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Patient outcomes before and after implementation of a selective pre-hospital spinal immobilization protocol: A comparative cohort pilot study in a level 2 trauma center

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ABSTRACT

Background: A new selective preventive spinal immobilization (PSI) protocol was introduced in the Netherlands. This may have led to an increase in non-immobilized spinal fractures (NISFs) and consequently adverse patient outcomes.
Aim: A pilot study was conducted to describe the adverse patient outcomes in NISF of the PSI protocol change and assess the feasibility of a larger effect study.
Methods: Retrospective comparative cohort pilot study including records of trauma patients with a presumed spinal injury who were presented at the emergency department of a level 2 trauma center by the emergency medical service (EMS). The pre-period 2013–2014 (strict PSI protocol), was compared to the post-period 2017–2018 (selective PSI protocol). Primary outcomes were the percentage of records with a NISF who had an adverse patient outcome such as neurological injuries and mortality before and after the protocol change. Secondary outcomes were the sample size calculation for a larger study and the feasibility of data collection.
Results: 1,147 records were included; 442 pre-period, and 705 post-period. The NISF-prevalence was 10% (95% CI 7–16, n = 19) and 8% (95% CI 6–11, n = 33), respectively. In both periods, no neurological injuries or mortality due to NISF were found, by which calculating a sample size is impossible. Data collection showed to be feasible.
Conclusions: No neurological injuries or mortality due to NISF were found in a strict and a selective PSI protocol. Therefore, a larger study is discouraged. Future studies should focus on which patients really profit from PSI and which patients do not.

1. Background

Application of preventive spinal immobilization (PSI) is widely implemented in prehospital and in-hospital trauma care to prevent secondary neurological injury [1–3]. However, currently no evidence exists to support or reject PSI [4]. Additionally, numerous adverse events of preventive spinal immobilization (PSI) have been described. These adverse events include anxiety [5], pressure injuries [6,7], pain, and an increase of intracranial pressure due to a cervical collar [6,8].

Furthermore, application of PSI increases the time on scene and consequently arrival time in a trauma center [9], which may negatively influence patient outcome [10]. These adverse events related to PSI have led to a protocol change towards more selective pre-hospital PSI in several countries [11–15]. In the Netherlands, the EMS nurses work autonomously supported by a National Protocol Emergency Medical Service (NPEMS), which is approved by a committee of medical specialists The change of the national prehospital PSI protocol towards more selective PSI was implemented in 2016 [16–20]. Before 2016, the

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indication for PSI was based on strict criteria [21]. These criteria were high energy trauma, decreased Glasgow Coma Score, neurological deficits, vertebral pain, intoxication, distracting injuries, facial injuries, and suspicion of a skull base fracture (Fig. 1) [21]. In the new selective PSI protocol, these criteria were changed into inadequate communication, neurological deficits, vertebral pain, intoxication, distracting injuries, and 'immobilize the patient when in doubt' (Fig. 1) [20]. Theoretically, a selective PSI protocol may lead to an increase in patients with spinal fractures who are not immobilized (non-immobilized spinal fractures (NISFs)). Previous studies showed a NISF prevalence of 0–0.1% [15,22]. Regarding adverse outcomes in NISF patients, Stroh and Braude found that one in five NISF patients had a neurological injury, in which it was unclear if the neurological injury was caused by NISF [23]. Burton et al described no emerging neurological injuries in 20 patients with NISF [15]. Currently, it is unclear how often patients have neurological injuries due to NISFs.

Therefore, a pilot study was conducted to describe the adverse patient outcomes in NISF before and after the PSI protocol change and assess the feasibility of a larger effect study the effects of the PSI protocol change on adverse patient outcomes in NISF.

