

EFFECT OF LOCAL COOLING APPLICATION ON PAIN INTENSITY AND SIZE OF HEMATOMA AMONG PATIENTS WITH INGUINAL HERNIA REPAIR

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ABSTRACT

A large proportion of patients' experiences severe post-surgical pain following inguinal hernia repair within the first 24 hrs post operatively. Pain control has been shown to improve postoperative recovery; also, poor pain control can lead to the development of chronic pain. Local cooling is a widely used technique in the immediate care of traumatic injury protocols for postsurgical rehabilitation and treatment of pain. We hypothesized that patients who receive local cooling would report lower pain scores as a primary outcome. The aim of the current study is to evaluate the effect of local cooling on pain intensity and size of hematoma among patients with inguinal hernia repair. Design: One group pretest/posttest quasi-experimental research design. Subjects: A convenient sample of 70 adult male patients immediately post inguinal hernia repair over a period of six months. Setting: Surgical Departments at one of educational

hospital in Egypt. Tools: Three tools used to gather data (1) Demographic and medical data sheet (2) Numeric Rating Scale (NRS) for pain intensity (3) Hematoma Formation and Size Assessment Scale. Results: there was a highly statistical significant difference in the mean pain intensity score before and after ice application at 6, 12 and, 24 hours postoperatively at (P -value ≤ 0.005) with total mean difference 9.642 ± 4.010 and the diameter of hematoma decreased. The results of the study revealed that ice bag application to the surgical site in patients after inguinal hernia repair effective in reducing postoperative pain intensity and hematoma size, it considered cost effective intervention. Recommendation: Nurses should consider using this technique while developing evidence-based protocols to care for patients with inguinal hernia repair.

Key words: Hernia, pain, local cooling, hematoma

INTRODUCTION

A hernia is the bulging for the content of the abdominal cavity through a weakness in the abdominal wall. Inguinal hernia (IH) defined as a rupture by the patients, commonly in men than women. There are two basic types that are fundamentally different in anatomy, causation and complications. However, they are anatomically very close to each other, surgical repair techniques are very similar and ultimate reinforcement of the weekend anatomy is identical, so they are often referred to together as (IH) (Modi, & Modi, 2019).

Worldwide, inguinal hernia repair (IHR) is one of the most common surgeries, performed on more than 20 million people annually. In Brazil, from 2015 to 2016 the National Health System treated more than 117,090 cases of unilateral inguinal hernia through the open technique and 901 cases through laparoscopic techniques. More than 770,000 procedures being performed each year in the United States (US) and 160,000 in France. Many studies have described the laparoscopic (IHR) resulting in a lower incidence of postoperative pain, edema formation and an earlier return to normal activities than the Lichtenstein technique (Mendonça, Miranda, Jorge .2017 and Mercier, et al .2018).

Surgical treatment is successful in the majority of cases, but recurrences necessitate reoperations in 10–15% and long-term disability due to chronic pain (pain lasting longer than 3 months) occurs in 10–12% of patients. Approximately 1–3% of patients have severe chronic pain. This has a tremendous negative effect globally on health and healthcare costs. The risk factors for (IH) include: family history, previous contra-lateral hernia, male gender, age, abnormal collagen metabolism, prostatectomy, and low body mass index. Peri-operative risk factors for recurrence include poor surgical techniques, low surgical volumes, surgical inexperience and local anesthesia. Lifetime occurrence of groin hernia viscera or adipose tissue protrusions through the inguinal or femoral canal is 27–43% in men and 3–6% in women. Inguinal hernia is almost symptomatic; and the only cure is surgery. A minority of patients are asymptomatic but even a watch and-wait approach in this group results in surgery in approximately 70% within 5 years (The Hernia Surge Group. 2018 & Teodoro et al. 2018).

