Quality of life following trauma before and after implementation of a physician-staffed helicopter

K. S. Funder[1], L. S. Rasmussen[1], R. Hesselfeldt[1], V. Siersma[2], N. Lohse[1], A. Sonne[1], S. Wulffeld[1] and J. Steinmetz[1]

[1]Department of Anaesthesia, Centre of Head and Orthopaedics 4231, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark
[2]The Research Unit for General Practice and Section of General Practice, Department of Public Health, University of Copenhagen, Copenhagen, Denmark

Correspondence
K. S. Funder, Department of Anaesthesia, 4231 Centre of Head and Orthopaedics, Rigshospitalet, Blegdamsvej 9, DK-2100 Copenhagen, Denmark
E-mail: milafun@hotmail.com

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Background: Implementation of a physician-staffed helicopter emergency medical service (PS-HEMS) in Denmark was associated with lower 30-day mortality in severely injured trauma patients and less time on social subsidy. However, the reduced 30-day mortality in severely injured patients might be at the expense of a worse functional outcome and quality of life (QoL) in those who survive. The aim of this study was to investigate the effect of a physician-staffed helicopter on long-term QoL in trauma patients.
Methods: Prospective, observational study including trauma patients who survived at least 3 years after injury. A 5-month period prior to PS-HEMS implementation was compared with the first 12 months after PS-HEMS implementation. QoL was assessed 4.5 years after trauma by the SF-36 questionnaire. Primary endpoint was the Physical Component Summary score.
Results: Of the 1994 patients assessed by a trauma team, 1521 were eligible for inclusion in the study. Of these, 566 (37%) gave consent to participate and received a questionnaire by mail, and 402 (71%) of them returned the questionnaire (n = 114 before PS-HEMS; n = 288 after PS-HEMS implementation). Older patients, women and patients with trauma in the after PS-HEMS period were more likely to return the questionnaire. No significant association between QoL and period (before vs. after PS-HEMS) was found; the Physical Component Summary scores were 50.0 and 50.9 in the before and after PS-HEMS periods, respectively (P = 0.47). We also found no difference on multivariable analysis with adjustment for sex, age and injury severity score.
Conclusion: No significant difference in QoL among trauma patients was found after implementation of a PS-HEMS.

Editorial Comment
In this analysis, the authors examined trauma victims and long-term recovery from periods before and after changes were made in prehospital system medical staffing. They were unable to find differences in the very patient-important outcome, quality of life after trauma, for subjects treated before vs. after this medical system change. The confidence in the result of this comparison is affected by the large loss of subjects for follow-up.

The first physician-staffed helicopter emergency medical service (PS-HEMS) was implemented in Denmark in May 2010. Observed short-term effects were reduced time to specialised care, fewer secondary transfers and lower 30-day mortality for severely injured trauma patients.[1] Internationally, time gain and mortality are the outcome variables most often applied in studies evaluating ambulance helicopter services against ground services[2,3,4,5]; however, death does not provide any information about functional outcome or the quality of life (QoL) saved, and it could be speculated that increased survival is at the expense of reduced functional or psychological well-being.

A growing public interest in understanding the impact of healthcare interventions on people's lives has emphasised the need for more studies assessing QoL, but few have investigated the possible effect of transport mode (ambulance helicopter vs. ground ambulance) on QoL after trauma.[6,7] Reduced time to specialised treatment by an ambulance helicopter compared to ground ambulance might not only improve short-term outcome after injury but also lead to better QoL. However, reports are sparse, and a Dutch study failed to demonstrate better QoL 2 years after trauma in patients transported by an ambulance helicopter.[6]

A recent study of the same cohort as the present evaluated long-term labour market affiliation and found that the implementation of the PS-HEMS was associated with a significant reduction in time on social transfer payments.[8] However, labour market affiliation was only assessed in patients on the labour market and who were between 18 and 60 years old; hence, QoL assessment may capture long-term outcome in a larger proportion of the patients.

