ORIGINAL ARTICLE

Comparison of Submuscular Locking Plate and Titanium Elastic Nail in children with fracture midshaft of the femur

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ABSTRACT

Aim: To compare the submuscular locking plate and titanium elastic nail with fracture midshaft of the femur in children in terms of functional and radiological outcomes and complications.
Methods: This randomized controlled trial was performed using a probability simple random sampling technique at the Department of Orthopaedic Surgery, Mayo Hospital Lahore,from January 2014 to December 2016. The sample size was 102 children, ages between 6 to 12year closed midshaft fracture femur were included, and children with midshaft fracture femur previously managed with spica cast, bone malignancy, multiple fractures, osteopenia, osteomalacia or osteomyelitis, and skeletal dystrophy were excluded. They were randomly divided into group A, and group B. Group A was treated with titanium elastic nail, and group B children were treated with the sub-muscular plate. Treatment outcomes for infection, implant failure was assessed clinically, and union and hip function were compared using Hammer et al[10] criteria and Flynn [11] criteria, respectively
Results: All of the children had a mean age of 9.05 ± 1.69 years. There were 78(76.5%) male and 24(23.5%) female children. Superficial infection was present in 03 (5.9%) in group A, and no superficial infection was present in group B. No deep infection was observed in group A and 01 (1.9%) deep infection was observed in group-B. There was no case of implant failure. The radiological union in both study groups was statistically the same (p-value > 0.05). The functional outcome at 12th week was significantly better in group-B than group-A, (p-value = 0.031).
Conclusion: The functional outcome was batter with a submuscular plate, while the union was comparable in two groups. Superficial infection was more with titanium elastic nailthan the submuscular plate.
Keywords: Children, femur fracture, internal fixation, submuscular, titanium, union, functional outcome.

INTRODUCTION

The femur is the stiff, long, and dense tubular bone of the human body and major load-bearing bone in the lower extremity[1]. The fracture of the femoral shaft is the most frequent major pediatric fractures. It usually occurs due to a fall or a road traffic accident. This fracture is more critical than its homolog in adults because the psychological, social, and financial situation affects the entire family[2]. High-velocity accidents are now more common and produceviolent and complex injuries[3].The shaft of femur fractures in children represents 1.5% of all fractures in childhood. Non-operative treatment includes hip spica, and short term overhead traction is the treatment of choice in children below 04 years of age. Femoral shaft fractures should be treated surgically during the age of 5 to 16 years[4].

Different treatment modalities are available for the shaft of femur fractures among children which comprises of the skin or skeletal traction, immediate hip spica, pontoon spica, closed reduction with minimally invasive percutaneous plate osteosynthesis(MIPPO), Dynamic Compression Plate(DCP) fixation, external fixator, and intramedullary nailing[5,6]Titanium elastic intramedullary-nailing(TEN) has gained international approval in treating and managing the femoral fractures in children[2]. Recently, the trending treatment method for femoral fractures is submuscular bridge plating. In the past twenty years, a large number of reports have displayed many technical challenges and complications, lessening their use at the same time similar pieces of evidence have emerged in support of sub-muscular plating. Although complications that are associated with sub-muscular plating are also well-reported, comprising minor leg-length discrepancies, plate fracture, re-fracture after plate removal, and mal-alignment of fracture. The studies on this methodology are still in the early stages. In addition to this, extensive long term and voluminous researches are required before a complete safety profile is understood.[7-9]. A study reported that most complications of hardware failure in the Titanium elastic nail(TEN) group were seen in 15% of the children.[9] Eidelman M et al. [5] reported no complications related to hardware failure after the application of a sub-muscular locking plate.[5]This debate inspired us to conduct this study.

This study's objectivewas to compare the treatment of fracture midshaft of the femur with submuscular locking plate and titanium elastic nail in children in terms of functional, radiological outcomes and complication rate.

Received on 03-09-2020
Accepted on 13-11-2020

METHODOLOGY

This randomized-controlled trial was conducted using a probability simple random sampling technique at the Department of Orthopaedic Surgery, King Edward Medical University, Mayo Hospital Lahore, from January 2014 to

December 2016. The sample size was 102 children, either gender,age between 6- 12year, closed midshaft fracture femur presented within the first week of injury were included, andchildren withmidshaft fracture femur previouslymanaged with spica cast,bone malignancy, multiple fractures, osteopenia, osteomalacia or osteomyelitis,and skeletal dystrophy were excluded.

Ethical approval from University institutional review board and advanced studies research board was obtained. Informed consent was taken from parents or guardians of the children. Children were randomly divided intogroup A and group B using the lottery method. Group-A participants were managed by Titanium elastic nail (TEN), and Group B participants were managed using sub-muscular locking plating. All types of implants used in this study were available in the hospital. Treatment outcomes for infection, implant failure, union, and hip function were compared in both groups.

