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RESEARCH ARTICLE

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SPINAL ANESTHESIA USING LOW CONCENTRATION HYPOBARIC BUPIVACAINE FOR ANORECTAL SURGERY. A RANDOMIZED CONTROLLED TRIAL.

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ABSTRACT

Background: To study the efficacy of spinal analgesia with low concentration bupivacaine for anorectal surgery as compared to low dose bupivacaine epidural analgesia.
Methods: This randomized control study was conducted on 60 adult patients undergoing elective anorectal surgery. The patients were randomly allocated into one of three groups of 20 patient's each. The two treatment arms received spinal analgesia with 0.1% bupivacaine or 0.083% bupivacaine, respectively whereas the control arm received epidural analgesia with 0.375% bupivacaine. The primary outcome measure monitored was preservation of sphincter tone. A number of other variables were monitored including: time taken to perform spinal or epidural analgesia; onset time of the sensory block and upper level of the sensory block; extent of motor block; and adequacy of analgesia. Complications during the intraoperative period and during the first 24 hours post-operatively were also recorded. Comparison of the outcome variables in the three groups was made using appropriate statistical analysis.
Results: Sphincter tone was preserved in19 patients in group 2 compared to 15 in group1 and 11 in group 3. All patients in groups 1 and 2 had adequate intraoperative analgesia whereas 4 in group 3 needed supplementation with general anesthesia through mask. The time taken to perform the spinal procedure is shorter than the epidural procedure and the onset time of the sensory blockade for the spinal groups was shorter than the epidural group. No major complications were observed in any group.
Conclusions: Low concentration spinal analgesia using 0.1% or 0.083% bupivacaine provides selective sensory blockade with good preservation of sphincter tone and is a good alternative to low dose bupivacaine 0.375% epidural analgesia for the anorectal surgeries.

KEYWORDS

Hypobaric bupivacaine, anorectal surgery, spinal anesthesia

INTRODUCTION

Surgery of the anal canal, such as for anal fistulae and anal fissures that pathologically involves anal sphincters, is quite common. Preservation of the anal sphincter tone is considered essential to successfully perform a complete fistulectomy or fissurectomy[1]. Though general anesthesia may be used for anorectal surgery, it may be contraindicated in some patients, such as those with cardiovascular instability or respiratory compromise. Also, the need to maintain the sphincter tone may lead to the patient being maintained in a 'light' plane of anesthesia resulting in complications such as laryngospasm during manipulations in the anal canal[2].

Regional anesthesia is safer, and cheaper than general anesthesia. However, with conventional spinal anesthesia the pelvic floor and sphincter become totally relaxed and the surgeon is unable to assess the sphincter tone or the extent of the pathology in relation to the sphincters. Probing and incising without feeling the tight sphincter may either lead to inadequate surgery[3] or traumatic damage to the puborectalis muscle and external anal sphincter[4]. Kausalya and Jacob have suggested using a low dose of epidural bupivacaine, which will preserve the sphincter tone by producing selective sensory blockade of the desired segments[5]. However, in their study, 20% of patients who received 0.375% epidural bupivacaine had either reduced or absent sphincter tone. Other studies have showed that hypobaric spinal anesthetic with 5ml, bupivacaine 0.1% was effective and safe for anorectal surgery with well preserved motor power[6]. Given the success with the use of low concentration bupivacaine spinal anesthesia, we decided to repeat the study comparing low dose hypobaric bupivacaine (0.1%) with low dose epidural bupivacaine (0.375%), and also assess whether an ever lower concentration of bupivacaine (0.083%) would lead to better preservation of the sphincter tone while providing adequate analgesia.

MATERIALS AND METHODS

This randomized controlled study was conducted on 60 adult patients after receiving the approval from the research and ethics committee of the Christian Medical College, Vellore.

Adult (>18 years of age) male patients undergoing elective anorectal surgery in lithotomy position in whom preservation of the anal sphincter tone during surgery was considered necessary were included in the study after obtaining informed, written consent. Only patients belonging to ASA grade 1 and 2 who were fit to undergo either spinal or epidural analgesia were included. Patients belonging to ASA grades 3,4 and 5, female patients or those with anomalies of the spine, infection or surgical scar in the lumbar region were excluded.

