Renal Replacement Therapy

REVIEW

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# Pharmacological interventions for pain management during arteriovenous fistula puncture in adults and adolescents undergoing maintenance haemodialysis: a systematic review

Abdul Rehman Arshad[1*], Umair Ijaz[1] and Babar Rafique[1]

## Abstract

**Introduction** Pain is a stressful experience for patients receiving haemodialysis through arteriovenous fistulas. This systematic review assessed the effectiveness of different pharmacological interventions for reducing pain during cannulation of arteriovenous fistulas among adolescents and adult patients with end-stage renal disease.

**Methods** The protocol was prospectively registered with PROSPERO (Registration number CRD42024497355). A PRISMA-compliant systematic literature search was conducted on PubMed, Cochrane CENTRAL and Google Scholar. The primary and secondary outcomes were a reduction in the severity of pain and incidence of side effects respectively.

**Results** In total, 15 studies were included in this review, all of which had some or serious concerns about the risk of bias. Compared with EMLA, cryotherapy with ice packs at the fistula site was superior, with a pain intensity of 1.05 (95% confidence interval 0.21, 1.89) points lower on the visual analogue scale, and there was no difference in the incidence of adverse effects. There was a greater reduction in pain intensity with EMLA cream than with piroxicam gel (mean difference 1.30; 95% confidence interval 0.68, 1.93). No difference in the incidence of adverse effects was noted. Compared with lidocaine spray, EMLA cream was associated with a lesser degree of pain (mean difference 2.09 points; 95% confidence interval 1.81, 2.38). Compared with placebo, cryotherapy with ice packs at the Hoku point was better, with a pain intensity of 2.53 (95% confidence interval 1.23, 3.83) points less on the visual analogue scale.

**Conclusions** Available evidence supports the use of cryotherapy with ice packs and EMLA cream for reducing pain during cannulation of arteriovenous fistulas.

**Keywords** Cryotherapy, EMLA, End stage renal disease, Fluori-methane, Lidocaine, Lidocaine Prilocaine drug combination, Lignocaine, Nonsteroidal antiinflammatory agents, Renal replacement therapy

## Introduction

End-stage renal disease (ESRD) is a global health problem associated with significant morbidity and a risk of mortality. It is estimated that nearly 300 per million people require haemodialysis (HD) globally [1]. This is indeed the most prevalent renal replacement therapy, albeit it

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has its own risk of complications. Arteriovenous fistula (AVF) is the best form of vascular access for this treatment, with patients requiring six venipunctures every week [2]. This comes at the cost of a significant psychological impact. Needle phobia is often cited as a common barrier to HD; it has been reported in 25–47% of patients refusing this treatment [3]. Puncture-related pain of variable intensity is universal among patients on maintenance HD. It not only generates anxiety and fear among patients but also negatively affects quality of life and can affect compliance with treatment [4]. Thus, controlling such pain is of paramount importance. Many interventions, both pharmacological and non-pharmacological, have been attempted in this regard. However, most of the published studies have small sample sizes and often provide conflicting results. Furthermore, a preliminary literature search of PubMed revealed a dearth of meta-analyses comparing different pharmacological interventions with each other or placebo. We therefore planned to summarize the available evidence through a meta-analysis. This study aimed to answer the following question: In adolescents and adult patients on HD for ESRD, how effective are different pharmacological interventions in reducing pain during cannulation of AVF?

