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A comparative study of epidural ropivacaine 0.2% with nalbuphine and ropivacaine 0.2% with fentanyl in unilateral total knee replacement surgeries

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Abstract
Background: Total knee replacement (TKR) is associated with intense early postoperative pain. Epidural opioids have unique advantages over conventional, intermittent IV/ IM administration, in that sooner in the postoperative period.
Materials and methods: This is prospective, double blind study where twenty patients in group A received Ropivacaine 0.2% with Nalbuphine and twenty patients in group B received Ropivacaine 0.2% with Fentanyl. Patients were assessed for hemodynamic changes, VAS scores, sedation scores and side effects.
Result: There was no statistically significant difference in the baseline parameters between the two groups. Rescue analgesics required in the first 24 hours of postoperative period in group A were significantly higher ($p < 0.01$) when compared with group B. Nalbuphine group had a good sedative action than Fentanyl group (P=0.04).
Conclusion: Fentanyl group is better in terms of quality of postoperative analgesia, lesser incidence of side-effects and patient satisfaction.

Keywords: Fentanyl, nalbuphine, ropivacaine, TKR

Introduction
Analgesia is one of the components of anaesthesia. It has now extended to relief of postoperative pain, chronic pain. Surgical patients require effective intra operative as well as post-operative pain control [1].
The spinal cord has taken the centre stage in analgesia practice following the demonstration of analgesia with intrathecal Morphine by Yaksh and Rudy (1977) [2]. In 1947, Manuel Martinez Curbelo (1906–1962) was the first to describe placement of a lumbar epidural catheter [3].
Total knee replacement (TKR) is associated with intense early postoperative pain [4]. It is associated with high demands of analgesics. Proper management of pain after TKR is not just for the humane purpose of freeing patients from suffering. Rather, it is essential for successful TKR outcome in terms of improving patient satisfaction and quality of life and prevention of complications. Improving the pain management techniques and rehabilitation programs has a huge impact on postoperative outcome.
The use of epidural analgesia is the preferred technique of postoperative analgesia for unilateral total knee replacement [5]. A local anaesthetic -opioid combination provides superior analgesia during perioperative and postoperative period.
Epidural opioids have unique advantages over conventional, intermittent IV/IM administration, in that patients given epidural opioids have fewer respiratory complications and can be mobilized sooner in the postoperative period.
Nalbuphine, a derivative of 14-hydroxymorphine is a strong analgesic with mixed k agonist and μ antagonist properties. The analgesic potency of Nalbuphine has been found to be equal to Morphine but unlike Morphine, it exhibits a ceiling effect on respiratory depression. Nalbuphine has the potential to maintain or even enhance μ-opioid based analgesia while simultaneously mitigating the μ-opioid side effects [6].
Fentanyl binds with stereospecific receptors at many sites within the central nervous system. It increases pain threshold, alters pain perception, inhibits ascending pain pathways.

It is highly selective μ receptor agonist which appears to be specifically involved in the medication of analgesia. Opioids appear to exert their effects by increasing intracellular calcium concentration, which in turn increases K^+ conductance and hyperpolarization of the excitable cell membranes decrease in membrane excitability that results may decrease both pre and post synaptic responses.

The aim of the present study was to compare the postoperative analgesic effect of Nalbuphine 20 mg and Fentanyl 300 μg as an adjuvant to continuous infusion of epidural Ropivacaine 0.2% in adult patients undergoing unilateral total knee replacement.

Materials and methods

Present study was done at DVVPF'S Medical College, Ahmednagar during 2018– 2019 on 40 patients in between age group of 20-60 years of ASA grade I and II undergoing unilateral total knee replacement after obtaining approval for the study from Institutional Ethics Committee. Written consent was obtained from all the patients included in the study.

Inclusion criteria

Patients posted for elective unilateral total knee replacement under ASA Grade I and II including both males and females in between age group of 20-60 years.

Exclusion criteria

1. Patient's refusal
2. Allergy to study drugs
3. Obese patients
4. Uncontrollable hypertension
5. Uncontrollable diabetes mellitus
6. Severe CVS abnormalities
7. Renal or hepatic failure
8. History of neurological surgeries
9. Spine deformities
10. Coagulation defects and patients those on anti-coagulants.

