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Original Research Article

A HOSPITAL BASED PROSPECTIVE STUDY TO ASSESS THE COMPARISON OF COMBINED EPIDURAL & GENERAL ANESTHESIA VERSUS GENERAL ANESTHESIA FOR LAPAROSCOPIC CHOLECYSTECTOMY AT TERTIARY CARE CENTER

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Abstract

Background: Laparoscopic cholecystectomy (LC) is a proven, gold standard surgical procedure for management of gallbladder stones. Laparoscopic cholecystectomies are usually performed under general anesthesia (GA) with endotracheal intubation and controlled ventilation. In this randomized study, we aimed to investigate the availability, safety and side effects of combined epidural anesthesia with general anesthesia (CEGA) and comparison with general anesthesia (GA) for laparoscopic cholecystectomies. **Materials and Methods:** A study was carried out in 40 patients of either sex, undergoing elective laparoscopic cholecystectomy using epidural anesthesia and general anesthesia in tertiary care center. The patients were divided into two groups of 20 each: group A receiving combined epidural anesthesia with general anesthesia (CEGA) and group B receiving general anesthesia (GA) alone. Postoperative pain was assessed at 0, 4, 8, 12 and 24 hours by using the Visual Analogue Scale (VAS) after completion of procedure. Other postoperative events, either related to surgical or especially to anesthetic procedure, such as discomfort, nausea and vomiting, shoulder pain, urinary retention, headache and other neurological sequel, were recorded. **Results:** Postoperative shoulder pain was observed in 5 patients in CEGA group (25%) and 12 patients in GA group (60%), this difference was significant (P<0.05*). The patient's satisfaction score was statistical significant (P<0.05*) in CEGA group as compared to GA group. There was no significant difference between the groups for nausea/vomiting, headache, urinary retention and hypotension. VAS score was highly significant postoperatively at 0, 4, 8, 12 and 24 hours while comparing both the groups, which suggests that group CEGA had better analgesia than that of group GA alone. **Conclusion:** We concluded that combining epidural to general anaesthesia results in rapid recovery as compared to plain general anaesthesia and also helps in providing good postoperative analgesia.

INTRODUCTION

Laparoscopic cholecystectomy has become very popular after it was first described in 1987 by Phillipe Mouret in France.[1] Laparoscopic cholecystectomy (LC) is a proven, gold standard surgical procedure for management of gallbladder stones. Early and easily recovery, less hospitalization day and less operative morbidities are the superiorities of laparoscopic cholecystectomies comparing with open surgical procedures.[2]

Laparoscopic cholecystectomy under regional anesthesia alone has been reported only occasionally in the past; these reports included patients unfit to receive general anesthesia, mainly patients with severe chronic obstructive airway disease.3 First laparoscopic cholecystectomies with spinal and epidural anesthesia were very limited and mostly cases with chronic respiratory disease which have GA contraindication.[3]

Laparoscopic cholecystectomies are usually performed under general anesthesia (GA) with endotracheal intubation and controlled ventilation. By this way secondary aspiration, abdominal discomfort and respiratory distress due to carbon dioxide pneumoperitoneum could be prevented and avoided from hypercapnia.[4] Hamad and Ibrahim El-Khattary,[5] used spinal anesthesia for laparoscopic cholecystectomy for the first time in a small series of healthy patients but they had used nitrous oxide as a pneumoperitoneum instead of standard carbon dioxide. Recently, it has been shown that laparoscopic cholecystectomy can be done successfully using carbon dioxide pneumoperitoneum under spinal anesthesia in healthy patients with symptomatic gallstone disease.[6]

Also, the incidence of postoperative morbidity like nausea, vomiting, dizziness, respiratory complication, thromboembolism and pneumonia was much less as compared to general anesthesia.[7] Also, the total cost of spinal anesthesia with respect to hospital stay, induction and recovery, the need for postoperative antiemetics and analgesia and the incidence of other complication was much lower when compared to general anesthesia.[8] In this randomized study, we aimed to investigate the availability, safety and side effects of combined epidural anesthesia with general anesthesia (CEGA) and comparison with general anesthesia (GA) alone for laparoscopic cholecystectomies.

MATERIALS AND METHODS

A study was carried out in 40 patients of either sex, undergoing elective laparoscopic cholecystectomy using epidural anesthesia and general anesthesia in SJP Medical College & Attached RBM Hospital, Bharatpur, Rajasthan, India from April 2023 to February 2024 (One years) after taking permission from Institutional Ethical Committee or Research Board. Patients aged between 18 and 60 years with ASA physical status I and II were included in the study. The patients with ASA grade III and IV high risk patients, all emergency procedures, bleeding disorders, acute cholecystitis, pancreatitis and acute cholangitis, previous open surgery in upper abdomen, contraindication for pneumoperitoneum, cardiovascular disorders, respiratory disorders, renal disease and liver disease, circulatory instability, and patients with known sensitivity to local anesthetics were excluded from the study.

