

ARE SCORING SYSTEMS USEFUL FOR PREDICTING RESULTS OF TREATMENT FOR CLUBFOOT USING THE PONSETI METHOD?

OS SISTEMAS DE PONTUAÇÃO SÃO ÚTEIS PARA PREVER OS RESULTADOS DO TRATAMENTO DE PÉ TORTO EQUINOVARO PELO MÉTODO DE PONSETI?

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ABSTRACT

Objective: The aim of this study was to verify whether the Pirani and Dimeglio clinical scoring systems could predict results of Ponseti therapy. **Methods:** Forty-seven patients with clubfoot deformities treated with the Ponseti method were enrolled in the study. Clinical evaluation with the Pirani and Dimeglio scoring systems was performed before the treatment and after the second cast fixation. The number of fixations, necessity for achillotomy, and recurrence of the deformity were determined as parameters of the therapy results. The patients were divided into three groups according to the severity of their deformities, and the groups were compared with one another. **Results:** Clubfoot correction required an average of 6.8 casts. Five patients developed a recurrence. Comparing the therapy outcomes among the groups, we found statistically significant differences in the Pirani classification after the second fixation (the number of casts [$p = .003$] and necessity to perform an achillotomy [$p = .014$]) and in the Dimeglio scores before therapy (number of casts [$p = .034$]) and after the second fixation (number of relapses [$p = .032$]). **Conclusion:** Although clinical scoring systems showed some dependence on the parameters of treatment outcomes, their predictive function can be used in only a limited way. **Level of evidence II, Prospective comparative study.**

Keywords: Club foot. Foot deformities, congenital, Foot.

RESUMO

Objetivo: O objetivo deste estudo foi verificar se os sistemas de pontuação clínica de Pirani e Dimeglio poderiam servir para prever os resultados do tratamento com o método de Ponseti. **Métodos:** Quarenta e sete pacientes com diagnóstico de pé torto equinovaro tratados pelo método de Ponseti foram incluídos no estudo. A avaliação clínica com os sistemas de pontuação de Pirani e Dimeglio foi realizada antes do tratamento e depois da segunda fixação de gesso. O número de fixações com gesso, a necessidade de realização de aquilotomia e a recorrência da deformidade foram determinadas como parâmetros dos resultados do tratamento. Os pacientes foram divididos em três grupos, de acordo com a gravidade das deformidades, e esses grupos foram comparados entre si. **Resultados:** A correção do pé torto exigiu uma média de 6,8 gessos e cinco pacientes apresentaram recidiva. Ao comparar os resultados do tratamento entre os grupos, verificou-se diferença estatisticamente significativa na classificação de Pirani após a segunda fixação (número de gessos [$p = 0,003$], necessidade de realizar aquilotomia [$p = 0,014$]) e pontuação de Dimeglio antes do tratamento (número de gessos [$p = 0,034$]) e depois da segunda fixação (número de recidivas [$p = 0,032$]). **Conclusão:** Embora os sistemas de pontuação clínica tenham mostrado alguma dependência dos parâmetros dos resultados do tratamento, sua função preditiva pode ser usada de maneira limitada. **Nível de evidência II, Estudo comparativo prospectivo.**

Descritores: Pé torto equinovaro. Deformidades congênitas do pé. Pé.

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INTRODUCTION

Pes equinovarus congenitus (clubfoot) is the most common structural deformity of the foot with an incidence of 1–2/1000 births.¹⁻³ Nowadays, the Ponseti method represents the gold standard treatment option for clubfoot deformity. It showed to be more effective and save method with less complications compared to the primarily surgical treatment.^{4,5} The deformity is reduced by weekly

manipulation and application of plaster casts gradually correcting all components of the deformity.

According to various authors, about 7%–10% are treatment-resistant feet and they recorded up to about 14% of recurrences.⁶⁻⁸ Currently, it is difficult to determine the parameters that would reliably predict these cases at the beginning of treatment.

