Research Article

A comparative study of intrathecal 0.5% isobaric levobupivacaine with 0.5% hyperbaric bupivacaine for vaginal hysterectomy

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ABSTRACT

Background: Hyperbaric bupivacaine (0.5%) is frequently used in vaginal hysterectomy for spinal anesthesia due to longer duration and reliable motor and sensory blockade. However, the risk of cardiac and central nervous toxicity due to accidental intravenous injection resulted in search of better and safe alternative. This resulted into development of levobupivacaine. **Aims and Objectives:** To evaluate of 0.5% isobaric levobupivacaine for spinal anesthesia and compare with hyperbaric bupivacaine (0.5%) in terms of onset and regression of sensory, motor effect, hemodynamic parameter, and any side effects. **Materials and Methods:** A total of 60 patients belonging to ASA Class 1 and 2 of 30-60 years with 40-70 kg posted for surgery. Patients were equally divided into two groups. Group B patients received intrathecal bupivacaine hyperbaric (0.5%) 3.5 cc while Group L patients received intrathecal 0.5% isobaric levobupivacaine. Sensory block was assessed by pinprick method while the motor block was assessed by Bromage scale. Any complications observed intraoperative and postoperatively were noted. **Results:** A total of 11 patients failed to achieve adequate sensory level of anesthesia. Time of onset of sensory block and duration of sensory block were longer in Group L. Motor effect was adequate in all patients. Time of onset of motor block and duration of motor block were longer in Group L. One patient in Group B, and two patients in Group L required analgesia. Hypotension was higher in Group B and shivering was higher in Group L. **Conclusion:** The study showed that 17.5 mg of 0.5% isobaric levobupivacaine provide effective anesthesia for vaginal hysterectomy and can be good alternative to 0.5% hyperbaric bupivacaine.

KEY WORDS: Spinal Anesthesia; Levobupivacaine and Vaginal Hysterectomy

INTRODUCTION

Hysterectomy is surgery related to old age and associated with high level of anxiety. Although laparoscopic hysterectomy is gaining popularity; many of them are done through vaginal route to avoid incision on abdomen and associated with less complication and post-operative pain. Spinal anesthesia is the most popular and effective method for vaginal hysterectomy with advantage of dense sensory and motor block with less amount of drug, cost effectiveness and negligible risk of aspiration. At present, 0.5% hyperbaric bupivacaine is frequently used for vaginal hysterectomy but with the risk of increased systemic toxicity if drug accidentally is given intravenously. Levobupivacaine is S-enantiomer of racemic bupivacaine with the similar clinical profile. It has more protein binding capacity so lesser chance of toxicity. The drug used for spinal anesthesia is very small in an amount so question of toxicity is remote, but there will always be interest in evaluating the safer drug for its usefulness. Bupivacaine used for spinal anesthesia is hyperbaric. Hyperbaric local anesthetic solution is heavier than cerebrospinal fluid at 37°C.[10] Spread of hyperbaric solution depends on position of patients, in head up position it spread caudally and head down position it spread in cephalic position. The spread

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of isobaric local anesthetic solution does not change with position. The solution tends to remains puddled near site of action.[10] Dextrose is required to be added to make local anesthetic hyperbaric. Addition of any agent can compromise the sterility of the solution. It is recommended that not more than 5% dextrose should be added to local anesthetic agent as in higher concentration the solution becomes acidic and can cause tissue irritation.[10] If levobupivacaine has to get place in routine practice for vaginal hysterectomy, it has to be compared with gold standard 0.5% hyperbaric bupivacaine. Hence, this study was planned to compare the 0.5% isobaric levobupivacaine with 0.5% hyperbaric bupivacaine for vaginal hysterectomy.