The aim of this study was to investigate the effect of implementation of a PS-HEMS in the emergency medical system on long-term QoL in trauma patients. We hypothesised that trauma patients would have better long-term QoL after the implementation of a PS-HEMS compared with trauma patients before the implementation of a PS-HEMS.

Material and methods

Study design and setting

This was a prospective, observational study with a follow-up of 4.5 years. Eight centres contributed with data, including one level 1 and seven level 3- or 4-equivalent trauma centres.

Before the PS-HEMS implementation in May 2010, pre-hospital trauma care in the eastern part of Denmark was provided solely by the two-tiered ground emergency medical service consisting of a primary ground ambulance service staffed with either two ambulance assistants (basic life support providers) or an ambulance assistant and a paramedic (advanced life support provider). In selected cases, a physician-staffed mobile emergency care unit was dispatched simultaneously at the discretion of the emergency dispatch centre. After implementation of the PS-HEMS, the physician-staffed helicopter could be dispatched at the discretion of the emergency dispatch centre or requested by the ground unit on-scene in case of suspected severe injury, especially when the estimated driving time to the level 1 trauma centre in Copenhagen by a ground unit was expected to exceed 30 min. Physicians manning the PS-HEMS and the Mobile Emergency Care Unit (MECU) were specialists in anaesthesia and intensive care medicine. In addition, the PS-HEMS personnel included a pilot and a specially trained HEMS crew member (paramedic).

PS-HEMS operated only during daylight hours, covering a catchment area of 8400 km^2 with an eligible population of 1.1 million inhabitants.[1]

Data sources

Trauma records

Trauma data were retrieved from previously reported registration sheets.[1] Data included information on transport mode, demographics, time intervals, Injury Severity Score (ISS), mechanism of injury, type of injury, and initial on-scene and in-hospital vital signs. The ISS quantifies injury severity and ranges from 1 to 75 with an increasing score indicating increasing severity.[9] For the purposes of this study, ISS was categorised into three groups: ISS < 16 = low; 16 ≤ ISS < 25 = moderate and ISS > 24 = high.

The Danish Civil Registration System (DCRS)

The DCRS[10] is administered by the Danish government, which since 1968 has assigned a

unique civil registration number to all persons who take up residence in Denmark. The registry includes vital statistics and demographic information and is updated daily.

The SF-36 questionnaire

To assess QoL, we used the self-reported Short Form-36 (SF-36) questionnaire. The SF-36 is a commonly used generic tool to provide a brief general measure of QoL.[11] It was originally developed in the United States but has since been translated into many languages, including Danish.[11] The SF-36 questionnaire is often used in clinical studies and is well-suited for follow-up studies because it can be used for all patients over age 14 years, regardless of disease and a cultural sense of belonging.[12]

The questionnaire consists of 36 questions divided into two overall components: one relating to physical health (Physical Component Summary, PCS) and one relating to mental health (Mental Component Summary, MCS). Each of the two components comprises three subdomains and two overlapping subdomains. The three physical subdomains are Physical Functioning, Role Physical and Bodily Pain. The three mental subdomains are Social Functioning, Role Emotional and Mental Health, and the two overlapping subdomains are General Health and Vitality. Each subdomain and the MCS and PCS scores are standardised to a T-score with a mean of 50 and a standard deviation of 10 for a general US population sample. Hence, scores above and below 50 indicate above and below average levels of functioning, respectively, compared with the general US population. The T-scores help in the interpretation of the scores of the domains. Completing the questionnaire takes about 5–10 min.

Selection of participants and data collection

We identified all trauma patients who were admitted to any of the eight trauma centres in the PS-HEMS catchment area in a 17-month period from 1 December 2009 to 30 April 2011, which consisted of a 5-month period before implementation of the PS-HEMS and a 12-month period after the PS-HEMS implementation. For patients with multiple contacts during the inclusion period, only the first contact was included. We excluded all patients who upon arrival at the hospital were re-categorised as non-trauma patients, patients who arrived by any means other than ambulance or helicopter and patients under age 14 years. Likewise, patients who died before collection of QoL data were also excluded.

