Section: Anaesthesia

Research

THE EFFECTIVENESS OF INTRAPERITONEAL HYDROCORTISONE ON POSTOPERATIVE PAIN AND OTHER MORBIDITIES IN LAPAROSCOPIC CHOLECYSTECTOMY

Neera Valsan[1], Moona Abdul Kadiru[2], Farha P K[1], Sreejit MS[3]

[1]Assistant Professor, Malabar Medical College, Calicut, Kerala, India
[2]Associate Professor, Malabar Medical College, Calicut, Kerala, India
[3]MES Medical College, Perinthalmanna, Kerala, India

Received : 18/09/2022
Received in revised form : 25/10/2022
Accepted : 06/11/2022

Keywords:
Analgesia, Bupivacaine, Hydrocortisone.

Corresponding Author:
Dr. Moona Abdul Kadiru,
Email: moonakad@gmail.com
ORCID: 0000-0003-3910-3683

DOI: 10.47009/jamp.2022.4.5.96

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2022; 4 (5); 467-472

Abstract

Background: Postoperative pain increases morbidity and prolongs hospital stay after laparoscopic cholecystectomy. Intraperitoneal analgesia is a component of a multimodal approach to postoperative analgesia which is being increasingly investigated. This study compared the effects of intraperitoneal hydrocortisone and intraperitoneal bupivacaine on pain relief following laparoscopic cholecystectomy and evaluated postoperative morbidities like nausea and vomiting, and time for bowel function to return, time for oral intake, time for unaided ambulation, and length of hospital stay. **Materials and Methods:** The study included 30 participants who received intraperitoneal Bupivacaine and 30 participants who received intraperitoneal Hydrocortisone. The patients' intraoperative vitals were monitored, and they were followed for postoperative shoulder and abdominal pain using a VAS based on a 0–10 scale at 2, 4, 8, 12, and 24 hours, analgesic needs, the presence of nausea or vomiting; and times of the return of bowel function, oral intake, unassisted ambulation and length of hospital stay. **Result:** Abdominal and shoulder VAS scores were considerably lower in the Bupivacaine group of patients. An abdominal VAS score difference that was statistically significant was observed at 4 hours (p=0.031) and 8 hours postoperatively. At 8 hours (p=0.031) and 12 hours, there was a significant difference in the shoulder pain VAS score. The Bupivacaine group also required less rescue analgesia. In terms of the other postoperative factors examined patients were comparable. **Conclusion:** In terms of reducing pain and the need for analgesics after laparoscopic cholecystectomy, intraperitoneal administration of hydrocortisone is not as effective as intraperitoneal Bupivacaine.

INTRODUCTION

In the current era, laparoscopic procedures have surpassed conventional open abdominal surgeries the advantage being decreased stress response, postoperative pain, wound infection rate, intraoperative bleeding, impairment of respiratory function and pulmonary complications, a shorter recovery time, and better cosmetic appearance.[1,2] Postoperative pain is still a major complaint that can prolong hospital stay and lead to increased morbidity, which is particularly important in centres performing this surgery as a day-care procedure.[3] Following laparoscopic cholecystectomy, a multimodal approach to postoperative analgesia used both systemic (opioid and non-opioid) and regional (neuraxial and peripheral) approaches. A straightforward and inexpensive and non-invasive technique that effectively manages postoperative pain after laparoscopic surgery is the administration of intraperitoneal local anaesthetics (IPLA) alone or in combination with non-opioid analgesics.[4,5] Steroids have shown a vital role in reducing pain by attenuating the inflammatory response. Recent research has assessed how intraperitoneal hydrocortisone affects laparoscopic cholecystectomy pain alleviation.[6,7] Hence this study was done to compare the effectiveness of intraperitoneal bupivacaine and intraperitoneal hydrocortisone in relieving postoperative pain and other morbidities following laparoscopic cholecystectomy.

