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Research Article

COMPARISON OF EFFICACY AND SAFETY OF ISOBARIC LEVOBUPIVACAINE WITH HYPERBARIC BUPIVACAINE FOR EXPLORATORY APPENDICECTOMY UNDER SUBARACHNOID BLOCK WITH DEXMEDETOMIDINE AS SEDATIVE AGENT "AN OBSERVATIONAL STUDY"

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Background: Appendectomy in past was performed under general anaesthesia, in recent years there has been growing emphasis on the role of regional anaesthesia especially spinal anaesthesia. Bupivacaine is available in isobaric and hyperbaric forms for intrathecal use with addition of opoids to modify their effects.
Methods: Patients were divided into two groups. Group I recieved spinal anaesthesia with 3ml of 0.5% isobaric levobupivacaine plus 20mcg of fentanyl and group II with 3ml of 0.5% hyberbaric bupivacaine plus 20mcg of fentanyl and i.v dexmedetomidine started in both groups. Quality of anaesthesia, sensory and motor blockade characteristics, haemodynamics, sedation score and side effects were compared.
Results: The quality of anaesthesia was compared in both groups. The mean onset of sensory and motor block was faster and duration was significantly longer in group II. Side effects and haemodynamics were better in group I and side effects were comparable.
Conclusion: Both isobaric levobupivacaine and hyberbaric bupivacaine provide adequate spinal block. Levobupivacaine enables quicker recovery and better haemodynamic stability as compared with hyberbaric bupivacaine, while later is better for prolonged surgeries.

INTRODUCTION

The subarachnoid block is a widely used regional anaesthetic technique, particularly advantageous for lower abdominal surgeries including open appendicectomy. Regional anaesthesia is popular and offers several benefits to the patients. The top three from the patient's point of view are staying awake, early family contact and early food intake[1].For the anesthesiologist, cardiovascular and respiratory stability, rapid postoperative recovery and preservation of protective airway reflexes are the most advantages of regional anaesthesia[2].Some drawbacks are linked with regional anaesthesia techniques: pain at the puncture site[3], fear of needles and recall of procedure[4].These factors stress the importance of sedation that offers analgesia, anxiolysis and amnesia.

Administering sedation to local procedures for diagnostic and treatment purposes is recommended both to facilitate surgery at the surgeon's end and to ensure the patient's comfort[5].Sedation is a part of the general management of a patient receiving a regional block and being awake during the whole surgical procedure.

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The aims include general patient comfort, freedom from specific discomfort, and some amnesia for both the block procedure and the surgical operation, to meet the patient's preference and safety. The level of sensory blockade is required at T8 dermatome for the Appendicectomy procedure and duration of the procedures ranged between 45 and 60 min. The principal determinants of the extension and duration of the anaesthetic block depend on the type and concentration of the local anaesthetic used[6].For the selection of the local anaesthetic, it is known that the agent's onset and duration of action, sensory block level to motor block level and cardiac toxicity should be considered[7-11].The control of the spread of the drug in the cerebrospinal fluid that produces predictable levels of sensorimotor blockade without any major complication is the prime challenge in spinal anaesthesia[12].

Hyperbaric solutions tend to produce predictable sensory blockade and a higher level of a blockade than the plain solution. Isobaric solution of drugs often has variability with regard to onset, spread and duration of sensory and motor blockade in spinal anaesthesia[11]. But the use of truly isobaric solutions is less sensitive to changes in position and do not produce higher levels of the sympathetic blockade that result in severe hypotension or bradycardia[13].Traditionally, bupivacaine has emerged as the most commonly used drug for spinal anaesthesia. However, since it has undesirable effects

