## Prospective, Randomized Ponseti Treatment for Clubfoot: Orthopaedic Surgeons versus Physical Therapists

Derek Michael Kelly, Stephanie Ning Chen<sup>1</sup>, Tyler Daniel Ragsdale, Leslie Rhodes<sup>2</sup>, Lindsey Locke, Alice Moisan <sup>1</sup>UT-Campbell Clinic, <sup>2</sup>Le Bonheur Children's Hospital

INTRODUCTION: Clubfoot is a common congenital foot deformity in children. Over the past three decades, the Ponseti method has become the standard of care in clubfoot treatment. Currently, Ponseti clubfoot casting is performed in many centers by both orthopaedic surgeons and physical therapists; however, direct comparison of outcomes and complications of this treatment between these providers is limited. This study was designed to prospectively compare the outcomes of patients with clubfoot treated by these two groups of specialists.

METHODS: Between January 2010 and December 2014, all patients under the age of 12 months presenting with a diagnosis of clubfoot were included in the study. Exclusion criteria included age over 12 months at initial presentation, any foot deformities besides clubfoot, or any prior manipulation or casting. Patients were randomized to either an Orthopaedic Surgeon (MD) group or a Physical Therapist (PT) group. Following randomization, patients received weekly serial casting by the same treatment team until the deformity was completely corrected or until a percutaneous tendo-achilles tenotomy (perc TAT) was performed. Brace-wear was then implemented until 3 years of age. Pirani and Dimeglio scores were calculated at the initial visit, end of casting, and at each in-brace follow-up visit. Main outcome measures included the number of casts required to achieve correction, clinical recurrence of the deformity, and need for additional surgical intervention. The Fisher exact test and Welch's t-test were used to compare outcome measures between groups, with a significant difference considered to be a p value of <0.05.

RESULTS: One-hundred-twenty-six infants were included in the study. Patient demographics and characteristics (gender, race, family history of clubfoot, laterality, severity of deformity) were similar between treatment groups, with the only significant difference being the mean age of entry into the study (5.2 weeks in the MD group and 9.2 weeks in the PT group, p = 0.01). Mean length of follow up was 2.6 years. An average of 4.1 casts were applied during initial serial casting. The number of casts required trended toward a lower number in the MD group (3.8 casts in the MD group vs. 4.3 in the PT group for right-sided casting, p = 0.04, 3.9 in the MD group vs. 4.5 in the PT group for left-sided casting, p = 0.09). A perc TAT was performed in 84% of patients. There was no significant difference in the rates of clinical recurrence or additional surgical intervention between groups (Table 1).

DISCUSSION AND CONCLUSION: Ponseti casting for treatment of clubfoot performed by orthopaedic surgeons and physical therapists results in comparable outcomes without any difference in complications. While the number of casts required trended to a lower number in the MD group, this likely does not result in any clinical significance, as the difference in cast number equaled less than one week's difference in the overall duration of serial casting. These findings can hopefully give confidence to centers around the world that properly trained providers functioning in the setting of a clubfoot clinic can achieve equivalent results for babies with clubfoot deformity.

| Table 1. Comparison of clinical recurrence and additional surgery rates |           |             |            |            |            |
|---|-----------|-------------|------------|------------|------------|
|   | Follow-up | Total       | MD group   | PT group   | Difference |
|   | interval  |             |            |            | (P value)  |
| Recurrence based  | 6 months  | 39/120 (33) | 18/58 (31) | 21/62 (34) | 0.846      |
| on Pirani score   | 12 months | 51/103 (50) | 22/50 (44) | 29/53 (55) | 0.326      |
| (No. of patients/N  | 3 years   | 67/106 (63) | 29/51 (57) | 38/55 (69) | 0.229      |
| (%))  | -         | ì           | , ,        | , ,        |            |
| Recurrence based  | 6 months  | 30/120 (25) | 12/58 (21) | 18/62 (29) | 0.399      |
| on Dimeglio score   | 12 months | 46/102 (45) | 19/50 (38) | 27/52 (52) | 0.170      |
| (No. of patients/N  | 3 years   | 70/105 (67) | 31/50 (62) | 39/55 (71) | 0.408      |
| (%))  |           | , ,         | , ,        | , ,        |            |
| Additional surgery  | 6 months  | 3/120 (2.5) | 0/58 (0)   | 3/62 (5)   | 0.245      |
| (No. of patients/N  | 12 months | 11/100 (11) | 3/49 (6)   | 8/51 (16)  | 0.201      |
| (%))  | 3 years   | 25/100 (25) | 10/48 (21) | 15/52 (29) | 0.489      |