All the patients were examined to assess their preoperative condition, demographic data and routine investigations which were recorded. Patients were kept fasting overnight and the procedure of epidural anesthesia was explained and written informed consent was taken from the patient and his relatives. The patients were divided into two groups of 20 each: group A receiving combined epidural anesthesia with general anesthesia (CEGA) and group B receiving general anesthesia (GA) alone.

Anesthesia Procedure: All patients were prepared for surgery with IV line and 10-mL/kg ringer lactate solution for 30 minutes. In group CEGA epidural catheterization was performed in sitting position at L1-2 space via an 18 – gauge Touhy needle. The epidural space was identified by loss of resistance to air. After negative aspiration for cerebrospinal fluid and blood and a test dose of 3ml of 2% lidocaine with adrenaline was administered to confirm epidural block. If there were no untoward effects after 3 min, analgesic dose 10 ml 0.125% bupivacaine introduced before induction of general anesthesia. General anesthesia was induced and maintained as in the general anesthesia group together with propofol (2–2.5 mg/kg), fentanyl 1 µg/kg and rocuronium 0.6 mg/kg later all patients intubated via endotracheal way. Patients were ventilated with controlled mode (Vt = 6–8 mL/kg) mechanically. Respiration frequency set as $PETCO_2$ 32–36 mmHg. For maintenance of anesthesia sevoflurane (1.5%–2%) with the oxygen-air mixture (FiO_2 = 0.4) is used, later on rocuronium (0.015 mg/kg) is performed with repetitive doses as per requirement. At the end of the surgery residual neuromuscular block was antagonized with 2- to 2.5-mg neostigmine and 0.4 to 0.5-mg glycopyrrolate.

Surgical Procedure: Pneumoperitoneum was created with CO_2 gas by placing a Veress needle followed by placement of a sub umbilical 10-mm port with abdominal pressure maintained at 10 mmHg. A 30° 10-mm laparoscope was passed, and the operative difficulty was assessed based on the degree of inflammation, adhesions, condition of gallbladder wall.

The patient was placed in reverse Trendelenburg position and tilted to the left and surgery proceeded as standard procedure.

Postoperative pain was assessed at 0, 4, 8, 12 and 24 hours by using the Visual Analogue Scale (VAS) after completion of procedure which was managed by 0.125% bupivacaine in CEGA group and by intravenous infusion of fentanyl (50-80 mcg/hr) in GA alone group. Other postoperative events, either related to surgical or especially to anesthetic procedure, such as discomfort, nausea and vomiting, shoulder pain, urinary retention, headache and other neurological sequel, were recorded.

The patient's satisfaction was assessed by a questionnaire with closed answers in a five-point scale 'Likert' scale was used. The questions were related to demographics, social data users, and the overall service process in the outpatient Hospital. Likert scale ranged from 1 (extremely dissatisfied) to 5 (extremely satisfied). Furthermore, the scores were summated to give an overall score for satisfaction.

RESULTS

All anesthesia and surgery procedures were completed successfully and none of the patients need to transpose into open surgery. There was no significant difference between 2 groups for age, sex, body weight and body mass index. Requirement of rocuronium & sevoflurane during maintenance significantly less in CEGA group than GA group ($P < 0.05$*) and the patients satisfaction score was statistically significant (P<0.05*) in CEGA group as compared to GA group [Table 1].

All adverse events related to anesthesia and surgery was recorded for 24 hours postoperatively. Postoperative shoulder pain was observed in 5 patients in CEGA group (25%) and 12 patients in GA group (60%), this difference was significant (P<0.05). There was no significant difference between groups for nausea/vomiting, headache, urinary retention and hypotension [Table 2].

VAS score was highly significant postoperatively at 0, 4, 8, 12 and 24 hours while comparing both the groups, which suggests that group CEGA had better analgesia than that of group GA [Table 3].

There were no significant statistical differences as regard intra-operative and postoperative noninvasive mean arterial blood pressure (NMBP), heart rate (HR)and arterial oxygen saturation (SPO2) as shown in [Table 4-6].

Table 1: Characteristics of the patients.

