Effect of Lateral Wedge Insole on Pain and Function in Medial Compartment Osteoarthritis Knee- An Evidence Based Study

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ABSTRACT

Background: Osteoarthritis is the second most common rheumatologic problem & nearly 80% of population shows OA among the patient who claimed for knee pain and limitation in movement, out of which approximately 25% cannot perform their major daily activities of life.(WHO 2019)As per recent study, prevalence of knee OA in India is 28.7% with medial compartment more involved than lateral.

Purpose: To study the evidences regarding effect of lateral wedge insole patient with medial compartment osteoarthritis of knee on pain and function.

Methodology: The study was conducted according to Preferred Reporting Items for systematic reviews and meta-analysis guidelines. Evidences selected since year 2005-February 2019 from PubMed, Google Scholar, Physiotherapy Evidence Database(PEDro), ResearchGate, ScienceDirect, Wiley's online library and The Cochrane library. Key words used were: Lateral wedge insole, knee osteoarthritis, Pain and Function. Analysis was done using 2 scales: PEDro scale and Centre for Evidence-Based Medicine Levels of Evidence Scale. Total 200 articles were found, out of which 23 articles were relevant and from those 16 articles were included in the study and other articles were excluded as per eligibility criteria. Results: 13 studies were shown that lateral wedge insole is effective treatment for reducing pain and improving function.(Level of evidence-1a,1b,2b) 3 studies were showed that lateral wedge insole have none or same effect as other conservative treatment in knee osteoarthritis. (Level of evidence-1a,1b,2b).

Conclusion: Based on the evidences taken from search engines: PubMed, Google Scholar, Physiotherapy Evidence Database(PEDro), ResearchGate, ScienceDirect, Wiley's online library and The Cochrane library of year 2005-2019 and analysis of all concluded that, full length wedge insole is found to be an effective conservative treatment for reducing pain and improving function in medial compartment knee osteoarthritis.

Key Words: Lateral wedge insole, knee osteoarthritis, pain and function.

INTRODUCTION

Osteoarthritis (OA), also known as degenerative joint disease or osteoarthritis, is the most common form of arthritis and the leading source of physical disability with severely impaired quality of life in people. ^[8] Osteoarthritis is a disorder of cartilage degradation synovial inflammation, osteophytes formation, thinning of joints space and sub-chondral sclerosis. ^[1]

Globally knee OA ranks 4th most common cause of incapability in women and 8th in men.^[1] India impact, nearly 80% of population shows OA among the patient who claimed for knee pain, out of which approximately 20% reported incapability in daily activities and around 11% need peculiar care. Approximately 40% population of more than 70 years shows OA, in which nearly 2% have severe knee pain and disability.^[2] As per recent study a prevalence of knee OA is 28.7 %, this varies

slightly in the individual states- Agra (35.5%), Bangalore (26.6%), Kolkata (33.7%), Dehradun (27.2%), and Pune (21.7%).^[3]

Foot Posture has been suggested to be related to the development of lower limb musculoskeletal conditions because of it's potential influence on the mechanical alignment and dynamic function of the lower limb. ^[12] Lateral wedge insole placed under the sole of the foot and angulated so that it is thicker over the lateral than medial edge, transferring loading during weight bearing from the medial to the lateral knee compartment and reduce pain and improve functional activity. ^[11]

METHODOLOGY

Study Type: This is an Evidence Based Study was conducted according to Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines (Figure 1).

Search strategy: The search engines used for the finding out appropriate articles were: PubMed, Google Scholar, Physiotherapy Evidence Database (PEDro), Research Gate, Science Direct, Wiley's online library and The Cochrane library

Key words used for the search were: knee osteoarthritis, lateral wedge insole, Pain and function.

Eligibility criteria: Articles were selected from last 15 years (2004 April 2019).Total 200 articles were found, out of which 19 articles were relevant and from those 16 articles were included in the study (Table 1). Other articles were excluded because it didn't involve population of low back pain and outcome measures were other than pain and function. (1).

