Comparison of Modified Posteromedial Release and Complete Subtalar Release in Resistant Congenital Clubfoot: A Randomized Controlled Trial

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Objective: *To compare the surgical results of modified posteromedial release with modified complete subtalar release in resistant congenital clubfoot in a randomized controlled trial*
Material and Method: *Eighty six children with 128 clubfeet, at an average of 5.9 months old (3-12 months) were operated on between 1996 and 2006 by a single surgeon. They were randomized into two groups. Group A, the modified posteromedial release was performed on 47 children with 69 clubfeet from 26 boys and 21 girls. Group B, the modified complete subtalar release was performed on 39 children with 59 clubfeet from 22 boys and 17 girls. Both groups received the same postoperative protocols. The mean follow up time was 15.1 months in group A (3-90 months) and 23.7 months in group B (3-120 months).*
Results: *There were no statistically significant differences of both groups between age, sex, side, bilaterality, and Dimeglio pre-operative evaluation. Most of the children ended up with satisfactory appearance of feet without major complications, neurovascular injuries, talonavicular dislocation, or avascular necrosis of the talus. Mild forefeet adduction was found in 10 feet in group A and in 5 feet in group B but all feet were flexible and reducible to normal alignment of the feet. Two feet in group A and one foot in group B were re-operated by soft tissue release without bone surgery and had fair results. Four feet in group A and two feet in group B got soft tissue infection and resolved in a few weeks by dressing and antibiotics. The postoperative mean Ponseti score was 89.6 (75-100) points in group A and 88.2 (70-98) points in group B without statistically significant difference ($p = 0.25$). The Turco postoperative evaluation of both groups was not statistically significantly different ($p = 0.17$). The good and excellent results from Ponseti score was 85.5% in group A and 89.9% in group B. The correlation coefficient (r) between Ponseti and Turco evaluation was 0.81.*
Conclusion: *The clinical and statistical significant difference were not found in the surgical results of modified posteromedial release and modified complete subtalar release in resistant clubfeet.*

Keywords: *Modified posteromedial release, Modified complete subtalar release, Resistant clubfoot, Dimeglio, Ponseti, Turco*

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There are many treatment regimens for congenital clubfoot. The initial treatment should be started by non-operative management using manipulation and strapping or by casting. If the deformity did not resolve in 4-5 months surgical intervention was considered. Many surgical procedures were recommended including the soft tissue release (lengthening of the tendon and releasing the contracted capsule and ligaments), osteotomy, talectomy etc. In young children all surgeons normally do correction of the clubfoot only in the soft tissue by stretching, casting, and lengthening of the tendon. In 1971, Turco[1,2] introduced a one stage posteromedial release and presented the 83.8% good and excellent results in 1979. Mckay[3-6] presented the new concepts of horizontal subtalar rotation in 1983 and Simons[7] gave the 72% satisfactory results of the complete subtalar release in 1985. The following

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articles gave good surgical results in case series using only one of these two techniques[8-14] and both techniques became the standard treatment in resistant clubfeet. The comparison of the results of these two surgical treatments was few and made different conclusions by different research designs[15-20]. Even though both treatments were standard treatments in clubfoot, there were some different complications. The adduction and under correction of the forefoot were common in the posteromedial group and the valgus and overcorrection of the hindfoot were common in complete subtalar group. The aim of the present study was to compare the clinical surgical results between modified posteromedial release and modified complete subtalar release in better design by a randomized controlled trial.

Material and Method

From January 1996 to May 2006, after being approved by the hospital research ethical committee and complete explanation to their parents with informed consent, the children with an age range from 3 to 12 months with resistant congenital clubfoot were included in the present study. The children with arthrogryposis multiplex congenita, myelomeningocele, cerebral palsy, any syndromic clubfoot, and failed previous clubfoot surgery were excluded. Eighty-six children, including 48 boys and 38 girls in 128 clubfeet from 42 bilateral involvements were categorized into two groups by simple randomization. The surgeon blindly opened the envelope that indicated the type of surgery. All operations were performed by the same surgeon. Group A, the modified posteromedial release was performed on 47 children, 26 boys and 21 girls, in 69 clubfeet from 22 bilateral involvements. Group B, the modified complete subtalar release was performed on 39 children, 22 boys and 17 girls, in 59 clubfeet with 20 bilateral involvements. The demographic data of all children were recorded and shown in Table 1. The Dimeglio preoperative assessment was scored from 0-20 and divided into four groups from group 1 with soft feet to group 4 with very stiff feet[21] (Table 2).