such as hypotension, bradycardia, prolonged duration of motor paralysis, cardiotoxicity and central nervous system toxicity[14-17] there led to the identification of levobupivacaine, S (-) enantiomer of racemic bupivacaine. Levobupivacaine has similar efficacy but an enhanced safety profile when compared to bupivacaine, a major advantage in regional anaesthesia[18,19].
METHODS This study was carried out in a territiary care hospital. After obtaining institutional ethical committee approval and written informed consent from study subjects, 100 adult patients of age group 18-45 years, of either sex, belonging to American Society of Anesthesiologists physical Status (ASAPS) IE & IIE, undergoing emergency exploratory appendicectomy under spinal anaesthesia were included in the study. Patients were divided into two groups, based on computerised generated random numbers. GROUP Icomprise of 50 patients and patients in this group received 0.5% isobaric levobupivacaine 3ml with 20µg fentanyl intrathecally. GROUPII also comprise of 50 patients who received hyperbaric bupivacaine 0.5% 3ml with 20µg fentanyl intrathecally

Those with contraindications to spinal anaesthesia. pregnant and lactating women, history of liver disease., history of renal disease, history of allergy to local anaesthetics, ASA III or above, history of bradyarrhythmia, recent administration of sedative drugs or alpha-adrenergic antagonist, perforated appendicitis were excluded from study.

Spinal anaesthesia was given in sitting position with 3 ml 0f 0.5% hyperbaric bupivacaine and 25 mcg fentanyl using 27G Quinke needle. The sensory block was assessed by ice-cold test and motor block by the Modified Bromage scale79 : 0- No paralysis. 1- Unable to raise the extended leg. 2- Unable to flex the knee. 3- Unable to flex the ankle

Time to achieve the maximum level of block and duration was noted. After assessing subarachnoid block, dexmedetomidine loading 1µg/kg over 10 minutes followed by maintainance of 0.2- 0.6 µg/kg/hr was infused[32].The level of sedation was assessed using sedation score described by Chermik and Gillings[33] Grade 0=Wide awake. Grade 1=Calm and comfortable, responding to verbal commands. Grade 2=Sleeping but arousable. Grade 3=Deep sleep, but not arousable.

Patients feeling uncomfortable and interfering the surgical procedure were excluded from the study and were given general anaesthesia.Vitals including heart rate (beats/min), blood pressure (mmHg) and SPO2 were monitored and recorded at 10-minute intervals till end of surgery. Also, any side effects like hypotension, bradycardia, nausea vomiting,etc. were noted. The following variables were recorded in group I and II : 1. Time of onset and duration of sensory block. 2. Time of onset and duration of motor block. 3. Haemodynamic parameters (Heart rate, systolic, diastolic and mean arterial pressure), SpO2, Respiratory rate. 4. Level of sedation as assessed by Sedation score (Chermik and Gilling's sedation score). 5. Duration of postoperative analgesia. 6. Side effects, if any. In the postoperative period, the time to first analgesic demand was noted when VAS will be ≥ 4 and intravenous tramadol in 100ml normal saline with ondansetron (4mg i.v) was administered.

Descriptive statistics (mean +/-, median, a number [%]) and comparison between nominal data were done using independent T-test. Comparison between categorical data was done using chi-square test. Data were considered significant if P- value less than 0.05. . Statistical analysis was performed with the aid of SPSS Package (version 23).

RESULTS

Demographics and Vital Signs The groups were comparable with respect to age gender weight and asa status (table 1)

characteristics	Group I	Group II	P value
Age (mean±SD)	33.2±7.82 (19-45)	34.1±7.21 (18-45)	0.569
Gender (male:female)	27:23	29:21	0.687
Weight (mean±SD)	63.2±3.59(55-70)	64.7±4.47(52-75)	0.061
ASA (ASA I:ASA II)	43:7	45:5	0.538

There was no significant differences between two groups with respect to baseline vitals (heart rate, MAP, o_2 saturation, R/R) as shown in table 2

vitals	Group I	GroupII	p-value
HR/min	92.58±8.43	90.31±9.64	0.207
MAP(mmHg)	93.33±7.37	94.32±6.89	0.250
SPo2(%)	96±1.25	95.74±1.26	0.302
R/R(Breaths per min)	16.10±1.30	15.88±1.30	0.401

