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Original article

## Do demographic and perioperative parameters really affect the final outcomes of pediatric femur shaft fractures managed by elastic nails? A prospective study

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#### ABSTRACT

*Objective:* Pediatric femoral shaft fractures are more commonly treated with intramedullary titanium elastic nail system (TENS). Adhering to the principles, most studies had supported excellent results with this instrumentation and attributed the variation in age, weight, immobilization protocols, technical factors like fracture pattern, reduction and complications as reasons to poor outcomes in their individual studies. Hence, we wanted to identify the potential demographic and perioperative parameters that could affect the final outcomes in this cohort.

*Methods:* A prospective (level III) study done in a single center between November 2013 and January 2017 on isolated closed femoral shaft fractures in patients of age between 6 and 15 years managed with TENS. The demographic and perioperative parameters were recorded. The patients were followed up regularly with plain radiographs. The final outcomes were computed at end of one year and recorded as poor, satisfactory and excellent as defined by Flynn criteria.

*Results*: Among the thirty patients included, mean age was 8.2 years. 80% of the patients weighing over 40 kg had satisfactory to poor outcomes. (p = 0.005). 45% of patients with proximal and distal level fractures that were long oblique spiral or comminuted types had satisfactory outcomes; however it was not statistically significant. The mean delay to surgical fixation was 5.87 days, surgical time was between 45 and 150 min and open reduction was required in about 17 cases (57%). Patients with immobilization beyond 6 weeks had satisfactory outcomes (p = 0.001). We had 5 patients with minor complications (4 bursitis and 3 superficial infections) and one major complication (chronic osteomyelitis and deep venous thrombosis) leading to satisfactory and poor outcomes respectively. Significant osseous union was noted between 6 and 11 months with 97% of patients attaining union within 9 months.

*Conclusions:* Intramedullary TENS is an excellent modality to treat femoral shaft fractures in patients of school going age. However, factors like weight of the patient > 40 kg, immobilization beyond 6 weeks, minor and major complications in the perioperative period could pose risks for poor to satisfactory outcomes and should be anticipated and explained accordingly.

#### 1. Introduction

The management of Pediatric femoral shaft fractures has successfully evolved over the years.<sup>1</sup> Though traditional conservative methods like skeletal traction and spica application are still in practice, of late there has been an inclination to treat them aggressively with surgical methods owing to the difficulties of prolonged immobilization, need to return school early and associated injuries occurring more frequently.<sup>2,3</sup> With the need to preserve physis, surgical methods like external fixation, plating, and intramedullary devices have been debated over the years.<sup>4</sup> The intramedullary devices especially titanium elastic nail system is commonly being used as it is minimally invasive, minimal blood loss, preserving fracture site biology and early rehabilitation.<sup>5</sup> With most studies supporting excellent results<sup>6–8</sup> with the usage of elastic nails in school going children, there were patients with poor outcomes in their study and this was attributed to the variation in







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age, weight, immobilization protocols, technical factors like fracture pattern, reduction, choice of implant size and complications.<sup>7–9</sup> Hence, in this study, we wanted to identify which of the demographic and perioperative parameters really affect the outcomes of pediatric femoral shaft fractures managed by intramedullary titanium elastic nail system. Our hypothesis, some but not all factors affect the final outcomes.

#### 2. Material and methods

This was a prospective study done in a single center between November 2013 and January 2017 with the clearance obtained from the institution review board and ethical committee. [No. F 5(59)/2013/ BSAH/DNB/committee/30628]. All types of isolated closed femoral shaft fractures between age 6 and 16 years, hemodynamically stable, fixed with titanium elastic nail system and had a follow up for one year were only included. All the surgical procedures were done by two specialists under general or spinal anesthesia with the consent for the procedure and complying with the principles of the technique. Patient's age, sex, weight, mode of injury, level and type of fracture pattern, type and duration of surgery, immobilization and complications were noted. All patients had similar post-op rehabilitation and immobilization with knee brace during the nonweight bearing ambulatory period. The patients had serial follow up with plain radiographs and full weight bearing was advised when grade 2 callus was noted as per the grading of callus formation given by Anthony et al.<sup>10</sup> The final outcomes at the end of one year were given as poor, satisfactory and excellent based on the Flynn criteria. [Table 1].

All the data were entered into excel worksheet and analysis were done using SSPS software version 21.0. The categorical variables were presented in number and percentage and continuous variables were presented as mean  $\pm$  SD and median. Normality tested by Kolmogorov-smirnov test/nonparametric tests, if necessary. Statistical analysis was done using chi-square test/fisher's exact test. Statistical significance considered for P values less than 0.05.

