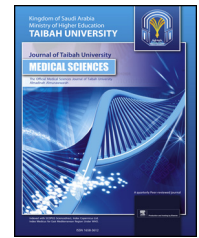




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Original Article

Factors predicting brace noncompliance among idiopathic clubfoot patients treated with the Ponseti method



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المخلص

أهداف البحث: تهدف هذه الدراسة إلى تحديد درجة امتثال والدي الأطفال المصابين بحنف القدم الذين عولجوا بطريقة "بونستي"، وتحديد العوامل التي قد تنبئ بعدم الالتزام باستخدام الدعامات.

طريقة البحث: تم تقييم عدد من العوامل التي تؤثر على امتثال العائلات للعلاج عن طريق توزيع استبانة على ١٠٨ مريضاً ممن يعانون من حنف القدم في الفترة ما بين ديسمبر ٢٠٠٩م ويناير ٢٠١٢م. تمت دراسة ديموغرافية كل أسرة، والدخل الشهري، والمستوى التعليمي للوالدين، وعدد الأطفال في كل أسرة بالإضافة إلى عوامل أخرى وتحليلها إحصائياً.

النتائج: جميع الـ ١٠٨ مريضاً كانوا يعانون من الدرجة الشديدة من حنف القدم. امتثل والدي ٧٢ (٦٦.٧٪) من المرضى لاستخدام الدعامات مقارنة بـ ٣٦ (٣٣.٣٪) لم يمتثلوا. كانت الإصابة بالحنف أحادي الجانب عامل خطورة مهماً في ما يخص عدم الامتثال مقارنة بالإصابة بالحنف المزدوج. وأظهر الوالدان ذوا ٣ أطفال فأكتر درجة أعلى من عدم الامتثال (٦٦.٧٪) مقارنة بالوالدين ذوي أقل من ٣ أطفال (٣٨.٩٪). كما صرح جميع الوالدين غير الممتثلين لاستخدام الدعامات بأن أطفالهم كانوا يبكون عند تطبيقها مقارنة بـ ٢٥٪ من والدي الأطفال الممتثلين. غالبية الوالدين غير الممتثلين (٩٤.٤٪) أبلغوا عن مللهم من استخدام الدعامات مقارنة بـ ٢.٨٪ من الممتثلين. لم نجد علاقة ذات أهمية لا بالدخل الشهري ولا بالمستوى التعليمي للوالدين.

الاستنتاجات: تبين أن تعدد الأطفال في الأسرة والحنف أحادي الجانب وعدم استطاعة أحد الوالدين وحده تثبيت الدعامات جميعها كانت عوامل رئيسية مؤدية إلى

عدم الامتثال في استخدام الدعامات. توعية الأسرة بأهمية الدعامات وتشجيعها على استخدام الدعامات قد يكون له الأثر الجيد في تحسين الامتثال في استخدامها.

الكلمات المفتاحية: بونستي؛ الحنف مجهول السبب؛ الامتثال؛ الدعامات

Abstract

Objectives: The purpose of this study was to determine the compliance of parents of children with clubfeet treated with the Ponseti method and to identify factors that may predict brace non-compliance.

Methods: A myriad of factors affecting families' compliance were assessed by administering questionnaires to 108 patients with clubfoot from December 2009 to January 2012. The family's demographic data, including monthly income, educational level of the parents, number of children in the family, and other factors, were studied and statistically analysed.

Results: All 108 patients had severe clubfoot. The parents of 72 (66.7%) patients complied with the use of the brace compared to 36 (33.3%) parents who did not comply. Unilateral clubfoot was a significant risk factor for non-compliant parents compared to bilateral clubfeet ($p = 0.05$). Parents with 3 or more children had more non-compliance (66.7%) compared to those with less than 3 children (38.9%). All non-compliant parents reported that their babies cried during the application of the brace in contrast to 25% of the complaint parents ($p < 0.0001$). The majority of non-compliant parents (94.4%) reported being "fed up" with using the brace compared to 2.8% of the compliant parents. No significant correlation was found between brace use and parents' monthly income or their level of education.

