

Planning Development Level of Evidence Pain Management in Pre-hospital Emergency Department: A Systematic Review

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Abstract

Introduction: Regarding pre-hospital pain management focus on the emergency department, safety of analgesics used is one of the concerned areas to be developed clearly. However, the current level of evidence in pre-hospital pain management of injured patients, focusing on the safety and effect of pre-hospital analgesia has not been explored. The aim of this study was to analyze the level of evidence in pre-hospital pain management of injured patients, focusing on the safety and effect of pre-hospital analgesia.

Methods: A systematic review was performed in this study with inclusion criteria adult-elderly injured patients in pre-hospital setting and used analgesic agents. Articles were sourced from electronic database Scopus, PubMed, Science Direct, Springer Link and ProQuest, which were searched to identify all the relevant articles published over the last five years in English. Fifteen studies were included are qualified as articles assessment with Preferred Reporting Items for Systematic Reviews and Meta-Analyses checklist.

Results: Nine studies were Randomized Control Trial, two studies cross-sectional and retrospective, and one study prospective descriptive and cohort. The result showed that many types of analgesic are used or planned in emergency areas, such as morphine, ketamine, fentanyl, NSAID with different route intravenous, intramuscular and subcutaneous with safety and monitoring continuously by healthcare professionals.

Conclusion: The use of pre-hospital analgesia for injured patient in pre-hospital setting is commonly used by health workers according to pain management standard and guidelines; planning developments are needed for safety and management as a concern for focus on quality of pain management status.

Keywords

analgesia; emergency; pain management; pre-hospital

INTRODUCTION

Pain control is a good example of how the management of pre-hospital care has evolved in the past years. Early pain control is one of general value. In the short condition, use of analgesia improves patients comfort,

assessment, or physiology (Riyapan & Chantanakomes, 2020). In the long term, pain control decreases the incidence of post-traumatic stress. However, acute pain in trauma patients in emergency department (ED) is still undertreated; pre-hospital medical providers administer analgesic agents at

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inappropriately low rates, and the delays until the initiation of pain therapy can be substantial. The use of regional analgesia in emergency departments has increased recently. Recent findings about various techniques and standards according to new guide from association of pain management suggest that the technique of doctors, nurses and others health workers need to improve safety and reduce pain and injury-related complications without increasing time management (William, 2018). The emergency center is a service center that specializes in emergency services, both patients come by themselves or by ambulance with life-threatening conditions that need service quickly, such as heart attack, stroke, malignant hypertension, severe dehydration, and life-threatening conditions due to accidents or disasters (Yousefifard & Askarian-Amiri, 2019). System emergency services include the handling of emergencies at the scene, during transport and in healthcare facilities. The systems above are interrelated, and aid performed at the scene will affect the outcome of the handling done in healthcare facilities. Handling of emergencies is divided into three parts, namely the pre-hospital, intra-hospital and post-hospital.

The purpose of the pre-hospital service is to minimize the systemic damage and in managing the life threatening condition. Most fatal injuries can be prevented or reduce the severity by performing pre-hospital service of adequately. Services pre-hospital cannot function alone, but are integrated among stakeholders. Pre-hospital system is designed to provide emergency services with secure and effective access to the healthcare system. Various barriers to pre-hospital pain management such as lack of knowledge, pain assessment challenges, language barriers, organizational culture, pain underestimation and practitioners' beliefs and attitudes have been highlighted.

Current guidelines and reviews of pre-hospital emergency care for pain management refer to evidence found in adult and can develop a good standard for other studies or from studies performed in EDs. The aim of this review was to analyze the current level of evidence (LOE) in pre-hospital pain management of injured patients, focusing on the safety and effect of pre-hospital analgesia.

MATERIALS AND METHODS

Study Design and Search Strategy

Systematic review design was reviewed from eligible full text articles. The researchers conducted a comprehensive search of electronic databases. Before searching for articles or journals, we used keywords and Boolean operators (AND OR AND NOT). The keywords in this systematic review are in accordance with the Medical Subject Heading (MeSH) guidelines are "analgesia" AND "emergency" AND "pre-hospital" AND "pain management" and were obtained with advice of an experienced researcher in the field.

