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COMPARATIVE ASSESSMENT OF THE ANALGESIC EFFICACY OF INTERPERITONEAL BUPIVACAINE ALONE TO COMBINED BUPIVACAINE AND DEXAMETHASONE AFTER LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT

Background: Acute pain has been linked to laparoscopic cholecystectomy and various methods have been adopted to reduce postoperative pain after laparoscopy.

Aim: The present study aimed to comparatively assess the analgesic efficacy of bupivacaine alone with combined bupivacaine and dexamethasone after laparoscopic cholecystectomy.

Methods: The study assessed 42 subjects who underwent laparoscopic cholecystectomy divided into two groups of 21 subjects each where Group I subjects, were given 40ml 0.25% bupivacaine and 16 mg dexamethasone and Group II subjects were given 40ml bupivacaine alone intraperitoneally. The time needed for the first analgesic, total rescue analgesic dose and VAS scores were compared between the two groups.

Results: Time taken for the need of the first rescue analgesic was significantly longer in Group I in comparison to bupivacaine alone with 417.3±276.2 min and 219.6±226.3 min with p=0.001. Total rescue analgesics taken in Group I was significantly lower compared to Group II with 60.73±29.82mg and 73.22±11.55mg respectively with p=0.01. Also, VAS scores were lower in Group I compared to Group II till 2 hours postoperatively with a mean difference of -1.0 and p<0.001.

Conclusion: The present study concludes that administration of combined 16mg dexamethasone and 0.25% bupivacaine intraperitoneally significantly reduces the postoperative need for rescue analgesic and postoperative pain following laparoscopic cholecystectomy in comparison to 0.25% bupivacaine alone.

Keywords: Analgesia, bupivacaine, cholecystectomy, dexamethasone, laparoscopy

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INTRODUCTION

For various operative and diagnostic procedures, laparoscopy is highly preferred over the exploratory methods in the present era owing to the various advantages associated with the laparoscopy method including the early resuming the day-to-day activities postoperatively, short stay duration at hospitals postoperatively, earlier recovery, and superior esthetic outcomes.[1] Also, the pain severity following laparoscopic techniques is comparatively lesser when compared to laparotomy, however, pain following laparoscopy is acute which demands a higher need for analgesics, and prolonged hospital care.[2]

Previous literature data has extensively assessed the methods for postoperative pain relief after laparoscopy including the intra-peritoneal administration of local anesthetics either alone or in combination with other agents including steroids, dexmedetomidine, and/or morphine, steroids, analgesic patches, and/or intravenous agents.[3]

Administration of local anesthetics via the intra-peritoneal route has been extensively used for postoperative analgesia after laparoscopy.[4] The local anesthetic agents used for injecting intra-peritoneally include bupivacaine, ropivacaine, and lidocaine. It has been reported that after gynecological laparoscopic surgeries, injecting a single dose of dexamethasone has proved to be an effective analgesic agent.[5]

The present clinical study aimed to comparatively assess the analgesic efficacy of bupivacaine alone with combined bupivacaine and dexamethasone after laparoscopic cholecystectomy. The study also aimed to compare the occurrence of hyperglycemia, vomiting, postoperative nausea, need for total rescue analgesic dose, and time for first rescue analgesics in two groups.

MATERIALS AND METHODS

The present clinical study aimed to comparatively assess the analgesic efficacy of bupivacaine alone with combined bupivacaine and dexamethasone after laparoscopic cholecystectomy. The study also aimed to compare the occurrence of hyperglycemia, vomiting, postoperative nausea, the need for total rescue analgesic dose, and the time for first rescue analgesics. The study was done after the clearance was given by the concerned Institutional Ethical committee. Informed consent in both verbal and written form was taken from all the subjects before study participation.

The study included subjects undergoing laparoscopic cholecystectomy after assessing the inclusion criteria for the study. After the final assessment for inclusion, a detailed study design was explained to all the subjects. The study included 42 subjects from both genders undergoing laparoscopic cholecystectomy, with ASA (American Society of Anesthesiologists) status I and II, and subjects in the age range of 18 years to 60 years. The exclusion criteria for the study were subjects with a history of abdominal surgery, pregnant females, subjects on steroids, study drug allergies, and with diabetes mellitus.

Finally included 42 subjects were randomly divided into two groups of 21 subjects each. After final inclusion, baseline blood sugar levels, Apfel risk scores,[6] demographic data, and postoperative vomiting and nausea were recorded for all the study participants. All the subjects

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were briefed on using VAS (visual analog scale) comprising of 10 points on pain intensity where 0 depicted no pain and 10 depicted worst pain.

On the day of surgery, peripheral venous access was gained along with the establishment of basic standard monitors. General anesthesia was given to all the participants comprising of 2 µg/kg of IV (intravenous) fentanyl, 0.1mg/kg vecuronium, and 2-2.5mg/kg of propofol using the endotracheal intubation. 1 µg/kg of IV (intravenous) fentanyl and Sevoflurane in 1-1.5 minimum alveolar concentration was used for maintenance of general anesthesia in cases where baseline systolic blood pressure and heart rate increased by more than 20%. Additionally, 0.03 mg/kg IV vecuronium was given when required. To maintain intra-abdominal pressure at 12-14 mm Hg, the peritoneal cavity was insufflated with carbon dioxide during the laparoscopy. After confirmation of pneumoperitoneum, the drugs were given via intraperitoneal route via umbilical port based on the group that subjects were allotted to.