Surgical techniques

The operations were done under general anesthesia using tourniquet in all cases. In group A, the standard posteromedial approach was used. The following procedures were followed, the tendoarchillis lengthening, tibialis posterior lengthening, releasing the abductor hallucis at the oigin, the capsulotomy of the talonavicular, the posterior tibiotalar, the talocalcaneal and the medial calcaneocuboid joint, division of plantar, calcaneofibular, superficial deltoid, spring ligament and master knot of Henry. The lengthening of the flexor hallucis longus and flexor digitorum longus were done in some selected feet with flexion of the toe occurring after correcting the feet in the neutral position. The deep deltoid and talocalcaneal ligament were preserved. In group B, the standard complete subtalar release using the Cincinnati incision without cutting the talocalcaneal and deep deltoid ligament approach was used. The talonavicular and calcaneocuboid joint were opened on both the medial and lateral sides. After surgery, both groups received the same postoperative program including the removal of Kirschner wires from talonavicular and talocalcaneal joint in 6 weeks and removal of the long leg casts in 12 weeks. The orthopedic shoes or Denis-Browne orthosis were prescribed.

All feet were evaluated according to Ponseti evaluation from score 0-100 points. In Ponseti scores the results were classified according to the points from excellent in 90 to 100 points, good in 80 to 89 points, fair in 70 to 79 point and poor in the score less than 70 points. The Turco evaluation (Table 4) was also used and graded from poor, fair, good to excellent results. Comparison between both groups, group A and group B was done.

The sample size calculation was done using the equivalent study formula because from the pilot study the mean Ponseti score was nearly the same in both groups.

$$\text{n / group} = \frac{2\sigma^2}{(\mu 1 - \mu 2 - \delta)^2}\left(Z_{\alpha/2} + Z_{\beta}\right)^2$$

(δ = the equivalent limit = 5, σ = the standard deviation = 5.22, $\mu_1 - \mu_2 = 0$, $\propto = 0.01$, $\beta = 0.01$, Power = 99, n = 48/group)

Statistical analysis

Mean and standard deviation (SD), range and frequencies (%) were used to describe patients' characteristics. Chi square test was used to compare categorical variables between group. Student's t test was used to assess differences between two means. All analyses were performed using SPSS program. A p-value of less than 0.05 was considered statistically significant.

Results

There were no neurovascular injuries. Four feet in group A and two feet in group B had skin infection and all resolved in a few weeks by dressing and

Table 1. General characteristic variables of both groups

Variables		Group A		Group B (N=39)		p-value
		Number of children	%	Number of children	%	
Sex	Boy	26	55.3	22	56.4	0.1
	Girl	21	44.7	17	43.6	
	Total 86 Children	47	100	39	100	
Side	Unilateral	25	53.2	19	48.7	0.8
	Bilateral	22	46.8	20	51.3	
	Total 86 children	47	100	39	100	

Table 2. Preoperative evaluation (Dimeglio) of both group

Dimeglio Group	Group A		Group B		p-value
	Number of feet	%	Number of feet	%	
1	1	1.4	2	3.4	0.06
2	26	37.7	28	47.5	
3	35	50.7	29	49.2	
4	7	10.7	0	0	
Total 128 feet	69	100	59	100	

Table 3. Results of surgery in Ponseti evaluation of both group

Ponseti score	Group A			Group B			p-value
	Number leg	%	Mean score	Number leg	%	Mean score	
Score > 90 Excellent	40	58.0		28	47.5		0.25
Score 80-89 Good	19	27.5		25	42.4		
Score 70-79 Fair	10	14.5	89.6 (75-100)	6	10.2	88.2 (70-98)	
Score < 70 Poor	0	0		0	0		
Total 128 legs	69	100		59	100		

Table 4. Results of surgery in Turco evaluation of both group

Turco result	Group A		Group B		p-value
	Number of feet	%	Number of feet	%	
Excellent	13	18.8	7	11.9	0.17
Good	38	55.1	31	55.5	
Fair	17	24.6	20	33.9	
Poor	1	1.4	1	1.4	
Total 128 feet	69	100	59	100	

antibiotics. All of the feet had no talonavicular subluxation by radiography and got plantigrade feet. Two feet in group A and one foot in group B had recurrent deformities with re-operations done. They ended with fair results. Mild forefoot adduction but flexible was a common complication. There were ten feet in group A and 5 feet in group B with mild adduction.

In Table 1, the comparison of the general characteristics of the children in both groups was no statistical difference in sex and side. The mean age was 5.8 months in group A (3-12 months) and 6.0 months (3-12 months) in group B. The mean follow up time was 15.1 months in group A (4-38 months) and 23.7 months (4-120 months) in group B. Both age and follow up time were not statistically significantly different ($p = 0.5$ and 0.1 respectively). In Table 2, the preoperative Dimeglio evaluation was also not statistically significantly different between both groups but group A had slightly more severe feet (7 feet) than group B (0 feet). In Table 3, the Ponseti evaluation of both groups, the mean score was 89.6 (75-100) in group A and 88.2 (70-98) in group B without statistically significant difference ($p = 0.25$). The 95% confidence interval of the difference was from -0.9 to 3.8. The good and excellent results were 85.5% in group A and 89.9% in group B. In Table 4, the Turco evaluation of both groups, the good and excellent results were 73.9% in group A and 67.4% in group B with no statistical significant difference between both groups ($p = 0.17$). The Turco had a higher score than Ponseti but also the correlation coefficient of both scores was high ($r = 0.81$).

