



A 14-year longitudinal comparison study of two treatment methods in clubfoot : Ponseti versus traditional

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The optimal management of idiopathic clubfoot has changed over three decades. Recently there has been an enthusiastic embracing of the Ponseti technique with a move away from the traditional stretch and strap technique. The purpose of this 14-year comparative prospective longitudinal study was to directly assess the differences in results between these two treatment methods.

Over the period of this study there were 52,514 births in the local population and all newborns with clubfoot were referred directly to the paediatric orthopaedic surgeon. Patient demographics, the Harrold & Walker Classification, and associated risk factors for clubfoot were collected prospectively and analyzed. If conservative treatment failed to correct the deformity adequately, a radical subtalar release (RSR) was undertaken (the primary outcome measure of the study).

There were 114 feet (80 patients) : 64 feet treated 'traditionally' and 50 feet with the Ponseti technique. Idiopathic clubfoot was present in 76.25% of patients. Mean time to RSR was 33.3 and 44.1 weeks for the traditional and Ponseti groups respectively. In the traditional group 65.6% (CI : 53.4 to 76.1%) of feet underwent RSR surgery compared to 25.5% (CI : 15.8 to 38.3%) in the Ponseti group. When idiopathic clubfoot alone was analysed, these rates reduce to 56.5% (CI : 42.3 to 69.8%) and 15.8% (CI : 7.4 to 30.4%) respectively. The Relative Risk of requiring RSR in traditional compared to Ponseti groups was 2.58 (CI : 1.59 to 4.19) for all patients and 3.58 (CI : 1.65 to 7.78) for idiopathic clubfoot.

Introduction of the Ponseti technique into our institution significantly reduced the need for RSR in fixed clubfoot.

Keywords : Ponseti ; congenital talipes equinovarus ; clubfoot ; radical subtalar release.

INTRODUCTION

Optimal management of clubfoot (Congenital Talipes Equinovarus) (CTEV) has been under much debate over recent years. Traditionally a period of stretching and strapping, or casting (5,10,17) is undertaken, with surgery for correction of any residual deformity. Soft tissue corrective surgery may be undertaken as an "a la carte" approach or a more radical single stage subtalar release through a Cincinnati incision (3,13,14). Surgical correction using bony procedures is reserved for older children

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or salvage surgery (4). A recent resurgence of the Ponseti method of treatment has seen increasing use worldwide, with good results when initiated early (2,15). Both methods have been used successfully for management of idiopathic clubfoot (2,4) however, until recently little literature existed on treatment of non-idiopathic (secondary) clubfoot with the Ponseti method (1,6).

To our knowledge, no prospective comparative studies of Ponseti vs traditional treatment of clubfoot exist. One study compared historic data of traditional treatment to the Ponseti method, they concluded, in their opinion posteromedial release could be avoided in most cases of idiopathic clubfoot (9). A more recent study (18) demonstrated a reduction in extensive surgery for idiopathic clubfoot in the United States over a ten year period. However, this was a retrospective study using International Classification of Diseases (ICD-9-CM) codes and as noted by the authors, was subject to errors due to the requirement for institutions to participate in data collection by the Nationwide Inpatient Sample (NIS), along with inherent errors associated with retrospective studies using ICD codes.

The aim of this study was to directly compare in a prospective longitudinal manner, the two treatment methods for clubfoot. The outcome measure was the rate of radical subtalar release surgery.

PATIENTS AND METHODS

At a single institution, a 14-year prospective comparative study of traditional vs Ponseti management of both idiopathic and non-idiopathic clubfoot was undertaken. The primary outcome measure was need for radical subtalar release (RSR) through a Cincinnati approach at a minimum of 13 months. Between January 1995 and December 2008, all newborns with clubfoot were referred to the senior author by paediatricians and obstetricians and a prospective database was kept. From this database all information was gathered. Patient demographics, the Harrold & Walker Classification (8), associated risk factors for clubfoot and operative intervention were analysed.

