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Original Research Article

Hemodynamic Changes with Dexmedetomidine and Fentanyl as Adjuvant To 0.5% Bupivacaine in Erector Spinae Plane Block For Perioperative Analgesia in Percutaneous Nephrolithotomy Patients

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Abstract:

Background: Erector spinae plane block is a paraspinal block in which drug reaches paravertebral, interfacial planes and provide pain relief. The drugs injected also causes hemodynamic fluctuations. Adjuvants used in block enhance these fluctuations which are noted in current study.

Objective: To know the Hemodynamic changes (Hypotension, bradycardia) in peri-operative period in patients receiving erector spinae plane block with 0.5% bupivacaine and adjuvants dexmedetomidine and fentanyl for percutaneous nephrolithotomy.

Methods: This prospective randomized double blinded study was carried outin the Department of Anesthesiology of tertiary care center from January 2019 to June 2020.

Results: The overall change in Pulse Rate (BPM) over time was compared in the three groups using the Generalized Estimating Equations method, significant difference in the trend of Pulse Rate (BPM) over time between the three groups ($p = <0.001$) is noted. The overall change in Systolic BP (mmHg) over time was compared in the three groups using the Generalized Estimating Equations method, significant difference in the trend of Systolic BP (mmHg) over time between the three groups ($p = <0.001$) is noted. The overall change in Diastolic BP (mmHg) over time was compared in the three groups using the Generalized Estimating Equations method, significant difference in the trend of Diastolic BP (mmHg) over time between the three groups ($p = <0.001$) is noted.

Conclusions: Statistical significance ($p <0.05$) was seen among 3 study groups in terms of hemodynamic variation ($p < 0.006$).

Keywords: Hemodynamic variation, Pulse Rate, Systolic BP, Diastolic BP, Erector spinae plane block.

Introduction

Acute intra and post-operative pain can be treated effectively by regional anaesthesia techniques as it helps in: Superior pain control, stable hemodynamics, pleasant and faster recovery from anaesthesia, reduced need of opioids and inhalational agents and their side effects and also enhanced recovery and early mobilization, earlier discharge from hospital, improved patient satisfaction, earlier return of activities and participation in physical therapy. [1]
PCNL is associated with considerable post-operative pain caused by percutaneous tracts, distension of pelvicalyceal system, Gerota's fascia and placement of nephrostomy tube. Like with any other surgery, optimal dynamic analgesia is crucial for better post-operative results.

Ultrasound guided Erector spinae plane block (ESPB) has emerged as an effective peri paravertebral regional anaesthesia technique. This technique is used in wide variety of surgeries and conditions to achieve pain control. It is reported to be easier and safe in administration, providing extensive and potent unilateral analgesia with minimal expectable complications. Hemodynamic fluctuations are not well documented with ESPB [3,4]

Pain transmission in the CNS and PNS involves a spectrum of neurotransmitters and pathways that are not easily blocked by one drug type. Alpha-2 agonists like clonidine dexmedetomidine, opioids like fentanyl, tramadol and steroids like dexamethasone have been used to prolong neural blockade and improve the quality of analgesia provided by blocks along with local anaesthetic agents. Based upon previous studies, as an adjuvant to regional anaesthesia, perineural dexmedetomidine and fen-

tanyl significantly prolongs the duration of analgesia, and prolongs the time to 1st analgesic request with minimal side effects. [5,6] Studies have used varying concentrations of dexmedetomidine and fentanyl as adjuvant to LA and optimum dosing regimen remains undefined. In current study we intend to compare the hemodynamic changes (Hypotension, bradycardia) in peri-operative period.

Materials and Methods: After obtaining clearance from Institutional Ethics Committee and written informed consent from all the patients, a prospective randomized double blinded study was carried outin the Department of Anaesthesiology at a tertiary care center from January 2019 to June 2020.

Comparative study was done between 3 groups. 90 patients undergoing elective PCNL surgery were randomly allocated into 3 groups of 30 patients each by envelope method, to receive ultrasound guided erector spinae plane block either using 0.5% Bupivacaine (Group B) or 0.5% Bupivacaine + 1mcg/kg Dexmedetomidine (Group D) or 0.5% Bupivacaine + 1mcg/kg Fentanyl (Group F).

Inclusion Criteria:

1. ASA physical status I or II patients.
2. Patients undergoing elective PCNL procedure.
3. Patients above 18 years of age and below 60 years of age.

Exclusion criteria:

1. Patient's refusal to the procedure.
2. Patients with coagulopathy or on anti-coagulants.
3. Patients with active CNS or local infections.
4. Patients with history of substance abuse (Chronic or stopped 24 hours prior to procedure)
5. Patients allergic to local anaesthetic agents.
6. Patients with liver or renal dysfunction.
7. Patients with spine abnormalities and body dysmorphism.