MATERIALS AND METHODS

A prospective cohort study with a comparison group and a sample size of 60 patients who underwent laparoscopic cholecystectomy was included in this

ISSN (O): 2687-5365; ISSN (P): 2753-6556

investigation, which was conducted at the department of anesthesiology. Patients with symptomatic, uncomplicated gallstone disease and American Society of Anaesthesiologists (ASA) grades I or II were included. Patients with refusal, use of opiates, tranquillizers, steroids, NSAIDs, and alcohol, allergies to local anaesthetics, pneumoperitoneum contraindications, acute cholecystitis, and chronic pain conditions other than gallstone disease were excluded from this study. Patients who required an abdominal drain or whose treatment had to be switched to open cholecystectomy due to serious cardiac, pulmonary, neurological, or bleeding issues also were excluded.

The approval of the institution's ethics committee was acquired. Thirty patients were chosen from each group met the inclusion criteria, and their written and informed consent was obtained. Each patient underwent a thorough physical examination, systemic evaluation, and full history as part of the pre-anaesthetic check-up. Basic research was conducted. The proper use of a 10 cm visual analogue scale was taught to the patients. Overnight, patients were kept on nil oral. The night before surgery, Alprazolam 0.25-0.5mg tablets were administered orally to each patient.

Baseline vitals in the operating room were noted. 5ml/kg of Ringer lactate was administered once an intravenous line was set up. Patients received IV Glycopyrrolate 0.01 mg/kg and IV Midazolam 0.05mg/kg as premedication agents. 2 µg/kg IV fentanyl and 2 mg/kg IV propofol were used to produce anaesthesia. Vecuronium IV 0.1 mg/kg was used for endotracheal intubation. To keep the heart rate and mean arterial pressure within 20% of baseline, the anaesthesia was maintained with a mixture of nitrous oxide and oxygen at a ratio of 50% and 50%, respectively, along with an IV infusion of propofol. Each patient got a repeated bolus of vecuronium to maintain muscle relaxation and 1µg/kg fentanyl hourly. Before making an incision, 3 mL of 2% lignocaine was injected into each trocar site.

Group 1 patients received a peritoneal instillation of 100 mg of hydrocortisone dissolved in 250 mL sterile saline before CO2 insufflation. Similarly, group 2 patients had their peritoneal cavity filled with 250 mL of normal saline and 100 mg of bupivacaine. A surgical scrub nurse administered the medications. After instillation, patients were put into the Trendelenburg, anti-Trendelenburg, left and right lateral decubitus, and finally the supine position (each for 2 minutes). All patients had standard laparoscopic cholecystectomy procedures using the 4-port technique while in the anti-Trendelenburg position with a left tilt (100). Intraabdominal pressure was held constant during laparoscopy at 12–14 mmHg. Included in the monitoring were end-tidal carbon dioxide monitoring, non-invasive blood pressure monitoring, peripheral oxygen saturation monitoring, and lead II of an electrocardiogram.

After the operation, the infusion of propofol was lowered and ultimately ceased and CO2 was carefully removed from the peritoneal cavity. The patient was reversed from muscle relaxation with intravenous glycopyrrolate, 0.01 mg/kg, and intravenous neostigmine, 0.05 mg/kg, to reverse the condition. After a successful recovery and spontaneous breathing, the trachea was extubated, and the patient was moved to the postoperative recovery area.

The moment the patient was extubated was taken into consideration for all measurements as time 0. 2, 4, 8, 12, and 24 hours after surgery, patients were checked for postoperative abdominal discomfort using the Visual Analogue Scale, which uses a 0–10 scale.

Postoperative abdominal pain was defined as both parietal pain (defined as superficial pain located on the abdominal wall; pain that one can "touch") and visceral pain (defined as deep, dull, and more difficult to localise, inside the abdomen).

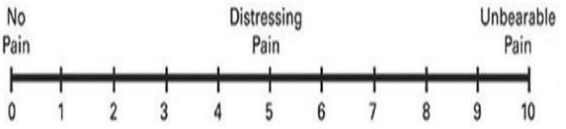

Figure 1: shows a visual analogue scale.

