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Research Article

A Comparative Study of Hyperbaric Ropivacaine with Dexmedetomidine As a Lower Abdominal Surgeries- A Double Blind Randomized Trial

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Abstract: **Background and Aims**: To compare the efficacy and safety of intrathecal hyperbaric Ropivacaine without adjuvant and with adjuvant Dexmedetomidine for lower abdominal surgeries. **Methods:** This was a prospective, randomized, double-blind, comparative study conducted among the patients who were ASA grade I or II, age 18 to 60 years planned for lower abdomen surgeries under spinal anaesthesia. Patients were randomly allocated to two groups (30 in each): Ropivacaine Group (control group or R group): spinal anesthesia with 3ml of 0.6% hyperbaric Ropivacaine (18mg) + 0.5ml NS. Dexmedetomidine Group (R+D or D group): spinal anesthesia with 3ml of 0.6% hyperbaric Ropivacaine (18mg) + 0.5ml Dexmedetomidine (5 mcg). All patients scheduled for operation were given oral tablets ranitidine 150 mg and Alprazolam 0.25mg in the night before surgery. **Results:** There was no significant difference in the basic characteristics between the groups. Heart rate, MAP and SpO2 were similar between the groups across time. The onset sensory levels and bromage were significantly ($p=0.0001$) higher among the patients of Group R compared with R+D. The 2 segment sensory regression (min), sensory regression S2 (hr), motor recovery (hrs), long term mobilization after spinal anesthesia, total amount of vasopressor given and total amount of Atropine given were significantly ($p<0.05$) lower among the patients of Group R compared with R+D. The percentage of complications was almost low in both the groups. **Conclusion:** Dexmedetomidine may be more suitable drug in surgeries in which muscle relaxation has greater value in lower abdominal surgeries**.**

Keywords: Spinal anesthesia, Hyperbaric ropivacaine, Dexmedetomidine, Intrathecal.

INTRODUCTION

Spinal anaesthesia is commonly performed at L2-L3 level. Drug is injected in to subarachnoid space. Various local anaesthetics are commonly injected like lignocaine, procaine, chlorprocaine, bupivacaine, ropivacaine to block the nerve transmission to spinal cord. Various adjuvant drugs are combined along with local anaesthetics to prolong the effects of local anaesthetics like fentanyl, alfentanil, sufentanil clonidine, dexmedetomidine, magnesium sulphate, neostigmine, epinephrine etc. Which one is better and best is always a controversy. Ropivacaine is a long-acting amide local anesthetic agent and first produced as a pure enantiomer. It produces effects similar to other local anaesthetics via reversible inhibition of sodium ion influx in nerve fibres. Ropivacaine is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibres, resulting in a relatively reduced motor blockade. Thus, ropivacaine has a greater degree of motor sensory differentiation, which could be useful when motor blockade is undesirable (Kuthiala, G., & Chaudhary, G. 2011).

Dexmedetomidine, an imidazole compound, is the pharmacologically active dextroisomer of medetomidine that displays selective dose dependent α_2-adrenoceptor agonism. Addition of clonidine or dexmedetomidine to bupivacaine prolong caudal analgesia in children undergoing lower abdominal surgeries (El-Hennawy, A. M). Dexmedetomidine has a

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dose dependant effect on the onset and regression of sensory and motor block when used as an adjuvant to bupivacaine in spinal anesthesia (Al-Mustafa, M. M. *et al*., 2009). Intrathecal dexmedetomidine along with bupivacaine produces significantly short onset of sensory and motor block, intra and post op sedation analgesia for longer duration Intrathecal dexmedetomidine is associated with prolonged motor and sensory block, hemodynamic stability, and reduced demand for rescue analgesics in 24 h as compared to fentanyl (Gupta, R. *et al*., 2011)**.** The present study was conducted to compare the efficacy and safety of intrathecal hyperbaric Ropivacaine without adjuvant and with adjuvant Dexmedetomidine for lower abdominal surgeries.

