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## Prospective randomized study comparing dural puncture epidural approach to conventional epidural approach for anesthesia in total knee arthroplasty

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### Abstract

**Background:** Epidural anesthesia reduces the exposure to other anesthetics and analgesics. The dural puncture epidural (DPE) approach improves caudal spread of analgesia compared with epidural (EPL) approach without the side effects observed with the combined spinal EPL method. The goal of this work was to evaluate the efficacy of DPE method versus standard EPL method as an anesthetic method in cases undergoing Total Knee Arthroplasty (TKA).

**Methods:** This prospective randomized double blinded study was carried out on 70 cases admitted for elective total knee replacement surgery. Cases were subdivided in to two equal groups: group I (EP): received fifteen millilitres of (0.25% plain bupivacaine and 50 µg fentanyl) over 5 min., there was no dural puncture in this group and group II (DPE): who received fifteen millilitres of (0.25% plain bupivacaine and 50 µg fentanyl) over 5 min., administered in the epidural space by epidural catheter at L3-L4 interspace, a dural puncture was created. All cases were assessed for time of onset of motor block, duration, number of top-up doses for 24 hours postoperative and adverse events.

**Results:** There was significant decrease in mean value of time till sensory block and time till motor block occurred in group II versus group I (p value <0.001). there was significant decrease in mean value of Breen Modified Bromage scale in group II (p value <0.05) at 5min and 8min versus group I. Intergroup comparison of duration from administration of block till first top up dose and number of top up doses revealed no difference between two approaches.

**Conclusion:** DPE method seemed to have faster onset of sensory and motor block versus standard EPL method.

**Keywords:** Dural puncture epidural approach, standard epidural approach, total knee arthroplasty, anesthesia

### Introduction

Regional anaesthesia has been found to provide various benefits over general anaesthetic for major orthopaedic surgery such complete hip or knee arthroplasty. Spinal and epidural anaesthesia are the most popular regional procedures, and both have the benefit of a catheter that may be used to extend the blockade during surgery and to achieve flexible pain management in the postoperative period [3].

Regional anesthesia decrease major postoperative complications in a wide variety of surgical orthopedic cases as deep vein thrombosis, pulmonary embolism, blood transfusion requirements, pneumonia, and respiratory depression [4].

Among the many uses of epidural anaesthesia (EPL) in the field of anesthesiology is its facilitation of pain relief during surgery. While effective as a main anaesthetic, it is most typically employed as an adjunct in pain treatment. One can get long-term pain relief from a single administration or via a continuous infusion. The use of this method has the ability to provide great analgesia, and it also decreases the case's exposure to other anaesthetics and analgesics, therefore minimising potential adverse effects [5].

Using a spinal needle to generate a dural perforation while avoiding intrathecal medicine delivery results in the dural puncture epidural (DPE) procedure. In comparison to the EPL approach, the DPE approach has been proven to increase caudal dissemination of analgesia, and it does so without the negative consequences seen with the CSE approach [6].

Up to date, no randomized trials compared the efficacy of dural puncture epidural anesthesia with epidural anesthesia only in cases undergoing total knee arthroplasty.

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Therefore, the current study will compare the efficacy and safety of both anesthetic approaches.

The development of total knee arthroplasty (TKA) was and is a watershed moment in the fight against intractable joint pain. Case outcomes including length of stay (LOS), overall cost, complication rate, peri-operative pain, opioid side effects, and overall case satisfaction have improved over time as surgical and anaesthetic approaches for TKAs have evolved [2].

The goal of this work was to evaluate the efficacy of DPE method versus standard EPL method as an anesthetic method in cases undergoing total knee arthroplasty.

### Cases and Methods

This prospective randomized double blinded study was carried out on 70 cases aged more than 45 years, with ASA physical activity I, II and III admitted for elective total knee replacement surgery at Meenakshi Institute of Higher Education and Research Centre, Kanchipuram, Tamil Nadu.