A thorough pre-anaesthetic evaluation was done for all patients considered for study. Visual Analogue Scale (VAS, 0 = No Pain, 10 = Worst imaginable pain) for postoperative pain assessment and categorical scoring system (0 = none, 1 = mild, 2 = moderate, 3 = severe) forpostoperative nausea and vomiting assessment was explained to the patient pre-operatively, during pre-anaesthetic evaluation visit. Any patient failing to comprehend these scoring systems was excluded from the study.

Subjects enrolled for the study were pre medicated the night before adequately. Randomization of subjects was done by sealed envelope assignment. Subjects were then allocated to one of the three groups. A minimum of 6 hours preoperative nil per oral status was ensured prior to procedure.

In pre-operative holding room, patient was examined again. Nil per oral status was confirmed. Patient was made to stand and spinous process of vertebrae was palpated and marked usingskin markers. IV access was made using 18G cannula and intravenous fluids were started. Patient was connected to monitors for Heart rate (HR), Respiratory rate (RR), Non-invasiveBlood pressure (NIBP), arterial oxygen saturation (SpO2) and continuous ECG monitoring. Baseline vitals were recorded prior to procedure. The side of surgery was noted and patient was placed in lateral position accordingly.

For ESPB, the spinous process of T9 was palpated and confirmed. Skin at the site of planned procedure was prepared. A high frequency (8 – 12 Hz) linear ultrasound transducer [Siemens ACUSON freestyle TM, Germany] was placed transversely on spinous process of T9 vertebra. Then the probe was moved laterally by 3 cm and scanned for Transverse process (TP) of T10. On locating TP of T10, probe was rotated 90º clockwise. Sub cutaneous tissue on the top and three muscle layers trapezius muscle (above), thin layer of rhomboid major muscle, if present (in the middle) and Erector spinae muscles (on the bottom) was recognized.A 22G 50mm Stimuplex needle (B Braun Melsungen AG, Germany) was inserted cephalo- caudally till tip of the needle is in contact with TP of T10 below Erector spinae muscle. Location of needle tip was confirmed by visible hydro-dissection which lifts erector spinae muscle off TP of T10.

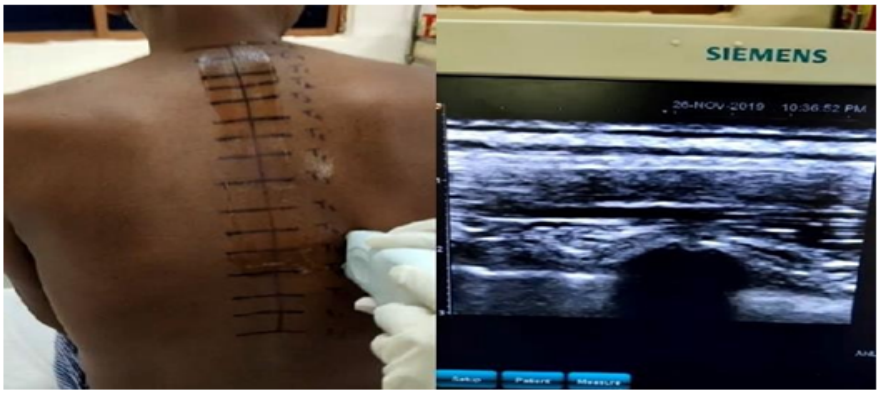


Figure 1: Surface and ultrasound anatomy of erector spinae plane muscles at T10vertebral level.

- In Group B patients, 20mL of 0.5% Bupivacaine was injected.
- In group F patients, 20mL of 0.5% Bupivacaine + 1mcg/kg Fentanyl was injected.
- In group D patients, 20mL of 0.5% Bupivacaine + 1mcg/kg Dexmedetomidine was injected

Completion of injection was considered as time 0 (T0). Patient was monitored for vitals every 10 minutes for 1 hour. Every 1 hour for next 24 hours. Intra operatively, patients were monitored for continuous electrocardiogram (ECG), Heart rate (HR), Respiratory rate (RR), Non-invasive blood pressure (NIBP), arterial oxygen saturation (SpO2), bi spectral index (BIS) and End tidal carbon dioxide (ETCO2) at regular time intervals.

General anaesthesia for PCNL, in all the 3 groups followed same standard technique. Pre medication with Inj Glycopyrrolate bromide 0.005mg/kg, Inj Midazolam 0.02mg/kg, Inj Ondansetron 0.1mg/kg IV. Pre oxygenation with 100% oxygen followed by Induction by Inj Propofol 2 – 2.5mg/kg IV, Inj Fentanyl Citrate 2 – 3mcg/kg IV. Inj Atracurium Besylate 0.5mg/kg IV was given for neuromuscular blockade.

