malignancies were the main causes of death in both groups (Table 2). Incidence rate per 1000PY was slightly higher for any event - including mortality and re-intervention - in the on-pump group, compared to the off-pump group (38.9 per 1000PY vs. 33.8 per 1000PY, Table 3). No significant difference for the outcome any event was observed between on-pump and off-pump CABG (HR 0.82, 95% CI 0.59–1.12, Fig. 1), corrected for age, sex, ethnicity, clinical characteristics and cardiovascular risk factors. For the separate evaluation of the outcomes mortality or re-intervention the results were similar (Table 3, Figs. 2 and 3).

3.3. OctoStent

Of the 275 OctoStent patients, 150 (54.5%) patients died during follow-up. In the PCI group 76 (56.7%) patients died and 74 (52.5%) in the off-pump group. CVD and malignancies were again the main causes of death in both groups (Table 2). Incidence rate per 1000PY was higher for any event in the PCI group, compared to the off-pump group (52.9 per 1000PY vs. 43.4 per 1000PY). This difference between the PCI and off-pump group is especially visible when the outcome is specified for re-intervention only (22.7 vs. 13.9 per 1000PY, Table 3). No significant difference between the PCI and off-pump group was observed for the outcome any event (HR 0.76, 95% CI 0.57–1.04, Fig. 1), after correcting for age, sex, ethnicity, clinical characteristics and CV risk factors. The off-pump group had significantly fewer repeat coronary revascularisations compared to the PCI group (HR 0.52, 95% CI 0.33–0.80, Table 3 and Fig. 3). For mortality no differences were observed between the off-pump and PCI group in the corrected model (HR 1.00, 95% CI 0.70–1.42, Table 3 and Fig. 2).

4. Discussion

The results of this long term follow-up of patients participating in two randomized trials do not show significant differences in survival of patients referred for revascularization treated with on-pump CABG, off-pump CABG or PCI. These findings suggest that for this population these treatment options perform equally with regard to long term survival. Off-pump CABG and PCI mortality outcomes are comparable, as in both initial procedures complete revascularization was achieved. Although, during follow-up off-pump has less re-intervention than PCI which could be due to a more durable revascularization strategy [13].

The decision regarding optimal revascularization continues to be a subject of considerable discussion. Off-pump surgery is favored for its lower risk of stroke; however, it introduces technical complexities and necessitates higher levels of expertise of the surgeons [14]. Conversely, on-pump surgery might offer greater surgical precision. As a result, earlier research hypothesized there could be a potential increase in the