Search Strategy

Search strategy in this study uses electronic journal databases including Scopus, PubMed, Science Direct, Springer Link and ProQuest which were searched for articles in the English language from 2015 to 2020. The next step after the articles found with the suitable criteria, is for them to be collected to analyze and form the articles according to the specified inclusion and exclusion criteria. Inclusion criteria for this systematic review are (1) adult-elderly patients, (2) injured patients in Emergency Department and used analgesic agents in the pre-hospital setting, (3) patients who are conscious and cooperative. Exclusion criteria in this systematic review are (1) patients experiencing complications (stroke, heart, kidney), and (2) patients who have dementia and aphasia (impairment in speech). The article search process was carried out in June until July 2020. The article search used keywords determined by the researchers and limited the inclusion and exclusion criteria. The data obtained were then selected one by one by the researchers to determine the suitability of the articles desired by the researchers and to delete the same articles or those that do not fit the criteria. After getting the articles according to the researchers, the articles were analyzed one by one and grouped to get the results. The next step was to discuss based on the points obtained from the selection results.

Selection Criteria

Selection criteria in a study must suitable with the subject area from guidelines and protocols concerning pre-hospital pain management, published as article journals or released in valid organizations' websites with relevant electronic databases included that consist of DOI number and ISSN in each journal or article.

Data Collection

The data collected from databases were saved in Mendeley to help connect with

automatic references. After reviewing the full text of these guidelines, data were filed in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist. Recorded data in the checklist consisted of title, year of publication, studied medications, study design, population and outcomes of study.

Quality Assessment of The Articles

Quality assessment of the articles was performed using *Joanna Briggs Institute (JBI)* guideline in order to determine the agreement and fulfilment of the criteria suitable for type of study.

Table 1. Quality assessment of article selection used *Joanna Briggs Institute (JBI)* guideline

| No | Author, Year | Question | | | | | | | | | | | | | Result |
|---|---------------------------------|----------|---|---|---|---|---|---|---|---|----|----|----|----------------|------------------|
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | |
| 1. | (Friesgaard & Riddervold, 2018) | √ | √ | √ | | √ | √ | √ | √ | √ | √ | √ | √ | √ | 12/13 (92.3%) |
| 2. | (Jones & Evans, 2019) | √ | √ | √ | | √ | √ | √ | | √ | √ | √ | √ | √ | 11/13 (84.6%) |
| 3 | (Fabbri & Ruggiano, 2020) | √ | √ | √ | √ | | | √ | √ | √ | √ | √ | √ | √ | 11/13 (84.6%) |
| 4. | (Jaeger & Dudley, 2017) | √ | √ | √ | | | √ | √ | | √ | √ | √ | √ | √ | 10/13 (76.9%) |
| 5. | (Wennberg & Norlin, 2019) | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | 13/13 (100%) |
| 6. | (Weldon & Ariano, 2016) | √ | √ | √ | √ | | √ | √ | √ | √ | √ | √ | √ | √ | 12/13 (92.3%) |
| 7. | (Andolfatto & Innes, 2019) | √ | √ | √ | √ | √ | √ | √ | √ | | | √ | √ | √ | 11/13 (84.6%) |
| 8. | (Oberkircher & Schubert, 2016) | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | 13/13 (100%) |
| 9. | (Pierik & Ijzerman, 2015) | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | 13/13 (100%) |
| JBI Cross-sectional study (Eight Question) | | | | | | | | | | | | | | | |
| 10. | (Lourens & Parker, 2020) | √ | √ | √ | √ | | √ | √ | √ | | | | | 7/8 (87.6%) | |
| 11. | (Siriwardena & Asghar, 2019) | √ | √ | √ | √ | √ | | √ | √ | | | | | 7/8 (87.6%) | |
| JBI Cohort (Eleven Question) | | | | | | | | | | | | | | | |
| 12. | (Scholten & Berben, 2015) | √ | √ | √ | | √ | √ | √ | √ | √ | √ | √ | | | 12/13 (92.3%) |
| JBI Descriptive or case series (Ten Question) | | | | | | | | | | | | | | | |
| 13. | (Vincent-Lambert & Kock, 2015) | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | | | 8/8 (100%) |
| 14. | (Hewes & Dai, 2018) | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | | | 8/8 (100%) |
| 15. | (Tanguay & Lebon, 2020) | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | | | 8/8 (100%) |