Adequate depth of anaesthesia with BIS 50 - 55 was maintained with 40% Oxygen in air, Sevoflurane, intermittent Inj Atracurium Besylate 0.1mg/kg IV bolus intermittently and Inj Fentanyl citrate as required. The fresh gas flows; dial setting of sevoflurane vaporizer, opioid usage was noted throughout the surgery. Prior extubation, residual neuromuscular block was reversed with Inj Neostigmine methyl sulphate 0.05mg/kg IV and Inj Glycopyrrolate bromide 0.01mg/kg IV.

At the end of 48 hours, quality of analgesia was graded as: Excellent (3): VAS ≤2, No side effects

Good (2): VAS 3 – 4, Minor complaint that required supplemental analgesics. Unsuccessful (1): VAS >4. Failure of procedure

Vitals (HR, RR, NIBP, SpO2) was monitored in the postoperative period in the recoveryroom and then in respective wards and any abnormality was documented and managed appropriately.

Hypotension was defined as fall in Mean arterial pressure (MAP) of ≥ 20% of baselinevalues. Bradycardia was defined as fall in HR ≥ 20% of baseline.

VAS score and time when patient first complains of pain in the post-operative period, was documented. If more than 3, patient was given rescue analgesics (Inj Paracetamol 1000mg IVor Inj Diclofenac sodium 75mg in 100mLof 0.9% normal saline IV) were administered. Time of administration was documented. Any other adverse effects such as nausea, vomiting, shivering, itching, respiratory distress, and hemodynamic instability were also documented and managed appropriately as per protocols.

Result:

Pulse rate:

Table 1: Comparison of the three Groups in Terms of change in Pulse Rate (BPM) Over Time (n= 90)

Pulse Rate(BPM)	Group			P value for comparison of the three groups at each of the time points (Kruskal Wallis Test)
	B	F	D	
	Mean(±SD)	Mean(±SD)	Mean(±SD)	
Baseline	74.07(±7.25)	77.67(±8.22)	75.53(±9.35)	0.224
10Minutes	69.80(±8.92)	73.67(±7.54)	73.00(±8.88)	0.095
20Minutes	71.93(±9.36)	71.00(±6.66)	71.67(±8.66)	0.922
30Minutes	70.80(±9.55)	69.80(±6.77)	70.27(±7.86)	0.968
40Minutes	70.37(±8.25)	68.60(±6.28)	70.40(±8.49)	0.671
50Minutes	70.73(±10.25)	68.13(±6.60)	70.93(±7.93)	0.335
1 Hour	72.33(±9.35)	70.80(±8.58)	73.20(±9.30)	0.578
2 Hours	79.27(±8.08)	76.40(±6.90)	75.67(±8.47)	0.239
3 Hours	74.53(±8.65)	75.67(±7.37)	72.33(±9.04)	0.179
4 hours	75.80(±5.88)	74.93(±8.08)	72.87(±7.57)	0.297
5 hours	72.13(±9.70)	75.27(±10.10)	72.27(±8.61)	0.371
6 hours	74.20(±8.19)	76.13(±9.71)	73.47(±8.55)	0.545
9 hours	72.13(±9.29)	75.40(±8.50)	73.87(±9.22)	0.314
12 hours	74.87(±8.40)	78.07(±8.70)	74.47(±9.11)	0.205
18 hours	74.60(±6.31)	79.53(±8.48)	73.80(±9.39)	0.020
24 hours	75.67(±6.71)	80.20(±8.90)	73.27(±8.21)	0.010
48hours	74.07(±10.04)	81.07(±10.62)	73.73(±7.62)	0.010
P Value for change in Pulse Rate (BPM) over time with-	<0.001	<0.001	<0.001	

in each group (Friedman Test)				
Overall P Value for comparison of change in Pulse Rate(BPM) over time between the three groups(Generalized Estimating Equations)	<0.001			

Non-Parametric tests were used to make statistical inference as data were not normally distributed. Kruskal-Wallis test was used to compare 3 subgroups in terms of Pulse Rate (BPM) at each of the time points (right-most column in the table above). Friedman test was used to explore the changes in Pulse Rate (BPM) over time within each group (second-last row in the table above). Generalized Estimating Equations method was used to explore the difference in change in Pulse Rate (BPM) between the three groups over time.