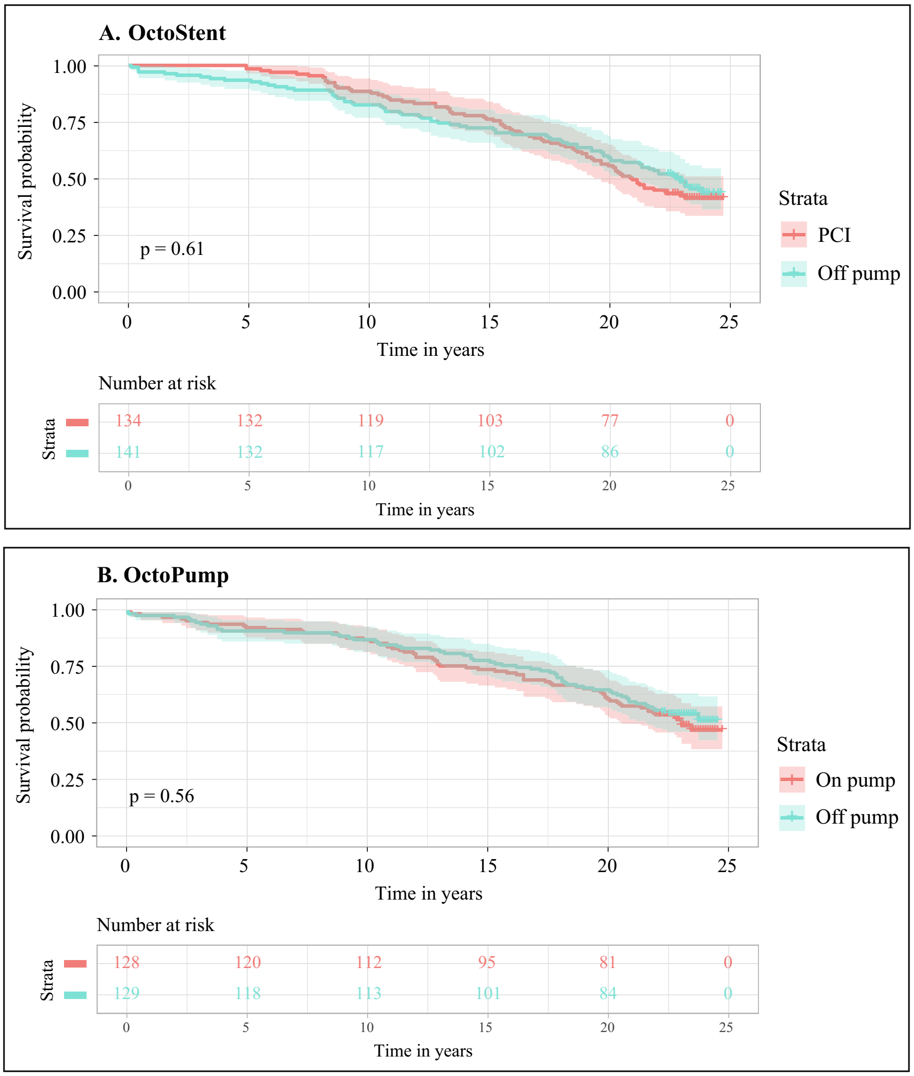

Fig. 2. Kaplan meier curves for the outcome mortality.

re-intervention rates with off-pump surgery during long-term follow-up [14]. However, our findings do not support this view as we observed equal re-intervention rates between on-pump and off-pump surgery patients during 20 years of follow-up.

In the comparison of on-pump versus off-pump surgery, our study's findings are in line with existing literature, such as the ROOBY RCT, which also reported no significant differences in survival outcomes between the two approaches after 10 years of follow-up [15]. In addition, a previous analysis showed no differences in cognitive decline between off-pump and on-pump surgery after 5 years of follow-up [9].

Meanwhile, the less invasive approach of PCI is associated with a lower rate of procedural complications compared to CABG, but it may have limitations in achieving full revascularization, especially for patients with complex CAD [16]. Several studies observed no differences in survival and major adverse cardiac or cerebrovascular events between PCI and CABG in low risk CAD patients during 5–10 years of follow-up [17–19]. In patients with three-vessel disease CABG is preferred over PCI, considering the lower adverse event rates for CABG patients. [17,18,20] The OctoStent's criteria ensured the feasibility of both CABG and PCI as viable treatment for all lesions, ensuring complete revascularization could be achieved with either choice post-randomization. However, our results showed a significant lower risk of re-interventions during follow-up among patients who underwent off-pump surgery, compared to PCI. This is in line with results of several studies, also showing the increased need of re-interventions in patients after PCI [18,19,21]. Although it needs to be considered that these are different revascularization methods, and the stents used two decades ago may have implications for the current results. Additionally, clinical protocols for staged full revascularization or single-procedure revascularization have been adjusted over the years.

Individual patient characteristics and coronary anatomy play an important role in selecting the most appropriate revascularization approach, but aspects regarding surgeon experience and cost effectiveness should be considered as well. Previous cost-effectiveness analysis revealed reduced expenses associated with off-pump surgery when compared to on-pump surgery, as well as for PCI in comparison to off-pump surgery, while maintaining comparable cardiac outcomes across all groups. Therefore, from an economic standpoint, when a patient can be effectively treated using all three strategies PCI may be the preferred choice over off-pump surgery, and similarly, off-pump surgery may be favored over on-pump surgery. Although reintervention rates should be considered as well [8]. Future research should aim to refine decision criteria, to improve patients outcomes while considering the changing landscape of cardiovascular treatments.

