Effect of cold application on intramuscular injection pain among patients with fractures

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Background
Intramuscular injection (IMI) is an invasive and painful procedure that is routinely used in health care settings. The knowledge regarding the efficiency of nonpharmacological methods of pain management, including cold application, is limited and needs further research studies.
Aim
The aim of the study was to evaluate the effect of cold application on IMI pain among patients with fractures.
Design
A quasi-experimental design (pre-posttest nonequivalent control group design) was used.
Setting
This study was conducted in the inpatient clinic of Orthopedic Surgical Department in Beni Suef University Hospital.
Sample
A convenient consecutive sample of 64 adult male and female patients was enrolled in the study.
Tools
Two tools were used for data collection: (a) structured interview assessment form, including sociodemographic and medical-related data, and (b) pain assessment forms.
Results
The study findings revealed that the mean age of the study and control groups was 39.2±11.1 and 34.8±11.9 years, respectively. When analyzing the numerical pain scale, a statistically significant difference was found between both groups, with higher reduction in the total mean score of pain from 6.78±1.6 to 2.34±0.9 among the group that received cold application before IMI. It also showed that there were highly statistically significant differences in the total mean score of the observational checklist of nonverbal pain indicators of the study group between preintervention and postintervention results during movement and at rest ($P \leq 0.001$).
Conclusion
This study concluded that cold application was an effective nursing measure in reducing the pain intensity associated with IMI.
Recommendations
Continuous education for nurses must be provided to improve their knowledge and practice regarding nonpharmacological methods such as cold application and its effect on relieving pain arising from IMI into the vastus lateralis muscle.

Keywords:
cold application, fracture, intramuscular injection, pain

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Introduction

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage (Diwan and Deer, 2018). Accordingly, the relief of pain should be recognized as a human right; thus, all invasive procedures, however minor, should be performed putting the goals of pain management into consideration (The International Association for the Study of Pain IASP, 2018). Furthermore, the control of pain and associated inflammatory edema is a major concern for orthopedic surgeons, especially for patients with fractures (Mitchill *et al.*, 2018).

Bone fractures are defined as a partial or complete break in the continuity of bone that most often occurs under mechanical stress. Bone fracture could be associated with hemorrhage, inflammation, edema, fibrosis, and severe pain. Indeed, fracture pain is one of the most common and costly problems caused by bone injury or diseases (Chew *et al.*, 2016).

The consequences of the fracture induce synthesis of many inflammatory mediators. Inflammation causes pain, vasodilatation, increased capillary permeability, and fluid exudation to the interstitial space, which delay wound healing. Accordingly, immediate administration of anti-edematous medication to relieve inflammatory edema and tissue destruction that occurs with bone fracture is important. Most of these medications are administered intramuscularly (Hitcings *et al.*, 2019).

Intramuscular injection (IMI) is a fairly uncomfortable invasive procedure used to deliver a medication deep into the muscles (Kara and Gunes, 2016). A total of 16 billion injections are given worldwide each year. The intramuscular route is favored owing to the increased vascularity of muscle tissue and the corresponding increase in the bioavailability of drugs when administered. Approximately 90% of the injections are given into muscle or skin (subcutaneous or intradermal) to administer medications (Joseph, 2019).

There are many factors that can cause pain during IMI, including the injection site, the volume of the drug to be injected, position of the patient during injection, the needle size, the technique, the chemical composition of the drug, and the speed of injection (Cooper and Gosnell, 2019). Actually patients are often afraid of receiving injection because they perceive that the experience would be painful which may lead a patient to postpone medical help (Salari *et al.*, 2018).

When considering IMI sites, the nurse should select a site that is safe distance from nerves, large blood vessels, and bones; free from injury, abscesses, and tenderness; and sufficiently large enough to accommodate the volume of medication (Tanioka *et al.*, 2018). For this reason, the vastus lateralis muscle is an appropriate site for IMI as it is free from major nerves and blood vessels; however, it is rich with small nerve endings that cause the injection in this site to be very painful (Nakajima *et al.*, 2020).

Cold application on the vastus lateralis muscle creates a conduction block to tissues similar to the effect of local anesthetics. It activates descending inhibitory neurons that prevent the ascending nociceptive neurons from sending pain signals to the brain. So, the cooling of a target tissue would decrease discomfort and pain (local analgesic) that result from IMI (Freire *et al.*, 2016; Khalil, 2018). In a study conducted in Egypt, it was recommended that medical departments should use cold application for 30 s before IMI to reduce the needle puncture pain as a routine postinjection care (Ramadan *et al.*, 2016).