In Group I, dexamethasone and bupivacaine were given with 16 mg dexamethasone and 40 ml of 0.25% bupivacaine, whereas, in Group II, 40 ml of 0.25% bupivacaine alone was administered. For drug administration, a 50 ml syringe was utilized which was attached to the umbilical port. After drug administration, subjects were placed in the Trendelenburg position for 10 minutes for the drug spread. Following deflation of gas, all subjects were given 4 mg IV ondansetron and IV paracetamol in 1 gram infusion. At the surgery end, after residual neuromuscular blockade reversal using 8 µg/kg glycopyrrolate and 50 µg/kg neostigmine, tracheal extubation was done. Subjects that needed open cholecystectomy were converted to open surgery and subjects needing drain insertion were excluded from the study.

The study assessed VAS scores for pain using the VAS scale at 0, 1, 2, 4, 8, 12, 16, and 24 hours post-surgery. The study also assessed adverse outcomes in the first 24 hours of surgery, postoperative nausea and vomiting, hyperglycemia occurrence, total rescue analgesic dose, and time needed for the first rescue analgesic. The rescue analgesic used in the present study was diclofenac from the IV route in 75 mg dose and was only used when VAS scores were more than 3. The time needed for the first rescue analgesic was calculated in milligrams and as minutes. Hyperglycemia was considered when the blood sugar levels were more than 200 mg/dl assessed using a glucometer at 4 hours and 24 hours postoperatively.

The data gathered were analyzed statistically using SPSS software version 21.0 (IBM Corp. NY, USA) with Fisher's exact test, chi-square test, and t-test. The data were expressed as mean and standard deviation and frequency and percentages. The statistical significance was taken at a p-value of <0.05.

RESULTS

The present clinical study aimed to comparatively assess the analgesic efficacy of bupivacaine alone with combined bupivacaine and dexamethasone after laparoscopic cholecystectomy. The study also aimed to compare the occurrence of hyperglycemia, vomiting, postoperative nausea, the need for total rescue analgesic dose, and the time for first rescue analgesics. Finally included 42 subjects were randomly divided into two groups of 21 subjects each. After final inclusion, baseline blood sugar levels, Apfel risk scores, demographic data, and postoperative vomiting and

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nausea were recorded for all the study participants. Group I subjects were given 40ml 0.25% bupivacaine and 16 mg dexamethasone and Group II subjects were given 40ml bupivacaine alone intraperitoneally.

The mean age of the study subjects in Groups I and II was 35.3±12.2 and 35.2±11.0 years respectively. There were 14.28% (n=3) males and 85.71% (n=18) females in Group I, whereas, there were 23.80% (n=5) males and 76.19% (n=16) females in Group II. Baseline blood sugar level in Group I and II subjects was 113.4±25.9 and 123.3±31.0 mg/dl respectively. The weight of study subjects in Group I and II was 60.2±8.5 and 60.2±11.7 kg respectively. Apfel scores of I and II were seen in 47.61% (n=10) and 52.38% (n=11) subjects respectively from Group I and 33.3% (n=7) and 66.6% (n=14) in Group II subjects respectively. ASA status was I and II in 66.6% (n=14) and 33.3% (n=7) subjects from Group I and was 52.38% (n=11) and 47.61% (n=10) subjects respectively as shown in Table 1.

VAS score assessment in Group I and II at 0 hours showed that VAS scores were significantly higher in Group II at 3.6±2.4 compared to Group I where it was 2.2±1.6 with p=0.003. Similar results were seen at 1 hour where VAS scores for Group I and II were 1.9±1.2 and 3.0±1.3 respectively with p=0.001. At 2 hours, VAS scores were significantly higher for Group II where only bupivacaine was used compared to the combined use of dexamethasone and bupivacaine with values of 1.9±0.8 and 2.9±1.4 respectively, and p-values of <0.001. A non-significant difference in VAS scores was seen in Group I and II at 4, 8, 12, 16, and 24 hours with p-values of 0.13, 0.88, 0.22, 0.07, and 0.32 respectively as depicted in Table 2.

Concerning the study variables and outcomes, it was seen that a significantly higher total rescue analgesic dose was needed in Group II compared to Group I with 73.19±11.55 mg and 60.73±29.82 mg respectively, and p=0.01. The mean first rescue analgesic time was significantly higher in Group I with 417.3±275.8 min compared to 219.6±225.9 min with p=0.001. Mean random blood sugar levels at 24 hours had a non-significant difference with p=0.42. At 4 hours, random blood sugar levels had a non-significant difference between Group I and II with p=0.53 (Table 3).

