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ORIGINAL ARTICLE

TO EVALUATE THE EFFICACY OF INTRATHECAL ISOBARIC 0.75% ROPIVACAINE WITH THE COMBINATION OF ISOBARIC 0.75% ROPIVACAINE AND DEXMEDETOMIDINE IN GERIATRIC HYPERTENSIVE PATIENTS UNDERGOING UROLOGICAL SURGERIES: A PROSPECTIVE, RANDOMISED, CONTROLLED, DOUBLE-BLIND STUDY

Yerramsetti Atchyutha Ramaiah[1], Srinivasa Rao Manduri[2], B. Sowbhaghya Lakshmi[3], Pydi Lalitha[4]

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ABSTRACT: Spinal Anaesthesia is the most common approach for geriatric patients undergoing urological surgeries. Efforts to find a better adjuvant in regional anaesthesia are underway since long. Various adjuvants have been used with local anesthetics in spinal anesthesia to improve quality of intraoperative analgesia and to provide prolonged postoperative analgesia with haemodynamic stability and minimal sideeffects. Dexmedetomidine, the new highly selective α2-agonist drug, is now being used as a neuraxial adjuvant. **AIM:** The aim of this study was to evaluate the efficacy of intrathecal isobaric 0.75% Ropivacaine with the combination of isobaric 0.75% Ropivacaine and 5μg of Dexmedetomidine in Geriatric Hypertensive patients undergoing Urological surgeries. **MATERIALS AND METHODS:** Fifty patients classified in American Society of Anesthesiologists classes II and III scheduled for Urological surgeries were studied. Patients were randomly allocated to receive either. **Group R**: 1.9 ml of 0.75% isobaric Ropivacaine + 0.1 ml normal saline. **Group D**: 1.9 ml volume of 0.75% isobaric ropivacaine +5 μg Dexmedetomidine (0.1ml). **RESULTS:** Patients in Dexmedetomidine group (D) had a significantly longer sensory and motor block time than patients in Normal Saline group (R). The mean time of the two segment regression time in group D (115.6 ± 14.5 min) was significantly higher than group R (57.4 ± 6.3 min) (P<0.001). The regression time of motor block to reach modified Bromage 0 was (246.4 ± 25.7 min) in group D and 140.1 ± 32.3 min in group R (P<0.001).The meantime of rescue analgesia is (425.4±18.9 min) in group D when compared to group R (210.3 ± 14.2). **CONCLUSIONS:** Intrathecal dexmedetomidine as a adjuvant is improved the quality of intraoperative analgesia and postoperative analgesia better, produced prolonged motor and sensory block, hemodynamic stability, and reduced demand for rescue analgesics in 24 hours as compared to control group.

KEYWORDS: Intrathecal, Spinal adjuvant, Dexmedetomidine, Spinal anaesthesia.

INTRODUCTION: Advancing age is not a contraindication for either surgery or Anaesthesia, however, Identification of age related diseases and estimation of physiological reserve in that particular patient is the key for successful outcome.[1]

Age-related physiological changes interact with anesthetic agents, modifying patient response and risk for complications**.** Co-morbidities in the elderly, especially geriatric syndromes, modify the risk profile of the patient and can interact with anesthetic agents, leading to different responses. There is a need to include these factors in assessing an elderly patient prior to a surgical procedure.

DOI: 10.14260/jemds/2015/52

Hypertension is often co-exisitng morbidity in the elderly and is often associated with haemodynamic instability especially those on irregular treatment. This problem is further compounded by type of surgeries like urological surgeries like TURP, as it is also associated haemodynamic instability and also with spinal anaesthesia as it is associated with Hypotension and bradycardia. Choosing right Local anaesthetic and also Spinal adjuvants is detrimental in providing analgesia during perioperative period, stabilizing haemodynamics and preventing complications. So there is continuous search for spinal adjuvant to meet the requirements of particular surgery and the patient.