A common complication following (IHR) is hematoma. It is diagnosed early after surgical procedure and is spontaneously, or after evacuation, resorbed (Chmatal, & Keil, 2020). Independent risk factors for the development of groin hematoma included warfarin use and recurrent hernia. Hematoma following (IHR) is an infrequent complication that can cause significant patient discomfort, require reoperation, and delay postoperative recovery (Zeb et al., 2016)

Immediate postoperative pain is an important issue that can delay ambulation and return of gastrointestinal motility, therefore, delaying hospital discharge. Besides, the presence of chronic pain after herniorrhaphy, which can affect up to 50 % of patients, is a growing concern (de Castro, Magalhães, Lopes, Pinho & Santiago, 2011). Pain is an unavoidable consequence of open abdominal surgery there is evidence that the chronic pain seriously affects patients'. Although cryotherapy, the application of ice to a surgical wound site, has been shown to be effective in reducing postoperative pain in orthopedic, gynecologic, and hernia operations, it has not been assessed in patients who undergo major open abdominal operations. Ice packs are a simple, cost-effective adjuvant for decreasing postoperative pain and narcotic use in patients undergoing major abdominal operations (Watkins, et al.2014 and Qiu, Chen, Tang & Chen. 2018).

Cold application is a non-pharmacological method of pain control. It is the oldest and easiest forms of treatment; it increases the threshold of pain and reduces the conduction velocity of nerve fibers transmitting pain stimuli from the peripheral to the central nervous system (Bayındır, Çürük, & Oguzhan, 2017). It is widely believed that the therapeutic application of cooling aids leads to a reduction in pain and swelling. It can be delivered to just one area, or you can opt for whole-body cooling. Localized cooling can be administered in a number of ways, including through ice packs, ice massage, coolant sprays, ice baths, and even through probes administered into tissue. Cooling mechanism of action is multifold. It reduces inflammation and swelling which facilitates oxygenation of cells. Also, it slows the cell's metabolic rate, thereby reducing oxygen demand in an environment of reduced oxygen accessibility. Its suppression of exotoxins also limits tissue damaging free radicals. Additionally, it can prevent neural plasticity and chronic pain by decreasing free nerve ending

sensitivity, increasing nerve firing thresholds, and slowing synaptic activity (Song, et al. 2016 and Ravindhran, Rajan, Balachandran, & Mohan 2019).

The proper time for ice application is 15-20 minutes but never longer, it can cause further damage to the tissues, including frostbite, by icing for too long. Allow the area to warm for at least 45 minutes or an hour before beginning the icing routine again. Repeating ice application can be helpful as inflammation and swelling can be prolonged processes (Cluett, 2020). Therefore, the 15 to 20 min application time was selected in the present study to maximize the efficacy of local cooling and to ensure that no adverse reactions from cold occurred.

SIGNIFICANCE OF THE STUDY

Hernia surgery performed in the ambulatory setting is widely implemented worldwide, and when performed skillfully, can result in excellent outcomes. Researchers observed that hematoma and pain are two disturbing signs for patients post hernia repairs. Hence, immediate postoperative pain and local complications may, however, negatively affect outcomes. A number of theories have been put forward to explain the mechanism by which application of an ice pack may attenuate tissue injury and act as a local analgesic. This includes reduction of tissue metabolism and induction of vasoconstriction that may reduce the production of inflammatory cytokines, and reduce oedema and bleeding (Champault, Paolino, Valenti, & Barrat, 2014). In addition to affecting patients outcome, as reduction in pain; reduction in swelling, improved function; and time taken to return to participation. Indeed; as scanty researches adopted and focus on prevention of pain and hematoma for such patients. So it is crucial to emphasis on preventions of these complications

SUBJECTS & METHODS

Aim of the study

The aim of this study is to evaluate the effect of local cooling on pain intensity and size of hematoma among patients with (IHR)

Research Hypotheses

H1: There will be a difference in pain intensity the mean score before and after ice cooling application among patients with (IHR).

