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Original Article

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Comparison of titanium elastic nailing and spica casting outcomes in preschool children following femoral diaphyseal fractures

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ABSTRACT

BACKGROUND & OBJECTIVE: Pediatric femoral diaphyseal fractures are common fractures in preschool children. The titanium elastic nailing technique is becoming prevalent in developed and developing countries. To compare the frequency of efficacy, safety and mean surgical fixation outcomes among patients who underwent titanium elastic nailing versus spica casting in diaphyseal femur fractures

METHODOLOGY: A prospective study was conducted at department of orthopedics, Pakistan Ordinance Factory (POF) hospital. The study duration was 2 years (March 2018-March 2020). A sample size of 42 children was calculated using WHO calculator. Children selection was made on the basis of non-probability (consecutive) sampling. Group TEN underwent titanium elastic nailing, while group SPICA underwent hip spica casting. Patients were followed for six months. We used SPSS version 24 for the analysis of data. Fisher exacts and independent T-test were applied for measuring associations and comparisons of two groups. $p \leq 0.05$ was considered significant.

RESULTS: Total of 42 patients were included in the study. The mean age of patients was 3.4 years±1.4SD. The TEN group showed satisfactory results in malalignment ($p \leq 0.000$) and complications ($p \leq 0.000$). SPICA group showed significantly high assisted weight bearing duration ($p \leq 0.000$), full weight bearing duration ($p \leq 0.000$), greater operative time ($p \leq 0.000$), lower range of motion ($p \leq 0.000$) and less patient satisfaction ($p \leq 0.000$) as compared to TEN group.

CONCLUSION: Titanium elastic nailing is safe, effective, and allows faster recovery in pediatric patients with diaphyseal femoral fractures. We recommend titanium elastic nailing as a valid treatment option for femur fractures in preschool children.

KEYWORDS: Diaphyseal femoral fractures, Titanium elastic nailing, Spica casting.

INTRODUCTION

Pediatric femoral fractures account for more than 1.6% of skeletal injuries among children, with an initial peak in early infancy found in the United States [1]. An estimated 38% of femur fractures were found in Gujranwala, Pakistan [2]. These fractures can occur as a result of sports trauma, road accident trauma, high-energy trauma, or injury due to abuse. In pediatric traumatology, diaphyseal fractures of the lower limb are the most frequent fractures. Children with these fractures require hospitalization. The most common complications of diaphyseal fractures are angular rotational deformities, infection, late consolidation, pseudoarthrosis, and leg length discrepancies [3].

Diaphyseal fractures are associated with significant functional loss; however, they can be treated effectively. Several treatment options are available for diaphyseal femur fractures, including i) spica casting, ii) open reduction internal fixation (ORIF), iii) post-traction spica casting, iv) external fixation, and v) intramedullary nailing. Previously

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diaphyseal femur fractures were treated nonoperatively with traditional interventions[4]. Moreover, with advances in surgical techniques, surgical treatment tendencies tends to improve in the last few decades. The purpose of diaphyseal fracture treatment is to bring a child to a normal family environment as soon as possible and to reduce negative psychological effects on children life [5].

Elastic Titanium elastic nailing had several advantages over other surgical interventions in pediatric age >5 years. These advantages include simple process, load sharing internal splint, alignment maintenance, and early mobilization. Faster external bridging callus formation is associated with micromotion conferred by the elasticity of fixation. The process is less likely to get infected due to intact periosteum and closed procedure, leading towards less effect and fracture hematoma [6].

Evidence exists that the most common conservative method of treating femur fractures in preschool (<5 years) children is spica cast immobilization. However, this method is associated with several drawbacks, including skin problems, serial radiographs, insufficient reduction leading towards sequential cast changes (under general anesthesia), increasing social and economic impact, and need for day care. In contrast, titanium elastic nailing is an internationally approved technique for femur fracture treatment among school-age children (6-11 years). Despite the fact that titanium elastic nailing is an easy and safe technique, there is limited practice in using it in preschool children (<5 years) due to a lack of awareness and acceptance among parents [7,8]. The study rationale was based upon the fact that using an advanced technique, TEN will be helpful in less hospital stays early recovery of children, and more satisfaction of their parents. Our study was conducted to provide evidence regarding TEN outcomes in preschool children.

