

I - Rationale

Clubfoot is the most common lower limb birth defect. For the last 2 decades, Ponseti Method has become the preferred treatment for clubfoot. Worldwide, it allows an initial correction rate superior to 90%. Usually, a total of 5-6 casts and a percutaneous Achilles tenotomy are necessary. A foot abduction orthosis (FAO), consisting of 2 straight open shoes united by a bar, is prescribed after removal of the last cast, to avoid rerecurrences. Failure to use the brace adequately is the most significant risk factor for relapse. Bracing is first recommended for 23 hours per day during 3 months and then at least for 10-12 hours daily, until 3 or 4 years of age.

Recurrence rates range from 10 to 50%. Researchers have not succeeded to explain why fully corrected clubfeet relapse. Although noncompliance with bracing seems to be associated with recurrence, little is known about the etiology of relapses or about risk factors that predispose families to interrupt the bracing protocol. Recurrences are inevitably associated with costs for the child, the family and healthcare. Identifying factors that may predispose a child to have a clubfoot recurrence is important, as it may allow healthcare professionals to develop and enable appropriate allocation of supports and resources to at-risk children and families.

II - Research Question

In children with clubfoot treated by Ponseti technique in the first year of life, what are the predictors for a recurrence?

III - Objectives

Primary Objective: To determine the predictors for a recurrence in children treated in their first year of life by the Ponseti Method.

Secondary Objectives: To determine if, in children with clubfoot treated by Ponseti technique in the first year of life:

1. Age at which bracing is interrupted predicts the occurrence of recurrence.
2. Overall bracing duration predicts the occurrence of recurrence.
3. Existence of difficulties coping with bracing predicts recurrence.
4. Number of casts needed to treat the clubfoot predict recurrence.

IV - Study Design

A **case-control study** will be used to assess the relationship between possible predictors (number of casts needed to treat, age when treatment started, initial Pirani score, tenotomy performed or not, existence of previous non-Ponseti treatments, existence of difficulties during bracing, overall duration of bracing, age at which bracing was interrupted, number of children in the family, level of education of the parents, socio-economical status) and the occurrence of a relapse after age 5. This study design was chosen because it is a powerful strategy to investigate potential rare events.

V - Methodology

Ethics, population, enrolment, and retention

Research Ethics Board approval will be obtained before conduction of any study procedures. The **target population** of this study are children with clubfeet treated by Ponseti Method before the age of 1 year. The study sample will be obtained by from the

population of patients with clubfeet treated by Ponseti technique at European participating hospitals. Attending physicians and physiotherapists will identify eligible patients. Physicians or research assistants will approach and recruit patients to participate in the study. Enrollment starts on October 1, 2013.

‘Cases’ will be patients who had a clubfoot initially corrected by Ponseti Method and sustained at least one recurrence, which demanded casting, physiotherapy or surgery.

A diagnosis of recurrence will be considered if at least one foot shows features of: hindfoot equinus, hindfoot varus, midfoot cavus, forefoot adduction or dynamic supination of the forefoot. Recurrence is defined as any condition clubfoot-related perceived by the treating team as needing physiotherapy, casting or surgery.

‘Controls’ will be patients with age >5 years old, who have been treated for clubfoot and do not have any signs of relapse.

Inclusion criteria:

- Children age >5 years.
- Diagnosis of idiopathic clubfoot / clubfeet.
- Ponseti treatment (at least last cast) at the participating hospital.
- Bracing with boots-and-bar initiated at the participating hospital.
- Consent (agree to participate in the study).

Exclusion criteria

- Children with Syndromic clubfeet.
- Children under care of foster families or institutions.

***EPOS Members willing to participate may contact
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