



Efficacy of Combined Epidural-General Anaesthesia [CEGA] in Attenuating Hemodynamic Responses to Pneumoperitoneum in Laparoscopic Cholecystectomies: A Prospective Randomised Study

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ABSTRACT

Background: Pneumoperitoneum in laparoscopy is associated with cardiorespiratory changes. Combination of epidural with General anaesthesia (GA) will offer benefit of hemodynamic control and perioperative analgesia. We aimed to study the efficacy of Combined Epidural- General Anaesthesia (CEGA) with pre-emptive activation over general anaesthesia in laparoscopic cholecystectomies.

Methods: In this prospective double blind –randomised study, 90 surgical inpatients were studied in two study groups. Group GE (n=45) received Lumbar Epidural analgesia with ropivacaine 0.2% along with GA and Group G (n=45) received only GA. Heart rate (HR), Mean arterial Pressure (MAP), systolic blood pressure (SBP), diastolic blood pressure (DBP), Capnogram (ETCO₂), saturation (spo₂), VAS score, Ramsay sedation score, requirement of propofol, muscle relaxants and analgesics were studied.

Results: Statistical analysis was carried out with SPSS version 20. Statistical value of $p < 0.05$ was considered significant. We noted significant difference in MAP, SBP, DBP, muscle relaxants, Propofol, Fentanyl and lesser pain scores in Group GE than Group G i.e ($p < 0.001$).

Conclusion: Combination of epidural and general anaesthesia technique with pre-emptive activation has the benefit of better control of hemodynamics. It reduced requirements of analgesics and anaesthetic drugs and had faster recovery with less post operative pain in laparoscopic cholecystectomies.

Introduction

Laparoscopic cholecystectomy is a well-known surgical procedure for its advantage of early mobility, lesser postoperative pain and better cosmetic scar. Laparoscopy involves carbon-di-oxide pneumoperitoneum, which is associated with significant cardio-respiratory changes, intracranial pressure effects and post operative pain [1]. The cardio-respiratory

changes induced by pneumoperitoneum have detrimental effects in elderly, cardiac and asthmatic patient which needs to be attenuated [1].

General anaesthesia is the technique of choice for laparoscopic procedures. The advantages of control over hemodynamics, postural effects, superior muscle relaxation and surgeon comfort makes general anaesthesia a safe choice [1-2]. Pneumoperitoneum induced cardiorespiratory changes under general anaesthesia are attenuated by use of intravenous drugs

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such as propofol, fentanyl, esmolol, clonidine, and dexmedetomidine. Intravenous drugs are associated with side effects of hypotension, post operative sedation and delayed recovery [2-3]. General anaesthesia is associated with high morbidity in elderly, respiratory disease, cardiac and sick patients. Hence, regional anaesthesia has gained importance as an alternative technique.

Thoracic epidural anaesthesia, combined spinal-epidural anaesthesia and spinal anaesthesia are used as sole anaesthesia technique or in combination with general anaesthesia to overcome the pneumoperitoneum induced cardio-respiratory changes. Use of regional anaesthesia alone for laparoscopic surgeries has drawbacks of hypotension and poor tolerance to intra-operative postural changes [1]. The combination of general anaesthesia with epidural analgesia will have the benefits of attenuation of pain stimulus at the site, control over postural changes, intra operative and post operative analgesia, lesser consumption of anaesthetic drugs and early post operative recovery [2-3]. There is insufficient evidence for the use of regional anaesthesia only or combination of regional with general anaesthesia for laparoscopic procedures. Several studies have compared spinal, epidural with general anaesthesia for laparoscopic surgeries; But there is lack of data on the use of combined epidural and general anaesthesia with pre-emptive activation in laparoscopic surgeries [1,3-4]. Hence, we studied the efficacy of combined epidural Analgesia [CEGA] with pre-emptive activation in combination with general anaesthesia [GA] techniques in attenuating pneumoperitoneum response in laparoscopic cholecystectomies.

