Comparative study of total knee replacement Vs non-surgical treatment regarding management of knee osteoarthritis

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Abstract
Osteoarthritis (OA) is a type of joint disease that results from breakdown of joint cartilage and underlying bone. The most common symptoms are joint pain and stiffness. Osteoarthritis (OA) is a common disease of aged population and one of the leading causes of disability. Incidence of knee OA is rising by increasing average age of general population. Age, weight, trauma to joint due to repeating movements in particular squatting and kneeling are common risk factors of knee OA. Several factors including cytokines, leptin, and mechanical forces are pathogenic factors of knee OA. Treatment options for osteoarthritis typically depend on the severity of the condition and the particular joints involved. They most often include medication, physical activity, stretching, and weight management, physical and occupational therapy, with or without assistive devices and surgery. The most common surgeries to treat knee arthritis are total knee replacement (total knee arthroplasty), partial knee replacement (unicompartmental knee arthroplasty), knee osteotomy (tibial osteotomy or femoral osteotomy), knee arthroscopy and cartilage repair and restoration. In this randomized, controlled trial, we enrolled 90 patients with moderate-to severe knee osteoarthritis who were eligible for unilateral total knee replacement. Patients were randomly assigned to undergo total knee replacement followed by 10 weeks of nonsurgical treatment (total-knee-replacement group) or to receive only the 10 weeks of nonsurgical treatment (nonsurgical-treatment group), which was delivered by physiotherapists and dietitians and consisted of exercise, education, dietary advice, use of insoles, and pain medication. The primary outcome was the change from baseline to 10 months in the mean score on four Knee Injury and Osteoarthritis Outcome Score subscales, covering pain, symptoms, activities of daily living, and quality of life (KOOS4); scores range from 0 (worst) to 100 (best). A total of 80 patients completed the 10-month follow-up assessment. In the nonsurgical-treatment group, 11 patients underwent total knee replacement before the 10-month follow-up; in the total-knee-replacement group, 1 patient received only nonsurgical treatment. In the intention-to-treat analysis, the total-knee-replacement group had greater improvement in the KOOS4 score than did the nonsurgical-treatment group. The total-knee-replacement group had a higher number of serious adverse events than did the nonsurgical-treatment group. In patients with knee osteoarthritis who were eligible for unilateral total knee replacement, treatment with total knee replacement followed by nonsurgical treatment resulted in greater pain relief and functional improvement after 10 months than did nonsurgical treatment alone. However, total knee replacement was associated with a higher number of serious adverse events than was nonsurgical treatment, and most patients who were assigned to receive nonsurgical treatment alone did not undergo total knee replacement before the 10-month follow-up.