Characteristics	Group CEGA (N=20)	Group GA (N=20)	P-value
Mean age (yrs)	39.23±5.86	38.74±6.23	>0.05
Sex (Male: Female)	15:5	14:6	>0.05
BMI (kg/M2)	29.63±3.58	28.55±4.53	>0.05
Duration of surgery (Minutes)	72.12±8.35	66.26±7.58	<0.05*
Patients' satisfaction score (Linkert's scale)	4.38±0.98	3.93±0.75	<0.05*

Table 2: Post operative adverse events

Post operative adverse events	Group CEGA (N=20)	Group GA (N=20)
Shoulder pain	5 (25%)	12 (60%)
Nausea/vomiting	1 (5%)	4 (20%)
Urinary retention	2 (10%)	0
Headache	1 (5%)	0
Hypotension	1 (5%)	1 (5%)

Table 3: Visual analogue Scale Score

Interval (hours)	Group CEGA (N=20)	Group GA (N=20)	P-value
0	2.24±0.41	4.16±0.72	<0.0001***
4	2.02±0.25	3.64±0.67	<0.0001***
8	1.36±0.43	3.22±0.77	<0.0001***
12	1.12±0.28	3.10±0.68	<0.0001***
24	1.10±0.30	2.34±0.55	<0.0001***

Table 4: Comparison of non invasive mean arterial pressure (NIMBP) in both groups intra and postoperatively.

NIMBP (mmHg)	Group A (n=20)	Group B (n=20)	P-value
Intraoperative:	**Mean±SD**	**Mean±SD**	
Before epidural insertion	97.4±8.11	97.8± 7.67	>0.05
After epidural insertion	88.7±8.95	89.3±5.1	>0.05
After intubation	84.43±20.09	92.3±4.52	>0.05
After skin incision	84.21±12.66	90.8±10.25	>0.05
15 min	77.51±9.40	82.65±9.43	>0.05
30 min	79.56±9.12	85.37±11.56	>0.05
1 hr	77.21±11.09	84.5±13.82	>0.05
After extubation	88.54±11.09	92.54±9.86	>0.05
Postoperative:			
30 min	82.7±7.53	84.5±12.11	>0.05
1hr	84.77±5.42	87.19±10.76	>0.05
2hr	83.43±5.35	84.2±6.30	>0.05
4hr	84.31±5.25	86.48±5.76	>0.05
6hr	85.18±5.46	85.38±6.62	>0.05
8hr	84.67± 4.48	86.12± 4.75	>0.05
12hr	85.59±5.42	84.28±4.33	>0.05
24hr	90.74±1.85	89.57±4.33	>0.05

Table 5: Comparison of heart rate (HR) in both groups intra and postoperatively.

HR (Beat per min.)	Group A (n=20)	Group B (n=20)	P-value
Intraoperative:	**Mean±SD**	**Mean±SD**	
Before epidural insertion	88.9±14.67	87.76±10.47	>0.05
After epidural insertion	85.8±13.09	88.67± 8.43	>0.05
After intubation	87.78±9.06	88.38±7.90	>0.05
After skin incision	85.58± 6.54	89.48±10.22	>0.05
15 min	80.22±13.10	84.48±14.76	>0.05
30 min	77.58±16.13	85.23±13.34	>0.05
1 hr	78.4±12.18	82.6±13.24	>0.05
After extubation	86.5±10.38	86.25±10.88	>0.05
Postoperative:			

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30 min	80.4±9.33	81.4±11.55	>0.05
1hr	82.24±8.64	85.4±6.64	>0.05
2hr	81.4±6.72	80.32± 7.6	>0.05
4hr	81.02±6.66	82.48±5.12	>0.05
6hr	78.6±6.33	77.8±7.12	>0.05
8hr	77.57± 4.46	78.76±5.09	>0.05
12hr	80.38± 3.4	81.63±7.10	>0.05
24hr	81.38±5.77	78.49±5.09	>0.05

Table 6: Comparison of arterial oxygen saturation (SPO2) in both groups intra and postoperatively.

SPO2 (%)	**Group A (n=20)**	**Group B (n=20)**	**P-value**
Intraoperative:	**Mean±SD**	**Mean±SD**	
Before epidural insertion	98.2±0.93	98.5±0.90	>0.05
After epidural insertion	97.7±1.10	97.6±0.88	>0.05
After intubation	98.7±1.96	99.4±0.48	>0.05
After skin incision	98.8±2.04	99.6±0.53	>0.05
15 min	99.3±0.33	99.4±0.67	>0.05
30 min	99.2±1.57	99.4±0.52	>0.05
1 hr	98.7±1.60	99.2±0.56	>0.05
After extubation	98.7±1.40	99.4±0.48	>0.05
Postoperative:			
30 min	98.2±1.04	99.1±1.66	>0.05
1hr	98.56±1.53	99.2±0.50	>0.05
2hr	98.68±0.68	98.6±0.48	>0.05
4hr	98.2±2.45	98.5±0.33	>0.05
6hr	98.3±1.78	99.2±0.56	>0.05
8hr	98.2±1.06	98.8±1.48	>0.05
12hr	98.3±0.90	98.7±1.33	>0.05
24hr	98.2±1.95	98.8±1.32	>0.05

DISCUSSION

Laparoscopic surgical techniques have been rapidly accepted by surgeons worldwide with published reports describing the benefit of less postoperative pain, decreased hospital stay and earlier return to work.[1] Minimally invasive therapy is done with the general aim to minimize the trauma of interventional process whilst still achieving satisfactory result.[9] In this study we showed that CEGA is safe and available method for laparoscopic cholecystectomies and there is no difference from the GA except less requirement of rocuronium & sevoflurane during maintenance. Also, we showed that CEGA is superior to GA for postoperative pain control. The reason of more effective postoperative pain control for CEGA than GA is the continuous analgesic effect of drugs which are injected to epidural space.

