Comparison of postoperative pain relief following use of spinal anesthesia versus general anesthesia for patients undergoing laparoscopic cholecystectomy

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ABSTRACT

Objectives: Effective post-operative pain control is an essential component of care of surgical patients. Various analgesic regimens have been used to ensure adequate postoperative pain relief. We conducted this study to compare the efficacy of spinal anesthesia versus general anesthesia regarding post-operative pain following laparoscopic cholecystectomy.

Methodology: After approval of the hospital ethical committee, 120 females were included in our randomized, control trial from 1 July 2015 to 31 Dec 2015. Patients were explained about the study and informed consent was signed by them or their guardians. Patients were randomly divided into two groups; in Group-A patients, spinal anesthesia was achieved with 3 ml 0.5% hyperbaric bupivacaine hydrochloride and 25 µg fentanyl. Group-B was given GA. All the patients were premedicated with IV metoclopramide 10 mg and dexamethasone 8 mg; preemptive analgesia with 0.1 mg/kg nalbuphine was done. Induction of GA was done with propofol 2 mg/kg, muscle relaxation was achieved with atracurium besylate 0.5 mg/kg. Endotracheal intubation with 6.5 or 7 mm cuffed tube was done. Visual analogue scale (VAS) was used to assess pain severity at immediate post-operative period (S-0) and at 6 hours (S-6).

Data was analyzed using SPSS version 16.0. For quantitative variables like pain score and age, mean and standard deviation (SD) were calculated. For qualitative variables like severity of pain, frequency and percentages were calculated. Chi-square test was used to measure frequency of pain between two groups. P-value < 0.05 was taken as significant.

Results: The two groups did not differ in demographic profiles. At S-0, the mean score in Group-A was 2.89 ± 2.49 (mode = 1, median 2) versus 3.83 ± 2.56 (mode = 3, median = 3), p value 0.0364. At zero hours (S-0); 6 (10%) patients in Group-A had no pain (VAS less than 2), 28(46.6%) patients had mild pain and 26 (43.3%) patients had severe pain. In Group-B 8(13.3%) had no pain, 20(33.3%) had mild pain and 32(55%) patients had severe pain. The p value was 0.947, which is statistically insignificant. At S-6, the mean VAS was 6.94 (median = 7, mode = 8) in Group-A versus 6.23 ± 2.11 (median = 6, mode = 5) in Group-B, p value 0.0277. At six hours (S-6), 31(51.6%) patients no mild pain in Group-A, 24(40%) had mild pain and 5(8.3%) had severe pain. Whereas 30 (50%) patients had no pain, 8 (13.3%) patients had mild pain and 22 (36.6%) patients had severe pain in Group-B. The p-value was 0.022, which is statistically significant.

Conclusion: Our study has shown that single shot spinal anesthesia provides better postoperative analgesia in the postsurgical period. The addition of intrathecal fentanyl provides adequate analgesia, including relief from shoulder tip pain. So, spinal anesthesia can be safely used as sole anesthesia for laparoscopic cholecystectomy.
NTRODUCTION

Effective post-operative pain control is an essential component of care of surgical patients. Considerable research is being done in this field. Despite the advancements, the post-operative pain remains a challenge for the surgeon as well as the anesthetist involved in pain management. Inadequately treated pain can lead to detrimental physiological effects as well as psychological, economic and social adverse effects. Major abdominal surgeries with upper abdominal incisions leads to severe pain, which can cause shallow breathing, atelectasis, increased pulmonary complications. Minimally invasive surgeries are associated with reduced incidence of pain as compared to open surgeries. It is thought that laparoscopy necessitates endotracheal intubation to prevent pulmonary aspiration, abdominal discomfort and hypercarbia secondary to carbon dioxide pneumoperitoneum. Recently, various laparoscopic surgeries are increasingly being performed under spinal anesthesia (SA) with low pressure pneumoperitoneum. Regional blocks such as epidural, combined spinal epidural, spinal and low thoracic epidural has been used for laparoscopic surgery in patients with multiple co-morbidities, considered as not fit for general anesthesia (GA). Shoulder pain is the most common reason for avoidance of SA by surgeons. It has been shown that the addition of fentanyl reduces the incidence of post-operative shoulder pain.

Sinha et al showed that hyperbaric bupivacaine can provide adequate anesthesia for laparoscopic cholecystectomy. Sangeeta Tiwani et al. studied 235 patients who underwent laparoscopic cholecystectomy to compare general and SA. In their study, the mean anesthesia time was longer in GA group as compared to SA group (p-value 0.02). The pneumoperitoneum and total surgical time was similar in both groups. SA is associated with less anesthetic cost as compared to GA, lower post-operative pain and comparative hospital stay.

In our institute, laparoscopic surgeries are being done under GA. To our knowledge no study has been done in Pakistan to compare the postoperative pain relief after SA for laparoscopic surgery. The purpose of our study was to compare the frequency and severity of postoperative pain after laparoscopic cholecystectomy under SA and GA. We postulated that SA with local anesthetic in combination with an opioid can prove to be superior to GA regarding better postoperative analgesia. If proven superior to GA, SA can be recommended as anesthesia of choice for conducting laparoscopic cholecystectomy in developing countries where cost factor is a major issue.

