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Assessment AndComparison Of Effectiveness Of Multimodal Pain Management And Standard Pain Management In Patients Undergoing Primary Total Knee Replacement Surgery

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ABSTRACT
Background: *Parenteral narcotics continue to play a significant role in postoperative pain management, despite the fact that a variety of postoperative analgesia techniques have been researched in an effort to improve pain control following total knee arthroplasty. The benefit of local anaesthetics is that they limit the transmission of pain at its source and lessen the systemic negative effects connected with postoperative opioid use. In patients having total knee arthroplasty, this study was done to assess the advantages and safety of a multimodal analgesic regimen that included periarticular injection of substantial doses of local anaesthetics as compared to standard care.*
Methods: *A randomized open label study was conducted on the patients undergoing total knee arthroplasty were randomly divided into two groups to receive standard therapy (Group 1) with self-administered morphine alone and multimodal pain therapy (Group 2) administered with perioperative infiltration mixture primarily comprised of local anaesthetic and self-administered morphine. Pain assessment evaluation was performed using the VAS score and knee society score. Drug use, pain management, adverse drug reactions, plasma levels of the local anaesthetic (ropivacaine), and postoperative recovery were all assessed and compared.*
Results: *Out of total 48 patients, 24 received standard care (Group 1), and the remaining 24 received multimodal pain management (Group 2). According to the VAS score, group 1 experienced more pain than group II. In group 1, the mean VAS score at post-op after week 2 was 3.12 0.85 while it was 1.67 0.82 in group II. Following the completion of 6 weeks, group I's pain score decreased to 2.04 1.08 against 0.83 0.76 in group II. After day 1, day 2, week 2, and week 6, there was a statistically significant difference between the two groups in terms of their mean VAS scores. On comparison of knee society score after 2 weeks and 6 weeks group 2 has better results compared to group 1 and was found to be significant. (P value=0.0092). Significant P value (0.0265) in SLR was obtained with positive results in 16 (66.66) patients in group 1 compared to 23 (95.83) in group 2.*
Conclusions: *Compared to standard analgesic care, this multimodal perioperative analgesia approach that included local anaesthetic infiltration provided patients undergoing total knee arthroplasty with better pain management and fewer adverse effects.*

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I. Introduction

Total knee arthroplasty (TKA) have seen remarkable advancements during the course of last two decades, including minimally invasive methods, computer-assisted techniques, sophisticated rehabilitation protocols, and better perioperative pain control. The most significant developments in the field of total joint surgery have been related to the recent advancements in pain management. (1) Millions of patients around the world have been benefited from joint replacement (arthroplasty) as a surgical treatment for end-stage arthritis. (2, 3) India, a nation of 1.2 billion, has a sizable population of people who suffer from hip and knee arthritis. (4, 5) The arthroplasty market is predicted to expand in near future at a compound annual growth rate of 26.7%.(6) This data indicates that almost 70,000 joint replacement procedures were carried out in India in 2011 and further demand for joint replacement surgery is anticipated to increase.(7)

Major surgical procedure including arthroplasty is often accompanied by a great amount of postoperative pain affecting quality of life, prolonged hospitalization and delayed rehabilitation, resulting in

higher deep vein thrombosis rates. (8) Pain can result from arthroplasty, for a number of reasons. Significant tissue damage and inflammation can be brought on by the surgical treatment itself, which can be painful and uncomfortable. The replacement or repair of the joint may potentially irritate or harm nearby nerves, resulting in discomfort and suffering. (9)

Following surgery, pain may develop as a result of the healing process can be brought on by things like inflammation, tissue damage, and nerve irritation. The patient may be more prone to feeling pain until the joint has fully recovered and regained its strength, which means that discomfort can also be brought on by using the affected joint. (10)According to several studies, almost one-third of TKA patients' needs opioids within three months of their procedure. (11) TKA patients were twice as likely to need their opioid prescriptions refilled as total hip arthroplasty patients, and they received prescriptions for a higher total morphine equivalent dose for a longer period of time postoperatively. (12) In TKA patients, there is growing evidence that chronic opioid usage before surgery decreases their effectiveness in postoperative pain management and increases postoperative opioid use. (13) Additionally, the use of opioids prior to surgery is linked to early revision, postoperative complications, poorer clinical outcomes as a result of tolerance development, and hyperalgesia, which can impede recovery and rehabilitation.(14)

