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RESEARCH ARTICLE

COMPARISON OF EFFICACY OF COMBINED SPINAL-EPIDURAL ANAESTHESIA WITH GENERAL ANAESTHESIA IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY

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Abstract

Background: Initially general anaesthesia (GA) was considered the best suited technique for laparoscopic cholecystectomy (LC). Combined epidural with GA is considered for high risk cases but sole spinal/epidural anaesthesia is less popular due to some disadvantages. Given the significant benefits of regional anaesthesia over GA, the study aims to compare and evaluate the efficacy of combined spinal epidural anaesthesia (CSEA) and GA for LC.

Methods: 60 ASA grade I and II patients scheduled for LC were arbitrarily divided into two groups comprising of 30 patients each based on anaesthesia technique i.e. GA and CSEA. In both groups systolic and diastolic blood pressure, heart rate, cardiovascular complications, hemodynamic changes, oxygen saturation, intraoperative and postoperative pain assessment, nausea and vomiting were recorded.

Results: A significant difference in heart rate as well as intraoperative blood pressure was observed between GA and CSEA at various time intervals. The end tidal carbon dioxide values were not significantly different in two groups.(P<0.05) Postoperative VAS score and complications like nausea vomiting, incidence of shoulder pain, headache was more in patients of GA than in CSEA group which was statistically significant (P< 0.05).

Conclusion: CSEA can be a safe and suitable method of anaesthesia in healthy ASA grade I-II patients. It provides better hemodynamic stability, offers better intra and post-operative pain control with less incidence of nausea vomiting in LC patients.

Introduction:-

Laparoscopic cholecystectomy (LC) is the standard procedure for the management of gallbladder stones.[1]It facilitates easy and early recovery, reduced hospital stay, and fewer chances of morbidity as compared with open surgical procedures.[1]The procedure is generallycarried out under general anaesthesia (GA) with endotracheal intubation and controlled ventilation. This facilitates the prevention of aspiration and respiratory embarrassment caused by the induction of carbon dioxide pneumoperitoneum.[2, 3] However, it is contraindicated in respiratory dysfunction.[4]ButGA is frequently associated with significant post-operative complications such as pain, nausea/vomiting, airway trauma and pressorresponsesto intubation/extubation and due to pneumoperitonium.[5]

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Regional anaesthesia (RA)-low thoracic epidural, spinal and combined spinal-epidural anaesthesia (CSEA) with local anaesthestic (LA) in LC is used in patients with chronic obstructive airway disease. [4, 6]RA showed reduced post-surgical pain and neuroendocrine stress response compared with GA. RA conversely also harbors more complaints of abdominal discomfort and pain in the shoulder but previous studies regarding spinal and epidural anaesthesia for LC confirm the safety and feasibility of these procedures by managing the discomfort with sedation or adjuvants with LA.[7-10]A prospective randomized study concluded that CSEA is safe for LC with reduced pain in the surgical field, pain in the shoulder and postoperative nausea/vomiting compared to GA.[2]Given that LC being a fairly common procedure, the study aimed to compare the hemodynamic parameters, intra or post-operative discomfort and efficacy of analgesia using CSEA and GA for LC.

Material and Methods:-

The prospective, randomized study was performed from October 2016 to October 2018 following approval by the institutional ethics committee(Letter No.DMCK/2016/22/PA.PG). On obtaining a written, informed consent, 60 patients with ages ranging from 18 to 60 years of ASA grade I and II scheduled to undergo LC were included in the study.Patients contraindicated for CSEA, obese patients, those with signs of acute cholecystitis, allergic to the drugs used and pregnant patients were excluded. A pilot study was performed on 10 patients(five patients in each group,GA & CSEA)toevaluate the best mode of anaesthesia either CSEA or GA during LC and to identify unforeseen problems.

Patients were allottedby closed envelope method to one of two anaesthesia groups (GA & CSEA), each consisting of 30 patients. Preoperative evaluations were performedon all the patients and were administeredranitidine 0.1mg/kg, ondansetron0.08-0.1mg/kg and glycopyrrolate 0.004mg/kgby intravenous (i.v) route as premedication. Baseline and intraoperative ECG,heart rate (HR), blood pressure (NIBP), oxygen saturation (SpO_2), and endtidal CO_2($EtCO_2$)were recorded every 10 minutes till the termination of the surgery and postoperatively for two hours. Postoperatively VAS any events like discomfort, nausea and vomiting(PONV), shoulder pain, pruritus, headache, backache or any neurological sequel noted.

