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ORIGINAL RESEARCH

EFFECTIVENESS OF SPINAL ANESTHESIA VERSUS GENERAL ANESTHESIA FOR OPEN CHOLECYSTECTOMY: AN INSTITUTIONAL BASED STUDY

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ABSTRACT

Introduction: Cholecystectomy is performed either as an open or a laparoscopic route. Despite of a number of peri-operative and post-operative benefits of laparoscopic cholecystectomy, the traditional and invasive open cholecystectomy is still in frequent practice for various reasons. Therefore, this study was conducted to compare the effectiveness of SA for open cholecystectomy versus GA with respect to reducing post operative pain, analgesia requirement, respiratory complications and length of hospital stay.

Materials and Methodology: One hundred and forty patients were allocated randomly into two groups—SA group (spinal anaesthesia group, n = 70) and GA group (general anaesthesia group, n =70). And the two groups were divided as SA group underwent open cholecystectomy under spinal anaesthesia whereas GA group had undergone it under general anaesthesia.

Results: Out of all the 140 patients, 70 patients were allotted in each group, there were 120 females (85.85%) and 20 males (14.17%). Their age mostly ranged between 18 – 70 years, with a mean of 42.35 ± 12.66 years. There was no statistically significant difference between both the study groups with respect to age, sex distribution, body mass index (BMI) and ASA physical status. Intra-operatively, bradycardia and hypotension were more common in the SA group. Bradycardia less than 50/ min in 12 patients (16.66%) were treated by atropine 0.6mg IV. Bradycardia was the only side effect noted in both groups.

Conclusion: Since the conventional use of general anaesthesia in open cholecystectomy, this study displays that spinal anaesthesia is also a recommended alternative. It is therefore safe and more effective than general anaesthesia in providing prolonged post-

operative pain-free interval, less analgesic/ opioid requirement and no reported respiratory problems.

Keywords: Open Cholecystectomy, General Anaesthesia, Spinal Anaesthesia.

INTRODUCTION

The frequently performed procedure for the management of symptomatic cholelithiasis especially in developing countries like India is open cholecystectomy because of the lack of laparoscopic equipment or expertise.[1]But the laparoscopic cholecystectomy has always remains the gold standard choice for the effective management of symptomatic gallstones due to relatively short operative time, early mobilization, less postoperative pain, fast recovery, short hospital stay (LOS) and early return to work.[2]Both the open and laparoscopic cholecystectomies have conventionally been performed under general anaesthesia (GA) frequently. GA is basically taken into a favourable consideration because of its convenience, well studied and understood safety profile. But general anaesthesia could be potentially challenging for patients with cumbersome intubation, obstructive pulmonary and cardiovascular diseases. Although this GA is not without any disadvantages because of its adverse effects on pulmonary functions and associated post operative pain could effectively lead to anincreased days in hospital stay and therefore could strongly affect the cost of hospital stay.[3]In the recent times, regional blocks like low thoracic epidural[4] spinal[5] segmental thoracic spinal[6] and combined spinal-epidural blocks[7] have been administered in laparoscopic cholecystectomy and were found to be safe and effective alternate to GA with various advantages.

Hamad MA et al[8] has first used spinal anaesthesia (SA) in the effective management of laparoscopic cholecystectomy. Since all laparoscopic procedures are merely a change in access and still require the same anaesthesia; therefore, the difference from conventional surgery is reported to be small. It is therefore reported that SA can be an effective alternative in open cholecystectomy as in laparoscopic approach. Moreover, SA with fewer adverseeffects on respiratory functions, better post operative pain control, minimal surgical stress response and reduced incidence of deep venous thrombosis[9] can be a better choice than GA. *Sinha* R,[10] in India has observed the safety profile of SA for laparoscopic cholecystectomy in 3492 patients for 12 years. Therefore, the safety and efficacy of SA has not yet been researched for upper abdominal surgeries like open cholecystectomy.

Therefore, this study was conducted to compare the effectiveness of SA for open cholecystectomy versus GA with respect to reducing post operative pain, analgesia requirement, respiratory complications and length of hospital stay.

MATERIALS AND METHODOLOGY

The study was performed after obtaining the adequate approval from the institutional ethical committee and written informed consent were obtained from the patients. The various inclusion criteria that were followed in this studyare those patients with uncomplicated symptomatic gallstone disease who were undergoing open cholecystectomy and accustomed with American Society of Anaesthesiologists (ASA) physical status I or II, patients aged between 18 and 70 years of either sex and body mass index (BMI) $\leq$ 30 kg/m^2. Therewere few exclusion criteria which included pancreatitis, contraindication of SA, hypersensitivity to

bupivacaine and tramadol and severe cardiopulmonary disease for both SA and GA group. Likewise, the patients who were not willing to participate in the study were also excluded effectively.

