

Clinical efficacy of isobaric ropivacaine alone, ropivacaine-fentanyl and ropivacaine-dexmedetomidine in spinal anaesthesia for vaginal hysterectomy: A prospective randomized double-blind comparative study

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Abstract

Background: Around 40% of parous woman have problem of Pelvic organ prolapsed (POP) and it effects their life quality. Regional anaesthesia has good patient and surgeon acceptability as well as early discharge of the patient from the hospital. However there is limited data available in which ropivacaine alone and with fentanyl or dexmedetomidine has been used in SAB for vaginal hysterectomy in which there is more extensive surgery, needing more relaxation than above mentioned surgeries. This prompted us to plan present study. **Objectives:** Spinal anaesthesia with isobaric Ropivacaine alone (Group R), isobaric Ropivacaine with fentanyl (Group RF) and isobaric Ropivacaine with dexmedetomidine (Group RD) for vaginal hysterectomy was compared regarding: Onset, duration and extent duration of sensory and motor block. **Methods:** A double-blind comparative study was conducted with one hundred and five patients at Panna Dhai Mahila Chikitsalya, R.N.T. Medical College, Udaipur, Rajasthan. After applying inclusion and exclusion criteria participants who are ready to give written consent to participate in study are randomly divided in three groups and as per study protocol they were given anaesthesia and assessed for outcome. **Results:** Our study participants had comparable physical profile. In present study onset of sensory block was significantly shorter in Group RF and Group RD as compared to Group R. Sensory level of T4 was achieved in all patients of group RF, whereas range of T4 to T6 was achieved in Group R and Group RD. Duration of motor block was comparatively longer in Group RD as compared to other two groups. **Conclusions:** In all three group spinal anaesthesia produces sensory and motor blockade of sufficient duration with stable hemodynamic profile to accomplish vaginal hysterectomy.

Key Word: Dexmedetomidine, Fentanyl, Isobaric Ropivacaine, Spinal anaesthesia, Vaginal hysterectomy

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INTRODUCTION

Around 40% of parous woman have problem of Pelvic organ prolapsed (POP) and it effects their life quality.¹ Out of these effected women 11% requiring surgery and due to its recurrence previously treated 30% women may require additional surgery.² Uterus is supported by ligaments and other soft tissues damage to these structure leads to prolapsed of uterus. Pelvic organ prolapse is corrected by vaginal hysterectomy combined with prolapse repairs of the bladder and/or bowel and sling procedures for urinary incontinence. The operation can be performed under general anaesthesia or regional anaesthesia. General

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anaesthesia (GA) was commonly used in earlier days. But it is a well-known fact that GA leads to physiological and pharmacological changes in body, longer hospital stay, postoperative drowsiness, nausea, vomiting etc. So the need of regional technique arose. Amongst all regional techniques, the subarachnoid block (SAB) emerged as convenient, fast and effective method of anaesthesia for variety of surgical procedures and pain relief, especially for lower abdominal and lower limb surgeries. The SAB has got inherent advantages like intense motor and sensory blockade with faster onset, good relaxation, reliability, no postoperative respiratory depression, nausea, vomiting, drowsiness etc. SAB may lead to early discharge of patients so it is widely acceptable in patient and surgeon. In spinal anaesthesia intrathecal local anaesthetic agents are used to produce acceptable level of anaesthesia; lignocaine and bupivacaine were widely used since long. But lignocaine is associated with shorter duration of block and transient neurological symptoms and bupivacaine has significant cardio/neurotoxicity when inadvertently injected systemically.^{3,4} Due to reduced CNS and cardiac toxicity ropivacaine has shown a better safety profile over bupivacaine.⁵⁻⁷ Recent clinical data have shown that ropivacaine is clinically effective and safe for regional anaesthetic techniques with good tolerability. Ropivacaine has been successfully used in spinal anaesthesia for caesarean section, nephrotic surgery and orthopaedic surgery of lower extremity.⁸⁻¹² However there is scarcity of data in which ropivacaine has been used in SAB for vaginal hysterectomy in which there is more extensive surgery, needing more relaxation than above mentioned surgeries.¹³ This prompted us to plan present study. Local anaesthetic when used alone is associated with short duration of action. Thus, early analgesic intervention is needed in postoperative period. Various adjuvants have been used intrathecally to improve the quality and duration of the spinal anaesthesia along with better postoperative analgesia. When fentanyl or dexmedetomidine were added to intrathecal ropivacaine better clinical profile was noted as compared to ropivacaine alone.⁹⁻¹⁴ However, limited study material available comparing efficacy of fentanyl versus dexmedetomidine as an adjuvant to ropivacaine in spinal anaesthesia has been conducted to date. Therefore, we have planned present study using ropivacaine alone and with dexmedetomidine or fentanyl in spinal anaesthesia for vaginal hysterectomy.