Methods

Institutional Ethical Committee clearance was obtained. Study was registered at Clinical Trial Registry of India [CTRI/2021/12/038636]. Surgical inpatients posted for open/laparoscopic surgeries were enrolled for the study after obtaining written informed consent. The study was conducted over 2 months [January –March 2022] in different hospitals of the institution. All male and female patients in age group of 18-60 years, posted for laparoscopic surgeries, ASA 1 and 2, with BMI in 18-30 Kg Mt-2 were included for the study. Patients with contraindications to neuraxial techniques; allergy to study drugs; cardiovascular and respiratory diseases; obesity; pregnant ladies and difficult airway cases were excluded from the study.

We hypothesized that Combined Epidural and General Anaesthesia [CEGA] is associated with lesser increase in Blood Pressure during pneumoperitoneum [5]. Mean arterial pressure [MAP] was taken as effective parameter for sample size calculation. Expecting a change in MAP as 10mmHg with standard deviation of 16mmHg, minimum 39 patients were needed in each group. We

enrolled a total of 90 patients, keeping a margin for possible drop outs.

Ours was a prospective single blinded study. Primary objective in the study was to compare haemodynamic variables such as Blood Pressure[BP] and Heart Rate [HR] during pneumoperitoneum. Secondary objectives were to compare the consumption of induction agents, opioids and volatile inhalational agent; Duration of post-operative analgesia and post-operative sedation and adverse effects.

All willing participants were randomly allocated to two groups – Group G and Group GE by computer generated random numbers. Patients in Group GE received Combined Epidural and General Anaesthesia [CEGA] [n=45] and patients in Group G - General anaesthesia [n=45] was administered.

Written informed consent for general anaesthesia and regional anaesthesia was obtained. All patients were examined in pre- anaesthesia clinic. Tablet Alprazolam 0.5mg was administered orally on the night before surgery. On the day of surgery, intravenous line with 18 G cannula was secured and all patients were preloaded with 500 mL of intravenous ringer lactate.

In operation theatre, pre-induction monitors -Non Invasive Blood Pressure (NIBP), Electrocardiogram, pulse oximeter, End tidal carbon dioxide and temperature monitors were connected. Injection Midazolam 0.02 mg kg-1, Fentanyl µgKg-1 was administered intravenously. In Group G- General Anaesthesia was administered with propofol 2.5 MgKg-1 and muscle relaxant injection Atracurium 0.5 mg kg-1.

Entotracheal intubation with appropriate size tube was done. All patients were ventilated with Synchronised Intermittent positive pressure ventilation (SIMV) with Volume control mode with Air –Oxygen mixture and isoflurane 1-1.2% to achieve MAC of 1. Ventilation was adjusted to maintain EtCO₂ at 35-40 mmHg. Pneumoperitoneum was induced with slow inflation of carbon dioxide at rate of 4l/min and maintained at intra-abdominal pressure of 12 mmHg. Injection [Inj.] ondansetron 4mg and Paracetamol 1 g was administered intravenous [IV] 20 min before extubation.

In Group GE, patients were explained about the procedure for epidural catheter placement. Patients were placed in sitting position. Under aseptic precautions, 18G epidural catheter was placed at T10-T 11 intervertebral space. Test dose of Inj. lignocaine 2 % with adrenaline 3 mL was injected. Patients were placed in supine position and top up doses of Injection Ropivacaine 0.2% was injected through epidural catheter at 3ml doses to achieve sensory level of T6. After 15 minutes of completion of epidural drug administration, General Anaesthesia was induced as in Group G. Inj. ondansetron and paracetamol were administered as in Group G.

Heart rate [HR], Mean arterial Pressure [MAP], Systolic Blood Pressure [SBP], Diastolic Blood Pressure [DBP], ETCO₂ were recorded every 5 minutes from administration of premedication in operation theatre till 5 minutes after extubation. Readings of parameters after

premedication was taken as baseline values. Total doses of intravenous drugs used in every case were noted. Volume of inhalation agent used was recorded in milli Litres [mL] in gas monitoring system of Drager Avance S5 Anaesthesia machine. Post operatively adverse events, post operative sedation with Ramsay Sedation score, pain with visual analogue scale was assessed for period of 24 hours.

