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SURGERY IN LOW AND MIDDLE INCOME COUNTRIES

Do Ice Packs Reduce Postoperative Midline Incision Pain, NSAID or Narcotic Use?

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Abstract

Background Adequate postoperative analgesia, especially after major abdominal surgery is important for recovery, early mobility, and patient satisfaction. We aimed to study the effects of cryotherapy via an ice pack in the immediate postoperative period, for patients undergoing major abdominal operations.

Methods This prospective study was conducted at our tertiary care referral center in a low–middle-income country setting. The preoperative patient characteristics, intra-operative variables, and postoperative outcomes were compared between two sets of patients. Cryotherapy was delivered via frozen gel packs for 24 h immediately following laparotomy. Pain relief was assessed with visual analog pain scores (VAS). Comparisons between groups were measured by Chi-square test, Fischer's exact test, or Mann–Whitney *U* test as appropriate.

Results Sixty-eight patients were included in the study: 33 in the cryotherapy group and 35 in the non-cryotherapy group. Mean postoperative pain scores (VAS) were significantly lower in the cryotherapy group versus the control group (3.97 ± 0.6 vs. 4.9 ± 0.7 on postoperative day (POD) 1; $p < 0.001$, and 3 ± 0.5 vs. 09 ± 0.8 on POD2; $p < 0.001$). The median narcotic use in morphine equivalents was lesser in the cryotherapy group from POD 1–3 (66 (IQR-16) vs. 89 (IQR-17); $p = 0.001$). No significant difference was seen in the NSAID use between the groups. The cryotherapy group was also found to have a lesser incidence of surgical site infection ($p = 0.03$) and better lung function based on incentive spirometry ($p = 0.01$) and demonstrated earlier functional recovery based on their ability to perform the sit-to-stand test ($p = 0.001$).

Conclusion Ice packs are a simple, cost-effective adjuvant to standard postoperative pain management which reduce pain and narcotic use and promote early rehabilitation.

Introduction

Postoperative pain is an inevitable side effect of all major abdominal surgeries. Although it is mainly attributed to inflammation and nociceptor stimulation, the pathophysiology of postoperative pain is unique [1, 2]. Many patients experience severe pain after surgery and may develop chronic pain thereafter which might partly be a result of undertreated acute postoperative pain. Adequate postoperative analgesia prevents chronic pain and is essential for early recovery and patient satisfaction [3–6]. While narcotic medication is imperative in postoperative pain management, multimodal analgesia is increasingly being preferred [7–10], given the many dose-dependent side effects of narcotics and their abuse potential [11, 12].

Cryotherapy is the application of cold modalities to decrease pain secondary to trauma, injury, surgery or

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disease. It is also a relatively noninvasive and cost-effective technique targeting inflammation [13–16]. Although cryotherapy has been widely adopted in clinical practice, the efficacy of cryotherapy following major abdominal surgeries has seldom been investigated [17]. We hypothesized that patients undergoing major abdominal surgeries who receive cryotherapy via frozen gel packs in the immediate postoperative period would report lower pain scores and require lesser narcotics and NSAIDS.

Materials and methods

Patient population

We conducted this prospective study at our tertiary care referral center between June 2016 and September 2018. Seventy-five patients were enrolled during the study period. Inclusion criteria included adult patients (aged 18–64 years) undergoing an open trans-peritoneal abdominal surgery via a midline incision. Exclusion criteria included patients who underwent conversion from a laparoscopic procedure, reoperation during the same hospital stay, and patients who were not extubated immediately following the procedure. Epidural analgesia and intra-operative local analgesia were not used as exclusion criteria. The institutional review board approved this study, and written informed consent was obtained from all participants prior to inclusion into the study registry.

Cryotherapy administration

All patients were counseled regarding the study in the preoperative room and were assigned alternately to either the cryotherapy or non-cryotherapy group. The patients were assigned consecutively with a random start. Both sets of patients underwent surgeries performed by the same surgical team under the supervision of the senior surgeon of the treating unit. The attributes, including the preoperative characteristics, intra-operative variables, and post-operative outcomes, were analyzed. Cryotherapy was administered in the form of reusable frozen gel packs over the wound dressing. The frozen gel packs were applied as soon as the patient reached the postoperative ward and were kept for 24 h after surgery.

