A multicenter randomized control trial evaluating professional practice assessment of patient pain management after simulation training course: Study protocol

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ABSTRACT

Aims: Pain is underestimated and insufficiently treated in Emergency Departments (ED). The primary objective of this multicenter, prospective, observational, and interventional study is to analyze the clinical impact of a simulation-based training for Emergency Nurses on pain assessment and management. Secondary objectives are to measure instructed staff’s satisfaction with the simulation training and to evaluate the progress of participants as well as studying the clinical impact of this course: level of correlation between accuracy of analgesia and level of pain, assessment of patient and caregiver satisfaction.

Design: this study will be undertaken in EDs at two university hospitals (Paris, France: Bichat and Beaujon) with randomly selected experimental and control groups.

Methods: During the first phase, inventories in the EDs of current professional practice will be realized. Then, the control group will have theoretical classes and the experimental group will have both the theoretical class and simulation courses for all the nurses (with simulated patients in trauma pain scenarios). Post course assessment will be established of triage nurses’ and other nurses’ practice changes concerning trauma pain management in EDs. Moreover, this study will include an assessment of the impact on patient and caregiver satisfaction. All patients over 18 years old who are admitted to the ED for a non-vital trauma are included. Exclusion criteria are patients who are admitted by an EMS ambulance.

Clinical implication: this study seeks to demonstrate that the implementation of a theoretical course combined with a simulation session will improve pain management in EDs by Emergency Nurses.

1. Background

Pain is a symptom. Since 1976, the IASP (International Association for the Study of Pain) has defined pain as an “unpleasant sensory and emotional experience associated with present or potential tissue damage, or described in these terms” [1]. Acute pain is differentiated from chronic pain by its sudden onset and short duration [1]. In all circumstances, the physician must strive to relieve patient suffering using appropriate methods as well as by providing moral support [2]. An individual approach to pain management is useful [1]. However, pain management is not only a public health issue, thus a criterion for the quality and evolution of a health system, but a real societal problem. Its management answers a humanistic, ethical, and human dignity objective because of the numerous physical and psychological repercussions [3]. Pain is one of the main symptoms motivating patients to consult in emergency settings [4], and are the leading complaints and the leading sources of hospital admissions and repeat visits [5]. However, in Emergency Departments (ED), it is underestimated and insufficiently treated [6]. Pain is neither redemption, nor par for the course, nor punishment. Its mitigation can play a role in the healing of the ailing person [3]. It should be taken into account as soon as possible, in other words, during patient admission [4]. Assessment and management of pain by a dedicated triage nurse in EDs was recommended by the French Society of Emergency Medicine in 2013 [7]. Analgesia according to an ED’s protocol, once the patient is admitted to the ED, should be based on the intensity of the pain, as estimated on a pain intensity scale [8]. Assessment and management of pain are paramount. Moreover, the symptoms of pain
are integrated into all triage scales used today in the ED such as the «Emergency Severity Index» (ESI) [9], the «Manchester Triage Scale» (MTS) [10,11], the «Canadian Emergency Department Triage and Acuity Scale» (CTAS) [12], the «Classification Infirmière des Malades aux Urgences» (CIMU) [13]. However, pain assessment at triage is conducted infrequently because of insufficient education and needs to be improved [14].

2. Rationale and background of study aims

Usually in our hospitals, patients had a pain assessment at their arrival and many of them have no re-evaluation of that pain level. Consequently, the patient may have had inadequate analgesia in spite of a high level of pain. A training course for nurses is known to improve pain assessment and management, and consequently, to increase patient satisfaction [15]. Secondly, having completed this training, the Evaluation of Professional Practice (EPP) regarding pain management could represent a quality criterion for EDs [16]. When managing or researching pain management, acute pain should be differentiated from chronic pain [1]. Thus, the present study will focus on acute trauma pain.