H2: There will be decrease in the diameter of hematoma formation after ice application among patients with (IHR).

Research design

One group pretest/posttest quasi-experimental research design was utilized.

Setting

The study conducted at the surgical departments at one of Educational Hospital in Egypt.

Subjects

A convenient sample of 70 adult patients immediately post inguinal hernia repair and fulfill the inclusion criteria over (6 months) enrolled in the study.

Inclusion Criteria

Patients were eligible to participate if they were 18 years or older, were alert to be able to express pain, agreed to give informed consent, with primary repair, open technique.

Exclusion criteria

patients with vascular abnormality, peripheral neuropathy, Insulin-dependent diabetes mellitus, hepato-cellular disease, drug or alcohol addiction, psychiatric pathology, regular use of analgesic drugs, steroids, immunosuppressive agents or anticoagulant therapy.

Procedure

Once permission of the study was obtained; the researchers proceed in the study by firstly

The preparatory phase: The researchers meet the patients preoperatively inform them about the nature of the current study and get their approval to participate in the study then collect demographic and medical data such as age, gender, occupation, etc.. by the researchers.

The implementation phase: 6 hours postoperatively the researchers assess pain intensity using tool 2 before applying ice ; the cooling compress was then applied, using cooling bags (preserved in a plastic material) and placed directly on the surgical site that covered with light dressing for 15 to 20 min. Then this application repeated after 12, and 24 hours post operatively.

The evaluation phase: the researchers evaluate the pain intensity, using Numeric pain Rating Scale. Hematoma diameter was measured after 12, 24 and 72 hrs postoperatively using measuring tape.

Tools

In order to achieve the purpose of the current research three tools were used to gather data pertinent to the study variables as follows:

Tool (1): Demographic and medical data sheet

Consisting of two parts; **First part;** include demographic data as: patient code, age, gender, education...etc; while the **second part** include the medical data as: diagnosis, medication, past medical or surgical history...etc

Tool (2): Numeric Rating Scale (NRS) for pain

The commonly used standardized pain measurement scale, which measures pain intensity. Numeric Rating Scale (NRS) is a segmented numeric version of the VAS, and it has a single 10 point numeric scale in which respondents select a number from 0 (no pain) to 10 (sever pain) to reflect the intensity of their pain. NRS has high test–retest reliability in both literate and illiterate patients ($r = 0.96$ & 0.95 , respectively) (Hawker, Mian, Kendzerska, French, 2011). Therefore, NRS was used in this study to assess the pain intensity before and after each

cooling. The patients were requested to select the number that represents their pain intensity. The overall score of the NRS ranges from 0–10, and it can also describe pain intensity as no pain (0), mild pain (1-3), moderate pain (4-6), and severe pain (7-10)

Tool 3:Hematoma Formation and Size Assessment Scale (HFSAS)

Hematoma Formation and Size Assessment Scale (HFSAS): adopted from El-Deen, & Youssef (2018). This tool measure hematoma size using measuring tape at 12 hr, 24 hrs and 72 hrs after cooling application to assess their size. The presence or absence of hematomas sites recorded by observing any discoloration of the surgical site (pink, red, blue, purple, pale green, yellow and brown). Decreased in diameter of hematoma after local cooling indicates effectiveness of application

Ethical consideration

Once formal consent was taken from the participant. Each participant was informed about the nature and purpose of the study. The researchers emphasized that participation in the study is entirely voluntary; anonymity and confidentiality are assured though coding the data. And inform them that they have the right to be dropped out of the study based on their request at any stage of the research without rational.

Pilot study

Once permission was granted to proceed with the proposed study, a pilot study was carried out before starting data collection on 10 of targeted patients to evaluate the clarity, feasibility and applicability of the tools as well as estimate the time needed to collect data.

