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RESEARCH ARTICLE

HOW EFFECTIVE IS STEENBEEKS BRACE IN MAINTAINING CORRECTION IN CLUBFOOT AFTER PONSETI TREATMENT

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Abstract

Background: The term "clubfoot" refers to a variety of related congenital foot deformities. It is used interchangeably to refer to clubfoot deformities that are idiopathic, atypical, syndrome, and postural. Scales designed specifically for clubfoot, like the Pirani and Dimeglio Scales, are frequently used to categorize severity. Therefore, this study is aimed to evaluate the effectiveness of Steenbeek Foot abduction brace (SFAB) to maintain the correction achieved.

Methodology: A Cross-sectional study conducted at CTEV Clinic, Department of Orthopaedic, NSCB Medical College, Jabalpur from the period of 1st Jan 2021 to 31st June 2022 with a sample size of 50 estimated through $n = z^2pq / d^2$. Study participants include Child age-<=1.5 years and Unilateral / Bilateral Idiopathic Club Foot. Statistical analysis was done through IBM Software SPSS 21.0 and association was found with confidence Interval of 95% and p-value<0.05.

Results: Current study concluded that maximum are males (54%) with an age-group of <6 months (64%) presented Bilateral CTEV (60%). Furthermore, treatment effectiveness was highest in number with the significant association between treatment effective and sex (p-value<0.05). Meanwhile, relapse was found in females comparatively to males with no statistically association (p-value>0.05).

Conclusion: The desired goal of achieving minimal disability as a result of clubfoot can be assisted in its achievement by enhancing the education and counselling of parents, removing social barriers, strengthening the training of health providers, improving access to affordable braces, and eliminating social barriers.

Introduction:-

Congenital talipes equinovarus is a Latin-based term,congenital denotes being present at birth. Talus, which refers to the ankle bone, and pes, which means foot, are combined to form the word Talipes. As a child with clubfoot is seen to walk with the foot pointed downward, like how a horse walks, Equinus is related to the word for horse. The term "varus" refers to a bone that is abnormally angulated in the clubfoot presentation of the hindfoot (the back of the foot). A common colloquialism for the appearance of the foot as "clubbed" is "clubfoot." The term "clubfoot" refers to a variety of related congenital foot deformities. It is used interchangeably to refer to clubfoot deformities that are idiopathic, atypical, syndrome, and postural. The presence of co-morbid conditions, type, severity, and laterality all affect how each clubfoot is defined (**Table 1**).[1-3]

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Table 1:- Definition of Club-foot.

Laterality
Unilateral (right or left)
Bilateral
Type
Postural
Typical
Atypical / complex
Co-morbidities
Idiopathic / isolated
Syndromal (e.g., spina bifida, arthrogryposis)
Severity
Initial assessment (e.g., Pirani / Dimeglio Scales)

A foot in the equinus, adductus, varus, and cavus positions is referred to as having a clubfoot. Fifty percent of the time, it manifests as a bilateral disorder. Clubfoot is said to occur more frequently in the right foot in unilateral cases. [2-6] Why clubfoot manifests as a unilateral and bilateral disorder are still a mystery. Data from participants with unilateral and bilateral clubfoot are frequently combined in clinical trials, but it is unclear whether bilateral cases are simply two unilateral cases on the same person, or whether they signify a distinct disorder. Clubfoot can have varying degrees of severity. Scales designed specifically for clubfoot, like the Pirani and Dimeglio Scales, are frequently used to categorise severity. [7,8] Therefore, this study is aimed to evaluate the effectiveness of Steenbeek Foot abduction brace (SFAB) to maintain the correction achieved.

Methodolgy:-

Study Period
1st Jan 2021 to 31st June 2022 (18 months)

Study Centre
Regional Center of Clubfoot, Department of Orthopaedics N.S.C.B. Medical College & Hospital, Jabalpur (M.P.)

Source Of Data
CTEV CLINIC, Department of orthopaedics, N.S.C.B. Medical College, and Hospital Jabalpur.