(Joanna Briggs Institute Case Series, 2017; Joanna Briggs Institute Cohort, 2017; Joanna Briggs Institute CrosSec, 2017)

There was four types of study in this systematic review, nine were Randomized Control Trials (RCT) JBI with thirteen question, two cross-sectional JBI with eight questions, one cohort JBI with eleven questions and three descriptive or case series JBI with ten questions. From fifteen studies in Table I, It shows the final result from the Joana Briggs Institute Checklist (JBI Checklist) is more than fifty percent cut off value (> 50%), so it concludes that all articles were eligible and passed the quality and standard to be reviewed.

Search Outcome

Literature search resulted in 313 articles (80 from Scopus, 20 from ProQuest and 98

from PubMed, 53 from Springer Link 62 from Science Direct). After reviewing the abstract for relevance and matching to inclusion criteria, 50 articles were selected for full text review. There were 25 full text articles excluded for several reasons such as the suitability of the sample, the type of research and the health conditions. Articles were excluded (n = 25) for many reasons, first, the study design was a qualitative article (n=10), second the characteristic of sample had comorbidities (n=9) and third was sample having reduced hearing and communication (n=6).

The final selection of 15 articles was chosen for systematic review is shown in Figure 1.

Figure 1. Flow diagram and article selection process

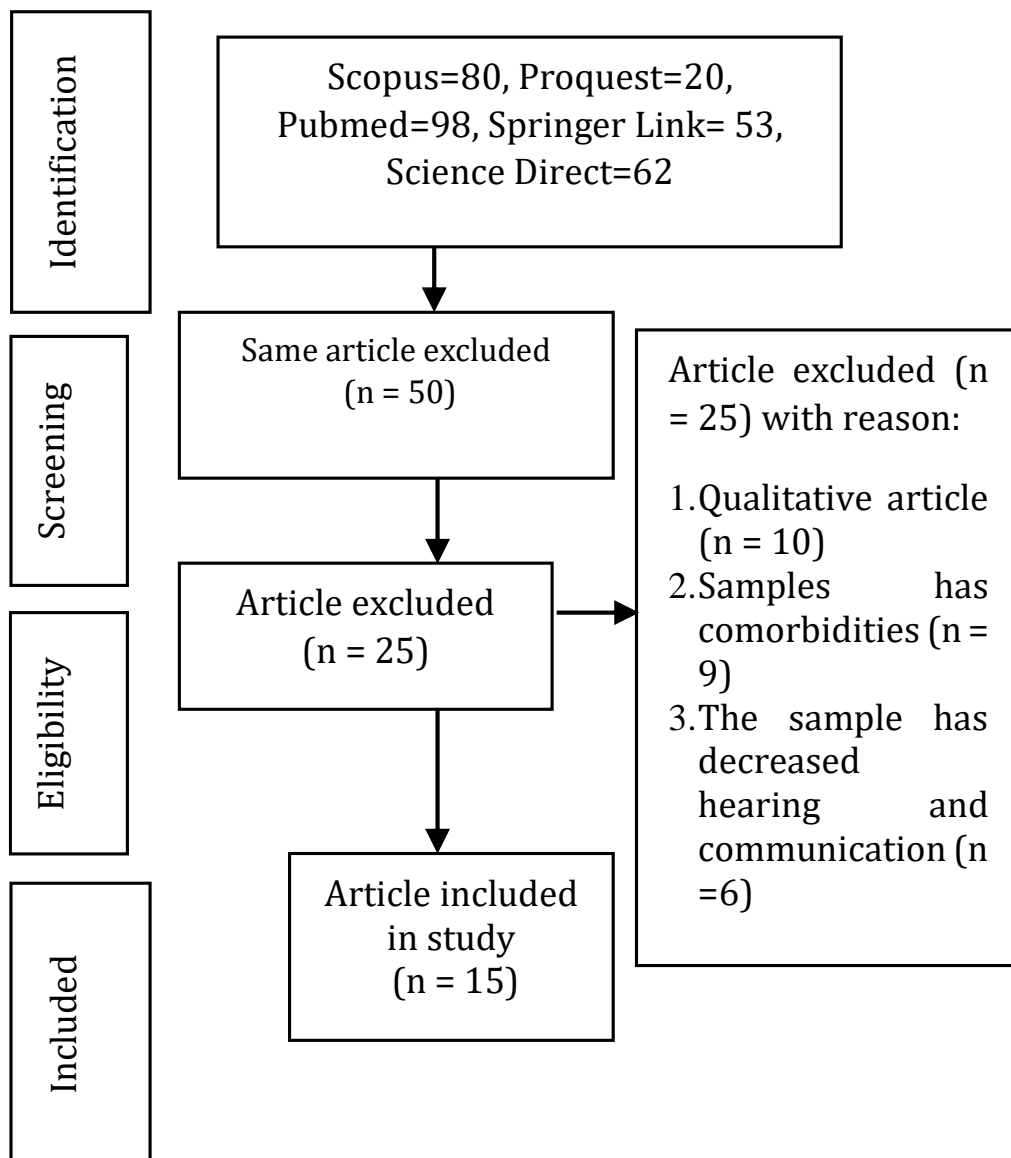


Table 2. Article selection development planning of pain management pre-hospital in emergency department (ED)

| No | Title Author | Study design | Population | Agents of intervention | Outcomes measures |
|----|---|---|-------------------------------|--|---|