Over the period of this study there were 52,514 births. Neonates with clubfoot were referred urgently and seen by the senior author within days of birth. In mid 2002 the

senior author changed his practice from a traditional stretching and strapping technique (1995-2002) to the Ponseti method (2002-2008). For the traditional technique Lloyd-Robert strapping (Great Ormond Street, London) (5) was used with below knee self adhesive tape to initially correct the forefoot adductus, followed by abduction and eversion of the midfoot. When correction of the fore -and mid-foot was obtained, that of equinus and varus of the heel was carried out. The strapping was changed at least weekly and maintained for 6 weeks. For the second group the standard Ponseti method was used (15) with cast change weekly and percutaneous tendoachilles release (TAR) where necessary. Boots and bars (open-toed straight-last shoes with a Denis Browne bar as per Ponseti protocol (15)) were used after removal of final cast, constantly for 3 months, then nights for 1 year. Compliance in boots and bars was recorded prospectively by one orthotist, who recorded both parents history of compliance and a clinical estimate of compliance. The orthotist reviewed the child weekly for 4 weeks then every 4 to 8 weeks. Where parents admitted non-compliance, this was recorded, however a further clinical assessment of compliance was made by examination of the boots for wear both inside and out, grease and other stains.

At initial assessment the neonates were examined and checked for evidence of other medical conditions, their feet were graded by the Harrold and Walker (H & W) system (8). This method was used as it is a reproducible and validated scoring system (12), also the study pre-dates other more recent scoring systems. Grading was completed by the senior author on all patients using 3 measurements of ankle equinus with a goniometer. An average of the readings was used to calculate the final grade. This was a reproducible measurement as the H & W system uses 20 degree increments and has only 3 grades (8,12). Where the readings were borderline (within 1 degree) the patient was given the higher grade of classification.

The primary outcome measure for this study was the requirement for radical subtalar release (RSR) for the two groups. After primary management with the traditional or Ponseti method, the senior author assessed all feet for response. In the Ponseti group, if there was a tight heel cord, this was initially released percutaneously. In both groups if there was failure to achieve adequate resolution of the cavus, adductus, varus and equinus the child underwent RSR by the Cincinnati approach (3,13,14) with post-operative cast immobilisation for 4 to 6 weeks. In both groups repeated casting was used where deemed appropriate and in the Ponseti group repeated tendoachilles release was undertaken when necessary.

Only patients with fixed CTEV were included in this study, those with mobile deformities were excluded.

Analysis of results was undertaken for patients with idiopathic fixed clubfoot. In addition, children with syndromes/primary causes were included in an extended analysis. Power calculations, performed for the two groups using relative risk of RSR in the Ponseti vs traditional group at the 5% significance level, demonstrated a power of 96.84%. Statistical analysis was undertaken on Microsoft excel (Microsoft, USA) and using StatsDirect statistical software V2.7.7 (<http://www.statsdirect.com>. England : StatsDirect Ltd.) Relative risk (RR), 95% confidence intervals and T-tests were used with a p-value <0.05 considered significant. Ethical Approval was gained by the senior author prior to initiation of the database in 1991.

RESULTS

Over the 14 year period 114 feet (80 patients) had fixed clubfoot, 64 feet (45 patients) were treated traditionally and 50 feet (35 patients) with Ponseti method. Over the study period there were 52,514 births with an incidence of fixed clubfoot of 1.52 per 1000 live births. There were 59 males and 21 females with a ratio of 2.8 to 1.

Idiopathic clubfoot was present in 76.25% of patients. Of the 19 patients with a primary cause for the clubfoot, 7 had Arthrogryposis, 8 had other syndromic causes and 4 had a history of maternal intravenous heroin use, with the neonates needing to be weaned off this drug at birth. Of these patients with non-idiopathic clubfoot 12 (63% CI : 38 to 84%) were bilateral and 15 (79% ; CI : 54 to 94%) were H & W type III (severe deformity). The two

groups contained similar numbers of feet with non-idiopathic clubfoot : 29% and 24% of feet in the traditional and Ponseti groups respectively. This gave a non-significant risk difference of 0.06 (95% CI : -0.1114 to 0.22) between the two groups.

