

REVIEW ARTICLE

Review article: Paramedic pain management of femur fractures in the prehospital setting: A systematic review

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Abstract

Femur shaft and neck of femur (NOF) fractures are often under-treated in the prehospital setting. These injuries can present unique clinical and logistical concerns in the prehospital setting. This systematic review aimed to investigate paramedic prehospital pain management of patients who had suffered NOF or femur fractures, and to investigate which interventions are effective. A systematic review was conducted in line with Preferred Reporting Item for Systematic Reviews and Meta-Analyses guidelines. Four databases were searched from inception date 23 March 2020. Articles were independently reviewed by two authors and conflicts resolved by a third author, followed by a hand search of the included reference lists. References were included if they addressed paramedic interventions for NOF or femur shaft fractures. Outcomes of interest were the effectiveness and complications of different modalities administered by paramedics. The search yielded 6868 articles, of which 19 met the final inclusion criteria. Studies investigated a variety of interventions including traction splints, intravenous (IV) analgesia and alternative analgesic options. Traction splinting and IV analgesia were

consistently reported as underutilised. Alternative analgesics such as auricular acupressure, transcutaneous electrical nerve stimulation (TENS) and fascia iliaca compartment block were found to be effective techniques that could be safely and competently employed by paramedics, reducing pain for patients with limited adverse events. NOF and femur shaft fractures are an undertreated injury in the prehospital setting. Traction splinting and IV analgesia remain the traditional methodologies of treatment for these injuries; however, there are alternatives such as TENS, auricular acupressure and fascia iliaca compartment block that appear to be emerging as safe and effective options for the prehospital setting.

Key words: *neck of femur, hip fracture, femur, paramedic, emergency medical technician, prehospital.*

Introduction

Femur shaft fracture and neck of femur (NOF) fractures are painful injuries which, if not managed correctly, can result in extended hospital stays and increased mortality.¹ Prehospital deaths due to femur shaft fracture have been reported to

Key findings

- Traction splints and intravenous analgesia are often underutilised in the prehospital setting for femur injuries.
- Auricular acupressure and transcutaneous electrical nerve stimulation provided a safe and non-invasive form of analgesia based on reported patient pain scores, with no adverse events.
- Fascia iliaca compartment block performed by paramedics in the prehospital setting appears to be a safe and effective intervention to assist in treating patients with NOF and femur shaft fractures.

occur at a rate of 3.5 per every 100 000 people.² Femur shaft fractures are also often accompanied by concurrent orthopaedic and internal injuries, and have a reported incidence of 21 per 100 000 people annually.² Essential treatment of these injuries early such as splinting, analgesia and fracture reduction has been associated with a reduction in mortality, reduced risk of fat embolism and assists with the management of haemorrhagic shock.¹

The Australian Institute of Health and Welfare reported an incidence of NOF fractures in the patients aged over 45 years occurred at a rate of 199 in 100 000, with a mortality rate of 5–8 times greater than the general population during the first 3 months post-injury.³ The Australian Institute of Health and Welfare also

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reported that NOF fractures are occurring mostly at home or in aged care facilities. Patients who sustain a NOF fracture require adequate early management of pain and splinting for both humane reasons as well as reducing the occurrence of sequelae, such as to decrease the risk of avascular necrosis, post-traumatic arthritis, chronic pain and decreased mobility.¹

When examining both NOF and femur shaft fractures, it is evident that there is bimodal distribution that contributes to the age of the patients that are affected by these injuries, with NOF occurring in older adults, and femur shaft fractures occurring more often in younger patients. However, on examination of femur shaft fractures in isolation, there is evidence of bimodal distribution of the age of patients, demonstrating that femur shaft fractures is not an injury that only affects younger populations.⁴ Prehospital management of both these types of injuries is centred around analgesia, splinting, extrication and management of other injuries. Within the somewhat limited scope of practice of non-physicians in the prehospital setting, these may involve similar approaches to both injuries, including varying methodologies of analgesia, and splinting relative to the type of fracture.