Nurses have a central role in assessing patients' pain and providing pain treatment options; therefore, they are in a position where they can decrease the number of people experiencing pain and the under-treatment of pain. Moreover, they have a great responsibility to provide clinically excellent care to address a patient's pain (American Nurses Association ANA, 2018).

Clinically excellent pain management considers clinical indications, mutual identification of goals for pain management, ongoing reassessment with the patient of the efficacy of pain, relief interventions, interprofessional collaboration, and awareness of professional standards for the assessment and management of different types of pain. Health institutions have a responsibility to ensure staff competency in pain assessment and management as one of the patient rights (US Department of Health and Human Services, 2019).

Moreover, nurses should be familiar with the types of complementary therapy such as applying deep breathing techniques, massaging and cold application, providing quiet and comfortable environment, comfort devices, and education for patients and their families, which is mostly used in the professional setting. They are responsible for assessing its appropriateness. They should have sufficient knowledge of the action and effects of the therapy to assess the risks and benefits for the particular patient (Perry *et al.*, 2020). Effective pain management not only reduces physical discomfort but also improves quality of life (Tanioka *et al.*, 2018).

Nurses need to access available resources to obtain information about the intervention to determine appropriateness in the context of the situation. In addition, nurses have an important role in encouraging the patient to assess the effectiveness of the therapy continually using standard pain assessment techniques (Van Graan *et al.*, 2016). Therefore, this study was conducted to evaluate the effect of cold application on IMI pain among patients with fractures.

Significance of the study

Approximately nine million people worldwide experience fractures each year, of which 1.6 million were at the hip bone. It affects 18% of women and 6% of men globally (Kazley and Bagchi, 2020). The incidence of tibia fractures is 16.9/100 000

worldwide (Larsen *et al.*, 2016). In Egypt, nearly 75% of all hip fractures occur in women and 25% occur in men (Algarni and Almaki, 2019). It is stated in the literature that the annual incidence of tibia fracture is 5.6 per 100 000 (Saied *et al.*, 2019). According to Beni Suef University Hospital (2020), the numbers of admitted patients who had tibia and hip fractures were 239, 260, 313, and 246 in 2017, 2018, 2019, and 2020, respectively.

From the investigators' observation during clinical experience with students in the orthopedic department, almost all patients with fractures received IMI into the vastus lateralis muscle during the period of hospitalization. So, reducing pain during IMI is a major concern of the nurses (Czarnecki and Turner, 2018). Therefore, the findings of this study would alert nursing personnel and other health care providers working in orthopedic units to use cold application as a complementary therapy to minimize pain during IMI into the vastus lateralis muscle that could be reflected positively on patients care. Hopefully, the findings of this study can provide evidence-based data that can improve nursing practice in Egypt as well generate attention and motivation for further research in this topic.

Patients and methods

Aim of the study

The aim of this study was to evaluate the effect of cold application on IMI pain among patients with fractures.

Research hypotheses

H_1: The study group of patients with fractures who received cold application before IMI will have significant lower pain mean intensity scores than control group receiving routine hospital care.

H_2: The study group of patients with fractures who received cold application before IMI will have significant lower mean scores of nonverbal pain indicators than control group receiving routine hospital care.

H_3: The study group of patients with fractures who received cold application before IMI will have different mean scores of pain characteristics than control group receiving routine hospital care.

Research design

A quasi-experimental pre-posttest nonequivalent control group design was used to demonstrate causality between an intervention (cold application) and an outcome (IMI pain). In this design, the investigator had two groups: one experimental and one control where the outcome on the experimental group before and after the intervention would be measured. In addition, the investigator carried out the same measurements on the control group as that in patients who received the intervention. Although this design lacked the element of random assignment, the investigators exercised certain control and used criteria other than random assignment (e.g. an eligibility cut-off mark) to enhance the study's internal validity and thereby strengthen the quality of evidence (Wood and Haber, 2015).

Setting

This study was conducted at the inpatient Department of Orthopedic Surgical in Beni Suef University Hospital. The department was divided into three rooms: one large room for males and two small rooms for females. The capacity of the department is 31 beds. The average duration in which patient with tibia and hip fractures stayed at the hospital was 4–7 days.

