ORIGINAL ARTICLE

Comparison of the Outcome of Titanium Elastic Nail Versus Compression Plate in Diaphyseal Fracture of Femur in Children

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Abstract

Introduction: Different fixation types have been described for the diaphyseal femur fractures in children, aged 5 to 15 years. The main aim of the study was to compare the functional and radiological outcome of closed reduction and internal fixation (CRIF) with Titanium elastic nailing system (TENS)(Group A) and open reduction and internal fixation (ORIF) with compression plate (Group B) for diaphyseal femur fracture in pediatric age.

Methods: This was a prospective comparative study. A total of 50 patients (25 each) were studied. The final follow- up was at 6 months and the final data was taken.

Results: The mean operative time and mean blood loss in group A and group B was 58.80±6.96 vs 106.4.2±11.13min (p< 0.01) and 26±5.74 ml vs 118.8±13.56 ml. (p<0.01) respectively. Except for two cases of implant failure, 48 patients showed union by the last follow-up. The average time to union was 10.56 ± 4.98 weeks vs 14.09 ± 4.6 weeks in groups A and B respectively. There were significantly higher complications in group B (p= 0.01). The functional outcome was comparable between groups (p =0.129).

Conclusion: The functional outcome was comparable between the closed reduction and TENS groups and the open reduction and plate group. But closed reduction and TENS could be better in pediatric femur fracture surgical treatment as it had shorter operating time and union time, less intraoperative blood loss, and post-operative complications with better knee range of motion than open reduction and plating.

Keywords: femur fracture, outcome, TENS.

Introduction

Diaphyseal femur fractures account for 1.7% of all pediatric fractures.[1] The treatment of pediatric, age 5 to 15 years, femur fractures remains controversial.[2] This age group hasa higher risk of shortening, angulation, malrotation, and malunion when conservative treatment is used.[3–5]

Pediatric femur fractures represent 9.8% of fractures requiring surgical treatment; up to 76% of femur fractures are diaphyseal, and 62% of these are treated with elastic intramedullary nails, whereas only 10% are treated through open reduction and fixation with plates.[6] Surgical treatment can lead to the rapid mobilization of the patient, shorter hospital stays, and more rapid integration into previous school and daily life activities.[7–9]

Common options for surgical stabilization include open or submuscular plate fixation and flexible intramedullary nailing.[10] Plate fixation is stable and addresses the entire length of the femur but flexible nailing is minimally invasive and well suited to fractures of the central 2/3 of the diaphysis.[10]

Plating of femoral shaft fracture offers rigid fixation but it requires a larger exposure with the potential for increased blood loss and scarring, refracture risk, and known to cause growth disturbances.[2] Various American and European studies have recorded good outcomes following the use of titanium elastic nails and compression plating.[5,7–9] Flexible titanium nails have been found to be the preferred treatment for children between 5 to 12 years, weighing less than 50 kg and who had length stable fractures.[11]

As a result of these management dilemmas, we conducted this

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comparative study on the use of titanium elastic nailing (TENS) and dynamic compression plating for the treatment of children with diaphyseal femur fractures. The purpose of this prospective study was to investigate the radiological and clinical results of each technique and explore any possible complications.

Methods

The study was conducted in the Department of Orthopedics, B.P. Koirala Institute of Health Sciences, a tertiary care hospital in Eastern Nepal, for 18months; 1 year from September 2018 to August 2019for cases enrollment and surgery, and 6 months for follow-up after that. Ethical clearance was obtained from the Institutional Review Committee (IRC) (357/075/076).

All the children aged 5 to 15 years with mid diaphyseal fracture of the femur during the study period giving written informed parental consent were enrolled in the study.Patients presenting with open fractures, neurovascular compromise, neuromuscular disorders, pathological fractures, and with a history of surgery or fracture on the same thigh were excluded from the study.

Based on the medical record of last year of the same hospital the total number of cases of fracture shaft of the femur in children aged between 5 and 15 years was 40. So, on account of that population growth rate of 10% and 10% of patients not able to follow up:

Total sample size = 44+ (10%x 44) = 48.4 (approximately 50)

Group A consisted of Closed reduction and internal fixation (CRIF) with Titanium Elastic Nailing System (TENS)with 25 cases. GroupB included Open reduction and internal fixation (ORIF) with plating,and had 25 cases.

