The Effect of Severity of Club Foot based on Pirani Severity Score on the Clinical Outcome and the Foot Bimalleolar Angle at the end of treatment

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ABSTRAK

Pengenalan

Kebengkokan kaki yang berterusan adalah salah satu sisa kecacatan yang dihadapi selepas rawatan kaki belantan. Sudut bimalleolar Kaki (FBA) adalah kaedah yang objektif, spesifik dan berangka. diikuti penilaian klinikal oleh Jain et al yang lebih praktikal dan objektif. Kajian kami bertujuan untuk menilai korelasi antara skor awal Pirani berbanding FBA dan hasil klinikal Jain pesakit kami selepas rawatan.

Metodologi

Penjejakan kaki dengan tahap kedua-dua malleoli kanak-kanak yang selesai menjalani rawatan Ponseti dari Januari 2009 hingga Jun 2019 telah diambil. Sudut anteromedial antara paksi panjang kaki dan satah bimalleolar diambil sebagai sudut FBA. Skor keparahan Pirani awal dikumpulkan dari rekod perubatan pesakit, dan pesakit dinilai dengan FBA dan hasil klinikal Jain selepas rawatan Ponseti.

Keputusan

Perbandingan skor awal Pirani dengan FBA dan hasil Jain dilakukan pada 26 kaki (16 pesakit). Terdapat korelasi sederhana dan negatif secara signifikan ($r = -0.62$, $p = 0.001$, $n = 26$) antara skor Pirani dan FBA. Seorang kanak-kanak dengan peningkatan unit skor Pirani mempunyai 2.85 kemungkinan pengurangan FBA. Ujian Kruskal Wallis mendedahkan hubungan signifikan secara statistik antara skor keparahan Pirani dan hasil klinikal Jain ($p = 0.01$) serta hubungan yang signifikan secara statistik antara hasil klinikal FBA dan Jain ($p = 0.01$).

Kesimpulan

Skor keparahan Pirani awal mempunyai korelasi songsang dengan sudut bimalleolar kaki akhir. Skor Pirani tinggi dan sudut kaki yang rendah dijangka mempunyai hasil klinikal kurang bagusr.

Kata Kunci: Sudut Bimalleolar Kaki, Kaki Belantan, Skor Pirani, Hasil Klinikal Jain

ABSTRACT

Introduction

Persistent foot adduction is one of the residual deformity encountered after clubfoot treatment. Foot bimalleolar angle (FBA) has been recently described for initial clubfoot assessment as an objective, specific and numerical way of assessing foot adduction. There are several clinical and functional outcome scoring system after clubfoot treatment, but clinical outcome assessment by Jain et al is more practical and objective. The aim of this study is to evaluate the correlation of initial Pirani score with FBA and Jain clinical outcome in post treatment patients.

Methodology

Foot tracings with the level of both the malleoli of children who completed Ponseti treatment for clubfoot from January 2009 to June 2019 were taken. The anteromedial angle between the long axis of foot and the bimalleolar plane was taken as the FBA angle. Initial Pirani severity score was collected from patients' medical records, and patients were graded post Ponseti treatment according to Jain clinical outcome.

Results

Comparisons of initial Pirani score, FBA and Jain clinical outcome was done in 26 feet (16 patients). There was a moderate, significantly negative correlation($r = -0.62$, $p = 0.001$, $n= 26$) between Pirani score and FBA. A child with a unit increase of Pirani score has 2.85 odd of a reduction in FBA. Kruskal Wallis test revealed a statistically significant relationship between Pirani severity score and Jain clinical outcome ($p=0.01$) as well as a statistically significant relationship between FBA and Jain clinical outcome ($p=0.01$).

Conclusion

The inital Pirani score inversely correlates with post treatment FBA. Poorer FBA and higher initial Pirani score is associated with a tendency to have a poorer Jain clinical outcome.

Key Words: Foot Bimalleolar Angle, CTEV, Pirani score, Jain's clinical outcome

CHAPTER 1: INTRODUCTION

1.1 INTRODUCTION

Persistent foot adduction is one of the residual deformities encountered after clubfoot treatment. Most clubfoot severity scoring system are exemplary to be used at initial presentation, for example Pirani severity score, which is widely accepted as user friendly, reliable and predictable [1,4]. However, most severity score are not meant to assess the residual deformity after treatment [4] since the severity is scored as a whole and does not measure the residual adduction specifically and objectively with numerical angle measurement.