| 1. | Acute pain assessment and management in the pre-hospital setting, in the Western Cape, South Africa: a knowledge, attitudes and practices survey (Lourens & Parker, 2020) | Web-based descriptive cross-sectional survey | Responses of 100 participants | Intravenous analgesia (morphine or ketamine), | The primary outcome of the study was knowledge and attitudes regarding pain scores and percentages with secondary outcomes being factors influencing scores, gaps in pain knowledge, attitudes and practices, the proportion of selected barriers and enablers of pain assessment and management in the pre-hospital setting. |
| 2. | Acute pain in the pre-hospital setting: a register-based study of 41.241 patients (Friesgaard & Riddervold, 2018) | RCT | 41,241 patients | Intravenous fentanyl | More attention should be given to the management of acute pain, given the frequency and the broad range of causes in terms of main hospital diagnoses. |
| 3. | Use of morphine sulphate by South African paramedics for pre-hospital pain management (Vincent-Lambert & Kock, 2015) | Prospective descriptive design involving an Internet-based survey | 60 South African respondents | Morphine sulphate | Management of acute pain in pre-hospital |
| 4. | Rapid Analgesia for Pre-hospital hip Disruption (RAPID): findings from a randomized feasibility study (Jones & Evans, 2019) | RCT | 71 patients | Paracetamol, opioids, and Entonox; intravenous morphine (IV) | Satisfaction with care by the ambulance service, measured using a Quality of Care Monitor and Safety |
| 5. | Patient and clinician factors associated with pre-hospital pain treatment and outcomes: cross-sectional study (Siriwardena & Asghar, 2019) | Cross-sectional design | 4773 patients | Intravenous morphine administration | The outcome (dependent) variables used were administration of analgesia by the ambulance clinician and a clinically meaningful reduction in pain of 2 points or more on the Numerical Verbal Pain Score (NVPS) |
| 6. | Role of Inhaled Methoxyflurane in the Management of Acute Trauma Pain (Fabbri & Ruggiano, 2020) | RCT | 300 patients | Inhaled Methoxyflurane | Management of acute, moderate to severe trauma pain in adult patients, including pre-hospital/hostile environments |