MATERIALS AND METHODS

On approval from institutional committee present prospective comparative study was conducted in department of Anaesthesiology at Panna Dhai Mahila Chikitsalya, R.N.T. Medical College, Udaipur, Rajasthan. As there is limited study available in which effect of adding

intrathecal fentanyl versus dexmedetomidine as an adjuvant to ropivacaine has been studied, hence power analysis cannot be applied. Therefore, Sample size was calculated by "central limit theorem", which states that "if sampling distribution is symmetric, uniform without outliers, the sample size of 30 is adequate in each group. To compensate for dropouts and other reasons we enrolled 35 patients in each group hence sample size for the study was 105. Inclusion criteria: ASA physical status I-II posted for vaginal hysterectomy for uterovaginal prolapse under spinal anaesthesia. Exclusion criteria: a. Any contraindication to regional anaesthesia b. History of significant co-existing diseases like ischemic heart disease, hypertension, impaired renal functions, rheumatoid arthritis, severe liver disease and morbid obesity c. coagulation abnormality d. Atrio-ventricular block, incomplete or partial heart block e. Intake of alpha or beta blockers. Patients were randomly divided in three groups of thirty-five patients in each group using sealed envelope technique after they agree to take part in study and give informed written consent. This technique helps to randomly allot the patient in three groups. Three groups are **Group R**: Patients receive 4ml of 0.75% (30mg) Isobaric ropivacaine hydrochloride. **Group RF**: Patients receive 4ml of 0.75% (30mg) Isobaric ropivacaine with 25µg Fentanyl hydrochloride (0.5ml). **Group RD**: Patients receive 4ml of 0.75% (30mg) Isobaric ropivacaine with 5µg dexmedetomidine hydrochloride (0.05ml). All data were recorded in a proforma by the anaesthesiologist conducting the study as follows: -Patient demographics like name, age, weight, height, diagnosis, surgery performed. Using 24G hypodermic needle pinprick sensation assessed to check sensory block. Sensory-motor block assessment was started 3 min after spinal injection and repeated at every 2 minutes till 15 minutes. Modified Bromage scale was used to assess motor block. Onset time of sensory block was defined as the time between injection of intrathecal anaesthetic and absence of sensation at T10 dermatome level. Sensory block duration is time from end of injection of anaesthetic agent to sensory regression to S1. Onset of motor block defined as time to reach maximum Bromage score. Duration of motor block is time from the end of spinal injection to complete motor recovery assessed by Bromage score. Surgery was allowed to commence in spinal anaesthesia if T10 sensory level and Bromage score of 2 or 3 is achieved. Success rate was graded as: a. Completely successful, if no supplementation required during procedure b. Partially successful if ketamine/propofol/ fentanyl is required and c. Failure of procedure, if patient was converted to general anaesthesia. Success rate in each group was defined as percentage of cases in which surgery could be completed without supplementation. Data was entered into MS Excel and

analyzed using Epi info software. Qualitative data was presented as number (proportion) and compared using chi square test. Continuous variable was presented as mean±SD and compared using appropriate statistical test.

OBSERVATIONS AND RESULTS

All three groups well comparable with respect to demographic and physical characteristics. Mean weight of patients was 53.26 kg. Average duration required for surgery was 78.23 minutes. Around 87.6 % patients who undergone surgery were in ASA stage 1 classification. (Table 1) In our study, Time to reach T10 sensory level was 3.06± 0.34 min in Group RF, 3.63± 1.06 min in Group RD and 3.74 ± 0.98 min in Group R. Sensory level of T4 was achieved in all patients of group RF, whereas range of T4 to T6 was achieved in Group R and Group RD. Average time to reach peak sensory level was 11.43 min in Group R, 8.09 min in Group RF and 10.74 min in Group RD. Average time to achieve peak sensory level was significantly shorter in Group RF as compared to Group R.

There was no significant difference in time to reach peak sensory level between group R and group RD. In our study duration of sensory block was significantly longer in Group RD (428.71±10.31 min) and Group RF (324.00±24.32 min) as compared to Group R (304.85±27.65min). Thus duration of sensory block was longest with group RD and shortest with group R. Bupivacaine-Fentanyl produces sensory block of intermediate duration. (Table 2) In our study all patients of three groups achieved complete motor block. Mean time of onset of motor block assessed by Bromage score was 5.91±1.01 min in group R, 5.57±0.917 min in group RF, and 5.86±1.00 min in group RD respectively. There was no significant difference in onset of motor block among the groups. Duration of motor block was significantly longer in Group RD (360.14±16.52 min) as compared to Group R (284.43±16.57min). Duration of motor block was comparable in group R and group RF. (Table 3) Complete success rate was achieved in all groups as none of the case required supplementation.