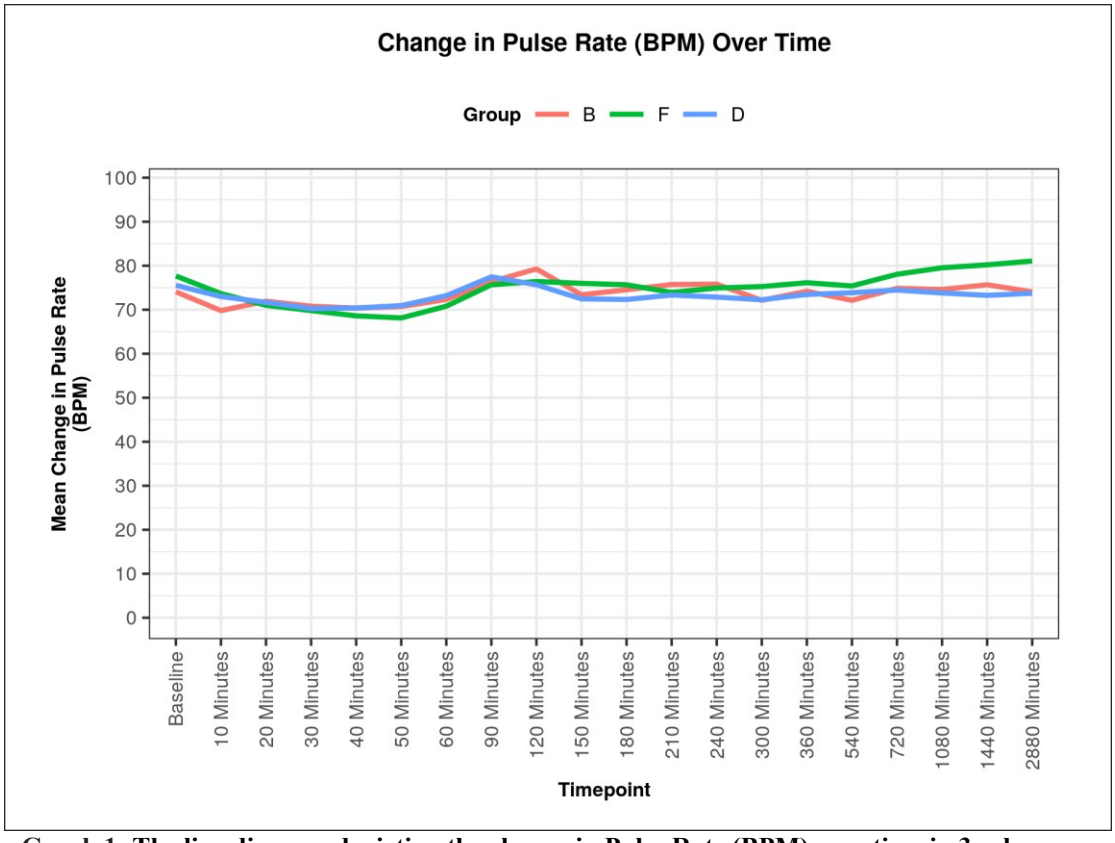
The 3 subgroups differed significantly in terms of Pulse Rate (BPM) at the following time points: 18 hours, 24 hours, 48 hours.

In Group B, the mean Pulse Rate (BPM) decreased from74.07BPMat the Base Line time point to a minimum of 69.80 BPM at the 10 Mins time point, and then increased to 74.07BPM at 48 hours' time point. This change was statistically significant (Friedman Test: $\chi2 = 124.0$, p =<0.001).

In Group F, the mean Pulse Rate (BPM) decreased from77.67BPMat the Baseline time point to a minimum of 68.13 BPM at the 50 Mins time point, and then increased to 81.07 BPM at the 48 hours' time point. This change was statistically significant (Friedman Test: $\chi2$=194.7, p= <0.001).

In Group D, the mean Pulse Rate (BPM) increased from75.53BPM at the Base line time point to a maximum of 77.47 BPM at the 90 Mins time point, and then decreased to 73.73 BPM at the 48 hours' time point. This change was statistically significant (Friedman Test: $\chi2 = 82.4$, p= <0.001).

The overall change in Pulse Rate (BPM) over time was compared in the three groups using the Generalized Estimating Equations method. There was a significant difference in the trend of Pulse Rate (BPM) over time between the three groups (p = <0.001).



Graph 1: The line diagram depicting the change in Pulse Rate (BPM) over time in 3 subgroups

Systolic Blood pressure:

Table 2: Comparison of the three Groups in Terms of change in Systolic BP(mmHg) over time (n = 90)

