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A Comparative Study of Ropivacaine with Dexmeditomidine and Fentanyl Spinal Anaesthesia in Uro-Gynacological Surgeries

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Abstract
This study was conducted in 106 adult patients with ASA physical status I-II planed for lower abdominal uro -gynac surgeries under spinal anaesthesia. We compared the onset & duration of motor and sensory block and time to two segment regression from maximal level achieved after giving 2.5ml of 0.75% Ropivacaine + 5µg dexmeditomidine (group-RD) versus 2.5 ml of 0.75% Ropivacaine + 25µg fentanyl intrathecally(group-RF).We observed that onset of sensory and motor blocks were not statistically significant in both groups. Duration of complete motor & sensory blocks were significantly shorter in group-RF as compared to group-RD. Time to 2 segment regression of sensory blockade from maximum level was statistically significant in group-RF compared to RD group. Haemodynamic parameters were comparable in both groups. Demand for rescue analgesia was later and number of doses of rescue analgesia was lesser in group RD Peri-operative and post-operative complications were less & comparable in both groups.To conclude, we found that intrathecal (5µg) DXM supplementation with 0.75% ropivacaine seems to be a better alternative to intrathecal (25µg) fentanyl with 0.75% ropivacaine since it produces prolonged sensory& motor blockade and more effective pain relief, thus making it a more lucrative option for lower abdominal and uro-gynacological surgeries.

Keywords: *spinal anaesthesia, Ropivacaine, Dexmeditomidine, fentanyl, uro-gynacological surgeries.*

Introduction

Spinal block is a regional technique used for abdominal, orthopaedic and uro-gynac surgeries. Ropivacaine is a long-acting regional anaesthetic structurally related to Bupivacaine. It is a pure S(-) enantiomer, unlike Bupivavaine which is a racemate, developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles. Ropivacaine causes reversible inhibition of Na ion influx and thereby, block impulse generation and conduction in nerve

fibres, by slowing the propagation of the nerve impulse and by reducing the rate of rise of the action potential[1]. This action is potentiated by dose-dependent inhibition of potassium channels. In general, the progression of anaesthesia is related to the diameter, myelination and conduction velocity of affected nerve fibres. Ropivacaine is less lipophilic then Bupivacaine and is less likely to penetrate large myelinated motor fibres; therefore, it has selective action on the pain-transmitting Aδ and C nerve fibres rather than Aβ fibres, which are involved in motor function. Fentanyl is a phenyl piperidine derivative, synthetic opioid agonist which is 75-125 times more potent than morphine.

The purpose of this study was to compare the efficacy and safety of intrathecal isobaric ropivacaine 0.75% 2.5ml with addition of fentanyl (25µg) or dexmeditomidine (5µg) to provide operative anaesthesia in urogyanocological surgeries with respect to: onset & duration of sensory and motor block, time to two segment regression of block from maximum block level, the hemodynamic changes following intrathecal injection and the efficacy of post operative analgesia, its complications

Materials & Methods

After obtaining institutional ethical committee approval and written informed consent, a randomised, double blinded study was conducted.106 adult patients, of 20 to70 years with ASA physical status I & II were selected by sealed envelope method. They were scheduled for various urological and gynacological surgeries under spinal anaesthesia during the year 2016 to 2017 and were divided into Group-RF who received Intrathecal 2.5 ml 0.75 % ropivacaine + fentanyl 25µg and Group-RD who received Intrathecal 2.5ml0.75% ropivacaine+dexmeditomidine5µg.The day before surgery, all patients underwent thorough pre-anaesthetic check up, which included routine history, general as well as systemic examination. Necessary investigations were obtained in indicated cases. Patients were kept NBM for at least 6 hours.

Exclusion criteria includes ASA Grade ≥III, Mental retardation (congenital anomaly) patients, those with bleeding disorders and local sepsis, those on anti-coagulants and anti-platelet agents, those allergic to amide anesthetic**,** Patient refusal for the procedure and Technical difficulties.

Anesthesia Technique: After taking patient in operation theatre, an intravenous cannula was secured and patients were preloaded with lactated ringer solution at 10ml/kg. All patients were monitored and recorded with automated non-invasive blood pressure, pulse oximetry and electrocardiogram. Spinal anaesthesia was given in the right or left lateral position with full aseptic precaution, with 25 gauge quincky spinal needle in lumber intervertebral space. The intra-op blood pressure, ECG and SPO2 monitoring were observed and recorded initially at every 5 minutes up to 30 minutes and then every 15 minutes up to the end of surgery.

