

Comparison of unilateral versus bilateral spinal anaesthesia using hyperbaric bupivacaine with clonidine in unilateral inguinal hernia surgery - A randomized controlled trial

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Abstract

Introduction: Unilateral spinal anaesthesia can be used for inguinal hernia surgery. The advantage is that it provides a stronger block on the side of surgery, accelerated recovery of the nerve block with better maintenance of cardiovascular stability. Hence it can be a valuable technique for high risk patients. **Materials and Methods:** The study design was randomized controlled trial including 60 patients undergoing elective hernionlasty. Patients were allocated to either group unilateral (LD) or group

undergoing elective hernioplasty. Patients were allocated to either group unilateral (U) or group bilateral (B) and received Inj Bupivacaine 0.5% heavy 12.5mg + inj Clonidine 15 microgram in sub-arachnoid block. Patients were kept in lateral position for 10min for group U & made supine immediately on the OT table for group B. Variation in hemodynamic parameters, onset, peak level, duration of sensory and motor block were noted.

Results: At 10, 15 and 20 min minutes after giving anaesthesia, the mean heart rate, systolic and diastolic blood pressures, mean arterial pressure were significantly higher in patients receiving unilateral anaesthesia. Mean duration of sensory and motor block, total duration of analgesia were significantly more in bilateral anaesthesia.

Conclusion: Unilateral spinal anaesthesia achieved stable hemodynamics, adequate duration of block for surgery and rapid recovery. So it can be a valuable technique in high risk patients.

Introduction

Surgical repair of inguinal hernia can be performed under regional anaesthesia, general anaesthesia, nerve blocks etc.¹ Unilateral spinal anaesthesia has found resurgence in recent

years. Conventional bilateral spinal anaesthesia is performed in most cases of inguinal hernia repair however unilateral spinal anaesthesia can be used.²

The basic objective of unilateral spinal anaesthesia is to limit the nerve block exclusively to the site of surgery. So important factors affecting successful unilateral subarachnoid block include-baricity and volume of drug, position of the patient, type of needle and its bevel direction and speed of injection.³

The advantage of unilateral spinal anaesthesia over bilateral spinal anaesthesia is that it provides a stronger block on the side of surgery and accelerated recovery of the nerve block. There is lower incidence of hypotension and better maintenance of cardiovascular stability. Hence it can be a valuable technique for high risk patients.⁴

In this study we aimed to compare the efficacy and safety of unilateral spinal anaesthesia versus bilateral spinal anaesthesia in terms of hemodynamic parameters, quality and duration of sensory and motor block, post-operative analgesia and side effects using hyperbaric Bupivacaine with Clonidine in patients undergoing unilateral inguinal hernia surgery.

Materials and Methods

After approval from Institutional Ethics Committee and written informed patient consent 60 ASA I and II patients aged 18-65 years, weighing 50-70 Kg, with height between 160cm and 180cm undergoing elective hernioplasty were included in this randomized controlled trial. Patients not willing for participation, with known neurological disease, psychiatric disorder, history suggestive of allergy to study drugs were excluded. Patient were allocated to either group U (Unilateral) or group B(Bilateral) by computer generated randomization table. Pre-anesthetic assessment was done in participated subjects. Procedure to be performed and Visual Analogue Score (VAS) were explained to the patients in their own language. Patients were kept nil by mouth overnight prior to surgery and Tab Alprazolam 0.25mg HS was given. In the operating room peri-operative monitoring was done with three lead ECG in standard lead II, non invasive blood pressure (NIBP), pulse oximetry. Baseline pulse rate, blood pressure, SpO₂ were recorded. Lactated Ringer's solution 10ml/kg was administered for preloading and 4ml/kg/hr intra-operatively. Inj Ranitidine 50mg & Inj

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Ondansetron 4mg iv were given as premedication. Under all aseptic precautions, a midline lumbar puncture was performed with 25 gauge Quincke needle at L3-L4 interspace with patients in lateral position with operative side downwards for both the groups.