METHODS

This was a prospective, randomized, double-blind, comparative study conducted among the patients who were ASA grade I or II, age 18 to 60 years planned for lower abdomen surgeries to be done under spinal anaesthesia. The study was carried in various Surgical Departments between August 2013-14, KGMU Erstwhile CSMMU, Lucknow, UP. The study was approved by the ethical committee of the institute and informed consent was obtained from all the patients. The patients aged 18 to 60 years, either sex, ASA grade I & II undergoing lower abdominal surgeries under spinal anesthesia and weight ±20% of ideal body weight were included in the study. The exclusion criteria were patients whom central neuraxial block was contraindicated, those with history of adverse reaction to any study medication, cardiovascular diseases, pulmonary diseases, chronic use of cardiovascular medications (β blocker, ACE inhibitor etc), history of analgesic use, chronic pain syndrome, where communication difficulties preventing reliable assessment, history of allergic drugs with study medication and pregnant and lactating females. Patients were randomly allocated to two groups: 30 patients in each group using the computer generated random table. Ropivacaine Group (control group or R group): spinal anesthesia with 3ml of 0.6% hyperbaric Ropivacaine (18mg) + 0.5ml NS. Dexmedetomidine Group (R+D or D group): spinal anesthesia with 3ml of 0.6% hyperbaric Ropivacaine (18mg) + 0.5ml Dexmedetomidine (5 µg). All patients scheduled for operation were given oral tablets ranitidine 150 mg and Alprazolam 0.25mg in the night before surgery. All patients were nil per orally for 6 hours. After arrival in operating room intravenous access was secured and standard monitoring with noninvasive blood pressure, electrocardiography and pulse oximetry was done. All the patients in the study group were catheterized. Baseline heart rate (HR), Mean arterial pressure and oxygen saturation were recorded. Drugs were prepared by anaesthetics who were not involved in study after the drug preparation. After taking adequate aseptic preparation drugs were made. Solution for control group was prepared by taking 4ml of 0.75% ropivacaine(30mg) in syringe and mixing it with 1ml of 25% dextrose to make it 0.6% hyperbaric ropivacaine(5ml), 2ml of this solution was discarded 3ml of this 0.6% hyperbaric ropivacaine (18mg) was mixed with ½ ml of 0.9% normal saline to make the final solution of 3.5ml of 0.6% hyperbaric ropivacaine (18mg). The specific gravity of solution was 1.010. Solution for dexmedetomidine group was prepared by taking 4ml of 0.75% ropivacaine (30mg) in syringe number 1 and mixing it with 1ml of 25% dextrose to make it hyperbaric ropivacaine, 2 ml of this solution was discarded. Then in syringe number 2, 1ml of dexmedetomidine taken and mixed it with 9ml of 0.9% normal saline to make the total volume 10 ml. Now solution contains 10µg dexmedetomidine per ml, ½ ml of this solution from syringe number 2 is mixed with 3ml of hyperbaric ropivacaine to make the final solution 3.5ml of 0.6% hyperbaric ropivacaine, (18mg) + 5µg of dexmedetomidine. Specific gravity of solution was 1.020.

Patients were preloaded with lactated ringer solution 10ml/kg body weight in 15 min. With all aseptic precautions, spinal was applied in sitting position at the level of L2-L3 with 25 G pencil point needle (Pancan, B.Braun, Melsungen, Germany) and the anesthetic solution was injected without barbotage or aspiration at the beginning or at the end of injection. All injections were made with hole in the spinal needle facing upward. The injection was made over a span of 15 seconds and the patients were returned to supine position immediately after completion the block. Sensory and motor assessment methods were described to all patients before starting of anaesthesia. Sensory level was assessed using Pinprick testing in midclavicular bilaterally and time taken to reach T10, T8 and peak sensory level was recorded. Time taken to Two segment sensory regression, time taken to sensory regression at S2 was also recorded. Motor blockade was determined using Modified Bromage Scale.