All patients were seen by the anesthetist on the day before surgery when the procedure was explained and informed consent was obtained. On the day of operation, all patients received a premedication of diazepam (0.2mg/kg) orally, approximately 60 to 90 minutes before the scheduled operation.

A pilot study was conducted in seven patients to obtain an estimate of the proportion of patients who had normal sphincter tone with spinal analgesia using 0.1% and 0.083% bupivacaine, respectively. These estimates were used for the calculation of sample size for the larger study. The patients were randomly

allocated into one of three groups, using a randomization table prepared by the statistician. Each group consisted of 20 patients. Group 1 received spinal analgesia with 0.1% bupivacaine; group 2 received spinal analgesia with 0.083% bupivacaine; group 3 received epidural analgesia with 0.375% bupivacaine.

On arrival at the operating room, an intravenous line was started with a #18g or #16g cannula for infusion of crystalloid. Electrocardiographic monitoring was done continuously. Arterial pressure using non-invasive blood pressure cuff and oxygen saturation using a pulse oximeter was monitored during the perioperative period. In groups 1 and 2, the patients were positioned in the lateral position with head down tilt of 20^0. Dural puncture was performed under strict aseptic condition using a #25G disposable Quincke spinal needle at the L3-4 interspace. 5 ml bupivacaine, 0.1% (group 1) or bupivacaine, 0.083% (group 2) was given into the subarachnoid space. After the injection of the solution into the subarachnoid space the patients were turned to the supine position. The low concentration solutions were prepared diluting 1ml 0.5 % bupivacaine with 4 ml (for 0.1%) or 5 ml (for 0.083%) distilled water in the OR prior to the administration. The specific gravity of 0.1% bupivacaine and of 0.083% bupivacaine was found to be 1.0055 and 1.0042, respectively. The baricity of 0.1% bupivacaine and 0.083% bupivacaine were estimated to be, 0.9986 and 0.9973, respectively. Therefore, 0.1%bupivacaine and 0.083% bupivacaine are hypobaric.[7,8]

In group 3, the patients were positioned in the lateral position with their hips flexed, and the operating table in neutral position. Under strict aseptic conditions the skin and subcutaneous tissue are infiltrated at the L3-4 or L4-5 interspace using 2% lidocaine solution. Following this, bupivacaine 0.375% was injected into the epidural space by using the Tuohy needle with the aid of the "loss of resistance" technique. The 0.375% bupivacaine was prepared by adding 4 ml of normal saline to 12 ml of 0.5% bupivacaine. The volume injected was: 12 ml for patients weighing less than 40 kg, 14 ml for those 40-60 kg and 16 ml for those over 60 kg. [5].

All the three groups of patient were monitored intraoperatively by the senior anesthetist who was blinded to the group 1 and group 2, but aware of who received epidural anesthesia. The surgeons were blinded to the anesthetic technique in all the three groups.

The primary outcome variable was preservation of sphincter tone during surgery. The other outcome variables monitored included: 1) time taken to perform the spinal or epidural analgesia; .2) onset time of the sensory block and upper level of the sensory block; 3) extent of motor block, measured at 1 minute intervals for the first 5 minutes, then every 5 minutes for 30 minutes using Bromage scale;[9].4) time of the bupivacaine injection to the start of surgical procedure and the duration of the surgery; 5) adequacy (assessed as adequate or inadequate) of analgesia for the surgical procedure, determined during the first forced manipulation by the surgeon; 6) drugs or supplementary anesthetics given during the procedure; 7) complications such as bradycardia (heart rate < 55/ minute, hypotension (systolic blood pressure < 20% of the base line value), shivering, nausea or vomiting were recorded; 8) complications during the first 24 hours post-operatively, specifically leg pain, headache, neurological deficit and urinary retention.

STATISTICAL ANALYSIS:

Assuming that sphincter tone is preserved in 100% of patients receiving spinal analgesia with 0.083% bupivacaine, to measure a 50% or higher difference in the proportion of patients with a preserved sphincter tone, an alpha error of 50% and beta error of 25%, a sample size of twenty patients was required in each arm.