Cases or their legal guardians gave their signed consent after receiving necessary information. Exclusion criteria were history of substance abuse, difficult communication, contraindication to epidural anesthesia (e.g.; infection near the site of administration, coagulopathy or bleeding disorder), history of allergy to local anesthetics. The double-blinded randomized research was done on 70 cases were randomly classified by simple randomization into two equal groups; 35 cases were enrolled in each group using closed sealed, opaque, sequentially numbered envelopes that were opened by chief nurse at the morning of surgery, who was not participate in the study or data collection and determine the group of each case, group I: Epidural anesthesia (EP) (n=35) who received fifteen millilitres of (0.25% plain bupivacaine and 50 µg fentanyl) over 5 min., administered in the epidural space by epidural catheter at L3-L4 interspace; there was no dural puncture in this group and Group II: Dural puncture epidural anesthesia (DPE) (n=35) who received fifteen millilitres of (0.25% plain bupivacaine and 50 µg fentanyl) over 5 min., administered in the epidural space by epidural catheter at L3-L4 interspace, a dural puncture was created by the spinal needle of B. Braun's Espocan® combined spinal epidural kit before insertion of epidural catheter (needle-through-needle approach) but intrathecal medication administration was withheld.

Hemodynamic parameters (HR, MABP) were monitored at the following time points: baseline before performance of the approaches, 5,10,15 min after end of administration of the drug, then every 15 min for one hour then every 30 min till the end of the surgery and In the postoperative period every 2 hours, any hypotension or bradycardia were recorded as adverse event and time till sensory block occur (Onset of anesthesia) was assessed of the onset by test sensory loss at T<sub>10</sub> by pin prick using sterile needle with blunt edge (Defined as time from end of administration of bolus dose to 1st sign of sensory block at T<sub>10</sub>).

Sensory loss was assessed at 2 min then every 3 min after end of administration of bolus dose of the drug till 30 min then every 15 min till the end of the surgery, if anesthesia is inadequate after 30 min of bolus dose of bupivacaine; the given epidural was classified as epidural failure, and case was withdrawn from the study.

Sensory level of the approaches which was assessed at 2 min after end of administration of the drug then every 5 min

till the 30 min then every 15 min till end of the surgery, Test will be done at T<sub>10</sub> level at the umbilicus, L1 inguinal crease midclavicular line, L2 anteromedial thigh, L3 medial femoral epicondyle above knee, L4 medial malleolus, L5 dorsum web between great & 2<sup>nd</sup> toe, S1 lateral calcaneus, S2 midpoint popliteal fossa.

Time of onset of motor block (time from end of drug administration to time of achieving BMBS grade 1) with the use of the Breen Modified Bromage Scale (BMBS): Whole-Block Instructions for First Grade (unable to move feet or knees), Grade 2: Almost complete block (can move feet but not knees); Grade 3: Partial block (can move feet and knees but not hips or torso); Grade 4: Detectable weakness of hip flexion while supine (fully flexed knees); Grade 5: No observable weakness of hip flexion while supine (fully flexed knees); Grade 6: Partial knee bend possible and it was assessed at 2 min then every 3 min after administration of the drug till 30 min then every 15 min till the end of the surgery.

Duration which was defined as time from administration of the drug to time of regression of sensory level and demand of first top-up dose.

Number of top-up doses for 24 hours postoperative were classified in to top-up was given intraoperative if there was regression in sensory level, top-up dose was given postoperative when VAS >3; VAS was measured after the end of surgery at PACU every 2 hours for the first 24 hours, intraoperative top-up dose was 5 ml of (Bupivacaine 0.25% + 25 µgm fentanyl) and postoperative top-up dose was 5 ml of (bupivacaine 0.125% + 25 µgm fentanyl).

Adverse events as bradycardia, hypotension, urine retention, PDPH, backache local anesthetic systemic toxicity (LAST and failed blockade) were assessed.

Post-operative failed block means preserved pain sensation at the incision site after 30 min. from bolus dose, bradycardia was treated by atropine intravenous administration (0.02 mg/kg) which was repeated if needed and hypotension received bolus of vasopressor (Ephedrine 10 mg), which was repeated if no response.

### Preoperative anesthetic approach

Medical and surgical histories of the case were taken, clinical examination of the case was performed, routine lumbar investigations were done. Cases were trained how to use VAS to express their pain.

