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Effectiveness of Spinal Anaesthesia versus General Anaesthesia for Open Cholecystectomy

Koju RB,[1,2] Dongol Y,[3] Verma R[4]

[1]Department of Anaesthesia and Critical Care, KIST Medical College, Imadol, Lalitpur, [2]Department of Anaesthesia& Critical Care, Korea Nepal Friendship Hospital, Thimi, Bhaktapur, [3]Department of Biochemistry, KIST Medical College, Imadol, Lalitpur, [4]Department of Urology, National Academy of Medical Sciences, Bir Hospital, Kathmandu, Nepal.

ABSTRACT

Background: Cholecystectomy is performed either as an open or a laparascopic route. Despite of a number of peri-operative 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. Spinal anaesthesia, therefore, could be a safe and effective anaesthetic procedure over general anaesthesia for open cholecystectomy.

Methods: 120 patients with uncomplicated symptomatic gallstone disease undergoing open cholecystectomy and complying with ASA I or II physical status, aged between 18 and 70 years of either sex and BMI ≤ 30 kg/m2 were enrolled for the study. They were randomly categorized into SA group (received spinal anaesthesia) and GA group (received general anaesthesia), each group containing 60 patients. Intra-operative events and post-operative events were observed up to 48 hours post-surgery and compared between the groups. Data is in percentage and mean with standard deviation and median. Statistical analysis was done using independent t-test, chi-square test, relative risks and ANOVA.

Results: Spinal anaesthesia is safe and effective in pain management post open cholecystectomy. The median pain-free intervalin SA group was 8hours as compared to 1 hour in GA group. The average mean pain score was also significantly less in SA group than in GA group at all intervals of time observed. Majority (90%) in SA groups were managed with intramuscular diclofenacsodium whereas majority in GA group were managed with intramuscular pethedine. Intra-operatively, SA group had more cases of haemodynamic instability than GA group, which were easily managed in both the groups. The differences in the incidence of post-operative nausea and vomiting and the days of hospital stay between the groups were not significant.

Conclusions: Spinal anaesthesia is safe and more effective than general anaesthesia for uncomplicated open cholecystectomy in terms of peri-operative events and, in reducing post-operative pain, as well as in terms of surgeon's satisfaction as well.

Keywords: Cholelithiasis;general anaesthesia; open cholecystectomy; pain; spinal anaesthesia.

INTRODUCTION

Open and laparascopy are two approaches of performing cholecystectomy. Laparascopic cholecystectomy is a gold-standard procedure for it is less invasive than open cholecystectomy and associated with less post-operative pain, reduced hospital stay and earlier return to daily activities.[1] However, open cholecystectomy is frequently performed where there is lack of laparascopic equipments or expertise.[2] Both procedures have traditionally been performed under general anaesthesia (GA),a gold-standardan aesthetic 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.[1] Recently, different types of regional blocks[3,5-9] are recognized as an effective alternative to GA in laparoscopic cholecystectomy.

Spinal anaesthesia (SA) as a sole anaesthetic technique

Correspondence: Dr Ram Bhakta Koju, Department of Anaesthesia& Critical Care, KIST Medical College, Imadol, Lalitpur, Nepal. Email: dr.koju@gmail.com, Phone: +9779841113271.

was first used by Hamad et al for laparoscopic cholecystectomy.10 Various studies had shown its efficiency over GA.[3,5-9] Laparascopic procedures, compared to open procedures, are merely a change in access and require the same anaesthesia. Therefore, SA is expected to be equally effective in open cholecystectomy as in laparascopic approach. We, thus, 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

This randomized study was conducted in Korea-Nepal Friendship Hospital, Thimi, Bhaktapur, Nepal from 1st August 2010 to 14th July 14 2014. The study was conducted after receiving the approval from the hospital authority and receiving the written informed consent from the patients. Inclusion criteria included patients with uncomplicated symptomatic gallstone disease undergoing open cholecystectomy and complying with American Society of Anaesthesiologists (ASA) physical status I or II, aged between 18 and 70 years of either sex and body mass index (BMI) ≤ 30 kg/m2. The exclusion criteria were pancreatitis, contraindication of SA, hypersensitivity to bupivacaine and pethedine and severe cardiopulmonary disease for both SA and GA group. Similarly, the patients who refused to participate in the study were also excluded.

One hundred and twenty patients were randomly allocated into two groups—SA group (spinal anaesthesia group, n = 60) and GA group (general anaesthesia group, n =60). The sample size was determined using G*power 3.1.7 software and assuming the medium effect size of 0.5 to differentiate average pain free interval at 90% power and 5% level of significance.[11] SA group underwent open cholecystectomy under spinal anaesthesia whereas GA group proceeded it under general anaesthesia.