Systolic BP (mmHg)	Group			P value for comparison of the three group sat each of the time points (Kruskal Wallis Test)
	B	F	D	
	Mean(±SD)	Mean(±SD)	Mean(±SD)	
Baseline	120.73(±6.72)	122.80(±7.78)	124.60(±10.21)	0.245
10Minutes	117.07(±7.33)	117.80(±6.99)	119.87(±8.72)	0.267
20Minutes	118.47(±5.08)	113.73(±5.91)	118.00(±8.94)	0.004
30Minutes	116.27(±6.08)	111.00(±6.41)	116.87(±7.06)	0.005
40Minutes	114.20(±6.55)	110.13(±7.05)	115.87(±8.57)	0.016
50Minutes	114.73(±5.60)	110.60(±7.76)	115.93(±8.28)	0.026
1 hour	116.00(±9.06)	115.20(±8.31)	120.87(±10.46)	0.030
2 hours	122.47(±12.28)	121.13(±6.38)	121.80(±10.08)	0.827
3 hours	115.37(±7.60)	120.73(±5.02)	119.33(±8.52)	0.010
4 hours	116.20(±6.59)	119.73(±6.25)	118.87(±8.86)	0.161
5 hours	118.00(±7.09)	119.67(±6.73)	119.93(±9.15)	0.487
6 hours	118.33(±7.37)	120.13(±7.33)	119.60(±9.30)	0.493
9 hours	115.20(±7.29)	119.67(±7.39)	118.93(±9.03)	0.016
12 hours	117.33(±7.30)	122.73(±6.76)	119.13(±8.69)	0.002
18 hours	117.67(±6.26)	122.47(±6.51)	119.27(±8.38)	0.003
24 hours	111.80(±8.47)	124.13(±7.52)	118.93(±8.58)	<0.001
48 hours	116.93(±6.01)	123.87(±7.14)	119.80(±8.13)	<0.001
P Value for change in Systolic BP(mmHg) over time with in each group (Friedman Test)	<0.001	<0.001	<0.001	
Overall P Value for comparison of change in Systolic BP (mmHg) over time between the three groups(Generalized Estimating Equations)	<0.001			

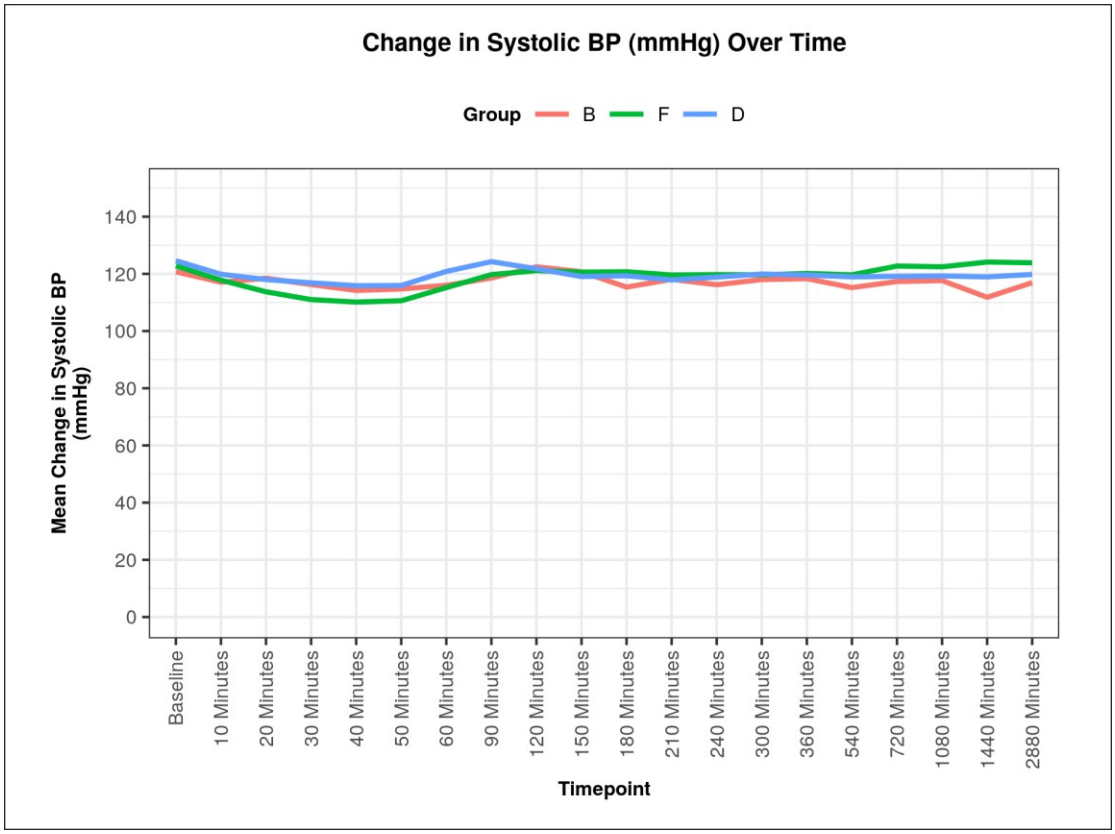
The three groups differed significantly in terms of Systolic BP (mmHg) at the following time points: 20Mins, 30Mins, 40Mins, 50Mins, 60Mins, 90Mins, 180Mins, 9hours,12 hours,18 hours, 24 hours,48 hours.