Haemodynamic data, including mean arterial pressure and heart rate, was recorded every 2 min in the first 15 min after spinal anesthesia, then every 5 minutes till 90. The anaesthesiologist recording the data, the surgeon, the patients, and the nursing staff were all blind to patient group assignment. Complications during surgery were treated as follows: Hypotension (defined as a mean arterial pressure of <65 mm Hg) was treated with adequate fluids and increments of 6mg mephentramine, Bradycardia (defined as a heart rate of <50 bpm) was treated with 0.4 mg of atropine, Oxygen desaturation (defined as pulse oximetry oxygen saturation <94% on room air) was treated with oxygen via Hudson's face mask. If a patient complained about discomfort or pain, midazolam and fentanyl by anaesthetics in titrated doses. In the event of inadequate spinal block (defined as pain severe enough to interfere with the surgical procedure General anesthesia was administered.

Nausea/ vomiting was treated by fluid, oxygen and ondansetron 4mg I.V. Shivering was treated by tramadol 0.5mg/kg body weight.

In the post-anesthesia care unit, pain was treated with intravenous injection of paracetamol 1000 mg titrated to patient comfort. In case of breakthrough pain, rescue analgesia was given using injection tramadol 25-100mg in titrated dose. The surgeon's and patient's satisfaction was recorded on 5-point Likert scale. The amount of tramadol administered, paracetamol administered after operation, time to first analgesic dose and the occurrence of any intraoperative or postoperative adverse events, including (but not limited to) nausea, vomiting, itching, respiratory depression (defined as a respiratory rate <12 bpm) and postural puncture headache, were documented and treated accordingly.

Statistical analysis: Continuous data was summarized as mean±SD while discrete (dichotomous/categorical) was in percentages. The primary outcome measures (HR, MAP and SpO_2) of two groups over the periods (time) were compared by repeated measures two factor (Groups and Periods) analysis of variance (ANOVA) using general linear models (GLM) followed by Turkey's post hoc test. Groups were compared by unpaired t-test. The categorical variables were compared by chi-square (χ^2) test. A two-sided (α=2) $p<0.05$ was considered statistically significant. All analyses were performed on STATISTICA (window version 6.0).

RESULTS

The basic characteristics viz. age, gender, weight, height and ASA grade of the two groups at admission (baseline) are summarized in Table-1.

Table-1: Basic characteristics of the groups

Characteristics	Group R (n=30)	Group R+D (n=30)	p value
Age (yrs)	43.10 ± 11.24	42.80 ± 10.96	0.91
Sex: Males Females	 20 (66.7%) 10 (33.3%)	 18 (60.0%) 12 (40.0%)	0.59
Height (cm)	159.13 ± 8.69	156.83 ± 8.11	0.29
Weight (kg)	62.53 ± 6.17	61.30 ± 4.59	0.38
ASA physical status: I II	 23 (76.7%) 7 (23.3%)	 22 (73.3%) 8 (26.7%)	0.76

There was no significant difference in the basic characteristics between the groups, both the groups were comparable. The mean HR in both the groups decreased over the periods as compared to baseline. However, the trend of HR over the periods remains similar in both R and R+D groups and no significant difference was found between the groups (Fig.1).