Characteristics of sensory and motor block

characteristics	Group I	Group II	P-value
Onset of sensory block(in min)	5.4±0.812	3.2±0.896	<0.001
Median level of sensory block	T8(T8-T10)	T6(T6-T10)	<0.001
Duration of sensory block(in min)	167±9.865	219±11.04	<0.001
Onset of motor block(in min)	7.6±0.907	4.5±0.952	<0.001
Duration of motor block(in min)	197.2±11.024	234.1±12.429	<0.001
Duration of analgesia(in min)	223.1±11.21	267.1±12.62	<0.001

Table 3 The mean onset of sensory block in group I is 5.4 min with a standard deviation of 0.812 andin group II the mean onset of sensory block is 3.2 min with a standard deviation of 0.896. The results are statistically significant with respect to the onset of the sensory block which is faster in group II as compared to group I (pvalue <0.0001) as shown in table 3

Sensory block of T6 was achieved by none in group I and 35 patients in group II. A Sensory block of T8 was achieved by 41 patients in group I and 13 patients in group II. Sensory block of T10 was achieved by 9 patients in group I and 2 patients in group II. On statistical comparison, the difference in level of sensory block achieved between two groups was statistically significant (p-value< 0.001) with more patients in group II achieving T6 level of sensory block and in group I achieving T8 level of block(table 3)

The mean duration of sensory block in group I was 167.7 mins with a standard deviation of 9.856 and in group II the mean duration of sensory block was 219.3 mins with a standard deviation of 11.041. The results are statistically significant for the duration of sensory block, that is prolonged in group II as compared to group I (p-value< 0.001) as shown in table 3

The mean onset of motor block in group I was 7.6 min with a standard deviation of 0.907 and in group II was 4.5 min with a standard deviation of 0.952. The difference in mean onset of motor block between two study groups was statistically significant (p-value<0.001), with an earlier onset of motor block in group 2(table 3). A motor block (Bromage scale) of Grade I was achieved by 21 patients in group I and none in group II. Motor block of Grade II was achieved by 29 patients in group I and 3 patients in group II and motor block of Grade III was achieved by none in group I and 47 patients in group II. The difference in the level of motor block achieved between

two study groups was statistically significant (p value <0.001), with patients in group II achieving a higher grade of the motor block as compared to patients in group I. The mean duration of motor block in group I was 197.2 min with a standard deviation of 11.024 and in group, II was 234.7 min with a standard deviation of 12.429. The difference in the mean duration of the motor block between two groups was statistically significant (pvalue < 0.001) with a longer duration of motor block in group II(table 3).

The mean duration of first postoperative analgesia in group I was 223.1 min with a standard deviation of 11.21 and in group, II was 267.9 min with a standard deviation of 12.62. The difference between the mean duration of first postoperative analgesia between the two study groups was statistically significant (p-value < 0.001)), showing late demand of first postoperative analgesia in group II as compared to group I.

Baseline mean MAP (mm Hg) was comparable between the two groups with value of 99.20±6.10 in group I and 97.72±6.02 in group II (p-value -0.224). A statistically significant difference was seen in mean MAP between the two groups after injecting the drug at 10 mins (p-value=0.023), 20 min (p-value=0.011), 30 min (p- value=0.037) and 40 min (p-value=0.024) with lower mean MAP in group II as compared to group I. At 50 min after injecting the drug, a lower MAP was observed in group II than group I, but the difference was not significant statistically (p-value=0.269). At 60 min after injecting the drug MAP was comparable between the two groups (p- value=0.951).

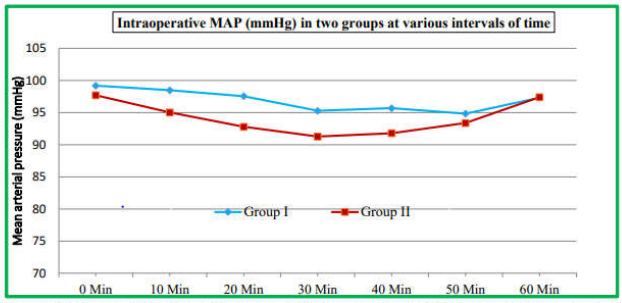

Figure-15:Line diagram showing intra-operative MAP in two groups at various time intervals.