2. Methods

A retrospective comparative cohort pilot study was conducted. The period in which the protocol with strict decision criteria was applied (Fig. 1, NPEMS 7.2), defined as pre-period, comprised the period 2013–2014. The post-period with a selective PSI protocol was represented by the years 2017–2018 (Fig. 1, NPEMS 8.0). To account for the previously mentioned unsure prevalence of adverse patient outcomes, two consecutive years were selected. To rule out compliance bias due to prior knowledge of the selective PSI protocol content, 2015 and 2016 were not included and the pre-period of 2013–2014 was chosen. The post-period was defined as two consecutive years after the implementation of the selective PSI protocol in 2016, assuming that the content of the protocol was completely adopted in the daily practice of EMS nurses.

This study was conducted in a level 2 trauma center in the Netherlands. Inclusion criteria were: medical records of trauma patients of all ages presented at the ED by the EMS within 48 h after the trauma with a presumed spinal injury. The definitions for presumed spinal injury were: trauma patients with pre-hospital PSI application, or patients who had radiographic diagnostics of the spine at the ED (X-rays, CT, or MRI scans). To complete inclusion, surgical and orthopedic

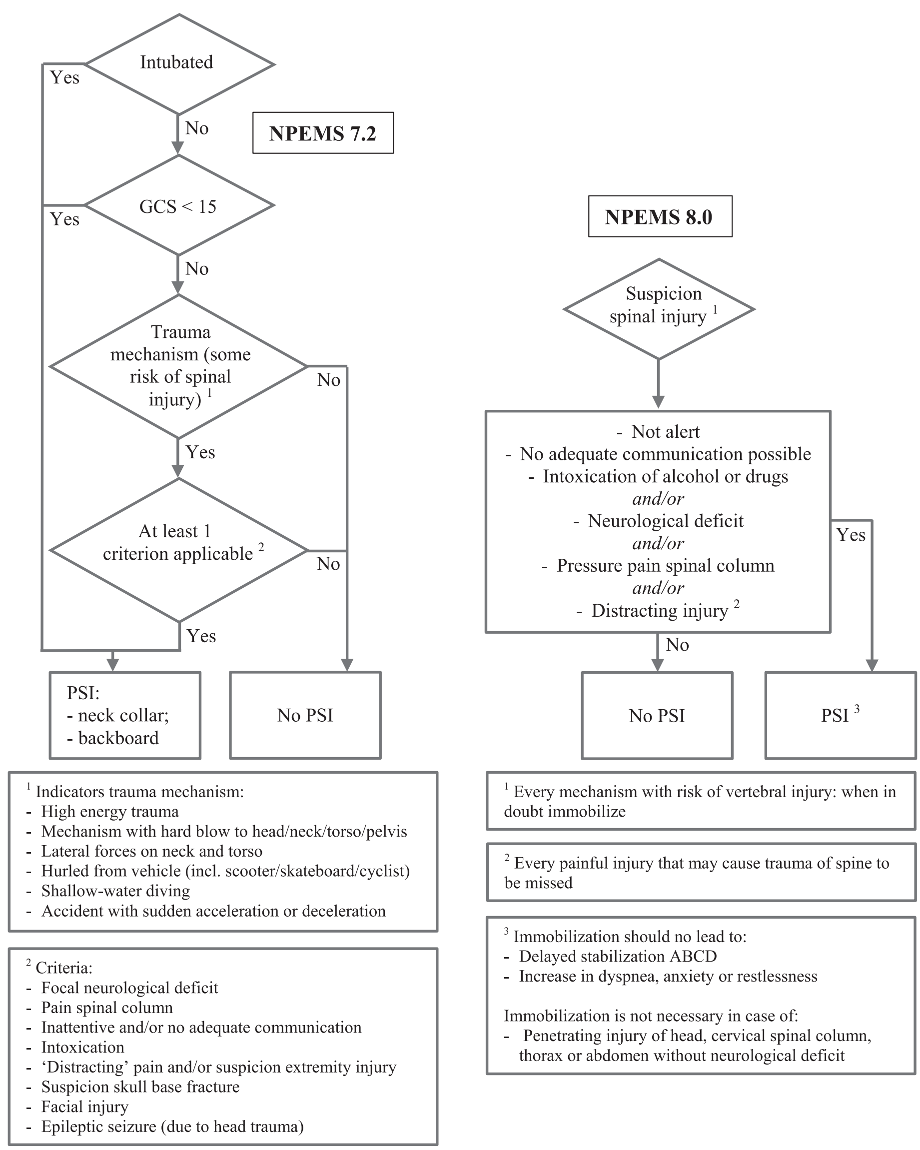

Fig. 1. National Protocol Emergency Medical Service versions, decision tree spinal immobilization.