Undertreatment of traumatic pain in the prehospital setting has been outlined in the existing literature, which is concerning as early reduction of pain is important not only for humane reasons, but also to manage sequelae of these injuries.⁵ Prehospital absence of analgesia is a significant issue, as the prehospital setting presents issues for both femur and NOF fracture, such as difficult, lengthy and at times unavoidably uncomfortable extrication from the scene of the injury. Recently, there has been an interest in prehospital fascia iliaca compartment block (FICB), and subsequently a systematic review by Hards *et al.*, which revealed that this technique is safe and effective in the prehospital setting.⁶ However, Hards *et al.*'s review focussed solely on FICB, and acknowledged that

comparing novel techniques such as this to intravenous (IV) analgesia would be beneficial. We aimed to further examine FICB as well as all other pain management modalities that are available for paramedic pain management for patients in the prehospital setting. This overarching review is needed to ensure that all modern methods of analgesia are explored as possibilities in the prehospital setting.

This review is focused on the prehospital pharmacological and non-pharmacological interventions provided by paramedics to NOF and femur shaft fractures in the prehospital setting to reduce pain. We aim to identify if these interventions are effective in terms of patient outcomes including pain level, success rate of intervention and adverse sequelae post interventions. Finally, identification of any emerging prehospital practices that could be employed further by paramedics will also be sought.

Methods

Our review topic of interest was primarily pain management and success rate of interventions provided to patients in the prehospital setting who have suffered a NOF or femur shaft fracture by non-physicians exclusively.

This review was prospectively registered with the International Prospective Register of Systematic Reviews (PROSPERO ID #CRD42019134809) in March 2019.⁷ It was also reported in line with the Preferred Reporting Item for Systematic Reviews and Meta-Analyses (PRISMA).⁸

Search strategy

A comprehensive search strategy was developed and was deliberately kept broad and sensitive so as to capture all articles of interest for our topic – prehospital pharmacological and non-pharmacological pain management by paramedics or non-physicians. A combination of medical subject headings (MeSH) and key words were used and adapted to suit the idiosyncrasies of the databases

searched. Such terms included: NOF, hip fracture, femur fracture, paramedic and prehospital. The full search strategy is available in Appendix S1. Databases searched were Medline, CINAHL, Embase and Evidence Based Medicine reviews, from date of inception until March 2020.

Inclusion and exclusion criteria

For an article to be included it had to detail femur fracture injuries and paramedic (or non-physician local equivalent) prehospital pain management. Articles were excluded if they were identified as: non-peer-reviewed publication, if they were not available in English, examined the management of femur fractures exclusively in hospital, if management was not performed by a paramedic or local equivalent, and if the article addressed pelvic fractures exclusively. Inclusion and exclusion criteria are documented in full in Appendix S2.

Article screening

Once the search strategy had been run, each article abstract was independently compared to inclusion and exclusion criteria by two contributors to ensure that they met the aim of the review, and conflicts for inclusion or exclusion were resolved by consensus from a third contributor. Following that, a full-text screening of the remaining studies occurred, again independently by two authors (SD, BS) then with a third author (KB) resolving the conflicts. Hand searching of reference lists and forwards reference chaining of final included studies occurred as the final step. Data was then extracted independently by two authors (SD, BS) using a data extraction form that was created by the authors, based on information from the Cochrane handbook for systematic reviews.⁹ Data extracted included study design information such as study type, setting, duration, sample size, interventions used and outcomes specific to patient pain scores and adverse effects.

Bias assessment

Articles identified for inclusion in this review were assessed for individual quality of data and study reliability using the National Heart, Lung and Blood Institute (NHLBI) study quality assessment tool.¹⁰ The NHLBI quality assessment tool allows for study-specific templates to be used for the different study designs and tabulating of specific areas of potential bias within each study design. This tool assists in the identification of potential bias areas within each study's design, categorising studies as 'poor', 'fair' or 'good'. The tool itself is not a tabulation of scores but allows the assessor to identify areas of potential bias and make an overall judgement on the quality of the study.¹¹ For qualitative research, the Joanna Briggs quality assessment for qualitative studies was utilised to identify studies that should be excluded based on risks of bias.¹² Quality assessments were undertaken independently by

two authors (SD and BS). Where initial consensus was not reached, a third author (KB) made the final decision.