Collection of QoL data

We aimed to collect data on QoL on all patients who were alive 4.5 years after the trauma, but for some patients, this collection was not possible. Some were no longer living in Denmark, and some were covered by research protection, a status available within Denmark for citizens who wish to refuse direct inquiries such as questionnaires for research purposes. Approximately 13% of the Danish population has used this option, and the highest proportion (up to 25%) is in the age group of 20–29 years.[13] For the remaining patients, the current address was obtained via the DCRS and used to obtain a phone number via an online information system. If we could not retrieve a phone number or the patient did not answer our phone calls, patients were registered as 'no contact'.

We contacted patients by telephone, requesting permission to send the SF-36 questionnaire by mail together with a cover letter, a stamped and addressed return envelope, and investigator contact information. Patients were contacted 4.5 years after the trauma (give or take 1 month) over the course of 17 months (corresponding to the 17-month inclusion period) in chronological order by the date of trauma, beginning in June 2014 with patients included in December 2009 and so on. This approach was chosen to account for differences in follow-up time between the first and last included patients.

Patients who for some reason were unable to complete the questionnaire (e.g., cognitively impaired) were allowed to receive assistance from a family member or healthcare professional. Patients who had not returned their questionnaires within 14 days received a reminder phone call and another call after another 14 days, if necessary. Messages were left on answering machines in case of no contact. Patients who returned an incomplete

questionnaire were phoned twice to obtain the missing data. All data were manually entered in a licensed database where scores were automatically generated via a series of SF-36 scoring algorithms.[12]

Intervention

We compared trauma patients from a 5-month period (1 December 2009 to 30 April 2010) immediately before implementation of the PS-HEMS with trauma patients from the first 12 months (1 May 2010 to 30 April 2011) after the PS-HEMS implementation.

Outcome measures

The primary outcome was PCS score at 4.5 years after trauma. The secondary outcomes were the MCS score and each of the eight subdomain scores at 4.5 years after trauma.

Statistical analyses

Continuous variables are reported as medians and interquartile ranges. Categorical data are reported as frequencies and proportions. Unadjusted associations between the PS-HEMS period and baseline variables were assessed by Mann–Whitney *U*-tests (continuous variables), as were differences in QoL outcomes between the two periods, and chi-square tests were used for categorical variables. In addition, for QoL outcomes between periods, the Hodges–Lehmann estimator for location shift was also calculated for the median of the differences between all possible pairs of observations from the before and after PS-HEMS periods, respectively.

Differences in PCS and MCS scores 4.5 years after trauma between exposure groups were assessed by linear regression, adjusted for sex, age and ISS.[9] In addition, in a multivariable logistic regression, we analysed, respectively, whether sex, age, ISS or period was associated with non-response. We defined non-response as the proportion of patients who were contacted by phone, gave consent for participation and received the questionnaire by mail, but who did not return the questionnaire despite several reminder phone calls. Non-planned sensitivity analyses on PCS and MCS scores were also performed on patients with an ISS $\geq$ 16.

We considered P values < 0.05 as statistically significant. SAS version 9.4 (SAS Institute Inc., Cary, NC, USA) was used for statistical analyses.

Ethics

The study was approved by the Danish Data Protection Agency (file number: 2013-41-1973 and 2013-231-0042) and by the National Board of Health (file number: 3-3013-352/1/HKR). Approval from the Ethics Committee is not required for studies using questionnaires only, according to Danish law.

Results

Of the 1994 patients who were received at one of the eight trauma centres, 1521 were eligible for inclusion in the study (Fig. 1). Only 37% (n = 566) of patients were successfully contacted, gave consent for participation and were alive by 1 May 2014 (Fig. 1); among them, 402 patients (71%) returned the SF-36 questionnaire (n = 114/177, 64% before; n = 288/389, 74% after PS-HEMS implementation) (Fig. 1). Patients in the before and after PS-HEMS groups were comparable in relation to sex, age, ISS, and type and mechanism of injury (Table 1).