| No | Title Author | Study design | Population | Agents of intervention | Outcomes measures |
|-----|--|-----------------------------------|-------------------------------|---|--|
| 7. | Pre-hospital Pain Management: Disparity By Age and Race (Hewes & Dai, 2018) | A retrospective descriptive study | 911 patients | Morphine and fentanyl were the most commonly administered medications to all age groups | To determine if pre-hospital pain management varies according to age of the patient To determine what types of pain medications are administered in the pre-hospital setting |
| 8. | Pain management in trauma patients in (pre)hospital based emergency care: Current practice versus new guideline (Scholten & Berben, 2015) | Cohort study | 1066 electronic patient files | Guideline, paracetamol is the pharmacological treatment of first choice, if necessary with additional use of non-steroidal anti-inflammatory drugs (NSAIDs) or opioids. Fentanyl and morphine can be given for severe to unbearable pain during emergency care. | whether current practice is in compliance with the guideline 'Pain management for trauma patients in the chain of emergency care' from the Netherlands Association for Emergency Nurses (in Dutch), and to evaluate early and initial pain management for adult trauma patients in emergency care. |
| 9. | Intranasal Fentanyl versus Subcutaneous Fentanyl for Pain Management in Pre-hospital Patients with Acute Pain: A Retrospective Analysis (Tanguay & Lebon, 2020) | A Retrospective Analysis | 1440 patients | Administration of fentanyl for acute pain management via invasive routes (intravenous [IV], intramuscular [IM], subcutaneous [SC]) has been studied in both pediatric and adult populations in the pre-hospital setting | Outcome was to retrospectively evaluate and compare the feasibility, effectiveness and safety of intranasal fentanyl (INF) and subcutaneous fentanyl (SCF) administration in patients of an Emergency Medical Services (EMS) system in the Canadian province of Quebec |
| 10. | Impact of an Offline Pain Management Protocol on Pre-hospital Provider Self-efficacy A Randomized Trial (Jaeger & Dudley, 2017) | RCT | 176 patients | Pain management practice use of opioid or use of fentanyl | Impact of pain management protocol (PPP) implementation and pain management education on pre-hospital providers (PHP) SE |
| 11. | Pre-operative pain management with nerve block in patients with hip fractures: a randomized, controlled trial (Wennberg & Norlin, 2019) | RCT | 127 patients | Pre-hospital analgesia and pre-hospital morphine | Improvement in pain management |

| No | Title Author | Study design | Population | Agents of intervention | Outcomes measures |
|-----|---|--------------|--------------|---|---|
| 12. | Comparison of Fentanyl and Morphine in the Pre-hospital Treatment of Ischemic Type Chest Pain (Weldon & Ariano, 2016) | RCT | 187 patients | Either morphine or fentanyl | The primary outcome of the study was incidence of hypotension and the secondary outcome was pain reduction as measured by the visual analog score and numeric rating score. |
| 13. | Pre-hospital Analgesia With Intranasal Ketamine (PAIN-K): A Randomized Double-Blind Trial in Adults (Andolfatto & Innes, 2019) | RCT | 120 patients | Intranasal ketamine versus 41% of placebo | The primary outcome was the proportion of patients with Verbal Numerical Rating Score (VNRS) score reduction greater than or equal to 2 at 30 minutes. Secondary outcomes were pain reduction at 15 minutes, patient-reported comfort, satisfaction scores, nitrous oxide consumption, and incidence of adverse events. |
| 14. | Pre-hospital Pain and Analgesic Therapy in Elderly Patients with Hip Fractures (Oberkircher & Schubert, 2016) | RCT | 153 patients | Analgesic (morphine) | Determined whether patients received adequate pain medication when suffering from an injury commonly associated high pain levels in the pre-hospital phase |
| 15. | Pain Management in the Emergency Chain: The Use and Effectiveness of Pain Management in Patients with Acute Musculoskeletal (Pierik & Ijzerman, 2015) | RCT | 697 patients | Analgesics administered (if any) were categorized as follows: i) no analgesics; ii) nonopioids such as paracetamol (acetaminophen) or nonsteroidal anti-inflammatory drug (NSAID); iii) mild opioids such as codeine and tramadol; and iv) major opioids such as morphine and fentanyl. | Investigated how often pain management is provided in the pre-hospital phase and emergency department (ED) and how this affects pain relief. |

Note : ED: Emergency Department; EMS: Emergency Medical Services; IV: Intra venous; IM: Intra muscular; INF: Intra Nasal Fentanyl ; NSAID's: Non-Steroidal Anti-Inflammatory Drugs ; NVPS: Numerical Verbal Pain Score; PHP: Pre-hospital Provider; PPP: Pain Management Protocol; RAPID: Rapid Analgesia for Pre-Hospital Hip Disruption; RCT: Randomized Control Trials; SC: Sub Cutaneous; VNRS: Verbal Numerical Rating Score.