Results

The initial database search yielded 6144 non-duplicate results, one of which was identified through the reference list of another included article. After title and abstract screening of these results, 90 remained for full-text review. After full-text review, 19 articles met the inclusion criteria. This process can be seen in the PRISMA flow chart in Figure 1. The included articles examined a variety of both pharmacological and non-pharmacological interventions, addressing a range of different specific interventions.

Study characteristics

Studies included ranged across both sample size and study design, and

details are included in Table 1. There were nine retrospective cohort studies, three prospective studies, four randomised controlled trials and three qualitative studies. Study participant sample size ranged from seven to 2140. The results of the search yielded a variety of interventions for review, with a majority focused on pharmacological analgesia, as well as alternatives such as transcutaneous electrical nerve stimulation (TENS), FICB and acupressure. Traction splints were examined in six studies, four of which were conducted in the USA, one in Iran and one in Qatar.

IV analgesia was the topic of interest in seven studies (one study examined both traction splints and IV analgesia), which included two Australian based studies and the remainder being European studies. TENS and auricular acupressure each had a single study each, both of which occurred in Europe. Five studies investigated FICB, with one occurring in Australia, three studies from the UK and one study from the Netherlands.

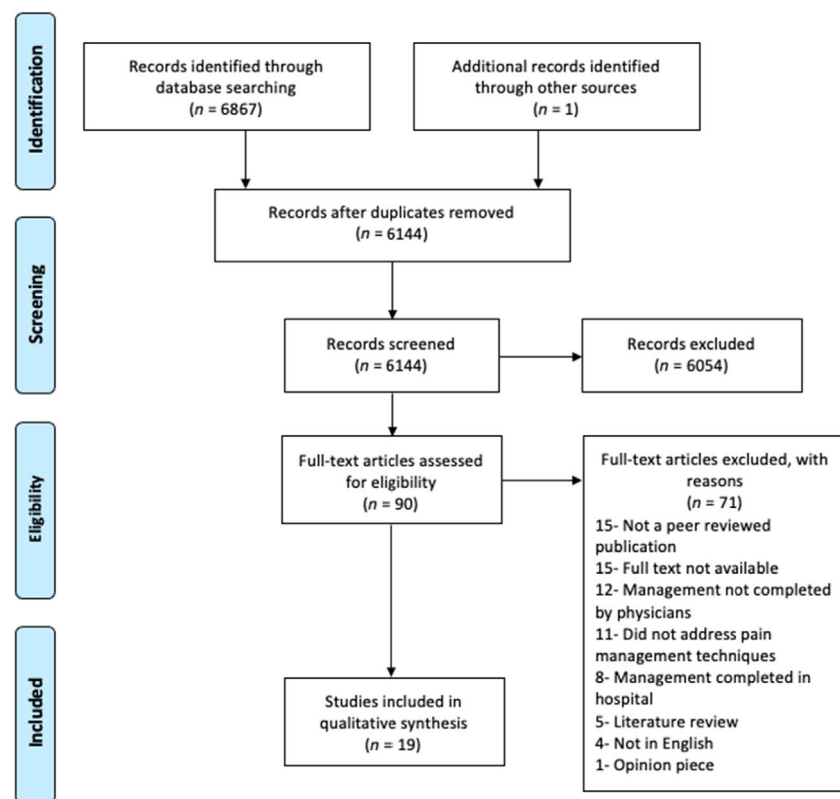


Figure 1. Preferred Reporting Item for Systematic Reviews and Meta-Analyses (PRISMA) flowchart.