General physical, systemic examination and lab investigation were carried out to look for underlying exclusion criteria. Informed written consent was obtained from each patient after explaining about procedures, complications, and possible outcomes. A detailed history regarding demographic profile, methods used, and relevant clinical and radiological data were recorded in pre-set pro forma. Cases were allocated to different treatment groups using the Excel random number generation technique. All cases had undergone surgery under General anesthesia. The cases were operated on by an experienced orthopedic surgeons of the respective units in which they were admitted in. The Patient was discharged on the second postoperative day after wound inspection and the patient came to follow up at 2 weeks, 6 weeks, 3 months, and 6 months at orthopedics outpatient department (OPD). Range of motion, malalignment in coronal view calculated on X-ray, and time taken for functional recovery were assessed as per the proforma on the final follow-up of 6 months. Flynn criteria were used for the functional outcome assessment.[12]

Collected data was entered in Microsoft Excel 2013 for validation and cleaning and transferred to SPSS (Statistical Package for Social Sciences) 11.3 version for statistical analysis.For descriptive data proportion, percentage, mean, and standard deviation were calculated. For Inferential analysis, Chi-square test and Fisher Exact Test for categorical data and independent sample t-test were applied to find out the significant differences between the two groups. In the study 95% confidence interval was taken and the p <0.05 was considered statistically significant.

Results

Out of 55 patients enrolled, 5 patients were excluded as 2 had a history of re-fracture and 3 cases had pathological fracture. A total of25 were allocated to each treatment group.Two cases from group A had implant failure at 6 weeks follow up, for which other methods of treatment were done and their data only up to 6 weeks follow up visit were analyzed.At the final follow-up (6 months post-operatively), a total of 48 patients were analysed (25 in group A and 23 in group B). Since the number of patients whose data were not analyzed was less than 10% (i.e. 5 for a sample size of 50 patients), it did not significantly affect the validity of our study.

Table 1: Demographic Characterstic of participants.

Variables		Groups		Total	p-value
		Group A n (%)	Group B n(%)		
Sex	Male	20 (80)	19(76)	39	0.10$
	Female	5(20)	6(24)	11	
Age groups	5-10 yrs	19(38)	14(28)	33	0.27$
	11-15 yrs	6(12)	11(22)	17	
Side	Right	15 (30)	15 (30)	30	1.00$
	Left	10 (20)	10 (20)	20	
Mode of injury	Fall on ground	4(8)	4(8)	8	.403ɣ
	Fall from height	18(36)	16(32)	34	
	Road traffic accident	3(6)	5(10)	8	

$: chi square test

ɣ: Fisher exact test

Mean age in group A and group B were 8.96±2.35 and 9.72±3.07 years respectively. The age distribution was not significant between the two study groups (p>0.33). However the age groups among the groups were not significantly different (p=0.27). (Table 1)

Table 2: Table showing distribution of different variables among two groups.

Variables	Group		p value
	Group A (n=25) (Mean ± SD)	Group B (n=25) (Mean ± SD)	
Time of presentation after injury (days)	1.2±0.5	1.72±1.25	0.064
Injury to surgery time (days)	2.32±0.69	3.16±2.15	0.069
Duration of Hospital stays(days)	4.32±0.74	5±1.95	0.111
Intraoperative time(minutes)	58.80±6.96	106.4.2±11.13	<0.01*
Blood Loss(ml)	26±5.74	118.8±13.56	<0.01*

*- Statistically significant

Table 2 shows that groups A and B were homogenous about

hospital stay, time of presentation after injury, and injury to surgery time. Intraoperative blood loss was found more in the case of the ORIF group (26±5.74) than the TENS group (127.4±19.4) and there was a statistically significant difference between the two methods (p< 0.01).

Table 3: Post-operative variables comparison between groups A and group B.

Variable		Group		p-value
		A (CRIF) N (%)	B (ORIF)	
Immediate post-operative pain (VAS score). (Mean ± S.D.)		3.76 ± 0.59	7.52 ± 0.87	0.0001$
Fracture union in weeks (Mean ± S.D.)		10.56 ± 4.98	14.09 ± 4.66	0.015$
Complications	Superficial infection	0	5(10)	0.01γ
	Skin irritation/ bursitis	1(2)	0	
	Implant failure	0	2(4)	
	None	24(48)	18(36)	
Knee Range of motion (degrees)	Full range (0-140)	22(46)	21(44)	1.00γ
	Mild restriction(0-120)	3(6)	2(4)	
	Moderate restriction (0-100)	0	0	
	Severe restriction (<100)	0	0	
Limb length discrepancy (centimetres)	<1	25(52)	23(48)	1.00γ
	<2	0	0	
	>2	0	0	
Malalignment	<5 degree	25(52)	23(48)	1.00γ
	<10 degree	0	0	
	>10 degree	0	0	
Flynn criteria	Satisfactory	1(2)	4(8)	0.129γ
	Excellent	24(50)	19(40)	
	Poor	0	0	

$: independent sample t test

γ: Fisher's exact test

Table 3 shows the differences in the range of motion of the knee between the two groups (Fisher's exact test, p-value 1.0). Among all cases analyzed in each group (25 in the CRIF group and 23 in the ORIF group) had limb length discrepancy of <1 cm. None of the cases had significant limb length discrepancies. The differencesin the range of limb length discrepancy were statistically not significant between the two groups (Fisher's exact test, p-value 1.0).