LC was performed by using the same standard four quadrant trocar technique by same laparoscopic surgeon in both the groups in 10-15 degrees of reverse trendelenberg position and intra-abdominal pressure was kept below 12mmHg to minimize the respiratory discomfort and shoulder pain due to pneumoperitonium.

Anaesthesia Procedures

Combined spinal-epidural anaesthesia

Patients were placed in lateral/sitting position.Under aseptic precautions and local infiltration with 2 ml of 2% lignocaine, loss of resistance to air technique was used to identify the epidural space. Tuohy's needle (18G) was inserted at T10-T11 or T11-T12 epidural space and a 25G spinal needle was passed throughat L2-L3interspinousspace. The proper placement of needlewas confirmed by the free flow of clear cerebrospinal fluid from the needle. Bupivacaine 0.5% (3.5ml) and fentanyl (25 mcg) were injected intrathecally through the spinal needle. Following that an 18G epidural catheter was introduced through epidural needle for 5cm inside and test dose of 3ml of 2% lignocaine with adrenaline injected. Catheter was fixed and patients were placed in the supine position with 5-10degree head down position to achieve higher (T4-T5) level of block. Oxygen was provided at the rate of 4 lit/min through a nasal cannula and $EtCO_2$ was monitored with nasal cannula. Fentanyl 50mcg and midazolam 0.05 mg/kg were given i.v.as premedication. The number of attempts at each phase of the procedure and episodes of any paraesthesia were noted. Upper level of sensory block was assessed by using pinprick sensation every 5 minutes after the SA and every 30 minutes after completion of surgery for six hours.Sensory block at T4 level was considered adequate to commence surgery. Epidural bupivacaine 0.5% 5 ml was given viathe epidural catheter to achieve desired height of block if not achieved by spinal dose. Pneumoperitoneum was created using CO_2 at pressures of 12mmHg with flow rate of 20L/min.Intraoperative shoulder pain was primarily treated with midazolam 0.5mg and fentanyl 0.5-1mcg/kg, if not relieved by addition ofketamine 1mg/kg was used. If the pain remained uncontrolled withfentanyl and ketamine, the thoracic epidural was activated using bupivacaine. If shoulder painwas not relieved on medication, then CSEA was converted to GA.Towards completion of surgery epidural top-up of 8ml of 0.25% of bupivacaine was given.

General anaesthesia

Premedication with i.v. fentanyl 1.5mcg/kg and midazolam, 0.05mg/kg was administered for all the cases. After pre-oxygenation with O2 for five minutes, anaesthesia was induced using propofol 2mg/kg and succinylcholine 2mg/kg was given to facilitate endotracheal tube insertion. Respiratory rate was at 14-16 breaths/min to maintained $EtCO_2$ concentration between 35-40mmHg. Continuous monitoring of Et CO_2 with side stream capnography was done. Anaesthesia was maintained using O_2& N_2O, vecuronium (0.08mg/kg) and sevoflurane, the minimum alveolar concentration of 1.5was maintained throughout the surgery. Pneumoperitoneum was created using CO_2 and intra-abdominal pressure was maintained at 12 mmHg. In the case of hypertension, and tachycardia,patients were administeredtop up dose of fentanyl0.5-1mcg/kg or increasing sevoflurane concentration. At the conclusion of the surgery neuromuscular blockade was reversed with 0.05mg/kg neostigmine and 0.008mg/kg glycopyrrolate. Patients were extubated and analgesic i.v.tramadol 100mgwas given.

Intraoperative complications such as bradycardia, tachycardia, hypotension, hypertension, and the pain weredocumented. Operative and recovery time was noted in all cases. Postoperative analgesia was assessed by a visual analog score (VAS) at 0 to 12 hours. The incidence of shoulder pain, PONV, and headache were also documented. In GA, postoperative 50-100mg of tramadol and /or i.v.diclofenac 50mg was used as rescue analgesia, which was given at 0, 3, 6, and 9 hours and in CSEA top ups with 8ml of 0.25% bupivacaine was given at 0, 6 and 12 hours.

Statistical analysis

Data were analyzed using R Studio V 1.2.5001 software. Continuousvariables (HR, systolic, diastolic blood pressure,SpO_2, $EtCO_2$) and VAS scoreswere expressed in mean ±standard deviation (Mean±SD). Students unpaired‘t’ test was used for comparison of continuous variables.Categorical variables (VAS score, incidence of postoperative complications)were expressed in frequency and percentage.Z test for proportion was used for percentages to find the significant difference in two groups. P<0.05 was considered statistically significant.

