Original Research Paper

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Anaesthesiology

A STUDY TO EVALUATE THE EFFICACY OF DEXMEDETOMIDINE AND FENTANYL AS ADJUVANT TO EPIDURAL BUPIVACAINE IN PROVIDING POST-OPERATIVE ANALGESIA TO PATIENTS UNDERGOING TOTAL KNEE REPLACEMENT.

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ABSTRACT **Background:** Knee osteoarthritis (OA) is the most common musculoskeletal condition affecting people worldwide. Peri-operative pain has been reported to be the major concern of patients in the post-operative period. There have been continuous searches for a pharmacological agent as an adjuvant which can prolong the analgesic action of local anaesthetic, so that the duration of analgesia can be prolonged in the post-operative period. Both dexmedetomidine and fentanyl have been used as an adjuvant to local anaesthetic delivered through epidural route for post-operative pain relief. **Aim of the Study**: We aim to compare the post-operative analgesic effects of dexmedetomidine and fentanyl as an adjuvant to epidural bupivacaine in patients undergoing total knee replacement. We will also note any side effects example nausea, vomiting, hypotension, bradycardia and pruritus for each of the study group. **Setting and Design:** This was a prospective randomized control trial in a tertiary hospital. **Materials and Methods:** Fifty consenting adult patients with physical status classes I and II, as determined by the American Society of Anaesthesiologists, scheduled to undergo elective total knee replacement, were randomly allocated to receive either Injection 0.5% Bupivacaine 10ml + Inj. Fentanyl 0.5 µg/kg in 2 ml NS (Group A) or injection 0.5% Bupivacaine 10ml + Inj. dexmedetomidine 0.5 µg/kg in 2 ml NS (Group B). The primary objective was to compare the post-operative analgesic effects of dexmedetomidine and fentanyl as an adjuvant to epidural bupivacaine in patients undergoing total knee replacement.. The secondary objective was to note any side effects example nausea, vomiting, hypotension, bradycardia and pruritus for each of the study group. **Statistical Analysis Used:** The results are discussed in the form of numerical values, percentages, mean and standard deviation. The α level for all analysis was set at 0.05 and p-value <0.05 was considered statistically significant. Demographic data like sex, weight, age and as grades of both the groups were compared using chi-square test. Comparison of incidence of hypotension was done using Chi-Square test. The software used for statistical analysis was SPSS (statistical package for social sciences) version 21.0 **Results:** At 2 hours after the first top-up dose, 15 out of 25 patients in Group B were having complete pain relief (i.e. NPRS 0) while this number in Group A was only 6. At 4 hours, none of the patients in Group A were having complete pain relief while there were 5 patients in Group B who had complete pain relief with NPRS 0. The trend of NPRS when observed at 6 hours exhibited the same pattern as at 4 hours. At 8 hours, in Group A there were just 2 patients which were having NPRS score 4 and rest of the 23 patients had complained of moderate pain with NPRS score 5. In Group B there were 7 patients with NPRS 3 at 8 hours and there were 13 patients with NPRS5. The mean time for NPRS 5 after first top-up was found to be significantly more in group B as compared to group A (p-value 0.004). study time required for second top-up was significantly prolonged in group B (8.40 hours) as compares to group A (6.64hours). The incidence of hypotension is more commonly associated with dexmedetomidine as compared to fentanyl and the incidence of nausea & vomiting is more common when fentanyl is used as an adjuvant with isobaric bupivacaine. **Conclusion:** Isobaric bupivacaine in 0.5% concentration in combination with Dexmedetomidine as an adjuvant provides better analgesia for a longer duration of time as compared to Bupivacaine & Fentanyl combination.

KEYWORDS : Epidural Anaesthesia, Isobaric bupivacaine, Dexmedetomidine, Fentanyl, Post-operative analgesia.

INTRODUCTION

Knee osteoarthritis (OA) is the most common musculoskeletal condition affecting people world wide [1]. Peri-operative pain has been reported to be the major concern of patients awaiting total knee replacement (TKR) [2], and the methods of managing early post-operative pain remain controversial [3]. Poorly controlled intraoperative and post-operative pain can lead to cardiorespiratory complications, and a decline in mental status, particularly in elderly patients.[4]

Improving the pain management technique and rehabilitation programs has a significant impact on postoperative outcome [5]. There have been continuous searches for a pharmacological agent as an adjuvant which can prolong the analgesic action of local anaesthetic so that the duration of analgesia can be prolonged in the post-operative period. Both dexmedetomidine and fentanyl have been used as an adjuvant to local anaesthetic delivered through epidural route for post-operative pain relief.

MATERIALS AND METHODS

After obtaining ethical approval from the institutional ethical committee and written informed consent from the patients, this study was conducted on 50 patients undergoing total knee replacement under epidural anaesthesia.

