



A prospective cohort study on comparison of early outcome of classical Ponseti and modified Ponseti post tenotomy in clubfoot management

Joseph Olorunsogo Mejabi^{a,*}, Oluwadare Esan^b, Olayinka Oladiran Adegbehingbe^b,
Joseph Effiong Asuquo^c, Akinyele Lawrence Akinyoola^b

^a Dept. of Surgery, Federal Medical Centre (FMC), Birnin Kebbi, Kebbi State, Nigeria

^b Dept. of Orthopaedics and Traumatology, Obafemi Awolowo University, Ile Ife, Nigeria

^c Department of Surgery, University of Calabar, Calabar, Nigeria

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ABSTRACT

Introduction: Ponseti method has become the main treatment modality for the management of clubfoot producing good long-term results. However, variation in cast application post tenotomy has not been evaluated.

Methods: A prospective cohort study involving 40 patients with 67 clubfeet were randomized into two groups: 32 above knee cast (AKC) and 35 below knee cast (BKC) after percutaneous tenotomy. All had foot abduction brace after post tenotomy cast. The median age was 21 weeks (range: 1–104 weeks) and 1.9:1 male/female ratio. 27 (67.5%) patients had bilateral clubfoot and unilateral in 13 (32.5%). Patients were followed-up for 6 months with documentation of the Pirani Score and the cost of treatment.

Results: No significant difference between AKC and BKC mean Pirani score before treatment ($p = 0.550$) and after treatment ($p = 0.702$). However, mean Pirani score at 6 months was significantly different ($p = 0.038$). Overall mean number of casting was 6.4 in AKC group and 4.7 in BKC group ($p = 0.003$). There was recurrence in 2 feet before completion of treatment (6.3%) among AKC and none among BKC group. However, there was no recurrence at 6 months after treatment in both groups. The mean cost for AKC and BKC were ₦10,427.34 (52.33 US dollars) and ₦7021.54 (35.24 US dollars) respectively ($p = 0.002$).

Conclusion: Early results of below knee cast after tenotomy were comparable to the classical above knee cast after tenotomy in Ponseti treatment protocol for clubfoot. There was also reduction in cost of treatment in the modified Ponseti compared to the classical Ponseti. Long-term result will be desirable.

1. Introduction

Clubfoot is a congenital musculoskeletal deformity characterized by heel varus, hindfoot equinus, mid-foot cavus and forefoot adduction [1]. It is a common developmental foot disorder with birth prevalence of 1–4.5/per 1000, the aetiology remains largely idiopathic [2].

The Ponseti method involves stretching of the deformity in synchronized technique followed by application of a long-leg cast. The standard Ponseti protocol uses weekly above knee plaster cast combined with specific manipulation techniques to correct the deformities. All components of the deformity usually correct within 4–5 weeks with the exception of the equinus which is corrected completely in most patients with percutaneous tendo-achilles tenotomy followed by a final plaster cast for three weeks [3]. The final cast in the classical Ponseti method is above knee cast post tenotomy with the knee in 90° which is left in place for 3 weeks before removal. The modified Ponseti is a below knee cast post tenotomy, the cast get to the junction of the

proximal third and the distal two third of the leg and is left in place for three weeks before removal.

Patients are thereafter placed in a foot-abduction brace after the casting phase. The Ponseti technique is well established and has been shown to be highly effective [4].

There is paucity of studies in the literature to determine recurrence rate in below knee cast after percutaneous tenotomy and then comparing this to the classical Ponseti treatment protocol of above knee cast post tenotomy. This study aimed at comparing the outcome and cost differentials of above and below knee cast after percutaneous tenotomy in Ponseti clubfoot management.

2. Methodology

It was a hospital based prospective analytical cohort study with a level 1 evidence designed to compare the outcome of two casting methods in Ponseti management of clubfoot post-tenotomy. The work

* Corresponding author.

E-mail address: mejajbos@gmail.com (J.O. Mejabi).

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complied with the STROCSS criteria. It was conducted at Obafemi Awolowo University Teaching Hospitals Complex (OAUTHC), Ile-Ife, in south-western Nigeria. The hospital has two units (Ife Hospital Unit, Ile-Ife and the Wesley Guild Hospital Unit, Ilesha) where clubfoot clinic runs on weekly basis. Ethical approval was obtained from the Ethics and Research committee of the hospital for this study with the number IRB/IEC/0004553 and Protocol number ERC/2012/10/08.

