

# Efficacy of Pre-operative Dexamethasone Administration for Post-operative Pain in Fracture Shaft Femur: A Prospective, Randomized, Double-blind, Placebo, and Controlled Study

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## ABSTRACT

**Introduction:** One of the most common fractures met in orthopedics is femur fracture. Spinal anesthesia is the most used anesthetic technique. Multimodal pain control is modality which practiced the use of multiple analgesic medications, opioids, and non-opioids for pain control in the post-operative period. This modality is beneficial in all patients undergoing orthopedic surgeries and provides benefit from several different medications such as potentiation of effect, reduce adverse drug reactions and decrease the dose of opiates post-operatively. The aim of this study was to assess the efficacy of dexamethasone administration combined with single dose Pregabalin on severity of post operative pain and analgesic requirement. **Methodology:** In this prospective, randomized, double blind placebo-controlled trial 42 patients were enrolled. All the enrolled patients were randomly assigned to Group A and received Tab. Pregabalin 300 mg orally/1 h before spinal anesthesia + Inj. NS/IV (placebo) and Group B: Tab. Pregabalin 300 mg orally/1 h before spinal anesthesia + Inj. Dexamethasone 0.1 mg/kg/IV. Placebo (NS) and dexamethasone injection was given after coming to the operation theater and just before induction of spinal anesthesia. Post-operatively, Inj. Acetaminophen was used as analgesic and Inj. Tramadol as rescue analgesic in addition on demand. Visual analogue score and dose of Tramadol consumption was compared. **Results:** Difference in the postoperative first 6hrs. Mean (SD) VAS score in group A and group B was statistically significant with  $P = 0.0004$ . It was 1.2 (0.7) in the dexamethasone group and 3.2 (2.1) in placebo group. Total dose of Tramadol administered in the first 24 h. of post operative period was less in dexamethasone group. **Conclusion:** Dexamethasone administration in preoperative period provides significant analgesic benefit in the early postoperative period and reduce postoperative analgesic requirement, following operative procedure in fracture shaft femur.

**Key words:** Bone injury, dexamethasone, fracture shaft femur

## INTRODUCTION

Amongst various fractures, fracture shaft femur is a common orthopedic problem in patients of all ages following trauma. It is a painful bone injury more common in elderly patients leading to considerable morbidity.<sup>[1]</sup> Mostly practiced anesthetic method for operative procedure of fracture shaft femur is Spinal anesthesia. Some of the advantages of this technique are early mobility, greater pain control and reduce thromboembolic morbidity.<sup>[2]</sup>

As per the various guidelines for the management of post-operative pain should be as per the requirement of surgical procedure. Combination of various non-opioid analgesics has been used to reduce opioid consumption and opioid related side-effects, better patient satisfaction, and faster recovery.<sup>[3]</sup>

In treatment of post-operative pain, many opioid sparing medications have been used in major orthopedic operative procedures.<sup>[4]</sup>

Various studies have observed the opioid-sparing effects of Gabapentinoids and Glucocorticoid in post-operative pain.<sup>[5,6]</sup>

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in relation to fracture shaft femur of these medications, or their combination, scientific data are lacking.

This study was conducted to assess the efficacy of dexamethasone administration combined with single dose Pregabalin on severity of post-operative pain and analgesic requirement.

## METHODOLOGY

This study was conducted after getting approval from the Institutional Ethics Committee. This prospective, randomized, double blind, and placebo-controlled trial was conducted at a tertiary hospital in India during May 2021–May 2022. After screening for inclusion criteria patients were enrolled in the study. Written and informed consent was obtained from all patients. Inclusion criteria were patients admitted to the orthopedic ward of the hospital for isolated femoral shaft fractures, Winquist Type II femoral shaft fractures with aged >65 years. Exclusion criteria were patients suffering from diabetes mellitus and other endocrine disorders, depression, on any form of corticosteroid treatment (topical, systemic, and inhalational) within the previous past 4 months, coagulopathy, head injury, altered consciousness, kidney disorder, and septicemia. All the enrolled patients were randomly assigned to Group A who will receive Tab. Pregabalin 300 mg orally/1 h before spinal anesthesia + Inj. NS/IV (placebo) after coming to operation theater and just before induction of spinal anesthesia. While for Group B: Tab. Pregabalin 300 mg orally/1 h before

spinal anesthesia + Inj. Dexamethasone 0.1 mg/kg/IV after coming to the operation theater and just before induction of spinal anesthesia, as shown in Figure 1. Randomization is done using computer generated randomization table and test drug (Normal saline and Hydrocortisone) solution was prepared by an anesthetist and was administered by a orthopedist (PI) and kept blinded for medication.