In Group B, the mean Systolic BP (mmHg) increased from 120.73mmHgat the Baseline timepointtoamaximumof122.47mmHg at the120Mins time point, and then decreased to 116.93mmHg at the 48hours time point. This change was statistically significant (Friedman Test: $\chi2 = 93.2$, $p = <0.001$).

In Group F, the mean Systolic BP (mmHg) decreased from122.80mmHgat the Baseline time point to a minimum of 110.13mmHgat the 40 Mins time point, and then increased to 123.87mmHg at the 48hours time point. This change was statistically significant (Friedman Test: $\chi2 = 229.0$, $p = <0.001$).

In Group D, the mean Systolic BP (mmHg) decreased from a maximum of 124.60mmHg at the Baseline time point to a minimum of 115.87mmHg at the 40 Mins time point, and then increasedto119.80 mmHg at the 48 hours' time point. This change was statistically significant (Friedman Test: $\chi2 = 96.1$, $p = <0.001$).

The overall change in Systolic BP (mmHg) over time was compared in the three groups using the Generalized Estimating Equations method. There was a significant difference in trend of Systolic BP (mmHg) over time between the three groups ($p = <0.001$).



Graph 2: The line diagram depicting the change in Systolic BP (mmHg) overtime in 3 subgroups.

Diastolic blood pressure:

Table 3: Comparison of the three Groups in Terms of change in Diastolic BP (mmHg) over time (n = 90)

Diastolic BP(mmHg)	Group			P value for comparison of the three group sat each of the time points (Kruskal Wallis Test)
	B	F	D	
	Mean(±SD)	Mean(±SD)	Mean(±SD)	
Baseline	79.33(±6.55)	80.40(±7.40)	81.20(±7.92)	0.487
10Minutes	76.23(±7.19)	76.93(±7.25)	78.73(±8.21)	0.283
20Minutes	75.50(±6.13)	73.60(±6.31)	75.47(±7.41)	0.362
30Minutes	75.00(±5.14)	71.07(±5.79)	74.47(±7.78)	0.053
40Minutes	73.93(±5.69)	69.27(±7.11)	73.67(±8.29)	0.016
50Minutes	72.53(±5.38)	69.33(±6.52)	73.47(±6.28)	0.036
1 hour	73.60(±7.82)	73.53(±7.48)	78.20(±9.83)	0.022
2 hours	82.47(±8.25)	78.60(±6.26)	77.47(±7.05)	0.169
3 hours	75.13(±5.79)	79.47(±4.78)	76.60(±7.70)	0.012
4 hours	75.60(±7.40)	78.33(±6.22)	76.53(±7.61)	0.289
5 hours	77.00(±6.72)	78.73(±6.61)	78.13(±6.99)	0.350
6 hours	78.53(±5.96)	79.20(±7.17)	78.73(±7.73)	0.585
9 hours	72.53(±7.95)	78.93(±6.88)	77.87(±8.19)	0.004
12 hours	77.73(±6.53)	81.47(±6.43)	77.33(±9.12)	0.042
18 hours	74.13(±6.58)	81.53(±5.42)	76.80(±7.87)	<0.001
24 hours	71.20(±8.18)	82.60(±6.13)	77.13(±6.55)	<0.001
48 hours	73.87(±6.81)	82.60(±6.91)	77.93(±7.34)	<0.001
P Value for change in Diastolic BP(mmHg)over time with in each group (Friedman Test)	<0.001	<0.001	<0.001	
Overall P Value for comparison of change in Diastolic BP (mmHg) over time between	<0.001			

the three groups (Generalized Estimating Equations)		

