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A prospective RCT comparing the outcome of above-knee and below-knee pop cast application for isolated tibial shaft fractures in children

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Abstract
Purpose: Above-Knee Cast has been standard treatment for treating tibial fractures in children. We conducted this study to evaluate the time of union, complication and cost of treatment between above-Knee and Below-Knee Cast groups in children with isolated tibial shaft fractures.
Study Design: Sixty children of age 6 months-15 years were randomized into Above-Knee and Below-Knee Cast group, who were followed and compared; till 6 months from January 2012 to March 2013. 10 children (6 torus, 2 undisplaced, 2 displaced fractures) lost to follow up at 6 months and were analyzed with missing value data analysis at 6 months.
Results: All fracture united (8.30±2.69 weeks in Above-Knee Cast, 7.70±2.54 weeks in Below-Knee Cast). The pre-reduction parameters were varus (2-8º), valgus (4-8º), anterior angulation (4-9º), Posterior angulation (2-10º), Internal Rotation (3-6º), External rotation (3-6º), shortening (6.46 mm). At 6 months, above parameters were 2.83º±0.85, 3.20º±0.44, 2.83º±1.32, 2.67º±0.84, 3.40º±0.54, 2.83º±0.75, 2.67±1.15mm respectively in Above-Knee group and 2.60º±0.84, 2.50º±0.52, 3.00º±1.00, 2.93º±1.32, 3.00º±1.41, 2.33º±0.57, 2.00±0.00mm respectively in Below-Knee group. Reinforcement requirement of plaster was higher in Below-Knee cast (p=0.014). There were no refractures, residual complications.
Conclusions and clinical relevance: Below-Knee cast is as effective as Above-Knee Cast for treatment of Isolated tibial shaft fractures in child with superior ROM at knee and low cost (p<0.000).

Keywords: Isolated, tibia, below-knee

Introduction
Tibial and fibular fractures are the third most pediatric most common pediatric long bone fractures (15%); after radial/ulnar and femoral fractures. (Shannak, 1988) [11] About 70% of pediatric tibial fractures are isolated injuries. Fifty to seventy percent occurring in distal third and nineteen to thirty-nine in the middle third. (Bennek & Steinert, 1966 [2]; Yang & Letts, 1997) [17] Most tibial fractures in children are closed injuries and traditionally managed conservatively with above-knee cast whether isolated or associated with ipsilateral fibular fracture. The standard treatment for the majority of closed tibial-shaft fractures consists of closed reduction and cast immobilization. (Bostman, 1986; Nicholl, 1964; Sarmiento *et al*. 1984; Watson-Jones & Coltart, 1982) [3, 8, [10, 16]. Contradicting statements can be found with the influence of intact fibula with hastening or delaying union and may complicate to angulate into varus position. (Klatt JWB, Stotts AK, & Smith, 2010; Nicholl, 1964; O'Dwyer, DeVriese, Feys, & Vercruysse, 1993; Yang & Letts, 1997) [7, 8, 9, 17]. Although immobilizing one joint below and one joint above is widely practiced and accepted, recent retrospective study has shown equally effective result of below-knee cast in isolated tibial shaft fractures in children and we evaluated prospectively to compare the effect between the Above-Knee Cast and Below-Knee cast. (Klatt JWB *et al*. 2010; Yang & Letts, 1997) [7, 17]

Materials and Methods
Total 60 children from age 6 months to 15 years with isolated fracture of middle and distal third tibia were included in this study who attended our institute from January 2012 to March 2013. Exclusion criteria were proximal tibial fractures, comminutes greater than Winquist and Hansen Grade I, segmental fracture, open fractures above Gustilo Grade II, intra-articular