Intraoperatively, all cases were connected to standard monitors including (Electrocardiography (ECG), Non-invasive blood pressure device (NIBP), Pulse oximetry). Peripheral intravenous line was established using a 18G cannula, Foley's catheter was inserted to monitor the urine output, and removed after discharge from PACU.

The approach was performed with the case in sitting position, leaning forward arching his back.

The skin on the operative area was sterilized by 2% povidone-iodine & sterile towel was utilised to cover all the back except site of insertion, iliac crest was palpated and thumb extended to meet the midline, feeling the space between L3-4, then by using B.

### Group I: Epidural anesthesia (EP)

Braun's Espocan®, Pencan® epidural needle with Diameter 1.30 x 88 mm, G 18 x 3 1/2" with Tuohy bevel and additional back eye in the Tuohy curve, Insertion done by loss of resistance to saline approach, A 20G catheter with

diameter 0.85 x 0.45 mm was placed five cm into the epidural space, after a negative aspiration for blood and CSF, test dose was administered using 4ml of 2ml lidocaine 1% and 2ml epinephrine 1:100000 to detect intravascular administration if there are (tachycardia \_increase heart rate 15% from baseline, increase blood pressure), also detect intrathecal administration if there was immediate numbness appear in lower limb, then all cases received initial dosing regimens as study protocol, the dose consisted of fifteen millilitres of (0.25% plain bupivacaine and 50 µg fentanyl) fractionated into three 5-mL boluses given over 5 min. through the catheter.

**Group II:** Dural puncture epidural Anesthesia (DPE) Braun's Espocan® with Pencan® spinal needle which Sleeve to center the spinal needle inside the epidural needle and the Tip of the needle exits straight through the back eye and Pencan® epidural needle with Diameter 1.30 x 88 mm, G 18 x 3 1/2" with Tuohy bevel and additional back eye in the Tuohy curve, insertion done by loss of resistance to saline approach, a needle-through-needle approach was performed to create a single dural puncture with confirmation of free-flow CSF. The 27G spinal needle protruded 1.2 cm beyond the epidural needle tip when fully inserted. A 20G catheter with diameter 0.85 x 0.45 mm was placed five cm into the epidural space, after a negative aspiration for blood and CSF, test dose was administered using 4 ml of 2ml lidocaine 1% and 2ml epinephrine 1:100000 to detect intravascular administration if there were (Tachycardia \_increase heart rate 15% from baseline, increase blood pressure), also detect intrathecal administration if there was immediate numbness appear in

lower limb, then all cases received initial dosing regimens as per study protocol, initial dosing consisted of fifteen millilitres of (0.25% plain bupivacaine & 50 µg fentanyl) fractionated into three 5-mL boluses given over 5 min. through the catheter.