One hundred and forty patients were allocated randomly into two groups—SA group (spinal anaesthesia group, n = 70) and GA group (general anaesthesia group, n =70). The sample size was basically determined using G*power 3.1.7 software.And the two groups were divided as SA group underwent open cholecystectomy under spinal anaesthesia whereas GA group had undergone it under general anaesthesia.

After evaluating the adequate pre-anaesthetic evaluation, patients who were randomly allocated to SA group werepremedicated with inj. ondansetron 0.1mg/kg and inj, midazolam 1mg (30 minutes before procedure).For spinal anesthesia, patients were injected with 3.5 ml of 0.5% (17.5 mg) heavy bupivacaine + 25 mg tramadol at L3-4 or L4-5 intervertebral space under aseptic protocols in sitting position with a long 25gauge spinal needle. Followed which the patients were maintained in Trendelenburg position for 3 minutes or till the level of sensory block of T4 was achieved. The level of sensory block was equally evaluated with a pin-prick stimulus every 30 seconds.

In GA group patients, patients were premedicated with inj. ondansetron 0.1mg/kg, inj. glycopyrrolate 0.2mg, inj. midazolam 1mg and inj. tramadol 2mg/kg IV; anaesthetic induction was done with propofol 2mg/kg and vecuronium 0.14mg/kg and were then maintained with isoflurane and vecuronium throughout the total surgical procedure. Haemodynamic parameters, ECG and SpO_2 were assessed continuously in all the study participants during the surgery. Neuromuscular block was reversed with 2.5mg neostigmine and 0.4 mg glycopyrrolate at the end of the surgery.

RESULTS

Out of all the 140 patients, 70 patients were allotted in each group, there were 120 females (85.85%) and 20 males (14.17%). Their age mostly ranged between 18 – 70 years, with a mean of 42.35 ± 12.66 years. There was no statistically significant difference between both the study groups with respect to age, sex distribution, body mass index (BMI) and ASA physical status, as seen in table - 1. There was a significant difference in post-operative pain-free intervalbetween SA group and GA group. SA group displayed a median of 0 pain score until 8 hours post-surgery whereas, GA group displayed a median of 4 pain score by one-hour post-surgery. By an hour of post-surgery, all the patients (i.e., 100%) in GA group recorded significant pain score as displayed in Table - 2.

There is significant mean difference in the post-operative pain scores that were observed between GA and SA group. The repeated measure ANOVA shows that pain scores in GA group is significantly greater than that of SA group at all time intervals observed in table 3. Post-operative pain was reportedly minimal and are easily treatable in SA group. It was effectively managed with diclofenac sodium 75 mg IM in 63 patients (90%) and with tramadol 50 mg IV in 7 patients (10%) whereas in GA group 63 patients (90%) were treated with nalbuphine 0.1 mg/kg IV and 7 patients (10%) were treated with tramadol 50 mg IV. Post-operative nausea and vomiting, observed in 12 patients(16.66%) in both SA and GA groups, and these patients were treated with inj. ondansetron 0.1 mg/kg IV. Post-dural puncture headache was observed in 8 patients(11.66%) in SA group and it was relieved

without any medications. Sore throat was not observed in any cases in SA group but was frequently observed in GA group, i.e, 41 patients (58.33%). There was, however, no respiratory depression in either group. The post-operative events were listed in Table - 4.

Intra-operatively, bradycardia and hypotension were more common in the SA group. Bradycardia less than 50/ min in 12 patients (16.66%) were treated by atropine 0.6mg IV. Bradycardia was the only feature noted in both groups where its relative risk for GA group compared to SA.Likewise, hypotension in 18 patients (25%) in the SA group was treated by mephentermine 6–12mg IV. Otherwise, patients in the SA group were haemodynamically stable. It was, probably, due to high level of sensory block of T4. On the other hand, in the GA group, 5 patients (6.66%) with bradycardia less than 50/min during retraction and abdominal packing of tetra were treated by atropine 0.6mg IV.Hypertension was seen in 6 patients (8.33%) which was treated with inj. esmolol 30mg IV.

Table 1: Demographic characteristics of the patients (n = 140)

Variables	SA (n=70)	GA (n=70)	P – value
Age (years)Mean ± SD	44.63 ± 12.78	42.12 ± 12.56	0.29
Sex			
Male, n(%)	11 (15%)	9 (13.3%)	
Female, n(%)	59 (85%)	61 (86.6%)	0.81
BMI (kg/m^2)Mean ± SD	23.39 ± 1.21	23.11 ± 1.72	0.311
ASA status			
ASA I	64	66	1.1
ASA II	6	4	

Table 2: Post-operative pain scores in SA and GA group

Time (hrs)	SA	GA	P – value
1	0	4	<0.001
2	0	1	<0.001
4	0	2	<0.001
8	1	6	<0.001
12	1	3	<0.001
16	3	6	<0.001
24	3	4	0.007
48	2	3	0.054