RESULTS

Fifteen of the resulting articles of the studies were of emergency rescue services, covering a total of 60 up to 41,241 patients, and the remaining fifteen studies were carried out in hospital emergency departments. Overall, the substances most commonly used for analgesia were the opiates fentanyl and morphine, followed by inhaled methoxyflurane, paracetamol, pentazocine, and ketamine sufentanil or combinations thereof. Table 2. Fifteen studies met the inclusion criteria of pain reduction but were highly heterogeneous. Research study analyzed from title, author, design of study, population, agents of intervention, and outcomes measures. Nine studies were Randomized Control Trial (RCT), two studies cross-sectional and retrospective, and one study prospective descriptive and cohort.

From fifteen studies, first study from Lourens (2020), Western Cape (WC), South Africa (SA) was a web-based descriptive cross-sectional in pain survey conducted among pre-hospital emergency care providers of all qualifications, registered with the Health Professionals Council of South Africa (HPCSA) and currently practicing in the WC, SA in 100 participants and showed that in knowledge and attitudes regarding pain with intravenous analgesia (morphine or ketamine) there are significant gaps in this cohort of pre-hospital providers, through insufficient attention during undergraduate education as well as lack of tailored, evidence-based pain educational initiatives and ongoing pain education for qualified practitioners. Future work should focus on describing the impact of educational initiatives on pain care as well as exploring the decline in pain knowledge and attitudes over time and what aspects may influence this decline. EMS systems must promote quality pain care and monitor the effectiveness and efficiency of the pain management practice in the pre-hospital setting, ensuring feedback to operational staff.

Next Friesgaard (2018) conducted an observational study of acute patients transported by ambulance to hospital in the Central Denmark Region over a 9-month period from 1 August 2015 to 30 April 2016 which showed that 41,241 patients were treated by IV fentanyl. More attention should

be given to the management of acute pain, given the frequency and the broad range of causes in terms of main hospital diagnoses (Friesgaard & Riddervold, 2018). Study by Lambert (2015) in sixty patients showed that in use of morphine sulphate as pain management participants appeared to be taking several factors into account when making a decision about whether to administer morphine for pain relief (Vincent-Lambert & Kock, 2015).

These include: the perceived level of pain being experienced and the patient's desire for pain relief; practitioners' fears of adverse effects; and transportation (mode, time and conditions). Participants indicated that many patients are unable to request analgesia due to decreased level of consciousness or a language barrier; therefore, establishing a pain score is not always possible. In such cases, participants indicated that they rely on the clinical presentation of the patient and vital signs, together with their clinical experience, to make a decision regarding the need for analgesia. Interestingly, multiple participants indicated they do not make use of a formal pain scoring system to guide their administration of analgesia. Research from Siriwardena (2018) about use of analgesia morphine for pain management in pre-hospital shows that effective pain assessment and analgesia in the ambulance are known to be associated with reduced pain on arrival at Emergency Department (ED), earlier emergency pain relief and improved perception of overall care quality (Siriwardena & Asghar, 2019). Previous studies have suggested that effective pre-hospital pain management may be impeded by paramedic and patient attitudes, such as reluctance to administer opioids for certain conditions or in the absence of clinical signs, uncertainty about the extent of pain reduction to aim for, concerns about potential malingering, and a fear of masking symptoms.