Table 1:	Characteristics	of ir	ncluded	studies

Sr No.	Title	Study Design &Duration	Articles Or Sample Size	Outcome Measures	Pedro And Level Of Evidence
1	The optimal degree of lateral wedge insoles for reducing knee joint load : a systemic review and meta-analysis ^[14]	Systemic review and meta-analysis	15 studies with total 415 participants	First EKAM VAS WOMAC	1a
2	Is the Wedged Insole an Effective Treatment Option When Compared with a Flat (Placebo) Insole: A Systematic Review and Meta-Analysis ^[15]	A Systemic review and Meta-Analysis	898	WOMAC FTA	1a
3	Ineffectiveness of lateral wedge insoles on the improvement of pain and function for medial knee osteoarthritis ^[16]	Meta-analysis	938 total 478 with LWI and 460 with set as control	WOMAC	1a
4	Lateral Wedge Insoles as a Conservative Treatment for Pain in Patients With Medial Knee Osteoarthritis A Meta- analysis ^[17]	Meta-analysis	502	WOMAC VAS	1a
5	Feasibility of Lateral Wedge Insole v/s Neutral Insole in combination with Neuromuscular Training on Pain and Function in patients with Medial Compartment Osteoarthritis of Knee – a Pilot Double Blinded Randomized Control Trial ^[18]	A randomized controlled trial (6 weeks)	10 in each	TUG VAS WOMAC	10/10 1b
6	The efficacy of a lateral wedge insole for painful medial knee OA after prescreening : A RCT ^[28]	A randomized controlled trial(8 weeks)	83	KOOS WOMAC	10/10 1b
7	A comparative study of the lateral wedge insole shoe modification on the patients with knee osteoarthritis. ^[29]	Comparative experimental study	65	WOMAC	2b
8	Knee and ankle biomechanics with lateral wedges with and without a custom arch support in those with medial knee osteoarthritis and flat feet ^[27]	A randomized controlled trial	26	VAS, 3D Gait analysis	6/10 1b
9	Clinical effect of lateral wedge arch support insole in knee osteoarthritis- double blind randomized study ^[20]	A randomized controlled trial (3 months)	90	KOOS	8/10 1b
10	A comparison of the biomechanical effect of valgus knee braces and lateral wedge insoles in patients with knee osteoarthritis [26]	Pre-post intervention Comparative study (2 weeks)	28	VAS WOMAC	7/10 2b

		Table 1: Continu	ed		
11	Lateral wedge insole for knee osteoarthritis: Rct ^[19]	A randomized controlled trial(8 weeks)	58	VAS WOMAC LEQUENSE QUESTIONNAIO RE	7/10 1b
12	Effect of length on laterally wedge insoles in knee osteoarthritis. ^[21]	Comparative study	13	Vicon motion analysis system	5/10 2b
13	The effect of various kinds of lateral wedge insoles on performance of individuals with knee joint osteoarthritis ^[25]	A randomized controlled trial (2 months)	36	WOMAC	5/10 1b
14	Lateral wedge insoles for medial knee osteoarthritis : 12 month controlled trial ^[24]	A randomized controlled trial (4 months)	200	NPRS WOMAC	7/10 2b
15	The effect of different elevation of laterally wedge insoles with subtalar strapping on medial compartmental osteoarthritis of the knee ^[18]	Prospective quasi- experimental evaluation	62	WOMAC	8/10 2b
16	An optimal duration of daily wear for an insole with subtalar strapping in patients with varus deformity osteoarthritis of the knee ^[23]	A randomized controlled trial (2 weeks)	81	LEQUESNE INDEX RADIOGRAPH for femorotibial angle	10/10 1b

Figure 1: Preferred Reporting Items for systematic reviews and meta-analysis (PRISMA)



Data Analysis: All 16 articles were assessed using 2 scales:

 (1). The PEDro scale: It assesses methodological quality and consists of a checklist of 11 criteria, 10 of which are scored. For each criterion the study met, 1 point was awarded. The points were tallied and presented as a score out of 10. The scale applies only to experimental studies. For this review, investigations with PEDro scores of 6 to 10 were considered high quality, of 4 to 5 were considered moderate quality, and of 0 to 3 were considered low quality.

The PEDro score has demonstrated 'fair' to 'excellent' inter-rater reliability (Intraclass Correlation Coefficient 0.53-0.91) for randomized controlled trials of physiotherapy interventions. Convergent validity is supported for the PEDro score through correlation with other quality rating scales including: the Jadad scale (0.35) and van Tulder 2003 scale (0.71) for clinical trials of physiotherapy related interventions. ^[7] (Appendix 1)

(2). The CEBM's Levels of Evidence scale: It assesses quality based on study design, which categorize the studies in a scale ranging from 1 to 5 with further subdivision for each. (Appendix 2)

RESULTS

Evidences were reviewed and analysis was done on the basis of PEDro score and CEBM's Level of Evidence Scale.

Total 200 articles were found, out of which 19 articles were relevant and from those 16 articles were included in this evidence-based study and other articles were excluded as per eligibility criteria. From total 16 studies, there are 2 meta analysis of RCT(1a),1 systemic review and meta analysis (1a),7 randomized controlled (1b).3 prospective randomized trial study(2b),1 comparative study (2b) shown that lateral wedge insole has significant medial compartment knee effect on osteoarthritis when compared to general treatment (conservative) and when combined with other exercises. Their Level of evidence was 1a,1b and 2b.