3. Hypotheses and aim of the study

We speculate that simulation-based education (SBE) will improve the impact of a theoretical course for Emergency Nurses. It will enhance the repeated assessment and management of traumatized patients’ acute pain in the ED as soon as they are admitted. We also speculate that immediate pain management by a triage nurse will be beneficial when directing these patients directly to the radiology department before they receive medical attention from the emergency teams. This should improve patient and caregiver satisfaction. The primary objective is to analyze the clinical impact of an SBE for Emergency Nurses on pain assessment and management. Secondary objectives are:

- To measure instructed staff's satisfaction with the simulation training
- To evaluate the progress made during this training
- To correlate adequateness of analgesia with the level of pain
- To assess patient satisfaction
- To assess caregiver satisfaction

4. Study design

This study is a multicenter, prospective, observational and interventional study. The study is scheduled from October 2018 to June 2019 (Fig. 1). All concerned nurses of the University Hospital of Bichat and Beaujon (in the Paris area) followed a class to manage pain in the triage zone of their Emergency Department. Then, one of the two EDs were randomized by the methodologist in the experimental group (Hospital of Bichat) and the second one in the control group (Hospital of Beaujon). The present study includes three phases:

- 1) Observational step: Assessment of current professional practice and patient satisfaction in both Bichat and Beaujon University Hospitals.
- 2) SBE step: All nurses of the University Hospital of Bichat and Beaujon (in the Paris area) followed a theoretical class to manage pain in the triage zone of their Emergency Department with pre and post-test evaluations of knowledge. Then, only in the experimental group, nurses will follow a SBE. Nurses who do not validate the training will have to repeat it, and deployment to the triage area is thus withheld, until validation.
- 3) Interventional step: Post course assessment of triage nurses' and other nurses’ practice changes in trauma pain management. Assessment of the impact on patient and caregiver satisfaction. After this step, for ethical reasons, nurses of the control group will follow the simulation sessions.
5. Methods and analysis

5.1. Setting and participants

This multicenter clinical trial is undertaken in the Emergency Department of the University Hospitals of Bichat and Beaujon. Strict criteria are applied to enroll the patients and the nurses in this study:

Inclusion criteria of the patients
- Patients over 18 years of age
- Admission to the ED for minor trauma, i.e., a non-vital trauma and non-severe trauma (hip fracture, open fractures)
- Study participation agreement

Exclusion criteria of the patients
- Patient unable to express free and rational judgment
- Patient not speaking French
- Patient admitted to the ED by an EMS ambulance. In France, there is an Emergency Physician and an Emergency Nurse that manage pre-hospital emergencies in the ambulance.

Inclusion criteria for the nurses
- Nurses who have more than six months experience in the ED University Hospital of Beaujon or Bichat. The goal is for nurses to know the ED protocols and to have worked in all areas of ED.

Exclusion criteria for the nurses
- Nurses who have not yet validated the training

5.2. Intervention

Firstly, professional practice and patient satisfaction prior to the SBE of the Emergency Nurses are actually carried out over a period of 4 months (from October 2018 to January 2019). In the University Hospital of Bichat and Beaujon, triage nurses have a protocol for directing patients with non-life-threatening limb trauma directly to the radiology department before they receive further medical attention from the emergency team. They have to manage the pain in the triage zone before having the X-ray done. The simulation course will be performed during February 2019 and will train Emergency Nurses on their organizational role and on the protocols related to the management of patient pain. This training will consist of a theoretical course lasting ½ a day for both groups and an additional practical simulation training lasting one day for the experimental group. They will be given instructions for performing all available analgesia techniques like the use of nitrous oxide and self-administered methoxyflurane inhalers (Penthrox) [17]. Then, they will participate in high-fidelity simulations (HFS) with simulated patients to manage trauma pain. The immersive simulation session scenario is that of a left shoulder dislocation in a 25-year-old male requiring pain assessment and management by the nurse before asking for X-rays and the call for an Emergency Physician to begin dislocation assessment and treatment. The scenario will be preprogrammed to be identical for all participants in terms of layout and objectives. Two independent raters from the Simulation Laboratory of our Faculty of Medicine will evaluate the performance and duration of the pain assessment. A self-administered satisfaction survey will be completed by the trainees to analyze the first two levels of the Kirkpatrick pyramid [18]. A pre- and post-test evaluation of knowledge and skills at the beginning and at the end of the training courses will be carried out to assess the second level of the Kirkpatrick pyramid. Then, changes in professional practices of the Emergency Nurses as well as the clinical impact of this course will be assessed to respectively analyze the third and fourth levels of the Kirkpatrick pyramid. Changes in pain management by the nurses in the triage zone and during the stay of the patients in the ED will be analyzed (from March 2019 to June 2019).