Table 3: Post-operative pain scores in SA and GA group

Time (hr)	Pain score in SA				Pain score in GA				P - value
	Min	Max	Mean	SD	Min	Max	Mean	SD	
1	0	1	0.02	0.14	3	4	3.87	0.41	<0.001
2	0	3	0.06	0.31	1	5	1.51	0.88	
8	1	3	0.32	0.76	2	5	4.13	1.22	
12	1	3	1.49	0.69	2	6	3.81	1.98	
24	1	5	3.37	1.41	0	7	4.28	2.02	

Table 4: Post-operative events in SA and GA group (n =140)

Variables	SA	GA
Median post-operative pain free interval (hrs)	8	1
Analgesia required		
Diclofenac	63 (90%)	-
Tramadol	7 (10%)	7 (10%)
Nalbuphine	-	63 (90%)
Significant respiratory difficulties		
Sore throat	-	41 (58.33%)
Respiratory depression	-	-
Post-dural puncture headache	8 (11.66%)	

Table 5: Intraoperative events in SA and GA group (n=140)

Variables	SA (n=70)	GA (n=70)
Bradycardia	12 (16.66%)	5 (6.66%)
Hypotension	18 (25%)	-
Hypertension	-	6 (8.33%)
Dragging pain	5 (6.66%)	-
Dyspnoea	3 (3.33%)	-
Nausea	5 (6.66%)	-

DISCUSSION

Though the feasibility and popularity of laparoscopic cholecystectomy has gained sky heights, open cholecystectomy is still in day today practice in places where there is a lack in adequate technologies and expertise in performing laparoscopic cholecystectomy.[2] For an effective open cholecystectomy in recent years, anaesthesiologists now have the options of GA and SA. Though there isa common practice of GA due to its major advantage viz., adequate muscle relaxation for surgery.[1] Spinal anaesthesia lacks to provide adequate muscle relaxation which might pose difficulties in performing surgery.[1] it has an added advantage over GA since it can be safely used in patients with cardio-respiratory co-morbid situations.[3,5-9]This present study intended to observe that open cholecystectomy could possibly be done in a very convenient way under SA. When compared with GA, it has few advantages such as the relatively longer post-operative pain-free interval (8 hours) and reportedlyminimal use of opioids in post-operative pain management. The major analgesia used for SA group was intramuscular diclofenacsodium which comes under non-steroidal anti-inflammatory drug and few patients were effectively managed with tramadol which is an opioid. But, in GA group, the opioids were used in all of the patients to combat the pain. Few were managed with tramadol and majority were managed with nalbuphine (an opioid). And the same prolonged pain-free interval and requirement of lesser opioids in SA group may be contributable to the interplay of various factors such as avoidance of endotracheal intubation-related discomfort, presence of adequate levels of residual analgesia and minimal stress response which is associated with spinal anaesthesia. Moreover, the confidence that had been gained and increased pain threshold attained by the patients during this pain-free interval also

attributed towards the satisfaction of patients in the effective pain management with simple analgesics.[1]

The major outcome of our study was that comparable to *Khan* et al where they had reported longer average pain free intervalin patients included in SA group than in GA group. As in our study, they also managed that majority of the patients in SA group by diclofenac sodium. But majority of the patients in GA group in our study was managed with nalbuphine (an opioid), whereas Khan et altreated them with ketorolac, an NSAID more potent than diclofenac.[1] No respiratory problems were encountered post-surgery in SA group whereas significant patients in GA group complained of sore throat for 2 days which subsided without any treatment, however, 7 patients in SA group experienced post-dural puncture headache for 2-3 days after surgery. There was no significant difference in hospital stay in SA group (3 days) and GA group (4 days). During the operation, in SA group 4 patients had dragging pain due to stretch on mesentery and liver retraction which was effectively managed with analgesic dose of ketamine and midazolam and gentle retraction of liver. Similarly, 3 patients in SA group complained of difficulty in breathing due to surgical manipulation during upward retraction and tetra packing which was tackled easily with O_2 supplement.[10-13] Intra-operative haemodynamic changes in SA group observed was mainly hypotension and bradycardia which was treated with mephentermineIV and atropine IV respectively. Therefore, the haemodynamic change observed in GA group was hypertension that was treated with esmolol IV. Inadequate muscle relaxation, which is an important problem in open cholecystectomy under spinalanaesthesia, causing difficulties in surgical procedure in SA group1was not experienced in this study. Surgeons were quite satisfied with SA. It was cumbersomesince to evaluate the difference of the patient's satisfaction over GA and SAfor various obvious reasons.[14-17]

CONCLUSION

Since the conventional use of general anaesthesia in open cholecystectomy, this study displays that spinal anaesthesia is also a recommended alternative. It is therefore safe and more effective than general anaesthesia in providing prolonged post-operative pain-free interval, less analgesic/ opioid requirement and no reported respiratory problems.

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