Sample Size:
50
Sample size(n) = z^2pq / d^2
where –n = sample size
z = 1.96 (considering 0.05 alpha, 95% confidence limits and 80% beta)
p = assumed probability of occurrence or concordance of results
q = 1 – p
d = marginal error (precision)

Inclusion Criteria:
1. Child age upto1.5 years
2. Ponseti method of serial casting is used for correction
3. Unilateral / Bilateral Idiopathic Club Foot

Exclusion Criteria:
1. Surgically corrected child
2. Child agegreater than1.5 years
3. Clubfoot associated with arthrogyposis multiplex congenital, Neurogenic, and syndromic clubfoot

Techniques Used:
1. Podograph before bracing
2. Buttressing of brace
3. Brace Features

Foot abduction bar with a distance from one shoe heel to the other equal to the width of the child'sshoulder. The shoes are externally rotated 60-70 degrees on the affected side or sides. (If the brace is not adjustable, the "normal" sidecan also be set to 60-70 degrees as normal feet externally rotate to 70 degrees easily). If the braces are adjustable, the unaffected or "normal" foot should be set to 40 degrees of external rotation. The shoe is positioned to give approximately 10 degrees of dorsiflexion. The shoe should have a heel cup to prevent the foot from slipping out of the shoe. There should be an 'inspection hole' on the medialside at the back of the shoe which is used to check that the heel is down.

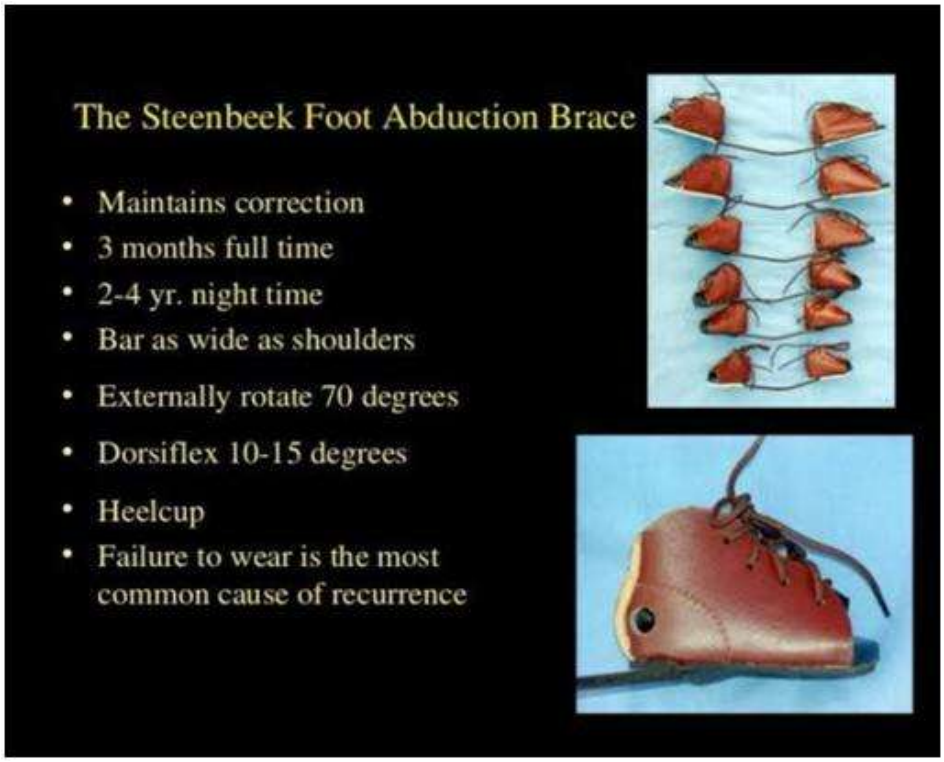

Figure 1:- The Steenbeek foot abduction brace.

Brace Timing

In children under walking age, the brace is worn 23 hours per day for 12 weeks. It is then worn at night and nap time until the child is 4 -5 years old. Wearing the brace must be started as soon as the last cast is removed to avoid the foot turning back into its previous position.

