Quantitative Analysis of Barriers to Clubfoot Treatment Experienced at a Tertiary Care Institute in India

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Abstract

Introduction: The Ponseti method of treating clubfeet is considered the gold standard. However, there are specific barriers to implementing the Ponseti method for clubfoot treatment, especially in developing countries like India.

Methods: This is a retrospective study on patients who underwent the Ponseti method for clubfoot treatment at a tertiary care hospital in India. A total of 110 patients were enrolled for this study and were interviewed at the initiation of treatment and at each follow-up to identify the barriers, and their correlation to dropout rate was analyzed.

Results: On applying binary logistic regression, which shows the cumulative effect of all variables, the effect of the parent accompanying the patient was significant on compliance and dropout rate.

Conclusion: Informed parents play a significant role in compliance with the treatment. The study results can help formulate an action plan to improve adherence to the Ponseti method for treating clubfoot throughout India and other developing countries.

Categories: Orthopedics, Health Policy

Keywords: India, quantitative analysis, dropout rate, compliance, barriers, clubfoot

Introduction

Clubfoot is a complex congenital deformity with a component of forefoot adduction, midfoot cavus, hindfoot varus, and ankle equines [1]. It can be idiopathic or a part of a syndrome like arthrogryposis multiplex congenita (a congenital condition with stiffness in multiple joints). As per the 2016 National Institution for Transforming India (NITI) Aayog Data, India has an annual birth rate of 20.4 births per 1000 people [2]. Considering the population of India, the annual birth rate, and the incidence of clubfeet as 1/1000 live births, the estimated number of infants born with clubfoot is approximately 27,000 per year. The deformity, if left untreated, can result in permanent physical disability, which in turn can result in a social, economic, and psychological burden on the individual and family.

Currently, the treatment of clubfeet by the Ponseti method is considered the gold standard [3]. The main components of the treatment are serial manipulation and casting followed by a percutaneous tendoachilles tenotomy and a foot abduction brace. The treatment can achieve complete correction in >95% of patients [4-11]. The treatment is relatively cost-effective compared to surgery, making it an ideal choice for developing countries like India.

Various studies worldwide have highlighted specific barriers to implementing the Ponseti method for clubfoot treatment. These barriers include poverty, cost of treatment, cost of traveling, caregiver’s compliance to the treatment, and the parent responsible for the treatment, to list a few [10,12-17]. The purpose of this study is to analyze the effect of these barriers on the dropout rates observed with the Ponseti method of clubfoot treatment.

Materials And Methods

A retrospective study was conducted at a tertiary care government-funded hospital in the western part of India, after obtaining approval from the institutional ethics committee. The patients who underwent the Ponseti method for clubfoot at the hospital were identified. All patients who presented with idiopathic...
clubfoot at any age and completed the entire treatment (completed three-four years of night bracing) or dropped out of the treatment were included in the study. These patients were followed up and proper treatment was administered at the institute.

At the hospital, there is a dedicated clubfoot clinic that operates thrice a week to reduce the waiting period at the hospital. All patients with clubfoot are treated by trained physicians using the Ponseti method, with strict adherence to the protocol as shown in Figure 1.

![Figure 1: The Ponseti method of clubfoot correction.](image)
A: Technique of manipulation and correction of the deformity prior to applying a cast. B-E: Serial correction of the clubfoot deformity using the Ponseti method of casting.

A pretested semi-structured questionnaire was filled for each patient by a physician or post-graduate trainee fluent in English and regional language by personal interview during the initial visits after obtaining informed written consent of their parents. This questionnaire includes sociodemographic variables like age, education status of parents (the highest educational degree amongst the parents), socio-economic status, earning parent, parent accompanying the patient (the parent who accompanied the patient at the majority of the visits), cultural beliefs of the parents (belief of parents that the clubfoot deformity is caused by the will of God, punishment from God, birth at the time of an eclipse, etc.), rural/urban area, distance to the clinic, and daily wage lost during the visit (average of the daily wage lost during the entire treatment was considered for analysis). As the state funds the entire treatment, the cost of the treatment is not recorded for these patients.

Data of these patients were extracted from the clubfoot clinic. After the end of treatment of all patients, different variables in patients who completed the treatment and patients who did not complete the treatment were evaluated and barriers were identified. Thus, variables associated with dropouts were identified and compared.

Patients who completed the treatment were considered compliant. Patients were considered dropouts from treatment if they missed three consecutive planned follow-up visits during the casting or bracing phase [16]. All patients with clubfoot as a part of a syndrome or secondary to other cause, recurrence after surgery for clubfoot, or patients under treatment were excluded from the study. For the calculation of the sample size, a pilot study was conducted and a variable (distance from the hospital) was evaluated. As per the pilot study, 7.8% of patients traveled a distance of more than 50 km for the treatment among dropout patients. Using this variable, the calculated sample size using these data by OpenEpi software was 110 at a 95% confidence interval.