diagnosis codes regarding advanced trauma life support, multi-trauma, trauma screening, and spinal (cord) injuries were assessed. All spinal fractures were included, regardless of the degree of stability. Cases with missing data regarding spinal immobilization were excluded.

The collected baseline characteristics were sex, age, trauma mechanism, intoxication, pain, consciousness, neurological injury, type of immobilization device, and type of radiological exams.

Primary outcomes were the percentage of records with a NISF who had an adverse patient outcome such as neurological injuries or mortality before and after implementation of the selective protocol. Adverse patient outcomes were defined as partial or complete paraplegia absent during the physical examination of the EMS nurse but emerging after presentation at the ED, and mortality within 30 days following trauma. Secondary outcomes were the sample size calculation for a larger study and the feasibility of data collection. The feasibility was focused on data availability in the EMS, ED and Radiology, the best filters for data extraction, and the best key for merging.

Approval of the Medical Research Ethics Committees United (dossier number W19.265, and A20.004), and the board of the Hospital (study number L2020005) were obtained. General Data Protection Regulation was applicable. No informed consent from patients was required.

2.1. Data collection

With help of data specialists of the EMS, ED, and Radiology, the availability of the data was checked on year-level. The extracted datasets were downloaded in MS Excel (version 2016, Microsoft Corp. Redmond, Washington, USA) and 30 records were checked on accuracy with the data specialists by comparing the Excel data with the source. Before merging the datasets, all the data were compared to the inclusion criteria. Only the data who met the inclusion criteria were part of the merge. After the merge, the data was randomly checked on accuracy of the merge and completeness of the data. In cases of an error of any item, all errors were manually checked. If necessary, the merge was optimized by adjusting the merge formula. In case of missing data on applied PSI as a result of under-registration by the EMS nurse or ED personnel, the digital EMS report and the EPR per patient were manually checked and adjusted if necessary.

2.2. Data analysis

All data were entered and merged in MS Excel (version 2016, Microsoft Corp. Redmond, Washington, USA). When prehospital immobilization status was missed in the EMS data, but described by ED personnel in the EPR, this data was added to the dataset, otherwise, the case was excluded. Patients with Reaction Level Scale scores of 4–8 [24] consistent with Glasgow Coma Scale scores of 3–8 were considered unconscious [25].

SPSS Statistics 23.0 (IBM Corp., Armonk, NY, USA) was used for data analysis. The independent-samples *t*-test for continuous normally distributed data, and the Pearson chi-square for categorical data. In the case of numbers ≤ 10 in the cross table, Fishers' exact was used. For continuous data with a skewed distribution, the Mann-Whitney *U* test was performed. The Wilson score was used to calculate 95% confidence intervals for categorical data, and no overlap between the intervals means statistical significance [26]. For continuous data, significance was set at $p < 0.05$. For descriptive data, numbers and percentages were calculated. Prevalence was calculated as (Number of cases present during a given time period/Population during the same time period) $\times$ 100. The prevalence is expressed in percentage (%). The required sample size for the larger study was calculated in Stata 16.0 (StataCorp LLC, College Station, Texas, USA, 2019) with an 80% power, an alpha of 5%, and the allocation ratio calculation as (Number of cases in the post-period/Number of cases in the pre-period), assuming a similar group as in the present study.

3. Results

3.1. Included patients

In total, 1,165 records were included. Because of missing data on PSI application, 7 of 449 records (1.6%) in the pre-period, and 11 of 716 records (1.5%) in the post-period had to be excluded. The remaining 1,147 records were categorized into 442 pre-period and 705 post-period (Fig. 2).