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Study was conducted at the Medical Faculty, Faculty Hospital, Masaryk University, Brno, Czech Republic.

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The most commonly used method to evaluate clubfoot is by using clinical classification systems. The most preferred are Pirani⁹ and Dimeglio scores¹⁰. Despite their sophistication, ratings are subject to the subjective view of the investigator in every scoring system.^{6,11} Their limitations do not quite define the aspects of the whole deformity of the leg, which can be crucially involved in the rate of success of deformity therapy (for example ultrasound parameters)¹²⁻¹⁴ which the scoring systems themselves do not have to take fully into account. Thus, a clear relationship between clinical classification and prognosis of treatment is still not clear. However, by using these scoring systems, it is possible at least partially to approximate an estimate of the further development of the deformity treated by the Ponseti method.

The aim of this prospective study was to determine the possible relationship between the Pirani and Dimeglio evaluation score systems at the start and during a treatment of clubfoot and the course and outcome of treatment on relatively large group of patients treated in our institution. The criteria for the success of the course and the treatment outcome were the number of necessary cast fixations for correction, the number of necessary percutaneous tenotomies of the Achilles tendon and the number of recurrences of clubfoot deformity.

MATERIAL AND METHODS

The set of patients

The analyzed group consisted of 47 patients, all treated by the first author of the study (JJ) between May 2013 and July 2016.

The group patients consisted of 30 boys (63.8%), 17 girls (36.2%), in 29 cases with right-side deformity (61.7%); in the remaining 18 (38.3%) cases, the left foot was involved. The mean age at the beginning of therapy was 20 days.

Inclusion criteria for inclusion to our study consisted of only patients with idiopathic and unilateral forms of deformity, who did not undergo previous or later treatment elsewhere and did not undergo any surgery on the affected limb prior to our initiation of Ponseti therapy. This work was approved by the Ethics Committee (03-12/ECUHB/2013) of our Hospital and with Informed Consent of parents of patients.

Clinical scoring systems

For incoming clinical evaluation and evaluation of the course of treatment, the controls were actually assessed by two clinical evaluation systems. One was a system developed by Professor Pirani (2002).⁹ The Pirani classification uses for the deformity component of the clubfoot 0, ½, and 1 point to evaluate the degree and severity of the deformity. In particular, the hind and medial part of the foot are evaluated separately. In each of these parts, we evaluated three parameters: the hind foot contracture score (HCFS), dorsal crease, empty heel, and rigid equinus; and the mid-foot contracture score (MFCS), medial crease, lateral edge convexity, and talus head position. The maximum number of points corresponding to the deformity is six. The European Paediatric Orthopaedic Society (EPOS) prefers and recommends a scoring system used by French authors from Montpellier, led by Professor Alain Dimeglio (1995),¹⁰ which uses for classification the degree of rigidity of the foot: I. st. soft-soft; II. st. soft-stiff; III. st. stiff-soft; and IV. st. stiff-stiff deformity. Dimeglio's classification has 20 points and distinguishes four basic parameters (equinosity in the sagittal plane, varus deviation in the frontal plane, deformation of the block calcaneus and forefoot, and adduction of the forefoot in the horizontal plane), evaluated on a scale from 0 to 4 points, and another four adverse symptoms (dorsal crease, medial crease, cavus deformity, and calf hypotrophy), rated 1 point each.

The patients were carefully examined clinically in our department, and the severity of the deformity was scored according to the

above-mentioned systems at the beginning of the therapy, prior to application the first cast, and subsequently repeated during the treatment. For statistical evaluation, the relationship between the severity of deformity according to both classification systems and the success-of-treatment criteria were used as the pre-treatment score and the score after a second cast fixation, respectively.

The number of required fixations was determined individually according to the condition of the foot, and the criteria for subsequent percutaneous achillotomy were also strictly defined. This was indicated when the dorsiflexion of the foot was impossible at least 10° after complete redress casting. We have consistently provided a classically adequate postoperative Ponseti regimen, with monitoring and other therapy (Figure 1).

