

<sup>1</sup> University of Medicine and Pharmacy "Iuliu Hatieganu" Cluj-Napoca, Surgical specialties department

<sup>2</sup> University of Medicine and Pharmacy "Iuliu Hatieganu" Cluj-Napoca, Medical informatics department

#### Abstract

The aim of this study was to find out the role and importance of foot abduction brace after the completion of clubfoot treatment by Ponseti method. In the interval 2014-2016, a series of 51 children (74 feet) suffering of clubfoot were treated according to the Ponseti method in our department. Of them, 36 children satisfied the inclusion criteria in the study. Compliance with orthoses was defined in the terms below: 23 hours/day in the first three months after the cast removal and minimum 8 hours/day up to the age of 3 years. Non-compliance was defined as the incapacity of observing the criterion mentioned above up to the age of 18 months.

Out of the 36 patients, 25 (69%) patients (35 feet) complied with the requirement and 11 (31%) patients (15 feet) did not comply with the foot abduction orthoses. At the age of 18 months, it was found out that in the non-complying group, the Pirani score increased significantly as compared to the complying group which means a deterioration of the initial result. Another finding with reference to the foot abduction orthoses complying group is that the Pirani score was maintained or improved significantly (p<0.05), while with the non-complying group the initial results obtained by plaster casts were damaged due to lack of use of orthoses (p<0.05).

We consider the correct use of the foot abduction orthoses as essential for the conservative treatment of the clubfoot according to the Ponseti method, in spite of the obstacles sometimes put by parents.

Key words: clubfoot, orthoses, Ponseti,

#### Introduction

Nowadays, the "golden standard" for clubfoot treatment is represented by the Ponseti method (manipulation and casting, followed by percutaneous tenotomy of the Achilles' tendon). At the end of the correction phase, the feet are placed in the foot abduction braces (FAB) to prevent the relapses [1].

The failures of the Ponseti method in the treatment of congenital clubfoot were associated with the noncompliance to the FABs due to the long period for utilization of the braces (2-4 years) and to the psychological factors associated with the usage of the splints [2, 3].

So far, the study of the extrinsic factors contributing to the success of the Ponseti method was neglected. The aim of this study is to evaluate the importance of foot abduction brace after the correction of the feet by the Ponseti method in preventing the relapses and the correlation between compliance to the brace usage and the level of education of the families of children treated by Ponseti method. Recognition of the risk factors associated with the relapses will allow a better analysis of the patients prone to relapses in order to improve the measures for successful outcome.

#### Material and method

In the period 2014 - 2016, 51 children (74 feet) were treated in our service for idiopathic congenital

clubfoot using the Ponseti method. Of them, 5 patients were above 6 months of age and were excluded from the study group. Mean age of the patients included in the study (46 patients) was 12 weeks (limits 2- 24 weeks). 8 patients from the group were lost at the 18 months follow-up and were excluded also from the study. Therefore, the final study group consisted of 36 children (22 unilateral clubfoot, 14 bilateral clubfeet) and 50 clubfeet.

In 2 cases (4 feet) the brace used was Dennis-Browne orthoses (fig. 1), and for the rest of the patients we used the Ponseti foot abduction brace. In all cases the distance between the heels was the bi-acromial distance and the abduction angle was  $60^{0}$  for the affected foot and  $30^{0}$  for the normal foot. The dorsiflexion angle was  $15^{0}$  in all cases.



Fig. 1 Dennis-Browne foot abduction brace

The compliance to the FAB regimen was defined as the usage of the braces for 23 hours/day in the first 3 months and at least 12 hours/day until the age of 4 years. The non-compliance was denied as the inability to conform to the above rules.

For the analysis of the risk factors associated with the unfavorable evolution (increase of the Pirani score) we calculated the relative risk using the EpiInfo software. For each variable we calculated the odds ratio in the confidence interval of 95% and p values [4].

# Results

25 patients (35 feet), representing 69% out of the total 36 patients in the study group were compliant the brace usage and 11 patients (15 feet, 31%) were not compliant. Sex ratio girls: boys was 1:2 in both groups. The mean age at first presentation in the compliant group was 10 weeks (limits 2-24 weeks) and 12 weeks in the non-compliant group (limits 6-24 weeks), without a statistical difference (p>0.05). The final evaluation was done at the age of 18 months, with a mean follow-up period of 18 months. The initial Pirani score before the treatment was not significant different between 2 groups (p>0.05). Mean number of castings was the same 6 (limits 1-7) in both groups. In the compliant group, the percutaneous tenotomy of the Achilles' tendon was performed in 31 feet and in 13 feet in the non-compliant group.