Keywords: Knee, osteoarthritis, total knee replacement, nonsurgical treatment

Introduction
Osteoarthritis is the most common form of degenerative joint disease, and is a leading cause of disability in people over 50 years of age. It is can be a very debilitating form of arthritis in that it tends to affect the load-bearing joints, especially the hips and knees, that are crucial for normal movement. Osteoarthritis occurs when the cartilage cushioning the joints breaks down and causes the bones to rub together, inducing a change in shape. Osteoarthritis is found most frequently in people over age 50, although it can occur at any age. It most commonly affects joints in the knees, hips, shoulders, elbows, ankles, and hands. Gradual onset of knee pain, stiffness and swelling are typical symptoms of knee osteoarthritis. Arthritis of the knee comes
in several forms. Osteoarthritis is by far the most common form, followed by some forms of inflammatory arthritis, such as rheumatoid arthritis and gout. There are several risk factors that make one more likely to develop the condition. The primary risk factors are advanced age (over age 45), prior knee injury, and excess weight. An arthritic knee has thinned, damaged or missing cartilage in the joint. The damaged cartilage is not in and of itself a source of pain or other symptoms. Instead, the damaged or missing cartilage causes friction between bones and other knee problems, which in turn cause knee pain and related symptoms. Knee pain and stiffness are classic signs of knee osteoarthritis. These symptoms tend to progress gradually and many people initially attribute knee soreness or discomfort to lack of exercise or getting older. Many dismiss their early knee arthritis symptoms as "no big deal" until they worsen and start to interrupt one’s ability to enjoy everyday activities. Chief risk factors for developing knee osteoarthritis are advanced age and obesity. In addition to these, other risk factors for developing knee osteoarthritis include joint trauma, family history, congenital defect or illness, joint stress and chronic injury. While no single test can definitively diagnose osteoarthritis of the knee, physicians use a comprehensive approach that is verified by diagnostic imaging to arrive at a clinical diagnosis. It is important to clarify that most individuals over age 50 will have signs of osteoarthritis in their major joints that can be seen on an x-ray, but most will have no symptoms, so the medical provider will not rely on diagnostic studies (such as an x-ray or MRI) alone. An accurate diagnosis will come following a comprehensive medical history and physical examination by the health care provider. While knee osteoarthritis is often a progressive and irreversible degenerative process, functional improvement and pain control are reasonable treatment goals. Earlier treatment intervention may improve the odds of preserving joint integrity and function for years - or even a lifetime - which can stave off debilitating pain and possible need for joint replacement surgery. Non-Surgical Treatments for Knee Osteoarthritis include physical therapy and exercise, Activity modification, Periodic rest, Warm or cold compress, Weight loss, Medications and injections for Knee Osteoarthritis (analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), topical analgesics and Glucosamine and chondroitin sulfate; Two types of injections are commonly used for treatment of severe pain from knee osteoarthritis: steroid injections and hyaluronic acid injections), Supportive devices and orthotics, Coping techniques. Generally, any knee surgery to alleviate arthritis pain is considered elective surgery, meaning it is up to the patient to decide whether or not to have surgery. Typically, patients who have knee arthritis consider surgery when quality of life is significantly affected because of pain and functional limitations, non-surgical solutions to control pain, such as medication and physical therapy, have been tried for several months or longer without satisfactory improvement, an X-ray or MRI confirms knee joint degeneration. The most common surgeries to treat knee arthritis are total knee replacement (total knee arthroplasty), partial knee replacement (unicompartmental knee arthroplasty), knee osteotomy (tibial osteotomy or femoral osteotomy), knee arthroscopy and cartilage repair and restoration. Total Knee Replacement Surgery (Total Knee Arthroplasty): Patients with moderate to severe knee arthritis who have exhausted non-surgical treatment options might consider replacing the entire knee joint. The surgery involves cutting the arthritically damaged ends of the tibia (shin bone) and femur (thighbone) and capping both with prostheses (like capping teeth). The two prosthetic pieces are made of either metal or a durable plastic called polyethylene. These new surfaces move smoothly against one another, creating a functional knee joint. Partial recovery typically takes 4 to 6 weeks and full recovery may take a few months to an entire year. Total knee replacement surgery provides most patients with pain relief and improved knee joint function. However, a replacement knee is not as strong and durable as a healthy knee, and patients are strongly advised not to engage in high-impact activities (such as jogging) that may speed up the wear-and-tear of the new joint. In this randomized, controlled trial, we enrolled 90 patients with moderate-to-severe knee osteoarthritis who were eligible for unilateral total knee replacement. Patients were randomly assigned to undergo total knee replacement followed by 10 weeks of nonsurgical treatment (total-knee-replacement group) or to receive only the 10 weeks of nonsurgical treatment (nonsurgical-treatment group), which was delivered by physiotherapists and dietitians and consisted of exercise, education, dietary advice, use of insoles, and pain medication. The primary outcome was the change from baseline to 10 months in the mean score on four Knee Injury and Osteoarthritis Outcome Score subscales, covering pain, symptoms, activities of daily living, and quality of life (KOOS4); scores range from 0 (worst) to 100 (best). A total of 80 patients completed the 10-month follow-up assessment.

Patients and Methods
Study design : This is a prospective cross-sectional study.
Approval : This study received approval from college ethical committee.
Setting : Hyderabd.
Participants : Ninety patients admitted in Hospital.
Study period : June 2016 – December 2017

Observations and Results
Enrollment and Follow-up: A total of 90 patients underwent randomization 43 of 45 patients in the nonsurgical- treatment group and 40 of 45 patients in the total-knee-replacement group completed the 10-month follow-up assessment. In the nonsurgical- treatment group, 11 of 45 patients had a total knee replacement before the 10-month follow-up. In the total-knee-replacement group, 1 of 45 patients decided not to undergo total knee replacement and received only the nonsurgical treatment. All 90 patients were included in the intention-to-treat analysis, whereas 23 of 44 patients in the nonsurgical-treatment group and 26 of 41 patients in the total-knee-replacement group were included in the per-protocol analysis.
Table 1: Baseline Characteristics of the Patients.