The study was conducted over a period of 12 months. ASA I and II patients of either sex, aged between 18-75 years of age who were scheduled for total knee replacement were included in the study. Patients with mental dysfunction or cognitive deficiency, history of psychiatric illness, with neuromuscular, vestibular, hepatic or major systemic illness, history of alcohol or drug abuse, history of allergy to local anaesthetic or patient with contraindication to epidural anaesthesia were excluded from the study. After a comprehensive pre-anaesthetic evaluation, the anaesthetic procedure was explained to the patient. The patient was also explained and familiarized with the methods of assessing analgesia.

Patients were randomly divided into two groups. Randomization was done using computer based random number generator and the allocation concealed in sealed envelopes, which was not opened until patient consent was obtained. Patients of Group A (n=25) were given Injection 0.5% Bupivacaine 10ml + Inj. Fentanyl 0.5 µg/kg in 2 ml normal saline and patients of Group B (n=25) were given injection 0.5% Bupivacaine 10ml + Inj. dexmedetomidine 0.5 µg/kg in 2 ml normal saline.

Anaesthetic Technique

No preoperative anxiolytic was administered, but patients were allowed to continue their medications. In the operating room, intravenous access was established in one of the forearms. All patients were preloaded with lactated Ringer solution (10ml/kg over 10-15 min.). The lumbar area was prepared aseptically and draped. The intervertebral space at L_3-L_4 or L_4-L_5 was identified.

With the patient in sitting position, a 18 G Touhy needle was inserted and epidural space as identified using loss of resistance technique. A test dose of 3 ml of 2% lignocaine with adrenaline was administered into epidural space and thereafter an epidural catheter was secured 3-5 cm in epidural space and patient was laid supine. The study solution was prepared by the third person who was not one of the investigators. The patients were placed supine after injection.

Clinical Assessment
A blinded investigator, who did not know which solution is injected, observed the developing block. Motor functions of the lower extremities of each patient were assessed using modified Bromage scores.

The post-operative pain assessment was done by "Numerical Pain Rating Scale" (NPRS) describing different levels of pain intensity. The tests were done 2 hourly after first epidural top up (which was given in the immediate post-operative period in the post-operative care unit.) that is 2 hours, 4 hours, 6 hours and so on and the time required for next top up was compared. The next top-up was given when the patient again complained of moderate pain that is NPRS amounting to 5.

In the recovery room, all patients were monitored by an investigator blinded to the type of anaesthetic technique administered.

OBJECTIVES

Primary:
To compare the post-operative analgesic effects of dexmedetomidine and fentanyl as an adjuvant to epidural bupivacaine.

Secondary:
To note any side effects example nausea, vomiting, hypotension, bradycardia, pruritus for each study group.

Sample size
We assumed α=0.05, β = 0.9, SD = 12 and the difference in pain score around 4. The minimum number of samples was 23 in each group. However, to have a margin of safety and round the figure, 25 patients in each group were included for the study.

Statistical Method
The results are discussed in the form of numerical values, percentages, mean and standard deviation.

The α level for all analysis was set at 0.05 and p-value <0.05 was considered statistically significant.

Demographic data like sex, weight, age and ASA grades of both the groups were compared using chi-square test.

Comparison of incidence of complication was done using Chi-Square test.

The software used for statistical analysis was SPSS (statistical package for social sciences) version 21.0

RESULTS

Demographic Data:
Age: The mean age of the patients was comparable in both the groups. p-value was found to be 0.203 using chi-square test. (Table 1, Fig. 1)

Table 1: Mean Age Of The Patients

Groups	Age (in years)				
	Mean	Std. Deviation	Mean Difference	t-test value	p-value
Group A	59.88	7.41	-2.48	-1.290	0.203
Group b	62.36	6.12			

No significant difference was found in the mean age between Group A and Group B.

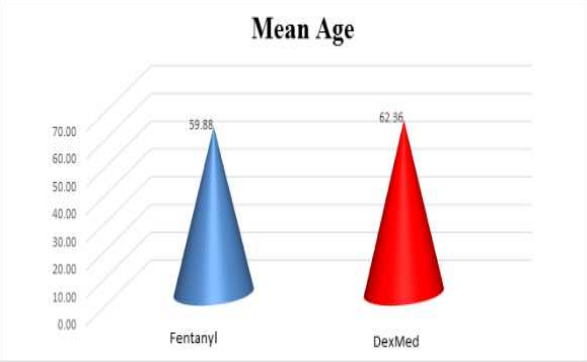

Figure 1: Comparison of mean age of the patients

Sex: The sex distribution of the patients was compared (Table 2, Fig. 2) using chi-square test and p-value was found to be 0.239, which is statistically insignificant.