Conventional dose of 0.5% Bupivacaine (H) for hernia repair under bilateral spinal anaesthesia in our institute has been 3-3.6ml, which is a high dose for U/L SAB. We wanted same dose for both the groups to avoid bias due to unequal amount of drug which directly affects the spread and duration of block and associated haemodynamic perturbations.

So we did a pilot study and arrived at a dose of 2.5ml which provided adequate block in both the groups.

We used Clonidine as adjuvant to LA in SAB. Clonidine improves quality and duration of the block. Dose dependent bradycardia and hypotension are the untoward effects. Based on the study by Thakur et al⁷ we chose 15 microgram as the dose.

So Inj. Bupivacaine 0.5% hyperbaric 12.5mg+ Inj Clonidine 15microgram was given over 15seconds, using 5cc syringe, by guiding the tip of the spinal needle to the side to be operated on group U and cephalic in group B. Only after confirming for clear and free flow of CSF drug was injected. Patients were kept in lateral position for 10min for group U & made supine immediately on the OT table for group B, with 10 degree head down tilt of the table. Surgeon was allowed to start the procedure when the level of block reached T8 sensory dermatome. In case of inadequate level of analgesia, patient was given intravenous sedation or general anaesthesia according to our institutional protocol & was labelled as failure. Sensory block was judged using pinprick method with the help of 23G hypodermic needle in mid clavicular line on both sides; motor block was assessed using Modified Bromage Scale. All assessments were performed on both sides simultaneously every 1minute till first 5 minutes and every 5minutes till 30 minutes then every 10 minutes till the end of surgery. Onset of sensory block, defined as time of injection to loss of pinprick at L1dermatome, was recorded. Peak level reached was judged when consecutive three assessments showed the same level. Time to achieve peak sensory level was recorded from time of onset of sensory block till peak sensory level achieved. Duration of sensory block, defined as the time taken from loss of pinprick at L1 dermatome till L1 regression was recorded. Duration of analgesia, defined as the time taken from loss of pinprick at L1 to the time patient complained of pain at the surgical site, was assessed. The onset of motor block defined as the interval from the injection of the drug to Modified Bromage Score of 1 was recorded. Maximum Bromage score achieved was recorded. Time to achieve maximum Bromage score was recorded from time to onset

of motor block till maximum motor block achieved. Duration of motor block defined as the interval between the onset of motor block and Modified Bromage score 0 was recorded.

Heart rate (HR), Systolic BP (SBP), Diastolic BP (DBP), Mean arterial pressure (MAP), peripheral oxygen saturation (SpO₂) were recorded at similar intervals. Hypotension (MAP<25% from baseline or systolic pressure <90mm of Hg) was treated with inj. Mephentermine 3mg iv bolus. Bradycardia (pulse rate <25% from the baseline or pulse rate <50 beats /min) was treated with inj Atropine 0.6mg IV. Total doses of Mephentermine and Atropine used were noted. Postoperative pain was assessed using VAS scale at every 30 minutes. Inj.Diclofenac Na 75mg IM was administered as rescue analgesic at VAS \geq 3 or at request by patient whichever was earlier. Time for rescue analgesia was noted. Side effects like nausea, vomiting, itching, urinary retention, sedation were recorded by yes/no survey.

The data was collected using epi info 7.2. The qualitative variables were expressed in terms of percentage and difference between two proportions was analyzed using chi square or Fisher exact test. The quantitative variables were expressed in terms of mean and standard deviation and analysed using student t test. All the analysis was 2 tailed and the significance level was set at 0.05.

Results

The age, sex, weight, height, ASA status and duration of surgery of the patients were comparable in the two groups. The basal haemodynamic parameters i.e. heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and peripheral oxygen saturation of the two groups were comparable. Failure rate was 1 case in group U and 3 cases in group B.

The difference between the means of heart rate was significant from 3 min to 20 min level intra-operatively. (p<0.05) At all levels the mean heart rates were higher in group receiving unilateral anaesthesia compared to bilateral anaesthesia.

The atropine doses required in the patients receiving bilateral anaesthesia were in 37.03% study subjects. But, there were no study subjects who required atropine in the patients receiving unilateral anaesthesia. This difference was statistically significant. (p<0.05).