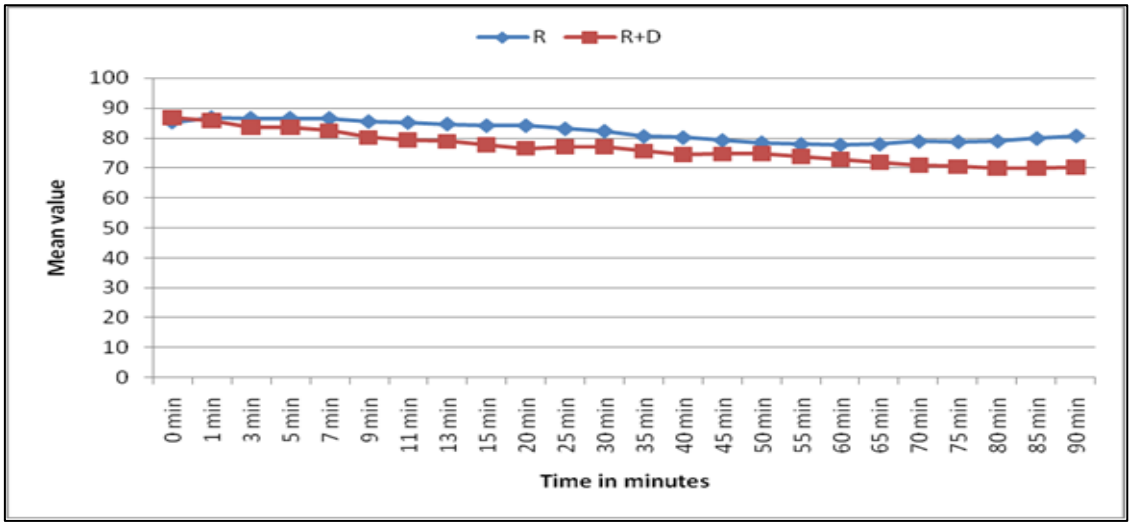

Fig.1: Mean heart rate at different time

The mean MAP and SpO_2 in both the groups were almost similar over the different time and were similar in both the groups respectively (Fig. 2 & 3).