Continuous variables were summarized by using mean and standard deviation, and categorical values were summarized by using frequencies and percentages. Statistical analysis was performed using Microsoft Excel 2019 (Redmond, WA) and R software (R Foundation for Statistical Computing, Vienna, Austria). Chi-square test and binary logistic regression analysis were used to detect the correlation between the barriers and dropout rate, and the result was considered significant if p < 0.05.

**Results**

Most of the patients were between one and two years of age at the initiation of treatment. The mean age of the patients was 1.8 years. The mean number of casts applied before tenotomy was 7.29 ± 2.51. The demographic and socioeconomic parameters for the 110 patients are outlined in Table 1.
TABLE 1: Analysis of the demographic and socioeconomic parameters (N = 110)

The relation between dropout rates and different parameters was measured using the chi-square test, and the result is outlined in Table 2 and graphically represented in Figures 2, 3. Barriers that had a significant relation (p < 0.05) with the dropout rate were age, education status of parents, socioeconomic status, parent accompanying the patient, cultural belief, rural/urban area, distance to the clinic, understanding of clinician advice, and motivation to complete the treatment.

| Parameters                        | N (%) |
|-----------------------------------|-------|
| **Age of child at the start of treatment** |       |
| <1 year                           | 15 (13.64) |
| 1-2 years                         | 55 (50) |
| 2-5 years                         | 35 (31.82) |
| >5 years                          | 5 (4.55) |
| **Parent accompanying the child**  |       |
| Both                              | 87 (79.09) |
| Father                            | 10 (9.09) |
| Mother                            | 13 (11.82) |
| **Education status of the parent**|       |
| Graduate                          | 8 (7.27) |
| Higher secondary                  | 61 (55.45) |
| Secondary                         | 34 (30.91) |
| Primary                           | 1 (0.91) |
| Illiterate                         | 6 (5.45) |
| **Distance to clinic**            |       |
| <10 km                            | 55 (50) |
| 10-15 km                          | 7 (6.36) |
| 15-20 km                          | 1 (0.91) |
| >20 km                            | 47 (42.73) |
| **Rural/urban area coverage**     |       |
| Rural                             | 43 (39.09) |
| Urban                             | 67 (60.91) |

| Compliant (completed the treatment) | Dropout | Chi stats | P-value |
|-------------------------------------|---------|-----------|---------|
| Age of patient at the start of treatment |         |           |         |
| <1 year                             | 14      | 1         |         |
| 1-2 years                           | 50      | 5         | 17.78   | 0.00*   |
| 2-5 years                           | 20      | 15        |         |         |
| >5 years                            | 3       | 2         |         |         |
| Parents having knowledge of clubfoot and its treatment on the first visit |         |           |         |
| Yes                                 | 59      | 16        | 0.03    | 0.87    |
| No                                  | 28      | 7         |         |         |
| Having cultural belief              |         |           |         |
| Yes                                 | 0       | 7         | 22.74   | 0.00*   |
| No                                  | 87      | 16        |         |         |
| Daily wages lost due to clinic attendance|       |           |         |
| Variable                                | No. | %   | Mean (SD) | P-value |
|----------------------------------------|-----|-----|-----------|---------|
| Household income (in INR)              |     |     |           |         |
| >1000                                  | 1   | 1   | 1         | 1       |
| 100-500                                | 35  | 13  | 3.39      | 0.18    |
| 500-1000                               | 51  | 9   | 6.58      | 0.04*   |
| Parent accompanying the child          |     |     |           |         |
| Both                                   | 70  | 17  | 0.42      | 0.02*   |
| Father                                 | 5   | 5   |           |         |
| Mother                                 | 12  | 1   |           |         |
| Education status of parent             |     |     |           |         |
| Graduate                               | 7   | 1   | 0.42      | 0.02*   |
| Higher secondary                       | 49  | 12  |           |         |
| Secondary                              | 29  | 5   |           |         |
| Primary                                | 0   | 1   |           |         |
| Illiterate                             | 2   | 4   |           |         |
| Socioeconomic status                   |     |     |           |         |
| High                                   | 3   | 0   | 10.08     | 0.01*   |
| Medium                                 | 80  | 17  |           |         |
| Low                                    | 4   | 6   |           |         |
| Earning parent                         |     |     |           |         |
| Both                                   | 0   | 1   | 10.03     | 0.08    |
| Father                                 | 87  | 22  |           |         |
| Rural/urban area coverage              |     |     |           |         |
| Rural                                  | 28  | 15  | 8.34      | 0.00*   |
| Urban                                  | 59  | 8   |           |         |
| Distance to clinic                     |     |     |           |         |
| <10 km                                 | 51  | 4   | 14.66     | 0.00*   |
| 10-15 km                               | 4   | 3   |           |         |
| 15-20 km                               | 0   | 1   |           |         |
| >20 km                                 | 32  | 15  |           |         |
| Understanding clinician advice fully   |     |     |           |         |
| Yes                                    | 87  | 15  | 26.31     | 0.00*   |
| No                                     | 0   | 8   |           |         |
| Motivation for completion of treatment |     |     |           |         |
| Yes                                    | 87  | 16  | 22.74     | 0.00*   |
| No                                     | 0   | 7   |           |         |