Table 2: Sex Distribution Among Groups

	Group A	Group B	Total
Male	11	7	18
	44.0%	28.0%	36.0%
Female	14	18	32
	56.0%	72.0%	64.0%
Total	25	25	50
	100.0%	100.0%	100.0%
Chi-square value= 1.389, p-value=0.239			

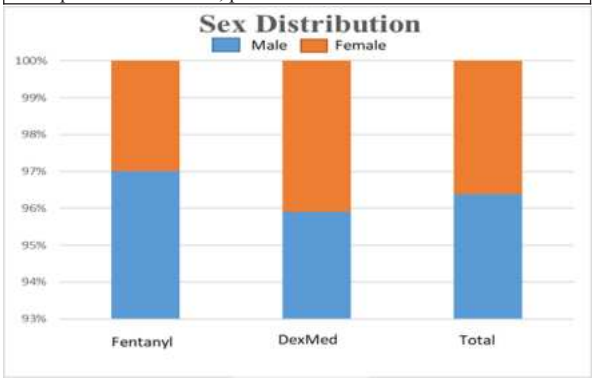

Figure 2: Comparison Of Sex Distribution In The Two Groups

ASA Grade: The grades were compared (Table 3, Figure 3) using chi-square test and was found to be statistically insignificant. (P-value 1.00)

Table 3: ASA Grading

ASA Grade	Group A	Group B	Total
I	13	13	26
	52.0%	52.0%	52.0%
II	12	12	24
	48.0%	48.0%	48.0%
Total	25	25	50
	100.0%	100.0%	100.0%
Chi-square value= 0.000, p-value=1.000			

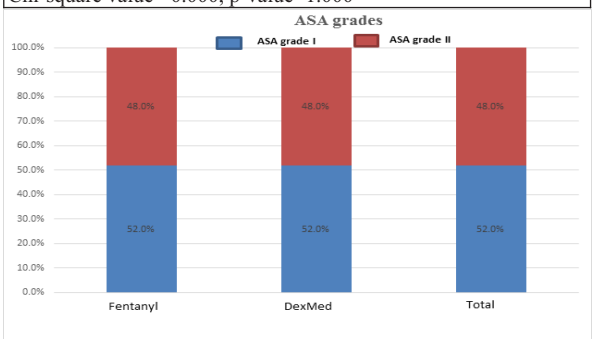

Figure 3: Comparison of ASA grades

Weight: The weight of the patients in both the groups were compared using chi-square test and was found to be comparable for both the groups with the p-value being 0.249.

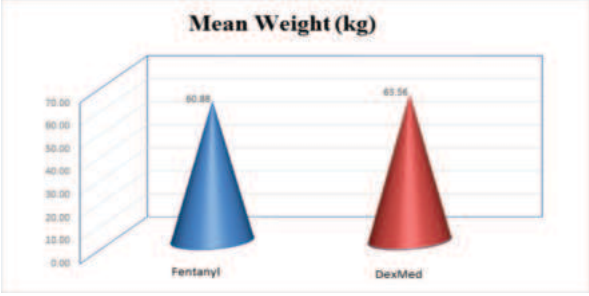

Figure 4: Comparison Of Mean Weights

Table 4: Mean Weight Of The Patients

	Weight (kg)				
Groups	**Mean**	**Std. Deviation**	**Mean Difference**	**t-test value**	**p-value**
Groups A	60.88	9.15	-2.68	-1.166	0.249
Groups B	63.56	6.95			

No significant difference was found for the mean weight between Group A and Group B.

NUMERICAL PAIN RATING SCALE:

At 2 hours: The distribution of NPRS at 2 hours was compared between Group A and Group B. Score 0 NPRS at 2 hours was present in more number of patients among Group B as compared to Group A. Score 1,2,3 and 4 was present more among Group A than B. None with score 5 was present in any group.

Table 5: Distribution Of NPRS At 2 Hours

NPRS at 2 hours	Group A	Group B
0	6(24%)	15(62.5%)
1	6(24%)	5(20.8%)
2	8(32%)	3(12.5%)
3	4(16%)	2(8%)
4	1(4%)	0(0%)
5	0(0%)	0(0%)
Total	25(100%)	25(100%)

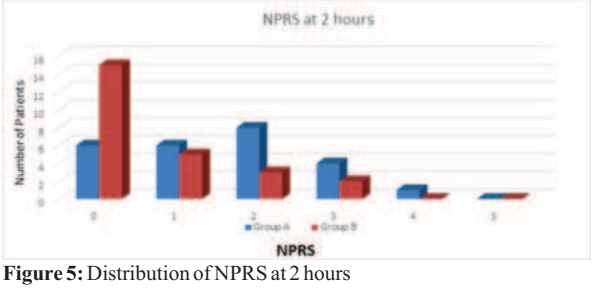

Figure 5: Distribution of NPRS at 2 hours

At 4 hours: The distribution of NPRS at 4 hours was compared between Group A and Group B. Score 0 and 1 and 2 NPRS at 4 hours was present in larger number of patients in Group B than A while, Score 3,4 and 5 was found in more number of patients in Group A as compared to Group B at 4 hours.