Hypertension was defined as an increase in MAP by 20% from baseline values; hypotension was defined as fall in MAP by 20% from baseline value. Bradycardia was defined as heart rate less than 60 beats per minute. Tachycardia was defined as increase by 20% from baseline. Tachycardia and hypertension was treated with combination of bolus dose of Propofol 1 MgKg-1 and Fentanyl 1 µgKg-1. Bradycardia was treated with injection Atropine 0.6 mg IV.

Statistical Analysis

Categorical data was presented as number and percentages. Continuous data was tested for normal distribution and presented as mean [SD] or median [IQR]. Chi-square test was used for categorical data and Student t test/ Mann Whitney U test was used for intergroup comparison. Paired t test was used for intra group comparison of continuous variables. Value of

$p < 0.05$ was considered statistically significant. SPSS version 22 was used for analysis.

Results

Demographic parameters were comparable between groups (Table 1).

There was significant difference noted in heart rate in the immediate post intubation period between groups, with group GE recording lesser change in heart rate in post intubation period (Table 2, Figure 1). There were no significant changes between two groups during pneumoperitoneum period with respect to heart rate.

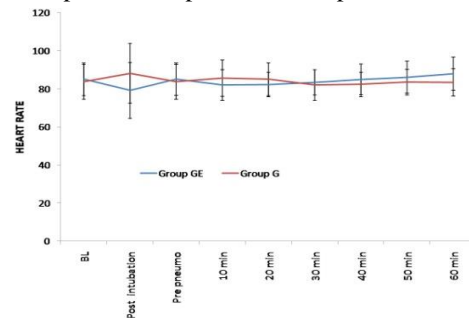


Figure 1- Heart rate changes

Table 1- Demographic Parameters

Parameter	Group GE	Group G	P value
Age	43±11.25	45.65±12.36	0.41
BMI	24.74±2.22	25.04±2.87	0.59
Duration of pneumoperitoneum	60.97±15.87	60.35±7.53	0.82
Gender(M:F)	20:25	22:23	

Table 2- Heart rate changes in study groups

Heart rate	Group GE	Group G	P value
BL	85.03±8.57	83.73±9.16	0.514
Post intubation	79.13±14.6	88.13±15.7	0.025
Pre pneumo	85.03±8.57	83.73±9.16	0.514
10 min	81.98±8.1	85.55±9.53	0.074
20 min	82.28±6.48	85.03±8.57	0.109
30 min	83.35±6.64	81.98±8.1	0.409
40 min	84.95±8	82.28±6.48	0.104
50 min	86.1±8.48	83.49±6.67	0.133
60 min	87.93±8.72	83.38±7.14	0.045

Statistically significant if $p < 0.05$

Systolic blood pressure [SBP] changes

The magnitude of SBP change during pneumoperitoneum was higher in Group GE [Group GE- 24.58±2.3 mmHg vs Group G- 4.34± 1.3 mmHg]. Significant difference was observed at Post intubation and during Pneumoperitoneum period. Group GE recorded lower SBP than Group G (Table 3) The SBP was lower in both groups after induction. Group GE maintained lower SBP in the range between 102-131mmHg whereas Group G recorded higher SBP in range 124-135 mm Hg (Figure 2).

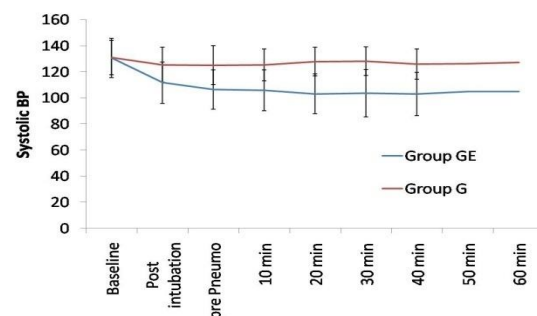


Figure 2- Systolic Blood Pressure Changes

Table 3- Systolic Blood Pressure changes in study groups

Systolic BP	Group GE	Group G	P Value
Baseline	130.47±14.9	130.80±17.9	0.938
Post intubation	111.60±11.3	125.37±19.9	0.002
Pre Pneumo	106.43±15.1	124.95±13.22	<0.001
10 min	105.7±15.83	125.15±13.23	<0.001
20 min	102.98±15.15	127.7±14.96	<0.001
30 min	103.65±15.72	128.1±12.2	<0.001
40 min	103±15.27	125.88±11.01	<0.001
50 min	104.9±18.23	126.18±11.06	<0.001
60 min	104.83±16.69	127.09±11.69	<0.001