We hypothesized that SA is superior to GA in reducing early postoperative pain after surgery. So conducted this study to compare efficacy of SA versus GA regarding postoperative pain following laparoscopic cholecystectomy. Pain measured at immediate postoperative (S-O) and six hours postoperative (S-6).

METHODOLOGY

This randomized, control trial was conducted at Department of Anesthesiology, Combined Military Hospital Rawalpindi, for a duration of 6 months (1st Jul to 31 Dec, 2015). WHO sample size calculator was used to calculate sample size of 120 (n = 60 in each case); with confidence interval of 5% and power of test 80%. Inclusion Criteria: females between the age 35-55 y, American Society of Anesthesiologist (ASA) physical status I and II and BMI < 30, who were to undergo elective laparoscopic cholecystectomy, were included in our study.

The patients with acute cholecystitis or pancreatitis, cholangitis and previous abdominal surgery were excluded from our study.

After the approval from the ethical committee, informed consent from patients was taken. Those who were willing and eligible for the study were divided into two groups by researcher using consecutive, non-probability randomization. In case of ineffective SA, patient was given GA and more patients were recruited to complete the study size.

On the day of surgery, all the patients were passed 18G IV cannula and monitoring started with ECG, NIBP,
SpO₂ and temperature. In Group-A, the patients were given a fluid preload of 10 ml/kg of ringer's lactate. Under complete aseptic measure, SA was achieved with 3 ml 0.5% hyperbaric bupivacaine hydrochloride and 25 µg fentanyl intrathecally. The patient were kept supine for 10 min and then handed over to the surgeon for cholecystectomy. Group-B was given GA. All the patients were preoxygenated with 100% for 3 min; premedication with IV metoclopramide 10 mg and dexamethasone 8 mg; preemptive analgesia with 0.1 mg/kg nalbuphine was done. Induction of GA was done with propofol 2 mg/kg, muscle relaxation was achieved with atracurium besylate 0.5 mg/kg. Endotracheal intubation with 6.5 or 7 mm cuffed tube was done, which was fixed after confirmation of bilateral air entry. Maintenance of anesthesia was done with isoflurane at 2-3%, 50% O₂ in 50% air (nitrous oxide is not available at our institute). Laparoscopic cholecystectomy was done by using the same technical principle for both groups and pneumoperitoneum was established and maintained by carbon dioxide at the maximum pressure of 10 mm Hg. At the end of surgery, the patients were given reversal of neuromuscular blockade with intravenous neostigmine 0.04 mg/kg and glycopyrrolate 0.5 mg. The patients were extubated once fully awake and the patient were shifted to the ward. Postoperative pain was assessed by using the visual analogue scale at the end of surgery, then at six hours postoperatively. A house surgeon did the pain assessment, he was kept blind regarding the intervention. Analgesia in case of pain was provided by intravenous nalbuphine 5 mg boluses, strictly on the demand of the patient during the first six hour. The data thus collected was recorded on performa. Visual analogue score was used for assessment of pain severity. The severity was assessed as mean VAS in the two groups. VAS less than 2 were taken as no pain, 3-6 as mild pain and more than 7 as severe pain. Final outcome was assessed at immediate post-operative (S-0) and 6 h (S-6).

Data was analyzed using SPSS version 16.0. For quantitative variables like pain score and age, mean and standard deviation (SD) were calculated. For qualitative variables like severity of pain, frequency and percentages were calculated. Chi-square test was used to measure frequency of pain between two groups. P-value < 0.05 was taken as significant.

RESULTS

A total of 120 females were studied in our randomized control trail. The two groups did not differ in demographic profiles. The mean age in Group-A was 42.57 years ± 5.77 versus 44.07 ± 5.62 y in Group-B, (p = 0.152). The overall mean body mass index in my study was 25.70 (± 2.34). The mean body mass index in Group-A was 26.00 ± 2.31 and 25.41 ± 2.36 in Group-B, (p-value 0.171), which is statistically insignificant. Group-A had 38 (63.3%) patients who belonged to American Society of Anesthesiologist physical status II; as compared to 46 (76.6%) patients of American Society of Anesthesiologists physical status II in Group-B; p-value was 0.081 which was statistically insignificant.

Visual analogue score was used to assess the severity of pain. At S-0, the mean score in Group-A was 2.89 ± 2.49 (mode = 1, median 2) versus 3.83 ± 2.56 (mode = 3, median = 3), p value 0.0364 which is statistically significant. At zero hours (S-0); 6 (10%) patients in Group-A had no pain (VAS less than 2), 28 (46.6%) patients had mild pain and 26 (43.3%) patients had severe pain. In Group-B 8(13.3%) had no pain, 20 (33.3%) patients had mild pain and 32 (55%) patients had severe pain. The p value was 0.947, which is statistically insignificant (Figure 1).