Spinal anesthesia was given by 25 G spinal needle with hyperbaric bupivacaine. The same three orthopedic specialists performed all surgical procedures for the fracture shaft femur.

Inj. Acetaminophen 1 g/IV was administered intraoperatively followed by 6 hourly thereafter for a week. Inj. Tramadol 50 mg/IM route was used as rescue analgesia and dose was increased depending on the severity of pain on visual analog scale (VAS).

Post-operative pain score was assessed on VAS from 0 to 10 as shown in Figure 2. VAS score was tested by an independent blinded observer at rest after entry of patient in operating theater, postoperatively after entry into recovery room, followed by 6 h, 12 h, 24 h, 48 h, 72 h, and 1 week. Requirement of Inj. Tramadol was also recorded.

### Statistical Analysis

Quantitative data were tested for normality and, as appropriate, analyzed using the unpaired two-tail Student *t*-test. Categorical data were examined using Chi-squared test. *P* < 0.05 was considered significant.

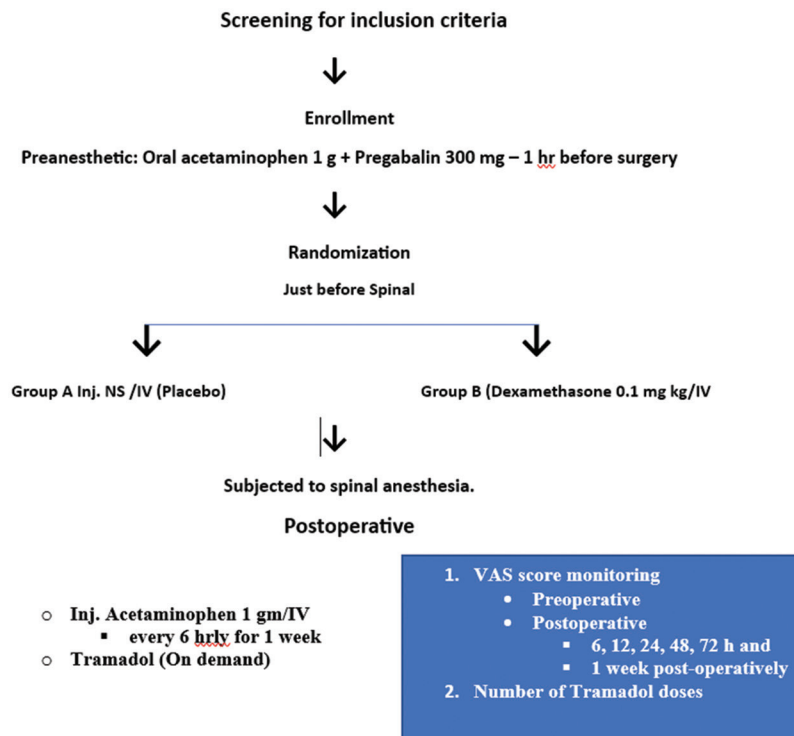


Figure 1: Study flow

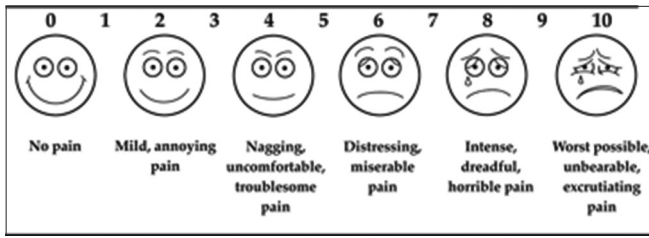


Figure 2: Visual analog scale

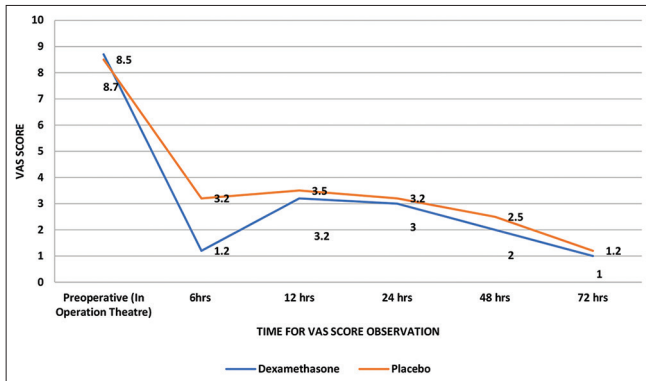


Figure 3: Effect on VAS score

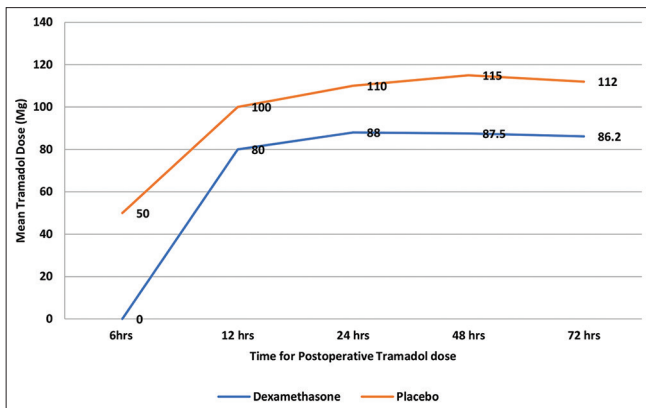


Figure 4: Post-operative tramadol consumption

Table 1 : Demographic characteristics of patients

Parameters	Placebo Group	Dexamethasone group
Gender		
Male	10	07
Female	11	12
Age	69±5	72±3

## RESULTS

Fifty-five patients were screened for the study of whom 42 could be enrolled, 11 patients were excluded because of exclusion criteria and two patients opted to perform the

surgery under general anesthesia. Demographic parameters of participants was as per Table 1.

As shown in Figure 3, pre-operative mean (SD) VAS score in dexamethasone group was 8.7 (0.6) and in placebo group was 8.5 (0.4). Post-operative first 6 h mean (SD) VAS score was lesser in the dexamethasone group compared with the placebo group, it was 1.2 (0.7) and 3.2 (2.1), respectively. This difference was statistically significant with  $P = 0.0004$ .