Quality assessment

When assessing for risk of bias using the NHLBI assessment tool, a majority of the quantitative articles (11/20) were rated as 'good', and subsequently had the least risk of bias. A number of studies (3/20) were rated as 'fair', meaning there was some risk of bias but not so significant that the results should be completely discounted. Two studies were deemed 'poor', highlighting there was a significant risk of bias in these two studies.¹⁰ For qualitative research, none of the three articles were excluded based upon assessment using the Joanna Briggs assessment tool, and their results were included in this review.¹² Due to the overall risk of bias in some studies our results from this review must be interpreted with caution and the affected areas of interest may require further research to validate the results.

Effectiveness of interventions

The outcomes data that were extracted included if the intervention

TABLE 1. *Included studies*

Lead author	Year	Design	Country	Study setting (metropolitan/ rural)	Study size (<i>n</i>)	Duration (months)	Quality assessment†
Traction splinting							
Abarbnell ¹³	2001	Retrospective cohort	USA	Metropolitan	16	12	Fair
Auerbach ¹⁴	1984	Retrospective cohort	USA	Metropolitan	15	2	Poor
Howland ¹⁵	2019	Retrospective cohort	Qatar	Mixed	69	9	Poor
Irajpour ¹⁶	2012	Prospective cohort	Iran	Metropolitan	32	Not reported	Fair
Nackenson ¹⁷	2017	Retrospective cohort	USA	Metropolitan	170	60	Fair
Wood ¹⁸	2002	Prospective cohort	USA	Mixed	40	12	Good
IV analgesia							
Friesgaard ¹⁹	2017	Retrospective cohort	Denmark	Mixed	2140	36	Good
Jakopovic ²⁰	2015	Qualitative (phenomological) – single interviews	Sweden	Metropolitan	22	Not reported	Include
Oberkircher ²¹	2015	Prospective cohort	Germany	Metropolitan	153	12	Good
Pfrunder ²²	2017	Retrospective cohort	Sweden	Metropolitan	722	12	Good
Simpson ²³	2013	Retrospective cohort	Australia	Mixed	333	8	Good
Vassiliadis ²⁴	2002	Retrospective cohort	Australia	Metropolitan	128	11	Good
Auricular acupressure							
Barker ²⁵	2006	RCT (double blind)	Austria	Metropolitan	38	Not reported	Good
TENS							
Lang ²⁶	2007	RCT (sham)	?Austria or Hungary	Metropolitan	72	Not reported	Good
FICB							
Dochez ²⁷	2014	Prospective cohort	Netherlands	Metropolitan	108	12	Good
McRae ²⁸	2015	RCT	Australia	Metropolitan	25	12	Good
Jones ²⁹	2019	RCT (feasibility)	UK	Metropolitan	71	12	Good
Evans ³⁰	February 2018	Qualitative (phenomological) – focus groups	UK	Metropolitan	11	Not reported	Include
Evans ³¹	December 2019	Qualitative (phenomological) – single interviews	UK	Metropolitan	7	Not reported	Include

†Quality assessment performed using NHLBI assessment¹¹ (good, poor or fair) for quantitative studies or Joanna Briggs Institute (include or exclude) assessment for qualitative studies.¹³

decreased the patient's pain, if the intervention was able to be applied successfully and if there were any reported adverse sequelae from the intervention (Table 2). Traction splint studies did not report on changes in pain scores so it is not

possible to comment on the effectiveness of this intervention on pain, it was, however, noted that a single patient had improved neurovascular status to the affected limb post splint application in one study.¹³ Traction splints were reported to be

underutilised, with the application rate ranging from 30 to 60% when indicated.^{13–18} Pharmacological analgesia was also reported to be underutilised, being used in a range of 15.4–67% when indicated, with only two of six studies reporting on

