

use. Subjects were tested using computerized measurement of radiological parameters like Tibiofemoral angle at first visit and after 3 months. Pain and activity levels were recorded using 50 feet walk time and VAS pain score. **Results and Conclusion:** Study population was female predominant (mean age 53 years, body mass index 25.1 kg/m2). Most of the patients reported immediate symptomatic improvement with less pain on walking. Though there was slight improvement in both tibio-femoral angle but it was statistically insignificant. Valgus bracing is effective in reducing pain and improving activity level in patients with OA with varus deformity.

KEYWORDS : tibio - femoral angle, knee osteoarthritis, valgus brace

INTRODUCTION

Osteoarthritis (OA) is a dynamic phenomenon occurring as a disparity between the mechanical stresses applied to the cartilage and the ability of the cartilage to withstand that stress. Among the elderly, knee OA is the leading cause of chronic disability in developed countries.¹ It presents as a severe disabling musculoskeletal disorder making it one of the most prevalent chronic disabiling condition². Joint involvement is usually asymmetrical with a predilection for weight bearing joints. It is more common joints (fingers, hip, knee, spine) than others (elbow, wrists and ankle)². Of the various common sites, OA knee is the most common, which could be uni-, bi- or tri compartmental; among which commonest is medial compartmental OA changes³. In primary OA, it is believed that excessive load causes failure of an otherwise normal joint⁴.

The load applied to the medial compartment is 2.5 times times more than the load applied to the lateral side⁵. It has been proved through prior research that patients have benefited from unloading the medial compartment using knee orthosis. This study was a sincere attempt to find out if there is any biomechanical effect with a particular aspect of non-pharmacological therapy viz. use of valgus knee orthosis or unloading knee brace in OA of medial compartment of knee with varus deformity by measuring parameters like visual analog scale (VAS) for pain, 50 feet walktime and Radiological measurement of Knee angle or tibio-femoral angle leading to reduction of pain, improvement in selfimage and achieving energy efficient gait pattern. Thereby, in improvement of quality of life (QOL), which was the goal of management.

MATERIALS AND METHODS

A prospective observational study was conducted at the. Sample size was calculated based on VAS and 50 feet walk time as outcome measures. A total of 32 patients were included in this study over a period of 18 months (June 2018 to December 2019. Patients suffering from mainly medial compartment OA of knee with varus deformity were selected for intervention after informed consent (considering inclusion and exclusion criteria). Every patient was explained about the course and prognosis of the disease, its present available management, the outcome, the orthosis and its wearing schedules and complications in a language that was understandable to them. All participants were given free choice to withdraw themselves from the study whenever they wanted.

INCLUSION CRITERIA:

Active and ambulatory patients of 40 years, who presented with nontraumatic chronic knee pain of at least 3 or more on VAS score for 3 months with Unicompartmental Osteoarthritis of knee, Grade ≥ 2 Kellgren Lawrence Radiographic severity of tibiofemoral Osteoarthritis in standing Antero-posterior(AP) view.

EXCLUSION CRITERIA:

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- 1. History of knee trauma or surgery in the past 6 months or amputation of lower limb joints.
- 2. Patients with hip or knee contracture.
- 3. Intra-articular steroid injection in the past 6 months.
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- 4. Intra-articular hyaluronic acid injection in past 9 months.
- 5. Symptomatic spine, hip, ankle or foot disease.
- 6. Hip and/or ankle pathologies, interfering with orthosis use
- 7. Calceneo valgus deformity.
- 8. Everted foot
- 9. Neurological disease interfering with cognition.
- 10. Varicosities.
- 11. Absence of independent walking
- 12. Any limb length discrepancies, congenital anomalies or neuromuscular disorders of lower extremity.

The selected patients were examined at baseline (visit 1). The age, height, weight, active and passive range of motion (ROM) in bilateral knee joints, VAS score for knee pain, and the Kellgren-Lawrence (K-L) grade for the stage and degree of bone destruction were evaluated at the baseline. Height was measured to nearest 1 cm using a stadiometer and weight was measured to nearest 1 kg while the subjects stood erect. Body mass index (BMI) was calculated using weight and height measurements (kg/ m^2). In addition, the range of motion for knee was measured to 1 degree by a goniometer. To adequately assess the changes in the knee joints, the antero-posterior (AP) were obtained in standing position. Radiographs were evaluated for changes in the characteristics of knee OA in the AP views using the Kellgren and Lawrence grade, as described in the Atlas of Standard Radiographs. The femorotibial angle was formed by a pair parallel lines drawn through the distal one-third of the femur and the proximal one-third of the tibia.