Statistical analysis

Statistical analysis of our data was divided into two levels. Descriptive data for the continuous variables are presented as an average and a standard deviation; percentage distribution (%) was used for the category variables.

In the first phase, the statistical analysis was used to evaluate the dependencies between the classification systems and the parameters determining the effect of therapy by the Ponseti method. Depending on the nature of the variables, the Pearson, Spearman, or dot biserial correlation coefficient was used.

In the second phase, patients were divided into three groups according to the severity of the deformity. Patients were divided by using the Pirani scoring system into group 1 with 3–4 points, group 2 with 4.5–5 points, and group 3 with 5.5–6 points. When using the Dimeglio classification, group 1 had 6–10 points, group 2 had 11–15 points, and group 3 had 16–20 points. The results of treatment were subsequently compared between groups by using the Kruskal-Wallis test for continuous variables (number of cast fixations) or Chi-square test for binary variables (achillotomy, recurrence).

IBM SPSS Statistics 20.0 software was used for statistical analysis, and all tests were performed at a statistical significance level of 0.05.

RESULTS

Of the 47 patients with unilateral equinovarus deformity, 36 of them (76.5%) underwent an achillotomy. Recurrence of deformity developed in five patients of the set (10.6%) during the follow-up period. To correct the deformity, it was necessary to use an average of 6.8 redress casts (4-10). The average preliminary score of 4.63 points by Pirani (3-6)



Figure 1. Ponseti casting.

and 15.4 points by Dimeglio (7-20) was assessed. Pirani's average score after the second fixation was 3.58 points (2-4.5) and Dimeglio's score at this stage of treatment was 11.22 points (6-16). The general characteristics of the population parameters are shown in Table 1. The relationship between the number of cast fixations and classification systems had a significant correlation in all cases, with the strongest dependence of correlation in the Pirani score after the second correction fixation ($r = .572, p < .001$).

Positive correlation was also found between the necessity of achillotomy and both classification systems. In this case, the correlation of the clinical score according to Pirani after the second cast fixation ($r = .492, p = .003$) showed the strongest.

Conversely, no significant correlation was found between recurrence and the classification system that was used, even in one case ($p = > .05$). The complete results of the relationship are shown in Table 2.

When dividing patients into groups according to the severity of deformity assessed according to classification systems, there was no difference between the groups in the treatment results, according to the Pirani score before treatment. On the other hand, a statistically significant difference was found in the number of cast fixations ($p = .003$) and the necessity to perform achillotomy ($p = .014$) between the groups when the scoring was performed after the second casting. A statistically significant difference was found in the Dimeglio scoring prior to therapy between groups in the number of cast fixations ($p = .034$) and in the same scoring system after the second cast fixation in the number of relapses ($p = .032$). Table 3.

DISCUSSION

Although the prediction of the course and outcome of clubfoot treated by Ponseti method would be very useful and desirable,

Table 1. General characteristics of population.

	Average
Age at the beginning of therapy (days)	20 ± 7.4 (7 – 42)
Pirani score before therapy	4.63 ± 0.8 (3 – 6)
Pirani score after second fixation	3.58 ± 0.7 (2 – 5)
Dimeglio score before therapy	15.4 ± 3.8 (7 – 20)
Dimeglio score after second fixation	11.22 ± 3.4 (6 – 16)
Number of cast fixations	6.8 ± 2.0 (4 – 10)
Follow-up (month)	13.3 ± 5.8 (8 – 34)
Sex (M/F)	30 (63.8%) / 17 (36.2%)
Side of deformity (R/L)	29 (61.7%) / 18 (38.3%)
Achillotomy (yes/no)	36 (76.6%) / 11 (33.4%)
Relapse (yes/no)	5/42

Table 2. Correlation of the clinical evaluation of equinovarus deformity before therapy and after a second cast fixation with parameters of the treatment outcomes.