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Conclusion: More children per family, unilateral clubfoot, and the inability of a single parent alone to apply the brace were found to be major risk factors for brace non-compliance. Families' awareness about the importance of the brace and encouragement might improve brace compliance.

Keywords: Brace; Compliance; Idiopathic clubfoot; Ponseti

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Introduction

Idiopathic clubfoot is one of the most common congenital deformities and is easily diagnosed at birth.¹ The Ponseti method is the most popular method for the treatment of idiopathic clubfoot.² With more careful attention to the technique and casting, many authors have reported satisfactory results.^{1,3,4} The use of a foot abduction brace (FAB) after initial correction is essential to avoid recurrence.¹ The FAB should be worn for 23 h per day in the first 3 months followed by wearing the brace at night-time and during naptime for 3–4 years, as recommended by Ponseti.^{1,5} This requires a significant commitment from the family. Compliance with the brace protocol is crucial, and relapses occur mostly as a result of parental noncompliance.^{7–9} The purpose of this study was to determine the compliance of families of idiopathic clubfoot patients treated with the Ponseti method as well as to identify factors that may be predictive of brace noncompliance.

Materials and Methods

A cross sectional study was carried out at a tertiary centre in Saudi Arabia from December 2009 to January 2012. The institutional review board approved the study. The cases of 108 patients with idiopathic clubfoot who had been treated with the Ponseti method⁵ at King Abdul-Aziz Medical City, Riyadh were reviewed. All patients used the Dennis Browne Brace (DBB). The inclusion criteria were a diagnosis of severe idiopathic clubfoot treated by the Ponseti method and a minimum of 2 years of follow up after the completion of the treatment in the clinic. Non-idiopathic clubfoot and patients who were treated with non-Ponseti methods were excluded from the study. The severity of the foot deformity was classified according to the Pirani score^{1,6} at the time of the presentation. Demographic data (the gender and age of the patient, educational level, income, and the number of children per family) were obtained from the parents during the direct interview in the clinic. The side involvement (unilateral/bilateral), the ability of the parents to contact a treatment team, and the ability of one parent alone to apply the brace were reported.

Compliance

Noncompliance was defined as failure to use the brace for 23 h per day in the first 3 months^{1,5} and for an average of 14 h per day at night-time and during naps.⁷ Information was collected from parents through direct interviews in the clinic asking about the duration of brace use, the clarity of the instructions provided to them by the treatment team, and any difficulty contacting the treatment team with concerns.

Statistical analyses

The Statistical Package for Social Sciences (SPSS) version 20 was used for data entry and analyses. The results were considered to be significant at the level $P < 0.05$.

Results

Family demographic data and doctor-specific information with respect to the brace compliant and noncompliant groups were analysed (Table 1). The study included 58 males (53.7%) and 50 females (46.3%). Fifty-eight patients (53.7%) had unilateral clubfoot, and 50 patients (46.3%) had bilateral clubfoot. All patients had severe clubfoot deformities with Pirani scores of 6/6. The age of 88 patients (81.5%) at the time of the Ponseti treatment was 2 months or less, while 20 patients (18.5%) were more than 2 months old. In 72 patients (66.7%), full compliance with brace use was reported, while 36 patients (33.3%) were noncompliant. There was a significant association between bilateral clubfoot and compliance, where it was found that the compliant patients were more likely to have bilateral clubfeet (55.6%) compared to noncompliant patients (27.8%), p -value = 0.05. On the other hand, the noncompliant parents were more likely to have 3 children or more (66.7%) compared to complaints parents (38.9%), p -value = 0.05. The ability to contact the treatment team (if there was a concern about the brace) was significantly more difficult for 14 noncompliant parents (38.9%) (p -value = 0.04). Other doctor-specific factors were not significantly different between the two groups.