The H & W classification for the two groups can be seen in table I. Although both groups have equivalent proportions of type I, the Ponseti group has a significantly higher proportion of type III compared to the traditional group. Figure 1 shows the percentage of feet undergoing RSR for the 2 groups depending on the severity of the H & W classification.

For the two groups there was no significant difference between the mean time to RSR : 33.3 and 44.1 weeks for the traditional and Ponseti groups respectively (p = 0.09, CI : -0.94 to 22.6). In the traditional group 65.6% (CI : 53.4 to 76.1%) of feet underwent RSR compared to just 25.5% (CI : 15.8 to 38.3%) in the Ponseti group, When idiopathic clubfoot was analysed separately these rates reduce to 56.5% (CI : 42.3 to 69.8%) and 15.8% (CI : 7.4 to 30.4%) respectively (see Fig. 2). The Relative Risk of requiring RSR surgery in 'traditional' compared to Ponseti groups was significant at 2.58 (CI : 1.59 to 4.19) for all patients and 3.58 (CI : 1.65 to 7.78) for idiopathic clubfoot. In the non-idiopathic feet 89.5% (CI : 66.9 to 98.7) of the traditional group and 66.7% (CI : 34.9 to 90.1) of the Ponseti group needed RSR (a non-significant RR of 1.34, CI : 0.93 to 2.32).

Table II shows the number of feet referred per year and the proportion of RSR's undertaken. With change of technique in 2002 the proportion of RSR

Table I. — H & W classification for the two groups, idiopathic and non-idiopathic clubfoot. Percentage in brackets

		Harrold and Walker classification			Total
		I	II	III	
Idiopathic	Traditional	13 (29%)	23 (51%)	9 (20%)	45
	Ponseti	9 (23.5%)	4 (10.5%)	25 (66%)	38
	p value	0.59	<0.0001	<0.0001	
Non-idiopathic	Traditional	0	4 (21%)	15 (79%)	19
	Ponseti	0	0	12 (100%)	12
	p value			0.089	