2 out of 16 (1 systematic review and 1 randomized controlled trial) studies. Their Level of evidence 1a and 1b. Their results showed that lateral wedge insole has same effect as neutral insole or as a placebo rather than actual effect on knee osteoarthritis. Which make it use of lateral wedge insole still controversial for use.

DISCUSSION

Total 16 studies were included in this evidence-based study. The methodological qualities of included studies were low to high. The sample size varied from 20-938 subjects.

Total 16 studies were reviewed from various search engines and included in this evidence-based study.

14 articles concluded that lateral wedge insole is effective in medial compartment osteoarthritis. (level of evidences:1a,1b,2b)

There are 3 strong scientific evidences (Meta analysis and systemic review) suggests that optimal angle of wedge that best for OA is with the lowest possible degree lateral wedge insole which cause overall reduction in biomechanical parameters.

There are 11 moderate to high quality of evidences (RCT, A prospective randomized study and pre-post comparative study) suggests that by placing the wedge under sole of foot which is angulated so that it is thicker over lateral side than medial edge, transferring loading during weight bearing from medial to lateral knee compartment.

So compared to control group lever arm of (GRF) Ground reaction force in frontal plane at knee get reduced with lateral wedge insole.

This study found that using 8 to 12 mm elevation wedge with subtalar strapping is more comfortable for daily use with optimal duration of 8 to 10 hrs in a day, full length and not just heel wedge insole is important as entire lateral border of foot is a key feature of the knee adduction moment for reducing loading.

2 Article concluded that there is no effect of lateral wedge insole in medial compartment osteoarthritis knee. (level of evidences : 1a,1b)

There is 1 strong evidence and 1 high quality of evidence which concluded that effect of lateral wedge insole was very small and clinical significance in only a minority of patients.

CONCLUSION

Based on the evidences taken from search engines: PubMed, Google Scholar,

Physiotherapy Evidence Database(PEDro), ResearchGate, ScienceDirect, Wiley's online library and The Cochrane library of year 2005-2019 and analysis of all concluded that, full length wedge insole is found to be an effective conservative treatment for reducing pain and improving function in medial compartment knee osteoarthritis.

Abbreviations

PEDro: Physiotherapy Evidence Database, CEBM: Center of Evidence Based Medicine, **PRISMA:** Preferred Reporting Items for systematic reviews and metaanalysis, OA: osteoarthritis, KAM: knee adduction moments (KAM), FPI: Foot posture index, MCL: Medial collateral ligament, LCL: lateral collateral ligament, ACL: Anterior cruciate ligament, PCL: Posterior cruciate ligament, LWI: lateral Neutral wedge insole. NI: insole. WOMAC: Western Ontario and mcmaster universities osteoarthritis index, VAS: Visual analogues scale, FTA: Femorotibial angle. **KOOS:** Knee injury and osteoarthritis, TUG: Timed up and go test, NMT: Neuromuscular training, NPRS: Numeric pain rating scale.

Acknowledgement: None

Conflict of Interest: There is no conflict of interest.

Source of Funding: None

Ethical Approval: Ethical approval was not required.

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How to cite this article: Rajwadi MH, Shukla YU. Effect of lateral wedge insole on pain and function in medial compartment osteoarthritis knee- an evidence based study. *International Journal of Science & Healthcare Research*. 2021; 6(2): 325-331. DOI: https://doi.org/10. 52403/ijshr.20210458

No.	Description	Yes / No
1	Eligibility criteria were specified (No points awarded)	
2	Subjects were randomly allocated to groups	
3	Allocation was concealed	
4	The groups were similar at baseline regarding the most important prognostic indicators	
5	There was blinding of all subjects	
6	There was blinding of all therapists who administered the therapy	
7	There was blinding of all assessors who measured at least one key outcome	
8	Measure of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated	
10	The result of between group comparisons are reported for at least one key outcome	
11	The study provides both point measures and measures of variability for at least one key outcome	

APPENDIX 1-PEDro SCALE

APPENDIX 2- CEBM'S LEVEL OF EVIDENCE

Level	Definition
1a	Systematic reviews of randomized controlled trials
1b	Individual randomized controlled trials
1c	All-or-none studies
2a	Systematic reviews of cohort studies
2b	Individual cohort studies or low-quality randomized controlled trials
2c	Outcome research
3a	Systematic reviews of case-control studies
3b	Individual case-control studies
4	Case series, poorly designed cohort or case-control studies
5	Animal and bench research, expert opinion