5.3. Study outcomes

Primary end point
- Use of a self-assessment scale for pain using a numeric rating scale (NRS). Use of NRS has been validated in EDs [19],
- Pain assessment duration (minutes).
- Secondary end points
  - Training
  - Measurement of the delta between pre and post test results after nurses' training,
  - Performance in simulation will be assessed, using the TAPAS scale, a valid and reliable scale (Cronbach alpha = 0.745, Intra-class coefficient = 0.862) [20],
  - Measurement of satisfaction by self-assessment survey (score of 0–10).
  - Care
  - Time to initiate analgesic treatment (time in minutes from patient arrival to delivery of treatment),
  - Use of analgesics in accordance with ED protocols,
  - Satisfaction of patients through a self-assessment survey (score of 0–10),
  - Satisfaction of caregivers through a self-assessment survey (score of 0–10).

Assessment tools
- Participant satisfaction survey for pain management training (Appendix 2)
- Anonymous written test at the beginning and at the end of training
- NRS for pain assessment, self-ranked on a 0–10 scale: 0 for none up to 10 for maximum pain (Appendix 3)
- Analgesia protocol in accordance with WHO and ANSM (the French National Agency for the Safety of Medicines and Health Products) recommendations [21]:
  - NRS score ≤ 3: PARACETAMOL
  - 4 < NRS score ≤ 7: PARACETAMOL and CODEINE
  - NRS score > 7: MORPHINE
- Association of self-administered methoxyflurane inhaler (Penthrox®) or nitrous oxide in moderate to severe trauma pain
- Patient satisfaction survey (Appendix 4)
- Caregiver satisfaction survey (Appendix 5)

5.4. Sample size and calculation

The website BiostaTGV of the University of Pierre-Marie Curie [22] was used for the calculation of the necessary cohort sizes. The sample size of patients for demonstrating the difference of pain management was based on a preliminary study that found a decrease in NRS after treatment from 4 to 3/10 with a standard deviation of 3 after the simulation course. Based on a comparison between pain management before and after simulation, an alpha risk of 0.05, a statistical power of 0.95, and using bilateral tests, we estimated that we would need 468 patients. Consequently, we hypothesized that 500 patients would be adequate, i.e. 250 patients before and after training in each center, to demonstrate a statistically significant difference in the improvement of pain management. Given our goal for patient satisfaction, we estimated obtaining a 10% improvement, the number of subjects required would be 970, i.e. 485 patients before and after training in each center (Fig. 2).

On a daily average, 320 patients are admitted to the EDs of the two University Hospitals of BICHAT and BEAUJON, of which about 40% come for trauma, i.e. 128 eligible patients. Because of an estimated non-inclusion rate of 50% and refusal rate of 50%, a study carried out four months before and four months after the SBE would allow the evaluation of professional practices. Moreover, it could provide evidence of significant improvement in trauma pain management after nursing staff training.

5.5. Recruitment

All patients admitted for non-vital trauma into the Emergency Department of the University Hospitals of BICHAT and BEAUJON (Paris area), are screened by the attending triage nurses. They are enrolled if they meet all of the inclusion criteria and none of the exclusion criteria.

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5.6. Data collection, confidentiality, storage, and archiving of study documents

Independent clinical research nurses are available at each participating hospital to help with running the study and with data collection. The data of the patients admitted to the EDs will be extracted from the ED’s electronic medical record system Urquial database (authorized by the National Commission on Informatics and Liberty). The data collected will be the following:

- Administrative data: date of birth, registration number, sex, date of admission to the ED, mode of arrival, time of arrival, triage category, time of first analgesic treatment (given by the nurse).
- Medical data: Evaluation of pain at arrival, before radiological assessment, during the handling of the patient in the radiology department, during the examination by the emergency physician, and at the exit of the ED. Furthermore, the analgesic treatment received will be recorded.