Statistically significant if p <0.05

Diastolic Blood pressure changes

Significant difference was observed at all time intervals during pneumoperitoneum. Group GE recorded lower DBP than Group G. Magnitude of change was 23.9 ±6.9 mmHg in Group GE and 4.84± 2.1 mmHg in Group G. There was no difference in baseline values (Table 4).

Post intubation values were significantly different between groups. Both groups had values below baseline values but DBP was lower in Group GE in pneumoperitoneum period (Figure 3).

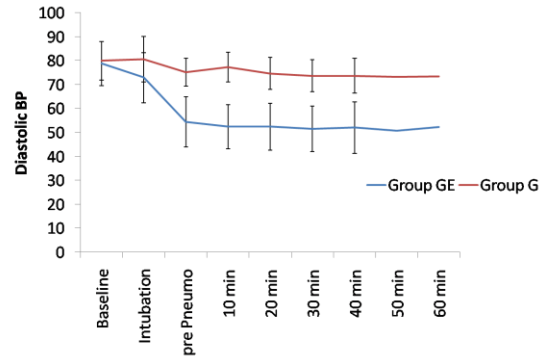


Figure 3- Diastolic blood pressure changes

Table 4- Diatolic Blood Pressure changes in study groups

Diastolic BP	Group GE	Group G	P Value
Baseline	78.80±9.32	80.07±11.92	0.648
Intubation	72.93±9.61	80.60±15.61	0.026
Pre pneumo	54.45±9.23	75.23±8.06	<0.001
10 min	52.4±10.49	77.3±9.41	<0.001
20 min	52.4±10.52	74.73±5.84	<0.001
30 min	51.55±9.23	73.75±6.13	<0.001
40 min	51.95±9.79	73.73±6.72	<0.001
50 min	50.68±9.55	73.33±6.62	<0.001
60 min	52.28±10.74	73.43±7.27	<0.001

Statistically significant if p <0.05

Mean arterial Pressures

Significant difference was noted for MAP throughout the study period from post intubation period (Figure 4). The magnitude of change in Group GE was 25.4±6.9 and Group E was 7.37±1.97. Significant difference observed at all time intervals during Pneumoperitoneum Group GE recorded lower DBP than group G and Group G recorded higher DBP than group GE (Table 5). Magnitude of change was Group GE-23.9 ±6.9; Group G-4.84± 2.1 mmHg respectively.

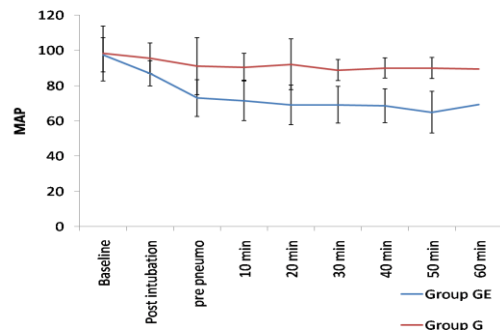


Figure 4- Mean Arterial Pressure changes

Table 5- Mean Arterial Pressure Changes

MAP	Group GE	Group G	P Value
Baseline	97.30±9.35	98.20±12.41	0.752
Post intubation	86.83±9.71	95.33±15.57	0.014
Pre pneumo	72.88±7.18	91.03±8.69	<0.001
10 min	71.45±10.45	90.33±16.14	<0.001
20 min	69±11.53	91.9±7.85	<0.001
30 min	69.1±11.27	88.7±14.41	<0.001
40 min	68.43±10.44	89.88±6.03	<0.001
50 min	64.8±9.67	89.9±5.71	<0.001
60 min	69.15±11.87	89.5±5.97	<0.001

Statistically significant if p <0.05

No difference noted in oxygen saturation and Et CO2 values in both groups during pneumoperitoneum (Figure 5-6).