DISCUSSION

The present study included 42 subjects who were randomly divided into two groups of 21 subjects each. After final inclusion, baseline blood sugar levels, Apfel risk scores, demographic data, and postoperative vomiting and nausea were recorded for all the study participants. Group I subjects were given 40ml 0.25% bupivacaine and 16 mg dexamethasone and Group II subjects were given 40ml bupivacaine alone intraperitoneally. The study design was similar to the previous studies of Asgari Z et al[7] in 2012 and Nanda A et al[8] in 2020 where authors assessed bupivacaine alone to combine bupivacaine and dexamethasone for their efficacy.

Concerning demographics, it was seen that the mean age of the study subjects in Group I and II was 35.3±12.2 and 35.2±11.0 years respectively. There were 14.28% (n=3) males and 85.71% (n=18) females in Group I, whereas, there were 23.80% (n=5) males and 76.19% (n=16) females in Group II. Baseline blood sugar level in Group I and II subjects was 113.4±25.9 and 123.3±31.0 mg/dl respectively. The weight of study subjects in Group I and II was 60.2±8.5 and

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On assessing the VAS scores, it was seen that Group I and II at 0 hours showed that VAS scores were significantly higher in Group II with 3.6±2.4 compared to Group I where it was 2.2±1.6 with p=0.003. Similar results were seen at 1 hour where VAS scores for Group I and II were 1.9±1.2 and 3.0±1.3 respectively with p=0.001. At 2 hours, VAS scores were significantly higher for Group II where only bupivacaine was used compared to the combined use of dexamethasone and bupivacaine with values of 1.9±0.8 and 2.9±1.4 respectively, and p-value of <0.001. A non-significant difference in VAS scores was seen in Group I and II at 4, 8, 12, 16, and 24 hours with p-values of 0.13, 0.88, 0.22, 0.07, and 0.32 respectively. These results were consistent with the studies of Aberer F et al[11] in 2021 and Srivastava V et al[12] in 2022 where authors reported higher VAS scores with bupivacaine alone compared to combined bupivacaine and dexamethasone.

Concerning the study variables and outcomes, it was seen that a significantly higher total rescue analgesic dose was needed in Group II compared to Group I with 73.19±11.55 mg and 60.73±29.82 mg respectively, and p=0.01. The mean first rescue analgesic time was significantly higher in Group I with 417.3±275.8 min compared to 219.6±225.9 min with p=0.001. Mean random blood sugar levels at 24 hours had a non-significant difference with p=0.42. At 4 hours, random blood sugar levels had a non-significant difference between Group I and II with p=0.53. These findings were consistent with Nasr Y et al[13] in 2022 and Upadya M et al[14] in 2015 where the clinical parameters comparable to the present study were reported by the authors.

CONCLUSIONS

Considering its limitations, the present study concludes that the administration of combined 16mg dexamethasone and 0.25% bupivacaine intraperitoneally significantly reduces the postoperative need for rescue analgesic and postoperative pain following laparoscopic cholecystectomy in comparison to 0.25% bupivacaine alone.

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TABLES

S. No	Characteristics	Group I (n=21)	Group II (n=21) (Bupivacaine alone)
1.	**Mean age (years)**	35.3±12.2	35.2±11.0
2.	**Gender**		
a)	Males n (%)	3 (14.28)	5 (23.80)
b)	Females	18 (85.71)	16 (76.19)
3.	**Baseline blood sugar (mg/dl)**	113.4±25.9	123.3±31.0
4.	**Weight (Kg)**	60.2±8.5	60.2±11.7

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5.	**Apfel score n (%)**		
a)	I	10 (47.61)	7 (33.3)
b)	II	11 (52.38)	14 (66.6)
6.	**ASA n (%)**		
a)	I	14 14 (66.6)	11 (52.38)
b)	II	7 (33.3)	10 (47.61)

Table 1: Demographic data of two groups of study participants

S. No	Time (postoperative in hours)	Group I (n=21) (Mean ± S. D)	Group II (n=21) (Mean ± S. D)	p-value
1.	0	2.2±1.6	3.6±2.4	**0.003**
2.	1	1.9±1.2	3.0±1.3	**0.001**
3.	2	1.9±0.8	2.9±1.4	**<0.001**
4.	4	1.7±0.9	2.6±1.2	0.13
5.	8	2.8±1.4	2.7±1.4	0.88
6.	12	2.3±1.0	1.9±1.0	0.22
7.	16	1.9±1.2	1.5±1.0	0.07
8.	24	1.3±0.4	0.11±0.9	0.32

Table 2: VAS scores in two study groups at different time interval

S. No	Variables	Group I (Mean ± S. D)	Group II (Mean ± S. D)	p-value
1.	**Total rescue analgesic dose (mg)**	60.73±29.82	73.19±11.55	**0.01**
2.	**First rescue analgesic time (min)**	417.3±275.8	219.6±225.9	**0.001**
3.	**Random blood sugar at 24 hours (mg/dl)**	140.2±154.6	118.6±19.4	0.42
4.	**Random blood sugar at 4 hours (mg/dl)**	127.7±29.7	132.0±31.4	0.53

Table 3: Comparison of different study variables in two groups of study subjects