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.¹ 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.^{2,3} With the need to preserve physis, surgical methods like external fixation, plating, and intramedullary devices have been debated over the years.⁴ 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.⁵ With most studies supporting excellent results^{6–8} 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.^{7–9} 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.¹⁰ 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 SPSS 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 ± 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 no 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 ± 2.13 days. There was no statistical

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 ± 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.^{1,2} 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.^{4,5} Most studies that used intramedullary titanium elastic nail system for pediatric shaft fracture management and computed the outcomes using criteria defined by Flynn et al¹¹ had supported excellent results.^{5–7} 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.^{7–9} 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 al⁷ 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 age 10 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

Table 1
Flynn et al¹¹ criterion for assessment of results.

	Excellent	Satisfactory	Poor
Limb Length Discrepancy	< 1 cm	< 2 cm	> 2 cm
Malalignment	Upto 5°	5° – 10°	$> 10^{\circ}$
Pain	None	None	Present
Complication	None	Minor	Major or lasting morbidity

Table 2
Demographic parameters with the outcome scores at end of 12 months.

Flyn et al outcomes	poor	satisfactory	excellent	total	P Value	Chi square statistics
Age distribution in years						
●5–6	0(0.00%)	2(33.3%)	4(66.67%)	6(100.0%)	0.251	X2 = 5.375
●7–8	1(3.33%)	0(0.00%)	11(91.67%)	12(100.0%)		df = 4
● > 8	0(0.00%)	3(25.0%)	9(75.0%)	12(100.0%)		
Mode of injury						
Fall	1(5.00%)	2(10.0%)	17(85.0%)	20(100.0%)	0.319	X2 = 2.288
RTA	0(0.00%)	3(30.0%)	7(70.0%)	10(100.0%)		df = 2
Sex						
Male	1(5.26%)	2(10.52%)	16(84.2%)	19(100.0%)	0.917	X2 = 0.172
Female	1(9.09%)	1(9.09%)	9(81.81%)	11(100.0%)		df = 2
Side involvement						
Left	0(0.00%)	2(15.38%)	11(84.62%)	13(100.00%)	0.654	X2 = 0.848
Right	1(5.88%)	3(17.47%)	13(76.47%)	17(100.00%)		df = 2
Level of fracture						
Proximal shaft	0(0.00%)	4(44.44%)	5(55.56%)	9(100.0%)	0.099	X2 = 7.801
Mid shaft	1(5.88%)	1(5.88%)	15(88.24%)	17(100.0%)		df = 4
Distal shaft	0(0.00%)	0(0.00%)	4(100.0%)	4(100.0%)		
Type of fracture pattern						
Comminuted	0(0.00%)	1(33.33%)	2(66.67%)	3(100.0%)	0.718	X2 = 3.692
Oblique	0(0.00%)	1(16.67%)	5(83.33%)	6(100.0%)		df = 6
Spiral	0(0.00%)	2(33.33%)	4(66.67%)	6(100.0%)		
Transverse	1(6.67%)	1(6.67%)	13(86.67%)	15(100.0)		

Table 3
Perioperative parameters and outcomes at end of one year.

Flyn et al outcomes	Poor	satisfactory	excellent	total	P value	Chi square statistics
Interval between trauma and surgery in days						
< = 5	0(0.00%)	2(15.38%)	11(84.62%)	13(100.0%)	0.654	X2 = 0.848
> 5	1(5.88%)	3(17.65%)	13(76.47%)	17(100.0%)		df = 2
Type of surgery						
open	1(5.8%)	3(17.64%)	13(76.5%)	17(100.0%)	0.690	X2 = 0.742
closed	0(0.00%)	2(15.4%)	11(84.6%)	13(100.0%)		df = 2
Weight in kg						
20–30	0(0.00%)	0(0.00%)	3(100.0%)	3(100.0%)	0.005	X2 = 14.62
30–40	0(0.00%)	2(12.50%)	20(87.50%)	22(100.0%)		Df = 4
40–50	1(20.00%)	3(60.00%)	1(20.0%)	5(100.0%)		
> 50	0(0.00%)	0(0.00%)	0(0.00%)	0(100.0%)		
Duration of surgery in minutes						
45	0(0.00%)	0(0.00%)	3(100.0%)	3(100.0%)	0.438	X2 = 5.868
60	0(0.00%)	2(12.50%)	14(87.50%)	16(100.0%)		df = 6
75	0(0.00%)	0(0.00%)	2(100.0%)	2(100.0%)		
90	1(11.11%)	3(33.33%)	5(55.56%)	9(100.0%)		
Post-operative Immobilization in weeks						
4	1(6.25%)	0(0.00%)	15(93.75%)	16(100.0%)	0.001	X2 = 11.56
6	0(0.00%)	2(18.18%)	9(81.82%)	11(100.0%)		df = 8
8	0(0.00%)	3(100.00%)	0(0.00%)	3(100.0%)		
full weight bearing in weeks						
8	1(14.29%)	0(0.00%)	6(85.71%)	7(100.0%)	0.324	X2 = 9.223
9	0(0.00%)	0(0.00%)	1(100.00%)	1(100.0%)		df = 8
10	0(0.00%)	1(9.09%)	10(90.91%)	11(100.0%)		
11	0(0.00%)	0(0.00%)	1(100.00%)	1(100.0%)		
12	0(0.00%)	4(40.00%)	6(60.00%)	10(100.0%)		

