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FACTORS PREDICTIVE OF OUTCOME AFTER USE OF THE PONSETI METHOD FOR THE TREATMENT OF IDIOPATHIC CLUBFEET

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Background: The nonoperative technique for the treatment of idiopathic congenital talipes equinovarus (clubfoot) described by Ponseti is a popular method, but it requires two to four years of orthotic management. The purpose of this study was to examine the patient characteristics and demographic factors related to the family that are predictive of recurrent foot deformities in patients treated with this method.

Methods: The cases of fifty-one consecutive infants with eighty-six idiopathic clubfeet treated with use of the Ponseti method were examined retrospectively. The patient characteristics at the time of presentation, such as the severity of the initial clubfoot deformity, previous treatment, and the age at the initiation of treatment, were examined with use of univariate logistic regression analysis modeling recurrence. Demographic data on the family, including annual income, highest level of education attained by the parents, and marital status, as well as parental reports of compliance with the use of the prescribed orthosis, were studied in relation to the risk of recurrence.

Results: The parents of twenty-one patients did not comply with the use of orthotics. Noncompliance was the factor most related to the risk of recurrence, with an odds ratio of 183 ($p < 0.00001$). Parental educational level (high-school education or less) also was a significant risk factor for recurrence (odds ratio = 10.7, $p < 0.03$). With the numbers available, no significant relationship was found between gender, race, parental marital status, source of medical insurance, or parental income and the risk of recurrence of the clubfoot deformity. In addition, the severity of the deformity, the age of the patient at the initiation of treatment, and previous treatment were not found to have a significant effect on the risk of recurrence.

Conclusion: Noncompliance and the educational level of the parents (high-school education or less) are significant risk factors for the recurrence of clubfoot deformity after correction with the Ponseti method. The identification of patients who are at risk for recurrence may allow intervention to improve the compliance of the parents with regard to the use of orthotics, and, as a result, improve outcome.

Level of Evidence: Prognostic study, Level II-1 (retrospective study). See Instructions to Authors for a complete description of levels of evidence.

Idiopathic congenital talipes equinovarus (clubfoot) is a complex deformity that is difficult to correct. The deformity has four components: equinus, hindfoot varus, forefoot adductus, and cavus. The goal of treatment is to reduce or eliminate these four deformities so that the patient has a functional, pain-free, plantigrade foot, with good mobility and with-

out calluses, and does not need to wear modified shoes.

There is nearly universal agreement that the initial treatment of idiopathic congenital clubfoot should be nonoperative, regardless of the severity of the deformity. Historically, this treatment initially consisted of forcible serial manipulations with the patient under anesthesia, followed by application of a cast¹. Today, nonoperative treatment typically involves serial gentle manipulations followed by the application of a short or long leg cast at weekly intervals¹⁻⁷. While this technique is the mainstay of nonoperative intervention in North America, phys-



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iotherapy and continuous passive motion without immobilization have been successfully used in France^{8,9}.

Although all of these methods have the potential to be successful when applied correctly, most authors have reported a success rate of only 15% to 50%¹⁰⁻¹². A notable exception is the Ponseti method, which involves serial manipulation, a specific technique of cast application, and a possible percutaneous Achilles tenotomy. The method has been reported to have short-term success rates approaching 90%¹³, and the long-term results have been equally impressive^{13,14}. Cooper and Dietz, in a review of the cases of forty-five patients who had been treated by Ponseti and followed for a mean of thirty years, found that, with use of pain and functional limitation as the outcome criteria, thirty-five patients (78%) had achieved an excellent or good outcome¹⁴.

The unsatisfactory results associated with complete soft-tissue releases at ten to fifteen years of follow-up^{15,16} and the long-term success reported with the Ponseti method have led to a renewed interest in this method among pediatric orthopaedists. Despite this interest, success with the Ponseti method when it has been used by other orthopaedists has not been demonstrated until recently¹⁷. Failure with the Ponseti method has been frequently attributed to noncompliance with the use of the orthosis after correction has been obtained¹⁸. This is not a trivial issue, given the expense and the time (two to four years) that is required, as well as the psychosocial factors, such as the stigma of prolonged use of an orthosis, which have an impact on compliance. No studies have previously addressed the issue of noncompliance and the factors that may contribute to the risk of recurrence after treatment with the Ponseti method.

The purpose of this study was to evaluate the patient characteristics and the demographic data on the families of fifty-one consecutive infants with eighty-six idiopathic clubfeet who had been managed with the Ponseti method, by a single surgeon, to determine the factors that might be predictive of recurrence. Recognition of important risk factors may eventually result in better patient selection for the currently available treatments of idiopathic clubfeet and may allow early intervention to improve compliance and outcome.