Table 6: Distribution Of NPRS At 4 Hours

NPRS at 4 hours	Group A	Group B
0	0(0%)	5(20%)
1	1(4%)	6(24%)
2	5(20%)	6(24%)
3	10(40%)	2(8%)
4	6(24%)	4(16%)
5	3(12%)	2(8%)
Total	25(100%)	25(100%)

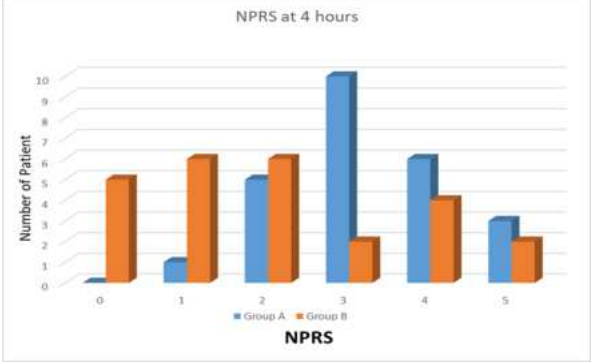

Figure 6: Distribution of NPRS at 4 hours

At 6 hours: The distribution of NPRS at 6 hours was compared between Group A and Group B. Score 1, 2 and 3 NPRS at 6 hours was present in more number of patients in Group B while, score 4 and 5 was significantly more among Group A than B at 6 hours. None of the patients in any group had score 0.

Table 7: Distribution Of NPRS at 6 hours

NPRS at 6 hours	Group A	Group B
0	0(0%)	0(0%)
1	0(0%)	1(4%)
2	0(0%)	6(24%)
3	4(16%)	8(32%)
4	5(20%)	2(8%)
5	16(64%)	6(24%)
Total	25(100%)	25(100%)

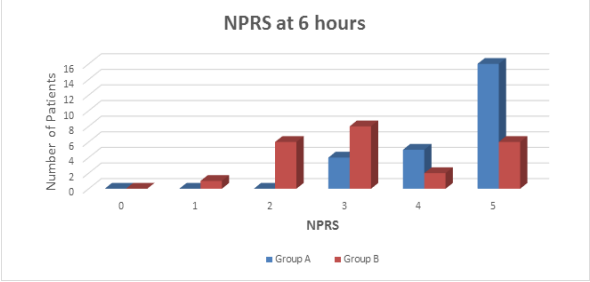

Figure 7: Distribution of NPRS at 6 hours

At 8 hours: The distribution of NPRS at 8 hours was compared between Group A and Group B. Score 3 and 4 NPRS at 8 hours was present in more number of patients in Group B than A while, score 5 was more among Group A than B. None of the patients in group 0, 1 & 2 had score 0.

Table 8: Distribution Of NPRS At 8 Hours

NPRS at 8 hours	Group A	Group B
0	0(0%)	0(0%)
1	0(0%)	0(0%)
2	0(0%)	0(0%)
3	0(0%)	7(28%)
4	2(8%)	5(20%)
5	23(92%)	13(52%)
Total	25(100%)	25(100%)

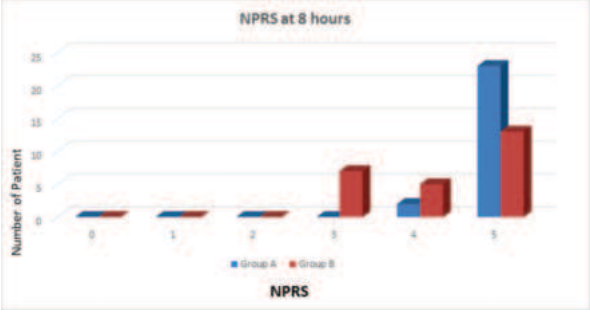

Figure 8: Distribution of NPRS at 8 hours

At 10 hours: The distribution of NPRS at 10 hours was compared between Group A and Group B. Score 4 NPRS at 10 hours was present in more number of patients in Group B than A. Score 5 was significantly more among Group A than B at 10 hours. None of the patients had score 0,1,2 &3.