Foot bimalleolar angle (FBA) has been recently described for initial clubfoot assessment as well. It has been described as an objective, specific and numerical way of assessing foot adduction [1]. There is a lack of studies describing FBA as a tool for assessing residual foot adduction after clubfoot treatment. There is also a paucity of studies describing influence of initial Pirani severity score onto FBA after treatment.

There are several clinical and functional outcome scoring system after clubfoot treatment, however some are deemed not practical and less reliable to use in a young child [2] since assessment involves pain and satisfaction like in Leevag and Ponseti functional assessment score. Clinical outcome assessment by Jain et al is practical and objective post treatment assessment [4] which assesses 3 main components of equinus, varus and hindfoot mobility. An initially severe Pirani score may result in residual adduction deformity which may also affect patient's clinical outcome. Knowing how one affects the other enables us to predict expected outcomes post treatment.

As such, our study was aimed to evaluate the relationship between Pirani score at initial presentation with FBA and Jain clinical outcome in our post treatment patients.

1.2 OBJECTIVE

General Objective

To determine association between initial Pirani severity score with post treatment FBA and Jain AK clinical outcome.

Specific objective

1. To determine association between initial Pirani severity score with post treatment FBA and Jain AK clinical outcome in group of non-surgical (Ponseti) and in group of surgical clubfoot treatment

2. To determine differences of post treatment FBA and Jain AK clinical outcome in non-surgical (Ponseti) versus surgical groups

3. To determine association between post treatment FBA and Jain AK clinical outcome.

CHAPTER 2: MANUSCRIPT

2.1 COVER PAGE

THE EFFECT OF SEVERITY OF CLUB FOOT BASED ON PIRANI SEVERITY SCORE ON THE CLINICAL OUTCOME AND THE FOOT BIMALLEOLAR ANGLE AT THE END OF TREATMENT

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2.2 ABSTRACT

Introduction

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Foot tracings with the level of both the malleoli of children who completed Ponseti treatment for clubfoot from January 2009 to June 2019 were taken. The anteromedial angle between the long axis of foot and the bimalleolar plane was taken as the FBA angle. Initial Pirani severity score was collected from patients' medical records, and patients were graded post Ponseti treatment according to Jain clinical outcome.

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Conclusion

The inital Pirani score inversely correlates with post treatment FBA. Increased FBA and lower initial Pirani score is associated with a tendency to have an excellent Jain clinical outcome.

Key Words: Foot Bimalleolar Angle, CTEV, Pirani score, Jain's clinical outcome

2.3 INTRODUCTION

Persistent foot adduction is one of the residual deformities encountered after clubfoot treatment. Most clubfoot severity scoring system are exemplary to be used at initial presentation, for example Pirani severity score, which is widely accepted as user friendly, reliable and predictable [1,4]. However, most severity score are not meant to assess the residual deformity after treatment [4] since the severity is scored as a whole and does not measure the residual adduction specifically and objectively with numerical angle measurement.

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There are several clinical and functional outcome scoring system after clubfoot treatment, however some are deemed not practical and less reliable to use in a young child [2] since assessment involves pain and satisfaction like in Leevag and Ponseti functional assessment score. Clinical outcome assessment by Jain et al is practical and objective post treatment assessment [4] which assesses 3 main components of equinus, varus and hindfoot mobility. An initially severe Pirani score may result in residual adduction deformity which may also affect patient's clinical outcome. Knowing how one affects the other enables us to predict expected outcomes post treatment.

As such, our study was aimed to evaluate the relationship between Pirani score at initial presentation with FBA and Jain clinical outcome in our post treatment patients.

2.4 METHODOLOGY

The study is a cross sectional cohort study which included children who completed Ponseti treatment for clubfoot from January 2009 to June 2019. All patients of either unilateral or bilateral clubfoot were assessed at least 1 year after completion of treatment, defined as those who underwent a course of Ponseti casting with or without Achilles tenotomy. Patient's clinic records are traced based on a list of patients collected by HUSM Paediatric Orthopaedic Clinic. Exclusion criteria include patients who already underwent correction and patients associated with complex disorders and syndrome such as arthrogryposis, teratologic disorder, myelomeningocele and other multiple complex disorders.