Sensory and Motor Blockade: Sensory block was assessed by using pin prick method with 25G needle and sensory blockade at T10 level was considered as onset of sensory block. Maximal sensory level of block was also noted. The time from intrathecal injection to two dermatome sensory regression from maximum blockade was recorded. Duration of block was assessed by sensory regression to S1 dermatome or on first demand of rescue analgesic which ever occurred earlier. Modified bromage scale was used for assessment of motor blockade. The motor block was assessed by asking the patients to move his lower limbs and Bromage III was considered as onset of motor blockade. Duration of motor block, assessed by regression to modified Bromage 0 was recorded. Sedation was assessed by modified Ramsay Sedation Scale.

We recorded the VAS scores postoperatively, in which we asked the patients to grade their severity of pain where 0 was minimal or no pain, and 10 was the ‘worst pain ever’ felt. We monitored the first demand for rescue analgesia. Rescue analgesia in form of intravenous tramadol 2 mg/kg was given if

VAS>4. No of inj. tramadol doses and the total demand of tramadol in 24 hours was observed.

Hemodynamic Changes

Intra-operative complications like hypotension, bradycardia, nausea/vomitting, shivering, itching, and respiratory depression were noted. Hypotension was considered when mean arterial blood pressure decreased ≥30% from the baseline value, they received inj. mephentermine & i.v. fluid loading. Bradycardia was considered when heart rate falls ≤50 beat/minute and was treated with i.v. inj. atropine 0.6 mg. Intra-op nausea and vomitting were treated with intravenous ondensetron 8.0 mg. Intra-operative shivering was treated with i.v. inj. Tramadol 25mg., itching was treated with inj. Chlorpheniramine. Respiratory depression was treated with O2 supplementation and if required respiratory support or intravenous naloxone wherever applicable. At the completion of surgery, the duration of surgery was noted and the patient was shifted in recovery room where vital parameters, duration of sensory and motor blockade and any side effects of the drugs were observed.

Statistical analysis: Sample size calculation was done to compare the effect of onset time of sensory block in group(RD) and group(RF). Power analysis was based on two samples with statistical significance of α(0.05) and β(0.90) power . It indicates that the sample size required to detect the standard difference of 0.69 are approximately 106 (53 in each group). Thus the power analysis indicated that the minimum number of patients in each group should be 53. Statistical analysis was performed using Statistical Package of Social Sciences i.e. SPSS version 12. Data are expressed as mean ± SD (standard deviation) for continuous variable & for categorical variables. Continuous variables were compared using Independent Student t-test and Man- Whitney U test. Fisher Exact test & Chi-squre analysis was used for comparing Categorical data. P-value <0.05 was considered to be statistically significant.

Results

This prospective study was carried out in 106 ASA I & II adult patients undergoing lower abdominal uro- gynac surgeries during the period of 2016-2017.

Table 1. Demographic data

Variables	Group-RD (mean+SD)(53)	Group-RF (mean+SD)(53)	p-value
Age(Yrs)	47.5 ± 20.03	45.9 ± 16.83	0.59
Wt(Kg)	57.6 ± 22.27	61.1 ± 12.35	0.3
Height(cm)	159.8 ± 11.53	158.5 ± 5.84	0.52
Duration of surgery (Min)	104.8± 69.6	94.6 ± 87	0.43

The characteristics of the two groups were comparable in terms of age, weight, height and duration of surgeries. There was no significant difference in the duration of surgery

Surgical Procedure

The type of surgeries done in both the groups are shown in the table 2. URS surgery are more in group-RF as compared to group RD. But number of lower abdominal surgeries was more in RD group.

Onset of Sensory Block

There was no statistically significant difference in the onset time of sensory block (T10) in both groups. The time to achieve T10 level was (2.77±8.11) min in RD group and (5.31±16.6) min in RF group. (p-0.319).In both groups maximum cephalad spread was up to T4 level except in two patients of RD group having T2 level.which was higher than RF group.

Duration of Sensory Block

The median duration of sensory block at S1 dermatome was significantly longer in RD group (303.46±71.5 min) compared with the RF group (275.2± 46.54 min) (P -0.018).