Written Informed consent was obtained after explaining the procedure. All patients were subjected to pre-anaesthetic check up on the day before surgery to find out systemic illness complicating anaesthesia. On the day of surgery, the patients were shifted to the operation theatre and baseline vital hemodynamic parameters such as heart rate, non-invasive arterial blood pressure, oxygen saturation and ECG were noted. Intravenous line was secured with an 18G intravenous catheter and preloading was done with 500 ml of Ringer's Lactate. Premedication was given with I.V. Ondansetron 4 mg. The patients were explained about the 10 point visual analogue of pain scale. Combined Spinal Anaesthesia (CSE) was decided to use for intraoperative and postoperative pain relief. After thorough aseptic precautions L1-L2 or L2- L3 space located and skin wheal raised by 26 gauge needle with 2% Lidocaine. Using a 18 gauge Huber point Tuohy needle epidural space was identified. With loss of resistance technique. Epidural catheter was inserted and aspirated to rule out subarachnoid or intravascular placement of the catheter. The placement was confirmed by 3 ml of 2% lidocaine with adrenaline 1: 2,00,000 and fixed. Then, L3-L4 intervertebral space was identified and 25 gauge spinal needle was introduced. 3 ml of injection Bupivacaine 0.5% (H) and injection Clonidine 15 μg was injected intrathecally (in both groups). After one hour of induction of anaesthesia, 10 ml of injection Ropivacaine 0.5% was given through epidural route (in both groups). All the patients in both the groups were given local knee infiltration of inj. Bupivacaine by operating surgeon. After surgery was over uneventfully, patient shifted to postoperative room and then after half an hour later study conducted postoperatively. The patients were randomly chosen into two groups.

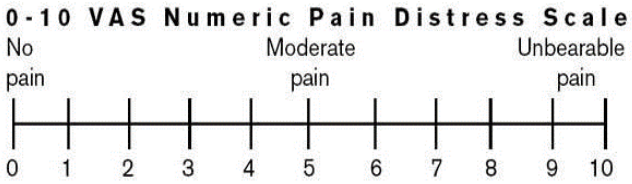
Group A: Injection Ropivacaine 0.2% with injection Nalbuphine 0.13 mg per ml at the rate of 6 ml per hour

Group B: Injection Ropivacaine 0.2% with Injection Fentanyl 2 μg per ml at the rate of 6 ml per hour

Ramsay Sedation Assessment Scale

Awake Levels	Patient anxious or agitated or both	1
	Patient cooperative, oriented and tranquil	2
	Patient responds to commands only	3
Asleep Levels	A brisk response to a light glabellar tap	4
	A sluggish response to a light glabellar tap	5
	No response	6

Patients were asked to mark a point scale on the 10-point visual analogue scale of pain according to the intensity of pain. The observation was done every 6 hourly. The pain relief is graded according to VAS as follows.



Rescue analgesia was given when VAS more than 4. The total number of rescue analgesics (inj. Paracetamol 1 gm IV and inj. Diclofenac 75 mg IV) in the first 24 hours were noted down to assess the quality of analgesia.

The side effects due to opioids like nausea, vomiting, pruritis, urinary retention were noted down. The Statistical software namely Open Epi, Version 2.3 was used for the analysis of the data and Microsoft word and Excel have been used to generate tables. Results on continuous measurements were presented on Mean ± SD and results on categorical measurements were presented in Number (%). Significance was assessed at 5 % level of significance. Significant (P value: $0.01<P<0.05$) and highly significant (P value: $P<0.01$) were considered.

Result

There was statistically no significant difference between mean age, weight, gender and ASA grading in both groups (Table – 1). There was no statistically significant difference in the baseline parameters between the two groups (Table – 2).

Table 1: Comparison of demographic data in both groups

Demographic parameters		Group A (n =20)	Group B (n=20)	p value
Age in years (Mean± S.D)		38.43±9.56	39.06±9.83	0.802
Weight in kg (Mean± S.D)		63.03±9.44	62.7±9.59	0.894
Sex	Male	22 (73%)	23(77%)	0.72
	Female	8 (27%)	7(23%)	0.72
ASA	Grade I	12(40%)	12(40%)	1.0
	Grade II	18(60%)	18(60%)	1.0

Table 2: Comparison of baseline variables

Baseline Parameters	Group A (Mean± S.D)	Group B (Mean± S.D)	p value
Heart rate	81.73 ± 9.43	81.23 ± 8.98	0.8333
Systolic blood pressure	127.6 ± 7.96	125.76 ± 7.49	0.3603
Diastolic blood pressure	83.23 ± 5.36	80.1 ± 7.78	0.07475
Mean arterial pressure	98.1 ± 5.1	95.13±6.92	0.06344
Respiratory rate	15.8±0.80	15.9±1.047	0.7446