Sample

A convenient consecutive sample of 64 adult male and female patients who were admitted to the orthopedic unit with tibia or hip fractures or both was included (32 in the study group and 32 in the control group). They were divided consecutively into control and then study group. The inclusion criteria included patients age more than or equal to 18 to less than 60 years, 48 h after admission and fixation of fracture, had pain intensity level more than or equal to 4 for numerical rating scale, received Fleboton medication into the vastus lateralis muscle, and not received analgesics either tablets or injection before administering the cold application. The exclusion criteria included patients with impaired circulation or peripheral vascular disease, patients with hip fracture in both legs, patients who took sedations, patients who were addicts, or patients with drug abuse. The sample size was calculated using a G-power, version 3.1.1 for power analysis. A power of 0.95 (β=1–0.95=0.05) at alpha of 0.05 (one-sided tail) and significance level of *P* value less than or equal to 0.05 were utilized.

Tools of data collection

To achieve the aim of the current study, two tools were utilized to collect data relevant to the study variables as follows:

Tool I: structured interview assessment form, which was developed by the investigators and included two parts:

(1) Sociodemographic data, which cover questions related to age, sex, level of education, and occupation.
(2) Medical-related data, such as location of current fracture and method and time of stabilization of the current fracture.

Tool II: pain assessment form. It included three parts:

Part 1 was the universal pain assessment scale, which included the numerical rating scale. It was adopted from Belcheva and Shindove (2014). It included six levels of pain quality and intensity clarified by word descriptors. The investigator asked the patients to select the numbers or descriptions that indicate the most appropriate pain perception immediately after the IMI. The total score ranged from 0 to 10. Zero indicates no pain, 1 to 2 indicates mild pain, 3 to 4 indicates moderate pain (interferes with tasks), 5 to 6 indicates moderate pain (interferes with concentration), 7 to 8 refers to severe pain, and 9 to 10 indicates worst pain.

Part 2 was the observational checklist of nonverbal pain indicators (OCNPI). It was adopted from Feldt (2000). It consisted of six behaviors that are associated with pain: vocalizations, facial grimacing or wincing, bracing, rubbing, restlessness, and verbal complaints as ouch that hurts, stop, or that is enough. Scoring includes observing patients while they are at rest and while they are moving. An item is scored as '1' if the behavior is observed during activity or rest and as '0' if the behavior is not observed, and the total score ranged from 0 to 12. The 0 score indicates no pain, 1–4 indicates mild pain, 5–8 refers to moderate pain, 9–12 refers to severe pain, with Cronbach's alpha reliability (r) of 0.78 for the current study.

Part 3 comprised characteristics of pain that result from IMI, which was developed by the investigator after extensive literature reviews (Turk and Melzack, 2011; Villanueva *et al.*, 2017; Mohammed *et al.*, 2019; Cooney and Colwell, 2021). It included questions such as 'Does the pain appear immediately after IMI?' 'Does the pain start gradually until it reaches its peak?', etc. Score 0 is given if the patient's answer was no or if the patient's answer was 'I cannot identify' and score 1 is given if the answer was yes. Reliability of this questionnaire was assessed using Cronbach's alpha (r=0.72).

Ethical consideration

The approval to conduct the proposed study was obtained from the Research and Ethics Committees at Faculty of Nursing, Cairo University (IORG0006883). Moreover, an official permission was obtained from hospital/clinic administrators where the study was conducted. Each patient was informed about the nature and purpose of the study as well as risks and benefits involved. The investigator emphasized that participation in the study was completely voluntary and patients could withdraw from the study at any time without affecting the medical care they receive. Then, those who chose to participate in the study were asked to sign a consent form. Additionally, confidentiality and anonymity were assured through coding the data.

Procedure

In the preparatory phase, an official permission was obtained to proceed with the proposed study. Participants who met the inclusion criteria were recruited individually. The nature and purpose of the current study was explained. Written consent was obtained from the participants who accepted to participate in the study. During this step, the investigator collected sociodemographic and medical-related data from the patient and medical record through using tool I (the structured interview assessment form).