So present study was conducted to compare the frequency of efficacy, safety and mean surgical fixation outcomes among patients who underwent titanium elastic nailing versus spica casting in diaphyseal femur fractures.

METHODOLOGY

A prospective study was conducted at, department of Orthopedics, Pakistan Ordinance Factory (POF) hospital, Wah Cantt. The study duration was 2 years (March 2018-March 2020). A sample size of 42 patients was calculated (21 patients in each group) with $\mu1=7.2$, $\mu2=6.2$, SD=1.2, 80% power of a study, 5% significance level using a WHO calculator [9]. Patients of diaphyseal femur fractures were selected through non-probability (convenience) sampling. We took ethical approval (ERC#POFH/ERC/2/18) from the research approval committee of POF hospital before the study conduction, and guardians of all participating patients signed a written consent form before participating. The inclusion criteria of patients were age 1-5 years, both genders, patients with diaphyseal femur fractures, femoral shaft fractures, and closed and winquist type I or III fractures. Patients with open fractures, metabolic bone diseases, neurological defects, pathological fractures, head trauma, cardiovascular disease, and congenital metabolic syndrome were excluded from the study. After selecting patients, they were divided into two groups using a computer-generated random number table. Group TEN underwent titanium elastic nailing, while group SPICA patients underwent hip spica casting.

Titanium elastic nailing surgical technique:

In group TEN, patients underwent general anesthesia in the spine position on the fracture table. We used 2 TEN of almost identical diameter. We used Flynn et al, [10](Diameter of nail = Width of the narrowest point of the medullary canal on Anteroposterior and Lateral view × 0.4 mm) formula for the selection of individual nail diameter. The purpose of choosing nail diameter is due to the occupation of each nail at least 1/3rd to 40% of the medullary cavity. Fluoroscopic guidance was used for reducing fractures. Retrograde fashion was used for fracture insertion (with medial and lateral incisions 2.5-3.5 cm above the physis). Sufficiently pre-bent nails ensure bowed nails apex resting at same level leading towards good equal recoil force establishment. Proximal derivation of nails leads them to be divergent and anchoring of tips (min 1 cm distal to physis). Patients were nursed in spine position postoperatively, and their operated leg was elevated on a pillow. Partial and full weight bearing was dependent upon the configuration of fracture, associated injury, and callus response. Partial assisted weight bearing with walking was started at 6 weeks, along with knee range of motion exercise, and it progressed further to full weight bearing in the next 2-4 weeks.

Children were followed clinically and radiologically for 6 months. TENS were removed when the child marked painless full weight bearing on the fractured leg and radiologically, there was enough callus formation to bridge the fracture fully. Children were allowed to bear weight fully after TENS removal, and knee range of motion exercises were encouraged. In the SPICA group, a single cast was applied in general anesthesia on spica stand under an image intensifier. Spica was kept for 6-8 weeks until there were good signs of a radiological union; after spica cast removal, protector assisted weight bearing along with knee range of motion exercises. Patients in both groups were followed for 6 months.

Safety and efficacy were measured using Flynn et al, scoring system of limb length discrepancy, sequence disorder, pain, and complications [11]. At the same time, outcomes were measured in terms of alignment, post-operative duration of hospital stay, bone union, assisted weight bearing, full weight bearing and operative time, and parents'satisfaction (using satisfaction with life scale SWLS.

Data analysis was done using SPSS version 24. Mean, and standard deviation was measured for continuous data. However, we analyzed the frequency and percentage for categorical and nominal variables. We controlled effect modifiers like age and gender by process of stratification. Post-stratification Fisher exact test and t-test was applied. We found $p \leq 0.05$ as a significant value of results.