Materials and Methods

The cases of fifty-one consecutive infants with idiopathic clubfoot who had been treated by a single orthopaedist (M.B.D.) with use of the Ponseti method⁶ at St. Louis Children's Hospital and St. Louis Shriners Hospital for Children were retrospectively reviewed. Institutional review board approval was obtained for the retrospective chart review. Patients were excluded if they had any other congenital abnormality. The severity of the foot deformity was classified, according to the grading system of Dimeglio et al., at the time of presentation¹⁹. In this system, four parameters are assessed on the basis of their reducibility with gentle manipulation as measured with a handheld goniometer: (1) equinus deviation in the sagittal plane, (2) varus deviation in the frontal plane, (3) derotation of the calcaneopedal block in the horizontal plane, and (4) adduction of the forefoot relative to the hind-

foot in the horizontal plane. A score is assigned to each one of the four parameters on a 4-point scale, with 4 points indicating reducibility from 90° to 45°; 3 points, reducibility from 45° to 20°; 2 points, reducibility from 20° to 0°; 1 point, reducibility from 0° to -20°; and 0 points, reducibility of less than -20°. The sum of these parameters constitutes a 16-point scale. Four additional points, consisting of 1 point each for a posterior crease; a medial crease; evidence of plantar retraction or cavus; or poor muscle condition, such as fibrous, hypertonic, or contracted triceps, tibial, or peroneal muscles and the absence of voluntary dorsiflexion in eversion and pronation, can be added for a total of 20 points. Atrophy of the calf, a short foot, and a decreased leg length are to be disregarded because they are considered part of the natural history of clubfoot deformity. The feet are then classified into four categories with respect to the severity of the deformity. Grade-I feet have a mild deformity that is >90% reducible, with a score of 0 to 5 points. Grade-II feet have a moderate deformity, with a score of 5 to 10 points. Grade-III feet, the most common category, indicates a severe deformity, with a score of 10 to 15 points. Grade-IV feet have a very severe deformity, with a score of 15 to 20 points, and an arthrogryptic appearance.

The number of infants who received treatment before referral and the type of treatment performed were recorded. Other data that were noted included the number of casts required to obtain correction and the need for a percutaneous Achilles tenotomy to obtain correction of the equinus deformity. After correction was obtained, passive ankle dorsiflexion and plantar flexion as well as varus-valgus heel deformity were measured by a single examiner with a handheld goniometer. Any recurrent deformities were documented with regard to the age at the time of the recurrence, the severity of the recurrent deformity (according to the Dimeglio grading system), and any additional treatment necessary to regain correction.

Demographic data (the gender and race of the infant; the marital status, educational level, and income of the parents; and the type of insurance, i.e., public, private, or none) were obtained either from the hospital database or from voluntary disclosure from the parents during patient visits. Reports by the family with regard to the use of orthotics were used as a measure of compliance.

Statistical Analysis

All patient characteristics and demographic data on the family were analyzed with use of univariate logistic regression analysis modeling recurrence. Unadjusted odds ratios along with 95% confidence intervals and p values were calculated. Multivariate models were not created because sample size limitations did not allow adequate model fit to be achieved. For categorical characteristics, reference categories were indicated with an odds ratio of 1.00. Deformities were grouped as moderate (grade II), severe (grade III), or very severe (grade IV) for purposes of statistical analysis¹⁹.