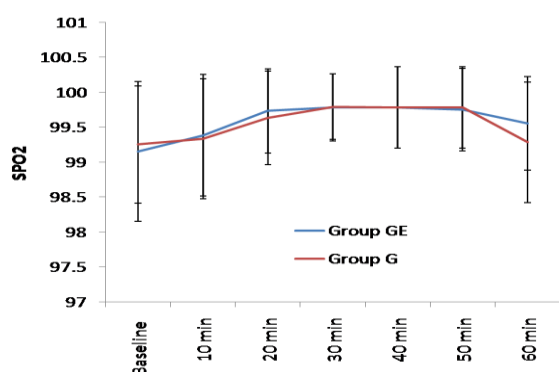


Figure 5- oxygen saturation in study groups

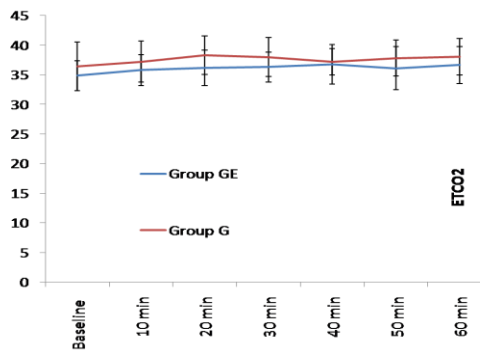


Figure 6- End tidal carbon di oxide levels in study groups

The requirement of general anaesthesia drugs were higher in Group G and Group GE had lesser consumption of propofol, fentanyl and isoflurane (Table 6).

Table 6- Consumption of General Anaesthesia Drugs

Variables	Group GE mean (SD), (95% CI)	Group G mean (SD), (95% CI)	P value
Opioid(µg/kg)-Fentanyl	116.25±20 (110-122)	159.88±28 (152-168)	<0.001
Muscle relaxants- Atracurium (mg)	49.5±5.62 (49.5-51)	51.9±6.64 (50-53.3)	0.085
Propofol(mg)	151±33.11 (141-161)	303.18±48.52 (289-317)	<0.001
Inhalational (mL)	10.73±2.27 (10.1 – 11.4)	13.80±1.6 (13.3-14.3)	<0.001

statistically significant if p <0.05

Intra-operative events

Hypotension

Incidence of hypotension was 30% in Group GE (Table 7).

Severity of hypotension was mild as MAP was >60mmHg. Vasopressor – The Median(IQR) requirement

of Mephenteramine in group GE was 6 mg (0-6) compared to 0 mg in Group G, which was clinically and statistically significant.

Incidence of hypertension in Group G was 52.5% (Table 8). The incidence of hypertension in Group GE is 7.5%

Table 7- Hypotension in study groups

	Group GE	Group G	P value	Odds ratio
Absent	28(70%)	40(100%)		
Present	12(30%)	0(0%)	<0.004	4.63(1.55-13.84)

Table 8- Hypertension in study groups

	Group GE	Group G	P value	Odds ratio
Absent	37(92.5%)	19(47.5%)		0.07(0.01-0.27)
Present	3(7.5%)	21(52.5%)	<0.001	

First line rescue drugs were propofol and fentanyl which was higher in group G. Second line rescue Inj. Esmolol was not used. No other adverse events in intraoperative period

Post operative Period

Severity of Surgical Site Pain

Patients were assessed for residual pain for 8 hours in post operative period. There was no difference in VAS score for upto 2 hours. Both groups had pain scores <4. Significant difference in pain scores were noted in after 4 th hour period, with less pain in group GE. Both groups VAS <4, did not need administration of analgesics (Table 9).