Foot tracings of patients were taken during follow-up to HUSM orthopaedic clinic, followed by a clinical assessment. The affected foot is painted with inkpad and kept plantigrade over white plain sheet on hard base held from upper leg. The tips of malleoli were marked by placing the edge of a ruler and transferred vertically down [1] to the footprint on the paper sheet perpendicularly. First line was drawn from the most convex part of the heel to the centre of second toe. Second line was drawn from the mark of medial malleolus to the mark of lateral malleolus on the paper. The anteromedial angle at intersection [1] was taken as foot bimalleolar angle [Fig 1, Fig 2.] The mean foot bimalleolar angle was considered to be 82.5º as observed by Jain et al [3]. Initial Pirani score [Table 1] was documented from patients' medical records, and patients were assessed and graded post treatment according to Jain's clinical criteria [3] [Table 2]. A single investigator performs the foot tracing (single tracing per foot), measures the angle and grades patients according to Jain clinical outcome.

Pearson's correlation analysis was used to test the correlation between Pirani severity score and FBA followed by single linear regression analysis. Meanwhile, a non-parametric test named the Kruskal Wallis test was applied to determine the association between Pirani severity score and Jain clinical outcomes. Between the Ponseti and surgical groups, FBA will be compared with independent T-test and Jain clinical outcomes compared with Chi square

test. Kruskal Wallis test was also used to determine the association between FBA and Jain clinical outcomes. The analysis was performed in SPSS Version 24. Differences were considered significant when the *p*-value was <0.05.

2.5 RESULTS

16 patients were recruited for this study, with 26 feet treated with Ponseti technique, and 1 foot treated surgically with an average age of 2.9 years old at outcome presentation. Out of 16 patients, 11 had bilateral CTEV while 5 had unilateral CTEV. We attributed the issue of insufficient recruits to the clinical efficiency of Ponseti casting in treating clubfoot at initial presentation [5,6], as well as lack of response due to restricted movement during the ongoing COVID-19 pandemic.

Out of 26 idiopathic clubfeet treated with Ponseti technique in this study, 12 (46.2%) were left side whereas 14 (53.8%) were right side. The mean Pirani severity score at initial presentation was 4.2 (range: 2.5 – 6), and the mean FBA was 81.6 degrees (range: 72-89 degrees; SD 4.61). By using Jain criteria for scoring clinical outcome, 20 feet (76.9%) had excellent, 5 feet (19.2%) had good, however 1 foot (3.8%) in this study had fair clinical outcome (Table 2).

The single foot which was treated surgically had a presenting Pirani score of 6, and resulting FBA of 70 degrees, and categorized as fair according to Jain clinical outcome even though no fair comparison could be made.

Pearson correlation analysis was used to determine the relationship between Pirani severity score and FBA. There was an inverse correlation between Pirani score and FBA which was statistically significant with p value of 0.001. Pearson correlation coefficient (r) was -0.62 which showed a moderate inverse correlation, as illustrated in Table 4.

Simple linear regression revealed that Pirani score has a significant inverse relationship with FBA. A baby with a unit increase of Pirani score has 2.85 odd of getting a reduction in FBA [95% CI, p = 0.001, slope(b) -2.85, constant(a) 93.6] as illustrated in Figure 3.

Non-parametric Kruskal Wallis test was used due to a small number of feet having a fair outcome in the Jain clinical outcome group. Kruskal Wallis test revealed a statistically significant relationship between Pirani severity score and Jain clinical outcome (p=0.01). The

Pirani severity score of feet having excellent clinical outcome was significantly different with the Pirani score from feet having good clinical outcome and this was proven statistically with non-parametric Kruskal Wallis test as in Table 5. Patients with good Jain clinical outcome has significantly higher Pirani severity score than those from the excellent Jain group.

Kruskal Wallis test also revealed a statistically significant relationship between FBA and Jain clinical outcome (p=0.01). The median FBA of feet having excellent clinical outcome was significantly different with the median FBA from feet having good clinical outcome and this was proven statistically with non-parametric Kruskal Wallis test as in Table 5. In other words, patients with good Jain clinical outcome has significantly lower FBA than those from the excellent Jain group.

Interobserver variation could have been decreased if the average/mean of multiple foot tracings of each individual foot was taken.