In the implementation phase, on the third day from patient admission, the investigator administered IMI of Fleboton medication (3 ml) without using cold application to both groups (control and study groups) and then measured the pain score through using tool II (universal pain assessment scale, OCNPI, and characteristics of pain that result from IMI) immediately after injection. On the fourth day of admission to hospital, the investigator used cold application before IMI to the study group on the vastus lateralis muscle for at least 30 s or until skin numbness occurred. Then, the investigator conducted the postintervention measurement. Pain score was measured through using tool II. On the contrary, the investigator administered IMI of Fleboton medication to control group according hospital policy and without using the cold application and then pain score was measured through using tool II.

In the evaluation phase, the patients were assessed before and after applying cold application for the study group and the progress was identified and compared in term of differences in the level of pain between both groups, in relation to tool II.

Statistical analysis

The obtained data were tabulated, computed, and analyzed using the Statistical Package for the Social

Sciences (SPSS) program, version 23 (IBM Crop in Armonk, New York). Descriptive statistics such as frequency, percentage, mean, and SD, in addition to inferential statistics including paired *t* test, analysis of variance, and χ^2 test were utilized to analyze data pertinent to the study. Level of probability errors were adopted at *P* value less than or equal to 0.05.

Results

The findings of the current study were presented into three sections: section I describes comparative description between the study and control groups on sociodemographic and medical-related data (Tables 1 and 2). Section II represents statistical analysis for research hypotheses between the study and control groups (Tables 3–6).

Section I: sociodemographic and medical-related data for study and control groups

Table 1 revealed that the mean age among the study and control groups was 39.2±11.1 and 34.8±11.9 years, respectively. A higher percentage of patients were sociodemographic male in the control and study groups (59.83 and 71.88%, respectively). Regarding educational level, a higher percentage of patients had secondary level of education among the control and study groups (31.25 and 40.62%, respectively). Regarding occupation, approximately one-third (31.25%) of the control group was employed, whereas 40.62% of the study group had casual work.

Table 2 shows that 62.50 and 65.63% had tibia fracture among the control and study groups, respectively. Regarding the method of current fracture stabilization, more than one-third (37.50%) of the control group had external fixation, and their fractures were stabilized on more than 2 days of admission to hospital. In addition, 37.50% of the study group had open reduction and internal fixation (ORIF), and 59.38% of them had stabilization of their fractures on the first day of admission.

Table 2 also shows that 43.75% of both groups had chronic diseases. Among yes responses, 12.50 and 15.63%% had cancer in the control and study groups, respectively. Moreover, the entire patients in both groups had previous experiences of receiving IMI. In relation to the site of IMI, 68.75 and 62.50% received previous injection on the dorsolateral muscle in the control and study groups, respectively. Moreover, all patients under the study had painful experience with IMI and received analgesic intramuscular (Diclofenac 75 mg) 3 ml two times per day and anti-edematous medication (Fleboton) 3 ml one time per day.

Section II: statistical analysis for research hypotheses between the study and control groups

Table 3 reveals that there was a highly statistically significant reduction in the total mean scores from 6.78 ±1.6 to 2.34±0.9 of the numerical pain scale of the study group (*P*=0.001).

Table 1 Frequency and percentage distribution of sociodemographic characteristics for the patients in study and control groups (*N*=32 for each group)

Variables	Control group [*n* (%)] *N*=32	Study group [*n* (%)] *N*=32
Age		
18–>30	14 (43.75)	6 (18.75)
30–>40	10 (31.25)	15 (46.87)
40–>50	2 (6.25)	3 (9.38)
50–≥60	6 (18.75)	8 (25.00)
Mean±SD	34.8±11.9	39.2±11.1
Sex		
Male	19 (59.38)	23 (71.88)
Female	13 (40.62)	9 (28.12)
Level of education		
Cannot read and write	5 (15.63)	6 (18.75)
Primary education	6 (18.75)	6 (18.75)
Preparatory education	4 (12.50)	1 (3.13)
Secondary education	10 (31.25)	13 (40.62)
University education or others	7 (21.87)	6 (18.75)
Occupation		
Does not work or retired	5 (15.63)	4 (12.50)
Employee	10 (31.25)	7 (21.88)
Casual work	9 (28.12)	13 (40.62)
Housewife	8 (25.00)	8 (25.00)

Table 2 Frequency and percentage distribution of selected medical-related data for patients in study and control groups (*N*=32 for each group)