Pre-anaesthetic evaluation was done by an anesthesiologist and diazepam 5mg was given orally to all the patients to relieve anxiety on the night prior to surgery. Patients were made clear about the visual analogue scale (VAS: 0 = no pain, VAS: 1-3 = Mild Pain, VAS: 4-5 = Moderate Pain and VAS: 6-10 = severepain). During the pre-anaesthetic evaluation, patients were randomly assigned to either the SA group or GA group using the sealed-envelope/ lottery technique.

In the operation theater (OT)—afterpatient's arrival—non-invasive monitoring such as electrocardiogram (EGC), heart rate, blood pressure and pulse oximetry were established. Intravenous (IV) access was achieved with 18 gauge cannula and 500 ml of Ringer lactate solution was commenced. All the patients were pre-medicated with 4mg ondansetron IV for prevention of intra-operative nausea and vomiting and ceftriaxone 1gm IV to prevent infections. Patients randomized to SA group were injected with 4ml of 0.5% (20 mg) heavy bupivacaine +10mg pethedine at L3-4 or L4-5 intervertebral space under aseptic precaution in sitting position with 25gauge spinal needle. Then after, the patients were kept in Trendelenburg position for 3 minutes or till the level of sensory block of T4 was achieved, whichever occurred the first. The level of sensory block was assessed with a pin-prick stimulus every 30 seconds.

In GA group patients, induction was done with pethedine1mg/kg, propofol 2mg/kg and vecuronium 0.14mg/kg and maintained with hallothane and vecuronium throughout the whole surgical procedure. Haemodynamic parameters, ECG and SpO2 were monitored continuously in all the patients during the operation. Neuromuscular block was reversed with 2.5mg neostigmine and 1.2 mg atropine at the end of the surgery.

Intra-operative events were carefully observed and managed accordingly. Hypotension, defined as arterial pressure decreased by more than 20% below the pre-anaesthetic value, as well as bradycardia, defined as the heart rate of or less than 60/min was treated with mephenteramine6 – 12 mg IV and atropine0.3 – 0.6 mg IV, respectively. Intra-operative O2 supplement at a flow rate of5ltr/min via mask was administered when SpO2 was less than 90% in SA group. Intra-operative pain, i.e., complaint of dragging sensation, during intra-abdominal packing of was treated with 30mg ketamine IV and midazolam 2 mg IV in SA group. Ketamine IV 0.2-0.5 mg/kg body weight is a recommended analgesic dose. Post-operatively, all the patients in GA were provided with 4-5ltr/min of O2 whereas in SA group O2 supplement was provided only if the patient complained of difficulty in breathing or SpO2 was less than 90%. After completion of surgery, s/he was requested to rank the technical difficulty (1 to 10): 1 referring "no difficulty" and 10 "extremely difficult".

The primary outcome of the study was pain free interval and post-operative pain score which was assessed by using visual analog scale (VAS) at 1,2,4,8,12,16,24 and 48 hours after the completion of surgery. All the other outcomes such as hypotension, bradycardia, nausea etc were the secondary outcomes assessed in this study. Post-operative care was provided as per the institutional monitoring protocol. The standard post-operative

analgesic rescue protocol in our hospital includes the use of NSAIDs (diclofenac IM) for mild pain of grade 1-3 in VAS score, NSAIDs or an opioid (tramadol IV) for moderate pain of grade 4-5 in VAS score and strong opioids (pethedine and phenargan IM) for severe pain of grade 6-10 in VAS score. In this study, the post-operative rescue analgesics selected and used were diclofenac IM, tramadol IV and pethedine+ phenarganIM depending upon the pain VAS score reported by the patients.Intra-operatively, anaesthesiologist not involved in the study was involved in the patient care and assessment of the intra-operative events. Whereas post-operatively, resident doctors who were blinded observers were involved in the patient care and data collection in the format provided. All the patients in the SA group were catheterized with Foley catheter.

RESULTS

Out of the 120 patients, 60 in each group, there were 103 females (85.85%) and 17 males (14.17%). Their age ranged from 18 – 70 years, with a mean of 42.33 ± 12.63 years. There was no statistically significant difference between both the study groups regarding age, sex distribution, body mass index (BMI) and ASA physical status, as shown in table 1.