Study documents will be de-identified and stored for 15 years, as per the French protocol for non-clinical trial notification (CTN) interventional studies. Data will be electronically stored on two step password-protected computers that will be stored in a locked, secure office. Final data sets will only be accessed by the principal investigator (AG) and the statisticians.

5.7. Statistics

Anonymized data will be tabulated using Excel 2016 (Microsoft®). Statistical analysis will be performed using Statview® software version 4.5 (SAS Institute Inc., Cary, NC). The scores will be standardized on a 0 to 10 scale (assessment test for the course, pain scale, satisfaction scales). Ordinal and continuous variables (age, years of professional experience, duration of drug use, etc.) will be described by mean and standard deviation (or median and interquartile range). The categorical variables (gender, trauma categories, education level, analgesic treatment, number of doses used for the self-administered methoxyflurane inhaler, etc.) will be summarized by the numerical value and the corresponding percentage for each of the modalities. The normality of the distribution for each parameter will be investigated using the Kolmogorov-Smirnov test. Ordinal and continuous variables will be compared with a series of pairwise comparisons, before and after training, using a Student t-test or a Mann-Whitney U non-parametric test if necessary. The overall variation of NRS over time will be analyzed with ANOVA for repeated measures or with the Kruskal-Wallis nonparametric test. Comparison of the categorical variables will use a Chi2 test. Finally, rater reliability for level of agreement with recommendations on analgesia protocol will use Cohen’s Kappa statistic. Pearson’s correlation analysis will be performed between the post-test scores, simulation performance scores, and the clinical pain assessment. A p-value < 0.05 will be considered significant.

6. Ethics

The clinical trial will be carried out according to the principles of the Declaration of Helsinki. It was registered by the Thai Clinical Trial Registry (a WHO-approved primary registry) under the number TCTR20170910001. It was approved by the local ethics committee of the University Hospital of Bichat and considered as an evaluation of the professional practices by the ANSM and registered under the number 2017-A01073-50.

For the patients’ information, we have planned:

- To place a poster, in the emergency room for the duration of the study period, explaining that a study on the management of pain is under way and specifying the objectives of the survey element,
- To inform each patient admitted during the study period of the terms and objectives of this study,
- To provide an information leaflet to each included patient (Appendix 1),
- To obtain the free and informed consent of all included patients.
7. Discussion

Acute pain affects most patients admitted to emergency departments, but pain relief in this setting remains insufficient [23]. In spite of laws, recommendations, and ethical and moral obligations, only a third of patients receive analgesia during initial triage and rates of optimal analgesia are very low [24]. Evaluation of pain followed by its treatment at the time of patient triage accelerates the administration of analgesia. The assessment of pain intensity by a validated pain scale is a critical initial step, and a patient’s self-reporting is widely considered as the key to effective pain management [23]. Pain management protocols have benefits but need to be regularly monitored to optimize pain management in the ED [25] and in the EMS [26]. In EDs in which nurses are allowed to administer analgesia, implementation of revised guidelines has significantly increased analgesia administration. Despite ED pain management training, the proportion of patients who receive analgesia remains low [27]. A recent study found that a modern approach, including e-learning and simulation, lead to increased knowledge of acute pain management. The transfer of this new knowledge into clinical practice could not be demonstrated calling for further studies to show how this increased knowledge is transferred to clinical practice [28]. We speculate that a combination of a written protocol given to each patient for pain assessment and simulation-based education would improve pain management in EDs. The addition of a simulation training courses for the assessment and management of pain to a theoretical course will improve the evaluation and, especially, the re-evaluation of the pain felt by patients. It should improve patients’ analgesia as soon as they arrive in the ED by reducing the time before an analgesic treatment is administered. Consequently, we hypothesize that an improvement will be shown in the satisfaction of both the patients and the caregivers. Moreover, the implementation of the self-administered methoxyflurane inhaler (Penthrox®) under the supervision of the trained triage nurses should offer the opportunity to reinforce analgesic efficiency. In association with other pain treatments, it could constitute easy and feasible multimodal pain management to optimize pain relief [24]. Moreover, use of multimodal analgesia protocols by trained Emergency Nurses would allow pain management before the first contact between the patient and the Emergency Physician. In the context of non-severe trauma, protocolized management of pain with methoxyflurane inhalers (Penthrox®) would offer additional opportunities to perform an X-ray prior to seeing the Emergency Physician. These changes in professional practices would impact patient management and improve the functioning of the ED. Kirkpatrick’s evaluation framework can be used to determine the effectiveness of medical training courses [29]. Few studies of simulations evaluate the four levels of the Kirkpatrick pyramid. Usually, only the first and second levels are assessed [18]. The first level assesses how trainees react to the training. The second level measures the improvement in knowledge, skills and attitudes after the simulation course. Some studies evaluate the third level which is the change in practices and behavior by self-assessment. It is usually assessed by self-administered surveys. At this level, few studies analyze how trainees apply the information to assess concrete changes. Studies that analyze the fourth level in the medical field, i.e. the impact of the SBE on the patient, are rarer still [30,31]. In this study, our aim will be to assess modifications of professional practices and their impact on the patients and the ED. Frequency of pain assessment will be assessed from arrival to exit of the ED. Additionally, levels of pain will be assessed during ED discharge, before and after the SBE. We hypothesize that there will be an increase of analgesic use stemming from the increase of trauma pain assessments. Consequently, levels of pain at the exit of the ED should be lower after the SBE with higher satisfaction of patients and caregivers.