Major technological developments that have the potential to considerably enhance the field of postoperative analgesia have occurred and are still in progress throughout the past few decades, notably the last few years. Both peripheral and cerebral processes underlie postoperative pain in TKA patients. Therefore,to adequately relieve postoperative pain following TKA, monotherapy may not be sufficient. Targeting a variety of pain pathways, multimodal analgesia is now thought to be the best technique for perioperative pain control of TKA. (15) It consists of preoperative, intraoperative, and postoperative analgesic regimens with the goal of maximizing analgesic efficacy by the fusion of several analgesic regimens and reducing unwanted side effects. (16)

The present study aims to compare the multimodal pain management with standard pain management in patients who underwent total knee replacement surgery with a primary focus on clinical outcomes, complication rates and patient satisfaction.

II. Materials and Methods

Study Design

This is a randomized, controlled, open label study, approved by the Scientific Board of the Department of Orthopedics at Tata Main Hospital, Jamshedpur. Patients scheduled for TKA at the Department of Orthopedic Surgery, Tata Main Hospital, Jamshedpur were recruited during October 2017 to September 2018.The study and associated analgesic procedures were fully disclosed to the participants. To have their data included in this study, all patients were provided with written informed consent. The identical orthopedic surgical team used the same surgical approach for each procedure. The Tata Main Hospital, Jamshedpur has an institutional Ethical Committee, and all procedures were carried out throughout this study complied with its ethical guidelines.

Study Population: All the patients between 40-80 years, of both gender and fit for undergoing TKA during the study duration were included in the study. Patients who required revision of total knee replacement, history of hypersensitivity to study drugs, patients with adjacent joint arthritis and patients with lower back pain including sciatica were excluded from the study.

All the patients recruited were randomly distributed among two groups i.e group 1 (receiving standard pain therapy) and group 2 (receiving multimodal therapy).

Intervention and Control groups

All of the patients in group 1 were in the control group and got standard pain medication, whereas all of the patients in group 2 received multimodal preoperative, intraoperative, and postoperative pain medication.

Please mention drug regimen for both the groups to be compared

Preoperative care: Prior to surgery, all patients received thorough explanations on pain management and instruction in VAS pain assessment. Patients in group 2 also receivedetoricoxib 90 mg, tramadol 50 mg, pregabalin 75 mg, and ketorolac 10 mg orally 24 and 6 hours prior to surgery.

Surgical care: The same surgeon from a four-person surgical team performed each operation. Peripheral intravenous access was obtained during surgery, and vital indicators such blood pressure, respiration rate, end-tidal carbon dioxide/ETCO2 (PetCO2), and peripheral capillary oxygen saturation (SpO2) were tracked. The same epidural anaesthesia was administered to each patient. At the L2-3 or L3-4 interspaces, continuous epidural anaesthesia was administered to establish bilateral sensory block between T8 and T10. To keep the patient sedated throughout surgery, an intraoperative ropivacaine infusion was used. Blood pressure, heart rate, bispectral index, and other variables were used to modify the level of anaesthesia. The conventional medial parapatellararthrotomy was used in all procedures, along with an inflatable tourniquet with a pressure adjusted at the patient's systolic pressure + 100 mmHg (1 mmHg = 0.133 kPa).

The intramedullary alignment technique was used to resect the femur, and then the femur's four surfaces were osteotomized. The extramedullary alignment approach was used to accomplish a tibia resection. After size assessment, the prosthesis was implanted. All TKAs employed a posterior stabilised knee prosthesis from Zimmer Biomet (US) attached with bone cement.Morphine (3 mg) was administered via the epidural catheter to all the patients which was withdrawn at the end of the surgery. Additionally, an analgesic cocktail was injected into the posterior articular capsule, medial collateral ligaments, peripatellar soft tissue, and infra-patella fat pad in patients belonging to group 2 prior to the prosthesis being implanted.

For intraoperative pain management a periarticular injection of drug cocktail consisting of 0.75mg ropivacaine, 4mg morphine, 300 mcg adrenaline and 1 gmtranexamic acid reconstituted with saline was used.