Table 1. Demographic characteristics of the patients (n = 120)

Variables	SA (n = 60)	GA (n = 60)	P-value
Age (years)			
Mean ± SD	44.60 ± 12.73	42.05 ± 12.50	0.27
Sex			
Male, n (%)	9 (15%)	8 (13.33%)	
Female, n (%)	51 (85%)	52 (86.67%)	0.79
BMI (kg/m²)			
Mean ± SD	23.31 ± 1.19	23.00 ± 1.68	0.247
ASA Status			
ASA I	56	57	1.0
ASA II	4		

There was 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 diaplayed 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 (Table 2).

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

Time (Hour)	SA [Median (Q1, Q3)]	GA [Median (Q1, Q3)]	P-value
1	0 (0,0)	4 (4,4)	<0.001
2	0 (0,0)	1 (1,2)	<0.001
4	0 (0,0)	2 (1,3)	<0.001
8	0 (0,0)	5 (3,5)	<0.001
12	1 (1,2)	3.5 (2,6)	<0.001
16	3 (2,4)	6 (4,7)	<0.001
24	3 (2,5)	4 (3,6)	0.006
48	2 (1,3)	3 (1.25,4)	0.051

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 (Table 3 and Figure 1). Figure 2 elucidates the larger area under curve (AUC) for pain in GA group than in SA group.

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. Post-operative nausea and vomiting, observed in 10 patients(16.66%) in both SA and GA groups, might be related to either surgical or anaesthetic procedure and was treated with ondansetron 4 mg IV. Post-dural puncture headache were observed in 7 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, 35 patients (58.33%). There was, however, no respiratory depression in either group. The post-operative events were tabulated in Table 4.

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 – 0.6mg 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). Similarly, hypotension in 15 patients (25%) in the SA group was treated by mephenteramine 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, 4patients (6.66%) with bradycardia less than 50/min during retraction and abdominal packing of tetra were treated by atropine 0.3 – 0.6mg IV and hypertension in 5patients (8.33%) were treated by esmolol 30mg IV.

Table 3. Pain scores at different time intervals in GA and SA group

Time (Hour)	Pain Score in SA				Pain Score in GA				P-value
	Minimum	Maximum	Mean	Std. Deviation	Minimum	Maximum	Mean	Std. Deviation	
1	0	1	0.02	0.13	3	4	3.83	0.38	<0.001
2	0	2	0.05	0.29	1	4	1.48	0.85	
8	0	3	0.30	0.74	2	5	4.03	1.18	
12	1	3	1.42	0.65	1	6	3.75	1.94	
24	1	5	3.32	1.35	0	7	4.22	2.00	

Table 4. Post-operative eventsin SA and GA group (n =120)

Variables	SA	GA
Median postoperative pain-free interval	8 hours	1 hour
Analgesic required		
Diclofenac sodium	54 (90%)	-
Tramadol	6 (10%)	6 (10%)
Pethedine + Phenargan	-	54 (90%)
PONV	10 (16.66%)	10 (16.66%)
Significant respiratory problem		
Sore throat	-	35 (58.33%)
Respiratory depression	-	-
Post-dural puncture headache	7 (11.66%)	-

Similarly, during operation in the SA group, 4 patients (6.66%) complained of dragging sensation during intra-abdominal packing of tetra and upward retraction towards diaphragm and liver retraction. It was relieved by removal of retraction and was treated with ketamine 30mg and midazolam 2 mg IV.

Table 5. Intraoperative events in SA and GA group (n=120)

Variables	SA (n = 60)	GA (n = 60)
Bradycardia*	10 (16.66%)	4 (6.66%)
Hypotension	15 (25%)	-
Hypertension	-	5 (8.33%)
Dragging pain	4 (6.66%)	-
Difficulty in breathing	2 (3.33%)	-
Nausea	4 (6.66%)	-

*Relative risk of bradycarida for GA compared to SA is 0.40 (95% CI = 0.133, 1.205)

Similarly, in SA group intra-operatively, difficulty in breathing was observed in 2patients (3.33%) and was treated by 4ltr/minute of O2 supplement by face mask. Nausea in 4patients (6.66%) observed were treated by 4mg ondansetron IV. There was no need of conversion from SA to GA. There was no operative technical difficulty. The average surgical duration was 1hour (ranged from 30minutes to 90minutes). The intra-operative events were tabulated in Table 5.The average duration of hospital stay in SA group was 3 days whereas in GA group it was 4days.