Table 9: Distribution Of NPRS At 10 Hours

NPRS at 10 hours	Group A	Group B
0	0(0%)	0(0%)
1	0(0%)	0(0%)
2	0(0%)	0(0%)
3	0(0%)	0(0%)
4	0(0%)	3(12%)
5	25(100%)	22(88%)
Total	25(100%)	25(100%)

The distribution of NPRS 5 at 2 hourly differences was compared between Group A and Group B using the chi-square test. NPRS 5 was found to be present in significantly higher number of patients in Group A at 6 hours while, NPRS 5 was significantly more among Group B at 10 & 12 hours. At 2, 4 & 8, the difference was not statistically significant.

Figure 9: Distribution Of NPRS At 10 Hours

Table 10: Distribution Of NPRS 5 Two Hourly

	Group A	Group B
NPRS 5 at 2 hours	0	0
NPRS 5 at 4 hours	3	2
NPRS 5 at 6 hours	13	6
NPRS 5 at 8 hours	7	5
NPRS 5 at 10 hours	2	9
NPRS 5 at 12 hours	0	3
Chi-square value=10.567, p-value=0.032		

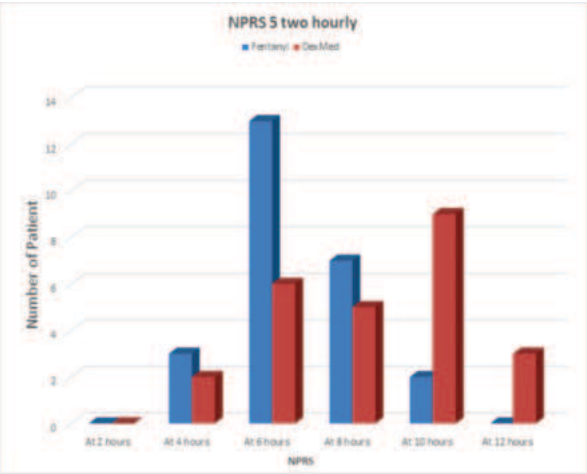

Figure 10: Distribution of NPRS 5 two hourly

Mean time for NPRS to be 5: The mean time to achieve NPRS 5 was compared between Group A and Group B using the unpaired t-test. The mean time was significantly more among Group B as compared to Group A.

Table 11: Comparison Of Mean Time For NPRS 5

Groups	Time (in hours) for NPRS score 5				
	Mean	Std. Deviation	Mean Difference	t-test value	p-value
Group A	6.64	1.60	-1.76	-3.066	0.004*
Group B	8.40	2.38			
Unpaired t-test			* Significant difference		

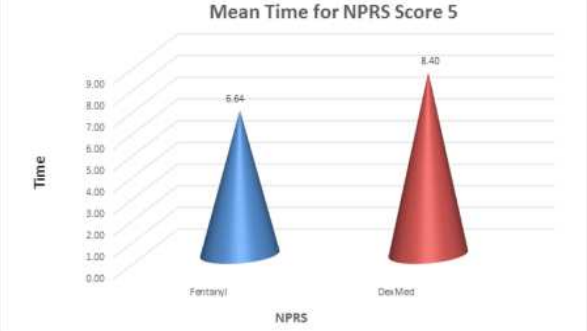

Figure 11: Comparison of mean time for NPRS 5

COMPLICATIONS:

Hypotension: The distribution Hypotension was compared between Group A and Group B using the chi-square test. The distribution of hypotension was significantly more among Group B compared to Group A.

Table 12: Distribution Of Hypotension

Hypotension	Group A	Group B
-	22	16
	88.0%	64.0%
+	3	9
	12.0%	36.0%
Total	25	25
	100.0%	100.0%
Chi-square value=3.947, p-value=0.047*		

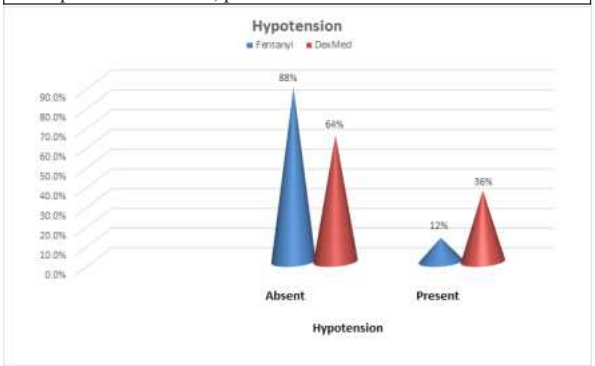

Figure 12: Distribution of Hypotension

NAUSEA & VOMITTING:

The distribution of nausea & vomiting was compared between Group A and Group B using the chi-square test. The distribution of nausea & vomiting was significantly more among group A as compared to Group B.