Table 2: Surgical procedures

Name of Surgery	**Group-RD**	**Group-RF**
URS	14	18
D.J.Stenting	1	1
Cystolithotripsy	7	4
Cystoscopy + VIU	3	2
TURP	2	6
TURBT	1	3
AP Repaire	1	0
CAPD Removal	1	0
Urethroplasty	8	4

HOLAP	2	1
Lower Ureterolithotomy	2	2
Lt RIRS	1	0
Progressive perineal Urethroplaty	3	1
Ureterocele Incision	0	1
B/L Open Hernioplasty	0	1
Open Diverticuloctomy	1	1
B/L Orchidetomy	0	1
PCCL	1	0
Abdominal myomectomy	1	1
Vaginal Hystrectomy	2	2
Vaginoplasty	1	3
Cystoceol Repair	1	1

Table 3: Development and regression of Sensory block

Parameter	Group-RD	Group-RF
Onset of sensory block at T10 (min)	2.77±8.11	5.31±16.6*
No of patients having maximum spread of sensory block upto T 4	21	10*
2 Segement regression time (min)	178.8 +49.7	155.8+44.4
Duration of Sensory block at S1(min)	303.46±71.56	275.21±46.54

Table 4: Onset and duration of motor block

Parameter	Group-RD	Group-RF
Onset of motor block (min)	7.18±9.55	8.41±16.6
Duration of Motor block(min)	258.80±64.19	229.59±48.58*

The onset of motor block i.e. the time to achieve modified bromage scale of 3 was earlier but non-significant (7.18±9.55 min) in the RD group, than RF group i.e (8.41±16.9) min. (p-0.645). The median duration of complete motor block (modified bromage scale 3) was significantly longer in the RD group (258.86 ±4.19) compared with the RF group (229.59±48.58). (P- 0.01).

Heart Rate: There was no statistically significant difference in the heart rate but bradycardia was observed in 2 patients in group RD in comparision with 1 patient in RF group. Heart rate comparison is shown in fig.1

Mean arterial pressure: There was no statistically significant difference in the mean arterial pressure between two groups and it is shown in fig 2.

Intra-op complications: Intra-op hypotension requiring treatment with i.v. mephentermine 10mg occurred in 7 patients in RD group and in 6 patients in the RF group. Two patients in the RD group also required i.v. atropine 0.6 mg for the treatment of bradycardia compared with none in the RF group. 6 patients in RF group required i.v.Tramadol 25mg for the treatment of shivering compared with 2 patients in the RD group and 5 patients required i.v. ondensetron for nausea/vomiting in RF group compared with 3 patients in RD group.

Table 5: Intra-op complications

Variables	Group-RD	Group-RF
Hypotension	7	6
Nausea/Vomiting	3	5
Sedation	3	0
Shivering	2	6
Brady cardia	2	1

Post-op complications

Post op side effects like shivering, vomiting, headache, pruritus where observed in minimum no. of patients in both the groups.

Table 6: Post-op complications

Variables	**Group-RD**	**Group-RF**
Shivering	0.0	2.0
Vomiting	1.0	2.0
Pruritus	0.0	1.0
Headache	0.0	1.0

Post op analgesia

The first demand for rescue analgesia occurred after a significantly longer duration in group RD as compared to Group RF. The total tramadol requirement was also significantly higher in group RF

Table 7: Post-op analgesia

Parameter	GROUP RD	GROUP RF
Total consumption of tramadol(mg)	111.6± 46.01	162.3±82.55*
Time for First rescue analgesia (Hrs)	11.7± 6.46	15.7±7.03*