Outcome measures

The primary outcome measures included the average pain score on postoperative days 0 to 3 and narcotic and NSAID use. The secondary outcome measures included the length of hospital stay, objective assessment of the time taken for functional recovery, incidence of surgical site infection, wound dehiscence, and postoperative ileus. Surgical site infections were taken into account from the immediate postoperative period up to 90 days after surgery. The analysis was done after assessment of the operative site on or after 90 days post-surgery. Wound dehiscence was also assessed at the follow-up visit, 3 months post-procedure. The average pain intensity was assessed on postoperative days 0–3 on a continuous 10-point visual analog pain scale (VAS). The requirement of NSAID and narcotic analgesics was documented from the patient charts and confirmed by the patient's nursing team. The patient's ability to perform sit-to-stand test on postoperative day (POD) 2 and the ability to perform incentive spirometry were assessed. The sit-to-stand test was used to objectively assess the functional capacity of the patients. The average number of repetitions that patients in either group could perform was documented and analyzed. The patients were also given a voluntary questionnaire to assess their tolerance. The nursing personnel taking care of these patients were also given a questionnaire to assess the patient compliance.

Statistical analysis

Power calculations suggested that 27 patients were required per group to detect a 15% difference in pain score between the two groups on a VAS assuming a 0.05 level of significance and a power of 90 percent. This calculation was based on similar studies which looked at the difference in VAS required to assess a change in pain perception [18–20].

The compliance of the data to a normal distribution was determined using the Shapiro–Wilk test. Quantitative data are expressed as mean ± SD, median and interquartile range, or median and range (maximum–minimum). Categorical data are expressed as *n* (number) or percentage (%). Data were analyzed at a 95% CI, and statistical significance was set at $p < 0.05$. The differences between groups were compared by using the Mann–Whitney *U* test, and categorical data were analyzed by the Pearson's Chi-square test, Fisher's exact, or continuity correction where appropriate. The results were analyzed using the Statistical Package for Social Science for Windows version 16 (SPSS Inc., Chicago, IL, USA).

Results

Of the 75 patients enrolled in the study, the attributes of 68 were analyzed. Thirty-five patients did not receive cryotherapy, and 33 patients received cryotherapy in the immediate postoperative period (Fig. 1). There were no