The study group comprised of children born with congenital Talipes equinovarus not associated with any other pathology. Subjects included in the study were patients born with congenital idiopathic Talipes equinovarus up to two years of age, while patients older than two years, patients who had been walking and wearing shoes with this deformity, syndromic and recurrent clubfoot were excluded.

Consecutive patients presenting at the outpatient clubfoot clinic of the hospital with idiopathic clubfoot, which satisfied the inclusion criteria, and whose parents/caregivers had consented to the study were recruited and were clinically evaluated. Variables of interest such as the biodata, and Pirani score at presentation were entered into a structured information sheet. Treatment was started as soon as they were referred, and consisted of gentle manipulation of the foot and the serial application of above knee cast with knee flexion to 90° without anaesthesia for the two groups initially. Plaster of Paris (Gypsona, Agary) was used for casting in these patients. After achieving 50°-70° abduction measured with the aid of a Universal Goniometer, the need for tenotomy was determined by the degree of dorsiflexion. If the dorsiflexion was not up to 15°, patient were considered for Tendo-achilles percutaneous tenotomy [5] Consecutive patients that needed tenotomy were randomized into two groups as they present: above knee cast(AKC-control) and below knee cast(BKC-study). All the subjects in the control group had the classical Ponseti cast for three weeks while those in the study group had below knee cast for three weeks immediately after the tenotomy. Consultants and Senior Registrars trained in Ponseti treatment protocol were involved in the manipulation, casting and performing of tenotomy for the patients in the two groups and a consultant was on ground to guide as to the adherence to treatment protocol.

Patients were given foot abduction braces following the completion of the casting phase of treatment. This is to be worn 23 h per day for the first 3 months after removal of the post tenotomy cast, and thereafter at nights throughout the study period. These patients were followed up in the clinic on regular basis for up to 6months after tenotomy. The initial follow up was 2 weeks after commencing foot abduction brace to see how patients were coping, then monthly for three months after which patients were reviewed at the 6th month after correction.

Other data that were collected included the number of casting sessions, whether it was above or below knee cast, recurrence, Pirani score at full correction, and at 6 months after full correction. Data analysis was performed using the statistical package for social sciences (SPSS; IBM; Chicago, Illinois) software for windows version 17. The comparability of patients in the 2 groups of clubfoot treatment was determined from the demographic data and baseline values. Changes in the mean hospital care cost and mean Pirani points were evaluated using Chi-Square test and ANOVA for parametric data and Mann-Whitney U technique was used to compare the two clubfoot groups for non-parametric data. A confidence interval (CI) of 95% $p < 0.05$ was taken to be significant. The cost of treatment has to do with hospital care cost; the cost of transportation for the patients and parent(s)/guardian(s) with the cost as a result of time spent away from work was not included. Also the cost of health care professionals was not included because there was no difference in the skill required for manipulation and casting in the 2 groups. The exchange rate used was 199.25naira to a dollar as obtained with Central Bank of Nigerian in early 2015. This article has been reported in line with the STROCSS criteria [6].

3. Results

40 patients (20 AKC and 20 BKC groups) comprising of 26 males

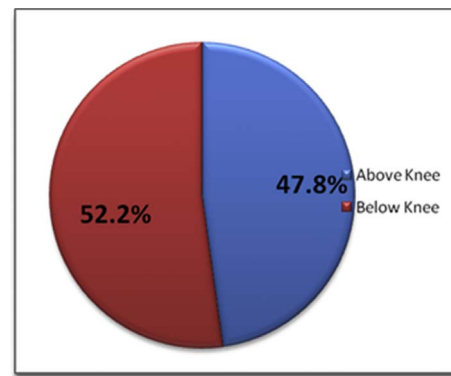


Fig. 1. Pie chart showing the percentage of feet in AKC and BKC groups.

(65%) and 14 females (35%) with sex ratio of 1.9:1 met the inclusion criteria. A pie chart showing the percentage distribution of the clubfeet in the two groups is as shown in Fig. 1 below.

21 weeks was the median age (range: 1–104 weeks). 34 (85%) patients out of the 40 presented within the first year of birth while the rest: 6(15%) presented for treatment after their first birthday. 27 patients (67.5%) had bilateral clubfoot while 13 (32.5%) had unilateral clubfoot. Among the 13 unilateral clubfoot, 6 patients (15%) were left sided while 7 (17.5%) were right sided. The numbers of clubfeet managed in these 40 patients were 67. The distribution of age, sex and foot affected in the two groups studied are as shown in Table 1 below.

The median age of the patients with AKC was 18.5 weeks (range: 1–104 weeks) and for the BKC group was 21.0 weeks (range: 1–104 weeks).