Our current study was carried out on patients planned for laparoscopic cholecystectomy. This surgical procedure has many benefits like small surgical incision, decreased or minimal intraoperative blood loss, decreased postoperative pain and short postoperative stay in the hospital.[10] Epidural analgesia inhibits the stimulation of the neuro-endocrine axis,[11] leading to hemodynamic changes depending on the level of sympathetic block, age and cardio vascular status of the patient.[12]

Pain assessed throughout any time in the postoperative period during the patients' hospital stay was significantly lesser in CEGA group as compared to general anesthesia group, which is due to analgesic effect of local anesthetic in epidural space.[6,13] Pain relief, an important component for rapid and smooth recovery, was seen in CEGA group.

Singh et al,[14] reported in a prospective feasibility study that LC under the CSEA revealed minimal postoperative pain and no requirement for analgesia for first 5 and 6 hours. These. Two studies comparing spinal anesthesia and GA for LC Tiwari et al,[15] and Tzovaras et al,[6] reported the better postoperative pain control and lower analgesic requirement in spinal anesthesia than GA due to lasting analgesia effect. This difference is considered that it could be related with methodological difference between the studies. The difference of the 2 studies from our study is standard postoperative intravenous analgesia and if needed additive opioids usage for patients.

Patient can complain Right shoulder pain after LC under the general anesthesia. Shoulder pain may be minor with no treatment requirement or may be more severe.[6,15] It is known that for minimize post-operative right shoulder pain intraoperatively intravenous opioids, subdiaphragmatic local anesthetic aerosolisation, lower pneumoperitoneum pressure during surgery (<10 mmHg) and position change may be helpful.6,14 Postoperative shoulder pain is explained by phrenic nerve irritation due to residual carbon dioxide similar with intraoperative pain.[3]

In our study cardiovascular changes were at minimal levels. Intraoperatively only one patient suffered from hypotension which is recovered with fluid replacement rather than a vasopressor requirement and none of the patients suffered from bradycardia. In their own case series of Tiwari et al,[15] and Tzovaras et al,[6] reported the hypotension incidence as 4.3% and 59%, respectively. Both CSEA and pneumoperitoneum have specific different hemodynamic effects. Regional anesthesia induces hypotension by sympathetic efferent blockage which

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result with peripheral vasodilatation.[16] Lower pneumoperitoneum pressure in patients with adequate intravascular volume replacement increase the venous return, cardiac output and arterial pressure by decreasing the splanchnic blood volume. Reduction in functional residual capacity is higher in GA group patients than the regional anesthesia.[17] Because of the less affected respiratory mechanism carbon dioxide can be more easily eliminated with regional anesthesia, so that this may be the reason for lower incidence of shoulder pain.

Nausea and vomiting are particularly troublesome after laparoscopic surgery; over 50% of patients required antiemetics, so prophylactic antiemetics had been given routinely. Regarding the postoperative complications, nausea, vomiting and dizziness were more common with general anesthesia due to intubation of trachea and intravenous drugs.

As regards hemodynamic changes, it was found that no significant statistical differences as regards intra-operative MAP, HR, arterial O2 saturation (SPO2), or postoperative MAP, HR, arterial O2 saturation between the two studied groups of patients (p-value>0.05). These findings agreed with Ozcan et al,[18] study, but it was against findings of study done by Casati et al,[19] on patients subjected to colon resection and found that patients received epidural 0.125% bupivacaine had lower MAP than epidural-saline group and epidural 0.0625% bupivacaine group. They observed that epidural bupivacaine decreased intra- operative isoflurane consumption without changing the thiopental dose used during induction. For us we started GA after confirmation of sensory block level, so, there were no significant statistical differences between the two study groups as regard hemodynamics.

There was no significant statistical difference between the study groups as regard intra and postoperative O2 saturation, while Kabon et al,[20] suggested that supplementation of GA with TEA improved oxygenation of peripheral tissues during prolonged abdominal surgery.

CONCLUSION

We concluded that CEGA is suitable, sufficient and safe for LC. Also, less postoperative pain, lower shoulder pain, lower nausea/vomiting incidence and with rapid recovery are the benefits of CEGA compared to GA. Intraoperative adverse events associated with CEGA can be easily treated.

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