| Characteristic                        | Nonsurgical Treatment Group (N = 45) | Total-Knee Replacement Group (N = 45) |
|---------------------------------------|--------------------------------------|--------------------------------------|
| Female sex — no. (%)                  | 27                                   | 28                                   |
| Age — yr                              | 63.0±8.7                             | 64.7±8.7                             |
| Body-mass index†                      | 31.0±4.5                             | 31.4±6.2                             |
| Kellgren–Lawrence score — no. (%)‡    | 2                                    | 5                                    |
|                                      | 3                                    | 20                                   |
|                                      | 4                                    | 23                                   |
| KOOS scores§                          |                                      |                                      |
| KOOS§                                 | 46.5±11.4                            | 47.4±13.4                            |
| Pain                                  | 49.5±13.1                            | 48.6±17.5                            |
| Symptoms                              | 58.6±15.2                            | 54.0±15.0                            |
| Activities of daily living            | 52.5±14.2                            | 55.0±17.0                            |
| Quality of life                       | 32.7±13.3                            | 32.3±15.3                            |
| Sports and recreation                 | 17.7±15.1                            | 18.0±14.7                            |
| Time on the timed up-and-go test — sec| 8.6±2.1                              | 9.4±2.4                              |
| Time on the 20-m walk tests — sec     | 12.1±2.5                             | 13.4±3.7                             |
| EQ-5D scores¶                         |                                      |                                      |
| Descriptive index                     | 0.661±0.147                          | 0.661±0.156                          |
| Visual-analogue scale                 | 63.8±16.1                            | 66.3±17.2                            |
| USED pain medication in the past week | 24                                   | 28                                   |

In the intention-to-treat analysis, the total-knee replacement group had a significantly greater improvement in the KOOS4 score than did the nonsurgical-treatment group, with a crude mean difference of 16.5. In the nonsurgical-treatment group, the increase in the KOOS4 from baseline to month 10 was 16.0. Furthermore, as compared with the nonsurgical-treatment group, the total-knee-replacement group had significantly greater improvements in the scores on all five KOOS subscales, the times on the timed up-and-go test and 20-m walk tests, and the scores on the EQ-5D descriptive index.

