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Acute Pain Assessment Inadequacy in the Emergency Department: Patients' Perspective

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Abstract

For many patients, acute pain is a common cause to seek treatment in an Emergency Department (ED). An inadequate assessment could cause inappropriate pain management. The aim of this study was to describe and explain patients' perceptions of acute pain assessment in the Emergency Department. The data were collected from ED patients (n = 114). Patients reported that nurses were asking about intensity of pain at rest, but only 52% during movement. According to the patients, the most common tools to assess acute pain were the verbal rating scale (VRS; 54% of patients), numerical rating scale (NRS; 28% of patients), and visual analogue scale (VAS; 9.7% of patients). Over twenty per cent of patients stated that ED nurses did not ask about the intensity of pain after analgesic administration. Twenty-four per cent of the patients were not pleased with nursing pain assessment in the ED. The assessment of acute pain is still inadequate in the ED. Therefore, ED nurses need to be more attentive to systematic acute pain management of patients in the ED.

Keywords

emergency department, patient, pain assessment, acute pain, pain management

Introduction

Pain, acute, sudden, or chronic is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage" (1). Pain management encompasses comprehensive screening and assessment (2). Patients' perceptions of pain assessment and management have become an important criterion and relevant outcome measure for healthcare institution (3,4). Patient' self-assessment is the most reliable and accurate evidence of the existence of pain and should be used whenever possible (5,6).

For many patients, acute pain is a common cause to seek treatment in an ED (7). However, pain management in the ED is challenging, and one of the main aims is to achieve patient satisfaction by reducing discomfort (8). Crowding EDs, and nurses' lack of knowledge may prevent nurses from performing adequate pain assessment and correct pain management (9–15). An inadequate assessment could cause underestimation of the patient's pain, leading to inappropriate pain management (8,16). According to governing organizations on pain, and guidelines, patients have the right to be involved in all aspects of their pain management (2,6,11,17).

Previous studies have shown that the accurate assessment of pain is a crucial step in providing effective pain management. Discrepancies between a patient's and nurse's assessments are identified as the most powerful predictor of poor pain management (4). Previous studies have shown that acute pain management has been concentrated on the components of the pain management process, including the assessment of pain, provision of interventions (18,19). Several pain scales are used to assess a patient's acute pain, of which the VRS, the NRS, and the VAS have been advocated as simple, valid, and reliable pain measuring methods within EDs (5,8,20,21). According to the EUSEM Acute Pain Management Guidelines (6), the VRS is the most used type of categorical pain scale. When pain measurement tools to be used in pain assessment, all relevant factors relating to the individual patient should be taken into consideration, including language, cultural, and emotional considerations (6). However, recent studies have shown

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that, pain scoring may not accurately reflect patient experience (22).

Studies of acute pain management in the ED are mainly based nurses' perceptions, pain management of older people, and perceptions of children and their parents (18,19,22). Less has been known, however, regarding interventions among adult emergency patients (23). Despite different guidelines, patients' acute pain has not always been properly treated (24). Inadequate pain management in the ED setting is still a challenge and there have been marginal reports of how the pain management process can be improved in EDs (11,22,25). This manuscript provides new improvement initiatives to the emergency patients globally with implications for translation of new acute pain assessment knowledge into practice. Earlier research has been international, however, no studies were found in the context of this contemporary research. The aim of this study was to describe and explain patients' perceptions of acute pain assessments in the ED. The research questions were as follows: how is patients' pain assessed in ED and how are the background variables related in current time to the patient's assessment of acute pain.

Method

Data Collection

This study was quantitative, descriptive, and cross-sectional in design. The study population consisted of 114 patients who entered at a ED. The data were collected by structured paper questionnaire. Data were collected over three months in 2020 and all data were collected before the patients left the ED. A university hospital ED were selected for study participation. The ED provided specialised care for the estimated 1.7 million inhabitants of the surrounding area (49 beds; 50 sitting places; staff n = 90–100). The ED treats 1000–1200 patients weekly and 100 000 patients per year.

Inclusion criteria for patients included: (1) aged < 18 years, (2) presence of acute pain, (3) Glasgow Coma Scale (GCS) <15, (4) self-reported pain score of 1 or higher on a scale of 1–10, (5) cognitive ability not severely impaired due to drug use, (6) no diagnosed memory disease, (7) ability to understand and speak Finnish language, and (8) ability to give consent to participate.