Fig 1 Heart rate comparison in two groups

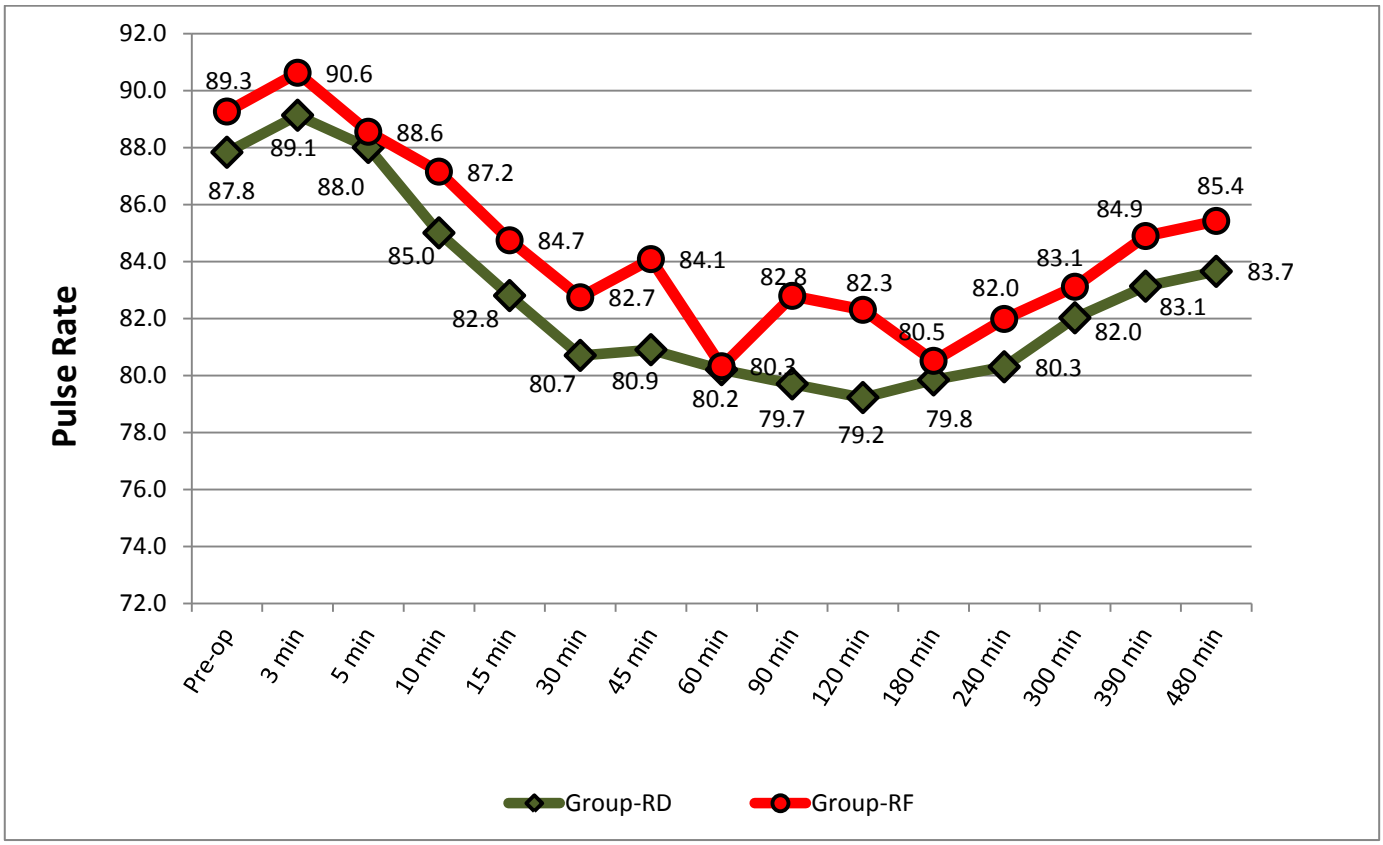