- None at all: 0,1
- Mild annoyance pain: 2,3
- Uncomfortable, bothersome, and causing some pain: - 4,5
- Uncomfortable, unpleasant pain: -6, 7
- Strong, terrible, horrendous pain: -8, 9
- The worst suffering imaginable, agonizing agony: -10

Injection Diclofenac 75mg IV was given as a rescue analgesic for VAS more than 4 postoperatively following the test dose. The use of analgesics, the presence of nausea and vomiting, the timing of independent ambulation, the recovery of bowel function, and the timing of hospital release were all observed in patients.

Statistical analysis

Data were analysed using SPSS (21.0 Version). Mean and Standard Deviation was calculated for all quantitative variables. Qualitative variables were expressed as percentages. The student’s t-test was performed to determine whether there were any differences in the quantitative characteristics between the Bupivacaine and Hydrocortisone groups. The mean change in values (heart rate, SBP, DBP etc.) at 30,60,120 and 150 minutes from the baseline values were also looked for. Paired 't' test was used to test the significance of a change in values from the baseline. Chi-square analysis was used to examine the differences between the Bupivacaine and Hydrocortisone groups regarding the use of rescue analgesics, nausea and vomiting symptoms, the restoration of bowel function, and independent ambulation.

ISSN (O): 2687-5365; ISSN (P): 2753-6556

RESULTS

Regarding the patient's demographic information [Table 1] and anthropometric measurements, there was no statistically significant difference between either group. Most of the participants in both the Bupivacaine group and the Hydrocortisone group belonged to ASA-PS 1. The two groups were similar regarding the distribution of participants according to ASA-PS. The mean duration of surgery was similar in the Bupivacaine group (119.8 minutes) and the Hydrocortisone group (121.0 minutes). Between the two groups, there was no discernible difference, as regards HR postoperatively and throughout all times that were recorded periodically [Table 2]. between the two groups, there was no discernible difference in mean arterial pressure both soon after surgery and at other times after surgery at various points [Table 3].

Table 1: Demographic data of the study population

Data	BUPIVACAINE	HYDROCORTISONE	P value
Age(years)	42.1±11.1	39.2±12.2	0.344
Gender(N): Male	11	7	0.260
Female	19	23	
Weight (kg)	60.2±9.0	61.7±8.5	0.508
BMI (kg/m2)	23.1±2.5	24.4±2.9	0.066
Duration of operation (min)	119.8±26.2	121.0±19.1	0.845
ASA-PS (N): ASA1	19	16	0.432
ASA2	11	14	

BMI: Body Mass Index
ASA-PS: American Society of Anesthesiologist physical status

Table 2: Comparison of heart rate

	Bupivacaine	Hydrocortisone	
TIME	MEAN±SD	MEAN±SD	P value
BASE LINE	83.3±12.7	86.3±11.9	0.345
30MTS	81.7±11.8	83.5±9.0	0.524
60MTS	78.5±12.0	80.1±9.6	0.555
90MTS	75.7±11.1	78.2±11.1	0.379
120MTS	75.3±14.2	80.4±10.4	0.313
150MTS	72.3±16.4	70.6±5.0	0.833

Table 3: Comparison of mean arterial pressure

MAP	Bupivacaine MEAN±SD	Hydrocortisone MEAN±SD	P value
BASELINE	94.4±11.5	88.2±12.6	0.052
30min	93.3±14.9	91.1±11.7	0.515
60min	97.6±19.9	92.7±9.1	0.224
90min	96.8±13.9	91.2±11.1	0.090
120min	91.1±14.2	91.9±10.9	0.877
150min	87.4±9.4	96.2±5.4	0.091