Questionnaire Development

Since there were no existing questionnaires suitable for this study, an acute pain assessment and management questionnaire was developed by the authors (Table 1 and 2). The content of this questionnaire was based on the current literature and previous research (14,21,26). The entire questionnaire was divided into four sections, with a total of 44 questions. The sections were: background, pain assessment, pain management (pharmacological and non-pharmacological), and hindering factors in pain management.

Table 1. Sociodemographic Characteristics of Nurses (n = 114, n, %).

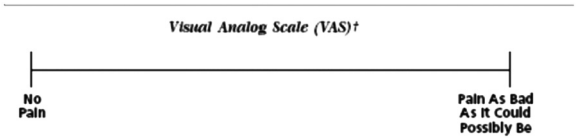
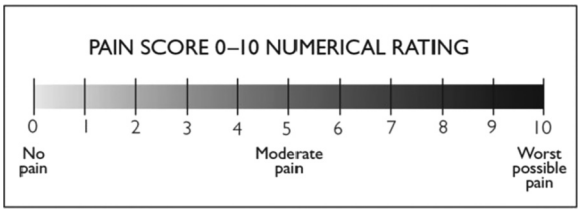
Characteristics		n	%
Age (years)	Under 24	19	17
(mean 40.8 years)	25–39	38	33
	40–58	41	36
	60 and older	16	14
Gender	Female	67	58.8
Marital status	Male	47	41.2
	Married	53	46.5
	Cohabitation	33	28.9
	Unmarried	15	13.2
	Divorced	10	8.8
	Widow	3	2.6
Educational level (degree)	Master's	39	34.2
	Vocational	34	29.8
	Comprehensive School	18	15.8
	College	14	12.3
	Bachelor's	9	7.9
Working life situation	Employee	60	52.6
	Lower Officer	13	11.4
	Pensioner	12	10.5
	Student	10	8.8
	Senior Officer	8	7.0
	Unemployed	6	5.3
	Enterpreneur	5	4.4
Long-term painful illnesses	No	110	96.5
	Yes	0	0
	Missing Value	4	3.5
Acute pain in current time (NRS 0–10), (mean 5,46) (n = 111)	4–7	80	70.2
	0–3	17	14.9
	8–10	14	12.3
	Missing Value	3	2.6

The respondents were asked to answer each question using a five-point Likert scale ranged from 1 (= strongly agree) to 5 (= strongly disagree) and were supplemented with open-ended questions. The survey included nine background variables.

Prior to the actual study and pilot study, eight nurses from different EDs evaluated the content validity of this questionnaire. These nurses assessed the reliability of the questionnaire, in terms of its components, content, and functionality, using a premade evaluation form. Items of the questionnaire were evaluated with response options. These evaluations were calculated using the full-form reliability index S-CVI/Ave, which yielded a reliability value of 0.89 (27).

A pilot study was performed in August 2020 prior to actual study. Ten patients participated in the pilot study. Inclusion criteria for the participants were the same as for the actual study. In the pilot, participants had the opportunity to provide their opinions regarding of the questionnaire. The pilot study did not reveal any modifications and the actual study was conducted using the same questionnaire. As no changes were made to the form, the results of the pilot study were also included in the analysis

Table 2. Patiens' Perceptions of Pain Frequency, Pain Scales, Pain Quality, and Pain Intensity (n = 114, n, %).

Items:	Strongly agree (n, %)	Partially agree (n, %)	Do not know, (n, %)	Partially disagree (n, %)	Strongly disagree (n, %)	Missing
Nurses' asked the location of my pain	82 (71.9%)	20 (17.5%)	0 (0%)	10 (8.8%)	1 (0.9%)	1 (0.9%)
Nurses' asked type of my pain	55 (48.2%)	36 (31.6%)	6 (5.3%)	15 (13.2%)	1 (0.9%)	1 (0.9%)
Nurses' asked my acute pain at entry	69 (60.5%)	26 (22.8%)	3 (2.6%)	15 (13.2%)	1 (0.9%)	0 (0%)
Nurses' asked my acute pain at departure	40 (35.1%)	32 (28.1%)	0 (0%)	17 (14.9%)	3 (2.6%)	22 (19.3%)
My pain was assessed several times while I was in the Emergency Department	57 (50.0%)	32 (28.1%)	0 (0%)	20 (1750%)	4 (3.6%)	2 (0.8%)
Assessing the intensity of pain is challenging	47 (41.2%)	57 (50.0%)	2 (1.8%)	8 (7.0%)	0 (0%)	0 (0%)
Nurses' assessed my pain with pain scale.	57 (50%)	23 (20.2%)	2 (1.8%)	6 (5.3%)	6 (5.3%)	20 (17.5%)
Pain assessment when the VAS [1*] was used (no pain- mild pain, moderate pain, severe pain, very severe pain, outstanding pain)	6 (5.3%)	5 (4.4%)	10 (8.8%)	2 (1.8%)	0 (0%)	91 (79.8%)
						