Dexmedetomidine, a second generation a2- adrenergic agonist,[2] appears to mimic many of the actions of mythical "ideal" sedative/analgesic agent[3] with its wide spectrum of actions encompassing the entire perioperative period and then beyond that into the critical care services. The food and drug administration (FDA) approved the use of Dexmeditomidine as an ICU sedative in 1999 and its use for non-intubated patients adult and padeiatric, requiring sedation prior to and or during surgical procedures in 2008. Dexmeditomidine has evolved as pancea for various applications / procedures with multiple promising deliveries.[4]

Ropivacaine is a first single enantiomer-specific compound, which has a reduced risk of cardiotoxicity,[5] neurotoxicity, and rapid recovery of motor function when given intrathecally.[6] Postoperative pain relief is an important issue with Ropivacaine.

Hence we have undertaken a study to evaluate the efficacy of inj. Dexmeditomidine 5 μg with 0.75% Ropivacaine[7, 8, 9] by intrathecal route compared to control group with normal saline and 0.75% Ropivacine in hypertensive patients undergoing urological surgeries

METHODOLOGY: This study was carried out in the department of Anaesthesiology, Rangaraya Medical College, Government General Hospital, Kakinada from November 2011 to November 2014. The study was conducted after approval of ethical committee of the institution. Written informed consent was obtained from all the patients.

In this study, 50 hypertensive male patients undergoing elective urological surgeries like Trans urethral resection of prostate (TURP) under Spinal Anaesthesia, aged between 45-75 years, belonging to American Society of Anesthesiologists (ASA) physical status II or III were randomly divided using a computer generated random numbers inserted into sealed in envelops marked 1 to 50, the patients were divided into two groups of 25 patients each.

Group R - 1.9 ml of 0.75% isobaric Ropivacaine + 0.1 ml normal saline.

Group D - 1.9 ml volume of 0.75% isobaric ropivacaine + 5 μg. Dexmedetomidine (0.1ml).

Inclusion criteria were, 50 Geriatric, hypertensive, male patients of age between 45 -75 years, posted for elective urological surgeries like TURP under Spinal Anaesthesia.

Exclusion Criteria:

- Patients not willing to participate in the study.
- Patient allergic to both the study drugs,
- Significant heart diseases like complete heart block / dysrrhythmia on ECG.
- Patients using α2receptors antagonists, angiotensin converting enzyme inhibitors.
- Infection at the site of injection, and
- Coagulation abnormalities.

DOI: 10.14260/jemds/2015/52

STATISTICAL DATA: Statistical analysis was done using the Statistical Package for Social Science (SPSS15.0 Evaluation version). To calculate the sample size, a power analysis of α=0.05 and α=0.90, showed that 25 patients per study group were needed. Data are expressed as either mean and standard deviation or numbers and percentages. Continuous covariates were compared using analysis of variance (ANOVA). The comparison was studied using the Chi-square test or Fisher's exact test as appropriate, with the P value reported at the 95% confidence interval. $P<0.05$ was considered statistically significant.

METHODOLOGY:

Pre-anaesthetic evaluation: During preoperative visit patient's detailed history, general physical examination, and systematic examination were carried out. Basic demographic data like age, sex, height, and weight are recorded.

During pre anaesthetic checkup the linear Visual anologue scale (VAS) was explained to all patients using 10 cm scale.

Regular Antihypertensives are continued on the day of surgery.

Informed consent was obtained from all the 50 patients after the detailed explanation of the procedure to be performed.

Pre-medication: All the patients were premedicated with Tab. Alprazolam 0.25 mg per orally on the night before surgery.

PROCEDURE: The pulse rate, respiratory rate, blood pressure and SpO_2 were recorded before starting the case. Peripheral venous canulation was done with 18G iv canula and all the patients were preloaded with Lactated Ringer's solution 10 mL/kg. They were monitored with automated noninvasive blood pressure, pulse oximetry, and electrocardiogram. The patients were placed in sitting position, and under strict aseptic precautions, spinal anaesthesia was given in L3–L4 interspaces with 25G Pencil point spinal needles.

All these patients were randomly divided into two groups and received either of the study drug.

Group R: 1.9 ml of 0.75% isobaric Ropivacaine + 0.1 ml normal saline (n =25) were received Intrathecally.