Table 1: Demographic and physical profile of patients in different groups

Characteristic	Groups (N=105, 35 In each group)		
	Group R (Mean±SD)	Group RF (Mean±SD)	Group RD (Mean±SD)
Age (Years)	53.89±9.90	52.54±8.38	53.34±8.41
Weight (Kg)	52.00±5.20	51.91±4.36	53.06±6.27
Height (Cm)	155.60±4.08	154.20±3.39	155.26±4.14
Duration of surgery (min)	77.91±10.42	80.49±8.55	78.29±8.39
ASA grade I (%)	30 (85.7)	32 (91.4)	30 (85.7)
ASA grade II (%)	5 (4.3)	3 (8.6)	5 (4.3)

Table 2: Sensory block characteristics in different group

Characteristic	Groups (N=105, 35 In each group)		
	Group R (Mean±SD)	Group RF (Mean±SD)	Group RD (Mean±SD)
Sensory onset (Time to achieve T10 in Min)	3.74 ± 0.98	3.06±0.34	3.63±1.06
P Value		0.001	0.578
Time to reach peak sensory level	11.43±2.83	8.09±1.59	10.74±1.80
P Value		0.001	0.187
Duration of sensory block	304.85±27.65	324.00±24.32	428.71±10.31
P Value		0.001	0.001

Table 3: Motor block characteristics in different group

Characteristic	Groups (N=105, 35 In each group)		
	Group R (Mean±SD)	Group RF (Mean±SD)	Group RD (Mean±SD)
Motor block onset	5.91±1.01	5.57±0.917	5.86±1.00
P Value		0.146	0.807
Duration of motor blockade (min)	284.43±16.57	291.86±24.32	360.14±16.52
P Value		0.114	0.001

DISCUSSION

Mean weight of patients was 53.26 kg. Prolapsed uterus is more common among menopausal woman so this mean age is supporting the observation. In present study time of sensory block onset was significantly shorter in Group RF

(3.06±0.34 min) and Group RD (3.63±1.06 min) as compared to Group R (3.74 ± 0.98 min). Similar to our study, Verma *et al*¹⁵ reported sensory onset was significantly faster when fentanyl was added to ropivacaine. In contrast to our study, other studies

comparing Ropivacaine versus Ropivacaine plus Fentanyl, there was no significant difference in sensory onset in two groups.^{9,10,16,17} It could be attributed to two factors, firstly, in study by Gupta *et al*¹⁶ and Seetharam *et al*¹⁷ normal saline was added in 'Ropivacaine only' Group to make equal volume as in 'Ropivacaine + Fentanyl' Group. Intrathecal solution in both Groups thus became hypobaric and similar sensory onset was observed. Secondly, in another study by two Indian authors named Chaudhary *et al*⁹ and Gupta *et al*¹⁰ dose of Ropivacaine was decreased in Ropivacaine - Fentanyl Group to make equal volume in both groups. As the dose of Ropivacaine was decreased in Group RF therefore sensory onset in two Groups was comparable. Median sensory level of T₄ was achieved in all patients. Other studies show that peak sensory level is not significantly altered by addition of fentanyl or dexmedetomidine to local anaesthetic agent.¹⁸⁻²⁰ Duration of sensory block was longest with group RD and shortest with group R. Bupivacaine-Fentanyl produces sensory block of intermediate duration. Gupta *et al*¹⁸ also reported that when dexmedetomidine is added to bupivacaine sensory block duration was significantly longer as compared to when fentanyl was used. There was no significant difference in onset of motor block among the groups. Other studies also demonstrated that addition of dexmedetomidine or fentanyl to ropivacaine in spinal anaesthesia accelerated the sensory onset but has no effect on motor block onset.^{10,13,16,21} Duration of motor block was significantly longer in Group RD (360.14±16.52 min) as compared to Group R (284.43±16.57min). Duration of motor block was comparable in group R and group RF. The studies done by Gupta *et al*¹⁰ and Verma *et al*¹⁵ used similar dose of fentanyl that used in our study, they show that addition of fentanyl to ropivacaine has no significant effect on duration of motor block and their results were comparable to our study.

CONCLUSION

Isobaric Ropivacaine with fentanyl or dexmedetomidine in spinal anaesthesia produced effective sensory-motor block of sufficient duration with stable hemodynamic profile to accomplish vaginal hysterectomy. Addition of Fentanyl offered the advantage of accelerating the sensory onset and prolonging sensory block without affecting motor block. Addition of dexmedetomidine to ropivacaine significantly prolonged motor and sensory block.

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