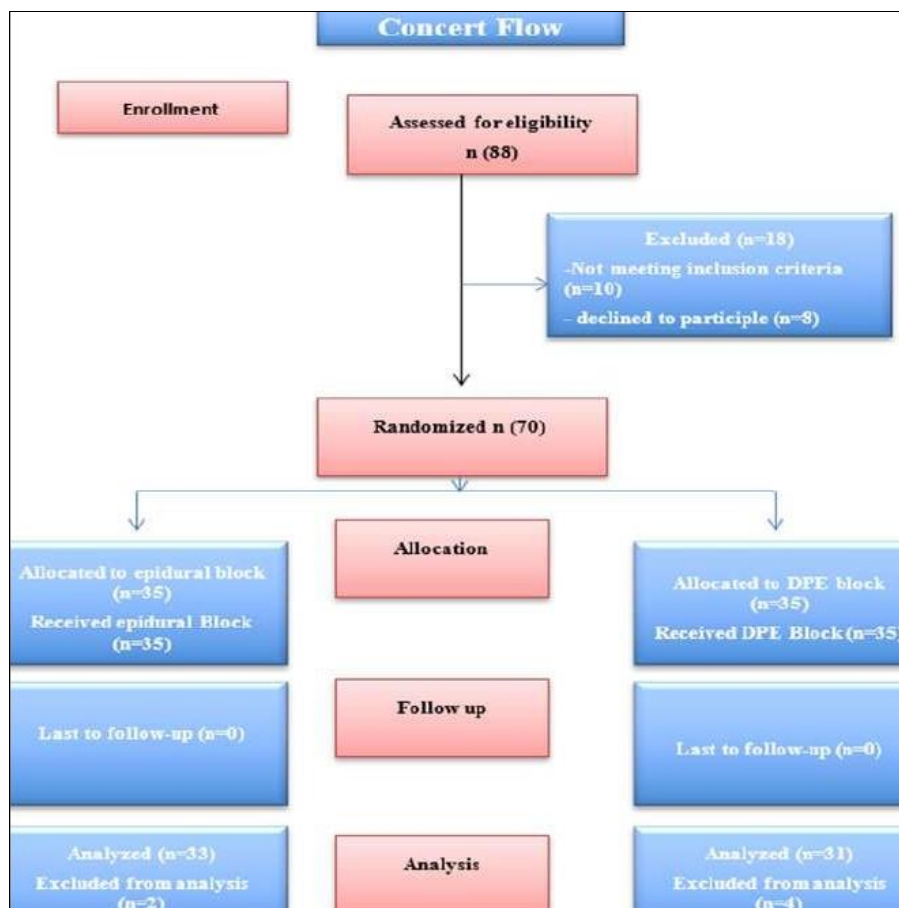
**Sample Size Calculation**

The sample size calculation was performed using G. power 3.1. The sample size was calculated as  $N \geq 31$  in each group based on 95% confidence limit and 80% power of the study, group ratio 1:1 and according to a previous study [7], the mean ( $\pm$ SD) of onset of analgesia (The primary outcome of our study) was 13.33 $\pm$ 3.4 min. with epidural block and 11 $\pm$ 3.8 min. with DPE block. Four cases were added to each group to overcome dropout, so the total required cases are 35 in each group.

**Statistical analysis**

Statistical analysis was done by SPSS v20 (Armonk, NY: IBM Corp). Shapiro-Wilk test was used to verify the normality of distribution. Quantitative variables were presented as mean and standard deviation (SD) and were compared by Student's t- test for the two approaches. Qualitative variables were presented as frequency and percentage (%). Chi-square test was utilised for categorical variables, to compare between different groups or Fisher's Exact test when more than 20% of the cells have expected count less than 5. A two tailed P value < 0.05 was considered significant.

**Results**



**Fig 1:** Consort flow chart of the study

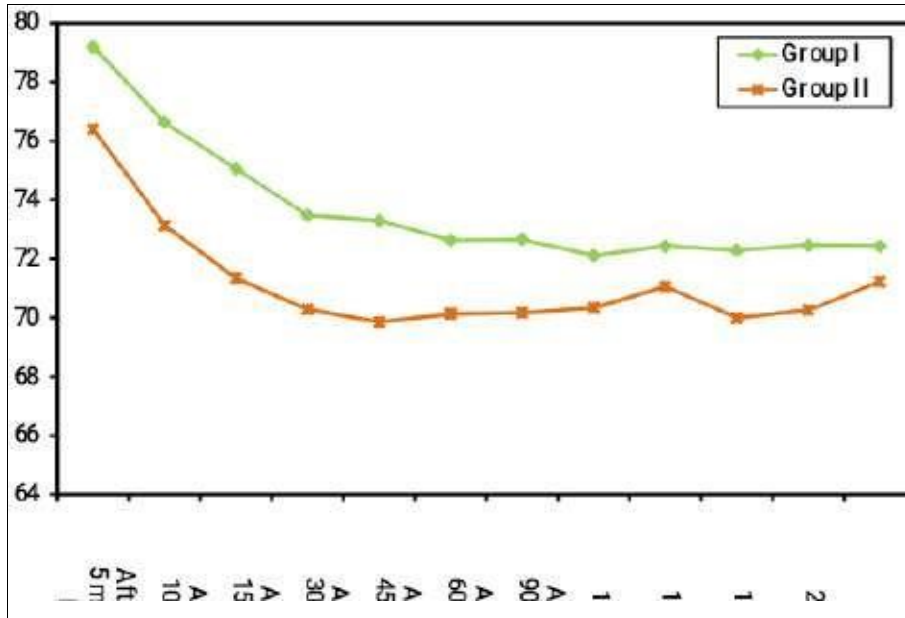
No difference in both approaches regarding their surgery. (Table 1) demographic data (Sex, age and BMI) and duration of

