Spinal Anaesthesia with Fentanyl Adjuvant is a Good Alternative of General Anaesthesia for Open Cholecystectomy Operation

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Abstract

Background: Open cholecystectomy is still widely practiced procedure in developing countries like ours which can be done either by General Anaesthesia or by Spinal Anaesthesia. This study was aimed to compare some advantages of Spinal Anaesthesia over General Anaesthesia.

Methods: This is a Quasi Experimental study done in Medical College Hospital, Kishoreganj from January, 2017 to July, 2019. Total 100 patients admitted for open cholecystectomy were divided into two groups, Spinal Anaesthesia Group (SA) & General Anaesthesia Group (GA) having 50 patients in each group. S/A group received Spinal Anesthesia with hyperbaric bupivacaine and preservative free fentanyl. GA group received General naesthesia with thiopental sodium (TPS), fentanyl citrate, vecuronium bromide and haĺothane. The main endpoint of this study were post operative pain free interval, analgesic requirements, respiratory complication and length of hospital stay in both groups.

Results: 100 admitted patients with symptomatic gall stone from January,2017 to July 2019 were divided into two groups, SA groupan GA group (50 patients in each group). Demographic characteristics of the two groups remained statistically insignificant. But VAS pain score at 2nd hour, 8th hour, 12th hour, 24th hour post operative were statistically significant (P<0.05) between two groups. Majority of SA group patients were satisfied with Diclofenac Sodium (80%) whereas majority of GA group patients (78%) required Ketorolac. Mean pain free interval was 7.6±1.2 hour in SA group and1.5±0.4 hour in GA group which were statistically significant (P<0.05). The mean hospital stay was found 3.0±0.9 day in SA group and 3.7±0.8 day for GA group which were again statistically significant (P<0.05).

Conclusion: For patients undergoing uncomplicated open cholecystectomy operation, Spinal Anaesthesia is safe and also more effective than General Anaesthesia in reducing post operative pain, analgesic requirements, respiratory problems and length of hospital stay.

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Introduction

Cholecystectomy is performed either as an open or a laparascopic route. Despite of a number of perioperative and post-operative benefits of laparascopic cholecystectomy, the traditional and invasive open cholecystectomy is still in frequent practice for various reasons. Though general anaesthesia is regarded as the gold standard anaesthetic technique, alternatives to it such as spinal anaesthesia, with its advantages, outweighs general anaesthesia.[1]

Open cholecystectomy is frequently performed especially in developing countries because of lack of laparoscopic equipments or expertise.[2]

Open cholecystectomy procedures have traditionally been performed under general anaesthesia (GA), a gold-standard an anaesthetic technique.[3] But, it can be fatal for patients with difficult intubation, and cardiorespiratory co-morbid conditions[4] and associated post-operative pain can lead to prolonged hospital stay.[5]

General anesthesia (GA) remains the choice for most open abdominal surgical procedures, and regional anaesthesia is preferred for patients who are at high risks under GA.[6]

Open cholecystectomy can be done very conveniently under SA. Compared to GA, it has certain advantages such as the significantly longer post-operative pain-free interval (8 hours) and significantly lesser use of opioids in post-operative pain management. Intend to compare the effectiveness of SA for open cholecystectomy against GA in terms of preoperative events, post-operative pain-free interval and analgesic requirement as well as surgeon's and patient's satisfaction.

Methods

The Quasi Experimental study was done in Medical College Hospital, Kishoreganj. Patients admitted with the symptomatic gall stone disease were randomly divided into two groups. SA Group represents those patients randomized to open cholecystectomy under SA and GA Group having same surgery under GA. American Society of Anesthesiology (ASA) physical status (PS) I and II patients of either gender, aged between 30 to 60 years, undergoing uncomplicated open cholecystectomy were included in the study. Patients with spinal problem such as backache, spinal deformity, back infection, bleeding or clotting disorders and those on NSAIDs or corticosteroids were excluded from the study. Hospital ethical committee granted permission for the study. Informed consent was taken from all participating patients. Pre operative preparation was same in both groups. On patients' arrival in the operating room, noninvasive monitoring (electrocardiogram, heart rate, arterial blood pressure, respiratory rate and pulse oximetry) was established and 500 ml of Ringer solution was commenced intravenously.

