Home Rehabilitation in Patients After Primary Total Knee Arthroplasty

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Statystical Analysis

Sample was calculated that 76 participants per group using media difference test with a standard deviation of 7 and an expected magnitude of difference at least five pints on the WOMAC scale with a power of β 80%, confidence 95% with statistically significant p of <=0.05 with a 20% error.

Brief Summary:

The investigators include patients attending the outpatient clinic in the area of Orthopedics and Traumatology of the investigators hospital with a diagnosis of knee osteoarthritis, which treatment requires surgery. Patients will be divided into two groups. In both groups, they will be given verbal, clear and detailed information on the approach to follow, the exercises given in brochures, and in the study group a schedule will be given in order to record rehabilitation exercises in patients after total knee replacement (TKA). Both groups will be assessed before and after surgery, together with outpatient follow-up by, WOMAC, Visual Analogue Scale and OKS (Oxford Knee Score).

Detailed Description:

Osteoarthritis (OA) is the most common rheumatic disease worldwide. OA cause joint pain and occupational disability in the adult population. In Mexico, OA is one of the top ten reasons of consultation in primary attention care.

Joint arthroplasty is a major advance in the treatment of chronic joint pain. It is indicated in patients in whose conservative medical therapy has failed. Total knee arthroplasty (TKA) is a surgery that reduces pain and improves function and quality of life in patients with knee disorders, actually is one of the most successful medical procedures. However, a critical consideration in patients with TKA is the successful control of postoperative pain. An adequate pain control allows faster rehabilitation, reduces complications and is highly correlated with patient satisfaction. A multimodal pain management decreases the use of narcotics, improve pain scores, increase patient satisfaction and allows early recovery.

Regarding postoperative rehabilitation, its suggested that rehabilitation programs are based on a biopsychosocial philosophy and integrate exercises and self-management interventions are effective in the treatment of osteoarthritis. Rehabilitation therapy an important area that should be considered. It helps people recover faster from their illness, injury or medical procedures and make possible to get back to their daily activities.

The WHO describes rehabilitation as a process that aims to enable people to maintain and achieve their physical, sensory, intellectual, functional, psychological and social level in an optimal way. It is known that rehabilitation involves contributions from various health disciplines, including physical therapy and occupational therapy and offered in inpatient, outpatient and community patients.

In patients with total knee replacement, rehabilitation interventions may involve education and exercise before surgery, early mobilization while being in the hospital and a postoperative program, along with an adequate pain management.

Perioperative care has shown an improvement in the recovery, it reduces hospital day stay, convalescent and risk of postoperative medical complications.

It has been shown that early initiation of rehabilitation within 24 hours after total knee arthroplasty reduces in-hospital time and decreases the number of sessions required to achieve autonomy, balance and normal gait. Madsen et al. demonstrated that rehabilitation exercises at home have the same effect as those made in rehabilitation group within six months postoperatively, based on a study of 80 patients randomly divided into a control- study group.

Optimal pain management is vital seeking to achieve the goal of recovery called fast track. It involves early therapy with specialized protocols, early discharge and quick recovery. Lamplot et al. demonstrated in a prospective randomized study of 36 patients, using this method, a decrease in opioid consumption and its adverse effects, a decreased pain score, a shortening time for physical therapy and an increase in patient satisfaction.

Postoperative analgesia can be achieved by a variety of techniques. These include: intravenous analgesia, epidural analgesia, techniques for peripheral nerve block and periarticular injections. All aim to control pain in patients and provide the better satisfaction.

Integrating these interventions in a clinical pathway, better functional results are obtained, hospital stay is reduced and there is an improvement in the patient's recovery, mainly in short-term.

Minimum Age: 18 Years Maximum Age: 90 Years Sex: All Gender Based: -

Accepts Healthy Volunteers: No

Criteria:

- Inclusion Criteria: Age between 18 and 90 years, Patients with Knee osteoarthritis (OA) grade 4 (Kellgren-Lawrence based on radiographic findings), Total Knee Arthroplasty (TKA) for primary OA and Rapid rehabilitation desire.
- Exclusion Criteria: Age <18 and > 90 years, Patients with Knee osteoarthritis grade 1-2 (
 Kellgren-Lawrence based on radiographic findings), Patients with associated Rheumatic
 syndromes, Patients with anticoagulant therapy, Patients with hepatic problems,
 Diabetes Mellitus, Coagulopathy, hearth conditions, immunodepressed, or infections,

Drugs abuse history, Physiatric disease, Pregnant patients and Patients with hemoglobin values < 11g/dl , platelets < 150,000/uL.