The intra operative heart rate,0_2 saturation and R/R were statistically insignificant(p value>0.5) at all time intervals. Intra-operative level of sedation was assessed using Chermick and Gilling's sedation score. There was no statistically significant difference between the two study groups, with respect to sedation score (p-value>0.05) at various study stages.

Side effects

Side effects	Group I	Group II	P value
nausea	3	4	0.695
vomitting	0	1	1.000
Dry mouth	0	0	-
hypotension	1	8	0.036
bradycardia	2	3	0.646

Table 4

The difference between the two groups for nausea, vomiting, dry mouth and bradycardia was statistically insignificant (p-value>0.05). There was a statistically significant difference for hypotension between the two groups (p-value=0.036) with the higher number of patients experiencing hypotension in group II (8) as compared to group I (1).

DISCUSSION

Our study was conducted in the Department of Anaesthesia and Critical Care SKIMS to compare the efficacy and safety of isobaric levobupivacaine with hyperbaric bupivacaine for exploratory appendicectomy under the subarachnoid block with dexmedetomidine as a sedative agent. The primary goals of our study were to compare the characteristics of motor block, characteristics of sensory blockade, compare the hemodynamic stability, sedation score and side effect profile between the isobaric levobupivacaine (with iv dexmedetomidine) and hyperbaric bupivacaine (with iv dexmedetomidine) after spinal anaesthesia in exploratory appendicectomy patients.The groups were comparable with respect to demographic data(age gender weight),ASA status and baseline parameters(table 1 and 2).Our results are in concordance with the study conducted by Helmi M. *et al*[26](2014), Upadya M *et al*[29] (2016), Sahin A *et al*[25] (2013), Luck J. F *et al*[22] (2008), Erbay H *et al*[23] (2010) who in their studies observed a comparable demographic data as in our study.

The mean onset of sensory block (in min) was faster in group II (Hyperbaric bupivacaine) as compared to group I (isobaric levobupivacaine) with values of 5.4±0.812 in group I and 3.2±0.896 in group II (p- value<0.001) as shown in table 3. This finding is in concordance with the studies conducted by Sajjan A. *et al*[31] (2019), Upadya M *et al*[29] (2016), Chen C.K *et al*[28] (2015), Goyal A *et al*[27] (2015) who in their studies observed earlier onset of sensory block with hyperbaric bupivacaine plus fentanyl as compared to isobaric bupivacaine plus fentanyl for spinal anaesthesia as in our study. In a study by Glaser C *et al*[20] observed that there was no significant difference between the onset of the sensory block between two groups. The contradiction may be explained by baricity of drug used as they have chosen isobaric drugs in both the groups and in our study we have chosen both isobaric and hyperbaric drugs. There is also a difference in the dosage of drug given: 3.5ml of drug used and in our study 3ml was used. In our study, there was a statistically significant difference between the two groups (p value < 0.001)) in terms of the level of sensory block achieved, with more number of patients achieving T6 in group II and T8 and T10 in group I(table 3). In studies done by Upadya M *et al.*[29](2016), Sannanslip V *et al*[34] (2012) observed a higher level of sensory block in the hyperbaric group as compared to isobaric group as in our study. In a retrospective cohort study conducted by Chen C.K *et al*[28] (2016) the maximum level of sensory block in hyperbaric bupivacaine group was T6 which is the same as in our study. However, the maximum level of sensory block in isobaric levobupivacaine group was also T6. This could be because the mean volume of levobupivacaine administered was 5.8ml in their study and our study the volume of levobupivacaine used was 3ml. Şahin *et al*[25](2014) reported a lower block height with the use of plain bupivacaine compared with levobupivacaine which is in contradiction to our study. Their study was performed in patients undergoing lumbar disc surgery in the prone position. This change in patient position may have resulted in unequal spread of the two study drugs. Mantouvalou M *et al*[35] (2018) compared the anaesthetic efficacy and safety of three local anaesthetic agents: racemic bupivacaine and its two isomers: ropivacaine and levobupivacaine, in patients undergoing lower abdominal surgery and found no difference in the upper extend of sensory