At S-6, the mean VAS was 6.94 (median = 7, mode = 8) in Group-A versus 6.23±2.11 (median = 6, mode = 5) in Group-B, p value 0.0277; which is statistically significant. At six hours (S-6), 31 (51.6%) patients had mild pain in Group-A, 24 (40%) had mild pain and 5 (8.3%) had severe pain. Whereas 30 (50%) patients had no pain, 8 (13.3%) patients had mild pain and
22 (36.6%) patients had severe pain in Group-B. The p-value was 0.022, which is statistically significant (Figure 2).

DISCUSSION

Our results showed no difference in immediate post-operative pain relief, p-value 0.0947. However, there was better pain relief at 6 h post-operatively in SA group, (p = 0.022). Our study correlates with a study done by Luiz et al., who studied 68 patients for comparison of SA and GA for patients undergoing laparoscopic cholecystectomy. They found that visual analogue score was significantly lower in the spinal group at 2, 4 and 6 h (p < 0.0005). There was no difference in pain scores at 12 h, p-value 0.93. However, we did not study pain at 12 h. Similar results were seen by Naghibi et al who studied 68 patients. They showed that patients in the SA group had significantly lower score of postoperative pain at rest: 3.4 ± 1.6 and 4.1 ± 1.2 at 2 and 4 h postoperatively versus 5.2 ± 1.5 and 5.8 ± 0.8 in GA group (p = 0.05). The amount of morphine requirement in 06 h postoperatively was significantly lower in SA group (p < 0.05) but there was no difference between two groups after 06 h.14,15

Laparoscopic cholecystectomy has become the gold standard for surgical treatment of cholelithiasis. As compared to classic open cholecystectomy, the hospital stay is shorter with a quicker convalescence in patients undergoing laparoscopic cholecystectomy.15 Laparoscopic cholecystectomy is being routinely performed under GA. However, recent studies have shown that regional anesthesia is safe, economical and has good post-operative pain control. Monitoring of patients under single shot SA is easier than GA. Complications of endotracheal intubation like damage to teeth, sore throat, failure to intubate or ventilate are avoided in SA.16

The postoperative pain after laparoscopic cholecystectomy may be due to multiple factors. These include rapid distension of peritoneum by carbon dioxide insufflation associated with tearing of blood vessels, traumatic traction of nerves, release of inflammatory mediators, excitation of phrenic nerve. Several techniques have been used for postoperative analgesia when laparoscopic cholecystectomy in done under GA. These include intravenous opioids and nonsteroidal anti-inflammatory drugs, perioperative pregabalin, intraperitoneal hydrocortisone, local irrigation of right hemi-diaphragm with 1% lignocaine, transversus abdominal plane block.17-20 According to the authors knowledge, laparoscopic cholecystectomy under SA has not be studied in Pakistan. We wanted to compare the efficacy of this procedure under SA versus GA. The post-operative VAS maybe influenced by infra-peritoneal pressure, use of local anesthetics, peritoneal irritation, psychological factors and type of incision. To rule out heterogeneity due to gender, all the patients were females. All the patients had intraperitoneal irrigation with 2% lignocaine as per surgical protocol at our institute. All the patients had two centimeter four port approach as per institute practice, which was not altered for our study.

In our study, we had utilized intravenous nalbuphine as rescue analgesia during the first six hours. Our results showed that almost 40-50% patients had VAS score > 7 at one hour of surgery and now intravenous paracetamol or ketorolac is being used routinely used with or without TAP block as part of multimodal analgesia. However, the incidence of severe pain was much lower at six hours postoperatively; and intravenous tramadol and ketorolac 8 hourly is being used for postoperatively now at our institute. The better postoperative analgesia in SA group observed by us and the others may be due to multiple factors. Firstly, the prolonged analgesia after SA can be due to persistence of neuraxial blockade. Secondly, absence of tracheal intubation and its associated discomfort may contribute to the better patient comfort. Thirdly, the hyperbaric intrathecal bupivacaine in combination with trendelenburg position may result in higher sensory block with better analgesia. Our study had certain limitations. All our patients were used for postoperative analgesia when laparoscopic cholecystectomy in done under GA.
females to rule out heterogenicity in VAS analysis. So the study may not hold entirely true for the male population. Only ASA physical status I and II were included in the study and the effect on respiratory mechanics were not studied. So the study cannot comment upon the effect of SA on patients with respiratory insufficiency (like bronchial asthma or chronic obstructive pulmonary disease, etc.) We studied the patients till 6 post-operative hours only (due to limited manpower) and cannot comment on comparison of analgesic advantage of SA at 24 h postoperative.

**CONCLUSION**

Our study shows that single shot spinal anesthesia provides better postoperative analgesia in the immediate post-surgical period. The addition of intrathecal fentanyl provides adequate analgesia, including relief from shoulder tip pain. So, spinal anesthesia can be safely used as sole anesthesia for laparoscopic cholecystectomy.

**Conflict of opinion:** Nil

**Authors’ contribution:**

AS: concept, data collection

AMB: manuscript writing and editing

SM: data collection, manuscript writing, literature search

Al: manuscript editing

RB: literature review

**REFERENCES**

postop pain and type of anesthesia