Postoperative management: No intravenous patient-controlled analgesia pump was used. All patients received intramuscular administration of ondansetron hydrochloride (4 mg).An intravenous dose of 1g paracetamol three time a day was administrated to the group 1 patients for 3 days and group 2 patients for 2 days. In addition to paracetamol, all the patients of group 2 had a uniform postoperative analgesia regimen which involved the use of ketorolac 10 mg, tramadol 50 mg and etoricoxib 90 mg twice a day orally for 5 consecutive days with pregabalin 75 mg orally for 15 days.While all patients in Group 1 had uniform postoperative analgesic regimen for 3 consecutive days, which included tramadol 50 mg and diclofenac 50 mg given intravenously. All the patients underwent a uniform rehabilitation protocol and were discharged from the hospital 3 days after the surgery. (this does not include self administered morphine?? What is being compared??)

Postoperative evaluations: The knee society score was assessed on the second and sixth weeks following surgery, and the VAS Score was used to assess pain levels immediately following surgery, on the first and second postoperative days, and on the second and sixth weeks following surgery. At each time point, pain assessment was performed for both the resting and active states (lifting the straight leg, bending and flexing the knee while lying flat).

Statistical analysis: All the data were analysed using Microsoft excel 2013. The significance of the difference in proportions was determined using the chi square test, which included both univariate and bivariate analysis. P value significance was determined to be less than 0.05. Independent t tests were used to determine the significance of the difference in means.

III. Results:

A total of 48 participants were enrolled in the study from which 24 patients had received standard therapy (Group 1) and the other 24 patients had received multimodal pain therapy (Group 2).

Table 1 shows the demographic parameters among the patients. A total of 48 patients were selected for the study of which 36 were males and 12 were females. The group 1 had 19 (79.2%) males and 5 (20.8%) females while in group 2, 17 (70.8%) were males and 7 (29.2%) were females. The majority of the patients were from 61-70 years age in both the groups. The mean age in group 1 and group 2 was 69.8 ± 5.6 and 69.9 ± 5.5 respectively. The majority of the patients were having BMI in the range of 18.5-22.9 in both the groups. 6 (25%) and 4 (16.67%) patients were having history of diabetes in group 1 and 2 respectively. In group 1 and 2, history of hypertension was observed in 2 (16.67%) and 4 (25%) patients respectively. No statistically significant difference found between the groups at baseline ($p>0.05$).

Parameters	**Group I N (%)**	**Group II N (%)**	**P value**
Sex			
Male	19 (79.17)	17 (70.83)	0.73 (NS)
Female	5 (20.83)	7 (29.17)	
Age			
45-60	0	1(4.17)	0.35 (NS)
61-70	10 (58.33)	10 (41.67)	
More than 70	10 (41.67)	13 (54.17)	
BMI			
<18.5	5 (20.83)	7 (29.17)	0.63 (NS)
18.5-22.9	9 (37.5)	9 (37.5)	
23-24.5	5 (20.83)	6 (25)	
≥ 25	5 (20.83)	2 (8.33)	
History of Diabetes			
Yes	6 (25)	4 (16.67)	0.72 (NS)
No	18 (75)	20 (83.33)	
History of Hypertension			
Yes	2 (8.33)	4 (16.67)	0.66 (NS)

No	22 (91.67)	20 (83.33)	

Table 2 shows distribution of patients according to preoperative pain score. The VAS score and Knee society score used to evaluate the pain in patients preoperatively. As per VAS score, in group I, 23 (95.83%) patients were having severe pain and 1 (4.17%) patient was having worst pain while in group 2, 21 (87.5%) patients were having severe pain while 3 (12.5%) patients were having worst pain. The Knee Society pain score was also used to evaluate pain in patient's pre operatively. Group 1 had 17 (70.1%) with fair and 7 (29.2%) with poor scores. Whereas 12 (50%) with fair outcome and 12 (50%) with poor outcome were present in group 2. There was no difference in knee scores between groups preoperatively and before the start of the pain management therapies. (write effectively)