Table 13: Distribution Of Nausea & Vomiting

Nausea & Vomiting	Group A	Group B
-	18	23
	72.0%	92.0%
+	7	2
	28.0%	8.0%
Total	25	25
	100.0%	100.0%
Chi-square value=3.388, p-value=0.046*		

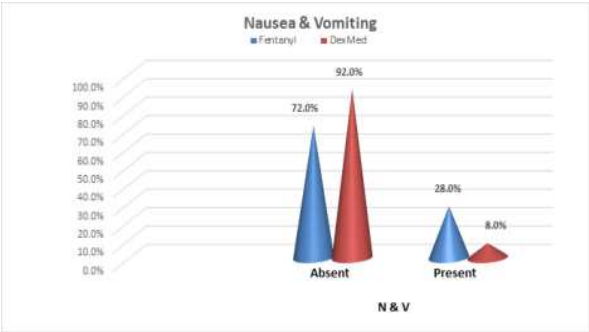

Figure 13: Distribution of Nausea & Vomiting

Shivering: The distribution of shivering was compared between Group A and Group B using the chi-square test. There was no significant difference in the distribution of shivering between Group B and Group A.

Table 14: Distribution Of Shivering

Shivering	Group A	Group B
-	19	23
	76.0%	92.0%
+	6	2
	24.0%	8.0%
Total	25	25
	100.0%	100.0%
Chi-square value=2.381, p-value=0.123		

Pruritis: The distribution of pruritus was compared between Group A and Group B using the chi-square test. There was no significant

difference in the distribution of shivering between Group B and Group A.

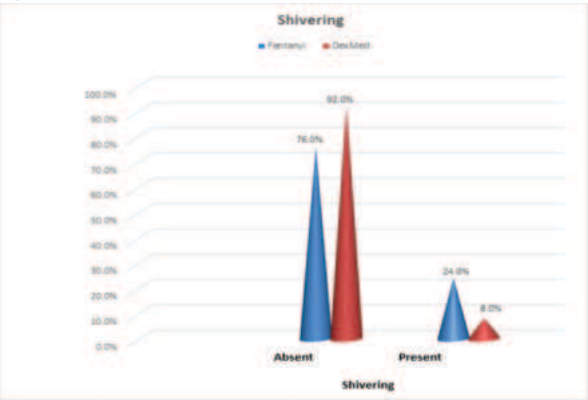

Figure 14: Distribution of Shivering

Table 15: Distribution Of Pruritis

Pruritis	Group A	Group B
-	21	23
	84.0%	92.0%
+	4	2
	16.0%	8.0%
Total	25	25
	100.0%	100.0%
Chi-square value=0.758, p-value=0.384		

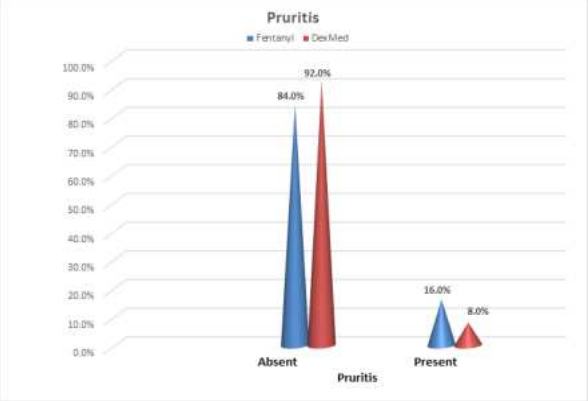

Figure 15: Distribution of Pruritis

Bradycardia: The distribution of bradycardia was compared between Group A and Group B using the chi-square test. There was no significant difference in the distribution of Bradycardia between Group B and Group A.

Table 16: Distribution Of Bradycardia

Bradycardia	Group A	Group B
-	21	16
	84.0%	64.0%
+	4	9
	16.0%	36.0%
Total	25	25
	100.0%	100.0%
Chi-square value=2.599, p-value=0.107		

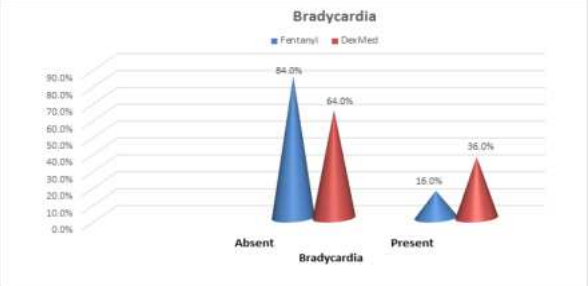

Figure 16: Distribution Of Bradycardia

DISCUSSION

Post-operative pain relief is one of the major concerns in total knee replacement surgery. Pitimanaaree et al[6] and Tanaka et al[7] conducted studies to evaluate pain intensities after total knee replacement and modalities to control postoperative pain. They concluded that after knee replacement post-operative periods are the most painful time and its necessary to control such pain for early rehabilitation and recovery.
Epidural anaesthesia is one of the techniques which can solely be used carry out both surgical procedures and managing post-operative pain using various drug regimes in surgeries involving lower limbs. Various drug combination with or without adjuvants have been tried till now. Kumar et al [8] conducted study to evaluate the use of epidural analgesia for pain management after major spinal surgery and concluded that most epidural analgesic regimens significantly reduce postoperative pain and the requirement for supplementary parenteral analgesics was minimal. Ezhevskaya et al [9] also concluded that postoperative epidural analgesia produced better pain control, less bleeding, and lower surgical stress response than general analgesia with postoperative systemically administered narcotic analgesia.