Children were followed up in the out-patient department (OPD) on 1st week,3rd week, 6thweek, and 12thweeks after the procedure. Infection and implant failure was assessed clinically. Union and hip function were assessed using Hammer et al.[10] criteriaand Flynn [11] criteria, respectively. We treated superficial infection with debridement and culture sensitivity antibiotics. Deep infection was reported in the fifth week and was treated as per standard protocols.

Data entry was done, and analysis was performed through SPSS ver. 20.0. Quantitative variables, for instance, age (years), were calculated as mean ± SD. Qualitative-variables such as sex, radiological-union, and functional-assessment were presented in the form of frequencies and percentages. An independent sample t-test was used in comparing the mean age in both of the groups. Chi-square test was used to compare radiological union, and functional assessment (as per operational definition) at each follow up (at1st, 3rd, 6thand 12thweeks). p-value ≤0.05 was regarded as significant.

RESULTS

The mean age of all children was 9.05±1.69 years while in group-A, and group-B, the mean age was 8.82±1.62 years and 9.27±1.74 years, respectively (p-value =0.179). There were 78(76.5%) male and 24(23.5%) female children. In group-A, there were 41(80.39%) male and 10(19.61%) female,and in group-B, there were 37(72.55%) male and 14(27.45%) female children. The male to female ratio was the same in both groups (p-value = 0.350). Superficial infection was present in 03 (5.9%) in group A, and no superficial infection was present in group B. No deep infection was observed in group A and 01 (1.9%) deep infection was observed in group-B (Table 1).

At 3rd week only 01 (1.95%) child had signs of the union, (p-value = 0.315), and in 6th week, there were 47(92.2%) children in group-A, and 48 (94.1%) in group-B had a union, (p-value 0.695). At 12th week 49(96.1%) children group-A and 51(100%) children in group-B had a union, (p-value =0.153). The radiological union in both study groups was statistically the same (p-value > 0.05). In the current study,02(3.9%) children in the nailing group had delayed union (Table 2).

At the first week, all children had poor functional outcome, and at 3rd week 42(82.4%) children in group-A and group-B had fair functional outcome while 09(17.6%) children in group-A and 03(5.9%) children in group-B had poor functional outcome with a significantly better outcome in group-B (p-value = 0.001). At 12th week 37(72.5%) in group-A and 47(92.2%) in group-B had excellent outcomes, 13(25.5%) children in group-A and 04(7.8%) in group-B had a good outcome, and 1(2.0%) children had a fair outcome. The functional outcome inthe 12th week was significantly better in group-B than group-A (p-value = 0.031) (Table 3).

Table 1: Demographic data of gender, age, superficial and deep infection

Variables	Group-A (N=51)	Group-B (N=51)	Total (N=102)
Gender of the children			
• Male	41 (80.39%)	37 (72.55%)	78 (76.5%)
• Female	10 (19.61%)	14 (27.45%)	24 (23.5%)
Mean±SD Age in years	8.82±1.62	9.27±1.74	9.05±1.69
Infection			
• Superficial infection	03 (5.9%)	00 (00%)	03 (2.9%)
• Deep infection	00 (00%)	01 (1.9%)	01 (0.98%)
• No infection	48 (94.1%)	50 (98.1%)	99 (97.1%)
Union			
• Primary union	49 (96.1%)	51 (100%)	100 (98.1%)
• Delayed union	02 (3.9%)	00 (00%)	02 (1.9%)

*SD= Standard deviation

Table-2: Comparison of the radiological union in both study groups

Radiological union		Study Groups		p-value
		Group-A	Group-B	
at 1st week	No	51 (100%)	51 (100%)	1.00
at 3rd week	Yes	00 (00%)	01 (1.96%)	0.31
	No	51 (100%)	50 (98%)	
at 6th week	Yes	47 (92.2%)	48 (94.1%)	0.69
	No	04 (7.8%)	03 (5.9%)	
at 12th week	Yes	49 (96.1%)	51 (100%)	0.15

Table 3: Comparison of functional outcome in both study groups

Flynn criteria		Study Groups		p-value
		Group-A (N=51)	Group-B (N=51)	
at 1st week	Poor	51 (100%)	51 (100%)	1.00
at 3rd week	Good	00 (0%)	06 (11.8%)	0.01
	Fair	42 (82.4%)	42 (82.4%)	
	Poor	09 (17.6%)	03 (5.9%)	
at 6th week	Excellent	00 (00%)	10 (19.6%)	0.004
	Good	42 (82.4%)	35 (68.6%)	
	Fair	09 (17.6%)	06 (11.8%)	
at 12th week	Excellent	37 (72.5%)	47(92.2%)	0.03
	Good	13 (25.5%)	04 (7.8%)	
	Fair	01 (02%)	00 (00%)	

DISCUSSION

The shaft of femur fractures is categorized at top musculoskeletal trauma that requires appropriate management in children where the occurrence of hospital admission for the shaft of femur fracture is calculated est. 27.2 out of 10,000 children in the US that comprises of roughly 22% of orthopaedic related hospital admission due to trauma[12,13]. Many femoral fractures in children are caused by the history of falls, vehicular, bicycle, and traffic-related mishaps, abuse, and incidents with the absence of trauma are found to be the major reasons for femoral fracture.