Variables	Control group [*n* (%)] *N*=32	Study group [*n* (%)] *N*=32
Location of fracture		
Hip fracture	12 (37.50)	10 (31.25)
Tibia fracture	20 (62.50)	21 (65.63)
Both	0	1 (3.12)
Method of current fracture's stabilization		
Casting	8 (25.00)	11 (34.38)
Traction	3 (9.38)	2 (6.25)
Open reduction and internal fixation	9 (28.12)	12 (37.50)
External fixation	12 (37.50)	7 (21.87)
Time of fracture stabilization		
On the first day of admission	11 (34.38)	19 (59.38)
On the second day of admission	9 (28.12)	13 (40.62)
More than 2 days of admission	12 (37.50)	0
Chronic diseases		
No	18 (56.25)	18 (56.25)
Yes	14 (43.75)	14 (43.75)
Among yes response		
Hypertension	2 (6.25)	2 (6.25)
Anemia	4 (12.50)	2 (6.25)
Heart disease	1 (3.13)	2 (6.25)
Respiratory disease	3 (9.37)	3 (9.37)
Cancer	4 (12.50)	5 (15.63)
Previous intramuscular injection		
Yes	32 (100)	32 (100)
Dorsogluteal muscle	22 (68.75)	20 (62.5)
Vastus lateralis	10 (31.25)	12 (37.5)
Painful intramuscular injection		
Yes	32 (100)	32 (100)
Current intramuscular medications		
Analgesics (3 cm – two times)	32 (100)	32 (100)
Anti-edematous medications (3 cm – one time)	32 (100)	32 (100)

Table 3 Comparison of total mean score of the numerical pain scale before and after intervention for patients in study and control groups (*N*=64) (32/each group)

	Study group					
	Before intervention		After intervention			
Variables	Mean	SD	Mean	SD	*t* test	*P* value
Numerical pain scale	6.78	1.6	2.34	0.9	13.6	0.001*
			Control group			
Numerical pain scale	6.43	1.45	6.46	1.43	0.08	0.93

**P* value less than or equal to 0.05.

Table 4 illustrates that there was a highly statistically significant difference between preintervention and postintervention scores among patients in the study group regarding the numerical pain assessment scale (χ^2=37.0; $P \leq 0.001$).

Table 5 shows that there were highly statistically significant differences in the total mean score of the OCNPI of the study group between preintervention and postintervention findings during movement and at rest ($P \leq 0.001$). However, in the control group, no statistically significant differences were observed between preintervention and postintervention findings during movement or at rest (P=0.8).

Table 6 demonstrates that there was a highly statistically significant difference in the total score of pain characteristics that result from IMI before and after intervention in the study group (P<0.001).

Table 4 Comparison between numerical pain scale before and after intervention according to pain categories among patients in study and control groups (*N*=64) (32/each)

Variables	Total score	Study group (*N*=32) [*n* (%)]				Control group (*N*=32) [*n* (%)]			
		Before	After	χ^2	*P* value	Before	After	χ^2	*P* value
No pain	0	0	0			0	0		
Mild	1–2	0	18 (56.30)	37.0	0.001**	0	0	0.06	0.96
Moderate	3–6	13 (40.60)	14 (43.80)			17 (53.10)	16 (50.00)		
Severe	7–8	15 (46.90)	0			13 (40.60)	14 (43.80)		
Worst pain	9–10	4 (12.50)	0			2 (6.30)	2 (6.30)		

**Highly statistical significance at $P \leq 0.01$.

Table 5 Comparison of total mean scores of the observational checklist of nonverbal pain indicators before and after intervention during movement and rest for the study and control groups (*N*=64) (32/each group)

	Study group						Control group					
	Before		After				Before		After			
Variables	Mean	SD	Mean	SD	*t* test	*P* value	Mean	SD	Mean	SD	*t* test	*P* value
Subtotal at movement	5.1	0.98	2.1	0.84	13.0	0.001**	4.7	0.97	4.8	0.97	0.38	0.7
Subtotal at rest	4.4	0.94	2.0	0.89	10.0	0.001**	4.2	1.0	4.2	1.1	0.11	0.91
Total score	9.5	1.8	4.2	1.7	11.8	0.001**	9.0	1.9	9.1	2.0	0.24	0.8

**Highly statistical significance at $P \leq 0.01$.

Table 6 Frequency and percentage distribution of pain characteristics that result from intramuscular injection before and after intervention for patients in the study and control group (*N*=64) (32/each)