The mean systolic blood pressure values were significantly higher in patients receiving unilateral anaesthesia at 10 min, 15 min and 20 min levels (p<0.05).

The mean of diastolic blood pressure were significantly higher in unilateral anaesthesia group at 10 min and 15 min level. (p<0.05).

Graph 1: Distribution of the study subjects with the mean heart rates at different time intervals pre-operatively and intraoperatively in both the groups



Chart 2: Distribution of the study subjects with the mean arterial blood pressure at different time intervals pre-operatively and intra-operatively in both the groups



The mean arterial pressure readings were significantly higher in case of unilateral Group U patients compared to Group B patients at 10 min, 15 min and 20 minute levels (p<0.05).

The mean heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and peripheral oxygen saturation of the two groups were comparable post-operatively.

| Table | 1 |
|-------|---|
|-------|---|

| | Group U | Group B | P value |
|--|-------------------------------|------------------------------|----------|
| Onset of sensory block | (1.48 ± 0.78) minutes | (1.37 ± 0.49) minutes | (p>0.05) |
| Peak sensory level | T4, T6 and T8 respectively in | T6, T8 and T4 in 58.62%, | 0.0010 |
| | 44.44%, 40.74% and 14.81% | 37.93% and 3.45%. | |
| Time to achieve peak sensory level | (8.55 ± 3.71) minutes | (8.44 ± 3.92) minutes | 0.9169 |
| Duration of sensory block | (254.88 ± 32.96) minutes | (215.75 ± 23.72) minutes | < 0.001 |
| Time to onset of motor block | (1.69 ±0.81)minutes | (1.74 ±0.76) minutes | 0.8086 |
| Highest grade of motor block | 3 | 3 | |
| Time to achieve highest grade of motor block | (6.37 ± 3.00) minutes | 6.58 ± 3.34 minutes | 0.8008 |
| Duration of motor block | (229.03 ± 36.04) minutes | (208.31 ± 27.88) minutes | 0.0191 |

In patients receiving unilateral anaesthesia, on operative side the peak sensory levels achieved in ascending order were T4, T6 and T8 respectively in 3.45%, 58.62% and 37.93% and on non-operative side the peak sensory levels in ascending order were L1, T12 and T10 in 13.79%, 34.48% and 48.28%. This difference was statistically highly significant. (p= 0.0010)

In unilateral group, on operative side the highest motor Bromage score was 3 in all the patients while on nonoperative side the highest motor Bromage score was 1 in 6.9%, 2 in 58.62%, 3 in 34.48% of the patients. The difference was statistically significant (P<0.001).

The Mean VAS score was higher in unilateral group compared with bilateral group but did not attain the level of significance. The mean duration of analgesia was significantly higher in the group receiving bilateral anaesthesia (223.62 ± 34.15) minutes when compared to the group receiving unilateral anaesthesia (188.24 ± 27.71) minutes. (p<0.05)

Two patients in bilateral group and none of the patients in unilateral group experienced vomiting. The difference was not statistically significant. None of the patients in any group had side effects like nausea, itching, urinary retention, sedation.

Discussion

Bilateral SAB is associated with higher incidence of hemodynamic instability and post-op prolonged stay.

Unilateral SAB provides relative hemodynamic stability, rapid return of motor function, extremely low incidence of urinary retention and patients are usually eligible for home discharge sooner. So it could be a better alternative to bilateral spinal anaesthesia.^{5,6}

Maintenance of the lateral decubitus position for a determined length of time is seen to restrict the surgical block to the side to be operated. But it is difficult to define the exact time for which the patient to be kept in lateral position. Literature says 10-20 min time is adequate to achieve unilaterality.⁸ In our study we kept patients in lateral position for 10 min in U/L group after giving spinal injection the use of the hyperbaric anesthetic results in a more predictable nerve block than hypobaric solution. So we used hyperbaric solution for our study.

Kristina Krusinemi found that neither the spread of sensory and motor blocks nor the corresponding recovery times appeared to be different with use of the commonly used Whitacre and Quinke needles.⁹ So we used 25 G Quinke needle in our study.