Treatment Regimen

The Ponseti method is used at our institution according to the

following regimen. Treatment is started as soon as possible after referral, preferably shortly after birth, and consists of gentle manipulation of the foot and the serial application of long leg plaster casts without the use of anesthesia, as described by Ponseti²⁰⁻²². We initiate this same treatment method even in the older infants (up to seventeen months of age) who are referred to us for the first time or in those who have had previous unsuccessful nonoperative treatment elsewhere. Occasionally, in infants who are twelve months of age or older, the serial casts are applied with the patient under general anesthesia because of the difficulty in holding the infant's knee in flexion while the plaster on the long leg portion of the cast sets. In all patients, the cavus is corrected first by supinating the forefoot and dorsiflexing the first metatarsal. Failure to supinate the forefoot as the first step ultimately leads to incomplete correction of the clubfoot. To correct the varus and adduction, the foot in supination is abducted while counterpressure is applied with the thumb against the head of the talus. Four to seven long leg casts, changed weekly after proper manipulation of the foot, are usually sufficient to obtain good correction^{6,13,23}. In the last cast, the foot should be markedly abducted (70°) without pronation. This position is crucial in obtaining complete correction and in helping to prevent early recurrence. If residual equinus is observed after the adduction of the foot and the varus deformity of the heel have been corrected, a simple percutaneous tenotomy of the Achilles tendon is performed. We prefer to perform the tenotomy in the operating room with the patient under general anesthesia, which allows optimal analgesia for the infant. This setting also provides the surgeon with a controlled environment, which hopefully optimizes the safety of this procedure. This approach differs from that of Ponseti^{21,24} and others¹⁷ who prefer that the Achilles tenotomy be done in the clinic with a topical and/or local anesthetic. Tenotomy was performed in seventy-four (86%) of the eighty-six clubfeet, and it is performed when 15° of dorsiflexion has not been obtained with the use of casts. After the tenotomy, an additional cast is applied and left in place for three weeks to allow for healing of the tendon.

An orthosis is used to prevent relapse of the deformity. This is best accomplished with the feet in well-fitted, open-toed, high-top straight-last shoes attached to a Denis Browne bar of approximately the length between the child's shoulders. The splint maintains the corrected foot in 70° of external rotation to prevent recurrence of the varus deformity of the heel, adduction of the foot, and toeing-in^{6,13}. The ankle should be in dorsiflexion, in an attempt to prevent equinus, and this is accomplished by bending the bar with the convexity of the bar distally directed. If the deformity is unilateral, the normal foot is placed in 30° of external rotation. The orthosis is worn full-time (twenty-two to twenty-three hours a day) for two or three months and then at night (ten to twelve hours) for two to four years^{6,13}. To help to prevent a recurrent equinus contracture, the parents are instructed about and given a handout on how to effectively perform range-of-motion exercises for the ankle when it is out of the brace. The exercises are performed with the patient supine. The parent uses one hand to stabilize the leg with the knee bent.

The other hand is used to grasp the heel and then place the ankle into maximum dorsiflexion followed by plantar flexion. The parents repeat this exercise twenty times at a setting. During the first three months, when the child is in the brace twenty-three hours a day, the parents perform the exercises only once a day when the brace is removed. When the child is wearing the brace only ten to twelve hours a day, the parents perform the exercises at every diaper change. These exercises have improved our ability to effectively maintain the ankle motion achieved at the time of the tenotomy.

The cast is changed weekly. If a tenotomy is required, an additional cast is worn for three weeks after the procedure. After the last cast is removed, the patient begins use of the orthosis and is seen one month after the initiation of splinting, then every three months until the age of three years, and then every six months to one year until the child is seven years old. After the age of seven years, the patient is seen once every two years until skeletal maturity is reached.

Most relapses occur in the hindfoot and are clinically evident by the development of equinus and varus deformity of the heel. The original correction may be recovered in four to eight weeks with manipulations and long leg plaster casts that are changed weekly and hold the foot in marked external rotation and as much dorsiflexion as possible at the ankle. This treatment is followed by a repeat Achilles tendon lengthening when dorsiflexion of the ankle is <15°. The tendon lengthening involves a complete release of the tendon and is done in a percutaneous fashion in patients who are up to twelve months of age; thereafter, the tendon lengthening is done through an open approach and is usually accompanied by a posterior release of the ankle and subtalar joint.

Results

Fifty-one infants (eighty-six feet) with idiopathic clubfoot deformity were treated. Thirty-two (63%) of the fifty-one patients were male. Forty-two infants (82%) were white, six were black, and three were of other races. The parents of thirty infants (59%) were married, and the parents of thirty-four patients (67%) had a high-school education or less. Thirty-one (61%) of the families had annual incomes of less than \$20,000. Approximately equal numbers of patients had private insurance (twenty-eight; 55%) compared with public or no insurance (twenty-three; 45%).

Of the fifty-one infants, sixteen had unilateral and thirty-five had bilateral involvement. Twenty-one infants (41%) were treated with a cast before referral, with a mean of seven casts (range, two to twelve casts) having been applied. No patient had any corrective surgery before referral. Treatment was initiated at our institutions at a mean of twelve weeks of age (range, one to sixty weeks). Treatment was begun at less than three months of age in thirty-six patients (71%). Only two patients had treatment initiated at more than twelve months of age.

