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Original Research Article

Intraperitoneal analgesia to reduce pain after laparoscopic hysterectomy

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ABSTRACT

Background: Laparoscopic hysterectomy is now an established operation, as it is less invasive and carries much less post-operative pain compared to open hysterectomy. However, post-laparoscopy analgesia is still a challenge. Intraperitoneal (IP) instillation of local anaesthetics has been shown to minimize postoperative pain after laparoscopic surgeries. This study was conducted to evaluate the efficacy of IP instillation of dilute analgesia prior the end of laparoscopic hysterectomy to reduce postoperative pain. The primary outcome was to assess postoperative pain scores. Secondary outcomes included assessment of postoperative analgesic requirements (type, amount, and timing), and frequency of nausea and vomiting.

Methods: 20 cases were enrolled for laparoscopic hysterectomy and were divided randomly into two groups, Group A: 10 cases, where IP analgesia (Bupivacaine and Magnesium Sulphate) was instilled -under vision- prior removal of trocars, and Group B: 10 cases, where no IP analgesia was used. After surgery, Visual Analogue Score (VAS) was recorded at 6, 12, 24 hours and 7 days. Postoperative analgesic requirements (type, amount, and timing), and frequency of nausea and vomiting were also recorded.

Results: The overall VAS during the first postoperative 24 hours was significantly lower in group A (P = 0.048, 0.049, and 0.003 at 6, 12, and 24 hours after surgery). Time to first of analgesia required (in hours) was longer (6.0±1.41 vs 3.20±1.48, P = 0.004) and total analgesic consumption (in mg) was lower (2.40±0.89 vs 3.30±0.67, P = 0.047) in group A compared to group B. The need for opioids was also significantly less in group A (3 cases vs 8 cases, P = 0.024). in group A, nausea and vomiting were less reported as well (P = 0.040).

Conclusions: The instillation of local IP dilute analgesia is an effective and safe method for reducing pain after laparoscopic hysterectomy.

Keywords: Intra-peritoneal analgesia, Laparoscopic hysterectomy, Pain after laparoscopy

INTRODUCTION

Laparoscopy is an established method to perform major surgeries, advantages over open procedures include: less haemorrhage; better cosmetic results; less postoperative pain; and shorter recovery time, leading to shorter hospital stay and less expenditure.[1] Hysterectomy is one of the most common gynaecologic procedures and approximately 90% of cases is due to benign diseases. It can be performed abdominally, vaginally, or laparoscopically depending on the patients' clinical characteristics and surgeons' expertise and preference. Laparoscopic hysterectomies have been increased recently due to the several advantages of minimally invasive surgery.[2,3] Postoperative pain management remains a major challenge after laparoscopic procedures. Effective pain control encourages early ambulation, which significantly reduces the risk of deep vein

thrombosis and pulmonary embolism; enhances patient's ability to take deep breaths to decrease the risk of pulmonary complications (e.g., atelectasis and pneumonia); and decreases the incidence of tachycardia and unnecessary investigations related to it.[4]

Pain after laparoscopic surgery has two components, a visceral component due to surgical handling, tissue injury, and the stretching of nerve endings. Pneumoperitoneum stretches the peritoneum and the diaphragmatic muscle fibres, which irritates phrenic nerve endings, this nerve shares a common route with nerves that innervate the shoulder. In addition, dissolved carbon dioxide is another factor for diaphragmatic irritation. The somatic component of post laparoscopy pain is due to the holes made in the abdominal wall for the trocars' entry.[5,6] Today, various therapeutic protocols are available for management of pain but still preventing and relieving the postoperative pain remains an important challenge.[3] It is thought that the postoperative pain is inadequately treated in approximately one half of all surgical procedures.[7] Clinical trials suggest that a high quality postoperative pain management improves recovery and reduces the risk of postoperative acute and chronic adverse effect after various procedures including hysterectomy.[8] Therefore, a multimodal approach, using local anaesthetics may help to improving the quality of analgesia, recovery and reduce opioid dose requirement and side effects.[9]

The purpose of this study was to assess the effect of IP analgesia to reduce postoperative pain after laparoscopic hysterectomy.