#### 3. Results

Forty-four patients had presented with shaft femur fractures. However, only 30 patients fulfilling the inclusion criteria were considered in the study. The mean age was 8.1  $\pm$  1.71 years (range-6–15 years). The majority of the patients (80%) were males (24) and involvement of the right side (66%) and most commonly due to road traffic accidents (20 patients). Variations in age, sex, laterality and mode of injury had in significant affection in the final outcomes. Midshaft fractures were seen more frequently (17 patients), followed by the proximal shaft and distal shaft (9 and 4 patients respectively). The most common type of fracture was of the transverse and short oblique type (15 patients). About 45% of patients with proximal and distal level fractures that were long oblique, spiral and comminuted types had satisfactory outcomes only. However, this was statistically insignificant with P values of 0.09 and 0.7 respectively [Table 2]. Valgus angulation was noted in 6 patients (4/9 proximal 1/3rd pattern and 2/17 midshaft pattern). Varus angulation was seen in 4 patients (3/4 distal 1/3rd fracture pattern and 1/17 midshaft pattern).

The interval between trauma and surgical fixation was between 1 and 12 days with a mean of 5.87  $\pm$  2.13 days. There was no statistical

Table 1					
Flynn et al <sup>11</sup>	criterion	for	assessment	of	results.

	Excellent	Satisfactory	Poor
Limb Length Discrepancy	< 1 cm	< 2 cm	> 2 cm
Malalignment	Upto 5 <sup>0</sup>	5 <sup>0</sup> –10 <sup>0</sup>	> 10 <sup>0</sup>
Pain	None	None	Present
Complication	None	Minor	Major or lasting morbidity

difference in the final outcomes between patients operated before or after 5 days (p = 0.6). The surgical duration was about 45–150 min but mostly done within one hour (63.33%). Open reduction was required in about 17 cases (57%) and it could be statistically said that there was no difference in final outcomes between the open or closed methods. Weight in kg appeared to be an important factor to affect the final outcomes with 92% of patients below weight 40 kg consistently showing excellent outcomes and about 80% of patients above 40 kg showing satisfactory to poor results (p = 0.005) [Table 3].

Postoperative immobilization was between 4 and 8 weeks on a case to case basis on viewing the follow-up radiographs with most patients receiving immobilization for 4 weeks (53.3%). Patients with prolonged immobilization beyond 6 weeks had satisfactory outcomes (p = 0.001).

The median hospital stay was 10.5 days. This could be attributed to the patient's apprehension to care for them independently. However, early discharge (< 5 days) or discharge after suture removal had no significance in final outcomes. Significant osseous union (3 or 4 cortical unions) was noted between 6 and 11 months post-surgery with 97% of patients attaining union within 9 months. This could also be correlated with the mean time to weight bear i.e.  $10.2 \pm 1.54$  weeks and range between 8 and 12 weeks. There was no significant change in final outcome among patients who had full weight bearing at 8 weeks or 12 weeks. (p = 0.32).

We had 5 patients with minor complications (4 bursitis and 3 superficial infections) and one major complication (chronic osteomyelitis and deep venous thrombosis). These patients were readmitted and managed accordingly. However, these patients ended up having satisfactory outcomes at end of 1 year with joint stiffness being common in patients with minor complications and poor outcome with osteomyelitis. (p = 0.001). [Table 4].

#### 4. Discussion

There has been a change in trend in the management of pediatric femur fractures from a conservative to surgical approach due to the problems of prolonged immobilization, loss of reduction and malunion, need to return to school at the earliest, change in the pattern of injury and more polytrauma.<sup>1,2</sup> Among the available surgical management of pediatric shaft of femur fractures, there is an inclination to use intramedullary elastic nail system more often, supported by its excellent results and patient outcomes.<sup>4,5</sup> Most studies that used intramedullary titanium elastic nail system for pediatric shaft fracture management and computed the outcomes using criteria defined by Flynn et al<sup>11</sup> had supported excellent results.<sup>5-7</sup> However, some set of patients did have poor outcomes in their studies. Variations in the age, weight, delayed presentation; associated complications and pattern of fractures were some of the reasons for poor outcomes.<sup>7–9</sup> Purpose of this study was to identify the possible demographic and perioperative factors that affect the final outcomes in this cohort.

The results from our single center study of thirty patients that were included showed that the weight of the patient was the single most demographic factor to affect the final outcomes assessed by Flynn et al. criterion. Among Patients below the weight of 40 kg, 92% of them have consistently shown excellent results. 80% of the patients weighing over 40 kg had satisfactory to poor results. Moroz et al<sup>7</sup> in their study of 222 patients from six centers showed that age and weight had the significant impact on the final outcomes. Patients with weight below 39 kg had excellent to satisfactory results, whereas patients with weight above 54 kg had poor to satisfactory results. The mean age in their study was 10.2 years and there was a significant association with children below age10 having excellent results and above 11 years having only satisfactory outcomes.

In our study with a mean age was 8.2 years (range 6–15 years); the age-matched final outcomes had shown no significant differences. With regard to the mode of injury, the isolated closed femoral fractures included in our study caused by either road traffic accident or fall during

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