Physical Component Summary scores before and after the PS-HEMS implementation were 50.0 and 50.9, respectively (Table 2). None of the eight subdomain scores or the MCS score were found to be significantly different between the before and after PS-HEMS group (Fig. 2), and all scores were above average (equivalent to 50) in both periods except before PS-HEMS Bodily Pain and Role Physical at 46.7 and 49.3, respectively (Table 2). The multivariable analysis revealed no significant difference in QoL between the two groups (Table 3).

In the multivariable logistic regression analysis, we identified advancing age (odds ratio (OR)=1.02 per additional year of age; 95% confidence interval (CI) 1.01–1.03, $P \leq 0.001$), female gender (OR=1.81, CI 1.20–2.70, P = 0.004) and after PS-HEMS implementation period (OR=1.71, CI 1.16–2.55, P = 0.007) as associated

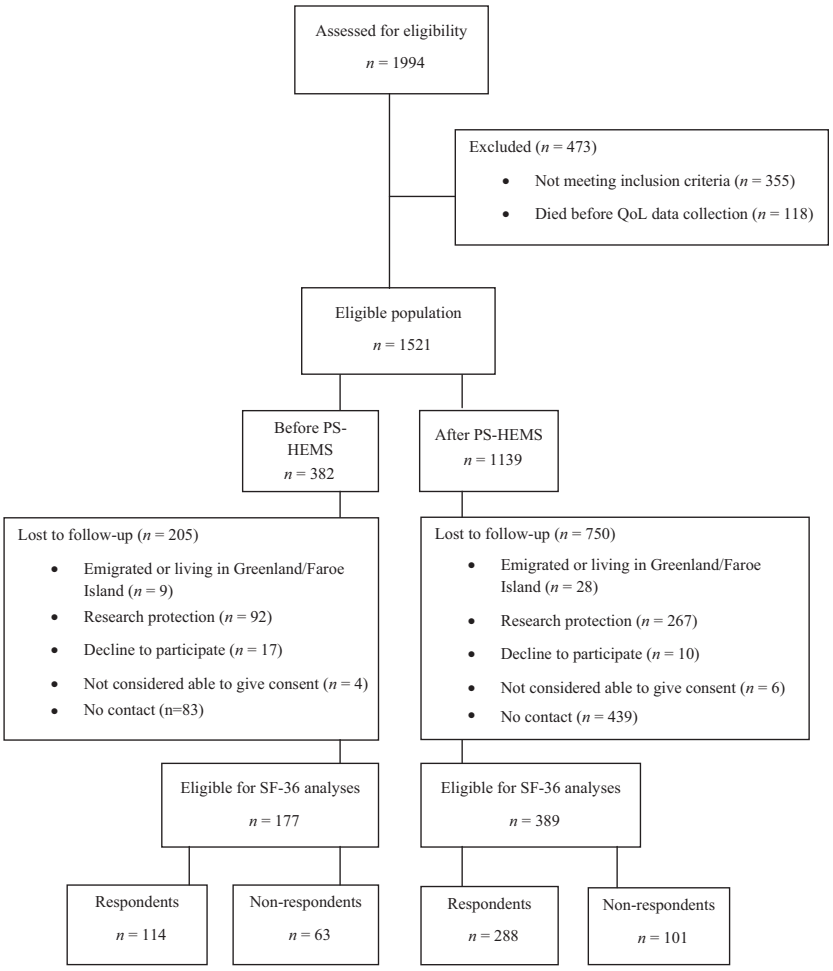

Fig. 1. Flowchart of included patients. PS-HEMS: Physician-staffed helicopter emergency medical service.

with a higher probability of returning the questionnaire in contacted patients.

We found that patients who did not return the questionnaire were comparable in relation to sex, age and ISS with patients who were registered under research protection in the DCRS. We found no significant differences in PCS and MCS scores between the before and after PS-HEMS groups of patients with an ISS $\geq$ 16.