MATERIALS AND METHODS

The study was conducted in 60 patients belonging to ASA Class 1 and 2 of 30-60 years with 40-70 kg weight posted for vaginal hysterectomy. Pre-anesthetic evaluation (1 day before surgery) and written informed consent from patient and relative were obtained. All patients were randomly divided (with the help of computer) equally into two groups. Group B patients received 0.5% hyperbaric bupivacaine 3.5 cc while Group L patients received 0.5% isobaric levobupivacaine 3.5 cc. On day of surgery, patient's vitals were recorded before giving premedication with injection glycopyrrolate 0.2 mg intravenously and injection midazolam 1 mg intravenously. After preloading with injection ringer lactate 10 ml/kg intravenously, patients were shifted into operation room and again vitals measured. After appropriate monitors were attached, spinal anesthesia was given with 23 gauge spinal needle at $L^{[3,4]}$ space in the lateral position. The person assessing the patients was blinded for the group to which the patient belonged. Vitals including sensory and motor level were recorded every 2 min up to 8 min, then every 5 min up to 30 min and after that every 15 min of interval up to the end of surgery. The duration from spinal anesthesia to obtaining sensory block level (pin prick method) of T_{10} and T_6 was noted. Highest sensory level and time to achieve it was also recorded. For assessment of motor blockade, Bromage scale was used, its onset and grading were noted. Postoperatively, patients were monitored in recovery room every 15 min for regression of motor and sensory effects. Time to two segments regression of sensory level from the maximum block was noted and finally time to complete sensory regression when visual analog score >3 was noted. Time to complete motor block resolution was noted. Postoperatively, patients were monitored every 15 min interval for regression of effects. To judge the quality of anesthesia, patients were assessed for feeling the sensation during operation and were graded as under: Grade A - No sensation through the operation, Grade B - feeling of sensation or mild pain on manipulation but no need of analgesic, and Grade C - Pain and need for analgesia. It was decided that Grade C patients will receive injection ketamine 0.5 mg/kg intravenously. These will be included in the study. Even after 2 doses if a patient complains of pain, general anesthesia will be supplemented and considered as fail case. Number of patients who required ketamine or general anesthesia were noted. All patients were watched for side effects such as hypotension, shivering, bradycardia, nausea, vomiting, and high spinal anesthesia. Data were entered into Microsoft Excel work sheet. Mean and standard deviation were calculated using Microsoft Excel program. Statistical analysis was performed with EPI 2000 software. $P < 0.05\%$ was considered as significant.

RESULTS

Mean age of patients in Group B and Group L was 41.1 and 43.2 years, respectively. Mean weight of patients in Group B and Group L was 48.6 and 49.7 kg, respectively. Mean duration of surgery in Group B and Group L was 127.66 min and 127.63 min, respectively. Mean of onset of sensory effect at T_{10} in Group B and Group L was 4.8 min and 8 min, respectively. The difference between two groups was statically significant ($P < 0.05$). Mean of onset of sensory effect at T_6 in Group B and Group L was 12.07 min and 17.52 min, respectively ($P < 0.05$). In Group B, sensory level of T_6 or above and below T_6 was achieved in 27 and 3 patients, respectively. In Group L sensory level of T_6 or above and below T_6 was achieved in 22 and 8 patients, respectively. When compared statistically the difference was not significant (Table 1).

Mean onset of motor Grade 3 in Group B and Group L was 8 min and 11 min, respectively. Time to achieved Grade 3 motor block was longer in Group L ($P < 0.05$) (Table 2).

Table 3 summarizes that there was no statistically significant difference in mean pulse rate and systolic blood pressure at the different time interval between two groups during the study period ($P > 0.05$).

Table 1: Highest sensory level achieved

	Number of patients (%)	
	Group B (*n*=30)	Group L (*n*=30)
T_4	7 (23.33)	5 (16.67)
T_6	20 (66.67)	17 (56.67)
T_8	2 (6.67)	7 (23.33)
T_{10}	1 (3.33)	1 (3.33)

Table 2: Time of onset of motor Grade 3

	Mean±SD		*P* value
	Group B (*n*=30) (min)	Group L (*n*=30) (min)	
Onset of motor Grade 3 (min)	8±5.31	11.9±8.4	<0.05

SD: Standard deviation

Table 3: Mean pulse rate at different time interval

Time interval (min)	Pulse rate (per min) (mean±SD)		*P* value	Systolic blood pressure (mm of Hg) (mean±SD)		*P* value
	Group B	Group L		Group B	Group L	
Base line	94.46±12.33	99.23±9.89	>0.05	130.26±8.97	131.1±12.78	>0.05
4	95.6±14.87	94.1±10.32	>0.05	122.27±13.85	122.03±12.46	>0.05
8	93.3±15.04	91.13±10.95	>0.05	114.8±15.28	120.06±12.74	>0.05
12	90.7±16.04	89.86±10.79	>0.05	115.4±15.05	116.66±12.14	>0.05
20	85.5±15.41	86.33±12.78	>0.05	112.06±16.21	119.1±11.05	>0.05
30	80.56±14.16	82.5±12.66	>0.05	111.11±15.26	116.2±11.45	>0.05
60	73.5±10.84	75.53±11.89	>0.05	104.96±20.98	112.93±10.94	>0.05
90	74.43±11.79	74.96±10.13	>0.05	111.4±11.73	111.3±10.65	>0.05
120	75.93±11.10	75.79±10.36	>0.05	112.63±11.95	116.73±7.91	>0.05

SD: Standard deviation

Table 4 summarizes that mean time to achieve visual analog score >3 in Group B was 228 min while in Group L it was 239 min which was comparable. Moreover, mean time to complete motor regression in Group B was 227 min while in Group L it was 240 min which was comparable.