RESULTS

Total 42 patients were included in the study. There were 29(69%) male and 13(31%) female. The mean age of patients was 3.4 years±1.4SD. There were 10(24%) patients in age 1-3 years and 32(76%) in age group 4-5 years. Causes of trauma were in vehicle accident 13(31%), off vehicle accident 9(21.4%), bicycle falling 11(26.2%) and falling from high place 9(21.4%). In our study, the majority of patients had middle fracture region 31(73.8%), following proximal 7(16.7%) and distal region 4(9.5%). Fracture pattern were spiral 18(42.9%), oblique 3(7.1%), transverse 19(45.2%), Winquist type 1 1(2.4%) and Winquist type 3 1(2.4%).

The majority of patients in TEN group showed more satisfactory results in limb length discrepancy as compared to SPICA group [20 (47.6%) vs. 17(40.5%) p=0.343(non-significant) Malalignment/sequence disorder was significantly satisfactory in TEN groups as compared to SPICA group [20(47.6%) vs 10(23.8%), p=0.001). Patients treated with spica casting are more likely to present with pain as compared to patients treated with TEN [19 (45.2 vs 17(40.5%), p=0.663]. Patients treated with TEN 21(50%) are associated with less development of major complications as compared to SPICA group 15(35.7%) (p=0.02), as shown in table-I.

Alignment of coronal plan angulation was significantly higher as compared in SPICA group as compared to TEN (8.4±0.6 vs 4.1±0.2SD, p≤0.000). Duration of assisted weight bearing, full weight bearing was significantly high in SPICA group as compared to TEN (p<0.001). However, Knee ROM was significantly better in TEN group as compared to Spica (p=0.000). Operative time was significantly high in spica group as compared to TEN (p≤0.000). There was a significant difference in hospital stay (3.19±0.4 vs 3.18±0.47, p≤0.000) and bone union (5.6±0.4 vs 5.7±0.4, p=0.000) in TEN and Spica group respectively as shown in table-II.

In TEN group parents of patients were more satisfied 20(47.6%) as compared to SPICA groups in which parents of patients were less satisfied 2(4.8%) with treatment procedure using the satisfaction with life scale (p≤0.000) as shown in table-III

In TEN group, pin site infection 1(4.7%) was the only complication that patients encountered. However, in SPICA group, the difficulty of a child handling plaster 4(9.5%), and parents un satisfaction regarding bone position on x-ray was 4(9.5%) following cast breakage 3(7.1%), pressure sores 3(7.1%), unable to maintain child hygiene 2(4.8%) and bone malunion 2(4.8%) as shown in figure-I.

Table-I: Comparison of efficacy of TEN group and SPICA group for pediatric femur diaphyseal fractures.

Scoring criteria	Interventional groups		Total n(%)	p-value
	TEN group n(%)	SPICA group n(%)		
Limb length discrepancy				
Poor (>2 cm)	1(2.4)	4(9.5)	5(11.9)	0.343
Satisfactory (≤2- ≤1 cm)	20(47.6)	17(40.5)	37(88.1)	
Malalignment/Sequence disorder				
Poor (>10°)	1(2.4)	11(26.2)	12(28.6)	0.001
Satisfactory (10°-≤5)	20(47.6)	10(23.8)	30(71.4)	
Pain				
Poor (present)	2(4.8)	4(9.5)	6(14.3)	0.0663
Satisfactory (absent)	19(45.2)	17(40.5)	36(85.7)	
Complication				
Poor (major complications/extended period for resolvable morbidity	0(0)	6(14.3)	6(14.3)	
Satisfactory (Mild to absent)	21(50)	15(35.7)	36(85.7)	0.021
Total	21(50)	21(50)	42(100)	

Table-II: Measurement of outcomes in TEN and SPICA groups.