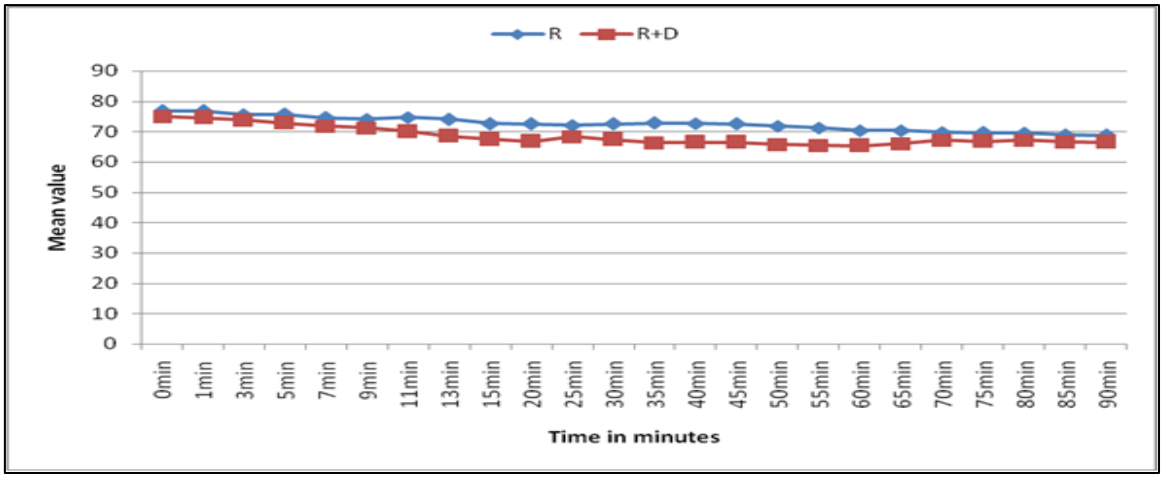

Fig.2: Mean MAP rate at different time

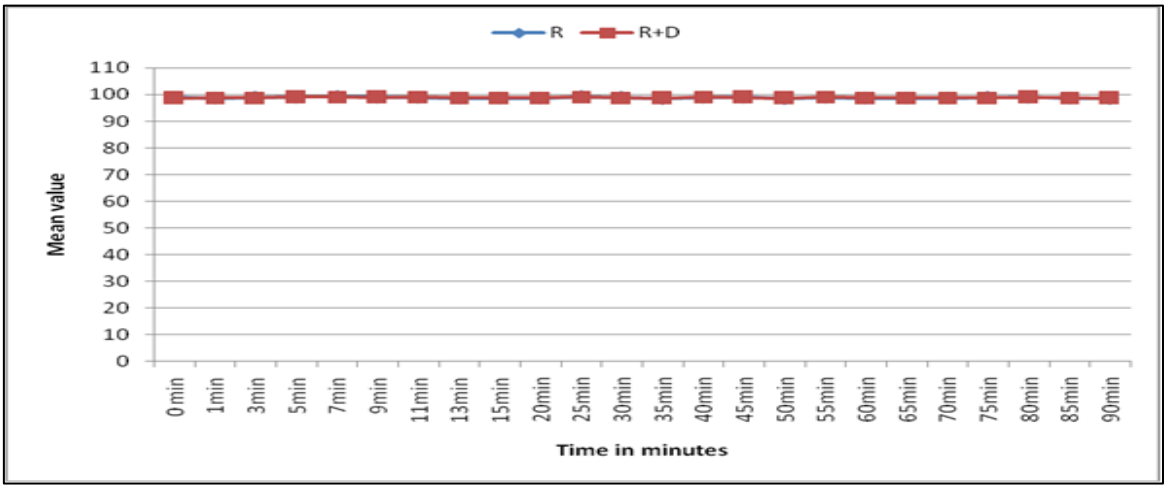

Fig.3: Mean SpO_2 rate at different time

The onset sensory levels were significantly (p=0.0001) higher among the patients of Group R compared with R+D. Similarly, the bromage levels were significantly (p=0.0001) higher among the patients of Group R compared with R+D. The two segment sensory regression (min), sensory regression S2 (h), motor recovery (h), long term mobilization after spinal anesthesia, total amount of vasopressor given and total amount of Atropine given were significantly (p<0.05) lower among the patients of Group R compared with R+D. The surgeon's satisfaction for intra-operatively sedation analgesia and motor blockade was higher in Group R+D than Group R, the difference was statistically significant (p=0.0001). Similarly, the patient's satisfaction for intra-operatively sedation analgesia and motor blockade was also significantly (p=0.0001) higher in Group R+D than Group R. (Table-2).

Table-2: Secondary outcome measures summary (Mean ± SD, n=30) of the groups

Secondary outcome measures	Group R	Group R+D	P value[1]
Onset sensory level:			
T10	5.17 ± 0.87	2.57 ± 0.50	0.0001*
T8	7.17 ± 0.87	3.73 ± 0.52	0.0001*
T6	10.43 ± 1.41	4.83 ± 0.59	0.0001*
T4	13.30 ± 2.26	6.83 ± 1.18	0.0001*
Bromage:			
B1	12.43 ± 2.11	7.77 ± 0.77	0.0001*
B2	9.13 ± 0.94	5.17 ± 0.75	0.0001*
B3	6.43 ± 0.94	3.77 ± 0.43	0.0001*
B4	3.87 ± 0.57	2.60 ± 0.50	0.001*
B5	2.30 ± 0.53	1.47 ± 0.51	0.001*
B6	0.73 ± 0.74	0.30 ± 0.47	0.009*
2 segment sensory regression (min)	28.43 ± 2.21	51.83 ± 5.65	0.0001*
Sensory regression S2 (hr)	2.03 ± 0.39	5.02 ± 0.65	0.0001*
Motor recovery (hrs)	1.83 ± 0.37	4.62 ± 0.65	0.0001*

Long term Mobilization after spinal anesthesia (hrs)	2.28 ± 0.41	7.22 ± 0.70	0.0001*
Total amount of vasopressor given (mephentremine) (mg)	9.33 ± 3.16	12.17 ± 5.94	0.02*
Total amount of Atropine given (mg)	0.48 ± 0.04	0.52 ± 0.08	0.01*
Surgeon's satisfaction for intra-operatively sedation analgesia and motor blockade (7 point Likert like verbal rating scale)	3.47 ± 0.51	6.77 ± 0.43	0.0001*
Patient's satisfaction for intra-operatively sedation analgesia and motor blockade (7 point Likert like verbal rating scale)	3.60 ± 0.50	6.77 ± 0.43	0.0001*

[1]Unpaired t-test, *Significant

The comparison of complications between the groups is depicted in Table-3.

Table-3: Comparison of complications between the groups

Complications*	R (n=30)	R+D (n=30)	p value
Nausea	3 (10.0%)	2 (6.7%)	0.64
Vomiting	4 (13.3%)	1 (3.3%)	0.16
Postdural Puncture Headache	0 (0.0%)	0 (0.0%)	NA
Hypotension	8 (26.7%)	12 (40.0%)	0.27
Bradicardia	6 (20.0%)	7 (23.3%)	0.75
Respiratory depression	0 (0.0%)	0 (0.0%)	NA
Urinary Retension	0 (0.0%)	0 (0.0%)	NA
Itching	0 (0.0%)	0 (0.0%)	NA
Shivering	5 (16.7%)	0 (0.0%)	NA
Long term complications in follow up of patients (6 wk to 6 months)	0 (0.0%)	0 (0.0%)	NA

*Multiple response

The symptom of nausea was observed among 10% patients of Group R and 6.7% in Group R+D. However, vomiting was observed among 13.3% patients of Group R and 3.3% in Group R+D. There was no significant ($p>0.05$) difference in the complications between the groups.