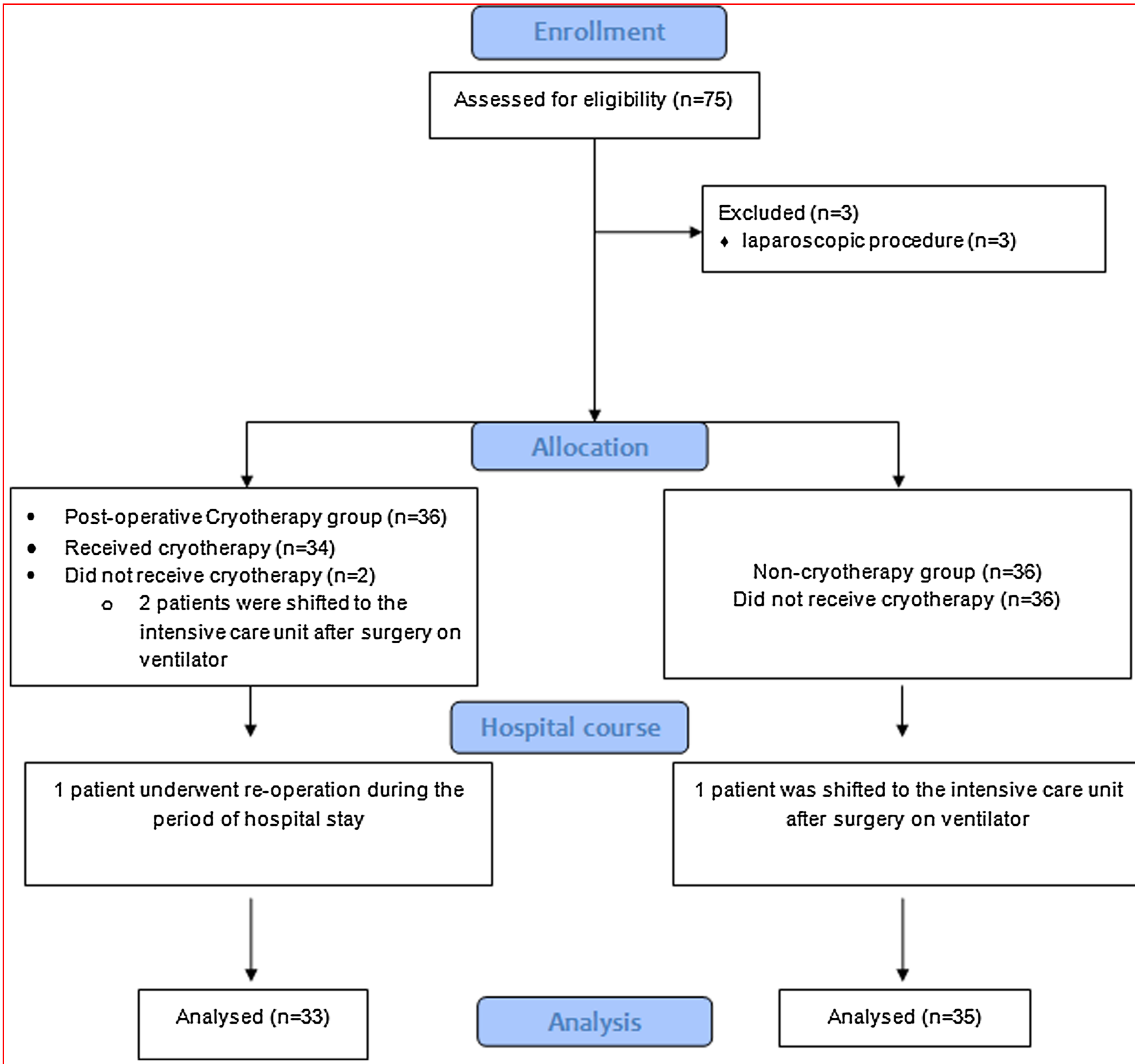

Fig. 1 Flow diagram of patients' progress during the study

statistical differences in any of the baseline preoperative characteristics as indicated in Table 1. Procedures included exploratory laparotomy, small bowel resection, colorectal resection, Graham's omental patch repair, stoma creation, abdomino-perineal resection or anterior resection, urinary bladder repair, vagotomy, and gastrojejunostomy. There were no statistical differences between the two groups in terms of incision length, additional incisions for drains, or duration of surgery (Table 2).

There were no significant differences between the groups in terms of intra-operative anesthetic variables such as duration of anesthesia, induction agent or inhalational agent used, dose intra-operative opioid or NSAID administered, or epidural analgesia (Table 3).There was no statistically significant difference between postoperative pain scores recorded immediately after surgery (5.4 ± 0.7 vs. 5.6 ± 0.9; $p = 0.2$) and 24 h after surgery between the two groups (4.8 ± 0.8 vs. 4.9 ± 0.7 $p = 0.725$). The cryotherapy group reported significantly lower pain scores on POD 2 (3.97 ± 0.6 vs. 4.9 ± 0.7; $p < 0.001$) and POD 3 (3 ± 0.5 vs. 4.09 ± 0.8; $p < 0.001$) (Fig. 2). The median narcotic requirement (morphine equivalents) of the cryotherapy group was significantly lesser than the non-cryotherapy group (66 (IQR-16) vs. 89 (IQR-17);

Table 1 Comparison of preoperative attributes between the groups

Attribute	Cryotherapy group (n = 33)	Non-cryotherapy group (n = 35)	p value
Age			
Median (IQR)	53 (33)	45 (32)	0.32
Sex, % male	57.6% (n = 19)	68.6% (n = 24)	0.26
Diabetes Mellitus	39.4% (n = 13)	45.7% (n = 16)	0.63
Hypertension	39% (n = 13)	40% (n = 14)	0.58
Ischemic heart disease	12.1% (n = 4)	8.6% (n = 3)	0.46
Chronic kidney disease	6.1% (n = 2)	1.9% (n = 1)	0.48
Preoperative pain score (VAS)			
Median (IQR)	5 (4)	7 (3)	0.1
Malignancy	21.2% (n = 7)	22.8% (n = 8)	0.87
(Stomach, small and large bowel)			
Hollow-viscus perforation	39.4% (n = 13)	31.4% (n = 11)	0.492
Benign conditions including mesenteric cyst, gastric outlet obstruction, splenic cyst	15.2% (n = 5)	8.6% (n = 3)	0.4
Mesenteric ischemia	12.1% (n = 4)	17.1% (n = 6)	0.6
Abdominal trauma	12.1 (n = 4)	20% (n = 7)	0.38