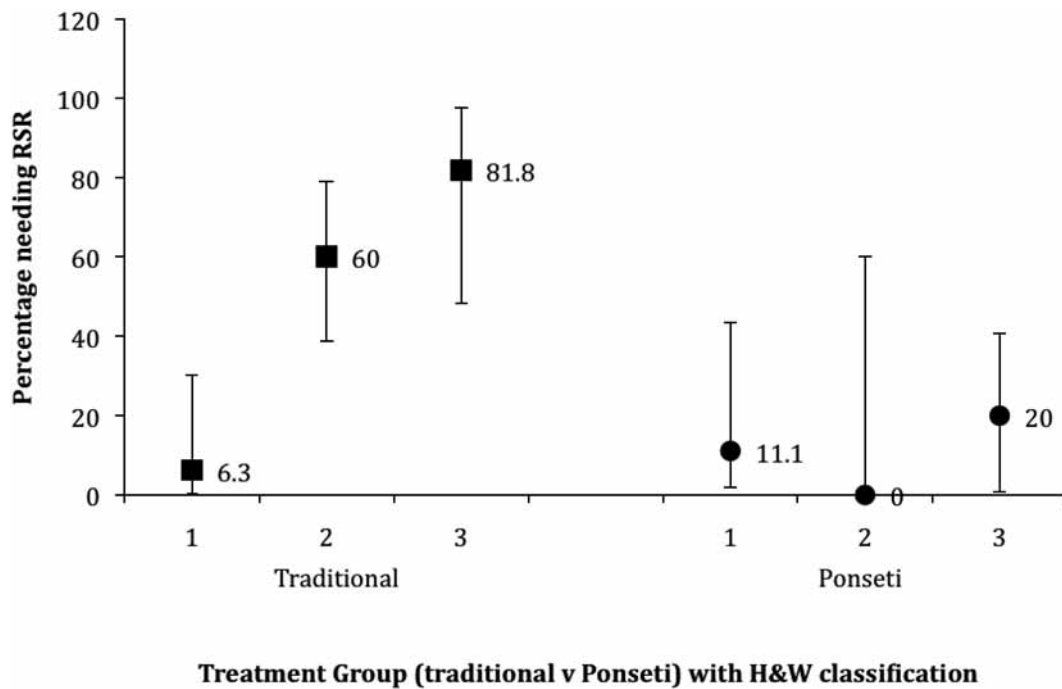


Fig. 1. — Idiopathic clubfoot- Percentage of feet requiring RSR for the traditional and Ponseti groups with reference to the H & W grade. 95% confidence interval shown as error bars.

decreased from this point. In 2003 5 feet (4 patients) underwent RSR : All had idiopathic clubfoot, 4 feet were H & W type III, 4 feet had TAR, with 2 re-cast and repeat TAR prior to RSR and 1 was non-compliant with boots and bars. One patient had a H & W I clubfoot that was refractory to Ponseti treatment. After initial casting, the foot drifted into equinus in boots and bars at 13 months of age. The senior author felt the tendoachilles and posterior structures were tight and elected to undertake a subtalar release. The child was last reviewed in outpatients at 4 years of age with a functionally excellent result and no significant residual deformity. This was the only case of RSR for a foot that was not classified as H & W III at presentation. In 2004 8 feet (4 patients) underwent RSR : all were H & W type III, all were associated with a primary cause (1 arthrogryposis, 1 syndrome and 2 maternal intravenous drug use) and 1 patient (2 feet) was non-compliant with boots and bars. Four feet (2 patients) had TAR prior to RSR. In 2005 one patient with a H & W III foot underwent RSR for unilateral idiopathic clubfoot. In 2007 one patient

with a syndromal cause for unilateral H & W III clubfoot had TAR. Failure to correct the deformity prompted RSR at 40 weeks.

Fifty six percent of feet treated by Ponseti method underwent TAR : 82.1% were H & W III, 14.3% H & W II and 3.6% H & W I.

Within the Ponseti group, the average time (and standard deviation) to boots and bars was 9.4 ± 5 weeks with a patient reported compliance of 86% (43 feet) but a clinically estimated compliance of only 62% (31 feet). Compliance rate was not related to the H & W classification or the presence of a primary cause.

DISCUSSION

The Ponseti method has demonstrated excellent short and long-term results for treatment of clubfoot (2,11), but it does not totally obviate the need for surgery. In Ponseti's own series (11) 46% had a transfer of tibialis anterior and 44% had further surgical procedures, including 2% of patients needing triple arthrodesis. Rates of early extensive soft