**Table 1:** Comparison in both approaches according to demographic data

		Group I (n=35)	Group II (n=35)	p
Sex	Male	16 (45.7%)	15 (42.9%)	0.810
	Female	19 (54.3%)	20 (57.1%)	
Age (years)		55.63±6.49	56.66±7.44	0.540
BMI (kg/m <sup>2</sup> )		29.83±2.26	30.0±1.83	0.728
Duration of surgery (hr.)		2.61±0.38	2.66±0.39	0.589

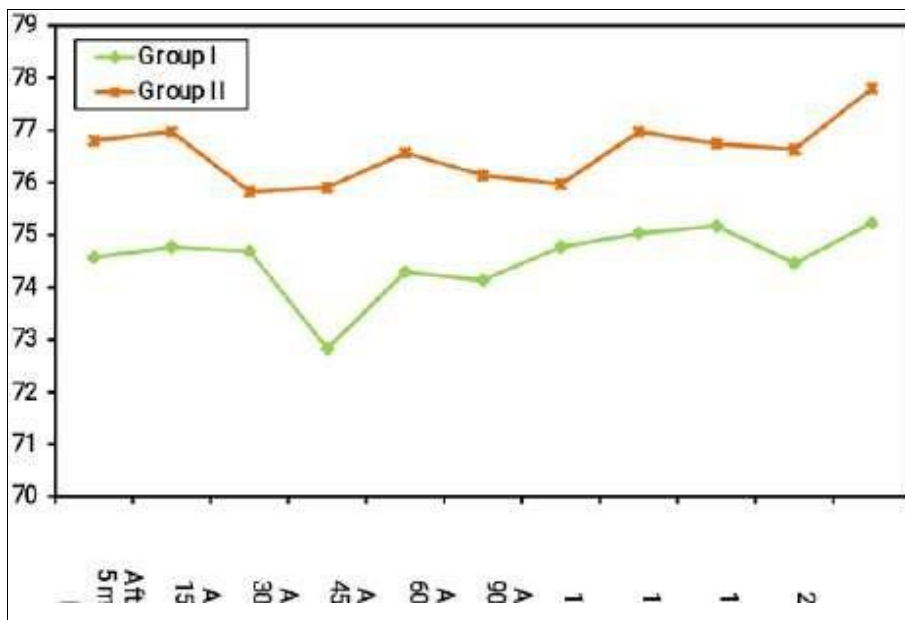
Data are presented as mean ± SD or frequency (%). BMI: Body mass index

Intergroup comparison revealed no difference in the mean value of heart rate at any time interval in both approaches. (Figure 1)



**Fig 2:** Comparison in both approaches according to HR

Intergroup comparison revealed no difference in value of mean arterial blood pressure (MAP) at any time interval in both approaches. (Figure 2)



**Fig 3:** Comparison in both approaches according to MAP

There was significant decrease in mean value of time till sensory block and time till motor block occurred in group II

versus group I (p value <0.001). (Table 2)