Results:-

The average age of 60 patients was 33.45±6.6 years. Detailed demography of patients of both groups is illustrated in Table-1.

A significant difference in heart rate (HR) was observed between GA and CSEA at different time intervals (P<0.05).-Table-2A significant difference was observed between mean systolic (SBP) and diastolic blood pressure(DBP) of patients received GA and CSEA. Thus patients in GA group had higher HR, SBP & DBP than in CSEA group.Intra-operative hypotension was in two case of CSEA who responded to i.v. fluids.Table- 3.No significant difference in SPO_2 was observed in both the groupsupto 60 min of procedure howeversignificant difference was observed between SpO_2at 70, 80 & 90 min which was less in GA group than in CSEA group but it was clinically insignificant. $EtCO_2$levels were well maintained between 35-40mmHg at different time intervals in both the groups with no significant difference.(P>0.05)Graph-1

The postoperative mean VAS scoresfor the complaint of abdominal pain of both the groups is summarized in Graph-2. All pain measures of the patient were significantly higher in the GA group at VAS 0and all patients required analgesia and repeated dose after 3, 6, and 9 hours. However, in CSEA group patients the level of pain was low, 27 patients did not requirepostoperative analgesia and only 3 patients required analgesia at 0 and 6 hours. Postoperatively the mean VAS scores at 0,2,4,6,8,10,12 hours were significantly higher in GA group. (P= $4.16e^{-14}$, $6.36e^{-12}$,$4.83e^{-12}$,$4.36e^{-12}$,$1.03e^{-11}$,$1.35e^{-11}$,$9.67e^{-12}$respectively).

The A significant proportion of PONV was noted in patients of the GA group (14,46%) when compared with the CSEAgroup (6,20%). All patients of GA were administered intraoperative analgesics fentanyl and tramadol postoperatively whereas, in CSEA group intraoperative analgesic besides fentanyl and tramadol, ketamine was administered in 10% (n=3) patients for the control of shoulder pain.Post-operative shoulder pain was seen in 18(60%) of GA cases whereas only 2(7%) of CSEA cases presented with it.No patientfrom group CSEA require conversion to GA due to inadequate block or shoulder pain.Postoperative urinary retention in two cases of CSEA whereas incidence of pruritus in three and shivering in four in each group observed who responded to the general measures.(P>0.05)Graph-3

Discussion:-

GA with endotracheal intubation is the most preferredanaesthesia technique for LCin order to avoid aspiration,hypercarbia and abdominal discomfort with pneumoperitonium, while regional techniques have been known to attenuate the metabolic and endocrine responses.[11]However, GA with its associated complications leads to a debate on its use as a conventional modality. The requirement for an additional modality of anaesthesia with GA had lead to studying various other options over the years. [8,11]

In previous studies, CSEA was compared with GA for LC, it was found that CSEA was safe, suitable, less post-surgical pain and shoulder pain. It also lower nausea vomiting incidence and can be used as an alternative to GA.[2,3,5]Therefore, the study was aimed to compare CSEA and GA for LC.

Low intraoperative hemodynamic changes were noted in patients of CSEA, only two patients had hypotension which was corrected with fluid replacement and none of the patients demonstrated bradycardia. Comparable results were seen in the study of Donmez T et al[2]Various other studies showed incidents of hypotension during spinal anaesthesia ranging from 4-60%.[11-12] Hypotension induced by CSEA can be easily corrected with 10ml/kg fluid before induction and maintenance of fluid infusion with 6ml/kg during the procedure. Lower pneumoperitoneum may prevent hypotension.[2] Mean SBP, DBP and HR were higher in the GA group than in the CSEA group, these findings were supported by the study of Sale et al.[11]

Postoperative shoulder pain is due to phrenic nerve irritation caused by carbon dioxide. Reduced functional residual capacity is higher in the patients of GA group than in regional anaesthesia.[13]Significantly higher incidence of shoulder pain post procedure and VAS score was observed in patients of GA than CSEA. Comparableobservations were made in other studies where a high incidence of shoulder pain (60 and 72.5%) was observed in patients who underwent LC under GA.[2, 14]Studies show a significantly lower proportion of patients complaining of shoulder pain (5.3% to 16.6%) under spinal and epidural anaesthesia. [15-17]Anotherimportant postoperative adverse event was vomiting andnausea. A significantly higher incidence of PONVwas observed in patients of GA than CSEA (P-0.0285). Similar results of various studies showed a lower incidence of nausea and vomiting with RA. [18-20]In a study of 180 patients of day care LC comparing surgical outcome following LC under SA & GA observed significantly less incidence of PONV and pain in SA group than GA who required overnight stay.[19]