Group D: 1.9 ml volume of 0.75% isobaric ropivacaine + 5 µg Dexmedetomidine (0.1ml). (n =25) were received Intrathecally.

The intrathecal drug formula was prepared by a separate anesthesiologist and under a sterile technique given to the physician who performed the spinal anesthesia and who was blind to the group to which the patient was allocated and the solution being injected. The surgeon, patient, and the observing anesthesiologist were blinded during the Study.

Sensory block Testing: The level of sensory block was assessed by bilatreal pinprick method, by loss of pinprick sensation to 23G hypodermic needle and dermatomes levels were tested every 2 min until the highest level had stabilized by consecutive tests. On achieving T10 sensory blockade level,

DOI: 10.14260/jemds/2015/52

surgery was allowed. Testing was then conducted every 10 min until the point of two segment regression of the block was observed. Further testing was performed at 20-min intervals until the recovery of S1 dermatome. Data regarding the highest dermatome level of sensory blockade, the time to reach this level from the time of injection, time to S1 level sensory regression, time to urination, and incidence of side effects were recorded.

Quality of motor blockade assessed by BROMAGE SCALE at 5, 10, 15, 20, 25, 30 minutes intervals.

BROMAGESCALE: Bromage scale for onset of motor blockade

Scale	Criteria	Degree of block
0	Free movement of legs, feet with ability to raise extended leg	None
1	Inability to raise extended leg and knee flexion in decreased but full extension of feet and ankles is present	Partial 33%
2	Inability to raise leg or flex knees; flexion of Ankle and feet present	Partial 66%
3	Inability to raise leg, flex knee or ankel, or move toes	Complete paralysis

Sedation was assessed by a modified Ramsay sedation scale.

Modified Ramsay sedation Scale:

- Anxious, agitated, restless.
- Cooperative, oriented, tranquil.
- Responds to commands only.
- Brisk response to light glabellar tap or loud noise.
- Sluggish response to light glabellar tap or loud noise.
- No response.

Hemodynamic Variables: The anesthesiologist performing the block recorded the baseline value of vital signs (BP, HR, SpO2,) and after performing the spinal anesthetic, the vital signs were recorded at 2, 5, and every 5 minutes in the operating room and every 15 minutes in the Post Anesthesia Care Unit.

Hypotension, defined as a decrease of systolic blood pressure by more than 30% from baseline or a fall below 90 mmHg, was treated with incremental IV doses of ephedrine 5 mg and IV fluid as required. Bradycardia, defined as heart rate < 50 bpm, was treated with IV atropine 0.3–0.6 mg.

The incidence of adverse effects, such as nausea, vomiting, shivering, pruritus, respiratory depression, sedation, and hypotension were recorded. Oxygen (2 L/min) was administered via a mask if the pulse oximeter reading decreased below 90%.

DOI: 10.14260/jemds/2015/52

Postoperatively, the pain score was recorded by using visual analogue pain scale (VAS) between 0 and 10 (0 = no pain, 10 = most severe pain), initially every 1 h for 2 h, then every 2 h for the next 8 h and then after every 4 h till 24 h. Diclofenac was given intramuscularly as rescue analgesia when VAS was >4. A follow-up was carried out 1 week postoperatively by the blinded anesthesiologist, who asked about postoperative headache as well as postoperative pain and dysesthesia in the buttock, thighs, or lower limbs.

Time of injection was recored as 0 hour in both the groups and the various parameters were studied.

RESULTS AND ANALYSIS: Fifty patients were completed the study protocol and were included in the data analysis. Thus, group D consisted of 25, and group R of 25 patients.

1. Demographic data like mean age, bodyweight, height, gender and type of surgeries of both the groups were comparable and there is no statistical significance. (p=0.877) table-1, table-2.

2. In our study the mean time of onset of sensory blockade at T10 in group D was 4.6±1.2 min, was significantly less than group R 4.9 ±1.4 min (P < 0.05).

	Mean	**SD**
Group D	4.6	1.2
Group R	4.9	1.4

Onset of sensory blockade at T10 (p = 0.0015)

3. In our study, the highest sensory level achieved is comparable and the difference is not statistically significant (p > 0.05).