Table 2: Distribution of patients according to Preoperative Pain Score

Pain Score	**Group 1**	**Group 2**	**P value**
VAS Score			
Mild (1-3)	0	0	0.60 (NS)
Moderate (4-6)	0	0	
Severe (7-9)	23 (95.83)	21 (87.5)	
Worst (10)	1 (4.17)	3 (12.5)	
Knee Society Score			
Excellent	0	0	0.23 (NS)
Good	0	0	
Fair	17 (70.83)	12 (50)	
Poor	7 (29.17)	12 (50)	

Post operation pain score in group I (use 1 and 2 uniformly through out the script) and group II was also compared with the help of VAS score and knee society score. As per VAS score group I had higher pain scales compared to group II. The mean VAS score at post operation after week 2 was 3.12 ± 0.85 in group 1 compared to 1.67 ± 0.82 in group II. After completion of 6 weeks the pain score was reduced to 2.04 ± 1.08 in group I compared to 0.83 ± 0.76 in group II. There was statically significant difference between two groups according to their mean VAS score after day 1, day 2, week 2 and week 6 which suggests multimodal pain therapy was better than standard therapy.

Knee society pain score was compared after 2 weeks and 6 weeks to evaluate the pain modality. At 2 weeks, 6 (25%) with excellent results, 12 (50%) with good results and 6(25%) with fair score in group 1 whereas 14 (58.3) with excellent results and 10 (41.7%) with good outcome and none with fair and poor outcomes in group 2. The group 2 has better results compared to group 1. This was found to be significant. (P value=0.0092). After 6 weeks, 16 had excellent, 7 had good and 1 had fair result in group 1 compared to 21 and 3 excellent and good respectively in group 2.

Table 3: Distribution of study participants according to post operation mean Pain Score

Pain Score (VAS) postoperatively	**Group 1**	**Group 2**	**P Value**
	Mean ± S.D	**Mean ± S.D**	
Day 1	4.88 ± 1.26	3.16 ± 1.24	**<0.001(Significant)**
Day 2	4.08 ± 0.717	2.63 ± 1.01	**<0.001 (Significant)**
Week 2	3.12 ± 0.85	1.67 ± 0.82	**<0.001 (Significant)**
Week 6	2.04 ± 1.08	0.83 ± 0.76	**<0.001 (Significant)**
Knee Society Score at 2 weeks (what about post op day 1 and 2)			
	N (%)	N (%)	P value
Excellent	6 (25)	14 (58.33)	**0.0092 (Significant)**
Good	12 (50)	10 (41.67)	
Fair	6 (25)	0	
Poor	0	0	
Knee Society Score at 6 weeks			
Excellent	16 (66.67)	21 (87.5)	0.1944 (NS)
Good	7 (29.17)	3 (12.5)	
Fair	1 (4.17)	0	

Poor	0	0	

Straight leg test (SLR) was performed with two groups at postoperative day 1, day 2 and week 2 and week 6 (Table 4). It was found that SLR was positive in 16 (66.66) patients in group 1 compared to 23 (95.83) in group 2. The P value (0.0265) suggests that there is significant difference in both the groups. SLR test was again performed on 2 day, the results had suggested that group I had 18 positive results while in group II all the patients had given the positive results. There is significant difference in results of both the groups. Proportion of those who were SLR positive more in multimodal pain therapy compared to standard group.

Table 4: Distribution of study participants according to straight leg raising (SLR) test at day 1 and day 2, week 2 and 6

SLR Tests		Group I N (%)	Group II N (%)	P value
SLR at Day 1	Negative (0^0)	8 (33.33)	1 (4.17)	**0.0265 (Significant)**
	Positive ($>0^0$)	16 (66.67)	23 (95.83)	
SLR at Day 2	Negative (0^0)	6 (25)	0	**0.0291 (Significant)**
	Positive ($>0^0$)	18 (75)	24 (100)	
SLR at week 2	Negative (0^0)	0	0	Not Applied
	Positive ($>0^0$)	24 (100)	24 (100)	
SLR at week 6	Negative (0^0)	0	0	Not Applied
	Positive ($>0^0$)	24 (100)	24 (100)	

Mean range of motion (ROM) was compared between two groups at Day 1, Day 2, week 2 and week 6 and shown in table 5. It was found that mean range of motion was much higher in multimodal pain group at day 1, day 2, week 2 and week 6 compared to standard pain management group. This was found to be statistically significant.