The studies demonstrate thatCSEA was a saferanaesthetic method for LC than GA and was more efficacious in pain management. Intraoperative complications such as hemodynamic and respiratory were less in CSEA than in GA. Better pain control in CSEA than GA is due to lasting analgesic effect. [6-7]In a study by Swathiet al. on sixty patients to compare SA with GA for LC regarding hemodynamic and respiratory stability using adjuvant clonidine 1mcg/kg with 3ml of heavy bupivacaine 0.5% observed significant stability in SA group with good sedation,less shoulder tip pain, requirements of rescue analgesics as compared to patients in group GA.Thus concluded that under SA diaphragmatic functions are preserved and addition of adjuvants like clonidine helps in reducing the incidence of shoulder tip pain under SA.[21]The cause of shoulder tip pain is direct irritation of the peritoneum by insufflating CO_2 and over stretching of diaphragmatic muscle fibres so measures like low insufflations pressures of 8mmHg than standard pressure of 14mmHg reduces the incidence of shoulder tip pain.[22]

Yu et al done a meta-analysis on seven randomized controlled trials of LC under SA (n=352) vs. GA(n=360) to study postoperative pain scores, operating times and postoperative compications.They found LC under SA group were having superior results in VAS scores , PONV and overall morbidity with no significant difference in operating time. Concluded that SA is safe and feasible.[23]This supports the findings of meta-analysis done by Rodgers et al.about use of neuroaxial techniques for variety of surgical procedures resulting in decreased neuroendocrine responses to surgical stimulus,avoids airway related complications, mortality and morbidity due to pain, PONV, thromboembolism, myocardial infarction and allows early ambulation.[24] Further in a study by Bayrak et al by comparing GA vs.SA for LC in sixty patients with COPD observed less postoperative $paCO_2$,pain scores and need of rescue analgesics with less hospital stay in SA group stating that SA is more safe technique for LC.[25]

Incidence of nausea/vomiting, shoulder pain, VAS was less in CSEA as compared with GA in our study thus shows the merits of CSEA over GA in various parameters including hemodynamic stability and pain reduction however it is limited by the smaller sample size and inclusion of only ASA I/ II cases and these factors could be considered in further research on the topic.

Table 1:- Demographical characteristics of patients.

Characteristics	CSEA (n=30)	GA (n=30)
Age (years)	28.00±6.00	38.9±9.20

Gender		
Male	15	14
Female	15	16
BMI	24.83±3.46	24.7±3.00
ASA status		
I	15	23
II	15	7
Duration of surgery (minutes)	71.33±4.72	69.16±6.44

BMI-body mass index, ASA-American society of anaesthesiologists classification, CSEA-combined spinal-epidural anaesthesia, GA-general anaesthesia.
P>0.05 for all the parameters (NS)

Table 2:- Heart rate according to different time intervals in both groups.

Time interval (minutes)	**HR (beats per minute)**		**P-value**
	CSEA	**GA**	
0	86.87±3.77	90.5±12.19	0.124=NS
10	81.9±5.71	1.01.87±10.07	$2.64e^{-09}$
20	81.37±6.16	97.53±10.31	$6.93e^{-08}$
30	78.93±4.45	96.13±10.71	$1.39e^{-08}$
40	76.63±6.77	94.27±8.06	$4.94e^{-10}$
50	78.63±7.04	93±9.21	$4.45e^{-08}$
60	84.77±7.24	93.87±10.57	0.000211
70	87.43±8.16	105.07±12.88	$8.10e^{-07}$
80	87.27±4.98	102.47±11.33	$2.07e^{-08}$
90	83.97±5.26	97.67±7.74	$9.78e^{-10}$