Bracing Protocol

a)Brace fitting instructions for clinicians/ technicians

Immediately after removal of the final cast post-tenotomy, i.e., on the same day

1. Fit most difficult foot first.
2. Gently flex the hip and knee and dorsiflex the foot as much as possible
3. Hold in position
4. Push the foot heel first into the shoe
5. Check through the inspection hole to make sure the heel is down
6. Close the tongue
7. Check again and tie laces or tighten the straps (if using a shoe with straps fasten the middle one first)
8. Then repeat with the second foot

b)Brace Fitting Instructions to Parents

1. Check Skin Condition / Circulation regularly
2. Use socks for comfort but check they are not creased
3. Must be a firm fit to avoid friction with movement
4. Constant usesignifiesmore Compliant Child

5. Check Heel Down
6. Advise to look for red marks, blisters, and cold toes
7. Wrap knees around mother's body, rather than feet, when carried on back
8. Inform them of their next appointment

Ethical Approval:
The study was conducted after getting ethical permission taken from the IEC committee of the medical college. Also, the written informed consent from the patients were taken prior to enrolling them for the study.

Statistical Analysis
Statistical analysis was done through IBM Software SPSS 21.0 and association was found with confidence Interval of 95% and p-value<0.05.

Sampling Method:-

Considering the best availability of the patients by reviewing the previous records of this health facility, to achieve the maximum sample size, random screening of all patients was done and only those were selected who fulfilled the inclusion and exclusion criteria. Informed and written consent was be obtained from each individualsparent.

Results:-

Table 1:- Distribution of Participants according to sex and age-group (n=50).

Sex	**N**	**%**
Female	23	46.00%
Male	27	54.00%
Total	**50**	**100%**
Age group	**N**	**%**
<6 month	31	62.00%
≥6 month	19	38.00%
Total	**50**	**100%**

Above tableconcluded that most of the cases were male i.e., 54%, however there is not a significant difference between male and female ratio (46%).The above table shows that, most of the cases belongs to the age group of <6 month.ie 62%, while minimal of the study participants were in age-group of more than or equal to 6 months.

Table 2:- Distribution of Participants according to the Site of CTEV (n=50).

Site	**N**	**%**
Bilateral foot	30	60.00%
Left feet	10	20.00%
Right feet	10	20.00%
Total	**50**	**100%**

From the table 2, it is observed that out of the total 50 patients, 60% were bilateral, 20% each of the patients presents with the left side and right side of CTEV.

Table 3:- Distribution of participants according to the Ponseti Cast (n=50).

Ponseti Cast	Count	Column N %
< 8	38	76.00%
≥8	12	24.00%
Total	50	100%

Table 3concluded that the ponseti cast was applied in all cases. This cast was divided into 2 categories i.e., <8 and ≥8. However, predominance was seen in the category <8, around 76%, while category≥8 was affected only by 24%.

Table 4:- Distribution of Participants according to the Tendoachilles Tenotomy (n=50).

Tenotomy	Count	Column N %
YES	30	60.00%
NO	20	40.00%

Total	50	100%

The above table shows that, tendoachilles tenotomy was done only in 60% (30) cases while in remaining 40% (20) cases,tentotomy was not required.

Table 5:- Effect of the CTEV treatment according to the sex andage-group.

Variable		Effective		Relapse		p-value
		N	%	N	%	
Sex	**F**	15	37.5%	3	16.70%	**0.03**
	M	25	62.5%	0	0.00%	
Age group	**<6 month**	23	57.5%	3	11.50%	0.14
	≥6 month	17	42.5%	0	0.00%	

The above table shows the effective status of the cases. Among 40 patients, effective treatment was shown by male patients (62.5%), while relapse was seen in the female patients (16.7%). However, there is a statistically significant difference been found in the treatment effectiveness and Sex **(p<0.05).**The above table also inferenced that, most of the effective cases and relapse cases were seen in the age group of <6 month i.e., 57.5% and 11.5%, respectively. However, there is no statistically significant association between the treatment effect of CTEV and the following age-group (p>0.05).