In our study the mean heart rate was significantly higher in Group U. Seyyed Mustafa et al⁴ found results similar to our results. They found that there was significant difference in incidence of bradycardia between the groups in favour of unilateral group. However Nazia et al⁵ found heart rates to be comparable between the unilateral and bilateral groups. But no study has commented upon comparative atropine use to treat bradycardia. Greater fall in heart rate in bilateral group could result due to local anaesthetic related sympathetic blockade or use of intrathecal Clonidine. With use of 15 micrograms of Clonidine, Thakur et al⁷ reported no incidence of bradycardia. So we feel that the bradycardia was related to higher sympathetic blockade associated with bilateral spinal anaesthesia in our study.

Prevention rather than treatment of haemodynamic disturbances is emphasized in patients undergoing spinal anaesthesia. Prophylactic measures include pre-hydration with intravenous fluids.¹⁰ We gave lactated ringer's solution 10ml/kg for pre-loading Subsequently 4ml/kg intra-operative fluid replacement was done considering hernia as intermediate fluid loss surgery.

A potential means for prophylaxis of hypotension is by manipulation of spinal anaesthesia to achieve a predominantly unilateral block. The systolic diastolic and mean arterial pressures were significantly higher in case of unilateral anaesthesia patients. Our results are in line with those by Nauman Akhtar et al.¹¹ They compared unilateral versus bilateral spinal anaesthesia with respect to haemodynamic changes in sixty ASA I & II patients age 45 years and above, posted for unilateral lower limb surgery. Both the groups received 1.5 ml. 0.75% hyperbaric Bupivacaine intrathecally. Patients were kept in lateral position for 10 minutes in unilateral group. From 1 minute till recovery unilateral group showed higher systolic BP, diastolic BP and mean arterial pressures which was statistically significant.

Faruk Cicekci et al¹² reported no significant difference between the groups in terms of the blood pressure when they compared unilateral and bilateral spinal anaesthesia with regard to limiting the nerve block exclusively to the area of surgery in unilateral inguinal hernia patients. They selected forty ASA I – II patients between ages 18 and 65 years, and divided them in two groups. Patients in both the groups received 0.5% hyperbaric Bupivacaine 15 mg + morphine 0.1 mg. Patients in the unilateral group were placed in the lateral decubitus position for 10 minutes on the side to be operated, while patients in the bilateral group were made immediately supine. There was no significant difference between the groups in terms of the pre operative and post operative systolic arterial pressure, diastolic arterial pressure, heart rate and peripheral oxygen saturation.

The number of doses of Mephentermine required was significantly higher in Group B. Similar results were reported by Guido Fanelii et al¹³ who conducted a prospective randomized study in one hundred ASA I – II patients between age group 18 and 65 years undergoing knee arthroscopy to compare unilateral and conventional bilateral spinal block to evaluate the efficacy and latency of surgical block. All patients received spinal anaesthesia with 8 mg 0.5% hyperbaric Bupivacaine. Vaso-pressor was required in five patients of conventional group (11%) and 0% in unilateral group.

The degree of sympathetic blockade in spinal anaesthesia is related to the height of sensory anaesthesia. Often the level of sympathetic blockade is several spinal segments higher, since the pre-ganglionic sympathetic fibers are more sensitive to low concentrations of local anaesthetics. The most important effects of sympathetic blockade during spinal anaesthesia are on the cardiovascular system causing decreased stroke volume and heart rate.¹⁴ An exclusively unilateral block affects the sensory, motor and sympathetic functions on the operative side and provides advantage over bilateral spinal block.¹⁵ So it is important to study the quality and duration of sensory and motor block to correctly correlate with haemodynamic data.

We have not found significant difference in onset of sensory and motor blocks between the groups. Faruk Cicekci et al¹² reported farter onset of sensory block in the unilateral group. They found that the time to reach L1, T12 and T10 dermatome sensory block were (2 ± 1.17) minutes, (3.34 ± 1.54) minutes, and (4.76 ± 2.11) minutes, (5.98 ± 2.04) minutes and (8.06 ± 3.3) minutes respectively for bilateral group. The difference was statistically significant.