Pain assessment when the VRS was used 0 = no pain 1–2 = mild pain 3–4 = moderate pain 5–6 = severe pain 7–9 = very severe pain 10 = worst possible pain	24 (21.1%)	38 (33.3%)	6 (5.3%)	0 (0%)	0 (0%)	46 (40.4%)
Pain assessment when the NRS [2*] was used (0 = no pain, 10 = worst possible pain)	17 (14.9%)	15 (13.2%)	0 (0%)	0 (0%)	0 (0%)	82 (71.9%)
						
My self-assessment of pain intensity is the most reliable	38 (33.3%)	52 (45.6%)	8 (7.0%)	12 (10.5%)	4 (3.5%)	0 (0%)
My self-assessment of pain is as valid as the assessment made by a nurse or doctor	29 (25.4%)	50 (43.9%)	5 (4.4%)	22 (19.3%)	5 (4.4%)	3 (2.6%)
I am pleased to with nurses' pain assessment	44 (38.6%)	44 (38.6%)	2 (1.8%)	17 (14.9%)	6 (5.3%)	1 (0.9%)
ED staff assessment adequately managed my pain	57 (50.0%)	33 (28.9%)	17 (14.9%)	5 (4.4%)	1 (0.9%)	1 (0.9%)
Nurses' asked my pain at rest	47 (41.2%)	40 (35.1%)	1 (0.9%)	20 (17.5%)	5 (4.4%)	1 (0.9%)
Nurses' asked my pain during motion	30 (26.3%)	29 (25.4%)	6 (5.3%)	35 (30.7%)	13 (11.4%)	1 (0.9%)
Nurses' asked my pain before analgesics	47 (41.2%)	26 (22.8%)	6 (5.3%)	24 (21.1%)	7 (6.1%)	4 (3.5%)
Nurses' asked my pain after analgesics	54 (47.4%)	22 (19.3%)	11 (9.6%)	18 (15.8%)	7 (6.1%)	2 (1.8%)

Range. 1 = fully agree 5 = fully disagree.
Abbreviations: ED, Emergency Department; VAS, visual analogue scale; VRS, verbal rating scale: NRS; numerical rating scale;.
[1*]VAS scale: https://greatbrook.com/visual-analog-survey-scale/.
[2*]NRS scale: https://www.physio-pedia.com/Numeric_Pain_Rating_Scale.

of the results. The present article was based on the pain assessment section, which contained 18 multiple-choice questions.

Data Analysis

The effective sample size was estimated using power analysis to determine the smallest sample size suitable for detecting the expected effect size of 0.3. The level of statistical significance was set to 0.05 and effect size of 80%, which calculated a sample size of 71 participants (28). This estimated sample size was achieved, in total, with the 114 patients who responded to the survey. Descriptive statistics (n, %) were used to characterise the patients and questionnaire items (Table 2). For the analysis, the background characteristics of age and acute pain in current time were transformed as categorical. Reliability of the 17 pain assessment items was tested with Spearman correlation test, and all items were over 0.8 (29).

Table 3. Results of Exploratory Factor Analyses of Acute Pain Assessment ($n = 114$) (Loadings, Eigenvalues, Cronbach's Alpha Values).

Factor Items	Loading	Eigen values	Cronbach`s alpha values
(1) Quality and frequency of the assessment of the acute pain		4.828	0.85
Nurses' asked the location of my pain	0.86		
Nurses' asked type of my pain	0.73		
Nurses' asked my acute pain at entry	0.79		
Nurses' asked my acute pain at departure	0.73		
My pain was assessed several times while I was in the Emergency Department	0.50		
(2) Patients' self-assessment of pain		1.43	0.75
My self-assessment of pain intensity is the most reliable	0.63		
My self-assessment of pain is as valid as the assessment made by a nurse or doctor	0.69		
I am pleased to with nurses' pain assessment ED staff assessment adequately managed my pain	0.74		
	0.81		
(3) Assessment of acute pain intensity at rest, and during movement, and intensity before and after administration of analgesics		1.23	0.67
Nurses' asked my pain at rest	0.84		
Nurses' asked my pain during motion	0.62		
Nurses' asked my pain before analgesic	0.71		