The different independent variables of interest were compared between the three

groups using Pearson's Chi square test for categorical variables. After checking the normality in the continuous variables, one way analysis of variables (ANOVA) was applied to assess the statistical significance of the observed differences. Further, the variables that showed a statistically significant difference at 5% level, the Bonferroni correction for multiple comparisons was applied. The SPSS PC+ version 6.0 for windows was used for statistical analysis.

RESULTS

The age and weight distribution of the patient belonging to the three groups in this study are shown in Table-1 and did not differ significantly between the 3 groups. The surgical procedure performed was lay-open fistula in 18, 13 and 16 patients in groups 1, 2, and 3, respectively and lateral anal sphincterotomy in 2, 7, and 4 patients in groups 1, 2 and 3, respectively.

Table 1
Age and Weight distribution of patients.

Variable	Group 1	Group 2	Group 3	P
Age in Years	37.45 (7.69) 25-55	42.20(10.01) 20 -62	40.60 (10.29) 28 -65	0.27
Weight in Kg	62.30 (11.63) 41 - 92	66.75 (14.90) 39 - 90	61.18 (12.33) 41 - 86	0.36

All the values are represented in Mean (SD) and Range.

Sphincter tone was assessed during surgery by the senior surgeon, who was blinded to the anesthetic procedure being used, using digital examination. The number of patients who retained normal sphincter tone was highest in group 2 (19/20, 95%) as compared to 15/20 (75%) in group 1, 11/20 (55%) in group 3.There was a statistically significant difference between the proportion of patients with preserved anal sphincter tone in group 2 and group 3 (p=0.01). Though a higher proportion of patients in group 1(P=0.31) had preserved sphincter tone as compared to group 3(P=0.18), the difference did not reach statistical significance, presumably because the study lacked sufficient power.

The time taken to perform the blocks and the time of onset, upper level of sensory blockade was statistically significantly shorter for groups 1 and 2, compared to group 3 (Table 2). The median (range) upper level of sensory blockade was T11 (L1-T8), T11 (T12-T6) and T10 (L1-T8), respectively in groups 1, 2 and 3. Motor blockade (Bromage score grade 1 and above) was observed in 1 (5%) and 6 (30%) of patients in groups 1 and 3 respectively, but none of the patients in group 2. There was a statistically significant difference in frequency of motor blockade between patients in group 2 and 3 (p=0.0066), though not between groups 1 and 3 (p=0.09).

Table 2
Time (minutes) taken to perform the block and onset of sensory blockade in the groups.

Variables	Group 1 Mean (SD)	Group 2 Mean (SD)	Group 3 Mean (SD)	P
Time to perform block.	2.68 (1.98)	2.35 (1.39)	5.60 (3.07)	0.000
Onset of sensory block.	3.30 (2.41)	3.45 (2.61)	12.95 (5.83)	0.000

All the values are represented in Mean (SD) .
Note: Bonferroni adjustment shows Group 1 Vs Group 3 P < 0.05. Group 2 Vs Group 3 P < 0.05.

The time from the commencement of anesthetic to the start of the surgical procedure was noted in all three groups, to see if there were any differences in between the three groups. The mean (standard deviation) values of anesthesia surgery interval in minutes for all the three groups are 15.80 (5.74), 17.5 (4.96), 23 (6.19) respectively. Anesthesia to surgery interval differed significantly between the groups. An overall statistical difference (P=0.00) was found between the three groups in anesthesia surgery interval. The Bonferroni multiple comparison test showed difference between group 1 and group 3 (P<0.05), and group 2 and group 3 (P<0.05).