**TABLE 2: Compliance according to different variables**

* Statistically significant observation with p < 0.05 as per the chi-square test.
Binary logistic regression was applied to the dataset, and cumulative effects of all variables were assessed as outlined in Table 3. On using enter model, the R square value was 0.832. This shows that around 83% of the variance was explained by this model. On applying the Hosmer-Lemeshow test, the significance level was 1.00, indicating that the model can be used for interpretation. As per Table 3, patients are more likely to be compliant if both the parents attend with the patient during each visit.
Thus, on applying the chi-square test, the effect of most of the variables was significant on the compliance of the patient. However, applying binary logistic regression, which shows the cumulative effect of all variables, the effect of the person accompanying the patient is significant on compliance.

**Discussion**

Various studies in low and middle-income countries such as Malawi, Uganda, China, Bangladesh, and India have used questionnaires to identify barriers to the successful implementation of clubfoot treatment programs [10,12-17]. Despite the differences in population, cultures, and resources, the barriers identified are similar in all these countries.

In Uganda, Malawi, China, Bangladesh, and India, poverty has been observed as a barrier to clubfoot treatment [10,12-17]. In our study, patients from lower and middle socioeconomic conditions had a higher dropout rate. The cost of treatment was identified as a barrier to a clubfoot treatment program in China [10]. The clubfoot program at the hospital in this study is entirely funded by the government, similar to Uganda [15]. So, the patient does not have to spend any money on casts or braces. Indirect financial burden in the form of daily wages lost on the day of attending clinics was considered as a potential barrier to the treatment. However, there was no relation between the financial burden in wages lost and the dropout rate.

Parents who were illiterate or had received only primary education had a higher dropout rate. Also, parents with strong cultural beliefs regarding clubfoot had a higher dropout rate. Parents’ knowledge about clubfoot and its treatment before the start of treatment did not correlate with the dropout rates, similar to the studies in Uganda and Malawi [12,14,15]. However, parents who understood the clinician’s advice and were motivated to complete treatment had a significantly lower dropout rate. Education and strong beliefs may hinder parents from completely understanding the clinician’s advice and affect compliance with treatment.

In the present study, the patient’s age was identified as a barrier to clubfoot treatment, with higher dropout rates observed in older children. Prolonged treatment duration for older children may have affected their compliance to the treatment and resulted in an increased dropout rate.

Patients from rural localities and those who traveled more than 50 kilometers to reach the clinic also had a higher dropout rate. All these factors make it difficult for parents to take a day off from work and incur the cost of traveling such a considerable distance to attend the clinic at regular intervals. A similar finding was observed in Uganda and China as well [10,15].

Based on this study, it is recommended to establish government-funded clubfoot clinics at the district and taluka level, which will help to serve the rural and urban locality, reduce the traveling distance, and hence the time spent on getting the treatment. Such clinics should be organized at least twice or thrice a week,
References

Human subjects: Consent was obtained or waived by all participants in this study. Institutional Ethics Committee, B.J. Medical College and Civil Hospital, Ahmedabad issued approval ECR/72/Ins/GJ/2015/RR-2019. Animal subjects: All authors have confirmed that this study did not involve animal subjects or tissue. Conflicts of interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following: Payment/services info: All authors have declared that no financial support was received from any organization for the submitted work. Financial relationships: All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. Other relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

Disclosures

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Conclusions

The study identified the barriers to clubfoot treatment, which significantly impacted compliance and dropout rates from the treatment. The barriers identified are a low level of education among the parents, lower socioeconomic status, rural locality, distance to the clinic, clinical beliefs, failure to understand clinician’s advice, lack of motivation to complete treatment, child’s older age, and parent accompanying the child.

However, considering the cumulative effect of all variables, the effect of the parent accompanying the patient is the single most important factor associated with compliance with treatment. The study results can help formulate an action plan to improve adherence to the Ponseti method for treating clubfoot throughout India.

Additional Information

Human subjects: Consent was obtained or waived by all participants in this study. Institutional Ethics Committee, B.J. Medical College and Civil Hospital, Ahmedabad issued approval ECR/72/Ins/GJ/2015/RR-2019. Animal subjects: All authors have confirmed that this study did not involve animal subjects or tissue. Conflicts of interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following: Payment/services info: All authors have declared that no financial support was received from any organization for the submitted work. Financial relationships: All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. Other relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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