Exploratory factor analysis (EFA) was used to analyse variables for the pain assessment. Principal axis factoring was applied. The rotation technique applied was the varimax method with Kaiser normalization. In varimax rotation, the factors are rotated for the best factor solution, which was the aim in this study. The Kaiser-MeyerOlkin test value for the responses was good (0.76), and the Bartlett's test of sphericity result was highly significant ($P < 0.001$); thereby confirming that factor analysis was appropriate for these items. This factor solution had 17 items, all of which met the correlate over 0.3 at least with one item and they loaded of over 0.3. A cut-off point 0.3 is generally selected for the correlations and loadings, as used in this study, too. The loadings over 0.3 show us the items will be included as elements of the factor (28).

According to the exploratory factor analysis, there were 17 observed pain variables constructed into three mean sum variables: 'the quality and frequency of the assessment of the acute pain' (Item 5), 'patients' self-assessment of pain' (Item 4) and 'assessment of acute pain intensity at rest, and during movement, and intensity before and after administration of analgesics' (Item 3). According to Watson and Thompson (30) in order for the results of a factor analysis to be reliable, it should be conducted on a dataset from a sample containing at least five subjects per item on the scale. However, it did meet the criterion suggested by some statisticians that three subjects per item on the scale are sufficient. It means that in this study 51 respondents were enough for EFA. Our convenience sample size was 114.

Reliability of the mean sum variables was tested, and Cronbach's alpha coefficients were calculated and ranged from 0.6–0.9, indicating that the new instrument has only modest degree of internal consistency (31) (Table 3). Based on the factor analysis, five questions were omitted from the sum variables because they showed weak negative correlations (- 0.141) (28). Normal distribution of the mean sum variables was tested using the Kolmogorov- Smirnov test, and they did not follow normal distributions. The Mann-Whitney and Kruskal-Wallis tests were used to detect differences between the background characteristics and mean sum variables. The level of significance was set at $p \leq 0.05$ (32). The STROBE (i.e. Strengthening the Reporting of Observational studies in Epidemiology) list was used for clear presentation of the study (Appendix 1).

Ethical Approval

The study was granted ethical approval by XXXX (XXX) in 2020 (XXX). Participation was voluntary and based on respondents' anonymity and informed consent. Participants were informed both verbally and with written, information about the study`s aim, procedures and requirements, and all participants signed written consents before participating. Participants were assured of their confidential participation and guaranteed that all data collected in this study would be pseudonymized and the results would not be associated with any participating individuals.

Results

Patient Characteristics

The study consisted of 114 ED patients. The mean age of the patients was 40.8 years, and 58.8% (n = 67) were female. Less than half of the participants (n = 43, 46.5%) were married. Regarding educational background, most had Master's degrees (n = 39, 34.2%), some had vocational degrees (n = 34, 29.8%), comprehensive school (n = 18,

Table 4. Relationships Between Background Variables and Pain Variables.

	Quality and frequency of the assessment of the acute pain	Patients' self-assessment of pain	Assessment of acute pain intensity at rest, and during movement, and intensity before and after administration of analgesics
Age[1] (years)	0.701	0.902	0.400
Under 24			
25–39			
40–58			
60 and older			
Gender[3]	0.210	**0.022****	0.170
Female		1.9 [2]	
Male		2.3 [2]	
Marital Status[1]	0.375	0.412	0.604
Educational level[1]	0.366	0.108	0.832
Situation in working life[1]	0.066	0.109	0.132

Note: *p-value < 0.1, **p-value < 0.05 considered significant and bolded.
[1] H = Kruskal-Wallis test value, [2] Mean, [3] U = Mann- Whitney U -test value

15.8%) or college (n = 14, 12.3%) degrees and a few had Bachelor's degrees (n = 9, 7.9%). In addition, more than half (n = 60, 52.6%) of the respondents were employees in the working life. None of the patients had long-term painful illnesses. The average score based on the NRS to assess the intensity of pain perceived by the patients was 5.46 (standard deviation [SD] = 1.9) (Table 1).