Discussion

At follow-up 4.5 years after trauma, we found no significant differences in patients' QoL between before and after PS-HEMS implementation, with no significant differences between PCS and MCS scores. The main strength of our study is the design, which allowed us to assess QoL 4.5 years after trauma in a large group of prospectively included patients in a well-defined region. We contacted patients in chronological order over the course of 17 months to avoid differences in time to QoL assessment. Patients were included independent of ISS, allowing us to study the full patient population seen in trauma centres. Finally, the unique personal identification number allocated to all citizens in Denmark allowed us to link information from clinical and administrative registries with that of the SF-36 survey.

One of the main limitations of this study, however, is the low proportion of patients who were contacted, partly due to research protection and partly due to an inability to obtain contact

Table 1 Patient characteristics.

	Before PS-HEMS (n = 177)	After PS-HEMS (n = 389)	Total (n = 566)	Missing	P value
Sex, n (%)					
Woman	71 (40.1)	135 (34.7)	206 (36.4)	0	0.22
Man	106 (59.9)	254 (65.3)	360 (63.6)		
Age, median (IQR)	42 (24–57)	39 (20–57)	40 (21–57)	0	0.46
ISS, n (%)					
Low	158 (89.3)	345 (88.7)	503 (88.9)	0	0.58
Moderate	9 (5.1)	27 (6.9)	36 (6.3)		
High	10 (5.6)	17 (4.4)	27 (4.8)		
Level of triage, n (%)					
PS-HEMS	–	56 (14.4)	56 (9.9)	0	
Mobile emergency care unit (physician)	72 (40.7)	92 (23.6)	164 (29.0)		
Ambulance	100 (56.5)	233 (59.9)	333 (58.8)		
Other emergency car (nurse, paramedic)	5 (2.8)	8 (2.1)	13 (2.3)		
Type of trauma, n (%)					
Penetrating	2 (1.1)	8 (2.1)	10 (1.7)	0	0.59
Blunt	175 (98.9)	380 (97.7)	555 (98.1)		
Other	–	1 (0.2)	1 (0.2)		
Cause of trauma, n (%)					
Traffic	123 (69.5)	258 (66.3)	381 (67.3)	0	0.16
Fall < 2 m	17 (9.6)	23 (5.9)	40 (7.1)		
Fall ≥ 2 m	15 (8.5)	50 (12.8)	65 (11.5)		
Sports	4 (2.2)	8 (2.1)	12 (2.1)		
Violence	1 (0.6)	12 (3.1)	13 (2.3)		
Other (e.g., crush injury, explosion)	17 (9.6)	38 (9.8)	55 (9.7)		
Respondents (SF-36), n (%)	114 (64.4)	288 (74.0)	402 (71.0)	0	0.02

ISS, Injury Severity Score; PS-HEMS, physician-staffed helicopter emergency medical service; IQR, interquartile range.

Table 2 Comparisons of unadjusted SF-36 scores between trauma patients before and after implementation of a helicopter emergency medical service.

	Before PS-HEMS (n = 131)	After PS-HEMS (n = 338)	P value	Hodges–Lehmann estimator* (95% CI)
Bodily Pain, median (IQR)	46.7 (38.21–55.55)	50.7 (38.41–62.00)	0.64	0.00 (0.00–4.03)
General Health, median (IQR)	50.8 (40.35–60.32)	50.8 (40.35–57.94)	0.85	0.00 (−2.38–2.38)
Mental Component Summary, median (IQR)	54.1 (45.25–59.62)	52.4 (41.04–58.74)	0.26	−1.15 (−3.29–0.86)
Mental Health, median (IQR)	53.5 (45.64–58.72)	50.9 (43.02–58.72)	0.15	−2.61 (−2.62–0.00)
Physical Component Summary, median (IQR)	50.0 (40.53–56.50)	50.9 (40.37–57.47)	0.47	0.77 (−1.40–3.07)
Physical Functioning, median (IQR)	51.8 (46.06–57.54)	53.7 (44.15–57.54)	0.79	0.00 (0.00–1.91)
Role Emotional, median (IQR)	56.2 (35.28–56.17)	52.7 (38.76–56.17)	0.60	0.00 (0.00–0.00)
Role Physical, median (IQR)	49.3 (39.19–57.16)	50.4 (39.19–57.16)	0.92	0.00 (0.00–0.00)
Social Functioning, median (IQR)	57.3 (47.31–57.34)	57.3 (42.30–57.34)	0.39	0.00 (0.00–0.00)
Vitality, median (IQR)	52.6 (40.72–61.51)	51.1 (40.72–58.54)	0.38	0.00 (−2.97–0.00)