DISCUSSIONS

The content of the discussion section includes: the explanation of results, and references to previous research. Pain is a common experience among the critically ill or injured while being transported (Mauermann & Ruppen, 2017). Factors that may contribute to patient discomfort and pain during pre-hospital transportation include vibration, thermal

changes, conditions and noise (Spilman & Lechtenberg, 2016). The nature of the pre-hospital environment may also hamper paramedics' ability to assess pain properly (Hector & Keith, 2016). Pain has been described as a 'fifth vital sign' and pain management should be prioritized, after the treatment of life threatening injuries (Mauermann & Ruppen, 2017). Despite this, pain in the pre-hospital emergency setting, as well as in the ED, remains poorly managed as regard the expectation and experience about pain being experienced by patients in the emergency setting or the indifference of emergency medical service providers to patients' complaints of pain (PAMI, 2016). Analgesia is an essential part of pre-hospital medicine. Several analgesic strategies consider the clinical situation, situational context, staffing, competencies of the pre-hospital providers, and availability of drugs and materials. Although the administration of analgesics or sedative drugs to an injured patient can be beneficial, it may also be a potential source of complications, such as hypotension and respiratory depression or arrest in some cases. Analgesics should not be administered without a prior risk or benefit assessment, alternative routes of administration and safety and monitoring. All of these factors must be considered, in addition to the patient's clinical situation, to define an efficient rescue strategy.

Alternative Routes of Administration

Analgesics should be administered intravenously in the context of emergency medicine. All analgesics approved for intravenous or IV administration can also be given by the intraosseous (i.o.) route. Intranasal administration is an alternative in both children and adults (Häske & Böttiger, 2017). Most analgesics have not been approved for intranasal use, but clinical experience with ketamine and fentanyl has been reported: opioids (morphine, fentanyl) or non-opioids (ketamine, nitrous oxide/oxygen, NSAIDs (ketorolac, ibuprofen, acetaminophen) or the combination of ketamine with either morphine or fentanyl; regardless of dose, frequency or route of administration (oral, subcutaneous, intravenous, intramuscular, intraosseous, intranasal, inhaled, transdermal) (Eidenbenz &

Darni, 2017). Administration of fentanyl for acute pain management via invasive routes (intravenous (IV), intramuscular (IM), subcutaneous (SC)) has been studied in both pediatric and adult populations in the pre-hospital setting. Even if they have shown pain relief capacity, the use of needles for injections or simply the needle-stick exposures can cause injury, pain, inconvenience and discomfort to patients because fear of needle (phobia of needle) and technical challenges for an intravenous access to paramedics. Compared to IV and IM, subcutaneous administration may be an easier and more effective option in the Emergency Medical Services (EMS) population (Tanguay & Lebon, 2020). In recent years, noninvasive routes (oral, intranasal (IN) and transmucosal) of delivering fentanyl are increasingly being used in patients for whom invasive routes are difficult to achieve. Among the various noninvasive routes of analgesic administration, intranasal is used most commonly.

Safety and Monitoring

The prerequisites for safe analgesia are knowledge of the pharmacological characteristics of the substances involved, training in their administration, and presence of emergency equipment for treatment of any complications, independent of the user (for example nurse, paramedic, or emergency physician) or the situation (pre-hospital or in the hospital) (Crewdson & Lockey, 2017; Parker & Rodgers, 2015)). The monitoring measures and the emergency equipment needed at hand depend on the expected complications and adverse effects (Samuel & Steiner, 2015). Monitoring of a spontaneously breathing patient under analgesia comprises ECG, blood pressure, breathing rate, heart rate, and SpO₂, together with capnography if required is important. Patients under analgesia should regularly receive oxygen. The equipment for mask ventilation and suction must be available, and every user must be in the position to keep the airway free and perform ventilation (Ariès & Montelescaut, 2016). An intravenous access is recommended for treatment of hypotension or administration of naloxone as an opioid antagonist. Titrated administration is advised to avoid respiratory depression.

CONCLUSION

Healthcare professionals must be in the position to carry out safe and effective analgesia used in pre-hospital setting, such as the emergency area. The basis is formed by physical measures for pain relief. The preferred means of administration of analgesic drugs is the intravenous route; however, other routes are possible. The use of pre-hospital analgesia for injured patient in pre-hospital setting is commonly used by health workers according to pain management standard and guideline; however, planning developments are needed for safety and management as a concern for focus on quality of pain management status. Our systematic review shows that there are very few comparable studies of acceptable quality to know about use of analgesic, pain management and safety monitoring in a pre-hospital setting. Analgesia must be carried out only by properly trained persons, the patient must be monitored without interruption, and emergency equipment for treatment of complications must be at hand.

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Conflict of Interest

None.

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