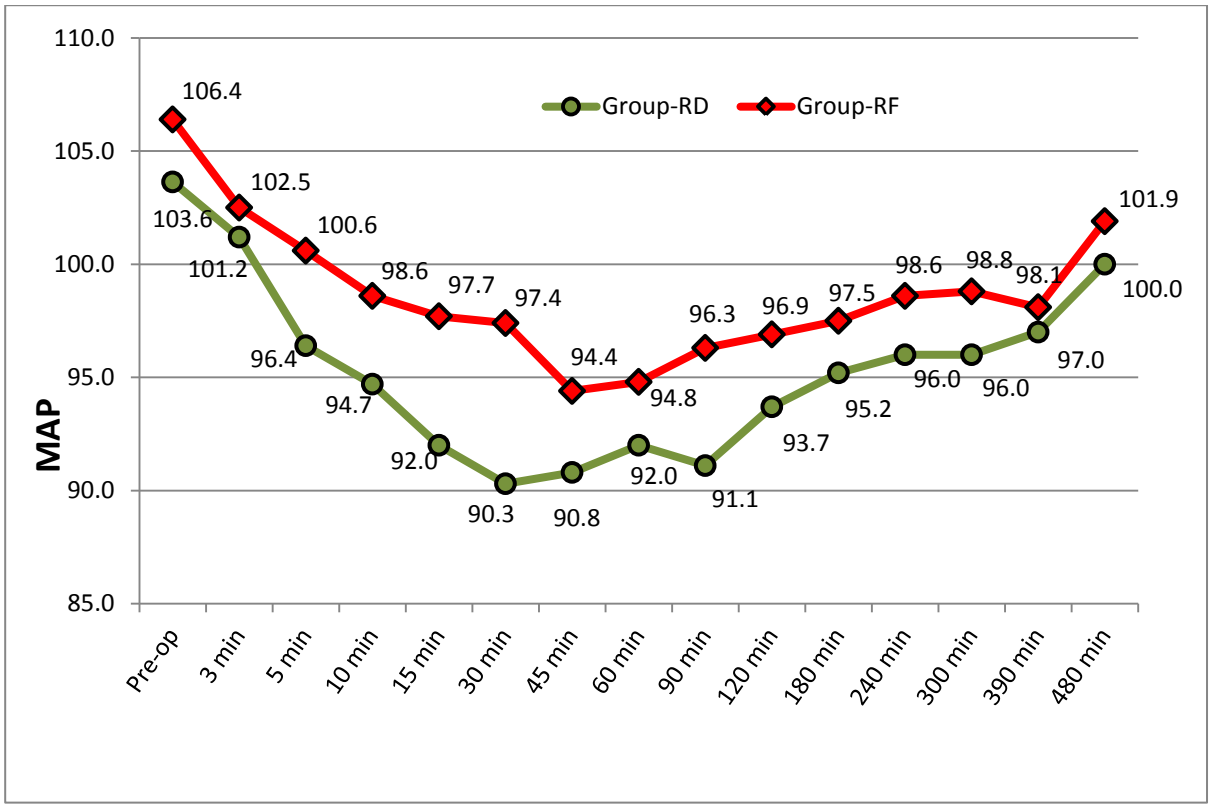