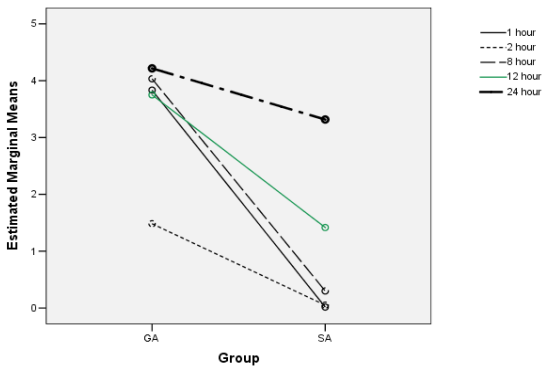

Figure 1. Average pain scores at different time intervals in both groups

Patients' level of satisfaction over GA or SA could not be compared for few reasons. Firstly, many of them had no previous experience of either GA or SA. Secondly, those who had undergone some form of surgery before had either experienced the same form of anaesthesia (GA only or SA only) or they do not remember enough, if they had experienced both form of anaesthesia, to make a comparison. Almost all the response from these patients was "I don't know".However, surgeons were quite satisfied with the SA approach in open cholecystectomy.

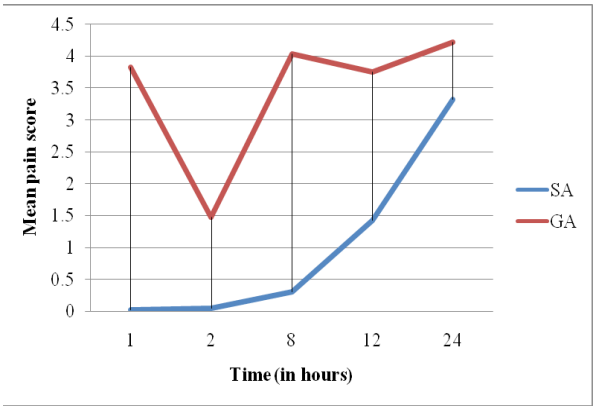

Figure 2. Pain curve for SA and GA group at different time

DISCUSSION

Despite of the feasibility and popularity of laparoscopic cholecystectomy, open cholecystectomy is still in practice in places where required technologies and expertise for laparoscopic cholecystectomy are limited or unavailable.[2]For open cholecystectomy, anaesthesiologists now have the choice of GA and SA, despite of the common practice of GA due to its major advantage, i.e., adequate muscle relaxation for surgery.[1] Spinal anaesthesia though provide inadequate muscle relaxation which might cause difficulties in surgery,[1] it has an advantage over GA for it can be safely used in patients with cardio-respiratory co-morbid conditions.[3, 5-9]

In this study, we observed that 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. The major analgesia used for SA group was intramuscular diclofenacsodium which is a non-steroidal anti-inflammatory drug and few patients were managed with tramadol, an opioid. Instead, in GA group, the opioids were used in all of the patients to manage the pain. Few were managed with tramadol and majority was managed with pethedine (an opioid) and phenargan (an antihistamine). Such prolonged pain-free interval and requirement of lesser opioids in SA group may be attributable 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 associated with spinal anaesthesia. Besides, the confidence gained and high pain threshold attained by the patients during this pain-free interval also contributed towards the patient satisfaction in pain management with simple analgesics.[1]

The primary outcome of our study was comparable to Khan et al where they also reported longer average pain-free intervalin SA group than in GA group. As in our study, they also managed majority of the patients in SA group by diclofenac sodium. However, majority of the patients in GA group in our study was managed with pethedine (an opioid), whereas Khan et al managed them with ketorolac, an NSAID more potent than diclofenac.[1]

PONV was equally prevalent in both the groups with lesser frequency (16.66%), probably due to prophylactic administration of ondansetron. It was reported that 50-70% of patients under GA suffer from PONV, especially in laparoscopic cholecystectomy.[12,13]

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 managed with analgesic dose of ketamine and midazolam and gentle retraction of liver. Similarly, 2 patients in SA group complained of difficulty in breathing due to surgical manipulation during upward retraction and tetra packing which was tackled easily with O2 supplement.

Intra-operative haemodynamic changes in SA group observed was mainly hypotension and bradycardia which was managed with mephenteramineIV and atropine IV respectively. However, 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 difficult, however, to assess the difference of the patient's satisfaction over GA and SAfor various obvious reasons.

CONCLUSIONS

Despite the traditional use of general anaesthesia in open cholecystectomy, this study shows that spinal anaesthesia is also a recommended alternative. It is safe

and more effective than general anaesthesia in providing longer post-operative pain-free interval, less analgesic/ opioid requirement and none respiratory problems.

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