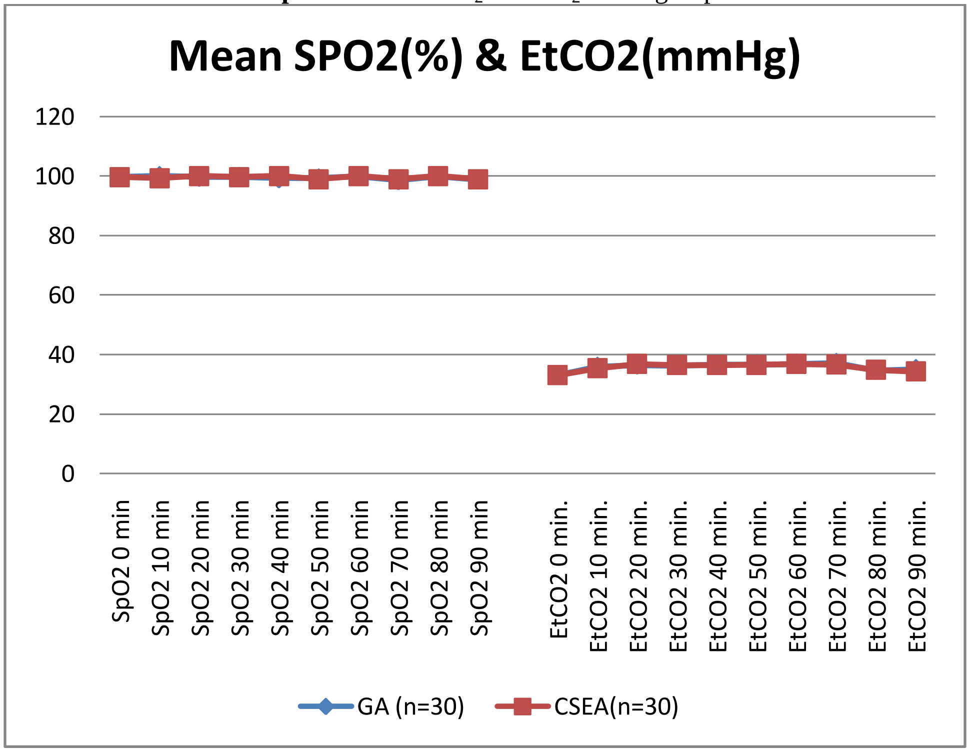
HR-heart rate, CSEA-combined spinal-epidural anaesthesia, GA-general anaesthesia,
P >0.05-NS=not significant, P<0.05=significant.

Table 3:- Systolic and diastolic blood pressure according to the different time interval.

BP at 10 min interval	**Mean SBP (mmHg)**		**P-value**	**Mean DBP (mmHg)**		**P-value**
	CSEA	**GA**		**CSEA**	**GA**	
0	128.33±7.71	124.33±14.19	0.18=NS	82.37±3.92	79.13±8.81	0.0731=NS
10	115.3±5.97	142.37±24.12	2.59E-06	72.27±5.04	90.33±14.48	$6.30e^{-06}$
20	114.37±8.24	139.87±19.15	3.82E-08	71.53±6.56	89.27±13.35	$2.24e^{-07}$
30	116.77±9.59	138.93±14.13	3.65E-10	73.07±7.2	88.73±8.79	$4.37e^{-10}$
40	117.63±8.29	139.4±13.35	3.83E-09	74.53±6.16	87.93±5.47	$2.71e^{-09}$
50	118.87±6.39	139.6±16.09	9.84E-08	75.53±5.4	87.93±9.56	$1.56e^{-07}$
60	120.33±5.2	140.07±16.19	2.66E-07	77.7±4.74	89.93±8.89	$7.35e^{-08}$
70	120.5±4.67	159.13±18.98	2.59E-12	77.87±4.55	100.13±11.1	$4.88e^{-10}$
80	121.57±4.69	151.33±15.44	8.11E-12	78.93±3.17	95.8±8.31	$3.03e^{-09}$
90	121.43±4.52	165±15.57	2.30E-11	78.77±2.42	94.93±11.32	$9.73e^{-09}$