TABLE 2. *Outcomes and adverse effects*

Lead author	Decrease in pain post-intervention	Success rate	Adverse outcomes/reported sequelae
Traction splinting			
Abarbnel ¹³	Not reported NVS improved in one patient post-TS application	3/5 application rate 2/3 success rate – 1 removed due to increased pain	Nil reported for traction splint Nil adverse sequelae reported for other forms of splinting
Auerbach ¹⁴	Not reported	Not reported	Nil
Howland ¹⁵	Not reported	Application rate 50% post training	Not reported
Irajpour ¹⁶	Yes – both simple and traction splint had reduction in pain immediately post-application Traction splint had greater reduction in pain over 1st, 6th and 12th hours	Three excluded from simple splint group due to contraindications Two declined participation in traction splint group	Nil
Nackenson ¹⁷	Not reported	22% received IV morphine 30% received TS when indicated	Nil specifically identified
Wood ¹⁸	Not reported	100% when applied Traction splint applied 38% of time when indicated	Contraindicated due to most commonly associated underlying pelvic fracture
IV analgesia			
Friesgaard ¹⁹	Not reported	27.3% received fentanyl in service where fentanyl was sole analgesic available	Six out of 584 patients received ondansetron for nausea
Jakopovic ²⁰	Not reported	Not reported	Nil
Oberkircher ²¹	Yes (7 to 2.8)	15.4% of patients treated by paramedics received any IV analgesia	Nil
Pfrunder ²²	Not reported	50% of patients received pain relief	Not reported
Simpson ²³	62% of patients had meaningful reduction in pain (>30% relative reduction)	67% of hip fractures received IV analgesia	Not reported
Vassiliadis ²⁴	Not reported	51% received some form of analgesia (methoxyflurane, Entonox, morphine)	Not reported
Auricular acupressure			
Barker ²⁵	Yes (65 to 40 using VAS score)	100% – nil removed	Nil
TENS			
Lang ²⁶	Yes (8.9 to 5.9)	100% – nil removed	Nil
FICB			
Dochez ²⁷	Yes (initial median 8 down to 3 after 30 min)	96% – 96 out of 100	Seven patients complained of nausea
McRae ²⁸	Yes	92% – 1 out of 12 unable to identify landmarks	Nil
Jones ²⁹	Yes	100%	One incident of local anaesthetic toxicity – successfully reversed with Intralipid
Evans ³⁰	N/A	N/A	N/A this is a qualitative review of paramedic experience as part of the RAPID feasibility trial
Evans ³¹	N/A	N/A	N/A this is a qualitative review of the patient experience as part of the RAPID feasibility trial

reduction in pain score as an outcome, and the remainder of the studies focussing on the rate of analgesia administration rather than the effectiveness of pain reduction.^{19–24} The FICB as an intervention was applied to indicated patients successfully in 92–100% of cases,^{27–29} and had a successful reduction in patient-reported pain scores for all three of the quantitative studies. However, only two studies^{27–29} noted that the reductions were statistically significant. Dochez *et al.*²⁷ regarded the intervention as a success 96% of the time due to a reduction in pain scores of 3 or more.

There were two interventions which each only had one study examining each intervention. TENS, a methodology that utilised controlled transcutaneous electrical impulses delivered via adhesive pads applied to the injury site, provided statistically significant reductions in pain scores, anxiety levels and heart rate.²⁶ Auricular acupressure was examined in a single study as well, and involved attaching 1 mm acupressure beads to three acupressure points on the patient's ear.²⁵ This non-invasive method also provided statistically significant reductions in anxiety, pain and heart rate when compared to the control group. While both these interventions are based on single studies, the low-risk, non-invasive nature should be considered to be a strength of both these interventions. Table 1 further explains the findings of both studies.

Adverse effects of interventions

Adverse effects of the various interventions were not commonly reported across the studies. Traction splints were reported to have no immediate adverse sequelae when compared with rigid splints,¹⁶ however, were withheld 38% of the time due to concurrent pelvic fractures.¹⁸ Studies investigating pharmacological analgesia did not report adverse outcomes post-administration but one study highlighted that six of 584 patients required an antiemetic for nausea during care.¹⁹ The three quantitative studies that examined FICB only reported one incident of

local anaesthetic toxicity across 204 patients, which was successfully reversed by the treating paramedic by administering Intralipid.^{27–29} Auricular acupressure and TENS did not have any adverse effects across either study.^{25,26}

Discussion

This systematic review has identified a variety of interventions, both pharmacological and non-pharmacological in nature, that are used by paramedics in the pre-hospital setting to treat pain for NOF and femur shaft fractures. The identified interventions included traction splinting, pharmacological analgesia, auricular acupressure, TENS and FICB. This review found that these interventions are or could potentially be combined to be used synergistically in the same patient in order to achieve optimal outcomes.