	Group R	**Group D**	**P- value**
T4	4	5	0.714
T6	11	11	1.0
T8	10	9	0.662

Highest Sensory level achieved p value > 0.05

4. In our study, the mean time to achieve maximum sensory level was significantly less in group D (6.3 ± 2.7) min compared to group R (9.5 ±3) min.

	Mean	**SD**
Group D	6.3	2.7
Group R	9.5	3.0

Time to attain maximum sensory level p < 0.0015

DOI: 10.14260/jemds/2015/52

5. In our study, the mean duration of onset time of motor blockade in group D was 9.68 ±1.56 mins, for group R was 10.76 ±2.8 min and the difference is statistically significant (p = 0.009).

	Mean	SD
Group D	9.68	1.56
Group R	10.76	2.8

Onset of motor blockade (P value < 0.05)

6. In our study, the two segment regression time in group D was 115.6 ± 14.5 min and in group R was 57.4±6.3 min. The statistical analysis showed that there is statistically significant difference (p = 0.001) between the groups.

	Mean	SD
Group D	115.6	14.5
Group R	57.4	6.3

The two segment regression time P value < 0.001.

7. The mean duration of Sensory blockade in Group D was 326.0±36.91 and Group R was 249.4 ±20.98. The statistical analysis showed that there is statistically significant difference (p = 0.001).

	Mean	SD
Group D	326.0	36.91
Group R	249.4	20.98

Duration of Sensory blockade p value < 0.05.

8. In Our study showed that duration of motor blockade was significantly prolonged in group D (140.1±32.3 min) compared to Group R (246.4 ±25.7) with pvalue <0.001 and is statistically significant.

	Mean	SD
Group D	140.1	32.3
Group R	246.4	25.7

Duration of motor blockade P value < 0.001

9. In Our study, duration of analgesia in group D 425.4±18.9 min was prolonged than group R 210.3±14.2 min and is statistically very significant.
(p-value < 0.0001)

DOI: 10.14260/jemds/2015/52

	Mean	SD
Group D	425.4	18.9
Group R	210.3	14.2

Duration of Rescue analgesia (p value < 0.0001)

10. Highest pain score on VAS scale: In our study, the mean highest pain scores on VAS scale for group D was 4, for group R was 7 and the difference is statistically significant (p value > 0.05).

	Mean	SD
Group D	4.0	1.0
Group R	7.0	2.0

Highest pain score on vas scale (p value = 0.001)

11. Haemodynamic Variables: The mean values of mean arterial pressure (Table 2) and the heart rate (Table1) in the first hour after performing the spinal anesthesia and the first hour in the PACU were comparable between the 2 groups (Figures 1-2). (p = 0.16)

In our study, the intraoperative Haemodynamic variables like SBP, DBP, MAP and heart rate were comparable in both groups. 20% (n=5) of patients in group R, 16% (n=4) in group D had bradycardia. 24% (n=6) in group R and 32% (n=8) in group D had hypotension. The statistical analysis by unpaired t test showed that there is statistically no significant difference (p = 0.16) between the groups.

12. Mean sedation scores were significantly higher in group D compared to group R as 64% patients in groupD had a sedation score of 3 as compared to 32% in group R (p-value <0.0001)which was statistically very significant.

Sedation Scores (VAS)	Group R	Group D	P-Value
1	13(52%)	4 (16%)	<0.0001
2	8 (32%)	5 (20%)	0.5813
3	4 (16%)	16 (6%)	<0.0001
4	0	0	___
5	0	0	___

Sedation scores P-Value <0.0001.

13. The Occurrence of the side effects is statistically not significant.

None of the patients in two groups had any other side effects like respiratory depression, shivering etc. Twenty-four hours and 2 weeks following discharge follow up did not show any neurological impairment related to spinal anesthesia such as back, buttock or leg pain, headache or any new neurological deficit.