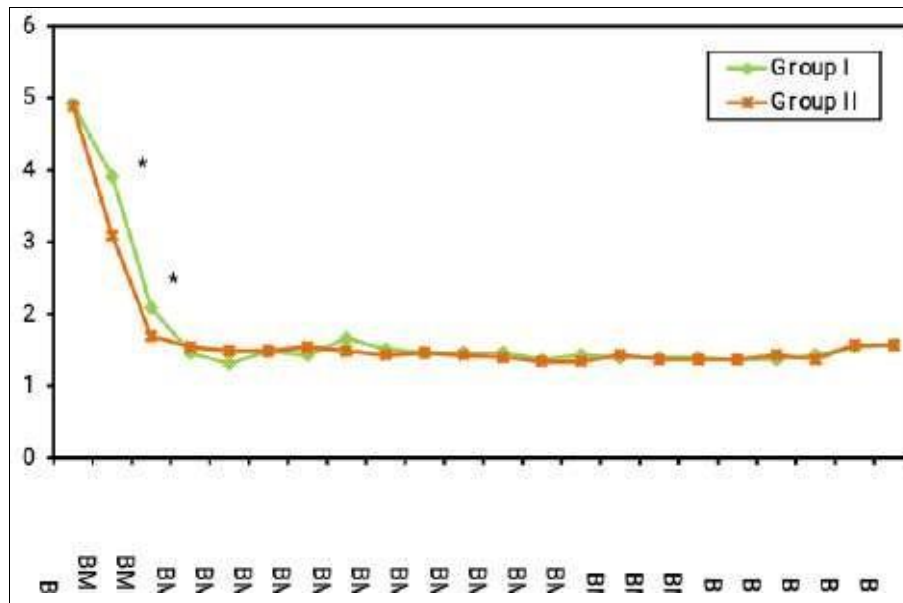
**Table 2:** Comparison in both approaches according to onset of sensory loss and motor block

	Group I (n = 35)	Group II (n = 35)	p
Onset of sensory loss	17.51 ± 5.56	10.66 ± 6.42	<0.001*
Motor block	17.94 ± 6.21	10.31 ± 6.51	<0.001*

Data are presented as mean ± SD. \* significant as p value <0.05

Intergroup comparison revealed there was significant decrease in mean value of Breen Modified Bromage scale (BMBS) in group II (p value <0.05) at 5min and 8min

versus group I, while no difference at any time interval from the block in both approaches. (Figure 3)



**Fig 3:** Comparison in both approaches according to BMBS

Intergroup comparison of duration from administration of block till first top up dose and number of top up doses

revealed no difference between two approaches. (Table 3)

**Table 3:** Comparison in both approaches according to onset of sensory loss and motor block and number of top-up doses for 24 hours postoperative

	Group I (n = 35)	Group II (n = 35)	p
Duration from administration of the drug to time of regression of sensory	91.80±8.76	93.46±8.41	0.422
Number of top-up doses for 24 hours postoperative	4.14±1.06	4.11±1.08	0.911

Data are presented as mean ± SD.

No difference in incidence of adverse events in both approaches. (Table 4)

**Table 4:** Comparison in both approaches according to adverse events

Averse events	Group I (n = 35)	Group II(n = 35)	p
Bradycardia	6 (17.1%)	4 (11.4%)	0.495
Hypotension	5 (14.3%)	3 (8.6%)	0.710
Urine retention	1 (2.9%)	2 (5.7%)	1.000
PDPH	0 (0.0%)	0 (0.0%)	—
Last	0 (0.0%)	0 (0.0%)	—
Failed Block	2 (5.7%)	4 (11.4%)	0.673
Backache	0 (0.0%)	0 (0.0%)	—

Data are presented as frequency (%).

**Discussion**

TKAs have become one of the most frequently done orthopaedic surgery procedures in the United States [2]. Epidural anaesthesia (EPL) is beneficial as a main anaesthetic, however it is most frequently used as an adjunct to pain treatment. For long-term pain management, a single

administration or a continuous infusion may be used. In addition to possibly delivering great analgesia, its usage decreases exposure to other anaesthetics and analgesics, hence reducing adverse effects. It has also been proven to lower cortisol levels, speed the recovery of bowel function, reduce the incidence of pulmonary embolism and deep vein thrombosis in the postoperative phase, and shorten hospital stays [8].

The Dural Puncture Epidural (DPE) procedure includes puncturing the dura sac and inserting a catheter into the epidural area. All drugs are administered through the catheter. DPE had quicker start, larger bilateral and sacral coverage, fewer top-up requests, and no change in hypotension rates versus EPL [9].