MAP:mean arterial pressure

There was no difference in the abdominal pain experienced as assessed on VAS at 2 hours in both groups. Whereas a significant difference in pain scores was noted between groups at 4 hours (BP – 1.6 on VAS and HC – 2.6 on VAS) and 8 hours (BP – 1.3 on VAS and HC – 2.0 on VAS). Thereafter at 12 hours and 24 hours, no significant difference was noted (table 4). Also, there was no difference in the shoulder pain experienced as assessed on VAS at 2 hours and 4 hours in both groups. Thereafter significant difference in shoulder pain was noted regarding the two groups at 8 hours (Bupivacaine 0.5 on VAS and Hydrocortisone 1.1 on VAS) and 12 hours (Bupivacaine 0.2 on VAS and Hydrocortisone – 0.7 on VAS). At 24 hours there was no significant distinction regarding the two groups. (Table 5) Rescue analgesic was required in only 8 out of 30 in the Bupivacaine group whereas 19 out of 30 in the Hydrocortisone group required rescue analgesia. This difference was found to be statistically significant ($\chi 2 = 8.15$, $p = 0.004$)

Most participants in both groups had no nausea/vomiting (90.9 % in the Bupivacaine group and 96.7 % in the Hydrocortisone group. This difference between the two groups was statistically not significant. A similar pattern of values was noted regarding the duration of hospital stay, time of the return of bowel function, time of unassisted ambulation, and time of oral intake in both the groups and hence it was not statically significant [Table 6]

Table 4: Comparison VAS Score for abdominal pain

VAS Abdomen	Bupivacaine MEAN±SD	Hydrocortisone MEAN±SD	P value
2hrs	2.2±1.3	2.2±0.9	0.908
4 hrs	1.6±1.4	2.6±1.8	0.031*
8 hrs	1.3±1.3	2.0±1.2	0.031*

ISSN (O): 2687-5365; ISSN (P): 2753-6556

12 hrs	1.3±1.4	1.5±1.7	0.620
24 hrs	0.7±1.3	1.0±1.0	0.280

*P value < 0.05; statistically significant
VAS - Visual analogue scale

Table 5: Comparison VAS Score for shoulder pain

VAS shoulder	Bupivacaine Mean±SD	Hydrocortisone Mean±SD	P value
2 hrs	1.0±1.1	1.5±1.3	0.110
4 hrs	0.8±1.1	1.2±1.4	0.218
8 hrs	0.5±0.6	1.1±1.4	0.035
12 hrs	0.2±0.5	0.7±1.3	0.047*
24 hrs	0.2±0.4	0.5±1.3*-	0.130

*P value < 0.05; statistically significant
VAS - Visual analogue scale

Table 6: Postoperative Outcomes

Postoperative Outcomes	Bupivacaine n (%)	Hydrocortisone n (%)	P VALUE
Need for rescue analgesia	8(26.7%)	19(63.3%)	0.004*
Nausea and vomiting	3(10%)	1(3.3%)	0.301
Return of bowel function at 12-24 hrs	23(76.7%)	25(83.3%)	0.808
Oral intake at 12-24 hrs	26(86.7%)	27(90%)	0.688
Ambulation at 24-48hrs	27(90%)	26(86.7%)	0.688

*P value < 0.05; statistically significant

DISCUSSION

This is a prospective cohort study with a comparison group. 30 subjects who were given intraperitoneal instillation of Bupivacaine and 30 subjects who were given intraperitoneal Hydrocortisone were included in the study. A similar study was conducted by Shahram et as a randomized controlled trial.[7]

Demographic Data

Old age is a known risk factor for gallstone disease.[8] Age was comparable in both groups, similar to a study conducted by Shukla et al.[9] The female sex is a nonmodifiable risk factor for cholelithiasis.[8] The majority were females in both groups, which was similar to the study by Papadima et al and Schulte-Stanberg.[10,11] Even though obesity was a modifiable risk factor for cholelithiasis,[8] the mean BMI was normal in our cohort.[12]

Intraoperative Data

Intraoperatively heart rate, non-invasive blood pressure, peripheral oxygen saturation, capnography, and electrocardiography lead II were monitored at baseline and 30,60,90,120,150 minutes. Based on the heart rate at different follow-up points, no discernible variation was seen in either group or the reduction in the heart rate from baseline at different time points was also not statistically significant. With regards to SBP, a discernible variation was seen regarding the two groups at 60 minutes follow-up (p=0.016) and 150 minutes follow-up (p=0.032). However, there were only 8 patients in Group BP and 5 patients in Group HC in whom surgery lasted up to 150 minutes.

