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A PROSPECTIVE RANDOMIZED STUDY TO EVALUATE COMBINED SPINAL AND GENERAL ANAESTHESIA VERSUS GENERAL ANAESTHESIA ALONE IN LAPAROSCOPIC CHOLECYSTECTOMY FOR POSTOPERATIVE ANALGESIA AND INTRAOPERATIVE HAEMODYNAMICS

Anaesthesiology

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ABSTRACT

Introduction: The haemodynamic and respiratory alteration associated with abdominal laparoscopy are due to high intraabdominal pressure caused by pneumoperitoneum creation. The most relevant haemodynamic changes are decrease in venous return secondary to inferior vena cava compression and increase in central venous pressure and arterial blood pressure. **Aim:** To compare postoperative analgesia and intraoperative hemodynamics in combined spinaland general anesthesia versus general anesthesia alone in laparoscopic cholecystectomy. **Method:** Prospective randomized study, carried out in Swaroop Rani Nehru Hospital, Prayagraj, for a duration of one year. Patients belonging to ASA I – II, age18-60 years, posted for laparoscopic cholecystectomy were recruited and allocated in one of the following groups: GROUP 1:Laparoscopic Cholecystectomy under general anaesthesia. GROUP 2:Laparoscopic Cholecystectomy under combined general anaesthesia and spinal anaesthesia. Following parameters were analysed in the two groups; baseline, before, during and after the procedure in both the groups: HR, MAP, SPO2, EtCO2 and VAS.**Result:** Combined spinal and general anaesthesia for laparoscopy provide better intra-operative haemodynamics as there was statistically significant difference in post induction heart rate and mean arterial pressure ($p < 0.05$) between Group 1 and Group 2. **Conclusion:**Combined spinal and general anaesthesia group have better intraoperativehaemodynamic stability and post-operative analgesia than general anaesthesia group.

KEYWORDS

Combined spinal and general anaesthesia, haemodynamic stability, HR, MAP, EtCO2, VAS.

INTRODUCTION

Laparoscopic cholecystectomy is a minimally invasive surgical procedure for removal of a diseased gallbladder. [1]. The haemodynamic and respiratory alteration associated with abdominal laparoscopy are caused by the high intraabdominal pressure due to pneumoperitoneum creation. The most relevant haemodynamic changes are decrease in venous return secondary to inferior vena cava compression and increase in central venous pressure and arterial blood pressure. Regarding respiratory adjustments, cranial displacement of the diaphragm causes a restrictive respiratory syndrome with decreased pulmonary compliance and increased pulmonary pressure and inspiratory peak. [2,3]. Hemodynamic changes include the alterations in arterial blood pressure, arrhythmias and cardiac arrest. These cardiovascular changes depend on the interaction of several factors including patient positioning, neurohumoral response and the patient factors such as cardiorespiratory status and intravascular volume. The principal responses are an increase in systemic vascular resistance, mean arterial blood pressure and myocardial filling pressures, with little change in heart rate [4]Laparoscopic surgery performed under combined regional and general anaesthesia have been demonstrated to be more efficient in controlling postoperative pain when compared to general anaesthesia alone.[5,6,7].

AIMS AND OBJECTIVES:

To compare postoperative analgesia and intraoperative hemodynamics in combined spinal anesthesia and general anesthesia versus general anesthesia alone in laparoscopic cholecystectomy.

MATERIAL AND METHODS:

- Prospective randomized study
- Carried out in Swaroop Rani Nehru Hospital, Prayagraj.
- Study Duration: June 2018-June 2019.

SELECTION OF CASES: Patients belonging to ASA I – II, between 18-60 years, posted for laparoscopic cholecystectomy were recruited in the study.

EXCLUSION CRITERIA

- ASA III and IV patients.
- Patients refusal.
- Patients with age <18 years and >60 years.Patients with pre-existing neurological disease, psychological disease and neuromuscular disease.
- Patients with cardiac or respiratory system failure.
- Pregnancy and lactating mother.
- Bleeding diathesis.
- Pancreatitis.
- Previous open surgery in upper abdomen.
- Contraindications for pneumoperitoneum.
- Contraindications for spinal anaesthesia owing to spinal deformity, local skin lesion.