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Minns Lowe CJ, Barker KL, Dewey M, Sackley CM. Effectiveness of physiotherapy exercise after knee arthroplasty for osteoarthritis: systematic review and meta-analysis of randomised controlled trials. BMJ. 2007 Oct 20;335(7624):812. Epub 2007 Sep 20. Review. PubMed ID: 17884861

Meier W, Mizner RL, Marcus RL, Dibble LE, Peters C, Lastayo PC. Total knee arthroplasty: muscle impairments, functional limitations, and recommended rehabilitation approaches. J Orthop Sports Phys Ther. 2008 May;38(5):246-56. doi: 10.2519/jospt.2008.2715. Epub 2007 Dec 14. Review. PubMed ID: 18448878

Labraca NS, Castro-Sánchez AM, Matarán-Peñarrocha GA, Arroyo-Morales M, Sánchez-Joya Mdel M, Moreno-Lorenzo C. Benefits of starting rehabilitation within 24 hours of primary total knee arthroplasty: randomized clinical trial. Clin Rehabil. 2011 Jun;25(6):557-66. doi: 10.1177/0269215510393759. Epub 2011 Mar 7. PubMed ID: 21382863

Kauppila AM, Sintonen H, Aronen P, Ohtonen P, Kyllönen E, Arokoski JP. Economic evaluation of multidisciplinary rehabilitation after primary total knee arthroplasty based on a randomized controlled trial. Arthritis Care Res (Hoboken). 2011 Mar;63(3):335-41. doi: 10.1002/acr.20398. Epub 2010 Nov 15. PubMed ID: 21080347

DiSotto-Monastero M, Chen X, Fisch S, Donaghy S, Gomez M. Efficacy of 7 days per week inpatient admissions and rehabilitation therapy. Arch Phys Med Rehabil. 2012 Dec;93(12):2165-9. doi: 10.1016/j.apmr.2012.07.003. Epub 2012 Jul 20. PubMed ID: 22819810

Ribinik P, Le Moine F, de Korvin G, Coudeyre E, Genty M, Rannou F, Yelnik A, Calmels P. Physical and rehabilitation medicine (PRM) care pathways: "patients after total knee arthroplasty". Ann Phys Rehabil Med. 2012 Nov;55(8):533-9. doi: 10.1016/j.rehab.2012.02.001. Epub 2012 Mar 3. PubMed ID: 22455993

Bandholm T, Kehlet H. Physiotherapy exercise after fast-track total hip and knee arthroplasty: time for reconsideration? Arch Phys Med Rehabil. 2012 Jul;93(7):1292-4. doi: 10.1016/j.apmr.2012.02.014. Epub 2012 Feb 27. PubMed ID: 22494947

Nakai T, Tamaki M, Nakamura T, Nakai T, Onishi A, Hashimoto K. Controlling pain after total knee arthroplasty using a multimodal protocol with local periarticular injections. J Orthop. 2013 Mar 17;10(2):92-4. doi: 10.1016/j.jor.2013.02.001. eCollection 2013. PubMed ID: 24403757

Madsen M, Larsen K, Madsen IK, Søe H, Hansen TB. Late group-based rehabilitation has no advantages compared with supervised home-exercises after total knee arthroplasty. Dan Med J. 2013 Apr;60(4):A4607. PubMed ID: 23651717

Ibrahim MS, Khan MA, Nizam I, Haddad FS. Peri-operative interventions producing better functional outcomes and enhanced recovery following total hip and knee arthroplasty: an evidence-based review. BMC Med. 2013 Feb 13;11:37. doi: 10.1186/1741-7015-11-37. Review. PubMed ID: 23406499

Lamplot JD, Wagner ER, Manning DW. Multimodal pain management in total knee arthroplasty: a prospective randomized controlled trial. J Arthroplasty. 2014 Feb;29(2):329-34. doi: 10.1016/j.arth.2013.06.005. Epub 2013 Jul 11. PubMed ID: 23850410

Links: URL: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3092498/

Description: Epidemiology of Knee and Hip Arthroplasty: A Systematic Review

URL: http://emedicine.medscape.com/article/320061-overview

Description: Total Joint Replacement Rehabilitation