Variables	Study group (*N*=32) [*n* (%)]		χ^2	*P* value	Control group (*N*=32) [*n* (%)]		χ^2	*P* value
	Before	After			Before	After		
Does the pain appear immediately after intramuscular injection?	32 (100)	32 (100)	0	1	32 (100)	32 (100)	0	1
Does the pain start gradually until it reaches its peak?	25 (78.1)	3 (9.4)	30.7	0.001**	20 (62.5)	21 (65.6)	0.06	0.79
Does the pain start suddenly?	7 (21.9)	29 (90.6)	30.7	0.001**	12 (37.5)	11 (34.4)	0.06	0.79
Does the pain begin at its maximal intensity and remain at this level until it goes?	7 (21.9)	29 (90.6)	30.7	0.001**	13 (40.6)	12 (37.5)	0.06	0.79
Is the pain radiate to any other areas?	32 (100.0)	32 (100.0)	0	1	0	1 (3.1)	1.0	0.31
Does the pain increase as a result of a certain position or movement?	25 (78.1)	2 (6.3)	33.8	0.001**	18 (56.3)	20 (62.5)	1.1	0.56
At movement	25 (78.1)	2 (6.3)	33.8	0.001**	19 (59.4)	20 (62.5)	0.06	0.79
Is there is (specific position or movement that reduces the pain?	25 (78.1)	2 (6.3)	33.8	0.001**	19 (59.4)	20 (62.5)	0.06	0.79
At rest	25 (78.1)	2 (6.3)	33.8	0.001**	19 (59.4)	20 (62.5)	0.06	0.79
Do you try to avoid injection as you know that it will cause pain?	32 (100)	30 (93.8)	2	0.15	32 (100)	32 (100)	0	1
Do you ask the nurse to stop giving injection?	32 (100)	10 (31.3)	33.5	0.001**	32 (100)	32 (100)	0	1
How do you feel the pain?								
I cannot identify	0	1 (3.1)			0	0		
Numbness	1 (3.1)	4 (12.5)			1 (3.1)	2 (6.3)		
Burning	4 (12.5)	4 (12.5)			4 (12.5)	4 (12.5)		
Dullness	2 (6.3)	0		0.02*	0	1 (3.1)		
Stabbing	5 (15.6)	5 (15.6)			3 (9.4)	3 (9.4)		
Tightening	4 (12.5)	2 (6.3)			4 (12.5)	4 (12.5)		
Sharping	10 (31.3)	1 (3.1)			9 (28.1)	10 (31.3)	1.8	0.93
Crushing	6 (18.8)	15 (46.9)			11 (34.4)	8 (25)		
Stinging	0)	1 (3.1)	16.6		1 (3.1)	2 (6.3)		
Total score of pain characteristics	24 (75)	15 (46.8)	23.8	0.001**	19 (59.3)	20 (62.5)	0.22	0.78

*Statistically significant at $P \leq 0.05$. **Highly statistical significance at $P \leq 0.01$.

However, no statistically significant difference was observed in the control group (P=0.78).

Discussion

IMI is most frequently used and causes painful experience for many hospitalized patients in orthopedic units. The pain resulting from IMI should not be underrated in the light of the fact that a painful injection might affect the nurse–patient relationship. Among many nonpharmacological pain management techniques, cold application is used to reduce pain associated with various types of injection (Soliman *et al.*, 2018). The following discussion will concentrate upon the findings and interpretations related to the study findings. It includes two sections: section I: explanation of study findings pertinent to sociodemographic and medical-related data, and section II: explanation of study findings concerning the pain assessment forms and research hypotheses.

Section I: explanation of study findings pertinent to sociodemographic and medical-related data

Regarding age, the current study findings revealed that more than one-third of the control group had age range from 18 to more than 30 years, and more than one-third of the study group had age range from 30 to more than or equal to 40 years, with a mean age of 39.2±11.1 and 34.8±11.9 years, respectively. This finding is consistent with Bilge *et al.* (2019), who found that the mean age of the patients who participated in the study was around 40 years, and Akcimen *et al.* (2019), who reported the same findings. These findings are incongruent with Ramadan *et al.* (2018), who reported that mean age of their studied patients was 53.58±6.94 years. In addition, Kant and Akpinar (2017), highlighted that the mean age of their studied patients was 20.28±1.3 years. This could be related to the risk of adults to be involved in motor vehicle accidents while looking for work and hazards that resulted from casual work.