In group 1 and group 2 all patients (100%) had adequate intraoperative analgesia. In group 3, four of the 20 patients (20%) had inadequate analgesia. These four patients required supplementation with general anesthesia with mask. None of the patients required endotracheal intubation. One patient each in groups 1 and 2 had sinus bradycardia. In group 3 none of the patients had bradycardia. One patient in group 1 had hypotension (BP 93/67 mm Hg) 30 minutes following spinal anesthesia which responded to intravenous fluid administration and did not require treatment with vasoactive drugs. One patient in group 1, three patients in group 2 and two patients in group 3 had shivering. All 7 patients were treated with intravenous injection of pethidine. None of the patients in any of the groups had nausea or vomiting. In all three groups none of the patients had urinary retention in the postoperative period. One patient in each of the group 2 and group 3 complained of mild leg pain postoperatively. One patient in each of the group 1 and group 2 complained of headache. Headache was not postural in nature and neither required further treatment. None of the patient in the three groups had neurological deficit in the post operative period.

DISCUSSION

The main finding of our study was that the sphincter tone was preserved in a higher proportion of patients who received spinal analgesia with 0.083% bupivacaine, as compared to the other two groups, though the difference between groups 1 and 2 was not statistically significant, probably as a result of inadequate statistical power. The only patient in group 2 who had reduced sphincter tone had a previous fistulectomy; it is possible that sphincter damage during that procedure nine years ago may have accounted for the lack of sphincter tone in this patient. In group 3, nine patients (45%) had reduced sphincter tone; of these, in four patients the reduced sphincter tone could be attributed to the general anesthetic supplement and the other five patients due to the epidural block itself. While more sophisticated methods for quantitating the tone of the anal sphincter, such as the manometric method, are available, Hallan et al., have shown that digital estimation was

equally as good an assessment of anal sphincter function as anal canal manometry[10].

The median level of sensory block recorded (T11) with spinal analgesia in our study was lower than that of Maroof et al[6]. However, one patient in group 2 had a sensory blockade of T6, but he was haemodynamically stable and had a normal sphincter tone. On the other hand, one patient in our study in whom a similar concentration (0.1% bupivacaine) was used for spinal analgesia as in the study by Maroof et al had motor blockade, as compared to none in their study.[6] The position of the patients for spinal analgesia was different in the two studies, and the numbers are small therefore no definite conclusions can be drawn from this finding. But, notably, motor blockade was not observed in any of the patients receiving the lower (0.0873%) bupivacaine.

Our study confirmed earlier findings that the time to perform the block and the onset time of sensory blockade were shorter with spinal anesthesia as compared to epidural analgesia, preventing delay in starting the surgical procedure.

A sensory blockade of T5 is chosen as the lowest level of sensory analgesia which could result in complete sympathectomy[11]. Imbelloni et al have shown previously in his study that a predominant sensory blockade and good hemodynamic stability is achieved in all the patients using 0.15% hypobaric bupivacaine.[12] In our study, we reduced the dose further to 0.1% and 0.83% and found that all the patients were haemodynamically stable and none required vasoactive drugs. This was probably due to the upper level of sensory block which only was between T10-T11 (median level) in the three groups. The hemodynamic stability was probably due to the hypobaric solution which remained localized in the 20^0 Trendelenberg position and low level of sensory blockade (T8-L1)[13].

Both group 1 and group 2 patients had adequate analgesia whereas 4 of group 3 patients had to be given supplementation with general anesthesia with mask. Possible explanation for the inadequacy of surgical analgesia in epidural group may be due to: (i) inadequate analgesia in epidural blockade due to the 'missed segments', or sparing of the larger L5-S1 nerve roots [9]. (ii) Faulty technique, which could have led to placement of the anesthetic solution in a plane which was not exactly in the epidural space[9].

CONCLUSION

In summary, spinal anesthesia with a low concentration bupivacaine has the following advantages: 1) quick onset of sensory blockade with adequate intraoperative analgesia with very low failure rate; 2) maintenance of sphincter tone and ability to contract the sphincter on demand by the surgeon and thus better outcome of surgery.; 3) well retained motor power to facilitate the positioning for the surgical procedure; and 4) hemodynamic stability in the intraoperative period. It is a very good alternative to epidural analgesia with low dose bupivacaine (0.375%). It may also be a good alternative technique for day care surgery. However, the importance of educating the patients preoperatively and preparing them well to experience the differential blockade, should be borne in the mind.

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