block among the three groups (P> 0.05). This different finding from our study may be explained by the use of plain levobupivacaine in their study, whereas in our study isobaric levobupivacaine was used. The mean duration of sensory block (in min) in group I was 167.7±9.856 and in group, II was 219.3±11.04. The results were statistically significant (p value<0.001) in terms of duration of sensory block, which was prolonged in group II as compared to group I.The mean onset of motor block (in min) in group I was 7.6± 0.907 and in group, II was 4.5± 0.952. The results were statistically significant (p value<0.001) with a faster onset of motor block in group II (hyperbaric bupivacaine) as compared to group I (Isobaric levobupivacaine).. In a study done by Lacassie HJ *et al*[36] (2003), it was observed that the relative motor-blocking potency was significantly higher for bupivacaine (P = 0.024). This also corroborates our results. The mean duration (in min) of motor block was significantly prolonged in group II (hyperbaric bupivacaine) as compared to group I (isobaric levobupivacaine) (197.2 ±11.024 in group I and 234.7 ±12.429 in group II) (p value<0.001). The results are in concordance with the studies by Sajjan A *et al*[31] (2019), Goyal A *et al*[27] (2015), Singh A *et al*[30](2018), Upadya M *et al*[29] (2016), Gautier P *et al*[21](2003), Sahin A *et al*[25] (2012) who in their studies observed that duration of motor block was longer in hyperbaric bupivacaine group than isobaric group as in our study.

In a study by Upadya M *et al*[29] (2020), Goyal A *et al*[27] (2015) and Erdil F *et al*[37](2009) observed that the mean HR was similar in the two groups (p value>0.05) as in our study. Also in the bupivacaine group, MAP values were significantly lower than in the levobupivacaine group, starting from 10 min until 30min after spinal anaesthesia (p value<0.05). Sajjan A *et al*[31] (2019) in their study observed that isobaric bupivacainefentanyl mixture was associated with better hemodynamic stability as compared with the hyperbaric bupivacaine-fentanyl mixture. The mean duration (in min) of first postoperative analgesia in group I was 223.1 ±11.21 and in group, II was 267.9 ±12.62. The difference between two groups was statistically significant (p value<0.001) in terms of analgesia demand which was earlier in group I (isobaric levobupivacaine) as compared to group II (hyperbaric bupivacaine).Similar results were obtained by Compagna R *et al*[24] (2012), Gautier P *et al*[21] (2003), Goyal A *et al*[27] (2015). Our results are in concordance with Chen C K *et al* (2016)[28], Singh A *et al* (2017)[30] , Upadya M *et al* (2020)[29], Sajjan A *et al* (2019)[31], Goyal A *et al* (2015)[27] who in their studies observed that incidence of hypotension was higher in bupivacaine group. Hence in our study, better hemodynamic stability was observed with the use of isobaric levobupivacaine.

CONCLUSION

Thus, we conclude that 0.5% both isobaric levobupivacaine with fentanyl and 0.5% hyperbaric bupivacaine plus fentanyl provide adequate spinal block for exploratory appendicectomy, with intravenous dexmedetomidine as the sedative agent. Isobaric levobupivacaine can be used for daycare surgeries with early ambulation and faster home discharges, while hyperbaric bupivacaine is better for surgeries who need prolonged duration of spinal anaesthesia. Relatively stable intraoperative hemodynamic profile observed with isobaric levobupivacaine makes it a suitable choice for patients who cannot tolerate significant hemodynamic alterations like patients suffering from cardiac disease.

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