Underutilisation

A common theme that emerged from the articles included in this review was the general underutilisation of prehospital interventions for both femur shaft and NOF fractures, this included both splinting and pharmacological interventions. Of the six articles that addressed the use of traction splinting, application rate of traction splints when indicated ranged from 30 to 60%.^{13–18} Traction splints are primarily indicated for immobilisation of femur shaft fractures; however, if inadvertently applied to a non-shaft fracture such as a NOF, there have been no adverse effects reported.^{32,33} Reasons for withholding included concerns about extended scene times taken to apply the splint in a major trauma patient, and contraindication due to other concurrent injuries, most commonly pelvic fracture.¹⁸

Pharmacological analgesia in the setting of NOF and femur fractures was also underutilised by paramedics. The highest rate of administration of any analgesia was reported by Simpson *et al.*, who outlined a rate of 67% of pain relief given to suspected NOF fractures when indicated.²³ Conversely, the

lowest rate of analgesia given to suspected NOF fractures was reported to be 15.4% of indicated patients.²¹ Reasons for withholding analgesia included concern of causing haemodynamic instability as a side effect of opioids and concerns about extensive scene times. When administered, the pharmacological analgesia included in this study could only be assessed for effectiveness in two of the six studies, as the remaining studies did not report on effectiveness on pain scores, but rather administration rates. Simpson *et al.*²³ and Oberkircher *et al.*²¹ both reported effective analgesia based on pain scores pre and post analgesia. It is therefore difficult to compare the effectiveness of pharmacological analgesia given that not all studies assessed whether pain relief administered had a significant impact on pain scores for the patient.

Alternative analgesic options

Given the discussion surrounding the underutilisation of widely accepted techniques of traction splints and traditional IV analgesia, it is important to address the alternative options for analgesia for pain management of all types of femur fractures. This review revealed that TENS and auricular acupressure can both produce statistically significant reductions in pain scores.^{25,26} The non-invasive nature of both interventions provides opportunity for all skill sets of prehospital providers to apply each method, with low-risk and zero reported side effects. TENS has been traditionally applied for usage in chronic pain, however, has recently been subject to experiments with acute pain, and is demonstrating promising results.³⁴

Another alternative, that is invasive in nature, was FICB. FICB has been shown to be a safe and effective method for application in ED, and recently the prehospital studies are demonstrating a promising level of analgesia coupled with low rates of adverse events. The positive in hospital results for this intervention warrants further investigation in the prehospital setting.^{35,36}

Barriers to application of analgesia

Barriers to methods of analgesia were addressed throughout the literature contained in this review. Traction splinting, indicated for mid-shaft femur fractures, occur often in the setting of major trauma. One article in our review expressed that the extra 5–6 min taken to apply a traction splint to a femur shaft fracture was ‘unacceptable’; however, this article is now two decades old.¹³ Pressure to minimise scene times has been discussed as a reason for paramedics to withhold traction splinting, prioritising rapid transport instead. Education pertaining to the benefits of traction splinting, as discussed by Howland *et al.*,¹⁵ has demonstrated that with regular skills updates, paramedics are able to ensure this intervention is undertaken in the prehospital setting prior to transport. Interestingly, it was found that when, what could be considered more time-consuming interventions such as FICB were used, there was no significant difference in scene times when compared to routine care.^{27–31}

As outlined in Table 2, auricular acupressure and TENS did not present any barriers for application.^{25,26} The successful application rate of both these interventions was 100%, with no adverse incidents reported, reinforcing the safety of such non-invasive interventions. FICB had a similarly high successful application rate, as is consistent with reports of ED application.^{27–29,36} The low risk associated with these interventions should be considered an important piece of evidence that supports further trial of the FICB, TENS and acupressure.

