



CODEN [USA]: IAJPBB

ISSN: 2349-7750

**INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES**

SJIF Impact Factor: 7.187

Available online at: <http://www.iajps.com>

Research Article

**A RANDOMIZED, CONTROLLED TRIAL OF TOTAL KNEE
REPLACEMENT****¹Dr Jawaria Nafees,²Dr Iram Zehra,³Dr Waqas Ahmad Khalid.**¹WMO, DHQ Hospital, Hafizabad.²WMO, DHQ Teaching Hospital, Gujranwala.³MO, Rural Health Center Raiwind, Lahore.**Article Received:** May 2020**Accepted:** June 2020**Published:** July 2020**Abstract:**

The most effective treatment for end stage osteoarthritis is known as total knee replacement therapy. The statistics of total knee replacements have been increased rigorously in the United States from 31.2 per 100,000 person-years. This randomized controlled trial including patients with knee osteoarthritis who were eligible for unilateral total knee replacement, to investigate whether total knee replacement followed by a 12-week nonsurgical-treatment program that consists of exercise, education, dietary advice, use of insoles, and pain medication provides greater pain relief and improvement in function and quality of life than do nonsurgical treatment alone.

The results indicate that total knee replacement when followed by non-surgical treatment shows effective outcomes whereas only pain relief therapy and improving quality of life 12 months in patients with moderate-to-severe knee osteoarthritis who are eligible for unilateral total knee replacement is not favorable. However total knee replacement has its ultimate consequences which are not favorable at all and participants who were assigned to get nonsurgical treatment alone were not underwent total knee replacement before the 12-month follow-up and clinically well improvements.

Corresponding author:**Dr Jawaria Nafees,**
WMO, DHQ Hospital, Hafizabad.

QR code



Please cite this article in press Jawaria Nafees et al, A Randomized, Controlled Trial Of Total Knee Replacement., Indo Am. J. P. Sci, 2020; 07(07).

INTRODUCTION:

The most effective treatment for end stage osteoarthritis is known as total knee replacement therapy [1]. The statistics of total knee replacements have been increased rigorously in the United States from 31.2 per 100,000 person-years [2]. In United States, total 670,000 knee replacements were administered in 2012 [3]. The main factor which points toward economic burden is increase in the age which ultimately leads to increase in the number of total knee replacement [4]. Some studies favor in the early use of non-surgical treatment. Recent literature have suggested that non-surgical treatment has moderate effectiveness in knee osteoarthritis [5] The available best evidence and clinical guidelines recommend basic treatment program which includes education about the disease, exercise, dietary plan, some other biomechanical interventions such as pharmacologic treatment and modified shoes or foot rest [6]. This randomized controlled trial including patients with knee osteoarthritis who were eligible for unilateral total knee replacement, to investigate whether total knee replacement followed by a 12-week nonsurgical-treatment program that consists of exercise, education, dietary advice, use of insoles, and pain medication provides greater pain relief and improvement in function and quality of life than do nonsurgical treatment alone.

METHODS:

Study design

Randomized controlled trial

Study population and inclusion criteria

Total 220 participants were included in the study who met the inclusion criteria. Kellgren-Lawrence scale has classified knee arthritis on the basis of severity, participants scoring more than 2 were defined eligible for total knee replacement and recruited in the study. The exclusion criteria were defined as any previous surgery of same knee, bilateral total knee replacement and existing knee replacement of same knee. The participants who had undergone total knee replacement were randomly chosen for 12 weeks non-surgical follow up. According to standard methods for insertion of a total cemented prosthesis with patellar resurfacing the total knee replacement was performed.

In the 12 week of non-surgical treatment program, there are five interventions included exercise, education, dietary advice, use of insoles, and pain medication.

The two groups of total knee replacement were performed in separately but identically, at the same facility, by specially trained physiotherapists and dietitians to ensure proper standardization and to

reduce the number of crossovers. Nonsurgical treatment has proven more effectiveness in the treatment of patients having knee osteoarthritis of a severity similar to that seen in the study participants.

Exercise

Neuromuscular training program was introduced to the participants who were eligible for the study according to the inclusion criteria. Those programs were added which have proven effective and were more feasible for the patients suffering from moderate to severe knee osteoarthritis.

Participants were introduced

The training program was consisted of 1 hour, group based and twice a week for 12 weeks. The main focus of exercise program was rehabilitation was building compensatory functional stability by functional alignment of the legs and improving sensorimotor control [8][9] Neutral dynamic alignment was emphasized to bring quality in exercise hence every patient was analyzed individually. Pain level was used to guide progression [10].

Education

One-hour detailed discussion was conducted on educational session about characteristics, treatments and self-help strategies. Patients in the treatment group of knee arthritis were actively engaged.