METHODS

This prospective, double-blind, randomized, controlled clinical trial, was conducted from September 2016, to April 2017. Approval of the local ethics committee and informed consent of Alexandria University Maternity Hospital (El-Shatby Hospital) was obtained. Among patients who attended the outpatient clinic of Alexandria University Maternity Hospital (El-Shatby Hospital), 20 patients aged 39-51 years were selected, and an informed written consent was obtained from each participant.

Cases were planned for laparoscopic hysterectomy (either total or sub-total, with either salpingectomy or salpingo-oophorectomy), indications for hysterectomy were either symptomatic leiomyomata, adenomyosis, or cystic endometrial hyperplasia, or atypical endometrial hyperplasia. Cases with the following criteria were excluded; those who were unfit for laparoscopic surgery, pregnancy, genital malignancy, deep pelvic endometriosis, or inflammatory bowel disease, current or recent opioid use. Medical and surgical history of all patients was collected, thorough general, abdominal, and local pelvic examination was performed. Then all cases were subjected to pre-anaesthetic check-up and routine investigations, such as complete blood count test, random blood sugar level, liver and renal function tests and coagulation profile were done.

Selected patients were randomly assigned to one of the following two groups:

- Group-A: 10 cases (analgesia group), where IP analgesia was installed -under vision- prior removal of trocars by the end of surgery, and
- Group-B: 10 cases (control group), where no IP analgesia was used.

Procedures

On arrival to operating room, standard intraoperative anaesthetic, analgesic, and antiemetic procedures were conducted for all cases. Laparoscopic hysterectomy was started by establishment of carbon dioxide pneumoperitoneum with insufflation pressure of 20 mmHg, main umbilical 10 mm access port. Trendlenburg's position was performed at 30 degrees and 3 accessory trocars were then inserted (two lateral pelvic and one suprapubic). Intraabdominal pressure was maintained at 14 mmHg. Operative procedures were either total or sub-total laparoscopic hysterectomies with bilateral salpingectomy. Bilateral oophorectomy was performed in selected cases according to age (close to or after menopause).

After finishing hysterectomy and prior removal of trocars, a 120-ml fluid was instilled intraperitoneally. For group A (analgesia group), the instilled IP fluid was a mixture of the followings:

- 2 vials 20 ml Bupivacaine (Marcaine) 0.5% (i.e. total of 40 ml).
- 4 ampules 10 ml Magnesium Sulphate ($MgSO_4$) (i.e. total of 40 ml).
- 40 ml Normal Saline (0.9% sodium chloride).

While in group B (control group), the instilled fluid was free of any medication and only normal saline was used. The instilled fluid was distributed as following: 20 ml under each diaphragmatic copula, and 80 ml (the remaining) at the pelvis and around the surgical field. All surgeries were performed by one skilled surgeon, who was not informed about the content of the instilled fluid for each case.

Outcomes

All basic and operative data were tabulated and compared. The total duration of surgery (skin incision to skin closure) was also calculated. After operation, the degree of postoperative pain was assessed using the Visual Analogue Score (VAS) and recorded at 6, 12, 24 hours and 7 days postoperatively. Patients were instructed how to use the 0-10 VAS; with end-points to be labelled "no pain" and "worst possible pain". Patients who had VAS >4, were administered a bolus of Aqueous

Diclofenac Sodium (75 mg) intramuscular injection as rescue analgesia. For severe pain a dose of (OPIOID) was given according to need. Time to first postoperative analgesic requirement was recorded, as well as total analgesic requirements, need for opioids, and occurrence of nausea and vomiting in the first 24 hrs postoperatively.