2.6 DISCUSSION

Idiopathic club foot is a perplexing foot deformation that is hard to address as a whole. It is a condition which varies both in severity and response to treatment. The objective of the treatment is to accomplish a flexible, pain free, functional, plantigrade foot [1-4]. Therefore, it is essential to portray the effect of treatment to the guardians, before and after, by using easily applicable, reproducible and objectively numerical method of assessment.

Jain AK et al [3] used the FBA as an evaluation method and found that 82.51 degrees was the mean FBA found in normal Indian infants. Jain AK et al also found that the foot bimalleolar angle could objectively evaluate the results of treatment in clubfoot. However, in term of assessing the initial severity of the clubfoot, Jain AK et al also utilized the grading system suggested by Harrold and Walker [7] which categorized the severity into either grade 1, grade 2 or grade 3 in which the higher grade signified more severe deformity. We preferred to use Pirani severity score which maintained its numerical value of the severity rather than graded them into categorical value which would dilute the statistical significance.

Dyer et al [8] successfully treated 70 idiopathic clubfeet using Ponseti method and found that there was a significant positive correlation between the initial Pirani score and number of casts required to correct the deformity. A foot scoring 4 or more was likely to require at least four casts, and one scoring less than 4 would require three or fewer, whereas, a foot with a hindfoot score of 2.5 or 3 had a 72% chance of requiring a tenotomy. Dyer et al also concluded that the Pirani scoring system was reliable, quick, and easy to use, and provided a good forecast about the likely treatment for an individual foot but a low score did not exclude the possibility that a tenotomy may be required.

In our study, we found a significant correlation between Pirani severity score and the foot bimalleolar angle in which clubfoot with higher severity score tended to have much worse foot adduction deformity. Pirani score was also the most commonly used scoring system, hence, it was worthwhile to correlate FBA with the respective severity of Pirani score.

One of the pathologies in clubfoot is the rotation of the calcaneus beneath the talus, which is revealed clinically as forefoot adduction and hindfoot varus. The FBA depends on the position of the forefoot and the shape of the heel. The improvement in the forefoot and the shape of the heel is a measure of the correction of the calcaneal rotation reflected by the correction of the FBA [3]. The use of FBA in our study was not to replace any system of clubfoot evaluation but to include a no-cost method to give objective evidence of improvement or deterioration of treated clubfoot.

Hutchins PM et al [9] and Simon GW et al [10] claimed that clubfoot with different severity would give different results eventhough they underwent a standard treatment procedure. This claim had highlighted us to investigate whether or not the initial Pirani severity score still had influence on the clinical outcome eventhough the foot already underwent treatment. Indeed, initial Pirani score did influence the clinical outcome of the already treated clubfoot in which clubfeet with a lower Pirani severity score tended to have a excellent clinical outcome compared to those with a higher severity score in our study.

Study by Jain AK et al [3] also supported the correlation of foot bimalleolar angle with the outcome of the treatment, coinciding the fact that the foot bimalleolar angle improved with the correction of the hindfoot alignment with the forefoot irrespective of the method used for correction. In our study, increased foot bimalleolar angle signified a better foot which was found to be higher in patients with excellent Jain clinical outcome compared to those with fair and good outcome. Jain clinical outcome assesses the equinus, hindfoot varus and mobility of the hindfoot, however it lacks the evaluation on residual adduction deformity. The FBA measurement would of course delineate the latter deformity and was the reason why we combined both evaluation methods in our study because we believe that we could have a better assessment in those clubfeet that we already treated.

Other methods of post treatment assessment for example radiolographic assessment was refuted in Turco et al [11] in which he concluded that the use of radiographic angles in

assessing the results may still show abnormal changes even in patients with satisfactory final results. The relation of the calcaneus and its normal alignment with the bimalleolar plane was confirmed by Cummings et al. [12] using a CT scan of ankle and foot. They found that the calcaneal bimalleolar angle was 80 degrees in the normal foot, which was quite similar to the mean FBA of 82.5 degrees in Jain et al by using foot tracings. Assessing the FBA without any risk of radiation in our study was seen as the main advantage compared to the study by Cummings et al. who used CT scan for determining the calcaneal bimalleolar angle.

Our study however was not able to address the correlation of foot bimalleolar angle and clinical outcome in clubfoot patients who underwent surgical correction due to insufficient samples. Its worth to note however that Obeidat et al [1] studied 125 resistant clubfeet treated surgically and found that foot bimalleolar angle correlated well with the clinical outcome after surgical correction regardless of the surgical technique used.