Dietary Advice

Participants who were having BMI more than 25 were added into dietary weight loss program which contains of 30 to 60 minutes per session. The main goal of the program was to lower the body weight by at least 5%. [11] After the initiation of the nonsurgical treatment a dietitian had communicated thorough telephone to support adherence for at least 30 minutes.

Insoles

The patients received individually fitted, full length insoles with medial arch support.

Pain Medication

If an orthopedic surgeon considered it to be necessary for participation in the exercise program medications were given to the patients. A prescription (reassessed every 3 weeks) was provided for acetaminophen, ibuprofen, and pantoprazole, to be used as needed.

Results

220 participants who met the inclusion criteria were recruited into the study. 97% participants of non-surgical treatment group completed the 12

months of follow up assessment and 91% of knee replacement group.

24% had total knee replacement before the 12 months of follow up in the non-surgical treatment group.

In non-surgical group there were 22% participants who had undergone total knee replacement before 12 month of follow up whereas the non-surgical group 29% had total knee replacement before the 12 month follow up. In the total knee replacement group 4% manifested to avoid total knee replacement therapy and underwent only non-surgical treatment.

The mean follow-up time after the initiation of nonsurgical treatment was 12.5 months in the nonsurgical-treatment group and 12.2 months in the total-knee-replacement group.

DISCUSSION:

The current study demonstrates that participants who had undergone total knee replacement and followed non-surgical group treatment has shown more efficacy as compared to those who were getting solely pain relief and improving function and quality of life after 12 months in patients with knee osteoarthritis who are eligible for unilateral total knee replacement. Some serious challenges were faced to those who had total knee replacement. These adverse effects need some clinically relevant improvements in both total knee replacement and non-surgical group. Before its frequent use there are number of literatures needed in the efficacy of knee replacement therapy [13]. Both groups in our study had substantial improvement with respect to most outcomes, and only 29% of the patients who were assigned to receive nonsurgical treatment alone underwent total knee replacement in the following year. Previous studies are in favor of non-surgical treatment for those patients suffering from moderate to severe knee osteoarthritis who are even eligible for total knee replacement. [14] Those participants who had followed a supervised exercise before undergoing the surgery have reported fast post-operative recovery. [15]

The study has some limitations. It has been comprehended that to some extent surgery and non-surgical treatments are linked with placebo effects. [16] These findings may over take the effects characterized to specific treatments and particularly in surgery.

The scores on the KOOS pain subscale that were obtained before surgery were similar to those obtained in previous studies of total knee replacement and indicated mild-to-severe pain during activities, but it is not known whether our

results are generalizable to patients with more severe pain [18] [19]. The intensity of nonsurgical treatment may have differed between groups owing to differences in clinical status at the time treatment was initiated. However, the intervention was standardized and administered in both groups by the same physiotherapists and dietitians. Since all patients received multimodal nonsurgical treatment, it is not possible to separate the effects of the individual modes of treatment. [22, 23] The combination of nonsurgical treatments that we administered complies with international recommendations on the treatment of knee osteoarthritis, which increases the generalizability of the results. [24] [25]

CONCLUSION:

The results indicate that total knee replacement when followed by non-surgical treatment shows effective outcomes whereas only pain relief therapy and improving quality of life 12 months in patients with moderate-to-severe knee osteoarthritis who are eligible for unilateral total knee replacement is not favorable. However total knee replacement has its ultimate consequences which are not favorable at all and participants who were assigned to get nonsurgical treatment alone were not underwent total knee replacement before the 12-month follow-up and clinically well improvements.

REFERENCES:

1. Carr AJ, Robertsson O, Graves S, et al. Knee replacement. *Lancet* 2012;379:1331-40.
2. Singh JA, Vessely MB, Harmsen WS, et al. A population-based study of trends in the use of total hip and total knee arthroplasty, 1969-2008. *Mayo Clin Proc* 2010; 85:898-904.
3. Agency for Healthcare Research and Quality. Healthcare Cost and Utilization Project database. 2012 (<http://hcupnet.ahrq.gov/Hcupnet.jsp>)
4. Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. *J Bone Joint Surg Am* 2007;89:780-5.
5. Lim HC, Adie S, Naylor JM, Harris IA. Randomised trial support for orthopaedic surgical procedures. *PLoS One* 2014;9(6): e96745.
6. Fernandes L, Hagen KB, Bijlsma JW, et al. EULAR recommendations for the non-pharmacological core management of hip and knee osteoarthritis. *Ann Rheum Dis* 2013;72:1125-35.
7. McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the nonsurgical management of knee osteoarthritis. *Osteoarthritis Cartilage* 2014;22: 363-88.