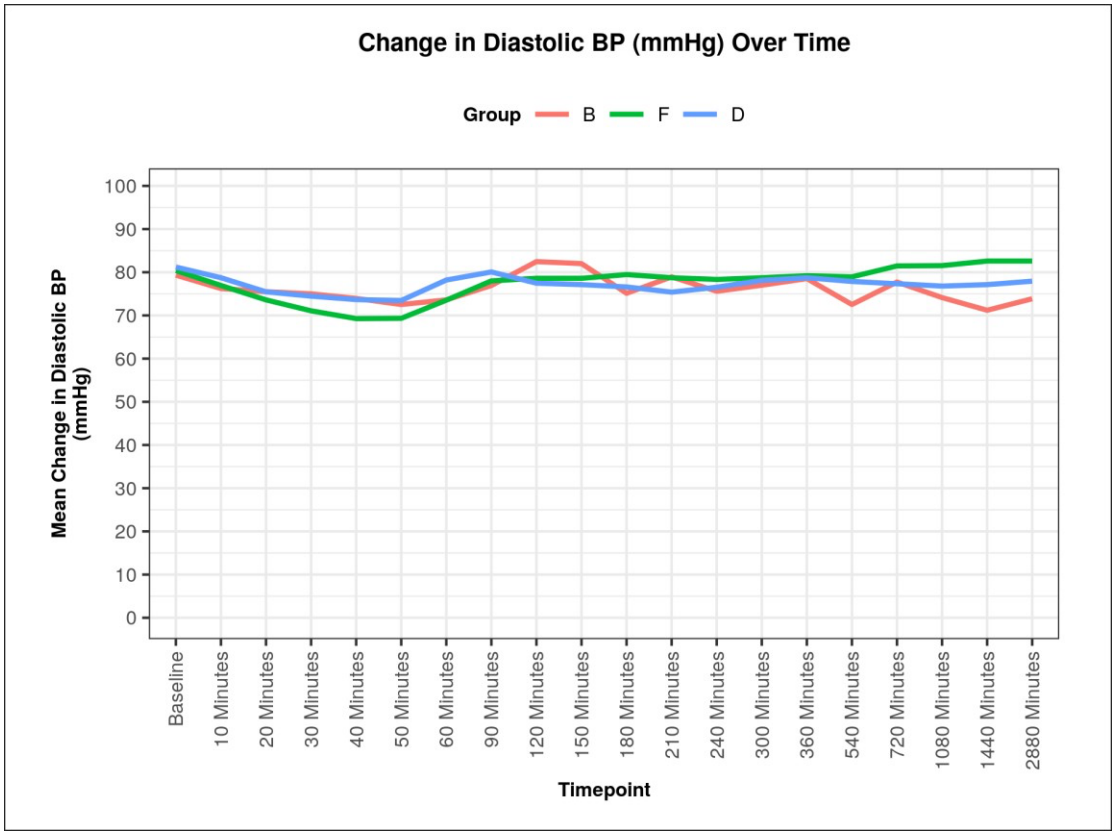
The 3 subgroups differed significantly in terms of Diastolic BP (mmHg) at the following timepoints: 40Mins, 50Mins, 60Mins, 150Mins, 180Mins, 9hours, 12hours, 18hours, 24 hours, 48 hours.

In Group B, the mean Diastolic BP (mmHg) increased from 79.33mmHg at the Baseline timepoint to maximum of 82.47mmHg at the 120Mins timepoint, and then decreased to 73.87mmHg at the 48hours timepoint. This change was statistically significant (Friedman Test: $\chi2$ = 143.9, p = <0.001).

In Group F, the mean Diastolic BP (mmHg) decreased from 80.40mmHg at the Baseline timepoint to a minimum of 69.27mmHg at the 40 Mins timepoint, and then increased to 82.60mmHg at 48hours timepoint. This was statistically significant (Friedman Test: $\chi2$ = 230.8, p = <0.001).

In Group D, the mean Diastolic BP (mmHg) decreased from a maximum of 81.20mmHgat the Baseline timepoint to a minimum of 73.47mmHg at the 50 Mins timepoint, and then increasedto77.93mmHg at 48hours timepoint. This was statistically significant (Friedman Test: $\chi2$ = 81.4, p = <0.001).

The overall change in Diastolic BP (mmHg) over time was compared in the three groups using the Generalized Estimating Equations method. There was a significant difference in the trend of Diastolic BP (mmHg) over time between the three groups (p = <0.001).



Graph 3: The line diagram depicting the change in Diastolic BP (mmHg)over time in 3 subgroups.