## Methods

The protocol for this systematic review was prospectively registered with PROSPERO on 26 Jan 2024 (Registration number CRD42024497355) and it was performed as per PRISMA guidelines. The search strategy included a combination of the following terms: chronic kidney failure, end stage kidney disease, end stage kidney failure, ESRD, end stage renal failure, hemodialysis, HD, renal dialysis, EMLA, eutectic lidocaine prilocaine, prilocaine/lidocaine, lidocaine, lignocaine, fluori-methane, cryotherapy, vapocoolant spray, non-steroidal anti-inflammatory agents, non-steroidal anti-inflammatory drugs, AVF, dialysis access and venipuncture. The exact search strings used were previously recorded in the protocol (available on the PROSPERO website). A literature search was carried out on PubMed and Google Scholar to download all studies up to 4 February 2024 and on Cochrane CENTRAL up to 11 Feb 2024. We also searched Clinicaltrials.gov and the Australian New Zealand Clinical Trials Registry to search for trials registered up to 11 Feb 2024. No date or language restrictions were applied at the time of the literature search. A literature search on ProQuest had also been initially planned, but this was later deleted from the protocol because of lack of access to the database, and an appropriate modification was recoded on PROSPERO website.

To be included in this review, there was a requirement for the studies to be randomized controlled trials/clinical trials and quasi-experimental studies, exploring the role of EMLA cream, lignocaine tape/gel, subcutaneous lignocaine, vapocoolant spray, topical nonsteroidal anti-inflammatory agents or cryotherapy. They had to be published in English. Studies done on a wider age range of patients (specifically including paediatric age group) were also eligible for inclusion if they described the results for adolescents and adults separately. We excluded other study designs, such as descriptive studies with no comparator arms. Other exclusion criteria included studies describing pain as a categorical variable, HD for acute kidney injury, HD being done through tunnelled dialysis lines or arteriovenous grafts or clinical trial registry entries with no results posted.

All the search results were imported into EndNote X9, and after deduplication, the titles and abstracts were screened for eligibility. Full texts for the eligible studies were arranged by a comprehensive search on different databases/Google search engine. The authors were also directly contacted via email or on ResearchGate in case full texts were not available elsewhere. For the studies finally included in this systematic review, the risk of bias was assessed using RoB 2 Tools for parallel group and crossover randomized trials and ROBINS-1 for nonrandomized studies. Data was extracted into Microsoft Excel, and Cochrane's Review Manager version 5.4 was used for the meta-analysis. The different interventions mentioned in the preceding paragraphs were compared with placebo or each other. A given comparison was subjected to meta-analysis if there were at least two studies describing this. Comparisons addressed in only one study were not included in the meta-analysis. Mean differences in pain intensity amongst different interventions were calculated for each study. A random-effects model was applied considering the diversity in patient population for each comparison. Heterogeneity amongst the studies was assessed using $I^2$ statistic. Sensitivity analysis was not planned at the time of protocol development, but after the results were available, we performed sensitivity analysis for all meta-analysis that included at least three studies and had considerable heterogeneity ($I^2 > 75\%$).

All steps for this systematic review were performed independently by two researchers, and discrepancies (if any) were resolved by seeking opinion of the third researcher.

## Results

The literature search revealed a total of 556 records retrieved from the three databases. The screening process is summarized in Fig. 1.

In total, six studies that appeared to fulfil the inclusion criteria were excluded, five of them reported inconsistent results; three of these studies reported only the