DOI: 10.14260/jemds/2015/52

Side effects	Group R N=25	Group D N=25	P-Value
Bradycardia	5(20%)	4(16%)	0.58
Hypotension	6(24%)	8(32%)	0.27
Nausea	4(16%)	4(16%)	1
Vomiting	1(4%)	1(4%)	1
Shivering	0	0	___
Dry mouth	5(24%)	4(20%)	0.6
Respiratory depression	0	0	___

Side effects P-Value > 0.05

DISCUSSION: The use of neuraxial opioids is associated with quite a few side effects, so various options including α – 2 agonists are being extensively evaluated as an alternative [10] with emphasis on opiod – related side effects such as resipiratory depression, nausea, urinary retention, and pruritus.

The pharmacologic properties of α–2 agonists have been extensively studied and have been employed clinically to achieve the desired effects in regional anaesthesia.

Dexmeditomidine has been growing popularity and expanding its role in anaestheisa since then Dexmedetomidine became a - 2 agonist of choice, due to its greatest a2: a1 affinity (8 times greater than clonidine). The increased selectivity results in more predictable and effective sedation and analgesia and fewer side effects.

The Demographic profile of our patients was comparable with respect to mean age, bodyweight, height, gender and type of surgeries.

In our study, the mean time of onset of sensory blockade at T 10 in group D was 4.6±1.2 min, was significantly less[11] than group R 4.9 ±1.4 min (P < 0.05).

In our study, the mean time to achieve maximum sensory level was significantly less[11] in group D (6.3 ±2.7) min compared to group R (9.5 ±3) min.

In our study, the mean duration of onset time of motor blockade[11] in group D was 9.68 ±1.56 mins significantly less when compared to group R was 10.76 ± 2.8 min (p = 0.009).

In our study, the two segment regression time [11] in group D was less (115.6 ± 14.5 min) when compared to group R was 57.4±6.3 min and is statistically significant (p = 0.001).

Recent studies indicate that Dexemeditomidine produces a dose dependent increase in the duration of the motor and sensory blocks induced by local anaethetics, regardless of the neuraxial route of administration (epidural, caudal, or spinal) without any evidence of neurotoxicity in human volunteers.

The mean duration of Sensory blockade [11, 12] in Group D was 326.0 ± 36.91 and Group R was 249.4±20.98. The statistical analysis by unpaired t test showed that there is statistically significant difference (p = 0.001) between the groups.

In Our study showed that mean duration of motor blockade [11, 12], was significantly prolonged in group D (140.1±32.3 min) compared to Group R (246.4 ±25.7) with pvalue <0.001 and is statistically significant.

DOI: 10.14260/jemds/2015/52

Adequate treatment of perioperative pain is essential especially in the elderly, because inadequately treated pain increases post-operative morbidity like post-operative hypoxia, tachycardia etc., and duration of hospital stay and may also lead to chronic pain.

In Our study, duration of analgesia [11, 12] in group D 425.4±18.9 min was prolonged than group R 210.3±14.2 min and is statistically very significant.

(p-value < 0.0001).

Similar results were obtained in a study conducted by B. Sukhminder Jit Singh et al, addition of dexemedetomidine to Ropivacaine as adjuvant, dexmeditomidine provided as a smooth and prolonged postoperative analgesia as compared to clonidine. There was prolonged time to two segmental regression (136.46 ± 8.12) as well as return of motor power to Bromage 1 (246.72 ±30.46 min) in dexmeditomidine group. Time for rescue analgesia was comparatively longer in dexmeditomidine group compared to clonidine (310.76 ± 23.75 min, p < 0.05)[13, 14]

---- I J A 2011 / Volume 55 / Issue 2 / Page: 116-121.

Regarding quality of analgesia, in our study highest pain score on VAS scale is 4 for group D when compared to control group of 7 and is statistically significant. (P = 0.001). So, the quality and duration of analgeisa improved with the addition of Dexmeditomidine.

The intraoperative and postoperative analgesic effect of intrathecal Ropivacaine was potentiated by intrathecal Dexmedetomidine. [15, 16, 17, 18]

Salgado PF et al also showed that there is clear synergisam between epidural dexemeditomidine and ropivacaine, prolonged sensory and motor block duration time (p < 0.05), also resulted in a more intense motor block.