Statistical analysis

The data was coded and tabulated using a personal computer. Statistical Package for Social Science (SPSS) version 20 was used. Data presented using descriptive statistics in the form of frequencies and percentage...etc. Inferential tests utilized as paired t-test in relation to research variables. Statistical significance will be considered at P-value ≤ 0.05 .

RESULT

Socio-demographic and medical back ground data tables (1&2)

Table (1). *Frequency and Percentage Distribution of Socio-Demographic Data among Study sample (n=70)*

Socio-demographic	No	%
Age		
20-	9	12.85
30-	16	22.85
40≥	45	64.30
Mean ± SD =	42.90±11.04	
Occupation		
Not working	14	20

Working	56	80
Education level		
Cannot read & write	6	8.6
Primary	20	28.6
Secondary	36	51.4
University	8	11.4
Place of residence		
Urban area	52	74.3
Rural area	18	25.7
Smoking		
Yes	54	77.1
No	16	22.9

As shown in table (1) in relation to age, all patients their age ranged between 20 to above 40 years; 64.30 % of the study sample their age \leq 40 years, followed by 22.85 % of them their age ranged between 30-39 year, and the mean age was 42.90 ± 11.04 . Regarding to the participants' occupation about, 80% of the study samples were worked. The same table showed that, 51.4% of them had secondary education. Concerning place of residence 74.3 % of them come from urban areas and 77.1% of the participant were smokers

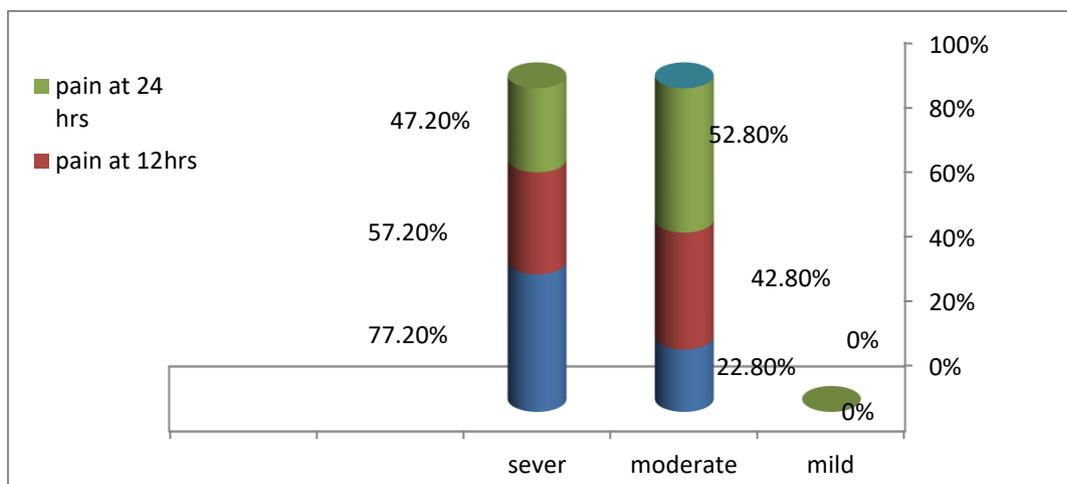


Figure (1): percentage distributions of Pain intensity scores at 6, 12 and 24 hrs before ice application

As shown in figure (1) regarding to pain intensity before applying the ice at 6hr that 77.2% of the participants had severe pain followed by 22.8% among respondents had moderate pain. In relation to pain intensity before applying the ice at 12 hrs, it was apparent that, pain intensity was severe followed by moderate intensity represented 57.2 %, & 42.8 %, respectively. Regarding the pain intensity before applying the ice at 24 hrs the same figure showed that, pain intensity had moderate followed by severe intensity represented 52.8 %, & 47.2 %, respectively.