Outcomes	Interventional groups		p-value
	TEN groups (n=21)	SPICA group (n=21)	
Alignment			
Coronal plane angulation (degree)	4.1±0.2	8.4±0.6	≤0.000
Sagittal plane angulation (degree)	3.2±0.1	6.0±0.4	0.663
Rotational malalignment (malalignment)	2.3±0.4	7.6±0.4	0.129
Hospital stays (days)	3.19±0.4	3.18±0.47	≤0.000
Bone union (weeks)	5.6±0.4	5.7±0.4	≤0.000
Assisted weight-bearing duration (Weeks)	4.2±0.4	6.7±1.09	≤0.000
Full weight-bearing duration(weeks)	5.8±0.42	7.3±1.1	≤0.000
Knee ROM (degree)	135±4.5	127±3.2	≤0.000
Operative time	23.09±1.37	28.7±2.7	≤0.000

Table-III: Comparison of parent's satisfaction with treatment in the TEN and SPICA group.

Parent's satisfaction (satisfaction with life scale)	Interventional groups		Total	p-value
	TEN groups (n=21%)	SPICA group (n=21%)		
Unsatisfied (5-20 scores)	1(2.4)	19(45.2)	20(47.6)	≤0.000
Satisfied (21-35 scores)	20(47.6)	2(4.8)	22(52.4)	
Total	21(50%)	21(50%)	42(100%)	

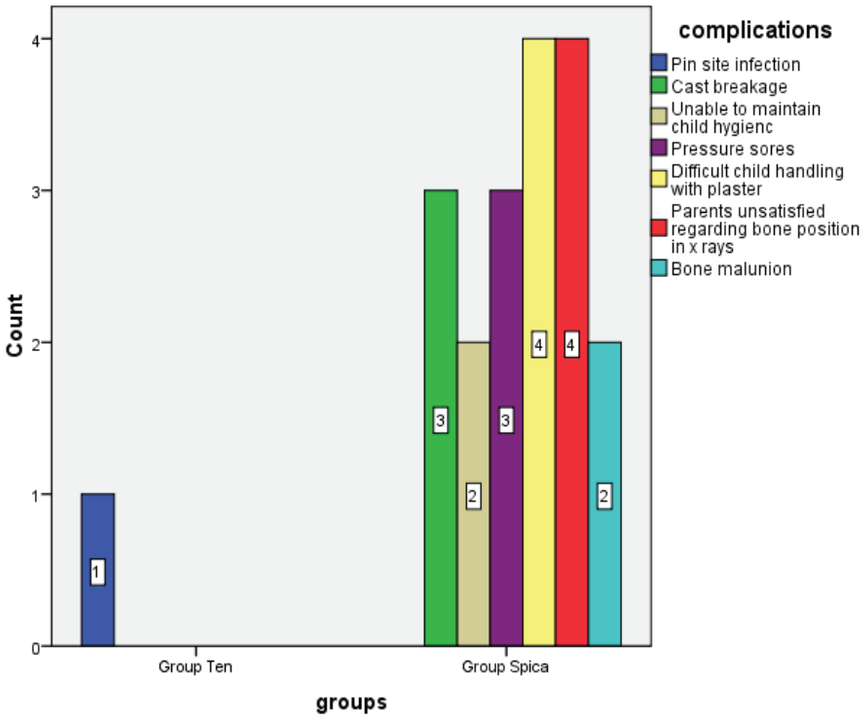

Figure-I: Safety profile of TEN group and SPICA group.