The Quality and Frequency of Assessment of Acute Pain

A vast majority 80% (n = 91) of patients reported that nurses asked the type of their acute pain and 89% (n = 102) of the patients stated that nurses also asked the location of their acute pain. The majority of the patients (n = 95, 83%) reported that ED nurses assessed their acute pain upon entering the ED. Nearly 63% (n = 62) reported that their acute pain was evaluated upon leaving the ED. Seventy-eight percent (n = 89) of the patients reported that their pain were assessed several times during their stay in the ED. Most of the patients (n = 94, 91.2%) reported that assessing their pain intensity was challenging. (Table 2).

The majority of the patients (n = 80, 70.2%) reported that nurses assessed their pain by using a pain scale. Nearly 54% (n = 62) of the patients reported that their acute pain was assessed by using the VRS, 28% (n = 32) of the patients reported that their pain was assessed by using the NRS, and 9.7% (n = 11) of the patients reported that nurses assessed pain with the VAS (Table 2).

Patients' Self-Assessment of Pain

Nearly 79% (n = 90) of patients stated that their self-assessment of pain was the most reliable method of assessing acute pain intensity. The majority of ED patients (n = 69, 79%) reported that their pain self-assessment was as valid as the assessment made by nurses or doctors. Over 77% (n = 88) of ED patients were pleased with the nurses' pain assessments. Approximately 79% (n = 90) of the ED patients felt that ED nurses adequately assessed their acute pain (Table 2).

Assessment of Acute Pain Intensity at Rest, and During Movement, and Intensity Before and After Administration of Analgesics

The majority of the ED pain patients, 76% (n = 87), reported that nurses were inquired about intensity of pain at rest, whereas nearly 52% (n = 59) patients reported that pain intensity was assessed during movement. Furthermore, 64% (n = 73) of the patients reported that ED nurses asked the intensity of their pain before administration of analgesics, and 66% (n = 76) patients stated that ED nurses asked the intensity of their pain after analgesics were administered (Table 2).

Relationships Between Background Variables and Pain Variables

The relationships between the background variables and acute pain sum variables are presented in Table 4. One of the sum variables was 'the quality and frequency of the assessment of the acute pain'. Neither age (H- test, p = 0.6), gender (U- test, p = 0.2), marital status (H- test, p = 0.4), education level (H- test, p = 0.4), nor situation in working life (H- test, p = 0.066) were not statistically significantly related to the quality and frequency of pain assessment (Table 4). Assessment of quality and frequency of pain intensity was a clinically significant result (H- test, p = 0.066).

One of the sum variables was 'patients' self-assessment of pain'. Patients' gender had a statistically significant relationship with the self-assessment of pain (U- test, p = 0.022). Women were more satisfied with the self-assessment of pain than men. Women also relied more on their own pain assessment and ED nurses' pain assessments than men. Neither age (H- test, p = 0.9), marital status (H- test, p = 0.4), education level (H- test, p = 0.1), nor situation in working life (H- test, p = 0.1) were not statistically significant with patients' self-assessment of pain (Table 4).

One of the sum variables was 'assessment of acute pain intensity at rest, and during movement, and intensity before and after administration of analgesics'. Neither age (H- test, p = 0.4), gender (U- test, p = 0.2), marital status (H- test, p = 0.6), education level (H- test, p = 0.8), nor situation in

working life (H- test, $p = 0.1$) had a statistically significant relationship with the observation of pain through facial expressions and gestures (Table 4).

Discussion

Discussion of Findings

This study describes and explains patients' perceptions of acute pain assessments in the ED. This study reveals that patients do not receive optimal assessments of acute pain in the ED. This study provided optimistic data suggesting that ED nurses asked about the location of patients' acute pain. However, 16% of patients reported that nurses did not ask about the quality of their acute pain. During the pain history, it is necessary to understand the location and quality of pain, and, as well as alleviating factors, and the impact of pain on function and quality of life (6). The assessment of quality and frequency of pain intensity were clinically significant results.

The majority of the patients reported that ED nurses assessed their acute pain upon arrival to the ED, but over 37% reported that their acute pain were not evaluated upon leaving the ED. Twenty- four percent of patients were not asked about their pain several times while being treated in the ED. A similar result was found in the study by Dale & Bjornsen, in which the emergency nurses did not ask enough regarding the patients' acute pain (33). According to EUSEM guidelines (6), reassessment of pain is important thing, and should take place at a frequency guided by the patients' pain severity (6,34). In addition, pain assessment in the ED should take place every 15 min (6). These results indicate that ED nurses should assess patients' acute pain more regularly.