The deformity was classified, according to the system of Dimeglio¹⁹, as grade II (moderate) in ten feet, grade III (severe) in seventy feet, and grade IV (very severe) in six feet. The mean number of casts that were applied to obtain

TABLE I Distribution of Patient Characteristics and Family Demographic Data According to the Status of the Fifty-one Patients with Respect to Recurrence

Characteristic	Variable	Recurrence of Deformity		Odds Ratio*	P Value†
		Yes (N = 16)	No (N = 35)		
Gender of patient	Male	9	23 (66%)	0.67 (0.20, 2.25)	0.52
	Female	7	12 (34%)	1.00	
Race of patient	White	14	28 (80%)	1.75 (0.32, 9.55)	0.52
	Other	2	7 (20%)	1.00	
Marital status of parents	Married	7	23 (66%)	0.41 (0.12, 1.36)	0.14
	Not married	9	12 (34%)	1.00	
Insurance	Private	9	19 (54%)	1.08 (0.33, 3.56)	0.90
	Public or none	7	16 (46%)	1.00	
Highest educational level of parents	High school or less	15	19 (54%)	10.71 (1.24, 92.22)	<0.03
	More than high school	1	16 (46%)	1.00	
Family income	≤\$19,999	10	21 (60%)	3.50 (0.37, 32.96)	0.46
	\$20,000-\$39,999	5	7 (20%)	4.66 (0.40, 53.93)	
	≥\$40,000	1	7 (20%)	1.00	
Classification of deformity at presentation	Moderate (grade II)	2	8 (23%)	1.00	0.59
	Severe (grade III)	10	25 (72%)	1.60 (0.29, 8.88)	
	Very severe (grade IV)	4	2 (6%)	8.00 (0.80, 79.65)	
Age of patient at first clinic visit	0-3 mo	10	26 (74%)	0.58 (0.16, 2.04)	0.39
	>3 mo	6	9 (26%)	1.00	
Patient noncompliant with use of orthosis	Yes	16	5 (14%)	183 (9.52, 3519)	<0.00001‡
	No	0	30 (86%)	1.00	
Patient received outside treatment	Yes	8	13 (37%)	1.69 (0.51, 5.60)	0.39
	No	8	22 (63%)	1.00	
Duration of follow-up§ (mo)		26.12 ± 2.8 (24-33)	25.9 ± 2.9 (24-35)	0.62 (0.17, 2.54)	0.46

*The values are given as the univariate (unadjusted) odds ratios, with the associated 95% confidence intervals in parentheses. †P values are reported for univariate logistic regression analysis modeling recurrence. ‡Logit estimators use a correction of 0.5 in the cell that contains a zero. §For the continuous measure (follow-up), the odds ratio reflects the odds of recurrence for every one-month increase in follow-up. The values are given as the mean and the standard deviation, with the range in parentheses.

correction was 4.16 ± 1.24 (range, three to seven casts). The more severe the initial deformity, the more casts were required to obtain correction. Seventy-four (86%) of the eighty-six clubfeet underwent a percutaneous Achilles tenotomy to correct a residual equinus deformity. The mean duration of follow-up was 26.71 ± 2.83 months (range, twenty-four to thirty-five months). The mean ankle dorsiflexion was $31^\circ \pm 6^\circ$ (range, 20° to 40°), and the mean plantar flexion was $54^\circ \pm 7.51^\circ$ (range, 30° to 60°). Initial correction was obtained in all eighty-six feet (100%) with the Ponseti method.

The families of twenty-one infants (41%) reported that they had not complied with use of the orthosis; all but one discontinued use during the first three months after the orthosis was prescribed. Noncompliance was reported as complete discontinuation of the use of the orthosis. The most

common reason given for noncompliance was inconvenience, which was the greatest problem in the first three months after the orthosis was prescribed, as it was to be worn for twenty-three hours a day. Relapse was detected in sixteen infants (31%; twenty-seven feet) at a mean age of six months (range, three to eighteen months), when there was $\geq 5^\circ$ of hindfoot varus and/or $< 15^\circ$ of ankle dorsiflexion. The parents of all sixteen infants who had a relapse reported noncompliance with the use of the orthosis. Five infants whose parents had not complied with the protocol did not have a relapse. The deformity in all five of these patients had been classified as grade II, according to the Dimeglio classification system, at the time of the initial presentation.