After a thorough pre anaesthetic examination,patients were explained about the type of anaesthesia and any doubt or apprehension was clarified. A written and informed consent was obtained.

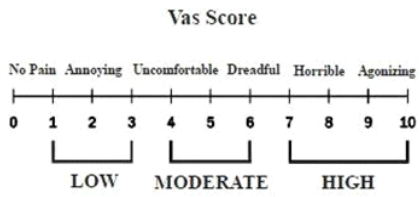
Patients were brought to the pre-operative holding area and baseline measurements including mean arterial blood pressure, heart rate, respiratory rate were noted using standard monitor.

After randomization, patients were allocated in one of the following groups:

GROUP 1: Patients undergoing Laparoscopic Cholecystectomy under general anaesthesia (GA group)

GROUP 2: Patients undergoing Laparoscopic Cholecystectomy under combined general anaesthesia and spinal anaesthesia with 0.5% bupivacaine (CGAS group)

General anaesthesia was given as per the standard protocol in group 1(n=30). In group 1,Inj. Fentanyl 1mcgm/kg iv was given as rescue analgesia.Inj. Paracetamol 10-15 mg/kg iv 8 hourly was given for postoperative pain management as per hospital protocol.Heart rate and mean arterial blood pressure, if increased by 20-30% intra operatively, considered as inadequate depth of analgesia after excluding other cause of inadequate depth of anesthesia and Inj. Fentanyl 1mcg/kg iv was given. Post-operative analgesia was evaluated with the help of VAS (visual analogue scale) and Inj. Fentanyl 1mcg/kg iv was given for break through pain when VAS score was >4 followed by Inj. Paracetamol 10-15 mg/kg iv 8 hourly.



Duration of analgesia [time from extubation to first requirement of analgesic supplement i.e. VAS> 4.] Visual Analog Score [76](VAS consist of score 0 to 10 with score 0 – no pain to score 10 worst pain) was explained to every patient pre- operatively.

Spinal anaesthesia was given in group 2 as per the standard technique(n=30). Thereafter, the patients receiving spinal anaesthesia were given general anaesthesia as per the same guidelines as given to general anaesthesia alone group. In group 2, Heart rate and Mean Arterial Pressure was measured at every 3 minutes for first 15 minutes then every 10 minutes for rest of surgery. Heart rate < 50 bpm was considered bradycardia and treated with inj. Atropine 0.01 mg/kg iv. A decrease in Mean Arterial Blood Pressure >20-30% of baseline Mean Arterial Blood Pressure was considered hypotension and treated with incremental dose of Inj. Mephentermine 6mgiv. Post-operative analgesia was evaluated with the help of VAS (visual analogue scale) and Inj. Fentanyl 1mcg/kg iv was given for break through pain when VAS score was >4 followed by Inj. Paracetamol 10-15 mg/kg iv 8hourly.Duration of analgesia [time from extubation to first requirement of analgesic supplement i.e. VAS> 4.] Visual Analog Score (VAS consist of score 0 to 10 with score 0 – no pain to score 10-worst pain) was explained to every patient preoperatively.

Following parameters have been monitored during laparoscopic cholecystectomy i.e. baseline, before, during and after the procedure in both the groups.

- HEART RATE – before procedure / during procedure / after procedure
- MEAN ARTERIAL BLOOD PRESSURE – before procedure / during procedure /after procedure
- PERIPHERAL OXYGEN SATURATION – before procedure / during procedure /after procedure
- END TIDAL CARBON DI OXIDE – during procedure
- POST OPERATIVE ANALGESIA ASSESED BY VISUAL ANALOGUE SCALE – after procedure.
- The observations were recorded and statistically analysed after completion of study to reveal the result. Appropriate statistical tools have been applied to find out statistical significance.Chi square test and student t-test(unpaired) were used where appropriate to test the significance of data. Data are being represented as Mean ±SD. A "p" value of <0.05 was considered significant.OBSERVATION AND RESULTS

A total of 60 patients were selected in the study i.e. aprospective randomized study to evaluate combined spinal and general anaesthesia versus general anaesthesia alone in laparoscopic cholecystectomy for postoperative analgesia and intraoperative haemodynamics comprising of 30 patients in each group