This study showed that ED nurses used three common pain scales when assessing patient acute pain: the VRS, NRS and VAS. The VRS was the most used pain scale, and nearly 54% of patients reported that their acute pain was assessed with this scale. This is consistent with the Acute Pain Management Guidelines (6), in which the VRS is the most used type of categorical pain scale (6). Previous studies have shown that the NRS results in higher pain measurements than the VAS (5,21). This study produced the same type of results. Previous studies have indicated that the NRS is easier to use than the VAS. The need for the patient to mark the line- can make the VAS impractical to use an emergency situation (5,21). Many protocols directed by pain scales in pain management in the ED setting. However, recent studies have shown that, pain scoring may not accurately reflect patient experience. Pain scoring evaluates pain intensity, which is only one component of pain experience (25).

In this study, most patients stated that their self-assessment of pain was the most reliable method of assessing acute pain intensity. This result consistent with the National Institutes of Health, which states that patient self-reporting is the most reliable indicator of the existence and intensity of pain (2). Also, most patients ($n = 69$) reported that their pain self-assessment was as valid as the assessment made by nurses or doctors. Overall, in this study, 24% of patients were not pleased with nurses' pain assessment in the ED. Previous studies have shown that patient participation in decision making regarding their pain assessment and management leads to better pain relief and patient satisfaction (2,4).

This study showed that, patient gender was significantly related to the patient self-assessment of pain. Females were more satisfied with pain self-assessment than males. Females also relied more on their own and ED nurse pain assessment than males. Previous studies have also shown differences with gender; women are at a higher risk for under-assessment of their pain levels than men (3,33). Also, women experience more intense pain and more sensitivity to pain, and one study found that women were less likely than men to receive analgesics (3,33).

In this study, most patients reported that nurses asked about intensity of pain at rest. A previous study has also shown comparable results (34). The finding that only half of the patients reported that ED nurses asked pain intensity during movement is consistent with the Acute Pain Management guidelines (6). Our findings suggested that ED nurses should inquire about patients' pain assessment during movement more often.

As a result of this study, patient pain was assessed prior to pain medication administration and nurses asked the intensity of pain after the analgesics is not line with previous study concerning pain assessment (2). In this study, over 20% of patients stated that ED nurses did not ask the intensity of pain after the analgesic. According to, these results, it is important to understand connection between pain assessment and pain medication, so that we can perform quality pain assessment and pain management.

Limitations

This study has limitations related to the validation of the questionnaire and the hospital unit. The questionnaire was developed for this study by the authors, and it might have had lower reliability than other questionnaires. This may be because it has not been validated. The contents of this questionnaire were based on previous research and current literature.

This study was conducted at a single Centre. While there is no a priori reason to suspect that acute pain assessment at this institution differs significantly from that at other institutions, it is certainly possible that differences exist.

Conclusion

In summary, pain is one of the most common problems of patients who arrive at ED. Despite the existence of guidelines, the assessment and treatment of pain is still inadequate, and it seems there is a lack of appropriate pain assessment in

the ED. Acknowledging those factors that can increase the risk for discrepancies in pain assessment is a necessary first step toward optimizing pain assessment and management in the ED. This study demonstrates how difficult and diverse it is to assess acute pain in the EDs. Patients with acute pain expect and deserve the utmost treatment. Acute pain management should include appropriate assessment together with the patient, and usually, resulting in a direct impact on patient pain management satisfaction.

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Author Contributions

Jenni Hämäläinen: Conceptualization, Methodology, Data curation, Writing Original draft preparation. **Tarja Kvist:** Writing- Reviewing and Editing. **Päivi Kankkunen**: Writing- Reviewing and Editing, Supervision.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical Approval

The University Hospital Ethical Board (an institutional review board, IRB) gave ethical approval (25/2020) for the study. Permissions to conduct the study were obtained from university hospitals. (permission no. HUS/1056/2020). A written informed consent was obtained from each participant.

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Supplemental Material

Supplemental material for this article is available online.

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Appendix 1

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1–2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2–3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	3–5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3–5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	3–4

(continued)

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	Item No	Recommendation	Page No
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	3–6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	3–6
Bias	9	Describe any efforts to address potential sources of bias	10
Study size	10	Explain how the study size was arrived at	3–5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4–7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy (*e*) Describe any sensitivity analyses	4–5
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	5–6
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	5–6
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time *Case-control study*—Report numbers in each exposure category, or summary measures of exposure *Cross-sectional study*—Report numbers of outcome events or summary measures	6–10
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	6–10
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	8–10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	8–10
Generalisability	21	Discuss the generalisability (external validity) of the study results	8–10
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	not applicable

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org