DISCUSSION

In our study, we have taken 18 mg of hyperbaric ropivacaine because it is safe in spinal anaesthesia and does not cause major side effect, improves the quality and prolong the duration of analgesia early mobilization (Yegin, A. *et al*., 2005). Bigat Z *et al*., concluded that 10 mg of 0.66% hyperbaric ropivacaine is preferred to 7.5 mg of 0.5% hyperbaric bupivacaine because it provided a more selective unilateral block and a faster recovery in outpatient knee arthroscopy (Bigat, Z. *et al*., 2006). Fettes *et al*., also found that addition of glucose 50 mg/ ml to ropivacaine 5 mg/ ml increased the speed of onset, block reliability, duration of useful block for perineal surgery, and speed of recovery (Fettes, P. D. W. *et al*., 2004).

In this study, 5 µg dexmedetomidine was taken because it was safe and produced a prolongation in the duration of the motor and sensory block, 24 hr analgesic requirement and hemodynamic stability without significant side effect[4]. In the present study, in both the groups a decrease in HR was found, however, it was similar in both the groups across the time intervals which was in agreement with the study by Mohamed *et al*., (2006) In this study, the mean arterial pressure and Spo_2 were stable over the time and no significant difference was observed between the groups over the time. Mohamed *et al*., had also reported that the intrathecal ropivacaine is better than bupivacaine in terms of hemodynamics stability (Khalili, G. *et al*., 2011). Our study showed significantly ($p<0.001$) rapid onset of peak sensory and motor blockade in R+D group in comparison to ropivacaine group as well as bromage motor block. It might be because we have used hyperbaric ropivacaine and following studies used hyperbaric bupivacaine. It had been reported that the addition of dexmedetomidine to ropivacaine intrathecally produced a prolongation in the duration of the motor and sensory block (Gupta, R. *et al*., 2011) which is in contrast to our study. Khalili *et al*., observed that 3µg dexmedetomidine added to 12 mg spinal bupivacaine produced the significant short onset of sensory blockade (Khalili, G.,. *et al*., 2011). In our study, we observed addition of dexmedetomidine (R+D group) caused significant ($p<0.001$) prolongation of two segment sensory regression (S2) in comparison to ropivacaine (R group) group. Our finding was correlated with the other studies (Al-Mustafa, M. M. *et al*., 2009; Gupta, R. *et al*., 2011). In the present study, the sensory regression and complete motor recovery was significantly ($p<0.001$) higher in dexmedetomidine group in comparison to control group so the total duration of sensory and motor blockade was significantly ($p<0.001$) higher in dexmedetomidine group in comparison to control group and prolongs the duration of sensory and motor blockade so mobilization was delayed in dexmedetomidine group as compared to ropivacaine group. Our observations are similar to the other studies (Al-Mustafa, M. M. *et al*., 2009; Shukla, D. *et al*., 2011). Early mobilization was possible in ropivacaine group when compared with dexmedetomidine group in the present study.

In the present study, it was observed that total amount of atropine and vasopressor (mephentrimine) given to patients were high in dexmedetomidine group in comparison to ropivacaine which consistent with the studies conducted by Aho *et al*., (Aho, M. *et al*., 1993) We observed surgeon's & patient's satisfaction for intra operative sedation analgesia and motor blockade significantly higher in dexmedetomidine group as compared to ropivacaine group. In our study, we observed nausea, vomiting and shivering in both the groups but it was not statistically significant between the groups. The symptoms of nausea and vomiting were lower in R+D group than R group. Salgado *et al*., reported that shivering and vomiting was higher in dexmedetomidine group in comparison to control group in epidural anaesthesia (Salgado, P. F. S. *et al*., 2008).