Discussion:-

In our study most of the cases were in age group <6 month.ie 62%. In a study done by **Dinesh et al** the mean age of starting treatment was 15.8 weeks (approximate 4 months) which is accordance with our study. [9] While the average age of participant was 2 years reported by **Agarwal et al.**which is in contrast with our study.[10] There is preponderance of male gender, i.e., 54% are male participants and 46% were female. In a study by **Agarwal et al**themale to female ratio was 6:1 which is quite higher than our study. Out of 50 patients 30(60%) were bilaterally affected and 20 were affected unilaterally 10(20%) were left side patients and 10(20%) right side patients.Most of patients were affected bilaterally.

In the present study we used SFAB (Steenbeek Foot Abduction Brace) among50 cases we found 7 (14%) were non-compliant with the brace and among 43 compliant cases, the relapse was observed among 3 only.The most popular braces in industrialized nations are the Mitchell Ponseti and Markell braces. M. **Thacker et al.** reported their experience with the Markell brace in 2005 on 30 patients (44 feet). They discovered 18% noncompliance with the brace, of which 57% (8 feet) showed recurrence with no recurrence in those who wore the brace as directed non-compliance of our study is supported by finding of **M.Thacker et al**. [11-12] In 84 feet (57 patients) with idiopathic clubfoot, the Mitchell Ponseti brace described for complex clubfeet was studied. **L. Zionts et al.** reported their findings in 2012 and found 40% noncompliance with 48% recurrence rate, of which 30% were noncompliant. In 18% feet, recurrence was observed despite being adherent to the brace [8]. Although these braces were proven to be effective and are frequently used in affluent nations, most people in underdeveloped nations cannot afford them due to their high cost (between $100 and $300).

In our study, recurrence occurred in 10 patients (20%), of whom 3 (6%) were brace-compliant and 7 (14%) were not compliant. After follow-up of 6 months with SFAB, 86% were compliant. We discovered that the significant factor affecting recurrence was brace compliance and failure of brace even after compliance. The reason for high compliance levels we saw in our studymight be due to the reason that in every visit, the parents received education regarding the sickness and the significance of the brace; the parents were required to apply the brace under supervision and they were urged to get in touch with us right away if they ran into any issues.

The SFAB is easy to obtain and maintain and is affordable by most people in developing countries. As a child grows they generally need 2-3 brace size changes in an year and the brace maintains its functional integrity for much longer duration and any minor wear and tear can be repaired easily to retain function, hence if it can be used at an institute like Regional Center of Clubfoot, Netaji Subhash Chandra Bose Medical College, which is a referral center for district with staff specifically assigned for clubfoot management, and resources to store and repair the brace and where patients can be expected to be in constant touch with the institute. The brace can be reused for another child after one grows out of the brace, this further reduces the per capita cost of the brace.

Conclusion:-

Although the Ponseti procedure has significantly improved the treatment of clubfoot, the deformity must be maintained for an extended length of time after it has been corrected. One of the trustworthy approaches that can be utilized to accomplish the goal is the SFAB (Steenbeek Foot Abduction Brace). Major obstacles in the treatment of clubfoot include patient adherence and recurrence of the condition. Because the brace needs to be worn for long period, the treatment process might be difficult. It is vital to adhere to known bracing protocols and standard SFABs in order to deliver the maximum benefit possible to patients. Until further evidence is released addressing the shorter length of bracing and the efficacy of novel designs, this information will not be available.

Recommendation:-

Present study recommended that the desired goal of achieving minimal disability as a result of clubfoot can be assisted by enhancing the education and counselling of parents, eliminating social barriers, strengthening the training of health providers, improving access to affordable braces.The minor complications like pressure sore, allergy, swelling can arise so, the parents must be counselled beforehand. Also, using of the bracing at night and nap time when the child sleeps is much more feasible.Furthermore, Parents also need to take regular follow-up to check the shoe size and bar length.Lastly the future intensive research on the various responses of the medial and posterior ankle soft tissues is required for the improvement in the brace's technique.

Funding:
Nil.

Conflict Of Interest:
Nil.

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