The brace-specific factors with respect to the brace compliant and non-compliant groups were also analysed (Table 2). There is a significant difference (p -value = 0.04) between compliant parents (86.1%) who liked the Ponseti method and non-compliant parents (61.1%). All of the noncompliant parents (100%) reported that their baby cried during brace use compared to 25% of the compliant group, which was a significant difference (p -value < 0.0001). Although none of the compliant parents noticed that their babies were unable to sleep tight at night because of the brace, 30 noncompliant parents (83.3%) mentioned that their babies woke from their sleep due to brace use (p -value = 0.00). The inability of one parent, without any assistance, to fit the brace on his/her baby was significantly more common in the non-compliant group (66.7%) (p -value = 0.007). Thirty-four noncompliant parents (94.4%) were fed up with using the brace, while 2 compliant parents (2.8%) had the same sentiment (p -value = 0.00). Although the majority of parents in both groups (94.4%) agreed that the brace was costly and expensive, there was no significant

Table 1: Family demographic data, doctor-specific information, and analysis stratified by brace compliance.

Variables		Noncompliant N = 36	Compliant N = 72	P-value
Age at time of Ponseti treatment	2 months and less	30 (83.3%)	58 (80.6%)	0.56
	More than 2 months	6 (16.7%)	14 (19.4%)	
Sex	Male	22 (61.1%)	36 (50.0%)	0.32
	Female	14 (38.9%)	36 (50.0%)	
Site	Unilateral	26 (72.2%)	32 (44.4%)	0.05
	Bilateral	10 (27.8%)	40 (55.6%)	
Children	2 or less	12 (33.3%)	44 (61.1%)	0.05
	3 or more	24 (66.7%)	28 (38.9%)	
Domestic helper	No	18 (50.0%)	42 (58.3%)	0.39
	Yes	18 (50.0%)	30 (41.7%)	
Previous experience with Ponseti method	No	28 (77.8%)	56 (77.8%)	0.63
	Yes	8 (22.2%)	16 (22.2%)	
Treating team described the brace use clearly	No	0 (0.0%)	2 (2.8%)	0.67
	Yes	36 (100.0%)	70 (97.2%)	
Difficulty to contact the treating team	No	22 (61.1%)	62 (86.1%)	0.04
	Yes	14 (38.9%)	10 (13.9%)	
Monthly income	<5000 SR	8 (22.2%)	10 (13.9%)	0.43
	5000–10 000 SR	22 (61.1%)	56 (77.8%)	
	>10 000 SR	6 (16.7%)	6 (8.3%)	
Father education level	Less than High School	28 (77.8%)	52 (72.2%)	0.46
	High School and above	8 (22.2%)	20 (27.8%)	
Mother education level	Less than High School	14 (38.9%)	36 (50.0%)	0.32
	High School and above	22 (61.1%)	36 (50.0%)	

SR: Saudi Riyal (US Dollar = 3.75 SR).

Table 2: Brace-specific factors, and analysis stratified by brace compliance.

Variables		Noncompliant N = 36	Compliant N = 72	P-value
Family likes Ponseti method	No	14 (38.9%)	10 (13.9%)	0.04
	Yes	22 (61.1%)	62 (86.1%)	
The baby crying during the brace use	No	0 (0.0%)	54 (75.0%)	0.0001
	Yes	36 (100.0%)	18 (25.0%)	
Brace fell off during the brace treatment period	No	22 (61.1%)	50 (69.4%)	0.38
	Yes	14 (38.9%)	22 (30.6%)	
The baby woke-up from his sleep because of the brace	No	6 (16.7%)	72 (100.0%)	0.00
	Yes	30 (83.3%)	0 (0.0%)	
Parents get fed up from using the brace	No	2 (5.6%)	70 (97.2%)	0.00
	Yes	34 (94.4%)	2 (2.8%)	
One parent only (no assistant) can fit the brace	No	24 (66.7%)	20 (27.8%)	0.007
	Yes	12 (33.3%)	52 (72.2%)	
Brace is expensive	No	2 (5.6%)	4 (5.6%)	0.75
	Yes	34 (94.4%)	68 (94.4%)	
Brace cost	300–500 SR	6 (16.7%)	24 (33.3%)	0.17
	>500 SR	30 (83.3%)	48 (66.7%)	
How many times have you changed the brace?	1	4 (11.1%)	10 (13.9%)	0.98
	2	10 (27.8%)	22 (30.6%)	
	3	16 (44.4%)	32 (44.4%)	
	4	4 (11.1%)	6 (8.3%)	
	5	2 (5.6%)	2 (2.8%)	
Does the Brace price affect your financial status?	Not really	6 (16.7%)	18 (25.0%)	0.39
	Partially	26 (72.2%)	52 (72.2%)	
	Yes significantly	4 (11.1%)	2 (2.8%)	

SR: Saudi Riyal (US dollar = 3.75 SR).

difference between the two groups (p -value = 0.75). The rest of the factors were not significantly different.