7.1. Limitations

We are aware of several limitations of this protocol. It will focus only on acute pain in minor trauma. As suggested in the literature, acute pain should be differentiated from chronic pain in research on pain management [1]. Consequently, other studies will be necessary to know if it is applicable to chronic pain. Another limitation is that the protocol is based on self-reported pain intensity since it is the gold standard for identifying pain [32]. It is not applicable to patients who were not able to self-report pain and who required pain management using observational pain assessment tools [32]. Finally, another limitation is related to external validity. The present study is ideally relevant to this European hospital or other developed countries with similar ED system, since other particular countries may not allow the dispensation of pain medication so readily.

8. Conclusion

Pain is one of the main symptoms motivating patients to consult in the ED. Despite relevant laws, recommendations, and ethical and moral obligations, pain management is not presently optimal. It should be applied from the moment the patient arrives. The goal of this multicenter prospective study protocol will be to demonstrate that the implementation of a theoretical course combined with a simulation session will improve the pain management in EDs by Emergency Nurses. It should positively impact patient satisfaction and ED functioning. We are planning to integrate this training into standard ED nurse on-site education regimen.

Competing interests

The authors declare that they have no competing interests.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2019.100331.

Appendix 1. Patients’ information

Dear Sir or Madam,
A study on the evaluation and the treatment of pain management is being conducted in the Emergency Departments of the BICHAT-Claude-Bernard and the BEAUJON University Hospitals. We have joined it to a satisfaction survey on the quality of health care concerning pain relief, according to the international recommendations of the World Health Organization (WHO).

This study is focused on the improvement of the quality of care in our emergency department.

The procedure for pain relief is as follows:

- Evaluation of the intensity of the pain upon your arrival by the triage nurse
- Analgesic treatment administered by the triage nurse, according to the intensity of your pain and our protocol for pain relief
- A follow up of the pain throughout your stay in our department.
In this survey, the following data are collected:

- Sociodemographic categories
- Medical administrative information
- Patient satisfaction.

The processing of all these data will be strictly confidential and anonymous.

The Emergency Department of Bichat has specific software intended for patient management. The registered information is reserved to the emergency department and can only be communicated to the following addresses:

- Dr Aïham Daniel GHAZALI, main investigator, Emergency Department of Bichat hospital
- Pr Enrique CASALINO, Department Head of the Emergency Department of Beaujon hospital

Dr GHAZALI is at your disposal to provide any information which you might consider useful.

According to articles 39 and following ones of the law N 78–17 of January 6th, 1978 modified in 2004 relative to computing, to files, and to freedoms, every person can obtain the communication and, where necessary, rectification or deletion of his/her corresponding information, by contacting Dr Daniel Ghazali (Bichat hospital, 46 rue Henri Huchard, 75018 Paris).