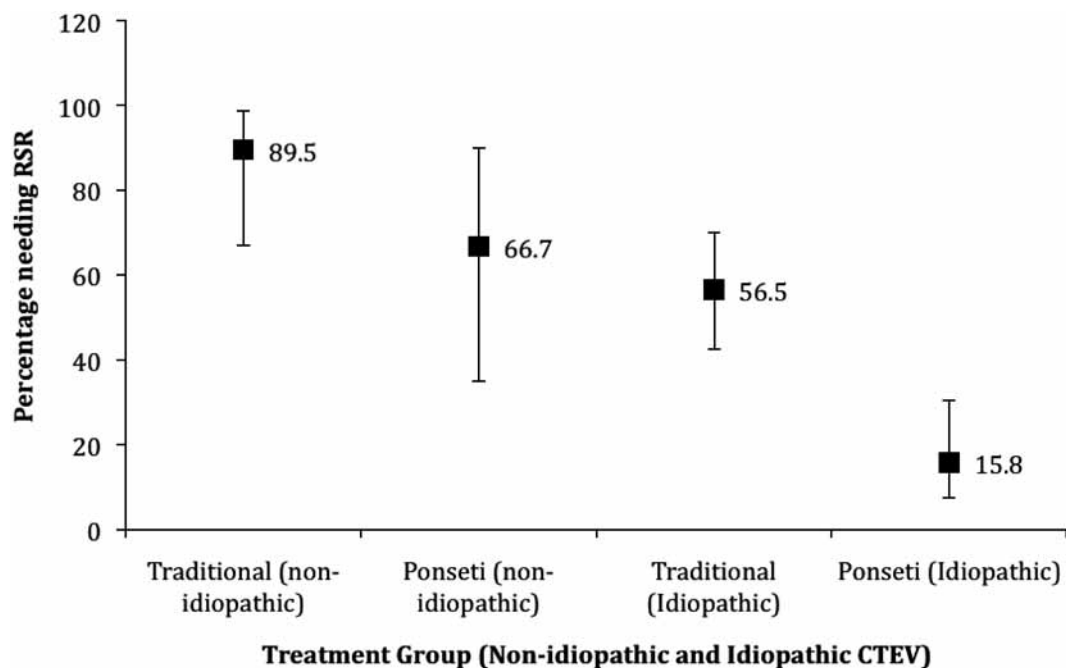


Fig. 2. — Percentage of feet requiring RSR for the traditional and Ponseti groups. Non-idiopathic and idiopathic. 95% confidence interval shown as error bars.

Table II. — Referral pattern over 14 years for Idiopathic and non-idiopathic clubfoot. Number of feet referred and proportion undergoing RSR

	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Idiopathic														
Number of Feet	7	8	6	5	5	4	10	0	8	5	5	3	6	11
Proportion RSR	43%	25%	33%	80%	60%	75%	80%	–	63%	0%	20%	0%	0%	0%
Non-Idiopathic														
Number of Feet	0	3	3	6	2	1	2	2	0	8	1	0	1	2
Proportion RSR	–	67%	100%	83%	100%	100%	100%	100%	–	100%	0%	–	0%	0%

tissue release in Ponseti treatment vary from 3% to 20% (7,9) and these rates are higher in traditional treatment (up to 91%) (9). Although numerous studies exist into both Ponseti and the more traditional stretch and strap technique, few compare the two (9) and to our knowledge no longitudinal comparative studies exist.

Our study allows direct comparison between two groups of neonates over a 14 year period. Eighty consecutive patients (114 feet) were compared with a change of practice from the traditional stretch and strap technique to the Ponseti method in 2002. The

second group of 35 patients represents the first patients treated by the senior author using the Ponseti method.

Our incidence of 1.5 per 1000 live births and male to female ratio of 2.8 to 1 is comparable to previous studies (11,17). For idiopathic clubfoot we noted a significant RR of 3.58 when comparing need for RSR between traditional and Ponseti groups. For the traditional group our rates of radical surgery are lower than other reports at 56.5% (9) and this may be due to a low proportion of H & W III feet (20%). A radical subtalar release rate of

15.8% was seen in the Ponseti group, which can be considered high when compared with previous series (9), however rates of 15% within 2 years (16) and 20% within an average 35 month follow-up (7) have been reported with the Ponseti treatment in other recent studies. In our Ponseti group there was a high proportion of H & W type III feet (66%) and a low level of compliance with boots and bars (62%). It can also be seen that the rates of RSR reduce as time passes (Table II) with 63% in the first year and 20% (1 foot of 5) in the 3rd year after change of practice. This one patient in 2005 had a severe deformity with a H & W III foot and parents who were non-compliant with boots and bars. He failed treatment with Ponseti casts and had a radical subtalar release at 67 weeks. In the last 3 years, no patient has had a RSR for idiopathic clubfoot and this reduction may represent an increasing confidence in the technique, of both the surgeon and the orthotist fitting and providing boots and bars.