Table 5 summarizes information regarding quality of anesthesia.

- Grade A: No sensation throughout the operation
- Grade B: Feeling of sensation or mild pain on manipulation but no need of analgesic
- Grade C: Pain and need for analgesia. It was decided that Grade C patients will receive injection ketamine 0.5 mg/kg intravenously.

Table 6 summarizes information about the incidence of side effects.

Table 4: Regression of motor and sensory effects

	Mean±SD		*P* value
	Group B	Group L	
Time to two segment regression	103.86±23.59	108.06±24.92	>0.05
Time to achieved VAS >3	228.8±40.58	239.86±46.8	>0.05
Time to complete motor regression	227.43±50.77	240.36±47.54	>0.05

SD: Standard deviation, VAS: Visual analog scale

Table 5: Quality of anesthesia

Quality of anesthesia	Group B (*n*=30)	Group L (*n*=30)
Category A	28	28
Category B	1	0
Category C	1	2

Table 6: Incidence of side effects

Side effects	Number of patients (%)		*P* value
	Group B (*n*=30)	Group L (*n*=30)	
Hypotension	6 (20)	4 (13.33)	>0.05
Nausea and vomiting	0 (0)	1 (3)	
Bradycardia	1 (3)	0 (0)	
High spinal	0 (0)	0 (0)	
Shivering	6 (20)	11 (36)	>0.05
Hypoxia	0 (0)	0 (0)	

DISCUSSION

This study showed that 0.5% hyperbaric bupivacaine had faster onset of sensory and motor effects while 0.5% isobaric levobupivacaine had comparable extent of sensory blockade and effective (Grade 3) motor block. No significant difference was seen between two groups in terms of hemodynamic parameter and side effects.

Result in this study showed mean duration of surgery was 121.66 ± 29.08 min and 127.63 ± 22.72 min in Group B and Group L, respectively. Results of this study were comparable with other studies,[1] in this study, time of onset of sensory analgesia at T_{10} was 4.8 ± 2.7 min and 8 ± 4.51 min in Group B and Group L, respectively, and the difference between both groups was significant. These results were comparable with other studies.[1-4] In this study, time of onset of sensory analgesia up to T_6 was 12.07 ± 5.95 min and 17.52 ± 8.3 min in Group B and Group L, respectively. Onset of sensory analgesia at T_6 was slower in Group L than Group B. These results were comparable with other studies.

In this study, all patients were achieved complete motor block. Time of onset of motor Grade 3 was 8 ± 5.31 min in Group B and 11.9 ± 8.4 min in Group L. When compared statistically the time required to achieve Grade 3 was longer in levobupivacaine. Results of this study were comparable with another study.[5] In this study, time for two segment regression of sensory level was 103.86 ± 23.59 min and 108.06 ± 24.92 min in Group B and Group L, respectively. In this study, time for complete regression of sensory level was 228.8 ± 40.58 min and 239.86 ± 46.8 min in Group B and

Group L, respectively. Complete motor regression time was 227.43 ± 50.77 min and 240.36 ± 47.54 min in Group B and Group L, respectively. No significant difference in sensory and motor regression in both groups indicated that duration was comparable in both groups. Results of this study were comparable with other studies.[2-5] In this study, 28 out of 30 patients in both groups had Category A quality anesthesia. One patient in bupivacaine group and two in levobupivacaine group had Category C quality of anesthesia. One patient in bupivacaine group had Category B quality of anesthesia. Results of this study were comparable with other studies.[5-7] In this study, hypotension was seen in 20% and 13.33% of patient in Group B and Group L, respectively. Nausea and vomiting were seen in only in Group L (3%). Bradycardia was seen in only in Group B (3%). Shivering was seen in 20% and 36% of patient in Group B and Group L, respectively. Both groups were comparable for shivering. Results of this study were comparable with other studies.[3,4,7-9]

Strength of the study (1) in all the cases spinal anesthesia was performed by experienced anesthesiologist. Hence, there is minimum interference in result due to different level of skill, (2) all the readings were taken by the single observer to minimize inter observer's bias. While limitations (1) this study has included women from 30 to 60 years of age so, the result cannot be applied to women <30 years, (2) this study included women of 40-70 kg weight so, the result cannot be applied to obese patients.

CONCLUSION

It is concluded that 17.5 mg of 0.5% isobaric levobupivacaine provides effective anesthesia for vaginal hysterectomy and it can be projected as an alternative to 0.5% hyperbaric bupivacaine.

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