Discussions

No strict guideline or protocol exists for the management of pediatric femur fractures.[13] Our study found that though the functional outcomes were comparable between groups, intraoperative blood loss was less, post-operative pain was low, time to union was shorter and had fewer complications in the TENS group when compared to the plate group in the treatment of pediatric femur fractures. The groups were homogenous and comparable in different preoperative variables and hospital stays.

In this study, the most common mode of injury was a fall from height (68%). Another study also reports that fallsare the common (35%) mechanism of injury in pediatric femur fractures.[14] Between 1 and 5 years old, presenting with femur fractures to an urban paediatric hospital over a 10-year period. The mean age was 36.6 months, with 155 (76.2%

In our study, the average duration of surgery (time from skin incision to closure) was 58.80minutes (S.D. 6.96 minutes) in the TENS and 106.4 minutes (S.D. 11.13 minutes) in the plating (p<0.01) groups. The duration of surgery in the study conducted by Reddy et al was 83 minutes in the CRIF group and 102.5 minutes in the ORIF group.[15] The surgery duration was comparable in plating groups but in our study, TENS groups had shorter operating time. They also had significant differences in surgery times between groups like ours. Another study reported intra-operative time for TENS ranging from 50-120 minutes which was nearly the same as our study.[16] Different studies report less than 60 minutes of intra-operative time in TENS which is similar to our study.[5,17]

The mean blood loss in CRIF and ORIF groups was 26±5.74 ml and 118.8±13.56 ml respectively and the difference was statistically significant (p-value =0.001). The result was similar to the study of Reddy et al which was 45.3±6.58 in the CRIF group and 106.5 ±10.89 ml in the ORIF group.[15] In the study by Luo et al the mean blood loss in TENS and plating groups were statistically significantly different (18.30 ± 29.74 vs 163.33 ± 5.80, p = 0.006). The blood loss was higher in the ORIF group as more muscle mass was dissected and the operative period was longer than the CRIF group. The open reduction group had more numbers of complications than the closed reduction (TENS) group. A similar study also reports more number complications in open reduction groups.[19]

The average time to union was significantly higher (p = 0.015) in the ORIF group(14.09 ± 4.66 weeks)than in the CRIF group (10.56 ± 4.98 weeks). In the study by Reddy et al, they found the radiological union at 16.1±1.12 weeks in the ORIF group and 11.3±1.22 weeks in the CRIF group.[15] Another study also report higher union time in open reduction groups (17.90±5.09 vs 13.00±1.37, p< 0.001). These results were similar to our observations and may be due to more periosteal stripping in open reduction groups compared to closed reduction.

In this study, malalignment was insignificant (<5 degrees) in both groups. However Saikia et al. reporteda 13.64% incidence of malalignment in cases treated with TENS.[16] Our cases had shorter follow-up periods so malalignment may not have been noticed.

In our study 43(90%) patients have full range of motion (0-140 degrees of flexion). In the study by Arora KK et al 80% of patients had a full range of movements at the knee and 20% of patients had mild restriction of movement.[5] None of our patients had moderate or severe restriction of movements.

In the present study, the outcome was excellent in 24(50%) in the CRIF group and 19(40%) in the ORIF group whereas 1(2%) in the CRIF group and 4(8%) in the ORIF group had a satisfactory outcome. None of the cases had poor outcomes on both methods. The differences in the functional outcome were not statistically significant between the two groups. In another study among 40 femoral shaft fractures treated, the outcome was excellent in 28 (70%) cases 14 in each group, satisfactory in 5 (25%) cases in the DCP group where 6(30%) in the TENS group and poor in 1(5%) of cases in DCP group.[15] Saikia et al in their study of 22 children with femoral shaft fractures had 13 (59%) excellent, 6 (27.2%) satisfactory, and 3(13.6%) poor result.[16] These findings were comparable to our study. A study compared the outcome of TENS vs spica casting.[20] The TENS group had earlier mobilisation so patients may have better functional outcomes as well.

Limitations

Though we had 6 months of follow-up, it may be less to conclude all the findings. Cases were also not operated by the same surgeon hence variability in operative performances could not be ruled out. The use of fluoroscopy during the surgery was not assessed in the study which may have an effect in the duration of the surgery.

Conclusions

The functional outcome was comparable between the closed reduction and TENS groups and the open reduction and plate group. But closed reduction and TENS could be better in pediatric femur fracture surgical treatment as it had shorter operating time and union time, less intraoperative blood loss, and post-operative complications with better knee range of motion than open reduction and plating.

Conflict of Interest: None

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