Our study revealed that initial Pirani severity score inversely correlates with post treatment FBA where a higher severity score results in a lower FBA which in turn means worse residual forefoot adduction deformity. We also concluded that patients with good Jain clinical outcome has significantly lower FBA than those from the excellent Jain group.

On a side note, FBA measurement on the foot tracing could become one of the objective criteria to be included in the assessment method while treating clubfoot. It provides objective data, good record in numerical format and can be given as indirect evidence of improvement or deterioration of clubfoot deformity following the Ponseti treatment.

2.7 CONCLUSION

The inital Pirani severity score correlates inversely with foot bimalleolar angle of clubfoot after Ponseti treatment. Increased foot bimalleolar angle after Ponseti treatment is associated with a tendency to have an excellent Jain clinical outcome. Patients with good clinical outcome has significantly higher Pirani severy score than those from the excellent clinical group. The initial Pirani severity score thus influences the final foot bimalleolar angle and the final clinical outcome of the clubfoot treated using Ponseti method. We were unable to compare FBA and clinical outcomes of Ponseti group vs surgical group in view of insufficient samples.

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2.9 TABLES & ILLUSTRATIONS

Figure 1&2: Foot tracings taken using ink pads on A4 paper

Figure 1

A right foot tracing of a 2 year old boy, post Ponseti casting. Foot bimalleolar angle (anteromedial angle of intersection) was 78 degrees with good clinical outcome. 'X' marks the projection of malleoli

Figure 2

A right foot tracing of a 3 year old girl with bimalleolar angle of 86 degrees, excellent clinical outcome

Table 1: 6-point Pirani Score

Deformity	Present and fixed (1)	Mild (0.5)	Absent (0)
Hind foot deformity			
Posterior heel crease	1	0.5	0
Empty heel	1	0.5	0
Rigidity of equinus	1	0.5	0
Mid foot deformity			
Lateral border curvature	1	0.5	0
Medial crease	1	0.5	0
Lateral head of talus	1	0.5	0

Table 2: Jain et al criteria for evaluating results of treatment for congenital talipes equinovarus

	Excellent	Good	Fair	Poor
Equinus	Nil	Tight (dorsiflexion, 5-10^0)	Heel strike reduced or absent (no dorsiflexion)	Heel high and fixed
Varus	Nil	<10^0 with weight bearing on plantigrade foot	>10^0 with weight bearing on plantigrade foot	Fixed varus with weight bearing on outer border of foot
Hindfoot mobility	Full	Reduced	Minimal	Totally stiff

Table 3: Descriptive table of statistical analysis for clubfoot treated with Ponseti casting (n=26)

VARIABLES		n (%)
CLUBFOOT	Left	12 (46.2)
	Right	14 (53.8)

VARIABLES		n (%)	MEAN (SD)
PIRANI SCORE			4.2 (1.0)
FBA			81.7 (4.6)
OUTCOME BY JAIN	Excellent	20 (76.9)	
	Good	5 (19.2)	
	Fair	1 (3.8)	

Table 4: Pearson's correlation between Pirani score and foot bimalleolar angle for clubfoot treated with Ponseti casting (n=26)

Variable	Foot Bimalleolar Angle (FBA)	
	Pearson's Correlation	p-value
Pirani Score	-0.62	0.001

Figure 3:
A single linear regression scatter chart showing the inverse relationship between initial Pirani severity score and the foot bimalleolar angle (FBA) documented during follow up. A unit increment in the Pirani score leads to a reduction in the FBA by 2.85 degrees. The Pirani severity score contributes as much as 38 percent (R^2 = 0.384) to the factors influencing the formation of FBA in this study.