Statistical analysis

The Data were collected and entered the personal computer. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS/version 20) software. Arthematic mean, standard deviation, number, and percent. For categorized parameters Chi square test was used while for numerical data t-test was used to compare two groups. The level of significant was 0.05.

RESULTS

Among the 20 cases enrolled in the study, there was no significant differences between the two studied groups with respect of basic characteristics (namely age, parity, body mass index (BMI) (Table 1).

Table 1: Basic demographic features and operative variables of the two studied groups.

Preoperative data	Group A n=10	Group B n=10	P
Age (in years)			
Range	43.0-51.0	39.0-52.0	0.929
Mean±S.D.	46.40±3.21	46.20±4.32	
Parity			
Range	1.0-5.0	0.0-5.0	0.908
Mean±S.D.	3.00±1.58	2.90±1.52	
Body Mass Index			
Range	30.0-33.0	26.0-36.0	0.228
Mean±S.D.	31.60±1.14	30.00±2.67	
Indication for hysterectomy			
Adenomyosis	4 (40.0%)	3 (30.0%)	0.820
Atypical hyperplasia	2 (20.0%)	1 (10.0%)	
Cystic hyp erplasia	0 (0.0%)	1 (10.0%)	
Leiomyomata	4 (40.0%)	5 (50.0)	
Uterine size (cm^3)			
Range	12-16	12-18	0.314
Mean±S.D.	14.00±2.00	15.25±2.12	
Type of hysterectomy			
ST+BS	4 (40.0%)	4 (40.0%)	0.852
T+BS	2 (20.0%)	1 (10.0%)	
T+BSO	4 (40.0%)	5 (50.0%)	
Duration of surgery (min).			
Range	100.0-180.0	90.0-200.0	0.816
Mean±S.D.	132.00±30.33	137.00±41.65	

Types of hysterectomy:
ST+BS = Subtotal hysterectomy with bilateral salpingectomy.
T+BS = Total hysterectomy with bilateral salpingectomy.
T+BSO = Total hysterectomy with bilateral salpingo-oophorectomy.

The pre-operative mean uterine size was comparable between the two groups (14.00±2.00 versus 15.25±2.12 cm^3, P =0.314). the same was also observed regarding indications for surgery (Table 1).

Operative variables (particularly type of hysterectomy and duration of surgery) were calculated. The mean duration of surgery was 132.00±30.33 minutes in group A and 137.00±41.65 minutes in group B. The two groups were comparable regarding type of hysterectomy and duration of surgery (Table 1).

Table 2: Comparison between the two studied groups regarding pain score at different periods of follow up.

VAS	Group A n=10	Group B n=10	P
After 6 hours			
Range	5.0-7.0	6.0-10.0	0.048*
Mean±S.D.	6.20±0.84	7.80±1.55	
After 12 hours			
Range	4.0-7.0	4.0-10.0	0.049*
Mean±S.D.	5.40±1.34	7.20±1.75	
After 24 hours			
Range	2.0-4.0	4.0-8.0	0.003*
Mean±S.D.	3.60±0.89	6.10±1.37	
After 7 days			
Range	1.0-3.0	1.0-3.0	0.622
Mean±S.D.	1.80±0.84	2.0±0.67	

Regarding postoperative pain assessment, VAS at 6, 12 and 24 hours after laparoscopy was significantly less in group A compared to group B. However, after 7 days there was no significant difference between the two groups. The pain intensity was significantly reduced in group A (Table 2). Postoperative analgesia was assessed by observing the time required for 1st analgesic dose, amount of analgesia needed, and need for opioids.

Table 3: Comparison between the two studied groups regarding postoperative analgesia.