In relation to sex, more than one half of the patients under the current study were males in both groups. This finding agreed with Akcimen *et al.* (2019), and Bhattacharjee *et al.* (2020), who found that more than half of patients in their studies were male. Moreover, Kara and Gunes (2016), reported the same findings. These findings are incongruent with Kant and Akpinar (2017), who found that more than half of the patients in their studies were female. This indicates that fracture is more common in youth and adult males owing to playing violent sports, falling from height, and motor vehicle accidents.

Concerning the level of education, the findings of the present study revealed that more than one-third of both groups had secondary level of education. This agreed with Jancy (2019), and Isseven and Midilli (2020), who reported that more than one-third of their studied patients had secondary level of education. The study findings were incongruent with Ramadan *et al.* (2016), who revealed that about one-third of their study patients had basic/primary education, and with Bilgic (2021), who reported that more than half of their study patients were elementary school graduates. This could be owing to increasing awareness level regarding the importance and necessity of education.

In relation to occupation, the result of the present study showed that about one-third of the control group was employed in addition to more than one-third of the study group had a casual work. This finding is supported by Ramadan *et al.* (2018), who reported that more than half of their study patients were working, and Shafii *et al.* (2019), who found that nearly one-half of the studied patients were self-employed. The current result is inconsistent with Mohammed *et al.* (2019), who found that one-third of both groups were housewives. This could be owing to unemployment in developing countries and patients had secondary education level, so few number of them got hired in governmental sectors and others had unstable jobs.

Concerning medical-related data in relation to the location of fracture, the findings of the current study revealed that about two-thirds of the patients in both groups had tibia fracture. This agreed with Clelland *et al.* (2016), who revealed that approximately a quarter of patients in their study were admitted with sustained tibia fractures. In addition, Sine *et al.* (2020), found that more than half of study patients had tibia fractures. This finding is inconsistent with Anandasivam (2019), who reported that more than one-third of the patients had femoral shaft fractures. This could be owing to tibia bears the weight of the main body in the lower leg, which can be easily exposed to fracture as a result of a fall, accident, or sport activity.

Regarding the method of current fracture's stabilization, the findings of the current study revealed that more than one-third of the control group had external fixation, whereas more than one-third of the study group had ORIF. This result agreed with Zhao *et al.* (2017), who reported similar findings. In addition, Wu *et al.* (2019), highlighted that more than one-third of patients under the study had external fixation and around half had ORIF. This may be owing

to patients' physical condition, type, and severity of fracture.

Regarding the presence of chronic disease, the current study revealed that more than one-third of patients in both groups had chronic disease. This finding is consistent with Shehata *et al.* (2020), who highlighted that more than one-third of their study patients had chronic diseases. Furthermore, Stumpf *et al.* (2020), highlighted the same findings. This could be related to low socioeconomic status, not following healthy diet or lifestyle, in addition to being stressed to not finding a job.

Regarding the current intramuscular medications, the study finding revealed that the entire study patients in both groups received IMI before and had painful experiences with the injection. This study finding is supported by Jancy (2019), and Bhattacharjee *et al.* (2020), who reported that the majority of their study patients had a previous experience with IMI. The finding is inconsistent with Bilgic (2021), who stated that more than half of his study patients did not fear from IMI, and the majority of them did not have negative or painful experience regarding IMI applications.

In relation to the site of IMI, the study findings revealed that more than half of the control and study groups received previous IMI on the dorsogluteal muscle. This finding is consistent with Gulnar and Ozveren (2016), who reported that more than half of their study patients received IMI into the dorsogluteal muscle, and also Karabey and Karagozoglu (2020), who reported the same findings. This finding is incongruent with Ayinde *et al.* (2021), who reported that the majority of their study patients received injection into the ventrogluteal muscle with less pain compared with the dorsogluteal muscle. This could be owing to that nurses are not adequately knowledgeable about the advantages of the ventrogluteal site, the muscle at the site is small, and the site is difficulty to landmark, and also, they think that this site is very painful for the patient.

Moreover, the study finding revealed that the entire study patients received analgesic and anti-edematous medications. This finding is supported by Vannucci *et al.* (2017), who found that all patients in their study wanted to receive analgesic drug as it was effective in the treatment of pain that results from fracture. This current study finding is inconsistent with Hsu *et al.* (2019), who reported that all patients with fracture refused to use analgesics. This could be owing to the effect of these medications in relieving pain and edema that result from fracture and its fixation.