At the end of the clubfoot treatment by Ponseti method, the mean Pirani score was the same in both groups.

At the 18 months follow-up, the mean Pirani score increased in the non-compliant group comparing with the compliant group (tab. I).

In the compliant group, the Pirani score remained the same or significantly improved, (p<0.05), whereas in the non-compliant group the evolution deteriorated (p<0.05) (tab. II).

In the study group, the parents of 10 children had university studies. Of them, 9 (90%) were compliant to the use of braces, whereas from the group of parents with high school studies (26 patients), 16 (61%) were compliant to the braces (tab. III).

#### TABLE I

Pirani score at the age of 18 months

Score	Compliant group (mean)	Non-compliant group (mean)	р
Pirani	0.5	1.0	0.02

# TABLE II

Evolution of the Pirani score at the age of 18 months

Score	Compliant group (mean)			Non-compliant group (mean)			
	End of treatment	At 18 months	Difference	End of treatment	At 18 months	Difference	
Pirani	0.5	0.5	0	0.5	1	+0.5 increase	

# TABLE III

Distribution of the patients according to the level of studies and compliance to the braces

Variable	Value	Compliance (no. patients)		Odds ratio	]
		Yes	No		
Level of parents' studies	High school (or lower)	10	16	5.63 (0.55- 137.03)	0.09
	University	1	9	1.00	-

# Discussions

Our study showed a significant percent (31%) of noncompliance to the brace regimen among children treated for clubfoot using the Ponseti method. This fact determined us to study the effects of noncompliance on the treatment results. The analysis of the non-compliant patients showed that they do not use anymore the braces after the 3 months of non-stop usage. Usually this is the moment when the parents are aware of the full correction of clubfoot deformities and they consider the end of the treatment. In the following months they continue the use of the orthoses as an established routine, but afterwards they discontinue the use of them.

Analyzing the risk factors for the relapses, we consider that the compliance rate is strongly associated with the relapse. The child in a family that is non-compliant to the bracing regimen is 33 times more prone to the relapse than a child compliant to the brace [5].

The education level of the parents of children with clubfoot does not significantly influence the compliance to the braces, but there is an increased tendency in the families with university studies to be more compliant (p=0.09).

The study of Dobbs et al. [6] in 2004 showed a 41% non-compliance rate amongst the children treated by Ponseti method. The authors showed a strong relationship between non-compliance to the brace regimen and relapses of clubfoot, and also between level of studies of parents and relapse rate, but other risk factors like sex, race, marital status of parents, family income, or age at first presentation were not confirmed.

Our study evaluated the results of clubfoot treatment by Ponseti method in compliant and non-compliant patients to the bracing regimen. Initial both groups were similar. All feet followed the same treatment protocol, with the same number of casts and the same percent of Achilles' tenotomies. The mean initial Pirani score was the same in both groups, but the evolution of non-compliant patients deteriorated until the age of 18 months. In the opposite, the evolution of the compliant patients improved.

# Conclusion

We consider that the correct usage and strict adherence to the bracing protocol are essential for the success of clubfoot treatment by Ponseti method and all the diligences should be made to the parents to strictly follow the recommendations.

#### References

- 1. Ponseti IV, Clubfoot management, J Pediatr Orthop. 2000; 20(6): 699-700
- McConnell L, Cosma D, Vasilescu D, Morcuende J, Descriptive epidemiology of clubfoot in Romania: a clinic-based study, Eur Rev Med Pharmacol Sci. 2016; 20(2): 220-224
- 3. Ponseti IV, Treatment of congenital club foot, J Bone Joint Surg A. 1992; 74(3): 448-454
- 4. Valeanu M, Cosma S, Cosma D, Moldovan G, Vasilescu D, Optimization date for redistributed system with applications, International Journal of Computers Communications & Control. 2009; 4(2): 178-184
- Cooper DM, Dietz FR, Treatment of idiopathic clubfoot, J Bone Joint Surg Am. 1995; 77: 1477-1489
- 6. Dobbs MB, Rudzki J, Purcell D, Walton T, Porter KR, Gurnett CA, Factors predictive of outcome after use of the Ponseti method for the treatment of idiopathic clubfeet, J Bone Joint