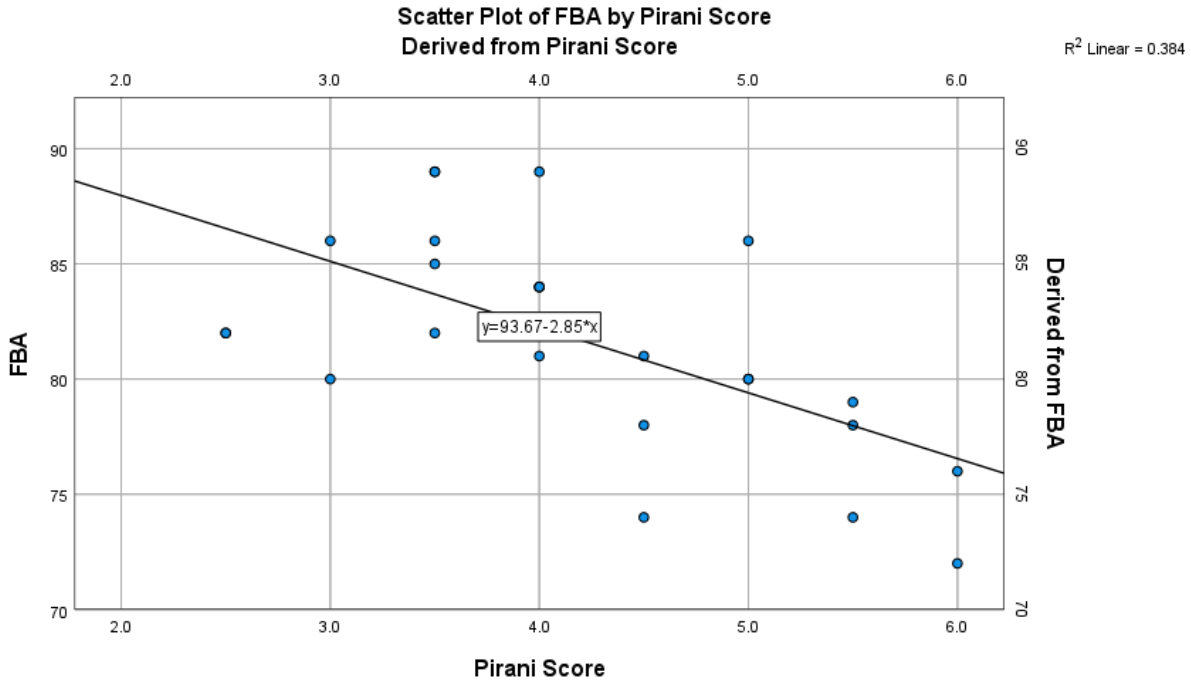

Table 5:

Kruskal Wallis Test between Pirani score and clinical outcome by Jain for clubfoot treated with Ponseti casting (n=26)

Variable		Median (IQR)	χ2(df)	p-value
Outcome By Jain	**Excellent**	4.0 (0.90)	9.52 (2)	0.009
	Good	5.5 (1.50)		
	Fair	5.5 (0.00)		

Kruskal Wallis test of comparison of foot bimalleolar angle and clinical outcome by Jain (n=26)

Variable		Median (IQR)	χ2(df)	p-value
Outcome By Jain	**Excellent**	83 (5.00)	13.55 (2)	0.001
	Good	74 (4.00)		
	Fair	78 (0.00)		

CHAPTER 3: APPENDICES

3.1 DISSERTATION PROTOCOL

TITLE: THE EFFECT OF SEVERITY OF CLUB FOOT BASED ON PIRANI SEVERITY SCORE ON THE CLINICAL OUTCOME AND THE FOOT BIMALLEOLAR ANGLE AT THE END OF TREATMENT

Introduction

Persistent foot adduction is one of the residual deformity encountered after clubfoot treatment. Most severity scoring system used in clubfoot are good at initial presentation. However this severity score are not widely used and meant to assess the residual deformity after treatment since it only scores the severity as a whole and does not measure the residual adduction specifically and objectively with numerical angle measurement.

Foot bimalleolar angle (FBA) has been recently described for initial clubfoot assessment as well. It has been described as more objective, specific and numerical way of assessing foot adduction. There is a lack of studies describing FBA as a tool for assessing residual foot adduction after clubfoot treatment, and the influence of initial Pirani severity score onto FBA after treatment.

There are several clinical and functional outcome scoring system after clubfoot treatment, however some are deemed not practical and less reliable to use in a young child since assessment involves pain and satisfaction like in Leevag and Ponseti functional assessment score. On the other hand clinical outcome assessment by Jain et al is more practical and objective which assesses 3 main components of equinus, varus and hindfoot mobility. Our study is aims to evaluate the correlation of initial Pirani score, FBA and Jain clinical outcome in our patients post treatment.