Adverse effects

As a further aim of this review, we sought to examine whether any adverse or unwanted sequelae was a common theme from the interventions identified. While no long term complications were reported in papers exploring different types of splints included in this review, it was noted that there was an increase in

pain experienced with the application of traction splints in one patient, resulting in the traction splint having to be removed post-application.^{13,16} Nausea was reported as an unwanted side effect of both FICB and IV fentanyl;^{19,27,28} however, one study highlighted that paramedics were able to respond with this complaint by administering an anti-emetic.¹⁹ Of the six articles that examined pharmacological analgesia, no mention of the need to use an opioid antagonist was noted.^{17,19–24} Local anaesthetic toxicity is a known adverse effect of FICB and due to the advanced skills required to manage this potential side effect, FICB administration has been traditionally reserved for use by a physician only. However, in the five articles that examined FICB, paramedics were able to recognise and manage local anaesthetic toxicity. While there was only one incident of toxicity across the studies, this was successfully reversed by paramedics, with no long-term sequelae noted.²⁹ Paramedics in the prehospital setting are well-acquainted with dynamic patient presentations, and the adverse effects that are discussed highlight the ability of paramedics to adjust their treatment according to patient response or effectiveness. Again, TENS and auricular acupressure had no reported adverse effects or sequelae and given that they are both non-invasive methodologies, the evidence that they can be applied without negative effects on patients, demonstrates the potential for widespread application to patients suffering femur injuries.^{25,26}

Strengths and limitations

The strength of this review lies within the broad search strategy that was used to encapsulate a large number of articles and techniques, allowing for a comprehensive overview of the existing literature. This led to identifying many new and existing practices utilised by paramedics to treat patients suffering from NOF and femur shaft fractures. The generally ‘good’ quality of the included studies is another strength and the overall risk of bias was low. Further

control trials of emerging practices, such as TENS, auricular acupressure and FICB, are still required before definitive conclusions can be made regarding their effectiveness in the prehospital setting. The majority of the studies included in this review were retrospective in nature, therefore control-intervention comparison was limited, and this limits the conclusiveness of our results. Furthermore, the inconsistencies in reported outcomes by included studies are something that needs to be considered when interpreting our results. The combination of both femur shaft and NOF fractures in the same study could be considered a limitation; however, the overlap of pharmacological analgesia and emerging alternatives such as TENS, acupressure and FICB demonstrates that there are a variety of pain management techniques that would benefit from further trials to compare the reduction of pain scores and adverse effects across all mediums. Additionally, while we believe our search strategy was extensive and minimised risk of bias, we did not search grey literature as we were analysing peer-reviewed research outcomes, and so there is a possibility that some evidence was missed by omitting this area of literature. In terms of implications of our research, we believe that undertreatment of pain is an issue that requires further attention in future research, but that there are emerging alternative analgesic options such as auricular acupressure, FICB and TENS that could be potentially used in conjunction with other modalities to achieve optimal pain relief.

Conclusions

This review presents several approaches to the management of NOF and femur shaft fractures in the prehospital setting by paramedics. Traction splints and analgesia are often underutilised, and it is difficult to gain an accurate understanding of the efficacy of these interventions as studies did not consistently report on the reduction of pain scores as a primary outcome. Auricular acupressure and TENS provided a safe and non-invasive

form of analgesia based on reported patient pain scores pre- and post-intervention, with no adverse events associated with either intervention. FICB appears to be a safe and effective intervention to assist in treating patients with NOF and femur shaft fractures, and has been implemented appropriately by paramedics in the prehospital setting. These alternative modalities of analgesia are an area for further research to determine if there is a more superior method of analgesia for femur fractures than what is currently being performed by paramedics.

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Competing interests

None declared.

Data availability statement

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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Supporting information

Additional supporting information may be found in the online version of this article at the publisher's web site:

Appendix S1. Search strategy.

Appendix S2. Article inclusion and exclusion criteria.