Rev Assoc Med Bras.2008 Mar – Apr; 54 (2): 110-

As an adjuvant to neuraxial anaestheisa, intrathecal a2- adrenergic agonists are found to have anti -nociceptive action for both somatic and visceral pain.[19, 20]

The analgesic action and hence the prolongation of sensory block of intrathecal a2-adrenoceptor agonists is by depressing the release of C-fibre transmitters and by hyperpolarisation of post-synaptic dorsal horn neurons [21] Furether, study by Salgado PF et al showed that there is clear synergisam between epidural dexmeditomidine and ropivacaine [22]

In our study, the intraoperative Haemodynamic variables like SBP, DBP, MAP and heart rate were comparable in both groups. The statistical analysis by unpaired t test showed that there is statistically no significant difference (p = 0.16) between the groups[23]

Mean sedation scores were significantly higher in group D compared to group R as 64% patients in groupD had a sedation score of 3 as compared to 32% in group R (p-value <0.0001)which was statistically very significant

The occurance of the side effects is statistically not significant.

CONCLUSION: In conclusion, low dose (5 µg) Dexmedetomidine seems to be an attractive alternative as an adjuvant to spinal Ropivacaine in urological surgeries in elderly patients, and also those requiring prolonged postoperative analgesia with minimal side effects.

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DEMOGRAPHIC DATA:

Age in years	group R	group D
45 – 55 years	9	8
56– 65 years	8	9
66 – 75 years	8	8
Mean	68.15	67.91
SD	8.8	9.39

Table 1: Age Distribution

p > 0.05

Weight (kg)	group R	group D
45 – 55	6	5
56 – 65	5	6
66 –75	8	5
76 – 85	5	8
Above 85	1	1
Mean	69.15	70.91
SD	8.89	9.09

Table 2: weight distribution

p > 0.05

(Base line)	Group D	Group R	P value
1 min	80 ± 2	78 ± 2	0.3
2 min	76 ± 3	80 ± 3	0.4
5 min	74 ± 2	76 ± 4	0.3
10 min	72± 2	74 ± 2	0.2
20 min	70 ± 2	72 ± 2	0.2
30 min	68± 1	69 ± 2	0.16
1 hour	68 ± 2	67 ± 2	0.16
2 hour	66 ± 2	66 ± 3	0.1
3 hour	64 ± 2	65± 3	0.18

Table 3: Changes in mean heart rate from baseline

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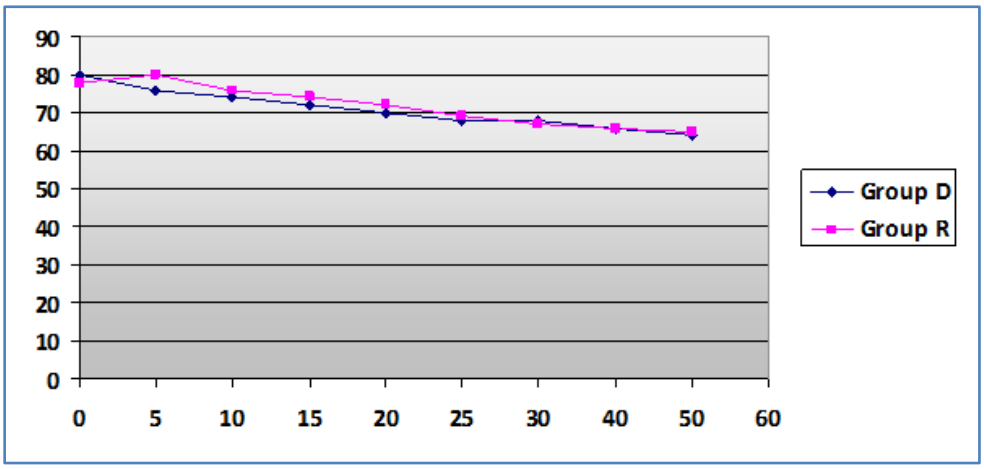