Table 2 Comparison of intra-operative surgical variables between the two groups

Surgical variables	Cryotherapy group (n = 33)	Non-cryotherapy group (n = 35)	p value
Duration of surgery			
Median (IQR)	195 (80)	170 (60)	0.1
Incision length (cm)			
Mean (SD)	13 ± 2	14 ± 1	0.2
Additional incisions (cm)			
Mean (SD)	2 ± 1	2 ± 1	1
Skin incision			
Scalpel	42.4% (n = 14)	48.6 (17)	0.635
Cautery	57.6% (n = 19)	51.4% (n = 18)	
Skin closure			
Sutures	66.7% (n = 22)	42.9% (n = 17)	0.06
Staples	33.3% (n = 11)	57.1% (n = 20)	

$p < 0.001$) during postoperative days 0–3. There was, however, no significant difference in the postoperative NSAID requirement.

The patients in the cryotherapy group were able to perform more repetitions in the sit-to-stand test compared to the patients who did not receive cryotherapy (4.2 ± 0.6 vs. 3.6 ± 0.5; $p < 0.001$). The patients in the cryotherapy group were able to generate an inspiratory capacity of 900 ml/min earlier than the non-cryotherapy group (1.9 ± 0.4 vs. 2.6 ± 0.7; $p = 0.01$) in the postoperative period. The patients in the cryotherapy group were found to have a significantly lower incidence of surgical site infections (12.1% (n = 4) vs. 20% (n = 7); $p = 0.03$).

There were no differences between the two groups in terms of length of hospital stay, wound dehiscence, and paralytic ileus (Table 4).

Based on the questionnaire given to the patients and nursing staff, all patients were very complaint in the cryotherapy arm. No patients reported discomfort or demanded the removal of ice packs.

Discussion

This pilot study intended to assess the impact of cryotherapy on pain control, narcotic use, NSAID use, and its bearing on postoperative recovery in patients

Table 3 Comparison of intra-operative anesthetic attributes between the groups

Attributes - Anesthesia	Cryotherapy group ($n = 33$)	Non-cryotherapy group ($n = 35$)	p value
Duration of anesthesia			
Median (IQR)	220 (100)	210 (70)	0.27
Epidural analgesia	39.4% ($n = 13$)	45% ($n = 16$)	0.3
Local infiltration with lignocaine	78.8% ($n = 26$)	68.5% ($n = 24$)	0.08
Induction agent			
Propofol	72.7% ($n = 24$)	54.3 ($n = 19$)	0.2
Ketamine	21.1% ($n = 7$)	28.6 ($n = 10$)	
Etomidate	6.1% ($n = 2$)	17.1% ($n = 6$)	
Intra-op Opioids			
Mean ± SD (Morphine equivalents)	2.88 ± 1.6	3.3 ± 1.34	0.4
Intra-operative Paracetamol (mg)			
Mean ± SD	800 ± 374	860 ± 355	0.19

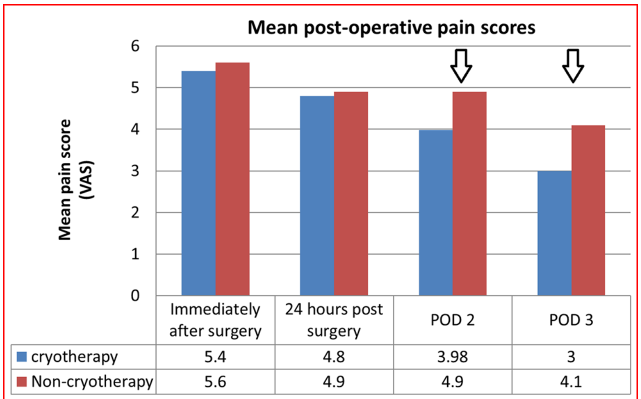

Fig. 2 Pain scores of patients in the cryotherapy and non-cryotherapy groups. Pain was measured using a visual analog scale. Pain measurements were taken preoperatively, immediately after surgery in the post-anesthesia care unit, and on each postoperative day. Pain among ice and control patients was significantly different on POD2 ($p < 0.001$) and POD3 ($p < 0.01$). *Statistically significant ($p < 0.05$)

undergoing abdominal surgeries via midline incisions. We took into account a variety of preoperative, intra-operative and postoperative confounders which may have influenced our primary and secondary outcomes.