Irrespective of commonality and effect, management of shaft of femoral fractures in children is still debatable, especially in children from 5-12 years of age group. Multiple variables enhance the conflict about the adequate management plan inclusive of diverse emerging treatment plans at hand and deficiency of sophisticated comparative evidence about the results of these procedures [14]. Lately, an article presented outcomes related to the management of femoral shaft fractures in children by the submuscular locking plate method. The researchers examined 16 children from 6-12 years who developed a femur fracture shaft were managed by minimally invasive percutaneous submuscular locking plate(MIPPO)[15]. Eidelman et al. [5] analyzed the results in 11 children (10 boys & 1 girl) with the shaft of femur fractures by using submuscular locking plate the age ranging from 8 to 16 years and average mean age at the time of procedure were 10.8 years. Saikia et al. [16].have examined 22 children (Eighteen boys and four girls) with the age group of 6 to16 years. In the current study,all children's mean age was 9.05±1.69 years (6-12 years) while in group-A and group-B the mean age was 8.82±1.62 years and 9.27±1.74 years respectively (p-value =0.179). There were 78(76.5%) male and 24(23.5%) female children. The male predominance and mean age are confirmed in this study as well as reported in the above studies.

A local study reported that the Titanium elastic nail (TEN) group's mean operative time was 29.91±4.61 minutes[1]. A study in 2015 reported that mean operative time was 58.25 minutes. The same study showed the functional results, as assessed by Flynn's criteria, showed that majority (n=29) of the children in the study had excellent functional results, of which 14(35%) were from Titanium elastic nail (TEN) group[2]. Saikia et al. [16] have examined twenty-two children. The evaluation of results was performed with the help of Flynn's criteria. Fracture union, which was observed radiologically, was attained at the mean of 8.7 weeks. Our study findings are consistent with the above-reported studies.

The capacity to bear complete weight was achieved at a mean time of 8.8 weeks. The mean days for hospitalization period were 9.8. The results were categorized as excellent, successful, and poor in 13(59%), 06(27.2%), and 3(13.6%) children, respectively. All of these children were back at school soon enough. The study concludes that an efficient treatment method through titanium elastic nailing(TEN) for intramedullary fixation incautiously chosen children from 6 to 16 years of age[3]. We did not compare operative time but in the current study.Inthe first week,functional outcomes were poor,and inthe 3rd-week,itwas significantly better in group B (p-value <0.001). Similarly, the functional outcome at the 12th week was significantly better in group-B than group-A (p-value = 0.031).

In our study found at 3rd week, only 01(1.95%) case in group B had signs of the union, (p-value = 0.315) and at 6th week there were 47(92.2%) children in group A, and 48(94.1%) in group B had a radiological union, (p-value 0.695). At 12th week 49(96.1%) children group A and 51(100%) children in group B had radiological union, (p-value = 0.153). The radiological union in both study groups was statistically the same (p-value < 0.05). In the current study,02(3.9%) children in the nailing group had delayed union. Moreover, Bekir Yavuz et al. [2]reported all of the TEN group's fractures united without the need for a second procedure, before three months with no delayed or non-unions in the study. Eidelman et al. [5]analyzed the results of 11 children having a union on radiographs that were visible after 6 to 10 weeks, and the solid union was observed after 12 weeks in all the children. Hardware-related complications were not observed in any case. Easy removal of plates in 5 children was conducted having no fracture afterwards. The author has concluded that the sub-muscular locking plate in the shaft of femur fractures managed with already contoured plates in adolescents was found to be a more beneficial and safe technique. Our study results are similar to Eidelman et al. [5].

Sink et al. [17]studied 27 children gone through sub-muscular locking plate to children with the shaft of femur fractures, which were not stable, having some contra-indications to fixation with titanium elastic nailing (TEN)

procedure. Reduction and implant failure were not observed in any case. Initial bone formation was observed by 6-8 weeks and firm bony-union up to 12 weeks in all children. The submuscular locking plate is quite an adequate surgical stability procedure of comminuted and unstable shaft of femoral fractures in children[6]. These findings regarding callus formation are in favour of the submuscular plate.

Our study's limitation was a short follow-up time,and we did not measure the limb length inadequacy and time of removal of the implant. The study's finding can be confirmed with new studies with extended follow-up.

CONCLUSION

The submuscular plate wasa better option for significant functional outcomes, but the radiological union was statistically the same in both groups. In the future, by using submuscular plates, we can gain better outcomes, early recovery, and return to school. In addition to that,the sub-muscular locking plate has benefits that include: it is less invasive, no need for splint cast post-operatively, low infection rates, a better functional outcome with early range of motion, quick callus formation and low rate of implant failure.

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