The patients were randomly assigned in each of the groups in a double-blind fashion in the following manner:

Table 1: Groupwise Distribution of Patients

GROUPS	DESIGNATION	No. of Patients
1	Patients undergoing laparoscopic cholecystectomy under general anaesthesia (GA)	30
2	Patients undergoing laparoscopic cholecystectomy under combined general anaesthesia and spinal anaesthesia (CGSA)	30

Table 2: Comparison of Distribution of Sex

	GROUP 1	GROUP 2
MALE	13	14
FEMALE	17	16

Chi square score – 0.0673 P value – 0.79525 (>0.05)

Sex distribution in both the groups were similar i.e. there was no statistically significant difference (p value > 0.05).

Table 3: Comparison of Distribution of Age

COMPARISION	GROUP 1	GROUP 2
AGE (Mean ± SD) (Years)	39.9 ± 4.7	40.4 ± 5.49
Range	32 – 55	32 – 52

p value: 0.7061 t-value: 0.379

Age distribution of both groups were similar i.e. there was no statistically significant difference (p >0.05).

Table 4: Comparison of Distribution of Weight

COMPARISON	GROUP 1	GROUP 2
Weight (Mean ± SD) (Kg)	57.06 ± 4.31	57.63 ± 5.35
Range	50 – 64	48 – 66
ANALYSIS	WEIGHT	
	t value	P value
GROUP 1 Vs GROUP 2	0.454	0.6512

Weight of patients of both groups were similar i.e. there was no statistically significant difference, p- value >0.05.

Table 5: Comparison of Distribution of Height

COMPARISON	GROUP 1	GROUP 2
HEIGHT (Mean ± SD) (cm)	158.83 ± 3.9538	158.5 ± 3.905
RANGE	155 – 165	152 – 165
ANALYSIS	HEIGHT	
	t value	p value
GROUP 1 Vs GROUP 2	0.325	0.7462

Height profile of both groups were similar i.e. there was no statistically significant difference, p- value >0.05.

Table 6: Timing of Observation

Timing	Designation
Pre-operative	T0
Post induction	T1
Post insufflations	T2
After Head Up	T3
Post exsufflation	T4
Post-Operative	T5

Table 6a: comparison of pre-operative (t0) parameters i.e. heart rate (HR), mean arterial blood pressure (MAP), peripheral oxygen saturation (spo2)

PARAMETERS	GROUP 1	GROUP 2
HEART RATE (Mean ± SD) (bpm)	75.7 ± 3.71	74 ± 5.1
MEAN ARTERIAL BLOOD PRESSURE (Mean ± SD) mm of Hg	93.4 ± 1.54	93.43 ± 1.56
PERIPHERAL OXYGEN SATURATION (Mean ± SD) (%)	99.3 ± 0.47	99.3 ± 0.44

ANALYSIS	HR		MAP		SPO2	
	t value	p value	t value	p value	t value	p value
GROUP 1 Vs GROUP 2	1.476	0.1452	0.075	0.9405	0.02	0.99

Pre-operative parameters were similar in two groups i.e. there was no statistically significant difference (p >0.05)

Table 7: Comparison of Post Induction (T1) parameters i.e. heart rate (HR), mean arterial blood pressure (MAP), peripheral oxygen saturation (spo2), end tidal CO2(EtCO2)

PARAMETERS	GROUP 1	GROUP 2
HEART RATE (Mean ± SD) (bpm)	94 ± 5.5	79 ± 5.27
MEAN ARTERIAL BLOOD PRESSURE (Mean ± SD) mm of Hg	103 ± 2.22	79 ± 2.36
PERIPHERAL OXYGEN SATURATION (Mean ± SD) (%)	99.9 ± 0.3	99.9 ± 0.3

END TIDAL CO2 (Mean ± SD) mm of Hg	31.1 ± 1.13	30.43 ± 1.453

ANALYSIS	HR		MAP		SPO2		EtCO2	
	T Value	P value	t value	p value	t value	p value	t value	P Value
GROUP 1 Vs GROUP 2	10.78	0.0001	40.57	0.0001	0	1	1.99	0.051

There was statistically significant difference in post induction HR and MAP between GROUP 1 and GROUP 2 (p< 0.05). Post induction SPO2 and EtCO2 were similar in the two groups i.e. there were no statistically significant difference.