Discussion

The Ponseti method is the most common conservative treatment for clubfoot after discouraging long-term results

from surgical treatment.^{7,10} Bracing is a critical component of the current standard treatment for clubfoot. Adherence to the bracing protocol is the main factor associated with the long-term success of the treatment.¹¹ The most critical factor leading to clubfoot relapse after a successful initial correction with the use of the Ponseti method has been shown to be noncompliance with brace use.^{2,9,12,13} Patients

who tolerated bracing had lower recurrence rates and underwent less surgery.¹ Many authors have mentioned parental awareness regarding brace use.^{8,9,14,15} Dobbs et al.⁸ showed that low levels of education (high-school education or less) were more frequent among noncompliance parents and were considered to be a significant risk factor for the recurrence of clubfoot deformity after correction with the Ponseti method. Although most of the fathers in both groups had a lower education level (less than high school) compared to the mothers (high school or more), education was significantly associated with compliance. Most of the clubfoot patients were cared for mainly by their mothers at home (with little influence from their fathers), which might explain the non-significant effect of parental education on the results. The number of children per family (3 or more) was found to be a significant risk factor among noncompliant parents (66.7%) compared to compliant parents (38.9%). This factor is important in our community because most Saudi families have 3 or more children, which might decrease parental compliance with brace use. However, while the presence of domestic helpers in Saudi families is very common, this was not found to be a significant risk factor, which may indicate that family awareness is critical to improving the compliance rate. The treating doctor or his/her assistant in the clinic educated all of the parents during the treatment period because a patient educator is not available in our clinic. The noncompliant parents had more difficulties in contacting the treatment team (38.9%) versus the compliant parents (13.9%), p -value = 0.04. We believe that patient educators play an important role in maintaining better contact with the parents compared to the treatment team. Garg and Porter¹⁶ reported that dedicated registered nurses at a clubfoot centre who worked closely with families during the treatment and brace period played a major role in parental compliance. We strongly agree with this statement. It has been noticed that most of the compliant group (86.1%) liked the Ponseti method compared to the noncompliant group, p -value = 0.04, which may explain their lack of enthusiasm for using the brace for this long period.

Another interesting factor was crying among all of the noncompliant patients during brace use compared to crying in only 25% of compliant patients, which also supports the need for patient educators to educate parents about the proper way of handling the brace as well as encouraging families to properly fit the brace. We agree with Hemo et al.¹⁷ that a fully corrected foot and a strong family–treatment team partnership are crucial for adherence with the brace protocol, subsequently decreasing the noncompliance rate. Unilateral clubfoot was found in 72.2% of the noncompliant group compared to 44.4% of the compliant group, which is a significant difference (p -value = 0.05). Although we have no clear explanation for this result, we assume that the unaffected foot played a role in dislodging the affected foot from the shoe by moving a bar from side to side (as described by parents). The inability of one parent to fit the brace, without any assistance, played an important role in the failure of parents to commit to the brace treatment. Twenty-four noncompliant parents (66.7%) had trouble fitting the brace alone, in contrast to 20 compliant parents (27.8%). These results demonstrate the necessity of educating parents on how to fit the brace alone.

Garg and Porter¹⁶ believed that using a dynamic foot abduction orthosis resulted in improved compliance compared to a standard straight abduction brace (DBB). On other hand, Hemo et al.¹⁷ concluded that the new and more expensive brace designs did not provide better compliance results compared to the DBB. They found that a strong family-treatment team partnership is crucial to adherence with the brace protocol.

Although many of the factors used in this study are subjective, we have highlighted family concerns about brace compliance, which might help during family education.

Conclusion

Compliance to brace use after treating clubfoot with the Ponseti method is challenging for many parents. Family awareness, encouragement, and the presence of a dedicated educator might improve compliance among all parents, especially those at risk for noncompliance.

Conflict of interest

The authors have no conflict of interest to declare.

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