3.2. Baseline characteristics

For baseline characteristics see Table 1. In both periods, 59% were male and the mean age was 42 years and 44 years, respectively. Compared to the pre-period, the percentage of patients with vertebral pain during physical examination (manual pressure pain in the spine) at the scene differed significantly: 49% (95% CI 45–54) versus 40% (95% CI 37–44). The percentage of records with diagnosed spinal fracture(s) dropped from 12% (95% CI 9–16) in the pre-period to 10% (95% CI 8–13) in the post-period. The percentage of records with HET with PSI differed in the pre-period: 70% (95% CI 63–76) compared to 49% (95% CI 44–54) in the post-period. The prevalence of records with pre-hospital PSI was higher in the pre-period 59% (95% CI 69–78) compared to 44% (95% CI 41–56) in the post-period. Nevertheless, the percentage of records with immobilized trauma patients without a spinal fracture increased from 86% (95% CI 82–90) in the pre-period to 88% (95% CI 83–91) in the post-period (Table 1). Finally, the percentage of records with non-immobilized patients who had a radiological examination of the spinal column increased from 48% (95% CI 41–56) in the pre-period to 73% (95% CI 69–78) in the post-period.

3.3. Percentage of NISF and adverse patient outcomes

The percentage of NISF was 10% (95% CI 7–16) in the pre-period and 8% (95% CI 6–11) in the post-period (Table 2). None of the records had adverse patient outcomes (Table 3).

3.4. Required sample size for larger study

The allocation ratio between the pre-period and post-period of adverse outcomes in NISF records is nil (Table 3). Therefore, calculating a sample size for a larger study based on confidence interval was impossible.

3.5. Feasibility of data collection

All required data were available. The extracted data corresponded exactly with the source. The best key for merging the EMS, ED and Radiology datasets was built on three items: 'Sex', 'Date of birth', and 'Date of arrival', and gave a 100%-match. Due to the range of registration possibilities in the DRF for EMS nurses, broad search filters had to be selected. Despite of the broad filters, 30% of the required data was missing, but could be retrieved by a manual search of the EPR. The data filters for the selected diagnoses resulted in a 97.1% accurate dataset, for the dataset from the EPR of radio diagnostics and fractures was 100% complete.

4. Discussion

This pilot study shows that the percentage of NISFs was 10% (95% CI 7–16) in the pre-period under a strict PSI protocol and 8% (95% CI 6–11) in the post-period under a selective PSI protocol. Furthermore, no adverse patient outcomes were found in both periods. We were unable to calculate a sample size for the follow-up study due to the absence of differences in the adverse patient outcomes between both periods. Collecting the data was feasible using a three item merge key and