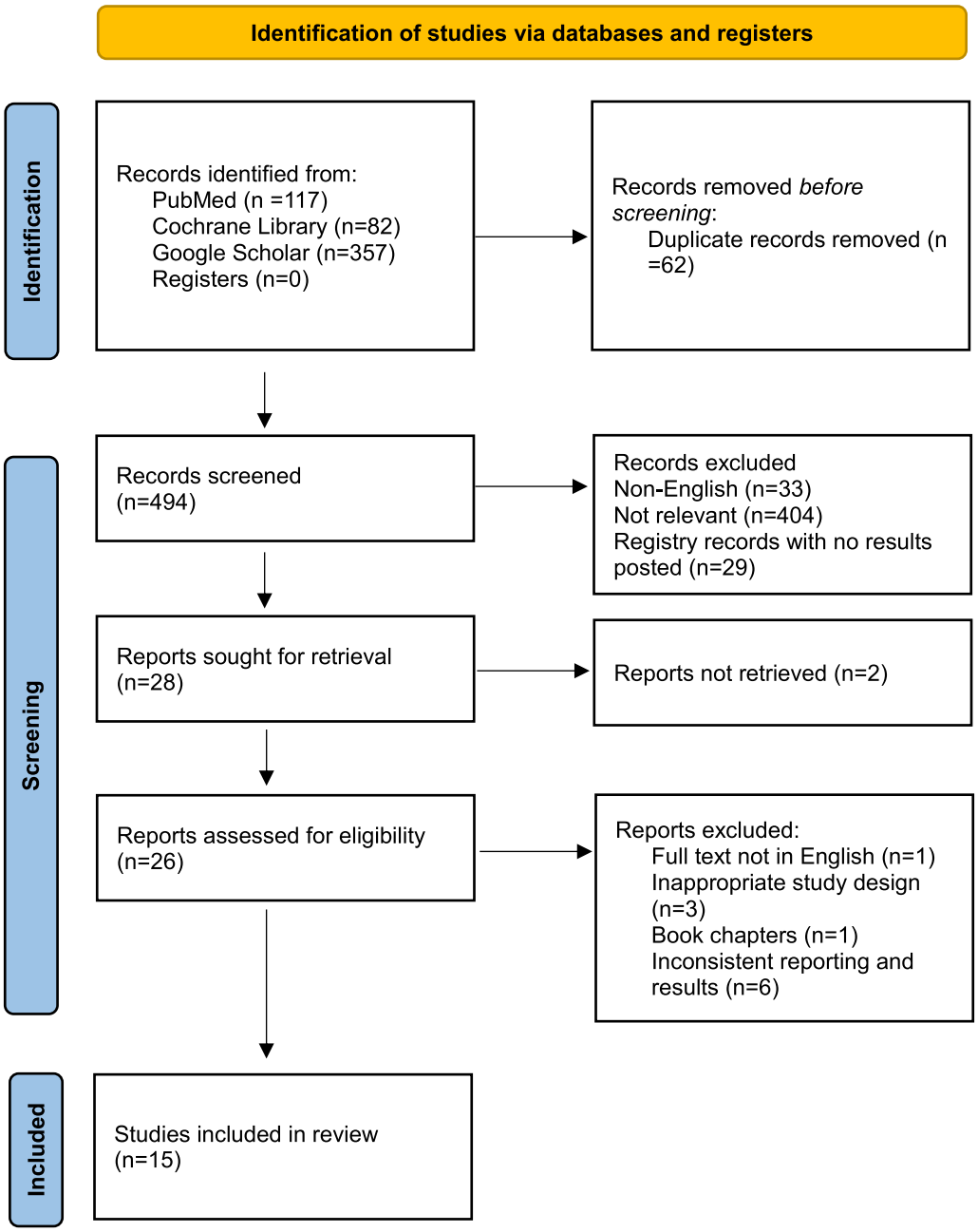


**Fig. 1** PRISMA flow diagram for screening literature

mean values, whereas standard deviations were missing for different intensities of pain measurements [5–7]. A study done by Issac, et al. was excluded because the values for the intensity of pain assessed by numerical rating scale were not mentioned anywhere in the article [8]. A randomized controlled trial by Liu, et al. was not included as the results described pain intensity with different interventions as a categorical variable, rather than a continuous variable [9]. Finally, another study authored by Abdrabouh, et al. was excluded because the methodology was not clear and there were no details about how cryotherapy was delivered to the patients [10]. A total of 15 studies were ultimately included in this systematic review. Their essential characteristics are shown in Table 1.

An assessment of the risk of bias for randomized and nonrandomized studies included in this review is presented in Fig. 2 and Table 2 respectively.