Table 5: Distribution of study participants according to mean range of motion (ROM)

Range of Motion (ROM)	**Group I Mean ± S.D**	**Group I Mean ± S.D**	**P value**
ROM at Day 1	4.17 ± 5.84	17.5 ± 8.97	<0.0001 (Significant)
ROM at Day 2	12.5 ± 7.94	30.83 ± 11.76	<0.0001 (Significant)
ROM at week 2	65.83 ± 13.16	80.83 ± 8.30	<0.0001 (Significant)
ROM at week 6	94.17 ± 8.81	105 ± 5.11	<0.0001 (Significant)

- **ROM can be written in heading once the day 1,2 etc**

Table 6 shows the extension of legs test among the patients. The P value was statistically significant after 2 day and 2 week. The 10 patients were able to extent the leg ($<10^0$) in multimodal pain therapy compared to 2 patients in standard therapy on day 2. After 2 week all the patients in group 2 had extend the leg while in group I only, 15 patients were able to extent the leg. There was statistically significant difference in 2 day and 2 week result as per P value.

Table 6: Distribution of patients based on extension of legs test

Extension Leg	**Group I N (%)**			**Group II N (%)**		
	2 day	**2 week**	**6 week**	**2 day**	**2 week**	**6 week**
$<10^0$	2 (8.33)	15 (62.5)	24 (100)	10 (41.67)	24 (100)	24 (100)
$10^0 – 20^0$	17 (70.83)	9 (37.5)	0	14 (58.33)	0	0
$>20^0$	5 (20.83)	0	0	0	0	0

***show p value in table aslo**

IV. Discussion

Total knee arthroplasty (TKA) can result in excruciating postoperative pain and discomfort. In order to achieve early ambulation, a quick recovery, and a shorter stay in the hospital, adequate postoperative pain control is crucial. In addition to an effective surgical procedure, adequate postoperative pain control plays a crucial role in recovery of the patients. The use of intrathecal morphine in neuraxial anaesthesia during TKA has been suggested by the International Consensus on Anaesthesia-Related Outcomes after Surgery group. Even this still causes opioid-related adverse effects as postoperative nausea and vomiting, itching, and respiratory depression. (17) Multimodal analgesia administered by different routes, including the periarticular injection (PI), has been widely used nowadays to increase the efficacy of postoperative pain control without inducing any systemic adverse effects. (18, 19)

Pain in Total Knee Arthroplasty (TKA) is brought on by release of bradykinin, serotonin and histamine from damaged tissues and injury activating the nociceptors, or pain receptors, in the knee joint. This starts the pain cascade, which involves the release of chemicals that cause pain, like prostaglandins and cytokines, which further excite pain receptors and heighten sensitivity to pain. (20) Chronic pain may result from this cycle of pain amplification and continuation.These mediators induce further recruitment of other inflammatory agents like IL-1, IL-6, TNF-alpha, Substance-P, Acetylcholine (Ach) etc. Substance-P, a vasoactive neuropeptides is responsible for further release of BK, histamine from mast cells and serotonin from platelets. (21)

Numerous studies have shown that traditional opioid based post-operative pain treatment frequently falls short of the required level. Using a VAS, an earlier performed study evaluated 1490 surgical inpatients three times per day. Despite obtaining acute pain management, 41% of the patients reported moderate to severe pain on Day 0, 30% on Day 1, and 19%, 16%, and 14% on Days 2, 3, and 4. (22) Chronic opioid use frequently causes an increase in the amount of opioids needed over time to maintain the intended analgesic effect. The emergence of tolerance is frequently cited as the reason for the need to increase the dose. Recent research suggests an alternate neuropharmacological phenomena, called opioid-induced hyperalgesia, which may explain the necessity of gradually increasing the opioid dose. The phenomena suggests that opioid medication may paradoxically result in hyperalgesia, or heightened sensitivity to pain. (23)

Multimodal pain management can provide a more comprehensive approach to reducing pain by targeting multiple peripheral and central pathways. It is based on integrating the use of several analgesic medications, each of which targets a different pain-related receptor, and thereby exhibits its pain reducing effect by way of a different mechanism of action. Combining two or more analgesic drugs reduces the risk of adverse drug reactions by allowing for the administration of each agent in lower doses. (24)