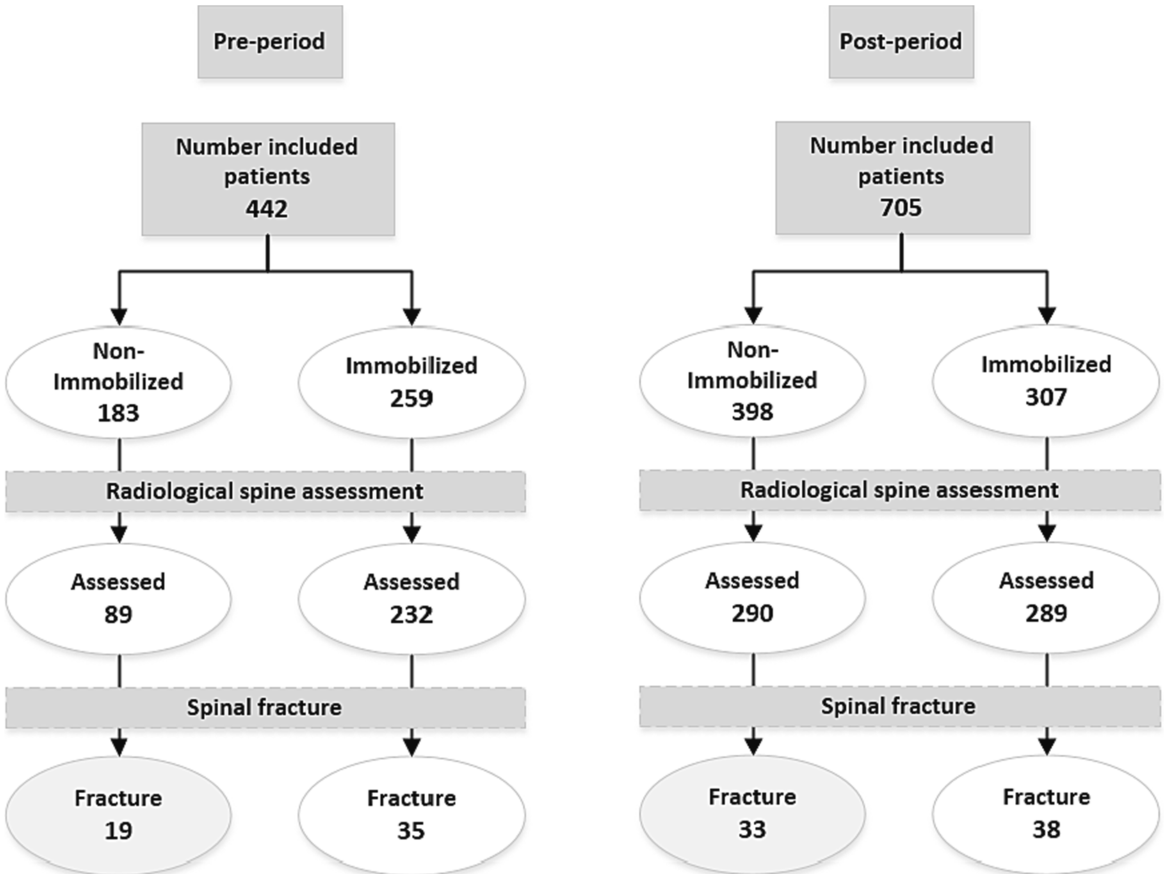

Fig. 2. Scheme of included patients.

manual supplementation of 30% of the EMS data.

In the post-period, 8% (95% CI 6–11) of the non-immobilized trauma patients records had a spinal fracture, which is substantially higher than the prevalence of 0–0.1% NISF described in the literature [15,22]. However, it is debatable if this is clinically relevant since none of these patients experienced any adverse patient outcomes (Table 3). This also prompts the question to what extent PSI application contributes to the prevention of secondary neurological injuries. Despite a significant decrease in PSI in the post-period, the percentage of immobilized trauma patients without a spinal fracture very high, increased from 86% (95% CI 82–90) in the pre-period and 88% (95% CI 83–91) in the post-period, thus increasing the burden on patients due to PSI. Burton et al. in their investigation of selective PSI protocol application showed a percentage of 99% immobilized trauma patients without a spinal fracture [11].

This pilot study allows for an interesting discussion. First, a follow-up study is discouraged due to the absence of differences in adverse patient outcomes. Sample size calculation based on the previous findings of Stroh and Braude and Burton et al., is also discouraged due to the low adverse patient outcomes [15,23]. Second, the fact that under the strict protocol the percentage of immobilized HET patients was not closer to 100%, may be explained by a reasoned protocol deviation by the EMS nurse. In cases of anxiety, restlessness, or nausea and no complaints like pressure pain or tenderness, EMS nurses may decide autonomously to deviate from the strict PSI protocol. By contrast, the selective protocol mentioned no explicit HET criteria, which means that PSI could be abandoned in these cases.

Some limitations cshould be mentioned. First, the number of patients with fractures and the number of NISF patients are small. These numbers of patients were insufficient to demonstrate statistically significant differences between the groups of NISF patients and may be resulted by chance. Second, it can be not ruled out, that due to under-registration of the EMS regarding the use of PSI, potentially relevant patients were missed, which may have influenced the outcomes. Finally, the setting was a level 2 trauma center. The population presented in the level 2 setting is different from that of a level 1 trauma center whereas the triage system directs the more severe trauma patients toward a level 1 trauma center. Due to the absence of a level 1 trauma center in the present study, the extent of generalizability of the findings is uncertain.