**Table 1** Characteristics of included studies

| Study ID | Study design | Setting | Number of patients | Age range | Main intervention | Other intervention(s) | Outcomes | Adverse events |
|---|---|---|---|---|---|---|---|---|
| Aghajanloo et al. [23] | Randomized clinical trial | Iran | 50 | Not explicitly mentioned in methods (50.2 ± 19 and 56.1 ± 15 in control and intervention groups respectively) | Cryotherapy | Placebo | Pain (VAS) | Not reported |
| Arab et al. [11] | Randomized clinical trial | Iran | 70 | ≥ 18 years | Hegu point ice massage | 2% lidocaine gel | Pain (VAS) | Not reported |
| Celik et al. [12] | Randomized, placebo-controlled, crossover study | Turkey | 41 | ≥ 18 years | Vapocoolant Spray | Lidocaine/Prilocaine Cream | Pain (VAS)<br>Participants' global judgment of the effectiveness of the allocated treatment | Reported |
| Fujimoto et al. [13] | Randomized crossover trial | Japan | 66 | ≥ 20 years | EMLA cream | Lidocaine tape | Pain (VAS)<br>Quality of life (SF-36)<br>Safety | Reported |
| Ghoreyshi et al. [25] | Clinical trial | Iran | 50 | > 18 years | Cold compresses | Xyla-P cream<br>Placebo | Pain (VAS) | Not reported |
| Ghoreyshi et al. [21] | Randomized clinical trial | Iran | 50 | > 18 years | Cold compresses | Xyla-P cream<br>Placebo | Pain (VAS) | Not reported |
| Gouda et al. [14] | Randomized controlled trial | Egypt | 108 | ≥ 18 years | Lidocaine spray | Cold packs<br>Flashlights<br>Control | Pain (VAS) | Reported |
| Kitamoto et al. [15] | Placebo-controlled, double-blind, cross-over design | Japan | 16 | Mean age 50 years | 10% Lidocaine gel | Placebo | Pain (scale of 5) | Not reported |
| Kortobi et al. [22] | Analytical prospective study | Morocco | 84 | 20–71 years | EMLA cream | Cryotherapy | Pain (VAS) | Reported |
| Malekshahi et al. [26] | Double blind clinical trial | Iran | 75 | > 18 years | Piroxicam | EMLA<br>Placebo | Pain (VAS)<br>Side effects | Reported |
| Mirzaei et al. [27] | Quasi-experimental study | Iran | 40 | > 18 years | Lidocaine spray | Ice pack<br>EMLA cream | Pain (VAS) | Not reported |
| Porramezani et al. [24] | Quasi- experimental study | Iran | 40 | > 18 years | Cryotherapy at Hoku point | No intervention | Pain (VAS) | Not reported |
| Shafii et al. [16] | Randomized double-blind controlled trial | Iran | 80 | > 18 years | Cooling spray | No intervention | Pain (VAS) | Reported |
| Shaheen et al. [28] | Randomized crossover clinical trial | Pakistan | 32 | 18- 75 years | EMLA cream | Piroxicam gel | Pain (NRS) | Reported |
| Sivagami et al. [29] | Quasi- experimental study | India | 30 | 18–65 years | EMLA cream | Lidocaine spray | Pain (NRS) | Not reported |

*NRS* numerical rating scale, *VAS* visual analogue scale

Three studies with 132 patients compared use of cryotherapy and EMLA at fistula puncture site. The former was better, as the pain intensity was 1.05 (95% confidence interval 0.21, 1.89) points lower on the visual analogue scale (Fig. 3). However, there was considerable heterogeneity among the results of these studies. Sensitivity analysis performed by removing the study by Kortobi, et al. from the model markedly reduced the degree of heterogeneity ($I^2$ = 38%), but did not affect the results. Only one of these studies reported the