Regarding to time till sensory block occur at T<sub>10</sub> (Onset of anesthesia) there was significant decrease in mean value of time till sensory block occur in group II, also regarding onset of motor block at T<sub>10</sub> there was significant decrease in

mean value of time till motor block occur in group II. Regarding motor block assessment which done by using Modified Bromage scale (BMBS), our study showed that, BMBS was lower in group II at 5 and 8 min.

In agreement with our study: Jadon A *et al.* [10] this study done on 30 full-term primigravida parturients between 20 and 35 years of age randomly divided into two equal groups: DPE (n = 15) and standard lumbar EPL (n = 15), 12 ml 0.125% bupivacaine was given slowly through the catheter over 5 min with repeated aspirations, they concluded that DPE provided faster relief of lumbar pain than the standard lumbar EPL.

In addition, Suzuki *et al.* [11] enrolled 40 cases (ASA physical status I or II) who were scheduled for lower abdominal surgery (Abdominal hysterectomy, oophorectomy, or inguinal herniorrhaphy). They were selected at random to either a control group (Standard EPL method) or DPE. As a test dosage, three millilitres of a 2% mepivacaine solution without epinephrine were delivered into the epidural catheter. Five min. following the administration of the test dosage, fifteen millilitres of the same solution was administered over the course of one minute. Five, ten, fifteen, and twenty min. after administration of a 15-mL dosage, the distribution of analgesia was evaluated through pricking. The caudal distribution of analgesia was substantially larger in the DPE versus the controls.

In addition, Puthenveetil N *et al.* [12], who contrasted the onset and duration of DPE analgesia with a standard EPL, randomized 60 cases into two approaches. Cases were given 20 mL of 0.1% ropivacaine and 30 g of fentanyl through epidural catheter. Upon observing the onset of analgesia, the amount of bolus doses necessary, and the pain levels, it was determined that both strategies were successful in providing labour analgesia. However, when intermittent epidural boluses were administered, the DPE approach with a spinal needle generated a quicker onset of analgesia than the EPL approach, without compromising the mother or foetal outcome.

in contradiction with our research: Gupta *et al.* [13] Who compared DPE approach with standard EPL method, this study done on 112 ASA Class I, II and III pregnant cases, Group A (n=63) cases received EPL analgesia for lumbar pain. Group B (n = 49) cases received DPE analgesia for lumbar pain. Per their analysis, The main advantage of DPE analgesia over EPL analgesia was a decreased rate of rapid failures of lumbar analgesia in cases who received DPE analgesia, but DPE method did not give improved lumbar analgesia over EPL method.

Regarding changes in hemodynamics intergroup comparison of heart rate found no significant difference in the mean value of heart rate at any time interval. Similarly, intergroup comparison of MAP revealed no significant difference in the mean value at any time period.

Gunaydin B, *et al.* [14] agreed with our results, he compared standard EPL method versus dural puncture epidural, this study found that no difference in both approaches regarding hemodynamics also the need for ephedrine rescue for hypotension was comparable between epidural and the DPE. Regarding time from administration of block till first top up dose, no difference in both approaches.

Regarding the number of top up doses, the results were comparable in the two approaches.

In line with our study: Yadav P *et al.* [15] in this study

duration of block of initial bolus dose was 99.37±23.175 min in group E (Standard epidural) and 98.77±24.955 min in group DE (Dural puncture epidural) ( $p>0.05$ ) so no difference between two approaches.

In our investigation, no difference in both approaches for the occurrence of complications (Bradycardia, hypotension, urinary retention, PDPH, backache local anaesthetic systemic toxicity (LAST), and unsuccessful blockade).

Similarly to our study, Puthenveetil N. *et al.* [12] found that 3, 3% of cases in each group complained of pruritus. One case in group DPE developed PDPH, but none of the cases in group EPL did; nevertheless, this difference was not statistically significant.

There are many limitations of this study as small sample size, equipment or drugs, case related factors can have an impact on the success rate of DPE.

## Conclusion

The use of either EPL method or DPE method in cases undergoing total knee arthroplasty were effective as an anesthetic approach without major complication. DPE method seemed to have faster onset of sensory and motor block versus standard EPL method.

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