5. Conclusions

No difference in neurological injuries or mortality due to NISF were found in a strict and a selective PSI protocol in a level 2 center. Therefore, this pilot study showed that a sample size calculation is impossible and thus a larger study is discouraged. Future studies should focus on which patients really profit from PSI and which patients do not.

Data statement

The dataset is available in.xlsx and.sav and can be requested via the corresponding author. The dataset is also available via: https://data.mendeley.com/datasets/6y3hwsz2zz/3.

Ethical Statement

Approval of the Medical Research Ethics Committees United (dossier number W19.265, and A20.004), and the board of the Maasstad Hospital (study number L2020005) was obtained. General Data Protection Regulation was applicable. No informed consent from patients was required.

Table 1
Characteristics of included records.

Item	Pre-period	Post-period	*p*-value
Total included records (n =)	**442 (%)**	**705 (%)**	
Sex-male	262 (59)	417 (59)	0.966
Age mean [med., IQR]	42 [40, 24–55]	44 [42, 25–59]	0.236
High energy trauma	195 (44)	393 (56)	<0.001
- With PSI	*137 (70)*	*193 (49)*	*<0.001*
- With fracture	*16 (8)*	*25 (6)*	*0.409*
Type of accident			
- Traffic	*280 (63)*	*487 (69)*	
- Home	*76 (17)*	*129 (18)*	
- Sport	*26 (6)*	*34 (5)*	
- Others	*60 (14)*	*55 (8)*	
Intoxication with alcohol/drugs	29 (7)	45 (6)	0.905
(pressure) Pain (part of) spine	218 (49)	285 (40)	0.003
Unconsciousness on scene of acc.	8 (2)	2 (0)	0.017*
Neurol. injury on scene of acc.	6 (1)	4 (1)	0.006
Patients with PSI:	*259* (59)	307 (44)	<0.001
- No fracture	*224 (86)*	*269 (88)*	*0.688*
- With unstable fracture(s)	*5 (14)*	*6 (16)*	*0.858*
Main immobilization device:			
- Backboard	*16 (6)*	*3 (1)*	
- Backboard + HNF	*204 (77)*	*3 (1)*	
- Vacuum mattress	*18 (7)*	*256 (83)*	
- Vacuum mattress + HNF.	*4 (2)*	*22 (7)*	
- Head or neck fixation	*19 (7)*	*16 (5)*	
- Unknown	*3 (1)*	*9 (3)*	
Patients with RSE	321 (72)	579 (82)	<0.001
RSE/pat. mean [med., IQR]	2.03 [2,1–3]	1.96 [2,1–3]	0.793
Exams per radiological modality			
- CT	*320 (49)*	*586 (51)*	
- MRI	*0*	*2 (0)*	
- X-ray	*331 (51)*	*572 (49)*	
Patients with spinal fractures	54 (12)	71 (10)	0.344
- Without PSI	*19 (35)*	*33 (46)*	*0.204*
Fractured vert./pat. mean [med., IQR]	1.91 [1,1–2]	1.48 [1,1–2]	0.462
Fracture part of spinal column:	103	105	
CSC	22 *(22)*	28 *(27)*	
TSC	*24 (24)*	*35 (34)*	
LSC	*54 (53)*	*40 (38)*	
SSC	*2 (2)*	*1 (1)*	
Stable fracture	91 (88)	96 (91)	0.826
CSC	18 *(82)*	23 *(82)*	
TSC	21 *(88)*	32 *(91)*	
LSC	51 *(93)*	40 *(98)*	
SSC	1 *(50)*	1 *(100)*	

Abbreviations: sd. = standard deviation; med. = median; acc. = accident; HNF = head a/o neck fixation; Neurol. = neurological; pat. = patient; PSI = preventive spinal immobilization; RSE = radiological spinal exams; vert. = vertebrae; CSC = cervical spinal column; TSC = thoracic spinal column; LSC = lumbar spinal column; SSC = sacral spinal column. * = Fisher's exact test.