Nonsteroidal anti-inflammatory drugs (NSAIDs) is an important component of multimodal pain management for knee arthroplasty. They function by preventing the synthesis of prostaglandins, which are chemicals implicated in the reaction to pain and inflammation. By inhibiting the cyclooxygenase (COX) enzyme, which prevents the conversion of arachidonic acid to prostaglandins and reduces the sensitization of pain receptors in response to injury, NSAIDs would work at the peripheral nociceptors. (25) Centrally, NSAIDs work by stimulating medullary and cortical areas involved in the descending inhibitory pain cascade in the brain and the spinal dorsal horn to suppress prostaglandin E2 (PGE2) production. This causes central sensitization and a reduced pain threshold in the nearby undamaged tissue.NSAIDs can be administered before or after knee arthroplasty surgery to lessen discomfort and swelling. (26) NSAIDs can assist increase the efficiency of other pain management methods, like nerve blocks and physical therapy, and may also lessen the need for opioids and other pain drugs by lowering pain and inflammation. Patients in the multimodal pain management group in the 2014 trial were given a mix of preoperative NSAIDs, gabapentin, and acetaminophen in addition to a continuous femoral nerve block and an intraoperative sciatic nerve block. (27)

Periarticular injections involves mixture of a local anaesthetic and/or corticosteroid and directly injecting into the region surrounding the joint to treat postoperative discomfort following arthroplasty. This enables the patient to begin physical therapy and rehabilitation sooner by reducing joint pain and edoema. A study published in 2014 found that periarticular injections of a mixture of ropivacaine and dexamethasone were effective in reducing pain and improving range of motion in patients undergoing total knee arthroplasty. (28) In another studyit was found that periarticular injections of bupivacaine, ropivacaine, and triamcinolone were effective in reducing pain and improving function in patients undergoing total hip arthroplasty. (29) It operates by preventing the brain from receiving pain signals from the joint, thereby decreasing localised pain and joint swelling and inflammation. This aids in relieving pressure on the nearby nerves and tissues, which lessens discomfort and enhances joint movement. (30)

Perioperative bleeding still poses a serious problem with TKA, contributing to edoema, anaemia, and an increased need for blood transfusions. Viral infections, transfusion-related responses, and fluid overload are serious side effects of blood transfusions that also considerably lengthen hospital stays and raise costs. Several techniques, such as controlled hypertension, tourniquets, intraoperative intravenous/intraarticulartranexamic acid (TXA), the use of cryotherapy after TKA, and the bandaging technique after TKA, have been used to reduce the incidence of bleeding, blood loss volume, and blood transfusion rate. (31)

Based on reported studies, the practice of administering intra-articular TXA during TKR has only recently begun to gain favour. Following drain closure of the incision, it can be administered as a topical wash or directly into the knee joint. Advocates of intra-articular TXA contend that advantages over intravenous treatment include simplicity of administration, capacity to produce optimum concentration at the bleeding site, and little systemic absorption. Additionally, utilising intra-articular haemostatic drugs intraoperatively is ideal in situations where the use of tourniquet results in minimal intraoperative blood loss but significant postoperative blood loss. (32) In the current study, patients who received intra-articular Tranexamic acid had consistent outcomes, including significantly lower drainage volumes, no need for blood transfusions, less postoperative knee discomfort and swelling, shorter hospital stays, and increased short-term satisfaction.

The current study also assessed the efficacy of multimodal analgesia with respect to VAS score, Knee Society score (KSS) and the ease of rehabilitation and revealed significant differences among both the analgesic methods. Patients who received multimodal anagesia achieved fairer knee society scores and significant difference in VAS score with earlier mobilization (full standing, walking in/out of room) compared to conventional method.

V. Conclusion

Aiming to maximise analgesic efficacy by combining several analgesic regimens, multimodal analgesia includes preoperative, intraoperative, and postoperative analgesic regimens. By providing early postoperative pain relief and better outcomes in terms of knee scores (VAS and Knee Society score), decressing blood loss (hence less decrease in hemoglobin postoperative), and minimizing undesirable adverse effects, it effectively improves patient satisfaction. Also multimodal analgesia offers improved postoperative pain management compared to monotherapy, promoting knee healing and lowering opioid usage and associated side effects.

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