Patients randomized to spinal anesthesia were injected with 3 ml of hyperbaric bupivacaine hydrochloride with 20 microgram preservative free Fentanylintrathecally at L2-L3 or L3-L4 intervertebral spaceunder aseptic conditions. The patient was placed intrendelenburg position for 3 minutes in order to achievehigh spinal anaesthesia. In patients randomized toreceive general anaesthesia, induction was done withthiopental sodium (4-6 mg/kg), fentanyl citrate (1-2μg/kg), andvecuronium bromide(0.08-0.1mg/kg). Balanced anesthesiawas then continued with halothane (0.5% to 0.7%), and 50% nitrous oxide in 50% oxygen. All patients were hemodynamicallymonitored continuously during the operation. Residual neuromuscular block was antagonized with 25 mg of

neostigmine methyl sulfate and 1 mg of atropine sulfate at the end of surgery.

Open cholecystectomy was performed by upper right paramedian, right transverse or oblique incision. In one patient upper midline incision was utilized as he had concomitant epigastric hernia. The main end points of the study were post operative pain free interval, analgesic requirements, respiratory complications and length of hospital stay in both the groups. Post operative morbidity was assessed on a preformed proforma which was filled in by the senior nurse on duty and dually checked by the doctor on duty. The nurse on duty was kept unaware of the type of anesthesia given in order to avoid any possible bias. Time of first complaint of post operative pain was noted and analgesia given in step ladder pattern starting from intramuscular diclofenac sodium, intravenous ketorolac and tramadol. Respiratory problems were recorded in both groups as presence of only cough, cough with clinical findings on chest examination and cough with clinical and radiological findings necessitating treatment in the form of intravenous antibiotics and hospitalization. The patients were allowed orally 8 hours postoperatively and discharged from the hospital when theywere fully mobilized, afebrile and taking soft diet.

Results

Mean age was found 43.7±7.4 years in SA group and 41.3±7.6 years in GA group. More than three fourth (76%) patients were females in SA group and 39(78.0%) in GA group. ASA score I was found 48 patients in SA group and 49 in GA group. Mean BMI was 23.1±2.0 kg/m^2 in SA group and 23.0±1.8 kg/m^2 in GA group. Mean operation time was found 50.6±9.9 minute in SA group and 53.2±9.3 minute in GA group. The difference were not statistically significant (p>0.05) between two group.

Table I: Demographic characteristics of the study patients (n=100)

Demographic characteristics	Spinal anesthesia (n=50)		General anesthesia (n=50)		P value
	n	%	n	%	
Sex					
Male	12	24.0	11	22.0	[a]0.812[ns]
Female	38	76.0	39	78.0	
ASA status					
ASA I	48	96.0	49	98.0	[a]0.500[ns]
ASA II	2	4.0	1	2.0	
Mean age (years)	43.7±7.4		41.3±7.6		[b]0.113[ns]
Range (min-max)	22-56		20-54		
Mean BMI (kg/m^2)	23.1±2.0		23.0±1.8		[b]0.793[ns]
Range (min-max)	18.9-25.3		18.5-24.7		
Mean operation time (min)	50.6±9.9		53.2±9.3		[b]0.179[ns]
Range (min-max)	38-70		44-72		

ns= not significant, [a]P value reached from chi square test, [b]P value reached from unpaired t-test

Table II: Pain score in different follow up (n=100)

Pain VAS score	Spinal anesthesia (n=50)		General anesthesia (n=50)		P value
	Mean	±SD	Mean	±SD	
At 1st hour	0.0	±0.0	3.0	±0.5	-
At 2nd hour	0.2	±0.1	1.5	±0.8	0.001[s]
At 8th hour	0.3	±0.7	2.9	±1.2	0.001[s]
At 12th hour	1.4	±0.6	2.8	±1.5	0.001[s]
At 24th hour	3.0	±1.2	3.9	±2.1	0.010[s]

s= significant, P value reached from unpaired t-test

Mean pain score at 2nd hour, at 8th hour, at 12th hour and at 24th hour were statistically significant ($p<0.05$) between two group.