Bupivacaine is a long acting, effective local anaesthetic that is commonly administered by epidural route for post-operative pain relief. In our study, we are using Bupivacaine heavy as the local anaesthetic agent for epidural administration. However, the search for an ideal anaesthetic adjuvant has been going on since a long time to enhance the onset and duration of analgesia and minimize the dose related side effects by decreasing the dose of local anaesthetic required to produce analgesia.

Use of opiods as an adjuvant to local anaesthetic is not uncommon and fentanyl is the most commonly used opiod as an adjuvant. Fentanyl is a powerful synthetic opioid which is similar to morphine and it is 50-100 times more potent. Kale et al [10] conducted a study to compare the effects of bupivacaine and bupivacaine plus fentanyl in lower limb surgeries. They found that the bupivacaine and fentanyl combination enhances the onset and duration of action for two segment regression. The time for rescue analgesic also increases in fentanyl group.

Since opiods like fentanyl is usually associated with common side effects like nausea and vomiting, pruritus and respiratory depression, newer adjuvants are being tried and their safety profile and analgesic effects are being compared with opiods.

α_2 agonist are novel agents which are being tried as adjuvants. Clonidine and dexmedetomidine are drugs among α_2 groups. Dexmedetomidine is a highly selective α_2 agonist which has been used as premedication and as an adjuvant to general anaesthesia. It reduces opioid and inhalational anaesthetics requirement. Intrathecal α_2 receptor agonists are found to have antinociceptive action for both somatic and visceral pain. Bogra et al [11] evaluated dexmedetomidine as an intrathecal adjuvant for postoperative analgesia. They concluded that addition of dexmedetomidine intrathecally to local anaesthetics produce a prolongation in the duration of the motor and sensory block.
In our study, we investigated the effects of Dexmedetomidine and Fentanyl in epidural anaesthesia in terms of post-operative pain control and associated complications.

Demographic Data

The comparison of mean age among the two groups was done (Table 1 and figure1) and both the groups were found to be comparable. The mean age of group A was 58.8 & that of group B was 62.36 with a p-value of 0.293.

The distribution of male and female in the two study groups was as shown in the table 2 & figure 2 with Group A having 11 males and 14 females and Group B having 7 males and 18 Females. Both the study groups were found to be comparable on the basis of sex (p-value being 0.239 which is statistically insignificant).

Patients of ASA grade 1 & 2 were included in the study. Group A had 13 ASA grades 1 patients and 12 ASA grade 2 patients while Group B had 13 ASA grade 1 and 12 ASA grade 2 patients as shown in the table 3 and depicted in figure 3. So, both the groups were comparable in terms of ASA grading of the patients (p-value=1.000).

The distribution of weight of the patients in the two groups is shown in table 4 and Figure 4. Mean weight of Groups A patients was 60.8 while the mean weight of Group B Patients was 63.56 with a standard deviation of 9.15 and 6.95 respective for Group A & B. Mean

difference was-2.68. Both the groups were comparable in terms of weight as the P value was 0.249 showing the difference was statistically insignificant.

Therefore the demographic data like ASA grades, age, weight etc were comparable in both the study groups.

Post-operative Analgesia

This was the primary objective of our study to analyse the post-operative analgesic efficacy of the two study drugs & to compare the duration of post-operative analgesia between the two groups.

Post-operative pain assessment was done by "Numerical Pain Rating Scale" (NPRS) scoring from 0 (no pain) to 10 (worst pain). Moderate pain was scored as 5.

The distribution of NPRS was compared between Fentanyl and Dexmedetomidine at every two hours since the first top-up dose.

It was seen that at 2 hours after the first top-up dose, 15 out of 25 patients in Group B were having complete pain relief (i.e. NPRS 0) while this number in Group A was only 6, this same pattern was also seen when NPRS score 1 was compared, having 6 patients in Group A and 15 patients in Group B. None of the patients in any of the groups complained of moderate pain (NPRS 5) by 2 hours. However, when higher scores that is NPRS 2 & 3 were compared, these were found to be present in higher number of patients in Group A as compared to Group B, with Group A having 8 & 4 patients, & Group B having 3 & 2 patients respectively. (Table5, Figure 5)

At 4 hours, none of the patients in Group A were having complete pain relief while there were 5 patients in Group B who had complete pain relief with NPRS 0. At this time, it was also seen that a larger count of the study population was having NPRS 3 in Group A (10 patients out of 25) in comparison to Group B in which only 2 patients reported this score. (Table 6, Figure 6).