The patients' distribution in the two groups in terms of sex, age and the foot affected was not statistically significant.

The mean number of casting sessions was 5.5(S.D. 2.4). 16 feet (23.9%) had more than 6 casting sessions. Out of the 67 feet of the 40 patients affected, 32 feet (47.8%) had above knee cast for three weeks after percutaneous tenotomy while 35 feet (52.2%) had below knee cast for 3 weeks after percutaneous tenotomy. There was recurrence involving a patient with bilateral clubfoot before completion of treatment in above knee group. This was attributed to withholding of manipulation and casting for about a week due to the skin infection developed by the patient. Ponseti treatment protocol was followed thereafter to manage the case until full correction. No recurrence in the 2 groups at 6months after full correction of clubfoot deformity.

In comparing the Pirani score for the 2 groups, the result showed that there was no statistical significance in the Pirani scores between the them before the onset of treatment ($p = 0.550$) and at full correction ($p = 0.702$) but at 6 months after correction, the difference was

Table 1
Demographic characteristics of clubfoot patients in AKC and BKC groups (Patients N = 40, Total Clubfeet = 67). *Pearson Chi-Square + Likelihood Ratio.

Patient Characteristics	Above Knee Cast (AKC)	Below Knee Cast (BKC)	Level of Significance (p value)
	Frequency (%)	Frequency (%)	
Age (weeks)			
< 52	15 (75.0)	19(95.0)	0.212*
> 52	5(25.0)	1(5.0)	
Sex			
Male	12(60.0)	14(70.0)	0.299+
Female	8(40.0)	6(30.0)	
Foot affected			
Bilateral	13(65.0)	14(70.0)	0.389*
Unilateral	7(35.0)	6(30.0)	
Left sided	4(20.0)	2(10.0)	
Right sided	3(15.0)	4(20.0)	

Table 2
Comparing the Pirani scores in AKC and BKC groups.

	AKC Mean and SD (N = 32)	BKC Mean and SD (N = 35)	Mean diff.	t	P
Pirani score before treatment	5.141 ± 1.018	5.000 ± 0.899	0.141	0.600	0.550
Pirani score at full correction	0.203 ± 0.333	0.171 ± 0.342	0.032	0.384	0.702
Pirani score at 6 months	0.313 ± 0.070	0.114 ± 0.062	0.198	2.121	0.038

Table 3
Showing the mean cost of treatment in Naira [US dollars in bracket] for AKC and BKC and the statistical significance (N = 67).

Cost of Items	Mean ± SD		Mean Diff.	Average cost	Mann-Whitney U	p value
	Above knee (N = 32)	Below knee (N = 35)				
Cost of casting	9357.34 ± 5101.26 [46.96 ± 25.60]	5951.54 ± 1937.72 [29.87 ± 9.73]	3405.80 [17.09]	7422.37 [37.25]	308.50	0.002
Cost of Tenotomy	1070.00 [5.37]	1070.00 [5.37]		1070.00 [5.37]		
Total cost	10,427.34 ± 5101.26 [52.33 ± 25.60]	7021.54 ± 1937.72 [35.24 ± 9.73]	3405.80 [17.09]	8492.37 [42.62]	308.50	0.002
Cost of FAB ^a	5000.00 [25.09]	5000.00 [25.09]		5000.00 [25.09]		
Overall cost	15,427.34 ± 5101.26 [77.43 ± 25.60]	12,021.54 ± 1937.72 [60.33 ± 9.73]	3405.80 [17.09]	13,492.37 [67.72]	308.50	0.002

^a FAB- Foot Abduction Brace.

statistically significant (p = 0.038) as shown in Table 2 below. The BKC group had better Pirani score at 6months compared to the AKC group.

The mean cost of treatment as at the time the study was conducted in the AKC group was ₦10,427.34 [52.33 US dollars] (S.D. ₦5101.26 [25.60 US dollars]) and for BKC was ₦7021.54 [35.24 US dollars] (S.D. ₦1937.72 [9.73 US dollars]) with difference of ₦3405.80 [17.09 US dollars] as shown in Table 3 below. There was statistically significant cost differential (p = 0.002) between the two groups in this study.

Average cost of casting was ₦7422.37 [37.25 US dollars]. Overall cost included the cost of casting, tenotomy and foot abduction brace with an average of ₦13,492.37 [67.72 US dollars] as shown in Table 3 above.

4. Discussion

Since the establishment of the Ponseti treatment protocol, there has been some modifications to the original method in literature with some having good outcome on short term basis [7].