Table 8: Comparison of Post Insufflation (T2) Parameters i.e. HR, MAP, SPO2, EtCO2

PARAMETERS	GROUP 1	GROUP 2
HEART RATE (Mean ± SD) (bpm)	96.4 ± 5.6	81 ± 5.13
MEAN ARTERIAL BLOOD PRESSURE (Mean ± SD) mm of Hg	105 ± 2.01	97.2 ± 2.39
PERIPHERAL OXYGEN SATURATION (Mean ± SD) (%)	99.8 ± 0.4	99.8 ± 0.4
END TIDAL CO2 (Mean ± SD) mm of Hg	34.9 ± 0.87	34.43 ± 1.202

COMPARISION	HR		MAP		SPO2		EtCO2	
	t value	p value	t value	p value	t value	p value	t value	p value
GROUP 1 Vs GROUP 2	11.107	0.0001	13.681	0.0001	0	1	1.735	0.0881

There was statistically significant difference in post insufflation HR and MAP between GROUP 1 and GROUP 2 (p <0.05). Post insufflation SPO2 and EtCO2 were similar in two groups i.e. there were no statistically significant difference(p >0.05).

Table 9: Comparison of After Head Up (T3) Parameters i.e. HR, MAP, SPO2,EtCO2.

PARAMETERS	GROUP 1	GROUP 2
HEART RATE (Mean ± SD) (bpm)	93.9 ± 5.1	79 ± 5
MEAN ARTERIAL BLOOD PRESSURE (Mean ± SD) mm of Hg	99.3 ± 1.85	93.5 ± 2.06
PERIPHERAL OXYGEN SATURATION (Mean ± SD) (%)	99.87 ± 0.34	99.7 ± 0.44
END TIDAL CO2 (Mean ± SD) mm of Hg	31.567 ± 1.1455	31.13 ± 1.231

ANALYSIS	HR		MAP		SPO2		EtCO2	
	P Value	P value	t value	p value	t value	p value	t value	p value
GROUP 1 Vs GROUP 2	11.427	0.0001	11.474	0.0001	1.67	0.O99	1.43	0.16

There was statistically significant difference in after head up HRand MAP between GROUP 1 and GROUP 2 (p<0.05). After head up SPO2 and EtCO2 were similar in the two groups i.e. there were no statistically significant difference (p> 0.05).

Table 10: Comparison of Post Exsufflation (T4) Parameters i.e. HR, MAP, SPO2, EtCO2

PARAMETERS	GROUP 1	GROUP 2
HEART RATE (Mean ± SD) (bpm)	88.3 ± 7.39	76 ± 6.1
MEAN ARTERIAL BLOOD PRESSURE (Mean ± SD) mm of Hg	97.3 ± 2.09	93 ± 1.97
PERIPHERAL OXYGEN SATURATION (Mean ± SD) (%)	99.7 ± 0.44	99.7 ± 0.44
END TIDAL CO2 (Mean ± SD) mm of Hg	31.03 ± 1.27	30.43 ± 1.086

ANALYSIS	HR		MAP		SPO2		EtCO2	
	t value	P value	t value	p value	t value	p value	t value	P Value
GROUP 1 Vs GROUP 2	7.031	0.0001	8.2	0.0001	0	1	1.96	0.06

There was statistically significant difference in post exsufflation HR and MAP between GROUP 1 and GROUP 2 (p < 0.05). SPO2 and EtCO2 were similar in post exsufflation in GROUP 1 and GROUP 2 i.e. there were no quite statistically significant difference (p > 0.05).