Figure 1: Measuring Tibio-Femoral angle using MATLAB Software

Lines were drawn through the middle of the femoral shaft and through the middle of tibial shaft. Please inser The angle subtended at the point at which these two lines met was based on a modification of the method of the Moreland et al⁶ and Felson et al⁷. The angle of 178° to180° was considered as varus. VAS and 50ft walk was time documented.

They were be applied the standard and properly fitted valgus/unloader knee brace as the primary management of their osteoarthritis knee and to be worn daily during day time activities except while using toilet and during rest in lying down position. All patients were educated about therapeutic life style changes and energy conservation techniques. In

Graph 2: Mean pain Score in VAS in two visits

every case progressive muscular strengthening rehabilitation program that mainly used quadriceps and hamstring exercises were prescribed and demonstrated.

The patients were examined using the above mentioned parameters after intervals of 3 months (visit 2).

The protocol for this study was approved by the Scientific and Ethical committee of Post Graduate Medical Education and Research (IPGME&R), Kolkata

RESULTANALYSIS

Data summarized using descriptive statistics Microsoft Excel to calculate the means with corresponding standard deviations (s.d.) and standard errors (s.e.)., Epi Info (TM) 3.5.3. Epi Info is a trademark of the Centers for Disease Control and Prevention (CDC) and MATLAB software for computerized measurement of angles through Radiographs and represented graphically. Paired test was used to determine significant between baseline and 3 month assessment. One Way Analysis of variance (ANOVA) followed by Tukey's Test was performed for each parameter with the help of Critical Difference (CD) or Least Significant Difference (LSD) at 5% and 1% level of significance to compare the mean values between visits (from V1 to V2). Test of proportion was used to find the Standard Normal Deviate (Z) to compare the difference proportions and chi-square (χ^2) test was performed to find the associations. Pearson Correlation Co-efficient (r) was calculated to find the correlations between different parameters. Paired t-test was used to test the difference between means. p≤0.05 was taken to be statistically significant.

In this study, the mean age (mean \pm s.d.) of the patients was 53.75 \pm 8.41 years with range 40-71 years and the median age was 53.0 years. 31.3 percent of the subjects were male while 68.8 percent patients were female. Test of proportion showed that the proportion of females was significantly higher than the proportion of males (Z=3.00; p<0.001).

The mean age (mean \pm s.d.) of the males was 54.60 \pm 9.28 years with range 45-71 years and the median age was 51.0 years. The mean age (mean \pm s.d.) of the females was 53.36 \pm 8.18 years with range 40-67 years and the median age was 53.0 years.

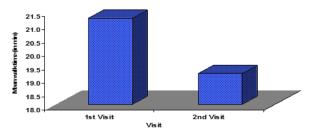
The mean Body Mass Index (BMI) (mean \pm s.d.) of the patients was 25.18 \pm 3.19 kg/m² with range 18.0-31.1 kg/m² and the median BMI was 25.0 kg/m². 6.3% of the patients were obese but there was no significant difference between proportion of obese and non-obese patients (p>0.05).

Test of proportion of Radiological grading of knee osteoarthritis (Kellegren &Lawrence) of the patients showed that the proportion of patients with radiological grade (K-L) 3 was significantly higher than the other grade (Z=3.26; p<0.001).

Patients were reassessed after 3 months valgus knee brace fitting of appropriated size and other standard rehabilitation protocol as mentioned. Only one patient complained of redness of skin and minor abrasion of the skin due to brace wear.

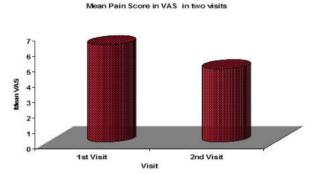
Paired t-test of 50 feet walk time in minutes (mean \pm s.d.) in two visits showed that mean walk time in the 2nd visit (19.15 \pm 5.82) was significantly lower (p<0.01) than the 1nd visit (21.21 \pm 6.89).

50 feet mean walk time (in minutes) in two visits



Graph 1: 50 feet mean walk time (in minutes) in two visits

Paired t-test VAS PAIN SCORE showed that mean pain score (VAS) in the 2^{nd} visit (4.75±1.29) was significantly lower (p<0.01) than the 1^{st} visit (6.31±1.11).