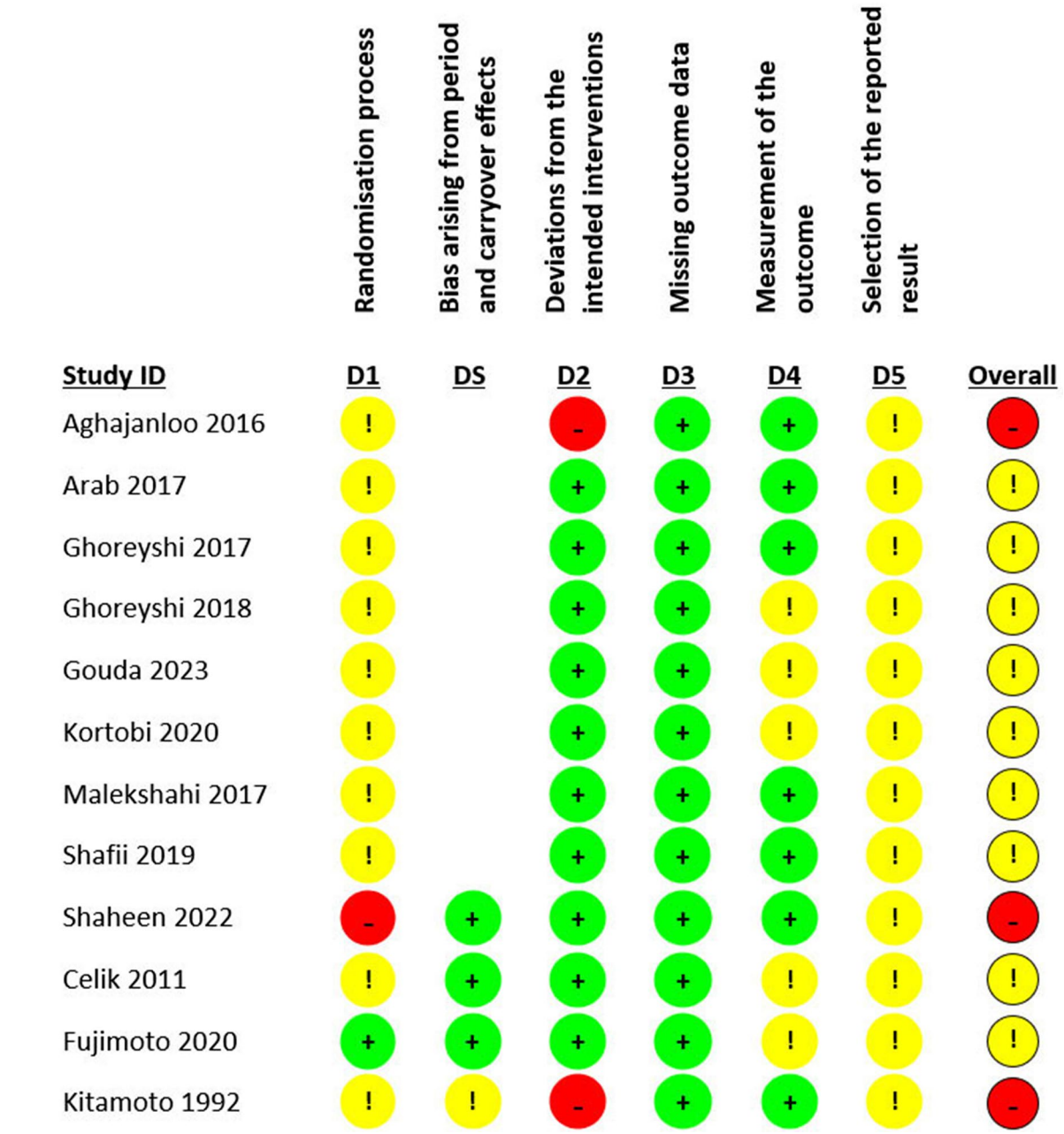


**Fig. 2** Risk of bias assessment

frequency of side effects in the two arms [21]. There were six events in the cryotherapy arm and none with EMLA.