Of the patients with non-idiopathic clubfoot, 89.5% treated traditionally and 66.7% of the Ponseti group underwent RSR, although there is a clinical difference in these rates, there was no significant statistical difference in relative risk between the two (Fig. 2). These were patients with severe deformities who are typically difficult to treat both operatively and by Ponseti methods (1,12). There were 7 patients (13 feet) with arthrogyposis, all were H & W type III feet and all but one patient were in the traditional group. The one patient in the Ponseti group (2004) had bilateral TAR and although compliant with boots and bars failed to respond to treatment and underwent staged RSR at 39 and 55 weeks. Although recent reports demonstrate a good response to Ponseti for arthrogyposis, with just one patient in this series, we cannot comment on the effectiveness in this condition with the Ponseti technique. Difficulty in treatment of arthrogyposis has been previously documented (1). Four patients (7 feet) in our series had to be weaned off heroin at birth for maternal intrauterine drug use. All feet were very rigid with H & W grade type III, 5 required RSR for resistance to non-operative treatment. 2 feet were treated in the traditional group requiring RSR and 5 in the Ponseti group (3 requiring RSR). Although fetal alcohol syndrome is

thought to be related to clubfoot (12) data on maternal drug use in early pregnancy is not available. The effects of substance abuse on the developing limbs in early pregnancy cannot be quantified, however these neonates demonstrated severely affected feet. It may be an effect of the impurities within the heroin injected, barbiturates and salicylate preparations have both been linked with clubfoot (17), or it may represent multi-drug or concurrent alcohol use. Although overall no significant reduction in RR was evident, it can be seen that the number of RSR for non-idiopathic clubfoot has reduced over the years, and this may be an increasing confidence in the technique by the surgeon and his team.

Although compliance within this group for boots and bars was acceptable at 86%, the clinically assessed compliance was lower at 62%, this is in agreement of previous studies (39%, 51%) (7,16). All casts were applied by the senior author and at 3 to 4 weeks of age the orthotist and parents were introduced. At this session the boots and bars were shown to parents who familiarised themselves with the equipment. The child was measured at this stage and the parents were told of the regime in detail, with any questions answered. Non-compliance was judged as wearing the boots for less than 22 hours per day in the first 3 months and removing the boots at night time prior to 1 year. Although non-compliance rate was high, there was no clinical or statistical relationship to rate of RSR, H & W classification or presence of a non-idiopathic cause.

Although initially we attempted to follow the Ponseti recommendation of 2 to 4 years of boots and bars, parental compliance was low with a sharp drop off at 8 months. This was in view of a parental education programme and open access review policy to allow further discussion. We therefore standardised the use of a one year period of immobilisation with boots and bars at night. We found that our patient group had a low compliance even in view of this shortened period. There is no good evidence that a prolonged period of immobilisation is necessary and future trials are needed to fully define the role of prolonged immobilisation. In our patient group H & W type I feet (less severe) treated 'traditionally' had a low recurrence rate of 6.3% with only 6 weeks of stretching and strapping and

no further immobilisation. This would suggest that in less severe feet, a shorter period of immobilisation may be appropriate.

Both the strengths and limitations of this study are the use of radical subtalar release as an end point. This gives a strong end point that allows direct comparison between the 2 groups. The Ponseti technique has had a direct influence on the need for radical surgery which has been clearly and significantly demonstrated. We admit that a longer term follow-up of clinical outcome would be advisable, however the average follow-up of the traditional group was 5 years and that of the Ponseti group 34.3 months (12.5 to 50.4). The average time to RSR was 39.57 weeks (95% CI : 36.15 to 42.99), less than the shortest follow-up of the Ponseti group (the later patients referred in December 2008). At the time of last follow-up there was no evidence of a recurrence of deformity demonstrated. For a short term study with a set endpoint, we believe adequate follow-up has been reached. Another limitation of this study is the classification system used. To keep the study as a level II comparative prospective study, only data collected within the database was used, as the database predates recent scoring systems, the Harrold and Walker classification was used throughout the study period. This is a validated system with good reproducibility and low intra-observer error (12).

These results represent a significant reduction in the need for radical surgery in our practice due to adopting the Ponseti method of treatment. We have seen excellent early results with this treatment change and the confidence of the surgeon and orthotist in the techniques used has grown over the years. We expect a continued reduction in need for surgery and although this is primarily a short term study, we aim to examine long term results in the future.

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