The original correction was recovered with the use of repeat application of serial casts in all sixteen patients (twenty-seven feet) who had had a relapse. This process required four

to eight weeks of manipulation and long leg plaster casts, with the foot held in marked lateral rotation. The casts were changed at weekly intervals. Before application of the last cast, a repeat percutaneous Achilles tenotomy was performed in six patients because 15° of ankle dorsiflexion had not been obtained with repeat application of casts. Additional education was provided to all sixteen families on the importance of the use of the orthosis to maintain correction. All families then received weekly telephone calls from the nursing staff to address any concerns they had about the orthosis. Only three families reported continued noncompliance with splinting, and, in all three, the child had a second relapse, requiring repeat application of casts followed by posterior release operations. At the latest follow-up examination, no patient required a complete soft-tissue release.

The results of the univariate logistic regression analysis modeling recurrence are reported in Table I. Noncompliance was the variable that was most strongly associated with an increased risk of recurrence. A patient whose family does not comply with the protocol for the orthosis is 183 times more likely to have a relapse than is one whose family complies (odds ratio = 183 and 95% confidence interval = 9.5 to 3519; $p < 0.00001$). Parental educational level also was a significant risk factor for recurrence. The risk that a clubfoot will relapse is increased tenfold when the parents have a high-school education or less compared with that when the parents have education beyond high school (odds ratio = 10.7 and 95% confidence interval = 1.2 to 92; $p < 0.03$). With the numbers available, no significant relationship was detected between gender, race, parental marital status, source of medical insurance, or parental income and the risk of a relapse of the clubfoot. In addition, the classification of the severity of the deformity, the age at the time of initiation of treatment, and previous treatment was not found to have a significant effect on the risk of recurrence.

Discussion

Although the meticulous method of serial manipulations and cast application as outlined by Ponseti²⁰ is essential to obtain initial correction of the idiopathic clubfoot deformity, our data demonstrated that noncompliance with the use of the orthosis is the primary risk factor for recurrent deformity. Compliance with bracing is a major factor required for the successful treatment with this method, as indicated by our noncompliance rate of 41%. One limitation of this study was the difficulty in accurately assessing compliance. Objective measures of compliance were not available; therefore, verbal reports with regard to the use of the brace were used as the primary means of assessing compliance. Compliance may have been overreported by the parents, and perhaps correction was maintained in some patients despite partial compliance or noncompliance. Compliance may also have been influenced by a gradual inability to adequately or comfortably brace the recurring foot deformity, such that noncompliance with the use of a brace does not cause the recurrent deformity but rather reflects

other intrinsic factors related to recurrence.

Although there was a trend ($p = 0.08$) toward an increased risk of recurrence in infants with the most severe deformity, our results demonstrated that the prevalence of recurrence is not dependent on the initial severity of the deformity, the age at the initiation of treatment, or whether the patient had treatment with a cast before referral. However, many subgroups were small in number, which may have precluded our ability to recognize the significance of some variables. Interestingly, in this series, two patients obtained successful correction despite treatment that was initiated after the age of one year. Morcuende et al., in a study from the University of Iowa, also reported success in treating children who were more than one year old with the Ponseti method²⁵. These cases provide support for orthopaedic surgeons who may be reluctant to treat these seemingly more challenging patients with the conservative Ponseti method.

Among the sociodemographic factors tested, only parental educational level that was at the high-school level or below was found, with the numbers available, to be a risk factor for relapse. These children had a tenfold increased risk of recurrence compared with children whose parents had more than a high-school education. It was of note that parental income and marital status, which are often associated with educational level, were not found to be significant factors in this study; however, a trend for both factors to be involved in the risk of recurrence was detected. Although a standardized information sheet explaining the Ponseti treatment method, the time commitment required, and the importance of compliance is given to each family in our clinic, we currently have no method to assess how well the parents understand this information. Furthermore, we speculate that some of the more educated parents may have been highly motivated to achieve success with the Ponseti method and therefore were more compliant with the use of bracing. Specific information about the Ponseti technique is available on the Internet²⁶. Interestingly, the parents of ten of our patients were referred from this source and sought this form of treatment over others. These parents, all of whom had more than a high-school education, complied with the use of the brace, and none of their children had a recurrent deformity.

When a surgeon is aware of the patient characteristics and demographic features relating to the family that are risk factors for recurrent clubfoot deformity after treatment with the Ponseti method, he or she can provide resources, such as additional educational materials and home nursing visits, for selected patients at the highest risk. Whether these additional resources will be beneficial or cost-effective in reducing recurrence and improving outcome remains a topic for future studies. Cost-analysis studies may also be helpful to determine the additional medical costs for patients who are noncompliant and require additional medical and surgical intervention. More provocatively, it may be argued that a selected subgroup of patients who are at high risk for noncompliance and recurrence may best be treated by early definitive surgical methods. ■

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