The present study establishes that dexmedetomidine is a superior drug as compared to hyperbaric ropivacaine for patients undergoing lower abdominal surgeries as it provides faster onset of anesthesia, better intraoperative and postoperative analgesia, sedation, patient comfort and better operating conditions, reduced need of postoperative analgesic requirement, however it is associated with delayed motor recovery, ambulation with adverse effect hypotension and bradycardia.

CONCLUSION

Dexmedetomidine may be more suitable drug in surgeries in which muscle relaxation has greater value in lower abdominal surgeries.

REFERENCES:

1. Kuthiala, G., & Chaudhary, G. (2011). Ropivacaine: A review of its pharmacology and clinical use. *Indian journal of anaesthesia*, *55*(2), 104.
2. El-Hennawy, A. M., Abd-Elwahab, A. M., Abd-Elmaksoud, A. M., El-Ozairy, H. S., & Boulis, S. R. (2009). Addition of clonidine or dexmedetomidine to bupivacaine prolongs caudal analgesia in children. *British journal of anaesthesia*, *103*(2), 268-274.
3. Al-Mustafa, M. M., Abu-Halaweh, S. A., Aloweidi, A. S., Murshidi, M. M., Ammari, B. A., Awwad, Z. M., ... & Ramsay, M. A. (2009). Effect of dexmedetomidine added to spinal bupivacaine for urological procedures. *Saudi Med J*, *30*(3), 365-70.
4. Gupta, R., Bogra, J., Verma, R., Kohli, M., Kushwaha, J. K., & Kumar, S. (2011). Dexmedetomidine as an intrathecal adjuvant for postoperative analgesia. *Indian journal of anaesthesia*, *55*(4), 347.
5. Yegin, A., Sanli, S., Hadimioglu, N., Akbas, M., & Karsli, B. (2005). Intrathecal fentanyl added to hyperbaric ropivacaine for transurethral resection of the prostate. *Acta anaesthesiologica scandinavica*, *49*(3), 401-405.
6. Bigat, Z., Boztug, N., Karsli, B., Cete, N., & Ertok, E. (2006). Comparison of hyperbaric ropivacaine and hyperbaric bupivacaine in unilateral spinal anaesthesia. *Clinical drug investigation*, *26*(1), 35-41.
7. Fettes, P. D. W., Hocking, G., Peterson, M. K., Luck, J. F., & Wildsmith, J. A. W. (2004). Comparison of plain and hyperbaric solutions of ropivacaine for spinal anaesthesia. *British journal of anaesthesia*, *94*(1), 107-111.
8. Sultan, M. A., Shams, T. M. A., Mageed, N. A., & El-Ebidy, M. G. (2006). Intrathecal hyperbaric ropivacaine versus hyperbaric bupivacaine in geriatric hypertensive patients. *EGYPTIAN JOURNAL OF ANAESTHESIA*, *22*(3), 203.
9. Khalili, G., Janghorbani, M., Sajedi, P., & Ahmadi, G. (2011). Effects of adjunct intrathecal magnesium sulfate to bupivacaine for spinal anesthesia: a randomized, double-blind trial in patients undergoing lower extremity surgery. *Journal of anesthesia*, *25*(6), 892-897.
10. Shukla, D., Verma, A., Agarwal, A., Pandey, H. D., & Tyagi, C. (2011). Comparative study of intrathecal dexmedetomidine with intrathecal magnesium sulfate used as adjuvants to bupivacaine. *Journal of anaesthesiology, clinical pharmacology*, *27*(4), 495.
11. Aho, M., Erkola, O., Kallio, A., Scheinin, H., & Korttila, K. (1993). Comparison of dexmedetomidine and midazolam sedation and antagonism of dexmedetomidine with atipamezole. *Journal of clinical anesthesia*, *5*(3), 194-203.
12. Salgado, P. F. S., Sabbag, A. T., Silva, P. C. D., Brienze, S. L. A., Dalto, H. P., Módolo, N. S. P., ... & Nascimento Jr, P. (2008). Synergistic effect between dexmedetomidine and 0.75% ropivacaine in epidural anesthesia. *Revista da Associacao Medica Brasileira*, *54*(2), 110-115.