With regards to DBP, a significant statistical difference was noted among the two study groups at 60 minutes follow-up (p=0.002). With regards to changes in SBP and DBP from baseline, both groups showed a significant reduction at 120 minutes and 150 minutes. However, at 120 or 150 minutes, fewer individuals were included in each group. Concerning MAP, both groups were similar at all time points and based on changes in MAP from baseline, a difference was noted regarding the two groups at 120 minutes (0.081) and 150 minutes of which this reduction was significant at 150 minutes (p=0.043).

Regarding SPO2, a distinction with statistical significance was noted in either group in the baseline value itself (p=2.96, p=0.004). There was a distinction with statistical significance noted at 120 minutes also concerning the two groups (p=0.012) which cannot be taken into consideration as baseline values were not comparable. But when we compare the percentage changes in SPO2 from baseline, a statistically significant difference was again noted at 120 minutes between the two groups (p=3.22, p=0.004). Based on ETCO2 from baseline and ETCO2 at different follow-up points, no discernible variation was seen among the groups.

It was observed that the SBP, DBP and MAP showed a rise in value at 60 minutes intraoperatively in both groups. As the statistical difference between the two groups on intraoperative vitals was noted more at 120 minutes and 150 minutes when the number of subjects was less, we cannot consider this to be significant. Thus, for intraoperative vitals, no significant difference can be noted in either group.

Pain Score

At 2, 4-, 8-, 12-, and 24 hours following surgery, patients were monitored for post – operative shoulder discomfort and abdomen pain (which included parietal and visceral pain) using the Visual Analogue Scale (VAS). When the VAS score goes above 4, a rescue analgesic was administered.

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Analysis revealed that there was a reasonable difference in the groups' pain scores at 4 hours (Group BP- 1.6 on VAS and Group HC- 2.6 on VAS) and 8 hours (Group BP– 1.3 on VAS and Group HC – 2.0 on VAS). At 2, 1, 12, and 24 hours, there was no observable difference. Between the two groups, there was a significant difference in shoulder discomfort at 8 hours (Group BP -0.5 on VAS and Group HC -1.1 on VAS) and 12 hours (Group BP - 0.2 on VAS and Group HC – 0.7 on VAS). There was no observable difference between the two groups at 2, 4, or 24 hours.

From the studies by Boddy et al,[3] Bisgaard et al,[13] and Joris et al,[14] it is seen that shoulder pain which is insignificant in the initial postoperative hour increases thereafter and becomes the main complaint in the second postoperative day. Our study demonstrated that the abdominal pain VAS score was more at 2 hours in Group BP and at 2 hours and 4 hours in Group HC, whereas the shoulder pain, VAS score in both groups showed a decrease from 2 hours to 24 hours. Rescue analgesic was required in only 8 out of 30 in Group BP whereas 19 out of 30 in Group HC required rescue analgesic The statistical significance of this difference was established ($\chi 2 = 8.15$, $p = 0.004$). Bupivacaine was therefore found to be more effective than hydrocortisone when administered intraperitoneally for postoperative analgesia.

According to Joris et al,[14] visceral as well as parietal pain was more severe than shoulder discomfort in the first eight hours following surgery. They demonstrated that visceral discomfort accounted for most of the pain experienced following laparoscopic cholecystectomy and that intraperitoneal Bupivacaine was ineffective for addressing any form of pain during the procedure. Similarly, Shabir et al,[15] also noted that when compared to parenteral analgesia with tramadol, Bupivacaine instillation and infiltration in laparoscopic cholecystectomy were not effective for postoperative analgesia. In a study by Arden et al,[16] it was determined that diluted Bupivacaine intraperitoneally instilled did not diminish postoperative discomfort or prescriptions for opioids. Shaw et al,[17] also could elicit similar results in their study.

According to Papadima et al,[10] the IPA group (with Levobupivacaine) produced a lower mean VAS score at rest and during movement compared to controls at all time points of measurement (p 0.02), while the control group consumed more rescue analgesic opioids. They concluded that two distinct intraperitoneally delivered doses of levobupivacaine caused a marked reduction in postoperative pain and the requirement for painkillers.