Table 9- Post operative Surgical site Pain Scores

VAS score	Group GE	Group G	P value
1 hr	1.46±0.6	1.69±0.95	0.2
2hr	1.44±0.55	1.88±1.16	0.17
4hr	1.44±0.55	2.03±1.05	0.001
6 hr	1.46±0.6	2.16±0.81	0.001
8 hr	2.44±0.64	3.1±0.78	<0.001

Shoulder Pain

Incidence of shoulder pain was 15% in GA group and 13% in Group GE. The severity was assessed in those with shoulder pain. Severity was significantly less in Group GE (Table 10). In both groups VAS was less than 4.

Residual Analgesia

Analgesia lasted longer in Group GE (Table 11). There was no difference in post operative sedation between groups, in both groups Ramsay sedation score was less than 2.

Table 10- Shoulder Pain - VAS Score

	Group GE	Group G	P value
1 hr	1.18±0.3	2.1±0.75	<0.001
2hr	1.24±0.4	2.18±0.7	<0.001
4hr	1.28±0.5	2.36±0.8	<0.001
6 hr	1.38±0.5	2.64±1.1	<0.001
8 hr	1.1±0.3	3.03±0.6	<0.001

Table 11- Duration of Analgesia

Group GE (hours)	Group G (hours)	P value
15.9±3.9	7.42±0.9	<0.001

Discussion

Hemodynamic response to pneumoperitonium increases heart rate and blood pressure within minutes of insufflation of carbon di oxide [1-3]. These changes are attributed to sympathetic stimulation, catecholamine release, carbon di oxide accumulation, stimulation of the

aortic and carotid chemoreceptors with increase in heart rate and blood pressure. Elevated intrabdominal and intrathoracic pressure can compress the major vessels and hamper the venous return [2-3,6]. Such sudden changes, if not attenuated can be detrimental in high risk patients. In our study, all patients were preloaded with 10ml/kg of ringer lactate. Insufflations were maintained at 4l/min and limited to abdominal pressures of 14.

Epidural drug administration causes sympathetic block and prevents the increase in heart rate and blood pressure [1-2]. It also contracts the intestine and makes the surgical handling of gut easy. Pan YS et al [7] compared effects of epidural in retroperitoneal laparoscopic surgery in combination with general anaesthesia. Pan YS et al [7] proved that stress response and catecholamine levels were less in patients who had received pre emptive epidural analgesia. Also, the stress response measured with heart rate and blood pressure were less in epidural group.

In our study, CEGA was compared with GA for hemodynamic changes during pneumoperitoneum. We placed epidural catheter at T12-L1 space and administered low concentration of local anaesthesia Inj.ropivacaine 0.25%, to achieve T6 level prior to induction. We recorded lower values of blood pressure in CEGA group. Sympathetic block achieved prior to pneumoperitoneum could be the reason for prevention of increase in BP and heart rate during pneumoperitoneum. In our study, opioid (Fentanyl) and propofol were used for induction in both groups and also as rescue drugs in GA group, which probably enhanced the depth of anaesthesia, thereby minimizing heart rate changes. There was no difference with heart rate between GA and

CEGA group. However, in our study catecholamine levels during pneumoperitoneum were not studied.

Intravenous drugs such as opioids, beta blockers, alpha agonists and TIVA are commonly used techniques. Intravenous drugs are associated with delayed awakening, prolonged sedation, adverse events of nausea, vomiting. Regional anaesthesia – spinal block and epidural block alone are not very useful in laparoscopic surgeries due to changes in positioning of patient [2-3]. However combination with general anaesthesia offers the benefit of control over hemodynamics, duration and position changes for laparoscopy; epidural and spinal anaesthesia provides sympathetic block and analgesia throughout pneumoperitoneum.

Epidural analgesia is known to reduce the requirement of GA drugs as well as analgesics. Bandewar et al [8] studied the effects of pre-emptive activation of epidural in CEGA for control of the pneumoperitoneum response, requirement of general anaesthesia and perioperative analgesia. CEGA group had lower BP and HR changes than GA group. Propofol and opioid requirement were significantly less in CEGA group. In our study, requirement of GA drugs - propofol, muscle relaxants, opioids and Fentanyl were significantly less in CEGA group. Likewise, Bandewar et al [8], epidural ropivacaine was pre-emptively administered before Induction. This could have attenuated the pneumoperitoneum response. However, we did not study the stress response to intubation or extubation. Our results substantiate the use of epidural in combination with GA.