*Difference in location shift. PS-HEMS, physician-staffed helicopter emergency medical service; IQR, interquartile range.

information. Hence, despite a good response rate, the overall proportion who provided QoL information was lower than in similar studies.[14,15] The majority of patients were lost to follow-up because of either a wrong address in the DCRS or a missing phone number (34%, n = 522). We might have had a higher response rate had we mailed the questionnaire to the

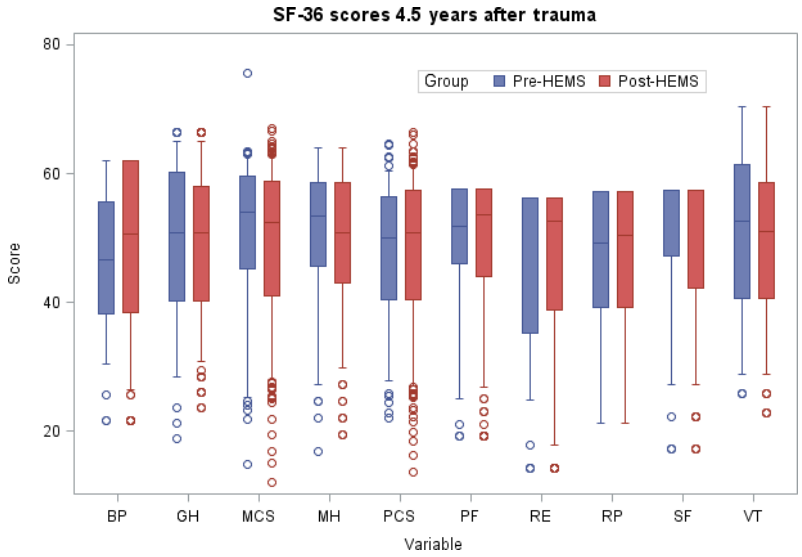

Fig. 2. Comparisons of SF-36 scores between trauma patients before and after implementation of a helicopter emergency medical service. Pre-HEMS: before implementation of a physician-staffed helicopter emergency medical service; post-HEMS: after implementation of a physician-staffed helicopter emergency medical service; RE: Role Emotional; MH: Mental Health; SF: Social Functioning; VT: Vitality; BP: Bodily Pain; RP: Role Physical; PF: Physical Functioning, GH: General Health; PCS: Physical Component Summary; MCS: Mental Component Summary; line in box: median score; box: interquartile range; whiskers: 5–95 percentiles; circles: outliers (observations beyond the value of 5–95 percentiles).

Table 3 Differences in mental and physical component summary scores 4.5 years after trauma between patients before and after implementation of a helicopter emergency medical service.

	Mean score in after PS-HEMS relative to before PS-HEMS period	SE	CI (95%)	*P* value
Physical component summary				
Unadjusted	0.43	1.23	(−1.88–2.95)	0.67
Adjusted*	0.22	1.16	(−2.02–2.55)	0.82
Mental component summary				
Unadjusted	−1.02	1.28	(−3.82–1.21)	0.31
Adjusted*	−1.00	1.29	(−3.82–1.24)	0.32

*Adjusted for sex, age and ISS. PS-HEMS, physician-staffed helicopter emergency medical service; CI, confidence interval; SE, standard error; ISS, Injury Severity Score.

proportion of patients with a valid address. It is possible that these patients would have differed in QoL from the rest of our cohort. Another attempt to increase the response rate could have been using a prospective design with patient enrolment for this study during admission, but regretfully we did not do that.