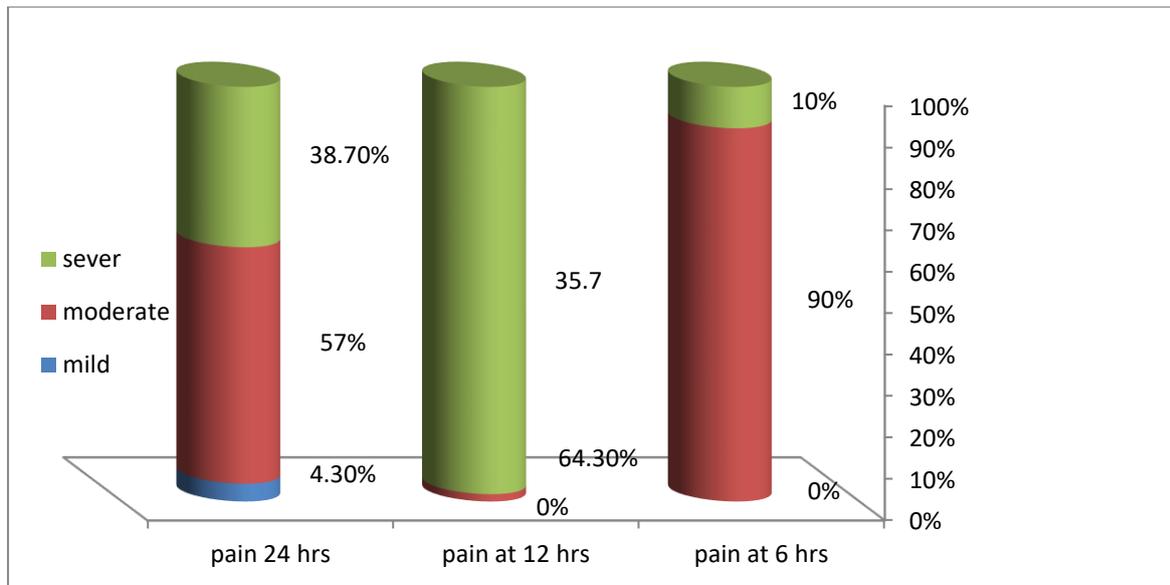


Figure (2): percentage distributions of Pain intensity scores at 6, 12 and 24 hrs after ice application

As shown in figure (2) regarding to pain intensity after applying the ice at 6hr that 90 % of the participants had moderate pain followed by 10 % among respondents had severe pain. In relation to pain intensity after applying the ice at 12 hr, it was apparent that, pain intensity was moderate followed by severe intensity represented 64.3%, &35.7 %, respectively. Regarding the pain intensity after applying the ice at 24 hrs the same figure showed that, pain intensity had moderate followed by severe and mild intensity represented 57%, 38.7% & 4.3 %, respectively.

Table (2) Comparison Paired T-Test for the mean differences pain intensity Score at 6, 12 and 24 hrs before and after ice application (n=70)

Items	Mean Difference	t	df	P
Pain intensity before and after 6 hrs.	2.714 ± 0.192	14.128	69	.000*
Pain intensity before and after 12 hrs.	3.171± 1.693	15.666	69	.000*
Pain intensity before and after 24 hrs.	3.757± 2.046	15.363	69	.000*
Total pain score before and after	9.642 ± 4.010	20.114	69	.000*

*Significant at the P value ≤ 0.05 probability level

It appeared from table (2) that, there was a highly statistical significant difference in the mean score of pain intensity before and after ice application at 6 hrs with the following t and p-value (t=14.128at p=.000) and mean score 2.714 ± 0.192. Also, before and after ice application at 12 hrs (t=15.666at p .000) with mean score 3.171±1.693 and between pain intensity before and after ice application at 24 hrs as the following (t=15.363at p=.000) with mean score 3.757± 2.046.