Discussion

Even though the non-operative treatment for congenital clubfeet is recommended and Ponseti[22] showed a high rate of success, the operative treatment still should be strongly considered in some selected cases after failure of non-operative treatment. The results of the present study showed no difference between limited and aggressive surgery. Most of the comparative studies[16-20] were not randomized controlled trials and showed superior results from complete subtalar release more than from posteromedial release except from the study Manzone[15]. The result of the present study was quite similar to Manzone[15] who studied 30 idiopathic resistant clubfeet with a prospective randomized study. In Manzone's study at short-term follow-up, no significant differences were found in radiological and functional results between the two surgical procedures for idiopathic clubfoot. The sample size in the present study was larger and adequate by sample size calculation with a longer period of follow up. The authors' personal experience found that the Cincinnati incision made more cosmetic scar than the posteromedial incision with also better exposure in releasing the posterior and lateral part of clubfeet. From the present research, the authors recommend that in resistant clubfeet, the limited Cincinnati incision should be used and the modified posteromedial release can be followed by this incision without opening the calcaneocuboid joint. The successful rate was not different with modified complete subtalar release by the present study.

Conclusion

There was no statistically significant difference between modified posteromedial release and modified complete subtalar release in resistant congenital clubfoot.

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การศึกษาเปรียบเทียบแบบสุ่มทดลองระหว่างการผ่าตัดรักษาโรคเท้าปุกในเด็กชนิด Modified posteromedial release และ modified complete subtalar release

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วัตถุประสงค์: *เพื่อศึกษาเปรียบเทียบแบบสุ่มทดลองระหว่างการผ่าตัดรักษาโรคเท้าปุกในเด็กชนิด modified posteromedial release และ modified complete subtalar release*

วัสดุและวิธีการ: *ตั้งแต่ปี พ.ศ. 2539 - พ.ศ. 2549, เด็กจำนวน 86 คน เป็นเท้าปุก จำนวน 128 เท้า อายุเฉลี่ย 5.9 เดือน (3-12 เดือน) ได้รับการผ่าตัดโดยศัลยแพทย์ท่านเดียว และสุ่มเลือกการผ่าตัดเป็น 2 วิธี กลุ่ม A ได้รับการผ่าตัดโดยวิธี modified posteromedial release จำนวน 47 คน เด็กชาย 26 คน เด็กหญิง 21 คน มี 69 เท้าปุกกลุ่ม B ได้รับการผ่าตัดโดยวิธี modified complete subtalar release จำนวน 39 คน เด็กชาย 22 คน เด็กหญิง 17 คน มี 59 เท้าปุก หลังการผ่าตัด ได้รับการดูแลเหมือนกันทั้งสองกลุ่ม และตรวจติดตาม เฉลี่ย 15 เดือน ในกลุ่ม A (3-90 เดือน) และ 23 เดือนในกลุ่ม B (3-120 เดือน)*

ผลการศึกษา: *ไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติของ 2 กลุ่ม ก่อนการผ่าตัดในเรื่องอายุ, เพศ, ข้างที่เป็น และการตรวจประเมิน Dimeglio ผลการรักษาส่วนมากดี ไม่พบผลแทรกซ้อนที่รุนแรง ผลแทรกซ้อนชนิดฝ่าเท้าเข้าใน 10 เท้าในกลุ่ม A และ 5 เท้าในกลุ่ม B มีการผ่าตัดซ้ำ 2 เท้าในกลุ่ม A และ 1 เท้าในกลุ่ม B และมีการติดเชื้อซึ่งหายดีใน 2 สัปดาห์ 4 เท้าในกลุ่ม A และ 2 เท้าในกลุ่ม B การวัดผลด้วยคะแนน Ponseti เฉลี่ย 89.6 (75-100) ในกลุ่ม A และ 88.2 (70-98) ในกลุ่ม B และคะแนน Turco ไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติ (p = 0.25) ผลการรักษาดีและดีมากด้วยคะแนน Ponseti 85.5% ในกลุ่ม A และ 89.9% ในกลุ่ม B*

สรุป: *ไม่พบความแตกต่างของผลการรักษาเท้าปุกด้วยวิธีผ่าตัดระหว่างวิธี modified posteromedial release และ modified complete subtalar release*