TABLE 11: ANALYSIS OF POST OPERATIVE VISUAL ANALOGUE SCALE AND DURATION OF POST OPERATIVE ANALGESIA IN BOTH GROUPS (By: MANN WHITNEY U TEST)

Comparison of VAS score between the two groups at different follow-up time periods (N=60)

VAS score	Study Group		Mann Whitney U test (P value)
	Group 1 (N=30)	Group 2 (N=30)	
VAS1 Median (IQR) (After 1st hour)	3 (3,4)	0 (0,1)	<0.001
VAS2 Median (IQR) (After 2nd hour)	4 (4,5)	1 (0,1)	<0.001
VAS3 Median (IQR) (After 3rd hour)	5 (4.75,6)	2 (1,2)	<0.001
VAS4 Median (IQR) (After 4th hour)	6 (6,7)	3 (3,4)	<0.001
VAS5 Median (IQR) (In 5th hour)	7 (6,8)	7 (6,7)	0.065
PA (hours) Median (IQR) (Post-operative Analgesia)	1.5 (1,2)	4 (4,4)	<0.001

The median VAS 1 was 3 (IQR3,4) in group 1 and it was 0 (IQR0,1) in group 2.

ThemedianVAS2was4(IQR4,5)ingroup1anditwas1(IQR0,1)ingroup2.

ThemedianVAS3was5(IQR4.75,6)ingroup1anditwas2(IQR1,2)ingroup2.

The median VAS 4 was 6 (IQR6,7) in group 1 and it was 3 (IQR 3,4) in group 2. The difference in the VAS 1, 2, 3 & 4between study group was statistically significant (P value <0.001). The median VAS 5 was 7 (IQR6, 8) in group 1 and it was 7 (IQR6,

7) in group 2. The difference in the VAS 5 between study groups was statistically not significant (P value 0.065). The median PA was 1.5 hours (1, 2) in group 1 and it was 4 hours (IQR4, 4) in group 2. The difference in the PA between study group was statistically significant (P value <0.001). (Table 11), (Mann Whitney U Test applied).

DISCUSSION:

The groups in the study were similar in respect to age, sex, weight, height, and duration of surgery as found with student t- test (p > 0.05). By including, ASA I and ASA II patients, it was tried to eliminate any systemic problems confounding our results.

In our study, haemodynamic responses to pneumoperitoneum creation and surgery were assessed and compared in patients receiving general anaesthesia along with spinal anaesthesia versus patients receiving general anaesthesia alone by haemodynamic parameters in pre and postoperative period by monitoring heart rate, mean arterial blood pressure, peripheral oxygen saturation and end tidal CO2 in both groups of patients and postoperative analgesia and surgical ease and feasibility was also compared in both groups.

H K Sale et al (2016) [8],Turgut Donmez et al 2017[9], Semra Calimli et al 2011[10] and Sangeeta Tiwari et al2013[11] concluded thatGA if combined with SA is a feasible, safe and effective alternative to GA alone, providing stable hemodynamic, less neuroendocrine stress response, good surgical conditions, pain-free post-operative period, and minimal post-operative sequel. Similarly, Mohammad Azad Majedi et al 2019[12]concluded from their study that the type of regional anaesthesia significantly affected the stress response: spinal anaesthesia produced a more favourable endocrine response than epidural anaesthesia.

The result of our study was consistent with the above-mentioned

studies, as there was statistically significant difference in post induction (T1) heart rate and mean arterial pressure ($p < 0.05$) between Group 1 and Group 2 as shown by Table 7. Heart rate and mean arterial pressure at T1 are greater in Group 1 than Group 2 and they are also showing more variation from the Preoperative values which were similar in both the groups ($p > 0.05$)in Group 1 than Group 2.Similarly ,at T2 (Post insufflation), T3 (After head up) and T4 (Post exsufflation) also, the heart rate and mean arterial pressure were greater in Group 1 than Group 2 as shown in Tables 8 and 9. In our study, Post-operative analgesia as shown by VAS was better in Group 2 than Group 1 and duration of postoperative analgesia was more in Group 2 than Group 1 as shown by Table 11 and Table 12.

CONCLUSION

Heart rate and blood pressure variation was less in intra-operative period in combined spinal and general anaesthesia group than general anaesthesia group. Visual analogue scaling post operatively showed less pain in patients of combined spinal and general anaesthesia group as compared to general anaesthesia group.The duration of analgesia was more in combined spinal and general anaesthesia group as compared to general anaesthesia group.Thus, post-operative analgesia was of longer duration in combined spinal and general anaesthesia group.

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