fractures, and with distal neurovascular deficit. Children were successfully randomized into Above-Knee cast and Below-Knee cast group according to random number generated list. Undisplaced, torus and minimally displaced fractures were not manipulated under anesthesia whereas non-cooperative and grossly displaced fractures were manipulated under anesthesia. For strict criteria to be followed, Rockwood acceptability criteria for <8 years and >8 years was chosen and applied. (Stephen & James, 2010) [12] Children were follow-up next day for plaster related complications and then followed up at 3 week, 6 weeks, 3 months and 6 months. Parameters were evaluated in terms of signs of union, range of movement at Hip, Knee and Ankle, Need for wedging, residual deformity, delayed union, malunion, time to union, plaster related complications, residual pain and disability, need for reinforcement and cost of treatment. In South-East Asia and developing country like ours, lost to follow-up is necessary evil, and people don't bother to visit for long time. 10 children (6 torus, 2 undisplaced, 2 displaced) were lost to follow-up at 6 months (all these children were already running and full-weight bearing by 3 months) and was analyzed using missing value analysis in SPSS. Little's Missing Completely at Random (MCAR) test with p value=0.217 and Expectation Maximization method with p value=0.817 suggested that patient lost were randomly and statistically insignificant. All data were collected were analyzed using SPSS (version 21). The significance level of *p* value was set at <0.05.

Results

The no. of children with less than 8 years were 38 and greater than 8 years was 22. Out of 60 children, 48 were boys and 12 were girls with male to female ratio being 4:1. Right leg was injured more commonly (Table 1).

All fracture united (8.30±2.69 weeks in Above-Knee Cast, 7.70±2.54 weeks in Below-Knee Cast). All children had full weight bearing ambulatory status by 12 weeks (average 2-12 weeks). (Table 2 and Table 3).

Table 1 Distribution of qualitative variables in the Above-Knee and Below-Knee Cast Groups

Variables	Group		Total	χ^2 test P value
	Above Knee (n=30)	Below Knee (n=30)		
Age				
Upto 8 Years	16 (53.3)	22 (73.3)	38 (63.3)	0.108
Above 8 years	14 (53.3)	8 (26.7)	22 (36.7)	
Sex				
Male	23 (76.7)	25 (83.3)	48 (80.0)	0.519
Female	7 (23.3)	5 (16.7)	12 (20.0)	
Dominant Limb				
Right	26	25	50	0.718
Left	4	5	10	
Injured Limb				
Right	16	18	36	0.602
Limb	14	12	24	
Time from injury to manipulation (hrs)				
<24	26	22	48	0.311
24-48 hrs	2	2	4	
>48 hrs	2	6	8	
Fracture Type				
Closed	26	29	55	0.206
GGI	3	0	3	
GGII	1	1	2	
Fracture Geometry				
Transverse	2	0	17	0.284
Oblique	5	2	15	
Spiral	22	27	21	
Comminuted	1	1	1	
Torus	1	5	6	
Mode of Injury				
Direct Hit	2	0		0.284
RTA	5	2		
Fall on ground	22	27		
Others	1	1		
Union Time				
3 weeks	1	3	4	0.152
6 weeks	13	9	22	
8 weeks	3	10	13	
10 weeks	6	4	10	
12 weeks	7	4	11	
Need For Remanipulation				
Required	30	29	59	0.313
Not Required	0	1	1	
Intactness of Plaster				
Intact Throughout	17(56.7)	6 (20.0)	18	0.014
Reinforced	12 (40.0)	22 (73.3)	39	
Need changing of cast	1 (3.3)	2 (6.7)	3	

Table 2: Association between independent variables and the two different cast groups

Variables	Cast group	Mean± SD	p value
Union time (in weeks)	A/K	8.30±2.69	0.379
	B/K	7.70±2.548	
Mobility at Knee (in degrees Arc)	A/K	95.33±10.49	0.000
	B/K	122.50±6.263	
Mobility at Ankle (in degrees arc)	A/K	27.67±5.20	0.702
	B/K	27.18±4.85	
Treatment cost (in Nepali Rupees	A/K	1095.66 ±409.85	0.000
	B/K	362.66±85.94	

A/K= Above Knee Cast group, B/K= Below Knee Cast group

Table 3: Ambulatory Status

Ambulation At (weeks)	Above-Knee cast group	Below-Knee cast group	p value
At 2 weeks			
NWB	24	24	1.000
PWB	6	6	
At 3 weeks			
NWB	15	11	0.417
PWB	14	16	
FWB	1	3	
At 6 weeks			
NWB	7	5	0.766
PWB	9	11	
FWB	14	14	

NWB=Non Weight Bearing, PWB = Partial Weight Bearing, FWB = Full Weight Bearing

Table 4: Correlation

Between Parameters		Pearson correlation co-efficient	p value
Age	Union time	0.369	0.004
Age	Cost treatment	0.513	0.000
Injury to reduction time	Union	-0.77	.560