Appendix 2. Nurse satisfaction after the simulation course for pain management

| Question                                                                 | I totally/strongly disagree (1) | I disagree (2) | I don’t know (3) | I agree (4) | I totally/strongly agree (5) |
|-------------------------------------------------------------------------|----------------------------------|---------------|-----------------|------------|-------------------------------|
| 1. I’m satisfied with the training “Pain care in the ED”                |                                  |               |                 |            |                               |
| 2. I’m satisfied with the theoretical training                          |                                  |               |                 |            |                               |
| 3. I’m satisfied with the practical training by simulation              |                                  |               |                 |            |                               |
| 4. This training is essential to my practice                            |                                  |               |                 |            |                               |
| 5. The simulations sessions were realistic                              |                                  |               |                 |            |                               |
| 6. I acquired theoretical knowledge on the pain care in the ED          |                                  |               |                 |            |                               |
| 7. I acquired practical knowledge on the pain care in the A&E department|                                  |               |                 |            |                               |
| 8. I acquired self-confidence in pain care in the ED                    |                                  |               |                 |            |                               |
| 9. This training is going to change my professional practice for pain assessment |                                  |               |                 |            |                               |
| 10. This training is going to change my professional practice for pain management |                                  |               |                 |            |                               |
| 11. Repetition of the simulations is necessary after this training      |                                  |               |                 |            |                               |
| 12. This type of training should be carried out during the initial training course |                                  |               |                 |            |                               |
| 13. This type of training should not be limited to pain management      |                                  |               |                 |            |                               |

What quality score between 0 and 10 (0 = none, 10 = maximum) would you assign to this training?

Do you have any suggestions for the training session? (Write below)
Appendix 3. Pain assessment and management

Patient ID tag

Date of admission: Time of admission: .......H........

Trauma category:  □ Fracture  □ Dislocation  □ Sprain  □ Wound

□ Other: ..............................................................

Pain scale (patient input)

| T0: (arrival) | T1: (triage zone exit) | T2: (during imaging procedure) | T3: (1st medical personnel interaction) | T4: (discharge) |
|---------------|------------------------|-------------------------------|----------------------------------------|---------------|

[Graphical representation of the pain scale for each time point]
**Appendix 4. Patients satisfaction survey**

**Dear Sir or Madam,**

You are at the Emergency Department (ED) of the University Hospital of Bichat and Beaujon. We kindly ask you to take a few minutes to answer this survey. This will allow us to improve our procedures and to continuously improve our quality of care.

Thank you.

Pr E. Casalino, Dr D. A. Ghazali

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**Analgesic treatment:**

| Area where analgesic administrated: | □ Triage | □ Medical bay |
|-------------------------------------|----------|---------------|
| Level 1                             | □ Paracetamol (Acetaminophen) |
| Level 2                             | □ Paracetamol codeine          |
| Level 3                             | □ Oramorph*, □ Actiskenan* 10 mg: 1 cp |

**Time of analgesic administration:** .........H.......

□ Pentroxx*

| Number of inhalers/vials administered: | □ 1 | □ 2 |
|----------------------------------------|-----|-----|
| Duration of patient Pentroxx* use:    | □ <15 min  | □ 15-30 min  | □ 30-90 min |
| Number of doses used:                 |     |     |

□ Nitrous oxyde

| Duration of use: | □ <15 min | □ >15 min |
|------------------|-----------|-----------|
Appendix 5. Nurse satisfaction in pain management

Could you, please, give a score from 0 (not at all) to 10 (totally agree) to all of the following questions:
### Suggestions to improve patient pain management:

| N° | Question                                                                 | Score |
|----|---------------------------------------------------------------------------|-------|
| 1  | Are you satisfied with your overall patient care?                         |       |
| 2  | Are you satisfied with your patient's pain management?                   |       |
| 3  | Do you feel stressed by the level of pain experienced by the patient?    |       |
| 4  | Have you met your patient's expectation in terms of analgesia?            |       |
| 5  | Do you think the time frame for the introduction of analgesia is satisfactory? |       |
| 6  | The treatment initiated seems effective to you at 5mn                     |       |
| 7  | The treatment initiated seems effective to you at 15mn                    |       |
| 8  | The treatment initiated seems sufficient to you                           |       |

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