Table III: Post-operative event of the study patients (n=100)

Post-operative event	Spinal anesthesia (n=50)		General anesthesia (n=50)		P value
	n	%	n	%	
Analgesia required					
Diclofenac	40	80.0	8	16.0	
Ketorolac	9	18.0	39	78.0	[a]0.001[s]
Tramadol	1	2.0	3	6.0	
Respiratory problems					
Yes	1	2.0	6	12.0	[a]0.056[ns]
No	49	98.0	44	88.0	
Mean pain free interval (hours)	7.6±1.2		1.5±0.4		[b]0.001[s]
Mean hospital stay (days)	3.0±0.9		3.7±0.8		[b]0.001[s]

s= significant, ns= not significant, [a]P value reached from chi square test
[b]P value reached from unpaired t-test

Majority (80.0%) patients treated with diclofenac sodium in SA group and 8(16.0%) in GA group. Mean pain free interval was 7.6±1.2 hour in SA group and 1.5±0.4 hour in GA group. The mean hospital stay was found 3.0±0.9 day in SA group and 3.7±0.8 day in GA group. Which were statistically significant ($p<0.05$) between two group.

Table IV: Intraoperative event of the study patients (n=100)

intraoperative event	Spinal anesthesia (n=50)		General anesthesia (n=50)		P value
	n	%	n	%	
Vomiting	1	2.0	2	4.0	0.500[ns]
Bradycardia	7	14.0	4	8.0	0.338[ns]
Hypertension	1	2.0	4	8.0	0.181[ns]
Dragging pain	2	4.0	0	0.0	0.247[ns]
Difficulty in breathing	1	2.0	0	0.0	0.500[ns]
Nausea	1	2.0	0	0.0	0.500[ns]
Headache	3	6.0	0	0.0	0.121[ns]

ns= not significant, P value reached from chi square test

Vomiting, bradycardia, hypertension, dragging pain, difficulty in breathing, nausea and headache were not statistically significant (p>0.05) between two group.

Discussion

In this study, we observed that the mean age was found 43.7±7.4 years in SA group and 41.3±7.6 years in GA group. More than three fourth (76%) patients were females in SA group and 39(78.0%) in GA group. ASA score I was found 48 patients in SA group and 49 in GA group. Mean BMI was 23.1±2.0 kg/m^2 in SA group and 23.0±1.8 kg/m^2 in SA group. Mean operation time was found 50.6±9.9 minute in SA group and 53.2±9.3 minute in GA group. The difference were not statistically significant (p>0.05) between two group. Ray and Bhattacharyya's study observed that 52 patients were females in SA group and 39 in GA group. The average age was 42.1 years in SA group and 40.2 years in GA group. Average operative time required in elective LC was 28.6 min in SA group and 32.6 min in GA group. Koju et al.[1] reported that he mean age was 44.6±12.73 years in SA group and 42.05±12.50 years in GA group. Majority (85%) patients were females in SA group and 52(86.67%) in GA group. Mean BMI was 23.31±1.19 kg/m^2 in SA group and 23.0±1.68 kg/m^2 in GA group. 56 patients were ASA score I in SA group and 57 in GA group. The difference were not statistically significant (p>0.05) between two group. Turkstani et al.[7] reported the mean BMI values were 25.38±5.2 kg/m^2 in SA and 26.03±2.22 kg/m^2 in GA groups respectively with no statistical difference (P>0.05).