In another meta-analysis of two studies with 57 patients, EMLA cream was superior to piroxicam gel, as it was associated with a greater degree of reduction in pain intensity (mean difference 1.30; 95% confidence interval 0.68, 1.93). No heterogeneity was documented amongst these two studies (Fig. 4). There was a no statistically significant difference in the frequencies of side effects with both these agents.

In the meta-analysis of two other studies on 55 patients comparing EMLA cream with lidocaine spray, EMLA cream was associated with a lesser degree of pain (mean difference 2.09 points; 95% confidence interval $1.81 \pm 2.38$) (Fig. 5). Considerable heterogeneity was present in both these studies, though on the same side of the line of no effect. Neither of these two studies reported

**Table 2** Assessment of risk of bias for nonrandomized studies

| Study | Bias due to confounding | Bias in selection of participants into the study | Bias in classification of interventions | Bias due to deviations from intended interventions | Bias due to missing data | Bias in measurement of outcomes | Bias in selection of the reported result | Overall Bias |
|---|---|---|---|---|---|---|---|---|
| Porramezani et al. [23] | Low | Low | Low | Low | Low | Serious | Low | Serious |
| Mirzaei et al. [26] | Low | Low | Low | Low | Low | Serious | Low | Serious |
| Sivagami et al. [28] | Low | Low | Low | Low | NI | Serious | Low | Serious |