Table (3) Frequency and percentage distributions of color of hematoma at 12, 24 and 72 hrs after ice application

Colors	Red		Yellow		Blue		Purple	
	N	%	N	%	N	%	N	%
After 12 hrs.	21	30.00	23	32.90	18	25.70	8	11.40
After 24 hrs.	24	34.3	26	37.10	12	17.10	8	11.40
After 72 hrs.	41	58.6	16	22.90	3	4.30	10	14.30

In relation to hematoma color after application of ice as delineated in table (3) that, the high frequency regarding color after 12 hrs were regard yellow, red, blue & purple were representing 32.9%, 30%, 25.7%, & 11.4 % respectively. Regarding the color after 24 hrs were the same yellow, red, blue & purple and representing 37.1%, 34.3%, 17.1%, & 11.4 % respectively. After 72 hrs the sequences change to red, yellow, purple& blue were representing 58.6%, 22.9 %, 14.3%, &4.3% respectively.

Table (4) Frequency and percentage distributions for hematoma diameter at 12, 24 and 72 hrs. After ice application

Diameter	1:2cm		3:4 cm		5:6 cm		7:8 cm	
	N	%	N	%	N	%	N	%
After 12 hrs.	-	-	2	2.9	38	54.2	30	42.9
After 24 hrs.	4	5.7	21	30	33	47.2	12	17.1
After 72 hrs.	24	34.3	33	47.1	9	12.9	4	5.7

Regarding hematoma diameter. After ice application *as* delineated in table (4) there were differences in hematoma diameter at 12, 24 and 72 hrs as follow. After 12 hrs the high frequency were ranged from 5:6 cm, 7:8 cm, &3:4 cm were representing 54.2%, 42.9%, & 2.9 % respectively. After 24hrsthe high frequency were ranged from 5:6 cm, 3:4 cm,7:8 cm, & 1:2 cm were representing 47.2%, 30%, 17.1 % &5.7% respectively. After 72hrsthe high frequency were ranged from 3:4 cm, 1:2 cm, 5:6 cm, 7:8 cm, & were representing 47.1%, 34.3 %, 12.9 % & 5.7 % respectively

Discussion

Pain and local complications are the major determinants of outcome after (IHR) when prevented, can result in excellent outcomes. Hernia surgery has been associated with severe pain within the first 24 hrs postoperatively. Local cooling, sometimes known as cold therapy, is the local or general use of low temperatures in medical therapy. It may be used to treat a

variety of tissue lesions, benefits attributed to local cold applications include the prevention of hematoma by reducing the accumulation of fluid in body tissues, reduction in inflammation, slowing of metabolism, controlling hemorrhage, retarding bacterial growth, decrease in excitability of free nerve endings and peripheral nerve fibers with a resultant increase in the pain threshold, decrease in enzymatic activity, temporary decrease in spasticity and facilitation of muscle contraction.

The aim of the current study was to evaluate the effect of local cooling on pain intensity and hematoma diameter among patients with (IHR). Our hypothesis was that

The simple maneuver of placing an ice pack on the incision reduces postoperative pain and decrease size of hematoma, the following representation addressed in details the analysis of the findings in relation to the aim of the current study. No patients discontinued from the study. It was crucial to start by **section I**; which shed a light on the personal and the medical characteristics for the study sample; then discussing the current research hypotheses in **section II**; in order to elaborate the significance differences after application of local cooling.

In this study, all participants were males as (IHR) occurs most commonly in men, their age ranged between 20 to more than 40 years with a mean age 42.90 ± 11.04 . The majority was educated, most of them were employed, similar with the current result previous study which examined the effect of cryotherapy application before versus after subcutaneous anticoagulant injection on pain intensity and hematoma formation indicated two thirds of the participants were males, the majority was educated, half of them were unemployed, their mean age was 45.34 ± 9.61 , (El-Deen, & Youssef, 2018). Another study investigate the impact of cold therapy on pain and hematomas on the injection site of enoxaparin, similarly showed that the mean age of the participants was 47.5 ± 20.7 , and the majority of them were males (Alabdahai, Mokabel, & Al-Ghuneimy, 2017).