Table 4
complications and the final outcomes at end of one year.

Flyn et al outcomes	Poor	Satisfactory	Excellent	total	P value	Chi square statistics
Major complications						
Nil	0(0.00%)	5(17.24%)	24(82.76%)	29(100.0%)	< 0.001	X2 = 30.00
Yes	1(100.0%)	0(0.00%)	0(0.00%)	1(100.00%)		df = 2
Minor complications						
●Nil	1(4.00%)	0(0.00%)	24(96.00%)	25(100.0%)	< 0.001	X2 = 30.00
●Yes	0(0.00%)	5(100.0%)	0(0.00%)	5(100.0%)		df = 2

recreational activities had not shown any significant variation in final outcomes. The mid shaft transverse fractures were the most common occurring pattern. 45% of patients in our study with proximal and distal level fractures that were long oblique spiral or comminuted types had satisfactory outcomes only because of the valgus and varus angulation respectively. However, this was statistically insignificant. These similar findings were supported by Moroz et al⁷ who reported a loss of reduction in proximal and distal fractures in some set of patients that correlated with age before and after ten years. However, the final outcomes did not show significant differences. The short working length and decreased resistance to axial loading in comminuted fracture patterns causes valgus/varus angulation at the respective sites.

Among the perioperative factors considered in our study, the time interval between trauma and surgery before or after 5 days, duration of the surgery (range- 45–150 min), undergoing open or closed reductions and hospital stay for the pediatric shaft femur fractures (mean 10.2 days) treated with TENS did not show any significant variation in the final outcomes. Immobilization beyond 6 weeks had a strong association with poor to satisfactory outcomes. Prolonged immobilization was required in only a few set of patients involving comminuted and long oblique fractures predisposing them to knee joint stiffness, hence the poor category of Flynn criterion. With regard to this association, we could not obtain literature to support or refute poor outcomes with elastic nailing system following prolonged immobilization. 99% of our patients had full weight bearing by 10 weeks and similarly had shown significant osseous union by 9 months. Similar results were exhibited by Saikia et al⁵ in a set of 22 patients who achieved grade 2 callus in an about 8.7 weeks and hence full weight bearing was possible in a mean time of 8.8 weeks.

In our study, both minor complications (entry site bursitis and superficial infections) and major complication (chronic osteomyelitis) significantly reported satisfactory and poor outcomes respectively. The similar was supported by Narayanan et al¹² in their 5 year experience with 79 pediatric femur fractures treated by TENS. They encountered pin site pain/irritation in about 41 patients and one deep seeded infection. Complications were usually minor and manageable with proper techniques and principles followed.

In the analysis of our patients with the Flynn criteria, the most commonly reported reason for the poor to satisfactory outcomes was the knee joint stiffness, followed by loss of varus angulation by 5° and rotational deformity greater than 5°. We encountered only 3 patients with limb lengthening. However, some series report limb lengthening to be the major reason for poor outcomes.^{13,14}

We had stringent criteria for selecting only closed pediatric femoral fractures that were hemodynamically stable and without associated trauma making our sample size limited. This is one of the few studies attempting to analyze the risk factors that affect the final outcomes of the pediatric shaft femur fractures treated by TENS.

5. Conclusion

Intramedullary titanium elastic nail system is an excellent modality

to treat femoral shaft fractures in patients of school going age. However, factors like the weight of the patient, period of immobilization beyond 6 weeks, possible minor and major complications could pose a risk for poor to satisfactory outcomes and should be anticipated and explained accordingly. Adhering to the proper indications and principles of the instrumentation may further reduce the complication rate and improve outcomes.

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