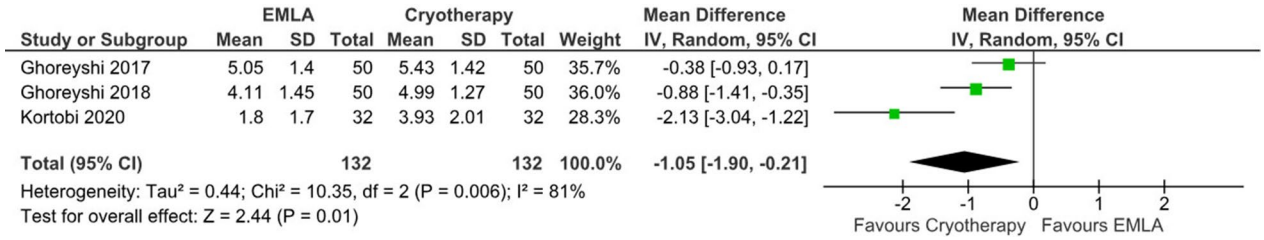


**Fig. 3** Forest plot for comparison of pain reduction between cryotherapy and EMLA cream

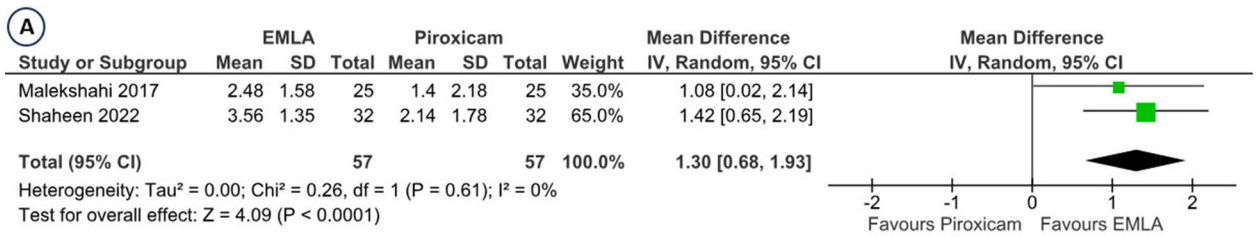


**Fig. 4** Forest plot for comparison of pain reduction between EMLA cream and piroxicam gel

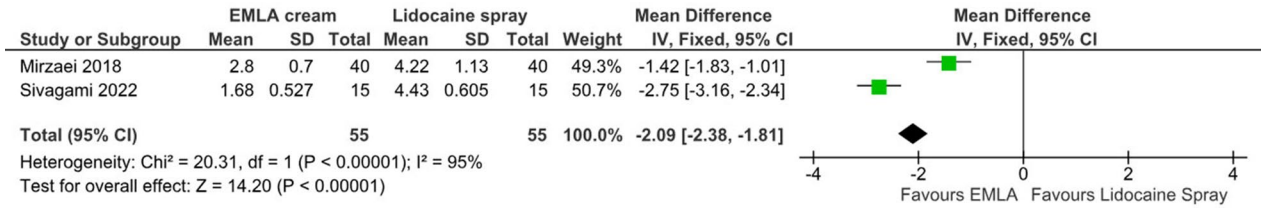


**Fig. 5** Forest plot for comparison of pain reduction between EMLA cream and lidocaine spray

the frequency of side effects associated with any of the interventions.

Another meta-analysis of two studies with 65 patients comparing cryotherapy at Hegu point with placebo showed that the former was associated with a lesser degree of pain during cannulation of AVF (mean difference 2.53; 95% confidence interval 1.23, 3.83; Fig. 6). There was considerable heterogeneity among these two studies. Neither of these two studies reported the frequency of side effects associated with any of the interventions.

Amongst other interventions, Hegu point ice massage was better than vapocoolant spray, cryotherapy with ice packs at fistula site was more effective than lidocaine spray, whereas EMLA cream was superior to both vapocoolant spray and lidocaine tape [11–14]. Lidocaine gel and vapocoolant spray were superior to placebo in pain reduction [15, 16].

## Discussion

Pain is a major problem for patients on maintenance HD, experienced by more than half of patients and poorly controlled in nearly three fourths of those affected [17]. This could be caused by frequent AVF punctures during HD, other procedures, such as the insertion of dialysis catheters or the creation of an AVF, venipuncture for blood sampling or related to complications of the disease, such as neuropathies. This has been shown to have negative effects on the quality of life of such patients [18]. Efforts to reduce pain are thus justified. As far as pain during needling of AVF is concerned, a number of pharmacological and non-pharmacological interventions have previously been attempted with variable success. This systematic review focused on comparing different pharmacological interventions. A total of 15 studies incorporating data on 832 patients were included. Cryotherapy with ice packs was found to be superior to both EMLA cream (a eutectic mixture of 2.5%lidocaine and 2.5% prilocaine) and placebo, whereas evidence also supported EMLA cream being better than piroxicam gel, lidocaine spray/gel and vapocoolant spray. Although cryotherapy at Hoku point and lignocaine gel were both better than placebo, a direct comparison between the two yielded superior results with the former intervention.

There was a variation in the way results were reported. Both the numerical rating scale and visual analogue scale were used for the assessment of pain intensity in different studies, as shown in Table 1. There are minor differences in these two scales, especially with regard to the pain dimensions measured. This subject is beyond the scope of this review and is discussed in detail elsewhere [19]. However, for the sake of simplicity, we included studies describing any of these and analysed them together.

Cryotherapy is a blanket term covering treatment options that use cold temperatures for pain relief [20]. This could be applied locally using ice packs, chemical cold packs or gel packs. Alternatively, ice massage could be done or specialised cryocuffs that circulate cold water are wrapped around a joint. Most of the studies on cryotherapy have used ice packs, but there was a significant disparity in implementation of this intervention across different studies. Some of the studies have applied this method on the fistula puncture site [14, 21, 22]. There are others that have used the Hegu point, located between the base of the thumb and the index finger, on non-fistula arm [11, 23, 24]. Kortobi, et al. used cryotherapy for 5 min and then needled the fistula immediately after removing ice packs [22]. Aghajanloo, et al. and Ghoreyshi, et al. applied this for 10 min before needling and continued doing so while the needles were being placed [23, 25]. In another study by Ghoreyshi, et al., the timing of the application of cryotherapy is not mentioned [21]. The same is true for the studies using EMLA cream, as there is a wide variation in the duration of application of this drug (10–60 min) [21, 23, 25–28]. The paper by Sivagami, et al. does not provide enough information in this regard [29]. It is not clear how the time duration for which these interventions were applied could have affected the results in these cases. Vapocoolant spray is also a form of cryotherapy. It cools the skin through evaporation and thus reduces pain. We listed this separately from cryotherapy while devising the literature search strategy because most of the studies on cryotherapy used ice packs, whereas vapocoolant spray was listed as a distinct modality in titles of other papers. None of the studies included in this