In our study the unilateral group showed adequate block on operative side compared to higher level of block in bilateral group. Similar results were reported by Guido Fanelli et al.¹³ Thus, as the level of sympathetic block ascends, the actions of the parasympathetic nervous system are increasingly dominant, and the compensatory mechanisms of the unblocked sympathetic nervous system are diminished. So higher the sympathetic blockade, more chances of bradycardia and hypotension are there.¹⁴

We have found highest grade of motor block similar in both the groups. However differential motor block has been reported by Guido Fanelli et al.¹³

Unilateral spinal anaesthesia is usually perceived to require more time for readiness to surgery. Most anesthesiologists are still concerned by the cost of wasting10 minutes of the operating room time. This disadvantage may be much more theoretical than practical, because comparing preparation times (from spinal injection to readiness for surgery) of either unilateral or conventional bilateral spinal block with the same small dose of bupivacaine resulted in only a small difference which may be statistically significant but clinically negligible.² We did not get significant difference regarding time to achieve peak sensory and motor level. However we allowed surgeons to begin when sensory level reached T_8 dermatome.

The degree of caudad or cephalad spread of drug in sub-arachnoid block depends on the interplay between density and patient position. The distance between left and right nerve roots in the lumbar and thoracic regions is about 10-15cm, which makes it possible to achieve unilateral spinal anaesthesia.⁴

Only a couple of studies have compared peak sensory level achieved on operative and non operative sides in unilateral group of patients. Study by Tapas Kumar Singh et al¹⁶ is one of them. They found significantly higher sensory level and more intense motor block in operative limb. In our study, in unilateral group, we have got more intense block on operative side of the surgery but the block was not restricted to operative side alone and in group U on operative side the highest motor Bromage score was 3 in all the patients while on non-operative side the highest motor Bromage score was 1 in 6.9%, 2 in 58.62%, 3 in 34.48% of the patients. The difference was statistically significant.

Recovery from spinal anaesthesia depends primarily on the local anaesthetic usage. For ambulatory surgery, length of hospital stay will depend on the dose and type of anaesthetic used.¹⁷ In our study unilateral group showed shorter duration of sensory and motor block although the block lasted for adequate duration for inguinal hernia surgery. C Stefanov et al¹⁸ compared the efficacy and cost effectiveness of unilateral spinal anaesthesia versus bilateral spinal anaesthesia in knee arthroscopy. They studied sixty ASA I & II patients. Unilateral group received 0.5% hyperbaric Bupivacaine 1.5 ml and bilateral group received 4 ml 0.5% isobaric Bupivacaine. The sensory and motor block duration in bilateral group was significantly longer (146.67 ± 13.30) minutes than unilateral group (86.97 ± 13.85) minutes and post operative period for unilateral group was significantly shorter (7.33 ± 3.70) hours than bilateral group (23.03±2.81) hours. Our findings are in line with those by C Stefanov et al. However opposite results were seen by Guido Fanelli et al.13

Though none of our patients as well as surgeons reported any discomfort during surgery, we have not looked for surgeon and patient satisfaction data. We have not looked for and assessed intermediate and long term side effects of spinal anaesthesia, between the groups.

Conclusion

From our study we found that unilateral spinal anaesthesia group had lower incidence of hemodynamic changes with respect to bradycardia and hypotension and lower requirement of Mephentermine and Atropine. So adopting a unilateral spinal block producing minimal hemodynamic fluctuations would prove beneficial.

There was no difference in onset of block and time to attain peak sensory and motor blocks between the groups. Unilateral spinal anaesthesia resulted in lower peak sensory level on operative side but similar grade of motor block on operative side and faster regression of sensory and motor blocks with no immediate side effects. But post-operative analgesia time was significantly prolonged in bilateral spinal anaesthesia.

So because of haemodynamic stability and faster recovery characteristics of unilateral spinal block, it can be used as a suitable technique in patients with limited cardiovascular reserve and for out -patient anaesthesia.

However we feel that unilateral spinal anaesthesia technique should be used routinely for uncomplicated inguinal hernia repair.

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