Section II

Regarding the numerical pain scale, the findings of the current study showed that there was a statistically significant difference between the study and control groups before and after intervention. This finding is consistent with Kalyan *et al.* (2019), who mentioned that cold application is effective in reducing the pain associated with IMI. Moreover, Bilge *et al.* (2019), and Karabey and Karagozoglu (2021), reported the same findings. This indicates a positive effect of cold application on reducing pain that results from IMI.

The findings of the current study showed that the total mean score of pain intensity of the study patients before intervention was severe, whereas it was moderate and mild after intervention. Moreover, it revealed that there were highly statistically significant differences in total mean scores of pain intensity before and after intervention. This was congruent with Petprasert (2019), who conducted a study aimed to evaluate efficacy of cold application on injection area to relieve pain from tetanus vaccination and the investigators highlighted its effectiveness. Moreover, Ramadan *et al.* (2016), and Jancy (2019), reported the same results. This answered the research hypothesis that patients who received cold application before IMI expressed lower pain mean intensity scores compared with patients who did not receive it. This could be related to positive effect of cold application that may cause local anesthetic effect so it reduces pain that results from IMI.

In relation to the OCNPI, the findings of the current study showed a highly statistically significant difference regarding the total score of behavioral responses to pain of patients under the study group before and after intervention. This finding is supported by Ramadan *et al.* (2018), who conducted a study aimed to evaluate the effect of cryotherapy versus Heifer technique on pain intensity among adult patients receiving IMI and reported the same findings. In addition, Mohammed *et al.* (2019), found that there were statistically significant differences among the study group regarding the total mean score of the OCNPI before and after intervention. This answered the research hypothesis that patients who received cold application before IMI expressed significant lower nonverbal pain mean indicator scores than patients who did not receive it. This could be related to the positive effect of cold application, which confirmed the research hypothesis of the current study.

Concerning the characteristics of pain that resulted from IMI, the present findings revealed lower incidence of behavioral responses to pain between study and control groups before and after intervention. The result was congruent with Mohammed *et al.* (2019), who revealed that there were statistically significant differences between mean pain score level in control and study groups, and also the current study findings indicated that the pain intensity was significantly higher in the control group. This answered the research hypothesis that patients who received cold application before IMI expressed different mean scores of pain characteristics compared with patients who did not receive it. This could be related to the positive effect of cold application, which confirmed the research hypothesis of the current study.

Regarding pain intensity level, the findings of the current study demonstrated that there was a statistically significant difference in the pain intensity that resulted from IMI of the study and control groups before and after intervention. This finding was supported by Bhattacharjee *et al.* (2020), who reported that cold application was significantly effective in reducing the needle stick pain of patients in the experimental group compared with the patients in the control group who received IMI without cold application. Moreover, Bilgic (2021), highlighted the same findings. This answers the research hypothesis that patients who received cold application before IMI expressed lower pain intensity scores compared with patients who did not receive it. This indicates a positive effect of the cold application on reducing pain that results from IMI.

Conclusion

Based on the current study findings, it can be concluded that cold application is effective in reducing the pain associated with IMI among patients with fracture. This helps to decrease patient suffering, shortens the length of hospitalization, and reflects positively on patients care.

Recommendations

(1) Replication of the study using a larger probability sample from different geographical areas in Egypt is needed.
(2) Booklet guidelines should be established for nurses to improve their knowledge and practice regarding the effect of cold application as a nonpharmacological method on reducing IMI pain.
(3) More attention should be given to using cold application for patients with fractures especially for those receiving IMI in vastus lateralis muscles.
(4) Continuous in-service training programs should be conducted for refreshing and updating the nurses' knowledge and practice regarding effect of cold application on IMI pain.
(5) All patients undergoing cold application should receive adequate knowledge and skills regarding the effect of cold application on IMI pain through booklets and posters that lead to positive outcome.

Nursing implications

This study brings to light the effectiveness of cold application in reducing the pain associated with IMI. Effective pain management not only reduces physical discomfort but also improves quality of care. In fact, proper pain intervention enhances patient's outcomes and decreases the length of hospital stay and cost of care. This study can be used as an informative illustration for staff nurses working in different wards in hospital to reduce patient suffering from pain associated with IMI. Additionally, it is hoped that this study opens the door to perform further research studies regarding the use of other nonpharmacological pain relief methods to build a body of knowledge that might be taught in the nursing curriculum.

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Conflicts of interest

There are no conflicts of interest.

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