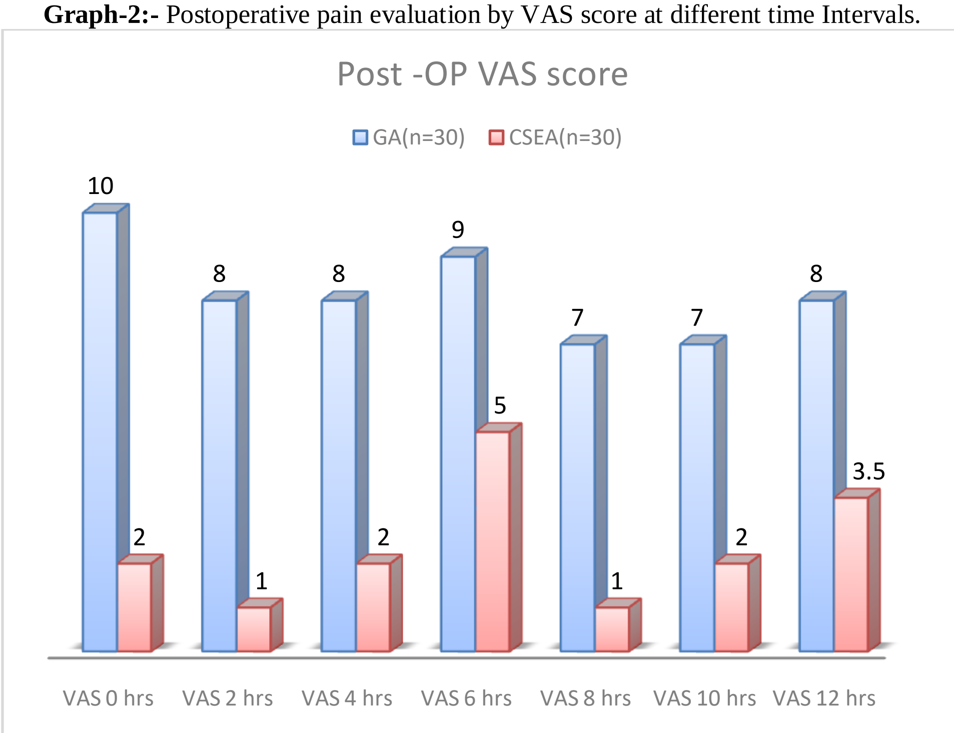
BP-blood pressure, SBP-systolic blood pressure, DBP-diastolic blood pressure, CSEA-combined spinal-epidural anaesthesia, GA-general anaesthesia NS-not significant, P<0.05-significant.

Graph-1:- Mean SPO_2& $EtCO_2$in two groups.



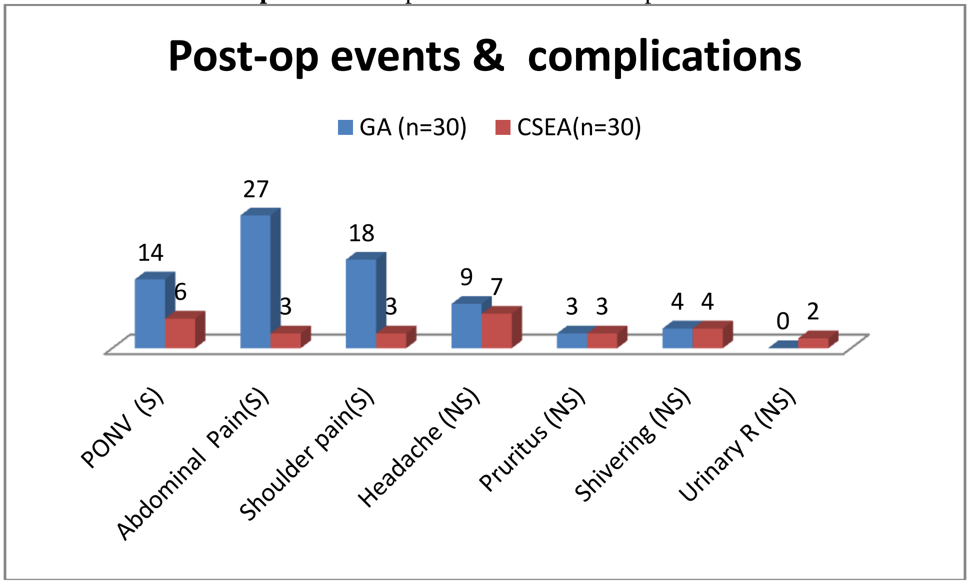
P>0.05,NS=Not significant from 0minto 60 min.
P<0.05 S=Significantly less SPO_2 in GA group at 70,80&90min.

Graph-2:- Postoperative pain evaluation by VAS score at different time Intervals.



P<0.0001(Highly Significant) at all times.

Graph-3:- Post-operative events & complications.



S=significant (P<0.05), NS=Not significant (P>0.05).

Conclusion:-

Thus we conclude that LC under CSEA with adjuvant fentanyl showed enhanced hemodynamic stability, excellent intraoperative pain control and reduced post-operative complications when compared with GA in healthy ASA grade I/II patients. The technique is safe and feasible as well as cost effective making it an appealing in hospital set ups where cost is a factor of concern.

Conflict of Interest:
Nil

Source of Support:
None declared

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