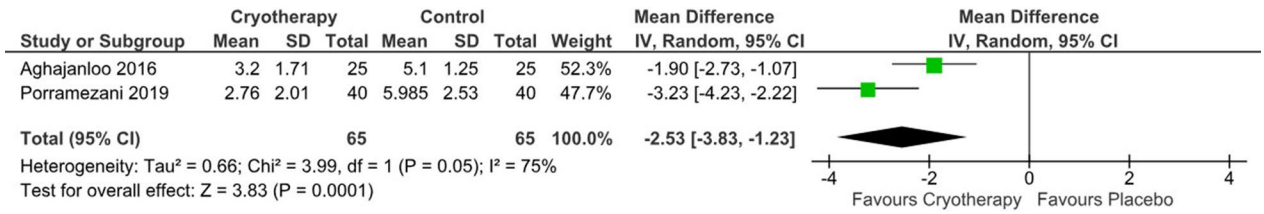


**Fig. 6** Forest plot for comparison of pain reduction between cryotherapy and placebo

review directly compared the two different techniques of cryotherapy: application of cold packs and vapocoolant spray.

A systematic review and meta-analysis by Jafari-Koulaee, et al. of eight studies with 422 participants has shown cryotherapy using ice packs at Hegu point to be effective in reducing pain during cannulation of AVF [30]. Intervention was shown to reduce the intensity of pain by 1.92 points (95% CI 0.92, 2.91). Interestingly, whereas cryotherapy at Hegu point and at the AVF puncture site have been evaluated independently in previous studies, no study has directly compared this intervention at these two different locations. We would thus suggest that this be evaluated in clinical trials in future.

This systematic review has policy implications as well. EMLA cream is expensive because it is imported into Pakistan, and is thus not freely available or widely used. Our results highlight the importance of local manufacturing so that more people can benefit from it.

A major strength of this review is the comprehensive coverage of all pharmacological interventions under one umbrella, a subject not covered in the past. Although most of the meta-analyses reported in this paper included only a few studies, we performed a sensitivity analysis wherever there were at least three studies that had considerable heterogeneity. This added to the reliability of our results. More than half of the included studies did not report side effects to different interventions studied. This is a significant limitation because choosing the best treatment option requires knowledge of the balance between efficacy and the risk of adverse events. Most of the studies involved a small number of patients, with nine of them not providing information about sample size calculation. They also had biases, mainly in the randomization process and selection of the reported result, raising some or serious concerns. The major methodological limitation of this review is that the literature search was carried out on a limited number of databases/search engines owing to resource constraints. Similarly, for ease of understanding, we included only articles in English language. This means that some other relevant literature on this subject might have been missed out.

## Conclusions

The analysis of studies included in this systematic review/meta-analysis has shown that cryotherapy using ice packs, both at the Hegu point and the AVF puncture site, and EMLA cream are effective at reducing pain during cannulation. However, this should be interpreted in the context of the degree of bias in the reported studies.

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**Author contributions**
A.R.A. conceptualized the work and carried out data analysis, manuscript revision and final approval; U.I. performed data acquisition, manuscript drafting and final approval; B.R. carried out data interpretation, manuscript drafting and final approval.

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**Availability of data and materials**
Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

## Declarations

**Ethics approval and consent to participate**
Not required for systematic reviews.

**Consent for publication**
No data for individual patients has been presented in this paper.

**Competing interests**
The authors declare that they have no competing interests.

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## Publisher's Note