The average pre-reduction parameters were varus (2-8º), valgus (4-8º), anterior angulation (4-9º), Posterior angulation (2-10º), Internal Rotation (3-6º), External rotation (3-6º), shortening (6.46mm). At 6 months follow-up period, above parameters were varus: 2.83º±0.85, valgus: 3.20º±0.44, Anterior angulation: 2.83º±1.32, posterior angulation: 2.67º±0.84, Internal Rotation: 3.40º±0.54, External rotation: 2.83º±0.75, Shortening: 2.67±1.15mm respectively in Above-Knee group and Varus: 2.60º±0.84, Valgus: 2.50º±0.52, Anterior Angulation: 3.00º±1.00, Posterior Angulation: 2.93º±1.32, Internal Rotation: 3.00º±1.41, External Rotation: 2.33º±0.57, Shortening: 2.00±0.00mm respectively in Below-Knee Cast. Reinforcement requirement of plaster was significantly higher in Below-Knee cast (p=0.014). Only one child of Above-Knee cast Group require changing of cast due to wetting and remaining observation period was uneventful.

All patient had one or the above ambulatory status by 6 weeks*)* and all were full weight bearing by 3 months. Range of Motion at knee was higher and treatment costs were lower significantly in Below-Knee Cast group (p=0.000); cost of treatment being nearly four times greater in Above-Knee cast group. There were no refractures, residual disabling pain and plaster related complications.

We found positive correlation with age and union time (r=0.369, *p=0.004)* and no relation between injury to reduction period with union time (Table 4).

Discussion

The mean age was 7.4 years comparable to other studies. (Allum & Mowbray, 1980; T. W. R Briggs, 1992) [1, 14] Male predominance is 4:1 and right side being more commonly involved compared to literature. (Hooper, Buxton, & Gillespie, 1981; T. W. R Briggs, 1992; Yang & Letts, 1997) [6, 14, 17] In terms of distribution with respect to age, gender, dominant limb and injured limb, they were similar suggesting randomization had been effective. Our average manipulation time was 17.30 hours following injury, many due to transport related issues and hospital constraint. TWR Briggs *et al*. suggested manipulation till 2 weeks as fractures are still malleable but not 3 weeks and more. (T. W. R Briggs, 1992) [14] We modified two parameters for widening our application range: first being contrary to Sarmiento *et al*, the recommended age of 11 years and above for Patellar tendon bearing cast was reduced to 5 years of age for children who were applied above knee cast. (Klatt JWB *et al*. 2010; Sarmiento *et al*. 1984) [7, 10] Second posterior angulation acceptability was increased to 5º for >8 years of age which is compatible to studies in other series. (Nicholl, 1964; Zionts & MacEwen, 1986) [8, 18]

Union

All fractures united at an average of 8.30±2.69 weeks in Above-Knee group and 7.70±2.54 weeks in Below-Knee groups which comparable to studies by Klatt JWB *et al*. average of 5.2 weeks and TWR Brigg's *et al*. (46 days). (Klatt JWB *et al*. 2010; T.W.R Briggs, 1992) [7, 14] Oblique fracture united the earliest at mean of 7.67±2.49 weeks, followed by Spiral fracture at 8.38±2.15 weeks, Transverse at 8.94±2.65 weeks. All torus fractures united by 6 weeks.

Changes in angulation, limb length and Remodeling:

Mean Coronal angulation was 4.6º and sagittal angulation was 4.8º, Rotation 3.91 and Shortening 4.94 mm in Above knee

group and 4, 4.27º, 3.20, 5.23 mm respectively in Below knee group at 1 month respectively. And at 6 month, mean angulation was 2.8º in coronal and 2.7º in sagittal plane with 2.80 rotation in above knee group and 2.50º and 2.8º mean angulation in coronal and sagittal plane with 2.25º rotation and 2 mm mean shortening in Below-Knee group. Joshua *et al*. in 4-year retrospective follow-up of 269 cases of isolated tibial fractures reported residual coronal angulation 2.1º, sagittal angulation of 2.5º in above-knee cast and. In the Below Knee cast group, residual angulation was 3.4º coronal and 1.1º sagittal plane. (Klatt JWB *et al*. 2010) [7] Although anterior and varus angulation corrected to some extent, rotation and valgus angulation didn't correct to large extent which is similar to the studies by other authors. (Dwyer, John, Mann, & Hora, 2007; Shannak, 1988; Zionts & MacEwen, 1986) [5, 11, 18]