Furthermore, the trend of NPRS when observed at 6 hours exhibited the same pattern. By 6 hours, most of the patients in Group A (16 out of 25) having Fentanyl as an adjuvant in the top-up complained of moderate pain with NPRS 5, whereas only 6 patients in Group B has this score. The lowest score of pain in Group A was found to be 3, while in Group B, there were 6 patients with NPRS 2 & 1 patients with NPRS 1 (Table 7 & Figure7).

At 8 hours, in Group A there were just 2 patients which were having NPRS score 4 and rest of the 23 patients had complained of moderate pain with NPRS score 5. In Group B there were 7 patients with NPRS 3 at 8 hours and there were 13 patients with NPRS5.

By 10 hours all the patients had moderate pain with NPRS 5 in Group A whereas in Group B there were 22 patients with NPRS 5 and 3 patients with NPRS 3 by 10 hours.

We have also compared the number of patients with NPRS 5 at different time intervals during our study since the first top-up dose. It was found that there was significantly more number of patients (13 patients i.e. 52% of patients) with NPRS 5 at 6 hours in Group A. On the other hand, NPRS 5 was achieved later in Group B that is at 10 & 12 hours (by 9 (36%) & 5 (20%) patients respectively) as shown in table 10 and figure 10. That is, the patients receiving dexmedetomidine as an adjuvant in their top-up doses were complaining of moderate pain after a longer period of time as compared to those receiving fentanyl.

In our study, we have also compared the mean time to attain NPRS 5 that is we have compared the duration after which the patients again complained of moderate pain. Unpaired t-test was applied and the mean time for NPRS 5 after first top-up was calculated. The mean time was found to be significantly more in group B as compared to group A (p-value 0.004). It can be well appreciated in table 11 & figure 11.

So, according to our study time required for second top-up was significantly prolonged in group B (8.40 hours) as compares to group A (6.64hours).

Gupta et al [12] conducted a study to evaluate the efficacy of dexmedetomidine and fentanyl when used as an adjuvant to 0.5% levobupivacaine. They found that the mean duration of sensory analgesia was significantly higher in dexmedetomidine group. Sarkar et al [13] all concluded that use of dexmedetomidine as an adjuvant helps in early sensory and motor blockade and prolongation of blockade. Dexmedetomidine also improves quality of sensory blockade without causing any opiods related side effects.

Complications:

Hypotension:

The distribution of hypotension was compared between the two groups using the chi-square test and it was found to be significantly higher in group B (36.0%) as compared to group A(12.0%). (Table 12 and Figure12). A study conducted by Soliman and Eltaweel [14] found that the epidural dexmedetomidine is associated with a higher incidence of bradycardia and hypotension compared to epidural fentanyl which supports our study except bradycardia which is not significant in our study.

Nausea & Vomiting:

The distribution of nausea and vomiting was compared between the two groups using chi-square test and the distribution was found to be significantly more in group A (28%) as compared to group B (8%). It was seen in 9 patients overall as shown in figure 13 & table 13.Liang et al [15] evaluated efficacy of dexmedetomidine on postoperative nausea and vomiting and they concluded that dexmedetomidine has protective role in post-operative nausea and vomiting as compared to opiods.

Shivering:

A total of 8 patients were found to have this complication. The distribution was compared among the two study groups using chi-square test. There was no significant difference found in the incidence of shivering between the two study groups. (Table 14 & Figure 14)

Pruritis:

The distribution of pruritis was compared between two study groups and no significant difference was found in the distribution of pruritis between the two groups. (Table 15 and Fig.15)

Bradycardia:

This was the most common complication which was found in our study. It was considered when the heart rate fell below 50 bpm. A total of 13 patients had this complication. 4 in group A while 9 in group B. The distribution of bradycardia was compared between the two study groups using chi-square test. There was no significant difference in the distribution of bradycardia between the two groups. (Table 16 & Figure 16)

Others:

None of the patients in our study had an episode of respiratory distress and post dural puncture headache.

CONCLUSION:

Isobaric bupivacaine in 0.5% concentration in combination with Dexmedetomidine as an adjuvant provides better analgesia for a longer duration of time as compared to Bupivacaine & Fentanyl combination. Both the drug combinations are not associated with any deleterious effects, however, the incidence of hypotension is more commonly associated with dexmedetomidine as compared to fentanyl and the incidence of nausea & vomiting is more when fentanyl is used as an adjuvant with isobaric bupivacaine.

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