According to the study by Sulekha 5, mean VAS was comparatively higher in the control group at initial hours and end hours in comparison to the Bupivacaine group. It was determined that intraperitoneal instillation of local anaesthetic is a simple, inexpensive, and non-invasive approach that offers effective analgesia immediately following laparoscopic procedures. In an intraperitoneal Hydrocortisone vs. normal saline study, Sarvestani et al,[6] discovered those patients in the Hydrocortisone group had significantly lower abdominal and shoulder pain scores (10.95 vs. 12.95, p0.01) and needed fewer rescue analgesics than those in the saline group (151.6649.9 mg vs. 61.6638.69 mg).

When they studied the outcomes of intraperitoneal HC and BP in laparoscopic cholecystectomy. Sharmam et al,[7] concluded that there was no significant statical difference when the abdominal and shoulder pain scores of both groups were compared. Abdalla,[18] studied the analgesic effect of adding HC to Ropivacaine intraperitoneally in laparoscopic gynaecological surgeries and showed that adding 100mg of HC to intraperitoneal ropivacaine can decrease pain postoperatively and analgesia required.

According to Roberts et al,[19] the intraperitoneal approach of local anaesthetic (BP) lessens postoperative discomfort and cuts down on recovery time in the operating room (p=0.04). After the laparoscopic procedures were done, Cunniffe et al.20 discovered that intraperitoneal irrigation with BP to both hemidiaphragm significantly decreased the frequency (p=0.003), intensity (p0.01), and the requirement for postoperative analgesia (p0.04).

According to Bisgaard et al,[13] local anaesthetic infiltration intra-abdominally has mixed effects and half the studies conducted showed a beneficial effect. The reasons for the variation in the result are not known. But it is believed that the time of injection (before vs after operation), the site of injection subdiaphragmatic, intraperitoneal or in the bed of the gall bladder) the local anaesthetic used (Bupivacaine, Ropivacaine, Levobupivacaine) and the concentrations used (0.25% vs0.5% Bupivacaine), instillation in head-down position versus supine position, pneumoperitoneum (volume, pressure, temperature), the volume of residual CO2 (causing diaphragmatic irritation), spillage of blood and bile are certain factors that play important role in this variation. Specific evidence 10 suggests that the local anaesthetic instillation intraperitoneally had a significant benefit in the early postoperative period, but not beyond this period.[20,21]

Postoperative Outcome

Most participants in both groups had no nausea/vomiting (90.9 % in Group BP and 96.7 % in Group HC). Regarding the timing of the recovery of bowel function, oral intake, ambulation, and hospital discharge, there was no discernible difference in the two study groups. There were no clinical signs of neurovascular or cardiovascular toxicity observed in patients of both groups.

ISSN (O): 2687-5365; ISSN (P): 2753-6556

CONCLUSION

In conclusion, intraperitoneal administration of Hydrocortisone is as effective as intraperitoneal Bupivacaine in reducing nausea/vomiting, return of bowel function, return of oral intake, return of unassisted ambulation and duration of hospital stay. But it was found to be not as effective as intraperitoneal Bupivacaine in decreasing pain and analgesic requirements after laparoscopic cholecystectomy. Considering the limitations of the study, further studies are required to evaluate the efficacy of intraperitoneal Hydrocortisone in postoperative analgesia after laparoscopic cholecystectomy more accurately.

Limitations

As pain is a subjective feeling, it cannot be accurately measured. Differences in the pain threshold among patients make the correlation between the visual analogue pain scale the and use of rescue analgesics difficult. The surgeries were not performed by a single surgeon. This led to some amount of drug solution being suctioned out at the end of the procedure by some surgeons; thus, affecting the efficacy of the drugs. Only ASA PS I and II were included in the study hence the results cannot be generalized to patients with ASA PS III and IV.

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ISSN (O): 2687-5365; ISSN (P): 2753-6556