Swann Oopers *et al*. reported that up to age of 10 years in boys and 8 years in girls, spontaneous resolution of angular deformity occurs. (Swaan & Oppers, 1971) [13] In our study, mean shortening in above-knee was 2.67mm and below knee was 2mm which is less as to study of Shannak AO *et al*. (Shannak, 1988) [11] (average 8 mm). And TWR Briggs *et al*. (T.W.R Briggs, 1992) [14] and contrary to the study by. Dwyer Amitabh *et al*. who found 14 isolated tibial fractures in children less than 12 years to have average limb lengthening of 8.9 mm which they attributed to hyperemia at fracture site leading to increased activity of physis. (Dwyer *et al*. 2007) [5] Isolated tibial fractures tend to have residual varus deformity. (Teitz, Carter, & Frankel, 1980; Yang & Letts, 1997) [15, 17] In our study, valgus and varus deformity occurred in equal proportion. It might be that though isolated tibial fractures are low energy trauma, plastic deformation of fibula is often overlooked and henceforth valgus deformity may occur during later period. (T. W. R Briggs, 1992) [14] none of the both groups had re-fractures. Re-fractures are reported to occur soon after union and plaster removal at average of 7 weeks as reported by Klatt WB *et al.* and TWR Brigg *et al*. (Klatt JWB *et al*. 2010; T. W. R Briggs, 1992) [7, 14]. However, in such small follow-up duration, it is difficult to comment on final residual angulation, shortening, rotation i. e. remodeling.

Ambulation and Mobility and Cost

Da Costa and Kumar Review reviewed tibial fractures 44 patients and found 28 patients ambulated early mean period 11.5 days which is comparable to our study (2wks-6wks). (Da Costa & Kumar, 1979) [4] Residual Knee and ankle stiffness was higher in Above-Knee cast group as occur after prolonged immobilization. (Teitz *et al*. 1980) [15]

Fig 1: = At Presentation, B= after application, C= at 6 weeks, D= at 3 months.

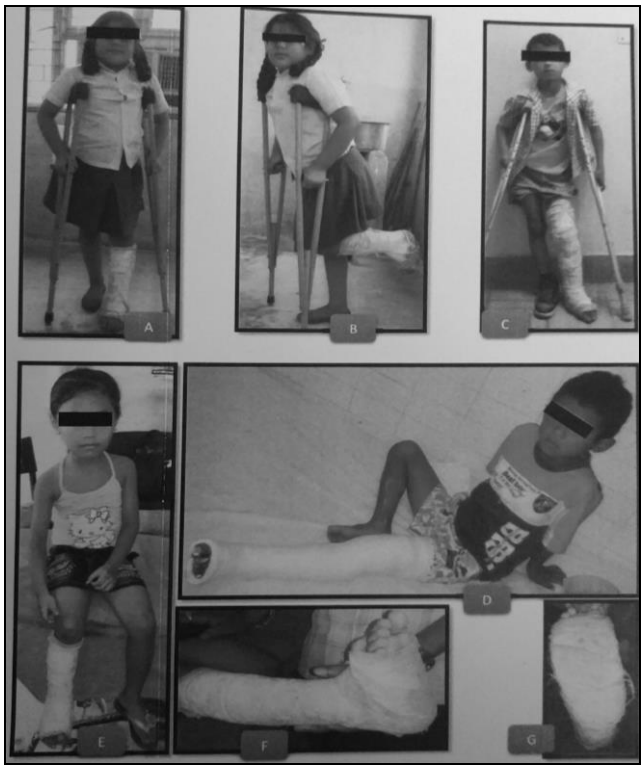

Fig 2: A, B, E – showing Freedom of Below-Knee Cast and C,D showing Above-Knee Cast and F and G showing weakening as child starting to bearing weight.

Conclusion

We can safely conclude and recommend the application of well molded Below-Knee cast for the isolated tibial shaft fractures in children up to age 15 years which gives superior ambulation and low cost as compared to Above-Knee Cast application.

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