8. Nelson AE, Allen KD, Golightly YM, Goode AP, Jordan JM. A systematic review of recommendations and guidelines for the management of osteoarthritis: the Chronic Osteoarthritis Management Initiative of the U.S. Bone and Joint Initiative. *Semin Arthritis Rheum* 2014;43:701-12.
9. Skou ST, Roos EM, Laursen MB, et al. Total knee replacement plus physical and medical therapy or treatment with physical and medical therapy alone: a randomised controlled trial in patients with knee osteoarthritis (the MEDIC-study). *BMC Musculoskeletal Disord* 2012;13:67.
10. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010;340:c869.
11. Schiphof D, de Klerk BM, Kerkhof HJ, et al. Impact of different descriptions of the Kellgren and Lawrence classification criteria on the diagnosis of knee osteoarthritis. *Ann Rheum Dis* 2011;70:1422-7.
12. Endres S. High-flexion versus conventional total knee arthroplasty: a 5-year study. *J Orthop Surg (Hong Kong)* 2011; 19:226-9.
13. Skou ST, Rasmussen S, Laursen MB, et al. The efficacy of 12 weeks non-surgical treatment for patients not eligible for total knee replacement: a randomized controlled trial with 1-year follow-up. *Osteoarthritis Cartilage* 2015;23:1465-75.
14. Ageberg E, Link A, Roos EM. Feasibility of neuromuscular training in patients with severe hip or knee OA: the individualized goal-based NEMEX-TJR training program. *BMC Musculoskeletal Disord* 2010; 11:126.
15. Ageberg E, Roos EM. Neuromuscular exercise as treatment of degenerative knee disease. *Exerc Sport Sci Rev* 2015;43:14-22.
16. Christensen R, Bartels EM, Astrup A, Bliddal H. Effect of weight reduction in obese patients diagnosed with knee osteoarthritis: a systematic review and metaanalysis. *Ann Rheum Dis* 2007;66:433-9.
17. Miller WR, Rollnick S. *Motivational interviewing: preparing people for change*. New York: Guilford Press, 2002.
18. Ageberg E, Bennell KL, Hunt MA, Simic M, Roos EM, Creaby MW. Validity and inter-rater reliability of medio-lateral knee motion observed during a singlelimb mini squat. *BMC Musculoskeletal Disord* 2010;11:265.
19. Roos EM, Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. Knee Injury and Osteoarthritis Outcome Score (KOOS) — development of a self-administered outcome measure. *J Orthop Sports Phys Ther* 1998;28:88-96. Gossec L, Paternotte S, Maillefert JF, et al. The role of pain and functional impairment in the decision to recommend total joint replacement in hip and knee osteoarthritis: an international crosssectional study of 1909 patients: report of the OARSI-OMERACT Task Force on total joint replacement. *Osteoarthritis Cartilage* 2011;19:147-54.
20. Roos EM, Toksvig-Larsen S. Knee Injury and Osteoarthritis Outcome Score (KOOS) — validation and comparison to the WOMAC in total knee replacement. *Health Qual Life Outcomes* 2003;1:17.
21. Collins NJ, Misra D, Felson DT, Crossley KM, Roos EM. Measures of knee function: International Knee Documentation Committee (IKDC) subjective knee evaluation form, Knee Injury and Osteoarthritis Outcome Score (KOOS), Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS-PS), Knee Outcome Survey Activities of Daily Living Scale (KOS-ADL), Lysholm Knee Scoring Scale, Oxford Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Activity Rating Scale (ARS), and Tegner Activity Score (TAS). *Arthritis Care Res (Hoboken)* 2011; 63:Suppl 11:S208-S228.
22. Roos EM, Engelhart L, Ranstam J, et al. ICRS recommendation document: patientreported outcome instruments for use in patients with articular cartilage defects. *Cartilage* 2011;2:122-36.
23. Podsiadlo D, Richardson S. The timed “up & go”: a test of basic functional mobility for frail elderly persons. *J Am Geriatr Soc* 1991;39:142-8. White DK, Zhang Y, Niu J, et al. Do worsening knee radiographs mean greater chances of severe functional limitation? *Arthritis Care Res (Hoboken)* 2010; 62:1433-9.
24. Szende A, Williams A. *Measuring self-reported population health: an international perspective based on EQ-5D*. Budapest, Hungary: SpringMed, 2004. 26. Wittrup-Jensen KU, Lauridsen J, Gudex C, Pedersen KM. Generation of a Danish TTO value set for EQ-5D health states. *Scand J Public Health* 2009;37:459-66. 27. *What is a serious adverse event?* Silver Spring, MD: Food and Drug Administration, 2014 (<http://www.fda.gov/Safety/>)
25. [MedWatch/HowToReport/ucm053087.htm](http://www.fda.gov/oc/medwatch/ucm053087.htm).
28. Skou ST, Roos EM, Laursen MB, et al. Statistical analysis plan (SAP) for MEDIC: total knee replacement plus physical and medical therapy or treatment with physical and medical therapy alone: a randomised controlled trial in patients with knee osteoarthritis (the MEDIC-study). Aalborg, Denmark: Aalborg University Hospital, 2014 (<http://vbn.aau.dk/da/publications/>)