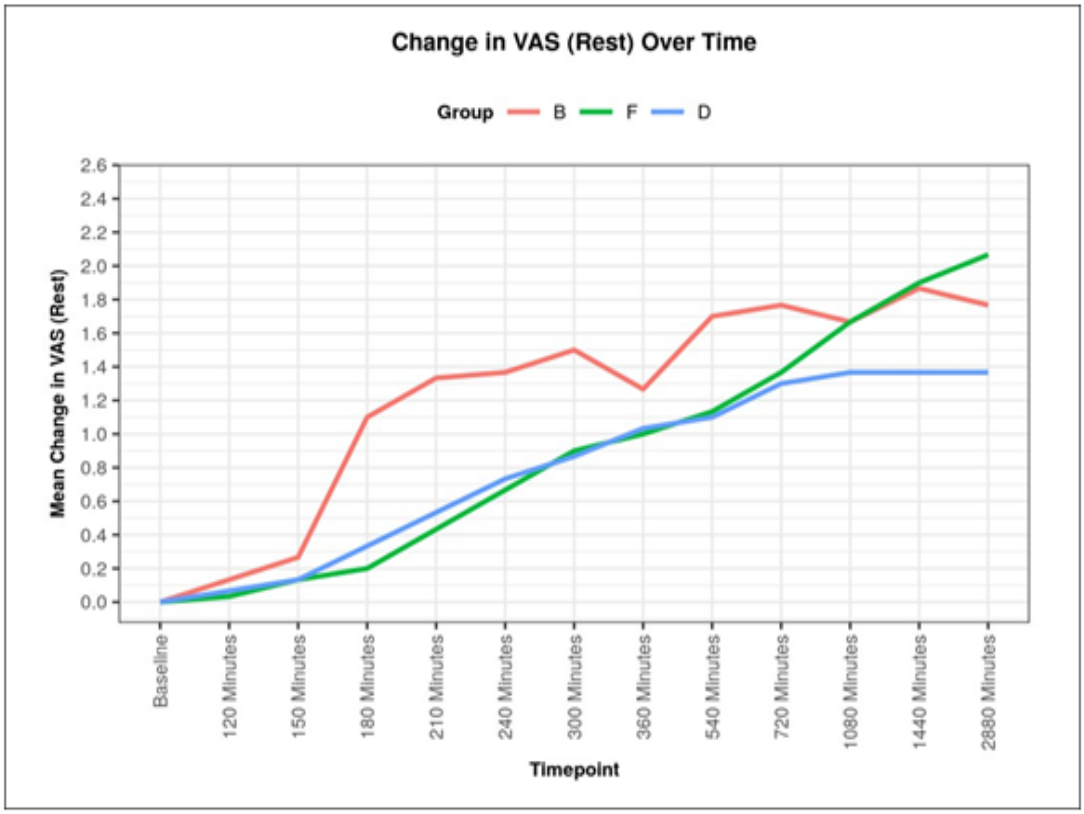
The three groups differed significantly in terms of VAS at rest at the following timepoints: 180 Mins, 210 Mins, 4 hours, 5 hours, 9 hours, 12 hours, 24 hours, 48 hours.

In Group B, the mean VAS at rest increased from a minimum of 0.00 at the Baseline timepoint to maximum of 1.87 at the 24 hours timepoint, and then decreased to1.77 at the 48hours timepoint. This was statistically significant (Friedman Test: $\chi2$=226.0,p=<0.001).

In Group F, the mean VAS at rest increased from a minimum of 0.00 at the Baseline timepoint to maximum of 2.07 at 48hours timepoint. This was statistically significant (Friedman Test: $\chi2$ = 310.0, p = <0.001).

In Group D, the mean VAS at rest increased from a minimum of 0.00 at the Baseline timepointtoamaximumof1.37atthe48hourstimepoint.Thischangewasstatistically significant (Friedman Test: $\chi2$ = 246.1, p = <0.001).

The overall change in VAS at rest over time was compared in the three groups using the GeneralizedEstimatingEquationsmethod.Therewasasignificantdifferenceinthetrendof VAS at rest over time between the three groups (p = <0.001).



Graph 4:ThelinediagramdepictingthechangeinVASatrestovertimein3 subgroups.

Discussion:

Ultrasound guided ESPB is a simple inter fascial plane block which provides perioperative analgesia without major adverse effects. It provides sensory blockade approximately about 6 vertebral levels above and below the level of injection. It also was found to provide visceral analgesia by spreading into paravertebral spaces. [3,7]

PCNL is a commonly done urological procedure to treat large or stag horn renal calculi. It isassociated with severe post-operative pain. The origin of pain post PCNL is visceral and somatic. Visceral pain arising from the kidneys and ureters and somatic pain from incision site. Pain from kidneys is transmitted through T10–L1, and pain from ureter is transmitted through T10–L2. [8] Incision site which is decided depending on the location of calculi is innervated by T10–T11 (T8–T12) spinal nerves.

Bradycardia was noted in 20% of patients of group D, 17% of patients of group F and none ingroup B. Hypotension was noted in 16% of patients in group D, 13% of patients in group F and none in group B. Patients receiving dexmedetomidine and fentanyl had significant level of bradycardia responding to glycopyrrolate compared to patients receiving only bupivacaine in block. Patients who received dexmedetomidine had significant level of hypotension compared to patients who were given only bupivacaine.

Dharmarao PS et al had noted bradycardia and hypotension in few patients who received dexmedetomidine as adjuvant in supraclavicular block. In current study, we noticed significant bradycardia and mild hypotension episodes in patients who received dexmedetomidine and fentanyl as adjuvants. Bradycardia was responsive to Inj glycopyrrolate 02mg IV. Hypotension was not seen in patients who were given IV fluids during nil per oral period and hypotension was responsive to IV fluids.

In this study we also noted that there was arousable sedation seen in patients who received dexmedetomidine and fentanyl in ESPB. Degree of sedation was much deeper in patients received dexmedetomidine. Sedation seen here can be considered as a beneficial side effect which reduced the requirement of anaesthetic agent at induction and for maintaining the depth of anaesthesia.

Conclusion

Statistical significance ($p < 0.05$) was seen among 3 study groups in terms of hemodynamic variation, sedation ($p < 0.006$).

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