Table 3: Comparison of VAS scores between the two groups

Time		Vas Score	
		0-4	5-10
0-6 Hours	Group A	20(100%)	0
	Group B	20(100%)	0
6-12 Hours	Group A	17(85%)	3(15%)
	Group B	18(90%)	2(10%)
12-18 Hours	Group A	18(90%)	2(10%)
	Group B	18(90%)	2(10%)
18-24 Hours	Group A	18(90%)	2(10%)
	Group B	19(95%)	1(5%)

The pain scores were similar in both the groups in the first six hours of postoperative period. 15% of patients in group A had a pain score more than 4 (VAS 5) during 6-12 hours of postoperative period as compared to 2 % in group B. Rescue analgesic (inj. Paracetamol 1 gm IV and inj. Diclofenac 75 mg IV) was given when VAS score was more than 4. Number of rescue analgesics required in the first 24 hours of postoperative period in group A were significantly higher ($p < 0.01$) when compared with group B (Table -3)

Table 4: Comparison of sedation score between two groups

Time		Sedation score	
		2-3	3-4
0-6 Hours	Group A	2 (10%)	18 (90%)
	Group B	17 (85%)	3(15%)
6-12 Hours	Group A	3(15%)	17(85%)
	Group B	18(90%)	2(10%)
12-18 Hours	Group A	4(20%)	16(80%)
	Group B	18(90%)	2(10%)
18-24 Hours	Group A	5(25%)	15(75%)
	Group B	19(95%)	1(5%)

There was statistically difference in sedation score (p value 0.04) between the two groups (Table – 4). Nalbuphine group had a good sedative action than Fentanyl group.

Table 5: Comparison of side effects in between both the groups

Side Effects	Group -A		Group -B		p value
	N	%	n	%	
Nausea and vomitting	3	10%	1	3.3%	0.3
Respiratory depression	4	13.3%	-	-	0.2
Urinary retention	-	-	-	-	-
Pruritis	3	10%	-	-	0.7
Hypotension	3	10%	2	6.6%	0.63
Bradycardia	2	6.6%	1	3.3%	0.5
Shivering	2	6.6%	1	3.3%	0.5

Comparison of side effects in between both the groups was statistically insignificant. All the side effects were treated immediately (Table-5).

Discussion

Regional techniques, such as spinal and epidural anaesthesia may offer advantages over general anaesthesia including reduced stress response to surgery and analgesia, which generally extends into the postoperative period [7, 8]. The CSE technique gives new dimension to the management of postoperative pain. Any mode of postoperative analgesia must meet three basic criteria: It must be effective, safe and feasible. In the majority of the patients after surgery, pain is not fully relieved with intravenous route of drugs [9]. The discovery of opioid receptors in the brain and spinal cord started a new era in the field of postoperative analgesia. Ropivacaine is a local anaesthetic, which belongs to the amide group of anaesthetic agents that has been widely used for local infiltration, peripheral nerve blocks, spinal and epidural anaesthesia. Various adjuvants have been added to the local anaesthetics to minimize the side effects of local anaesthetics and prolong the duration of intraoperative and postoperative analgesia [10].

In present study Demographic data comparing age, sex, weight shows no statistically significant difference among both the groups.

There was difference in sedation scores between two groups. Nalbuphine group had more sedative action than Fentanyl group. There was statistically no significant difference in the baseline parameters between the two groups.

In this study, the duration of postoperative analgesia in patients with the addition of Fentanyl was more prolonged as compared to Nalbuphine. Number of rescue analgesics required in the first 24 hours of postoperative period in group A were significantly higher ($p < 0.01$) when compared with group B. Nalbuphine is an opioid having agonistic action at kappa and antagonist activity at μ opioid receptors and provided reasonably potent analgesia in visceral nociception [11] was found to improve the quality of postoperative analgesia [12] with fewer side effects. Verma *et al*. showed that postoperative analgesia was significantly improved by the addition of nalbuphine [13].

In this study, there was statistically no difference in side effects between two groups.

Conclusion

This prospective, randomised, double blind study, where in epidural Nalbuphine 0.13 mg per ml with 0.2% Ropivacaine at 6 ml per hour and epidural Fentanyl 2µg per kg with 0.2% Ropivacaine at 6 ml per hour in unilateral total knee replacement concludes that both Nalbuphine and Fentanyl are effective for postoperative analgesia when used epidurally in patients undergoing unilateral total knee replacement surgery. However, Fentanyl group is better in terms of better quality of postoperative surgical analgesia, lesser incidence of side-effects and complications e.g. nausea, vomiting and respiratory depression. Fentanyl group has better patient satisfaction compared to Nalbuphine group.

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