Table 2: Outcomes at 12 Months

| Outcome                          | Total No. of Assessments* | Mean Improvement in Outcome from Baseline to 10 Mo | Between-Group Difference in Mean Improvement | (95% CI)                  | (95% CI)                  |
|----------------------------------|---------------------------|---------------------------------------------------|---------------------------------------------|---------------------------|---------------------------|
|                                  |                            | Total-Knee Replacement Group | Nonsurgical Treatment Group | Total-Knee Replacement Group | Nonsurgical Treatment Group | Crude | Adjusted† |
| Primary outcome                  |                           |                                    |                               |                           |                               |        |           |
| KOOS4                            | 168                       | 189                                 | 16.1                           | 31.5                      | 16.5                          | 14.4   |
|                                  |                           |                                    | (10.1 to 21.9)                | (26.6 to 38.3)            | (10.2 to 22.7)               | (10.0 to 21.5)           |
| Secondary outcomes               |                           |                                    |                               |                           |                               |        |           |
| KOOS subscale scores             |                           |                                    |                               |                           |                               |        |           |
| Pain                             | 178                       | 190                                 | 17.2                           | 32.7                      | 17.6                          | 15.3   |
|                                  |                           |                                    | (10.4 to 24.1)                | (28.1 to 41.5)            | (10.1 to 25.1)               | (10.4 to 23.8)           |
| Symptoms                         | 172                       | 194                                 | 11.4                           | 26.4                      | 15.0                          | 12.7   |
|                                  |                           |                                    | (4.4 to 18.4)                 | (21.5 to 31.4)            | (8.3 to 21.7)                | (6.6 to 17.6)            |
| Activities of daily living       | 170                       | 193                                 | 17.6                           | 30.1                      | 12.3                          | 12.9   |
|                                  |                           |                                    | (11.4 to 23.9)                | (22.7 to 37.2)            | (5.5 to 19.2)                | (6.8 to 19.1)            |
| Quality of life                  | 175                       | 194                                 | 17.8                           | 38.2                      | 20.4                          | 20.2   |
|                                  |                           |                                    | (11.2 to 24.4)                | (30.6 to 45.8)            | (12.8 to 27.9)               | (13.2 to 27.1)           |
| Sports and recreation            | 171                       | 193                                 | 19.3                           | 32.3                      | 15.2                          | 15.6   |
|                                  |                           |                                    | (10.8 to 27.7)                | (27.9 to 40.0)            | (6.7 to 23.7)                | (7.3 to 22.2)            |
| Time on the timed up-and-go test (sec) | 156                       | 185                                 | −1.1                           | −2.2                      | 1.2                           | 0.8    |
|                                  |                           |                                    | (−1.8 to −0.6)                | (−3.1 to −1.6)            | (0.4 to 1.9)                 | (0.2 to 1.5)            |
| Time on the 20-m walk tests (sec) | 160                       | 185                                 | −1.0                           | −2.5                      | 1.9                           | 1.5    |
|                                  |                           |                                    | (−1.5 to −0.4)                | (−3.8 to −1.9)            | (0.9 to 2.8)                 | (0.7 to 2.4)            |
| EQ-5D scores                     |                           |                                    |                               |                           |                               |        |           |
| Descriptive index                | 178                       | 189                                 | 0.118                          | 0.206                     | 0.091                         | 0.078  |
|                                  |                           |                                    | (0.061 to 0.156)              | (0.141 to 0.270)          | (0.026 to 0.155)             | (0.023 to 0.132)        |
| Visual-analogue scale            | 180                       | 193                                 | 10.2                           | 15.0                      | 4.9                           | 4.4    |
|                                  |                           |                                    | (4.6 to 15.7)                 | (8.6 to 21.5)             | (−2.2 to 12.0)               | (−1.8 to 10.6)           |
| Weight (kg)†                     | 134                       | 160                                 | −2.6                           | 0.1                       | 2.8                           | 2.8    |
|                                  |                           |                                    | (−3.9 to −1.4)                | (−1.5 to 1.7)             | (1.4 to 4.1)                 | (1.4 to 4.1)            |
Discussion
This randomized, controlled trial showed that total knee replacement followed by nonsurgical treatment is more efficacious than nonsurgical treatment alone in providing pain relief and improving function and quality of life after 10 months in patients with knee osteoarthritis who are eligible for unilateral total knee replacement. However, clinically relevant improvements were noted in both groups, and patients who underwent total knee replacement had a higher number of serious adverse events. We are not aware of any previous or ongoing randomized trials investigating the effectiveness of total knee replacement, despite its wide and increasing use. Previous reports on the effects of total knee replacement have been case series, without a control group for comparison. Both groups in our study had substantial improvement with respect to most outcomes, and only 22% of the patients who were assigned to receive nonsurgical treatment alone underwent total knee replacement in the following year. Previous reports have suggested a benefit of nonsurgical treatment in patients with moderate-to-severe knee osteoarthritis who are eligible for total knee replacement. Even for patients progressing to surgery, participation in supervised exercise before surgery has been associated with a faster postoperative recovery. The benefits and harms of the respective treatments underscore the importance of considering patients’ preferences and values during shared decision making about treatment for moderate-to-severe knee osteoarthritis. Our study has limitations. We did not include a sham-surgery control group; since surgery and, to a lesser extent, nonsurgical treatments are associated with placebo effects, the findings in this study may overestimate effects attributable to the specific treatments and to surgery in particular. The scores on the KOOS pain subscale that were obtained before surgery were similar to those obtained in previous studies of total knee replacement 39,40 and indicated mild-to-severe pain during activities, but it is not known whether our results are generalizable to patients with more severe pain. 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. The combination of nonsurgical treatments that we administered complies with international recommendations on the treatment of knee osteoarthritis, which increases the generalizability of the

Table 2: Serious Adverse Events.

| Events                          | Nonsurgical- Treatment Group | Nonsurgical- Replacement Group | P Value |
|--------------------------------|------------------------------|--------------------------------|---------|
| Overall                        | 6                            | 24                             | 0.005   |
| Involving sites other than the index knee | 5                            | 16                             | 0.04    |
| Musculoskeletal                | 0                            | 4                              |         |
| Skin                           | 1                            | 0                              |         |
| Gastrointestinal               | 0                            | 3                              |         |
| Other                          | 4                            | 9                              |         |
| Involving the index knee       | 1                            | 8                              | 0.05    |
| Occurred during total knee replacement | 0                        | 0                              |         |
| Occurred after total knee replacement | 1                        | 1                              |         |
| Stiffness requiring brisement force† | 1                        | 1                              |         |
| Deep infection                 | 0                            | 1                              |         |
| Deep venous thrombosis requiring | 0                            | 1                              |         |
| anticoagulation                | 1                            |                               |         |
| Supracondylar femur fracture   | 0                            | 1                              |         |
results.

Conclusions
In conclusion, our results show that total knee replacement followed by nonsurgical treatment is superior to nonsurgical treatment alone in providing pain relief and improving function and quality of life after 10 months in patients with moderate-to-severe knee osteoarthritis who are eligible for unilateral total knee replacement. However, total knee replacement is associated with a higher number of serious adverse events, and most patients who were assigned to receive nonsurgical treatment alone did not undergo total knee replacement before the 10-month follow-up and had clinically relevant improvements.

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