	Number of casts		Relapses		Achillotomy	
	Correlation coef.	Significant correlation	Correlation coef.	Significant correlation	Correlation coef.	Significant correlation
Pirani score before therapy	.385	.014	.212	.125	.452	.005
Pirani score after second fixation	.584	.000	.231	.110	.488	.003
Dimeglio score before therapy	.451	.005	.277	.073	.336	.034
Dimeglio score after second fixation	.497	.002	.277	.070	.337	.035

Table 3. A detailed analysis of the clinical trials of clubfoot between groups of different deformity severities and their analysis within the parameters of treatment success. The groups were divided according to the gravity of the deformity, which was determined by the respective scoring systems: Pirani scoring: Group 1 with 3-4 points, Group 2 with 4.5–5 points, and Group 3 with 5.5–6 points. When using the Dimeglio classification, Group 1 has 6–10 points, Group 2 has 11–15 points, and Group 3 has 16–20 points.

		Number	Cast fixation	Achillotomy	Relapses
Pirani score before therapy	Group 1	17	6.06 ± 1,53	11 (64.7%)	0
	Group 2	17	7.85 ± 2.28	14(82.3%)	3 (17.6%)
	Group 3	13	7.67 ± 1.52	11 (84.6%)	2 (15.3%)
	p - value		.091	.417	.347
Pirani score after second fixation	Group 1	14	5.66 ± 1.61	8 (57.1%)	0
	Group 2	17	6.83 ± 1.82	14 (82.3%)	2 (11.7%)
	Group 3	16	8.80 ± 1,38	14 (87.5%)	3 (18.75%)
	p - value		.003	.014	.332
Dimeglio score before therapy	Group 1	9	5.45 ± 1,83	5 (55.5%)	0
	Group 2	17	6.47 ± 1,52	13 (76.4%)	2 (11.7%)
	Group 3	21	8.02 ± 1,94	18 (85.7%)	3 (14.2%)
	p - value		.032	.050	.709
Dimeglio score after second fixation	Group 1	18	6.34 ± 1.23	11 (61.1%)	2 (11.1%)
	Group 2	18	7.77 ± 1.75	15 (83.3%)	0 (0%)
	Group 3	11	8.40 ± 1.94	10 (90.9%)	3 (27.2%)
	p - value		.077	.126	.037

there is lack of evidence of reliable systems which could predict conditions such as the recurrence of the deformity, number of casts required or the need of percutaneous tenotomy of Achilles tendon. These conditions, already used by different authors, could be considered as the parameters of successfulness of the therapy.¹² Although sophisticated scoring systems are widely used, especially Dimeglio¹⁰ and Pirani,⁹ it is a rating laden with a certain degree of subjectivity.^{6,11} Differences in the clinical evaluation of one deformity by different investigators are described in the literature.¹¹ In addition, from the already published work, a clear, reliable, statistical correlation between the clinical examination and the outcome of treatment^{12,13} has not been found.

Various parameters that could have an influence on the outcome of therapy for clubfoot deformity have been investigated in the literature, but there is no clear consensus among the authors.

Agarwal et al.,¹⁵ in a retrospective analysis, examined the dependence among the number of fixations, the age of the patients, and the Pirani score evaluated before the onset of Ponseti therapy itself. They found that the number of cast fixations is variable, but significantly influenced by age and by the initial Pirani score. In our group of patients, we started, practically always, before reaching the second month of age, averaging in 20 days. From this reason, the analysis of age and its predictive effect on the outcome of treatment was not justified. Furthermore, the positive correlation of the initial Pirani score and the number of casts was observed in our analysis as well. Nevertheless, this trend is anticipated as the severe clubfoot deformity normally requires more casts compared to the mild or moderate deformities. Thus, we believe, that the correlation on its own, as the only statistical test, cannot lead to the certain statement about the prognosis of the therapy.