Almost one in four people aged 20–29 years is registered with research protection in Denmark,[13] and in our study, this was the case in 24% of patients before and 23% after PS-HEMS implementation. Research protection reflects a conscious decision to decline participating in certain types of studies upfront. We found that these patients were comparable to those patients who chose not to respond to our survey (non-responders), but numerous studies have shown that the overall health profiles of non-responders are poorer than that of participants.[16,17,18,19,20,21] Consequently, because patients with research protection were similar to non-responders, the results might have shown lower SF-36 scores had they been included. The proportion of patients under research protection was similar in the two periods; however, so we would not expect a major impact from their absence on our results.

Female gender and increasing age were associated with a higher rate of response in our study, consistent with findings in other studies.[22,23,24] Nevertheless, like most trauma populations, the majority of patients in our study were younger men, which mean a greater risk of non-response and biased results. Young trauma survivors might be more likely to experience

lower QoL after trauma due to unfulfilled expectations regarding work, participation in sporting activities and social life.[25] They also may have more hazardous behaviour and be those who have high-velocity accidents and injury due to violence compared to older adults.[26,27] Non-response was more common before PS-HEMS, which could have led to a higher SF-36 score and an underestimation of a potentially beneficial effect of PS-HEMS in the after PS-HEMS implementation group.

A Swedish study found that preliminary notification of a survey by telephone increased retrieval rates significantly (OR=1.30, CI 1.08–1.56).[22] Few patients in our study declined participation during the telephone interview. Some patients expressed great disappointment with the health care system, however, and reported having received poor in-hospital treatment accompanied by insufficient information and follow-up after discharge, and therefore refused to contribute. These concerns are well-known from another study.[25]

The results of our study were derived from scoring algorithms standardised to a US population, which has shown high correlation to the Danish general population.[28] We found that both summary scores (PCS and MCS) were at or above average in both periods and consistent with the Danish general population.[28] One explanation might be that the majority of patients in both periods (above 88%) suffered only a low severity of injury (ISS < 16) and thus might have fully recovered after 4.5 years. Nevertheless, the subgroup analysis of the few patients ($n = 63$) with ISS at or above 16 showed scores at the same level as that of all patients, and no significant difference between the two periods. It seems possible that the two summary scores would have been lower if the number of patients were more equally distributed in the groups of low, moderate and severe injuries.

Not all of the questions on the SF-36 are relevant for elderly persons, who may interpret questions differently than younger persons.[29] As median age was not different between the two periods, this potential source of bias presumably did not influence the results.

Another challenge when interpreting QoL scores relates to the clinical importance of differences in scores. Differences in individual subdomains of 5 points or more have been suggested to be clinically relevant, although the current literature mainly describes differences in patients with medical and surgical conditions.[30,31,32] Our results showed no significant difference in any subdomain score, and it seems unlikely that a clinically important difference has been overlooked because none of the observed differences reached 5 points and the 95% CIs for the differences in PCS score did not exceed 3.1 (Table 2). The number of included patients, therefore, seems to enable us to detect a clinically relevant difference, but the number of severely injured patients (ISS ≥ 16, only 63 patients) is not adequate for a conclusive subgroup analysis. When evaluating the effects of trauma on QoL, it is important to allow sufficient recovery time to avoid overestimating the long-term burden of injury. In addition, differences in time from trauma to completion of the questionnaire may affect comparisons between groups. We provided an equivalent and sufficiently long time to complete the questionnaire in the before and after PS-HEMS periods, but the response rate was higher after the PS-HEMS implementation. If non-responders were missing completely at random both within and between exposure groups, outcome measures would have been unbiased. The higher response rates after PS-HEMS might reflect a difference in willingness to respond, possibly because patients treated after implementation of the helicopter find it more important to complete the SF-36 survey. This difference in response rate between the two periods may have introduced bias, which could be in either direction.

In conclusion, we found no significant difference in QoL among trauma patients after implementation of a PS-HEMS.

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