In this study regarding the researchers used **Numeric Rating Scale (NRS)** for pain evaluation at study endpoints of 6, 12 and 24 hours postoperatively; hence before applying ice bag it was clear that pain intensity before applying the ice at 6hr endpoint claimed that majority of participants had severe pain followed by moderate intensity for the subsequent percentage. While pain intensity before applying ice at 12 hrs endpoint, revealed the same previous result, and pain intensity before applying ice at 24 hrs endpoint indicated that nearly half of the studied sample had moderate pain and the other half had severe pain.

Regarding to pain intensity after applying the ice at 6hr almost of the study sample had moderate pain and the least percent had severe pain. In relation to pain intensity after applying ice at 12 hr, it was apparent that, pain intensity was moderate among more than half of participants. Regarding pain intensity after applying the ice at 24 hrs also more than half of study participants had moderate pain.

After ice application the researchers claimed that there was a highly statistical significant difference in the mean score of pain intensity before and after ice application at 6 hrs., 12 hrs and between pain intensity before and after ice application at 24 hrs. The simple application of placing an ice pack on the incision site reduces postoperative pain, so cooling should be complementary to other pain management strategies because it is easy, affordable, well

received by patients, and has minimal to no toxicity. The majority of patients were satisfied with ice packs being added to their postoperative pain management plan. These findings concur with those reported by (El-Deen, & Youssef, 2018) mentioned that, two intervention groups who received cryotherapy had significantly lower score of pain intensity than the control group. This result may be due to the cooling and analgesic effects of applying ice to the skin, causing a numbing sensation and relieving pain.

The effects of cooling have been also evaluated in a randomized trial using local anesthesia for ambulatory hernia repair in the UK, with a significant reduction of pain after cooling of the operative site (4°C versus 22°C) for 5 minutes (Champault, Paolino, Valenti, & Barrat, 2014). A study by Zhang, Zheng, Yan, Ma, Chen, & Li, (2018), investigating Cryotherapy relieves pain and edema following inguinal hernioplasty in males with end-stage renal disease agreed with the result of current study as Cryotherapy-treated patients reported lower pain scores from 30 min to 48 h post operation

The results revealed a statistically significant difference in hematoma formed after ice application 12, 24 and 72 hrs as patient who received cooling application had significantly smaller size of hematoma. A study by (El-Deen, & Youssef, 2018) congruent with the finding of the current study as they indicated that after 48hrs and 72hrs, the cryotherapy groups had a significant lower incidence of hematoma formation. Other studies indicated that cryotherapy has also been proven to relieve surgical site edema (Rana et al., 2013) as well as (Zhang, Zheng, Yan, Ma, Chen, & Li, 2018) claimed that lower incidence of scrotal edema in the intervention group can be attributed to the cooling effect.

Hematoma incidence had been reported in two studies (Sharma et al., 2015; Unal et al., 2019) that the patients in the intervention group had experienced less hematoma at injection sites compared with the control group (Mohammady & Sadeghi, 2020)

CONCLUSION

In inguinal hernia repair, preoperative cooling of the operative site for 15 to 20 minutes, using the ice bag compress significantly decreases early postoperative pain, resulting in a reduction of analgesic drug use. This approach is simple, easy to use, well tolerated, no-expensive, and safe. This cooling technique could be a reasonable alternative to intraoperative analgesic infiltration (dose related, allergies) and/or systematic use of analgesic drugs, which may have adverse effects.

Implications and Recommendations

Based on this study's findings we recommend the following:

1. Patients undergoing (IHR) should be provided with a simple and applicable strategy to control pain and hematoma size.
2. Healthcare providers, especially nurses, should frequently assess the patient's pain and teach the patient non-pharmacological strategies, such as cooling, to relieve it.
3. The development of an educational program to improve nurses' knowledge about pain and how to manage it using non-pharmacological interventions.

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