Cryotherapy could be included as part of the multimodal analgesic therapy because it is simple, economical and has minimal adverse effects. Cryotherapy has also been postulated to reduce chronic pain by decreasing free nerve ending sensitivity and prevent neural plasticity. These effects thereby increase a patient's pain threshold and can help reduce the need for pain medication [21–25].

Cryotherapy has been used to reduce postoperative pain in maxillofacial surgery, orthopedics, breast surgery, gynecology, thoracic surgery, and plastic surgery [18–22, 26–31]. There are very few studies which have investigated the effect of cryotherapy on postoperative pain for midline laparotomy wounds [17].

Our study affirms that cryotherapy can reduce postoperative pain and narcotic use in patients undergoing major abdominal operations via a midline laparotomy incision. We also noticed that the patients who were administered cryotherapy had a faster postoperative recovery compared to the other group based on their ability to perform functional fitness tests such as the sit-to-stand test and functional assessment of lung capacity. The incidence of surgical site infections was also lesser in the cryotherapy group. These outcomes could possibly be attributed to the ability of cryotherapy to reduce inflammation, edema, facilitate oxygenation of cells and suppress exotoxin mediated tissue damage [13, 21, 24, 25]. However, no significant differences were noticed in the NSAID usage between both groups. We also noticed no significant difference in the duration of hospital stay between the two groups. This may be attributed to similar durations of preoperative hospital stay between the two groups of patients. Although it is ideal to have a preoperative stay of zero days at the hospital, our center, being located in a low–middle-income country, caters to patients who come from long distances. For many patients, the preoperative optimization and workup took place after admission as inpatient, and 2–3 days before elective surgery.

Limitations of our study include non-randomization and data from a single center. The usage of a placebo was considered, but we felt that this would not qualify as a true placebo as patients would know it is at room temperature. We did not perform subgroup analysis to assess the efficacy of cryotherapy in one standardized surgery, which could have minimized the unconsidered confounders even

Table 4 Comparison of secondary outcomes between the two groups

Outcome	Cryotherapy group ($n = 33$)	Non-cryotherapy group ($n = 35$)	p-value
Narcotic requirement (morphine equivalents)			
Median (IQR)	66 (16)	89 (17)	0.001
Diclofenac requirement (mg)			
Median (IQR)	32 (75)	54.5 (75)	0.1
Paracetamol requirement (g)			
Mean, SD	8.37 ± 1.9	9.3 ± 1.5	0.138
Sit-to-stand test repetitions/minute			
Mean, SD	4.2 ± 0.6	3.6 ± 0.5	< 0.001
Days to generate 900 ml/min—Incentive spirometry			
Mean, SD	1.9 ± 0.4	2.6 ± 0.7	0.01
Surgical site infection	12.1% ($n = 4$)	20% ($n = 7$)	0.03
Wound dehiscence	6% ($n = 2$)	8.5% ($n = 3$)	0.1
Paralytic Ileus	9% ($n = 3$)	11% ($n = 4$)	0.7
Length of hospital stay (days)			
Mean (SD)	9 ± 6	8 ± 5	0.362

though there were no statistically significant confounders in our study. Also, the patients could have been given the option of continuing cryotherapy for as long as they wished, which may have further decreased their need for pain medication. Future studies could also consider a cost-effectiveness analysis following the use of cryotherapy because of faster recovery and reduced use of pain medications. The efficacy of cryotherapy could be evaluated in patients undergoing abdominal operations via other incisions such as the subcostal or transverse incisions.

In conclusion, the ice pack can be a simple, cost-effective treatment modality in standard postoperative pain management. It significantly reduces postoperative midline incisional pain and narcotic use and promotes early recovery in patients undergoing major open abdominal surgery; the low expenses and ease of use could be advantageous, especially in a resource-limited setting. The reduction in perioperative narcotic usage could also decrease the need for narcotic medications at discharge.

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