The study aimed at comparing the early outcome of treatment of clubfoot in classical Ponseti method using above knee cast with modified Ponseti method using below knee cast post-tenotomy. This study had a higher age group in comparison to other previous studies. This observation is at variance with studies from developed countries where patients presented much earlier. Brewster et al., in 2012 recorded mean age of 4.5 weeks among 51 cases of clubfoot [8]; Chaudhry et al. in New York also in 2012 recorded 123 clubfooted patients with age not more than 60 days [9]; Abbas et al. in India in 2008 found a mean age of 4.5 months among 100 patients [10]. Our study had patients at a higher age, which could be due to ignorance. Ignorance as regards the availability of treatment for this condition coupled with the fact that patients and caregivers may have to travel hundreds of kilometres to assess care. Adegbehingbe et al. also working in a less developed country reported an 18year old girl with unilateral neglected clubfoot treated with Ponseti technique in 2010 [11].

This study revealed male preponderance with male/female ratio of 1.9:1. This was in keeping with the studies done by other workers such as Pavone et al., in 2012 in Sicily [12] and Ponseti in 1963 [13]. The average Pirani score at presentation in the AKC group was 5.1 and in BKC group was 5.0. Other workers such as Harnett et al., in 2011 in England found a similar average Pirani score at presentation [4].

The average number of casting sessions was 5.5 in the two groups which were similar to what Pulak et al. in Ethiopia obtained. He found an average of 4.9 casting sessions (range of 3–10) [14].

To the best of our knowledge there is paucity of documented studies that compared above and below knee cast after percutaneous tenotomy but there are studies that have compared above and below knee cast from the onset of treatment with conflicting results.

Brewster et al., in 2008 in a study among 51 consecutive patients with 80 clubfeet over a 4 year period who had below knee cast from the beginning to the final cast concluded that a below knee softcast in conjunction with Ponseti manipulation technique showed promising initial results which were comparable to those using above knee plaster of Paris cast. Part of the modification they employed was below knee softcast applied directly over a stockinette, without padding thereby obtaining a snug fit. Moreover, particular attention was paid to the formation of a groove above the heel as suggested by Ponseti and Campos to prevent slippage of the cast [8].

Whereas, Maripuri et al., in 2013, in a prospective randomized clinical trial to compare treatment times and failure rates between above and below knee Ponseti cast with 26 children: 13 children (17 feet) in above knee cast and 13 (16 feet) in below knee cast stopped the trial early due to 37.5% failure (6 patients) in below knee cast and concluded that the use of a below knee Plaster of Paris cast in conjunction with the Ponseti technique leads to unacceptably high failure rates and significantly longer treatment times [15]. Our study only compared casting post-tenotomy and as such the outcome may not be significantly different between the classical method and the modified method. Reason being that the Achilles tendon has been severed at tenotomy and its plantar-flexion effect on the ankle effectively removed, hence application of above knee cast with the knee in flexion post –tenotomy may be superfluous. It is also noted in a study by Chaudhry et al. that above knee cast helps to keep the ankle and the foot from rotating [9], but in our study, the correction of the forefoot adduction would have been achieved before tenotomy.

Moreover, application of below knee cast will further decrease the overall cost of treatment as seen in our study. The cost of treatment in the two groups were compared and found to be statistically significant. This is important in a resource poor setting like ours. Most studies done on the cost benefits of methods of treatment focussed on comparing different treatment modalities and not variation in treatment technique

[11,16,17].

The limitation of this study was the short period of follow up of the patients treated. Standard follow-up need at least 3–4 years and some have been followed up for 30 years [7].

5. Conclusion

Early result showed that there was no difference in the recurrence rate between patients that had above and below knee cast after percutaneous tenotomy in the first six months but the total cost of in-hospital care in the above and below knee cast after percutaneous tenotomy was statistically significant. Due to the short follow up period, we therefore recommend that studies with longer follow up period will be necessary to validate these results. There was no conflict of interest. Funding was borne partly by the hospital where the research was conducted, the authors and the parents/guardians of the patients [7].

Ethical approval

Yes. Obafemi Awolowo University Teaching Hospitals Complex Ethics Review Committee. National Registration Number: IRB/IEC/0004553. International Registration Number: NHREC/27/02/2009a.

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The teaching hospital where the work was carried out and self.

Author contribution

Mejabi Joseph - study design, data collections, data analysis, writing.

Adegbehingbe Olayinka Oladiran - study design, data collections.

Esan Oluwadare-study design, data collection, writing.

Asuquo Joseph Effiong - writing.