Radiological assessment of response to therapy as measured from tibio-femoral angle (knee angle) in the visits shows that the (mean \pm s.e.) in the 1st Visit was Right knee was 180.65 \pm 0.26 and Left knee was 180.65 \pm 0.26 while in the 2nd Visit Right knee was 181.19 \pm 0.24 and Left knee was 181.11 \pm 0.27. ANOVA for Tibio-femoral angle of knee between the groups and within the groups was not significant (>0.05).

Table-1: Difference of means and level of significance for Tibiofemoral angle of knee

| | Difference of mean | Significance |
|---|--------------------|--------------|
| Right knee 1 st visit Vs 2 nd visit 0 | 0.46 | p>0.05 NS |
| Left knee 1 st visit Vs 2 nd visit 0 | 0.44 | p>0.05 NS |

NS-Not Significant

ANOVA showed that there was no significant difference in tibiofemoral angle of knee in two visits ($F_{3,124}$ =1.42;p<0.05).

DISCUSSION

This study showed that patients with unicompartmental osteoarthritis of knee can be helped by the use of a valgus brace. Age is an important factor for the occurrence of osteoarthritis as majority of the patients were old with mean age of 53.7 yrs. Though incidence osteoarthritis was also found in increasing numbers in the 5^{th} decade.

Majority of the patients were females, comprising 68.8 % of total study population which suggests that osteoarthritis is more prevalent in females as supported by many literatures. Though obesity is an important factor for occurrence of osteoarthritis of knee, the mean BMI (Basal Metabolic Index) of this study was 25.18. Majority of the patients had K-L (Kellgren-Lawrence) grade 3 osteoarthritis with 65.6 % of the total study population. Grade 1 were not included in the study, as most of Grade 1 patients do not have significant pain or deformity. For 50 feet walk time, it has been seen that there was significant improvement of 50 feet walk time in the study group after 3 months of regular use of orthosis. The same pattern of improvement was seen forVAS pain score. It is important to mention that none of the patients enjoyed pain reduction to zero on VAS scale. In most cases pain intensity was reduced and so was the need of pharmacological agent for pain management. Onset of improvement of pain while walking was seen immediately after donning of orthosis. The improvement in pain and function was supported by the results of Polloet. al (1994)⁸, Linenfeld et al $(1997)^9$ Hewett et al $(1998)^{10}$.

There was improvement of Tibio-Femoral angle on Radiological assessment after 3 months of orthosis wear but it was found to be statistically insignificant. This substantiates the findings of Horlick and Loomer (1993)¹¹, but contradicts with the results of Komistek et al.¹² The improvement in VAS pain score negatively co-related with tibio-femoral angle. The co-relation was found to be significant for left knee but not significant for right knee. Reasons of this could not be understood. So, no conclusion of association between VAS pain and Tibiofemoral angle could be established.

Though there was an increased sense of balance on wearing the brace but still compliance was difficult with average brace wear time as 6.5 hours/day mainly due to sweating and bulky orthosis

Further work is required to determine the extent the effectiveness of valgus braces with time, to investigate the alteration in internal load of the knee when the brace is worn and to determine whether there are biological consequences of unloading a degenerative area of articular cartilage.

LIMITATIONS

There were a few limitations arising out of the process of carrying out the study in our context. This was a short term study of the subjects at 0 and 3 months that was carried out to study the efficacy of knee orthosis. A longer time-period longitudinal study, extending for several months, in motivated subjects with long daily usage of brace, is desirable to have greater insight into the usefulness of these orthosis in OA knee. Further a randomized controlled, comparative study, comparing different type of Valgus brace along with Gait analysis data will be beneficial in understanding the efficacy and mechanism of responsible for improvements of symptoms.

CONCLUSION

Osteoarthritis is more prevalent in females. The incidence of osteoarthritis is in rise in younger age group of people eg.in 5th decade. Knee orthosis is an effective conservative approach of treating early to advanced osteoarthritis with varus deformity. Knee orthosis is effective in osteoarthritis knee in terms of reduction of pain, function, reduction of 50 feet walk time The effect of knee orthosis on Tibio-Femoral angle is present but statistically insignificant. Patient compliance is difficult as brace is bulky, though increased sense of balance and proprioception is present on wearing the orthosis. In conclusion, though there are many parameters other than pain which may disturb the gait pattern like changes in proprioception and lack of confidence in the affected limb and despite the fact that our study does not explain the mechanism which are responsible for improvement of symptoms, it does add objective evidence that valgus knee bracing for unicompartmental osteoarthritis of the knee is clinically effective in the early to advanced stages. There is pain and stiffness reduction, energy efficient gait, thereby improving quality of life.

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