Luchetti et al [4], compared the TIVA with combined epidural and General anaesthesia [CEGA] in laparoscopic cholecystectomies for its efficacy and safety. Epidural 0.5% bupivacaine was used. Heart rate, SBP, DBP, ETco₂, saturation, recovery was studied intra-operatively and post-operatively. It was concluded that CEGA had better control of hemodynamics, faster recovery and longer duration of analgesia. In our study, both groups had blood pressure lower than pre-pneumoperitoneum period but with significant difference between groups in SBP, DBP and MAP. Use of propofol and Fentanyl for GA in both groups could have lowered the MAP in both groups. Low BP readings in CEGA group could be due to additive effect of epidural drug. Residual post-operative analgesia lasted for upto 24 hours in CEGA group. Though analgesia lasted upto 8 hours in GA group, the VAS scores were less than 4. This could be due to NSAID paracetamol administered 20 min prior to extubation. We recorded similar results as Luchetti et al with respect to hemodynamics, respiratory changes, recovery and duration of post-operative analgesia.

Varsha et al [5] studied efficacy of CEGA in laparoscopic cholecystectomies. Hemodynamic response to intubation, pneumoperitoneum and extubation were analyzed. Along with stress response, operative condition

was assessed by surgeons. CEGA group had hemodynamic stability with controlled heart rate and blood pressure throughout surgery. Also operative condition in CEGA was scored as good. We did not study stress response throughout procedure and did not assess surgical comfort. However our study results matched with hemodynamic stability as in Varsha et al [5]

Calvo et al [2] compared combined spinal-GA [CSGAB] and combined epidural with GA [CEGAB] for hemodynamic stability in laparoscopic cholecystectomies. Lower blood pressures were noted in both groups but the severity of hypotension significant ($p < 0.001$) in spinal with GA group after semi-fowlers position. It was found that recovery, post-operative analgesia was shorter in spinal group. In study by Calvo et al [2] higher incidence of hypotension was due to higher dose of ropivacaine (150mg) used. Our study matches with control in heart rate and blood pressure. But the severity of hypotension was less as the dose was 30 mg of 0.2% ropivacaine

Epidural drugs can cause hypotension in pneumoperitoneum period. Hypotension may be exaggerated in hypovolemic patients. In our study Ropivacaine was preferred over Bupivacaine for its predominant sensory action. All patients were preloaded with 10ml/kg of Ringer lactate. Though we recorded 30% incidence of hypotension in CEGA group, it did not need vasopressor administration. The hypotension was as per definition for study, but the Mean arterial pressures were higher than 60 mmHg. Incidence of Hypertension was 52% in GA group which needed management with top-up drug with propofol and Fentanyl. Therefore, CEGA reduces blood pressure but prevents the occurrence of hypertension.

Adverse events in post-operative period were incision site pain and shoulder pain. There was no incidence of Nausea and vomiting which is commonly seen in laparoscopic surgeries. This is due to use of propofol and administration of ondansetron before extubation. Calvo et al [2] noted 25% incidence for shoulder pain, nausea and vomiting.

Certain drawbacks were noted in our study. We restricted the study period only to pneumoperitoneum phase. Extending the study period from induction to extubation would have provided more information on attenuation of stress response. We did not study the speed and quality of recovery from general anaesthesia, but only post-operative sedation was recorded. Supplemental doses were not administered in postoperative period in order to study residual analgesia. The rescue drugs used for attenuating hypertensive episodes were same as Induction drugs. The results would probably differ with if drugs such as beta blockers, alpha agonists were used.

Conclusion

We conclude that combination of epidural with general anaesthesia is effective in laparoscopic cholecystectomy surgeries. CEGA provides hemodynamic stability and perioperative analgesia.

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