Postoperative analgesia	Group A "n=10"	Group B "n=10"	P
Time for 1st analgesia (in hours)			
Range	4.0-8.0	2.0-6.0	0.004*
Mean±S.D.	6.0±1.41	3.20±1.48	
Amount of analgesia needed (in ampoules)			
Range	2.0-4.0	2.0-4.0	
Mean±S.D.	2.40±0.89	3.30±0.67	0.047*
Need for opioids			
Number (%)	3 (30.0%)	8 (80.0%)	0.024*

*= Significant difference

As demonstrated in Table 3, there was a significant increase in the time required for 1st analgesia in group A more than group B (6.00±1.41 hours versus 3.20±1.48 hours, P = 00.4).

Amount of analgesia needed was significantly less in group A compared to group B (2.40±0.89 versus 3.30±0.67 ampules, P=0.047). There was also a significant increase in the number of patients need for opioids in group B more than group A (Table 3).

Comparison between the two studied groups regarding postoperative nausea and vomiting were recorded in Table 4, results showed that patients in group A had significantly less nausea and vomiting compared to patients in group B (P = 0.040).

Table 4: Comparison between the two studied groups regarding nausea and vomiting.

Nausea and vomiting	Group A n=10	Group B n=10	P
Non			0.040*
Number (%)	8 (80.0%)	2 (20.0%)	
Mild			
Number (%)	2 (20.0%)	4 (40.0%)	
Moderate			
Number (%)	0 (0.0%)	2 (20.0%)	
Severe			
Number (%)	0 (0.0%)	2 (20.0%)	

DISCUSSION

Postoperative pain after operative laparoscopic surgeries might reduce the great advantage of laparoscopy as a minimally invasive surgical approach, leading to increased demands for analgesia and more prolonged hospitalization, and hence adding to hospital cost.[10,11] When searching for an optimum regime for pain relief in the postoperative period many methods have been investigated. Of these, trocar site injection of local anaesthetic agents offer theoretical and practical advantages, as well as transversus abdominis plane block and administration of IP analgesia, which have been used to reduce shoulder tip pain, overall pain, nausea and vomiting, and the time of hospital stay.[11-13]

The use of intraperitoneal local anaesthetics during laparoscopic surgery to decrease postoperative pain dates to the early 1990s. Its use was first reported for minimally invasive cholecystectomies.[13]

Magnesium reduces calcium influx to the cell, it also antagonises N-methyl-D-aspartate (NMDA) receptors, which are vital for neuronal signalling as well as pain processing in the central nervous system. Magnesium sulphate ($MgSO_4$) induces blockage of these receptors, and have an anti-nociceptive effect. therefore, $MgSO_4$ decreases post-operative pain as both somatic and visceral pain fibres are blocked.[14,15]

In the current study, instillation of IP local analgesia prior removal of trocars in cases of laparoscopic hysterectomy was associated with significant reduction of overall pain scores during the first 24 hours following surgery. This was reflected on the reduction of postoperative analgesia and opioid requirements. There was also reduction in the incidence of postoperative nausea and vomiting.

We utilized bupivacaine due to its cheap price and availability (compared to ropivacaine), which facilitates its use in many centres in developing countries.

In agreement with our study, Narchi et al. found that IP instillation of local anaesthetics are more effective in reducing pain up to 48 h postoperatively in patients undergoing diagnostic laparoscopy.[11]

Many studies have demonstrated a beneficial effect of local IP analgesia in general surgical procedures, namely laparoscopic cholecystectomy.[16,17]

Bisgaard et al. suggested that pain after laparoscopic cholecystectomy was divided into three components; incisional pain, which dominated over visceral pain, which in turn dominated over shoulder pain.[16] Investigators have reported that the visceral pain experienced after laparoscopic cholecystectomy can be theoretically blocked by IP analgesic instillation.[17] The results of the present clinical trial seem to be in accordance with the findings of these studies.