4.1. *Strength and limitation*

This study's strength is the randomized treatment allocation to three

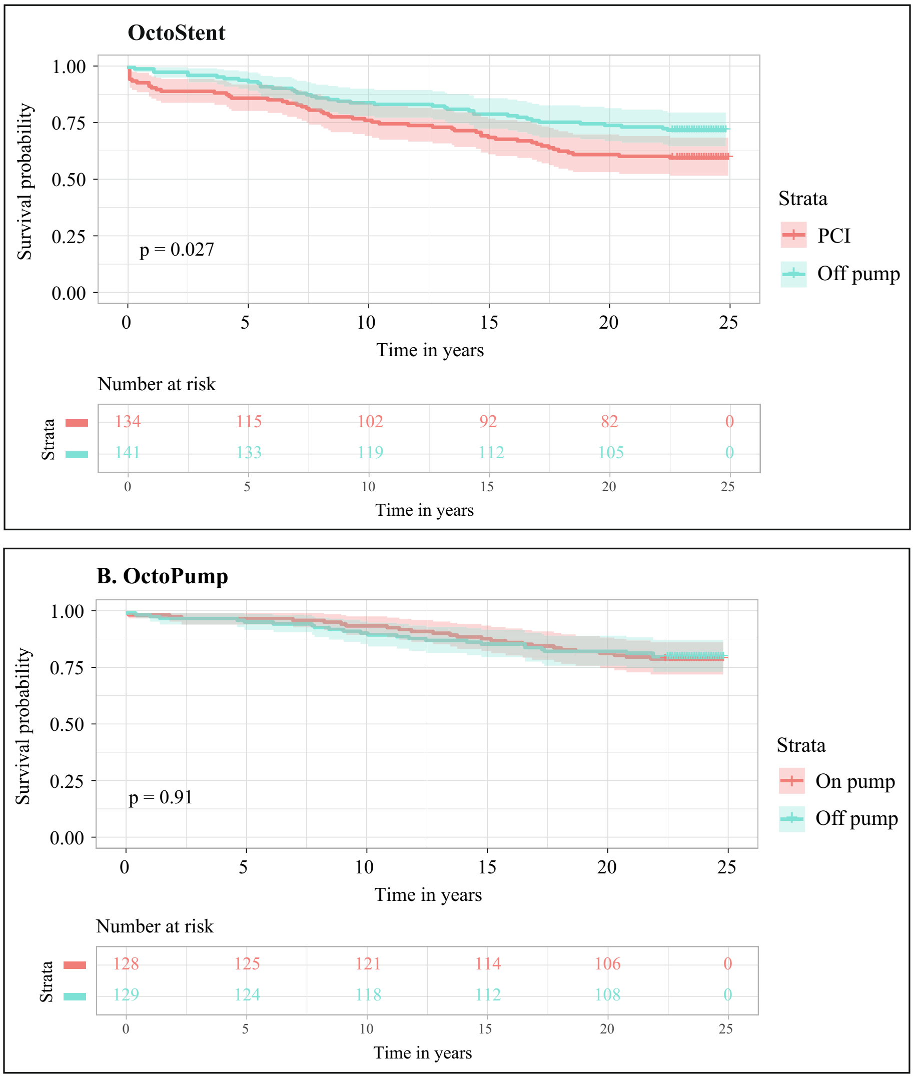

Fig. 3. Kaplan meier curves for the outcome re-interventions.

different revascularization strategies, which removes potential confounding by indication that could occur in non-randomized cohorts. Furthermore, with national data linkage the study achieved a 20-year follow-up period, examining survival and re-interventions by integrating randomized clinical trial data with national registries. It demonstrates the potential of linking data across diverse sources for future research needing re-intervention data or extended follow-up. A limitation involves potentially incomplete re-intervention data (missingness at random), trial follow-up was 5 years and NHR registration might be incomplete for the earlier follow-up years (2005–2007 for CABG and 2005–2013 for PCI). After these years NHR reached national coverage and thus there is no missingness. Furthermore, using 4-digit instead of 6-digit postal codes could have contributed to lower unique identifiers in earlier years of NHR data, using 4-digit postal codes might have complicated linkage due to possible digital twins—individuals sharing identical linkage values—which limits identification. However, this was only a random sample of 5% of the patients within the Octopus trials.

5. Conclusion

In conclusion, our findings in over 20 years of follow-up of patients randomized to on-pump CABG, off-pump CABG or PCI support the view that these treatment options have comparable survival while reinterventions are more common in patients treated with PCI. These findings may help physicians and patients to make informed decisions about the preferred management of symptomatic coronary artery disease.

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Key messages

What is already known: Percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) are established treatments for coronary artery disease (CAD), with CABG offering options like off-pump and on-pump surgery, yet long-term outcomes comparing PCI and CABG methods beyond 5 years are seldom reported.

What this study adds: After 20 years of follow-up, there was no significant difference in the combined outcome of mortality and re-interventions between on-pump and off-pump CABG, nor between PCI and off-pump CABG. Off-pump CABG patients underwent less re-interventions than PCI patients (HR 0.52, 95% CI 0.33–0.80).

Implications: Our findings support the view that these treatment options have comparable survival while reinterventions are more common in patients treated with PCI. These findings may help physicians and patients to make informed decisions about the preferred management of symptomatic coronary artery disease.

Tweet

This study finds no 20-year survival differences between on-pump vs. off-pump CABG or PCI vs. off-pump CABG. Off-pump CABG patients had fewer re-interventions compared to PCI patients.

CRediT authorship contribution statement

Yvonne Koop: Writing – original draft, Visualization, Software, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Hendrik Nathoe:** Writing – review & editing, Supervision, Conceptualization. **Michiel Bots:** Writing – review & editing, Supervision, Conceptualization. **Diederick E. Grobbee:** Writing – review & editing, Conceptualization. **Marijke Timmermans:** Writing – review & editing, Methodology, Conceptualization. **Raymond H. Wimmers:** Writing – review & editing, Conceptualization. **Monica Gianoli:** Writing – review & editing. **Diederik van Dijk:** Writing – review & editing, Supervision, Conceptualization. **Ilonca Vaartjes:** Writing – review & editing, Supervision, Resources, Methodology, Conceptualization.

Data availability

The data that support the findings of this study are available from Statistics Netherlands, but restrictions apply to the availability of these data due to privacy laws and regulations in the Netherlands, and thus are not publicly available.

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NA.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2024.132426.

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