Table 2
Characteristics patients with NISF.

Item	Pre-period (%, *95% CI)*	Post-period (%, *95% CI)*	*p*-value
NISF	19 *(10, 7–16)*	33 *(8, 6–11)*	0.412*
Sex-male	6 *(32, 15–54)*	12 *(36, 22–53)*	0.727
Age mean [med., IQR]	59 [57, 43–83]	68 [73, 53–86]	0.203
High energy trauma	3 *(16, 6–38)*	3 *(9, 3–24)*	0.656
Type of accident			
- Traffic	*1 (5)*	*8 (24)*	
- Home	*11 (58)*	*18 (55)*	
- Sport	*2 (11)*	*1 (3)*	
- Others	*5 (26)*	*6 (18)*	
Intoxication with alcohol/drugs	1 *(5, 1–25)*	1 *(3, 1–15)*	1.000
(pressure) Pain (part of) spine	12 *(63, 41–81)*	24 *(73, 56–85)*	0.541
Unconsciousness after accident	0 *(0)*	3 *(9)*	0.291
GCS mean on scene of acc. [med., IQR]	15 [15,15–15]	15 [15,15–15]	0.279
Neurol. injuries on scene of acc.	0 *(0)*	0 *(0)*	1.000
RSE/pat. mean [med., IQR]	1.84 [1,1–3]	2.30 [2,1–3]	0.306
Radiol. modality spinal fracture confirmed			
- CT	*11 (58)*	*14 (42)*	
- MRI	*0 (0)*	*0 (0)*	
- X-ray	*8 (42)*	*19 (58)*	
Number of fractured vert./pat. mean [med., IQR]	1.53 [1,1–2]	1.33 [1,1–2]	0.503
Fracture part of spinal column:	29	44	
CSC	*6 (21)*	*7 (16)*	
TSC	*5 (17)*	*14 (32)*	
LSC	*18 (62)*	*23 (52)*	
Stable fracture	28 *(97, 83–99)*	42 *(95, 85–99)*	0.704
CSC	5 *(83)*	6 *(86)*	
TSC	5 *(100)*	13 *(93)*	
LSC	18 *(100)*	23 *(100)*	

Abbreviations: med. = median; IQR = interquartile range; GCS = Glasgow Coma Scale; EMS = Emergency Medical Service; Neurol. = neurological; pat. = patient; Radiol. = radiological; RSE = radiological spinal exams; vert. = vertebrae; CT = Computed Tomography; MRI = Magnetic Resonance Imaging; CSC = cervical spinal column; TSC = thoracic spinal column; LSC = lumbar spinal column. * = Pearson chi-square test.

Table 3
Adverse patient outcomes.

Item	Pre-period	Post-period	*p*-value
NISF (n =)	**19 (%, *95% CI)***	**33 (%, *95% CI)***	**0.204***
Outcomes			
- Need for surgical stabilization	*1 (5, 1–25)*	*1 (3, 1–15)*	*0.687*
- Neurological injury	*0 (0, 0–17)*	*0 (0, 0–10)*	*1.000*
- Mortality	*0 (0, 0–17)*	*0 (0, 0–10)*	*1.000*

Abbreviations: NISF = Non-immobilized spinal fracture. * = Pearson chi-square test.

CRediT authorship contribution statement

Otto J. van de Breevaart: Conceptualization, Formal analysis, Investigation, Methodology, Resources, Validation, Visualization, Writing – review & editing. **Nancy W.P.L. van der Waarden:** Conceptualization, Formal analysis, Investigation, Methodology, Resources, Validation, Visualization, Writing – review & editing. **Lisette Schoonhoven:** Writing – review & editing. **Wietske H.W. Ham:** Writing – review & editing. **Niels W.L. Schep:** Conceptualization, Formal analysis, Investigation, Methodology, Resources, Validation, Visualization, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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