Fig.2: Mean arterial pressure comparison in two groups



Discussion

Spinal anesthesia is the regional anesthetic technique used especially for surgeries involving lower half of the body. It is simple, safe, economic and easy to perform. It is rapid in onset and provides reliable surgical anaesthesia and excellent muscle relaxation.

Delfino et al[1] compared 3.0 ml 0.5% isobaric ropivacaine with same dose of bupivacaine in orthopaedic surgery and found that there were no significant differences regarding the time to maximum sensory block level between two groups. However, the time of onset of non-stimulated pain at the surgical site and the duration of motor block were significantly shorter in the ropivacaine group. Another study by Mcclelland et al.[2] showed that 17.5mg ropivacaine (5mg/ml) produced a similar efficacy and tolerability profile compared with bupivacaine 17.5mg, although there was a shorter duration of sensory and motor block after ropivacaine administration without any neurotoxic effects. In order to maintain the advantage of low dose ropivacaine while improving intraoperative quality of anaesthesia, the use of analgesic adjuvants has been proven to be very valuable. Many adjuvants have been used with local anaesthetics intrathecally like fentanyl, clonidine, dexmeditomidine etc.

Dexmeditomidine is a highly selective α2 adrenoreceptor agonist used as Intravenous sedative and adjuvant to anesthesia. Intrathecal Dexmeditomidine when combined with spinal bupivacaine prolongs the sensory block by depressing the release of C-fibers transmitters and by hyperpolarisation of postsynaptic dorsal horn neurons[3]. Motor block prolongation by α2 adrenoceptor agonists may result from binding these agonist to motor neurons in the dorsal horn of the spinal cord[4]. Intrathecal α2-receptor agonists have been found to have antinociceptive action for both somatic and visceral pain[5]. We have compared the effect of onset and duration of sensory and motor block and analgesic efficacy of D exmeditomidine and Fentanyl in addition with ropivacaine. Other studies have demonstrated that the quality of analgesia with low dose ropivacaine can be improved by adding opioids. The addition of fentanyl to local anaesthetics has several advantages including a synergistic analgesic effect. Intrathecal opioids enhance analgesia from subtherapeutics doses of local anaesthetic and make it possible to achieve successful spinal anaesthesia using what would otherwise be an inadequate dose of local anaesthetics. Fentanyl increases the level and duration of sensory block, without altering motor block characteristics[6]. In one study Seewal et al[7] found a significant improvement in the duration and quality of analgesia produced by intrathecal fentanyl and bupivacaine compared to intrathecal bupivacaine alone and that was not dose related . This is consistent with the study of M Mantouvalou et al in 2008[16], They have found that ropivacaine without opioid presented a slower onset and a shorter duration of motor block, as well as a faster resolution of sensory block compared with bupivacaine. In our study DXM & Fentanyl were added to Ropivacaine & compared. We found that the duration of post-operative analgesia was significantly prolonged in patients in whom DXM was administerd as intrathecal α2-receptor agonists have been found to have antinociceptive action for both the somatic and visceral pain[9].We compared the onset and duration of sensory and motor blockade following intrathecal ropivacaine with Dexmeditomidine versus Fentanyl,. Similar study was done by Subhi M. Al-Ghanem et al[10] using isobaric bupivacaine(10 mg) with Dexmeditomidine 5µg versus 25 µg fentanyl and found that the onset of peak sensory to reach T10 level and motor blockage (bromage 3) were not significantly different between two groups but the duration of sensory and motor blockage was longer in groupD as compared to group F. The mean time of sensory regression to S1 was 274±73 min in groupD and 179±47 min in groupF (P<0.001). The regression time of motor block to reach modified Bromage 0 was 240± 60 min in group D and 155±46 min in group F (P <.0.001). Similar comparative study of intrathecal Dexmeditomidine and fentanyl as an adjuvant to bupivacaine was done by Rajni gupta et

al[11] compared 12.5mg hyperbaric bupivacaine with5µg DXM (group D) versus 25µg fentanyl (group F) and found that group D had a significantly longer sensory and motor block time than groupF. The mean time of sensory regression to S1 was 476±23 min in group D and187±12 min in group F (P<0.001). and the regression time of motor block to reach modified Bromage 0 was 421±21 min in group D and 149±18 min in group F ((P<0.001).

In our study we compared the intrathecal DXM (5µg) and fentanyl (25µg) as an adjuvant to 0.75% ropivacaine (18.75mg) and we found that the onset of sensory and motor blockade was earlier in RD group 2.77 min & 7.18 min as compared to RF group which was 5.31 min. & 8.41min. The duration of sensory and motor block was longer in RD group 295.73 min & 250.94 min as compared to RF group 276.29 min & 236.20 min. The mean time of sensory regression to S1 was 172.66 min in group RD and 161.18 min in group RF which was almost similar to the above studies. The most significant side effects reported about the use of intrathecal α2 adrenoceptor agonists were bradycardia & hypotension. In Subhi M.AL-Ghanem et al[10] study, these side effects were not significant which was confirmed by the findings of Kanazi report., hypotension was found more in fentanyl group than DXM group, meanwhile, hypotension occurred in 2 patients in DXM group and one patient in fentanyl group.Pruritus was noted in 40-70% in fentanyl group & only 13% in DXM group. In our study 13% patient of RD group developed hypotension & 3.7% patient develop brdycardia where as in RF group, 11.3% patient developed hypotension & 1.8% patient bradycardia ,which was not significant .but the other side effects like shivering, vomiting, itching was more in RF group as compared to RD group.

Suhminder jit singh bajwa et al[12] done comparative evaluation of dexmeditomidine (1µg/kg) and fentanyl (1µg/kg) as an adjuvant to 15 ml 0.75% ropivacaine for epidural anaesthesia in lower limb orthopaedic surgeries. They found that the onset of sensory analgesia at T10 (7.12 ± 2.44) vs 9.14± 2.94) and establishment of complete motor blockade (18.16 ± 4.52 vs 22.98± 4.78) was significantly earlier in the RD group which was similar to our study .Post-op analgesia was prolonged significantly in the RD group.(366.62 ± 24.42). time to two segmental dermatomal regression was (140.32± 10.21 in RD vs 110.84 ±9.48 in RF group) (p=0.004) as well as earlier return of motor power to bromage 1 in RF group(178.52 ±23.29) as compared to RD group patients (259.62 ± 21.38) (p=0.009).

Conclusion

To conclude, we found that intrathecal (5µg) DXM supplementation with 0.75% ropivacaine seems to be a better alternative to intrathecal (25µg) fentanyl with 0.75% ropivacaine since it produces prolonged sensory& motor blockade and more effective pain relief, thus making it a more lucrative option for lower abdominal and uro-gynacological surgeries.

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