Dyer et al.¹¹ advocated Pirani scoring system as a quick, useful, and practical to use. They found significant correlation with the sense of necessity of Achilles tenotomy. Similarly, Scher et al.¹⁶ found that higher scores by Pirani and Dimeglio indicated a high probability of the necessity to perform achillotomy. In our study, we can agree with this assertion in the first part of the statistical analysis, when

both systems showed a positive degree of statistical significance in correlation with the necessity to perform achillotomy. However, in the second part of our analysis of this statement, we can agree only on the assumption that it is evaluation during the treatment up to the second cast fixation according to the Pirani test.

Gao et al.¹⁷ found, that the Dimeglio and Pirani clinical scorings had a limited prognostic value, at least in the early stages of therapy. Our study results also support this statement, when the greatest significant differences between groups with different degrees of deformity were observed during the Pirani scoring after the second casting.

Goraiarov et al.¹⁸ focused their study on the occurrence of relapses after Ponseti therapy, and found a significant dependence between the Pirani score (total Pirani score and mid-foot score) evaluated before the therapy and the number of relapses. A similar trend in evaluation of relapses can be approximated in our analysis when we look at Dimeglio scoring after the second fixation between each group in the second part of the statistical analysis, when a statistically significant difference was found. However, the limitation factor is the small number of patients and recurrences in our analyzed group.

During statistical data processing, a certain degree of correlation between the clinical assessment of the deformity of the foot and some aspects of the treatment results was observed. The relationship was found in both the evaluation of the number of fixations necessary to correct deformity and the necessity of percutaneous achillotomy. On the other hand, we found no correlation between the important factor of the evaluation of the treatment outcome and the occurrence of relapse. The second part of our statistics was made to complement and extend the first part of the general correlations. In the second part, when evaluating groups with varying degrees of deformity, we found that it was best to provide a scoring according to Pirani after the second fixation. We found a significant difference in the number of casts and the necessity of achillotomy. Similarly, a statistically significant difference was found between these groups in the number of fixations by using Dimeglio scoring before treatment and in occurrence of relapses by using Dimeglio scoring prior to initiation of therapy.

The authors of the generally used classification systems emphasize the need not only to examine and score the deformity of the

foot during treatment, but always before the next fixation.^{6,11} This requirement is fully supported by some results of our prospective study. In the clinical evaluation of the foot by the Pirani score after the second casting was recorded, a statistically significant difference was found among the groups with different severities of deformity (in detailed analysis in the second part of the statistical analysis) in terms of the number of cast fixations required to correct the foot and the necessity for achillotomy. We did not reach the same or similar conclusion when we used Dimeglio's scoring system. On the other hand, it only confirmed our personal affinity for the Pirani system of assessment, which we considered simpler and more accurate and reproducible. From the results of a detailed statistical analysis, the results showed that the prediction based on the established parameters of the treatment results can only be applied in a limited way.

The advantage of the study is certainly a relatively large number of patients. On the other hand, the analysis was performed by one pediatric orthopedic surgeon and no interobserver variability was calculated. Furthermore, the evaluation of severity of the deformity was made at the beginning of the therapy and after the second fixation can be a question for discussion. We want to consider this point in our next work, with the aim to determine when clinical scoring will show significant dependence on all parameters when evaluating treatment outcomes.

CONCLUSION

Clinical evaluation before Ponseti's concept of casting shows some significant correlation with predictive factors in treatment outcome. A detailed analysis has shown that clinical scoring can be used in a very limited way to predict the outcome of the treatment. Better results in the prediction of the course and outcome of treatment were achieved in the evaluation and clinical scoring after the second cast fixation, but not in all the evaluated parameters. Thus, in the complexities of clubfoot deformity of the foot, Dimeglio and Pirani clinical scoring by itself before and during the treatment appears to be insufficient to predict the course and results of treatment by Ponseti concept.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. JJ (0000-0003-2504-087X)*: CPV - performed the surgeries and data analysis, and wrote the manuscript. TP: (0000-0001-5684-1886)*: MASP - drafted and reviewed the manuscript and contributed to the intellectual conceptualization of the study. *ORCID (Open Researcher and Contributor ID).

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