Akinyoola Lawrence-study design, writing.

Conflicts of interest

No conflict of interest.

Guarantor

Adegbehingbe Olayinka Oladiran.

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References

- [1] M.F. Yagmurlu, M.N. Ermis, H.E. Akdeniz, E. Kesin, E.S. Karakas, Ponseti management of clubfoot after walking age, *Pediatr. Int.* 53 (1) (2011) 85–89.
- [2] A.H. Cardy, L. Sharp, N. Torrance, R.C. Hennekam, Z. Miedzybrodzka, Is there evidence for aetiologically distinct subgroups of idiopathic congenital talipes equinovarus? A case-only study and pedigree analysis, *PLoS One* 6 (4) (2011) e17895.
- [3] J.A. Morcuende, L.A. Dolan, F.R. Dietz, I.V. Ponseti, Radical reduction in the rate of extensive corrective surgery for clubfoot using the Ponseti method, *Pediatrics* 113 (2) (2004) 376–380.
- [4] P. Harnett, R. Freeman, W.J. Harrison, L.C. Brown, V. Beckles, An accelerated Ponseti versus the standard Ponseti method: a prospective randomised controlled trial, *J. Bone Jt. Surg. Br.* 93 (3) (2011) 404–408.
- [5] D.M. Scher, D.S. Feldman, H.J. van Bosse, D.A. Sala, W.B. Lehman, Predicting the need for tenotomy in the Ponseti method for correction of clubfeet, *J. Pediatr. Orthop.* 24 (4) (2004) 349–352.
- [6] R.A. Agha, M.R. Borrelli, M. Vella-Baldacchino, R. Thavayogan, D.P. Orgill, S. Group, The STROCSS statement: strengthening the reporting of cohort studies in surgery, *Int. J. Surg.* 46 (2017) 198–202.
- [7] C.R. Jowett, J.A. Morcuende, M. Ramachandran, Management of congenital talipes equinovarus using the Ponseti method: a systematic review, *J. Bone Jt. Surg. Br.* 93 (9) (2011) 1160–1164.
- [8] M.B. Brewster, M. Gupta, G.T. Pattison, I.D. Dunn-van der Ploeg, Ponseti casting: a new soft option, *J. Bone Jt. Surg. Br.* 90 (11) (2008) 1512–1515.
- [9] S. Chaudhry, A. Chu, A.S. Labar, D.A. Sala, H.J. van Bosse, W.B. Lehman, Progression of idiopathic clubfoot correction using the Ponseti method, *J. Pediatr. Orthop. B* 21 (1) (2012) 73–78.
- [10] M. Abbas, O.A. Qureshi, L.Z. Jeelani, Q. Azam, A.Q. Khan, A.B. Sabir, Management of congenital talipes equinovarus by Ponseti technique: a clinical study, *J. Foot Ankle Surg.* 47 (6) (2008) 541–545.
- [11] O.O. Adegbehingbe, L.M. Oginni, O.J. Ogundele, A.L. Ariyibi, P.O. Abiola, O.D. Ojo, Ponseti clubfoot management: changing surgical trends in Nigeria, *Iowa Orthop. J.* 30 (2010) 7–14.
- [12] V. Pavone, S. Bianca, G. Grosso, et al., Congenital talipes equinovarus: an epidemiological study in Sicily, *Acta Orthop.* 83 (3) (2012) 294–298.
- [13] I.V. Ponseti, E.N. Smoley, The classic: congenital club foot: the results of treatment, *Clin. Orthop. Relat. Res.* 467 (5) (2009) 1133–1145.
- [14] S. Pulak, M. Swamy, Treatment of idiopathic clubfoot by ponseti technique of manipulation and serial plaster casting and its critical evaluation, *Ethiop. J. Health Sci.* 22 (2) (2012) 77–84.
- [15] S.N. Maripuri, P.D. Gallacher, J. Bridgens, J.H. Kuiper, N.T. Kiely, Ponseti casting for club foot - above- or below-knee?: A prospective randomised clinical trial, *Bone Jt. J.* 95 (B(11)) (2013) 1570–1574.
- [16] L.F. Ferreira, M.P. Nogueira, J.C. Pereira, P.S. Duarte, Comparison of hospital costs and duration of treatment with two different clubfoot protocols, *Iowa Orthop. J.* 31 (2011) 49–51.
- [17] V. Wu, M. Nguyen, H.M. Nhi, et al., Evaluation of the progress and challenges facing the Ponseti method program in Vietnam, *Iowa Orthop. J.* 32 (2012) 125–134.