As shown in Figure 4, post-operative mean (SD) tramadol dose requirement was significantly less in dexamethasone group compared with placebo group in 1<sup>st</sup> post-operative week. In the first 6 h post-operative period, the mean (SD) tramadol dose requirement was significantly low compare with placebo group, In dexamethasone group, first dose requirement of tramadol was after 12 h. Total dose of tramadol administered in first 24 h of post-operative period mean (SD) in Dexamethasone group was 168 mg (22), while in placebo group 260 mg (23).

## DISCUSSION

In this present study, significant observation was that pre-operative administration of Inj. Dexamethasone 1 mg/kg/IV has a significant analgesic effect in the first 24 h of early post-operative period of fracture shaft femur.

Orthopedic operative procedure can be one of the most painful conditions as this include major tissue manipulation, muscle stretching, and many implants required for adequate fixation.<sup>[7]</sup>

There is need of strong analgesic supplementation in perioperative and post-operative pain control for these procedures. This highlights that there is need to analyze the analgesic therapies in all stages of operative procedure. Multimodal method of pain control is most widely used for this and includes non-opioid analgesia including NSAIDs, Gabapentinoids, local anesthetics, Ketamine, and Glucocorticoids.<sup>[8]</sup>

Corticosteroids administration has an important role in multimodal methods of pain control. Corticosteroids provide various beneficial effects such as reduced opioid consumption and symptomatic improvement.

Glucocorticoids have strong anti-inflammatory action and provide analgesia by prostaglandins synthesis inhibition, reducing inflammation, and vascular permeability leading to edema.<sup>[9]</sup>

## CONCLUSION

Pre-operative administration of dexamethasone provides significant analgesic benefit in the early post-operative period following operative procedure in fracture shaft Femur

in the form of better pain relief and reduce post-operative analgesic requirement.

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**Conflicts of Interest:** None. **Source of support:** None.

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