DISCUSSION

The ideal treatment for pediatric diaphyseal fractures remained a constant challenge for orthopedic surgeons. Literature reported spica casting as a classic treatment option in children <5 years, and rigid intramedullary nailing, flexibleintramedullary nailing fixation, compression plate and external fixation are generally indicated among children 6-11 years. Spica castings has remained a preferred treatment in children and young adults for diaphyseal fractures in developed and developing countries. Over the last two decades, this trend is changing to avoid prolonged immobilization effects, provide better nursing care, reduce the psychological effects of spica, and reduce school days loss. A titanium elastic nailing system is a type of flexible intramedullary nailing associated with rapid mobilization and potentially low risk of developing complications in 6-11 years. However, in our study TEN showed excellent outcomes in children less than 5 years [12].

In the present study, TEN group is associated with excellent limb length discrepancy (p=0.343), sequence disorder (0.001) and complications 0.021 as compared to spica casting. Kim et al. reported that after TEN in pediatric patients, limb length discrepancy was ≥1 cm in 29(40.3%) patients. Fracture stability and treatment procedures were significantly associated with limb length discrepancy (p=0.005 and p=0.011, respectively) in their results [13]. Tayyab et al. reported that the mean limb length discrepancy was 1.09±0.81 cm following titanium elastic nailing in pediatric femoral diaphyseal fractures. They also reported that TEN is a simple effective, and minimally invasive fracture treatment procedure [14]. Hwaizi et al, reported that 2/20 patients in SPICA group showed limb length discrepancy >2cm at the time of union [15]. We found high degree of coronal plan angulation in TEN group as compared to SPICA (p=0.000). Kaiser et al reported that spica casting treatment is associated with loss of acceptable angulation [16].

In present study, parents were more satisfied with TEN as compared to spica casting (p=0.000). Van et al, reported that there is no significant difference in clinical and functional outcomes of spica and TEN. However, TEN is more acceptable and associated with more parents' satisfaction

In present study, parents were more satisfied with TEN as compared to spica casting (p=0.000). Van et al, reported that there is no significant difference in clinical and functional outcomes of spica and TEN. However, TEN is more acceptable and associated with more parents' satisfaction [17]. In our study, TEN group patients had only complication of pin site complication, while in SPICA group, there were multiple complications. Barnett et al, reported that pediatric femoral shaft fractures treated with spica casting are associated with skin irritation, prolonged immobilization, joint stiffness, malunion and late recovery [18]. Yaokreh et al, reported that TEN in the pediatric age group is associated with superficial infection and cutaneous irritation. However, the complications were reduced by short-term oral antibiotics treatment or after TEN removals [19]. Buechsenschuetz et al, reported that TEN technique is associated with less complication. Moreover, in case of complications, it might be due to technical errors like frame asymmetry, insertion of too thin nails, and malorientation of an implant. The surgeon's experience is an effective factor in better outcomes of the technique [20].

In our study, assisted weight bearing and full weight bearing was significantly high in SPICA group as compared to TEN. Huges et al. reported that titanium elastic nailing takes less radiological union and operative time (5.7 days±2.1 & 50.7 minutes±3.1SD) [21]. Another similar study reported less duration of assisted and full weight-bearing duration in TEN group as compared to conservative management (p=0.03) [22].

CONCLUSION

Titanium elastic nailing is safe, and effective and allows faster recovery in pediatric patients with diaphyseal femoral fractures. Titanium elastic nailing is associated with improved radiological and functional outcomes and minimum complications of femur fractures among preschool children. We recommend titanium elastic nailing as a valid treatment option for femur fractures in preschool children. Further research is required on the comparison of titanium elastic nailing with other conservative treatments.

LIMITATION: Duration of traction was not equal in all patients of SPICA group due to the parent's consideration, the surgeon's decision, and limited resources.

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Author's Contribution:

Muahmmad Ikram: Data collection and interpretation of data for the work.
Sajid Ejaz Rao: Acquisition, and analysis of data for the work.
Nadia Gul: Drafting the work for important intellectual content
Sadia Ijaz: Substantial contributions to the conception or design of the work.
Munawer Latif Memon: Drafting the work and reviewing it critically for important intellectual content.
Sohail Muzammil: Analysis, and interpretation of data for the work.

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