In contrast, Narchi et al., failed to demonstrate any reduction in postoperative pain after IP instillation of local anaesthetics in patients undergoing laparoscopic cholecystectomy. One possible explanation of the failed effect was the small amount of local anaesthetics used.[11]

In gynecologic laparoscopy, one previous study carried out by Goldstein et al. reported that the IP instillation of 20 mL of either 0.5% bupivacaine or 0.75% ropivacaine prevented postoperative pain and decreased the need for postoperative analgesia, when compared with placebo in patients undergoing laparoscopic gynaecologic surgery.[18] In another study by Callesen et al, combined port site and mesosalpinx infiltration and peritoneal instillation by using 285 mg of ropivacaine (50 mL) in a double-blind, randomized, placebo-controlled study on 80 patients undergoing laparoscopic tubal sterilization, have demonstrated similar efficacy.[19]

Many other clinical trials have studied pain relieving after gynaecologic laparoscopy, namely laparoscopic hysterectomy.[20,21]

Arden D et al. have compared instillation of 100 mg bupivacaine in 100 mL normal saline with instillation of 100 mL normal saline alone.[20] While Andrews V et al. have compared a 48-hour infusion of 100 mL of 0.5% levobupivacaine to an infusion of 100 mL normal saline.[21] Neither study found an improvement in pain control, narcotic use, length of hospital stay, or overall patient satisfaction associated with use of bupivacaine. The conclusions of these trials may differ from the

current work because we have added $MgSO_4$ to bupivacaine.

However, in another recent study, Rivard C et al, have demonstrated that administration of IP bupivacaine was associated with improved postoperative pain control in patients undergoing minimally invasive gynaecologic and gynae-oncologic surgery.[22] The median patient-reported pain scores were lower on the day of surgery in the intraperitoneal bupivacaine group (2.7 vs 3.2, p = .05). Similar results were observed by the current study, where the median VAS was lower during the first postoperative day in the IP bupivacaine group (VAS after 24 hours was 3.60±0.89 vs 6.10±1.37, p = 0.003).

In a more recent randomized controlled study, Saccardi C et al. have studied the efficacy of IP ropivacaine in the control of postoperative pain during the first 48 hours after operative laparoscopy for benign adnexal or uterine pathologies. They observed that this method showed clear benefits in reducing pain at 4 and 6 hours after adnexal surgery, while this effect was absent in uterine surgeries. They suggested that ropivacaine could better act on visceral pain, such as adnexal pain, while it may be less effective on somatic pain, as in case of uterine surgery.[23] Interestingly, they found that shoulder pain was reduced in both uterine and adnexal surgery after ropivacaine administration. They hypothesized that the local anaesthetic may act on neurotransmission of pain from the diaphragm to shoulder, which promotes faster mobilization of patients. These results agree with the current work, were early mobilization was reflected by the delay in first dose of analgesic needed in the group which received local IP analgesia.

Regarding the postoperative adverse effects, in our study, nausea and vomiting was significantly less when local bupivacaine was locally instilled in cases of laparoscopic hysterectomy. Compared to control group, results were statistically significant.

In disagreement with our study, Ranjita, et al, compare the analgesic efficacy of IP ropivacaine with placebo for postoperative analgesia after total laparoscopic hysterectomy, they found that, there were no statistical significant differences between IP group or placebo group regarding nausea and vomiting, this me be explained once more by the added analgesic effect of $MgSO_4$ used in the current study.[24]

The beneficial effect of $MgSO_4$ was also demonstrated in other studies; many clinical trials have proved a useful effect of combining local IP analgesia with $MgSO_4$ in reducing post op pain after lap cholecystectomy, however, to our knowledge, no publications have addressed the additive effect of both medications during gynaecologic laparoscopic surgeries.[25,26]

In the present study, the increased intensity and prolonged duration of analgesia can be attributed to the co-administration of $MgSO_4$ with bupivacaine as reported by other clinical researches.[25,26]

CONCLUSION

We conclude that IP instillation of bupivacaine in combination with MgSO4 in laparoscopic hysterectomy significantly reduces the postoperative pain and significantly reduces the analgesic requirement in the postoperative period as compared to control group (no IP analgesia).

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