Fig. 1: Changes in mean Heart rate from base line

Base line	Group D	Group R	P value
1 min	96.5 ± 4.12	98.2 ± 4.2	0.3
2 min	94.4 ± 3.12	97.3± 4.3	0.4
5 min	91.4 ± 2.08	95.6 ±3.7	0.3
10 min	90.6 ± 2.54	92.2 ± 2.1	0.28
20 min	89.8± 2.34	93.3 ± 4.3	0.4
30 min	88.6 ± 1.92	92 ± 4.5	0.4
1 hour	87.6± 2.16	90.8 ± 2.6	0.3
2 hour	86.5 ±3.08	88.5 ± 2.3	0.2
3 hour	85.7± 2.14	88.7 ± 3.1	0.2

Table 4: Change in mean arterial blood pressure from baseline

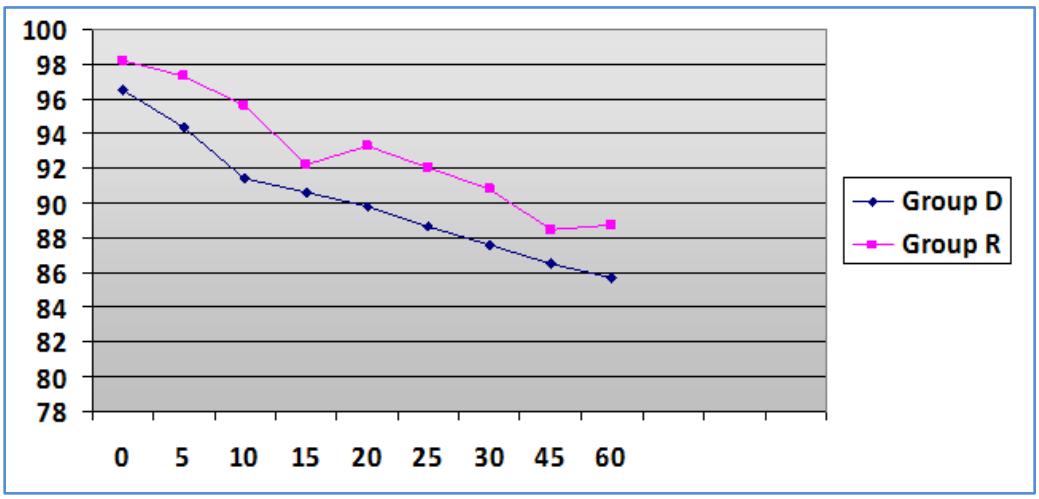

Fig. 2: Changes in mean Blood pressure from base line

DOI: 10.14260/jemds/2015/52

PARAMETERS	Group D	Group R	P VALUE
Onset of sensory blockade at T10	4.6± 1.2	4.9 ± 1.4	0.0015
Highest Sensory level achieved			> 0.05
Time to attain maximum sensory level	6.3 ± 2.7	9.5 ±3.0	<0.0015
Onset of motor blockade	9.68 ± 1.56	10.76 ± 2.8	< 0.05
The two segment regression time	115.6 ± 14.5	57.4 ± 6.3	< 0.001
Duration of Sensory blockade	326.0 ± 36.91	249.4 ± 20.98	<0.05
Duration of motor blockade	140.1 ± 32.3	246.4 ± 25.7	<0.05
Duration of Rescue analgesia	425.4 ± 18.9	210.3 ± 14.2	< 0.0001
Highest pain score on VAS scale	4.0 ± 1.0	7.0 ± 2.0	0.00

Table 5: Characterstics of Spinal block

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AUTHORS:

1. Yerramsetti Atchyutha Ramaiah
2. Srinivasa Rao Manduri
3. B. Sowbhaghya Lakshmi
4. Pydi Lalitha

PARTICULARS OF CONTRIBUTORS:

1. Assistant Professor, Department of Anaesthesiology, Rangaraya Medical College.
2. Assistant Professor, Department of Anaesthesiology, S. V. Medical College, Tirupati.
3. Professor and HOD, Department of Anaesthesiology, Rangaraya Medical College.
4. Post Graduate, Department of Anaesthesiology, Rangaraya Medical College.

NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Yerramsetti Atchyutha Ramaiah,
Assistant Professor in Anaesthesiology,
65-10-2, Mantri Pragadavari Veedhi,
Karanamgari Junction, Kakinada – 533003.
E-mail: yerramsetti.atchyuth@gmail.com

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