This study showed the mean pain score at 2nd hour, at 8th hour, at 12th hour and at 24th hour were statistically significant (p<0.05) between two group.Khan et al.[5] reported the average time of first complaint of post operative pain in SA Group was 4 hours as compared to 30 minutes in GA Group. Similar to some comparative studies of SA vs. GA in Laparoscopic Cholecystectomy[8-10] postoperative pain was significantly reduced in SA group patients and first complaint of post operative pain was significantly prolonged as compared to GA group (4 hours versus 30 minutes, P=<0.0001). Ray and Bhattacharyya[6] study observed that the incidence of vomiting and pain treated with injectable analgesics or with oral drugs was significantly more in patients of GA groups than SA groups (P<0.01). Pursnani et al.[3] noted that shoulder and neck pain occurred in two of six patients operated under epidural anesthesia, and they were easily managed. On the contrary, in the series of Hamad et al.[11] of 310 LC performed under SA, only one patient had to be given GA because of intolerable shoulder pain. Koju et al.[1] reported there is significant mean difference in the post-operative pain scores 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. Majority (80.0%) patients treated with diclofenac sodium in SA group and 8(16.0%) in GA group. Mean pain free interval was 7.6±1.2 hour in SA group and 1.5±0.4 hour in SA group. The mean hospital stay was found 3.0±0.9 day in SA group and 3.7±0.8 day in SA group. Which were statistically significant (p<0.05) between two group.

In present study we observed majority (80.0%) patients were satisfied with diclofenac sodium in SA group nut only 8(16.0%) in GA group. Mean pain free interval was 7.6±1.2 hour in SA group and 1.5±0.4 hour in GA group. The mean hospital stay was found 3.0±0.9 day in SA group and 3.7±0.8 day in SA group. Which were statistically significant (p<0.05) between two group. Khan et al.[5] reported 79% of the SA Group patients remained satisfied with inj.

Diclofenac as compared to 17% in GA Group. Only 5% of the patients in SA Group suffered significant respiratory problems as compared to 11% of patients in GA Group. Average length of hospital stay as compared to GA group (2.5 days Vs 4 days, P<0.0001) which is in line with the study by Yousef and Lasheen[8] however, Tzovaras et al.[10] did not find any difference between two groups. Oral and teeth injury during laryngoscopy, sore throat and stomach inflation as a result of mask ventilation are other hazards that might also be avoided in a regional anesthetic setting.[12] Ray and Bhattacharyya[6] the mean hospital stay was found 1.9 day in SA group and 2.1 day in GA group. The difference was not statistically significant (p>0.05) between two group. Koju et al.[1] observed post-operative pain was minimal and easily treatable in SA group. It was treated with diclofenac sodium 75 mg IM in 54 patients (90%) and with tramadol 50 mg IV in 6 patients (10%) whereas in GA group 54 patients (90%) were treated with pethedine 50 mg IM + phenargan 25 mg IM and 6 patients (10%) were treated with tramadol 50 mg IV. Sore throat was not observed in any cases in SA group but was frequently observed in GA group, i.e, 35 patients (58.33%). There was, however, no respiratory depression in either group. The average duration of hospital stay in SA group was 3 days whereas in GA group it was 4 days.

In current study observed Vomiting, bradycardia, hypertension, dragging pain, difficulty in breathing, nausea and headache were not statistically significant (p>0.05) between two group. Ray and Bhattacharyya 14(20.89%) patients were hypertension in SA group and not found in GA group.[6] Five (7.46%) patients were headache in SA group and not found in GA group. Thus, although Hartmann et al.[13] reported hypotension in 5.4% of their SA patients, Palachewa et al.[14] found an incidence of 15.7%, Throngnumchai et al.[15] found an incidence of 20.2%, and Hyderally[16] reported an incidence of 10–40%. Khan et al.[5] reported one of the most important problems of open cholecystectomy under regional anesthesia is inadequate relaxation of abdominal musculature causing difficulties in performing the operation.[4] Similar to studies by Lee et al.[17] and Tzovaras et al.[10] on laparoscopic cholecystectomy, our surgical team was quite satisfied with the technique and claimed that the relaxation was sufficient enough to perform the operation.Koju et al.[1] observedpost-operative nausea and vomiting, observed in 10 patients (16.66%) in both SA and GA groups. Intra-operatively, bradycardia and hypotension were more common in the SA group. Bradycardia less than 50/ min in 10 patients (16.66%) were treated by atropine 0.3-0.6 mg IV. Bradycardia was the only feature noted in both groups where its relative risk for GA group compared to SA is 0.40 (95% CI = 0.133, 1.205).

Conclusion

Patients undergoing open cholecystectomy, spinal anaesthesia is safe and also more effective than general anesthesia in reducing post operative pain, analgesic requirement, respiratory problems and length of hospital stay.

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