CHAPTER 1

1.1. INTRODUCTION

The World Health Organization (WHO) defines Osteoarthritis as a long term chronic disease characterized by the deterioration of cartilage in joints which results in bones rubbing together and creating stiffness, pain, and impaired movement. Osteoarthritis (OA) also known as osteoarthrosis or Degenerative Joint Disease (DJD) is a progressive disorder of weight bearing joints caused by gradual loss of cartilage and resulting in the development of bony spurs and cysts at the margins of the joints (Dorland's Medical Dictionary, 2007).

There are two different types of classification of OA available in literature based on radiological findings. The World Health Organization (WHO) in 1961 accepted the Kellgren and Lawrence classification of severity in DJD using five grades.

The classification is as follows: Grade 0; No features of degeneration, 1; doubtful joint space narrowing (JSN) with possible osteophytic lipping, 2; Possible JSN with osteophytes in a weight bearing radiograph, 3; multiple osteophytes with definite JSN, sclerosis and with possible bony deformity, 4; Severe sclerosis with
large osteophytes, marked JSN with a definite deformity. The Ahlback classification of osteoarthritis of knee joint (1968) is classified as grade 1: joint space narrowing (less than 3 mm), grade 2: joint space obliteration, grade 3: minor bone attrition (0-5 mm), grade 4: moderate bone attrition (5-10 mm) and grade 5: severe bone attrition (more than 10 mm). This classification has its own limitations of poor reproducibility and validity based on visual inspection of the joint (Weidow et al. 2006).

Osteoarthrosis is widespread in middle aged, elderly population age greater than 65 years and also younger people following injury and overuse. The strongest predictor of knee degenerative joint disease is the age, with increasing age it is expected to have greater occurrences. Women populations with DJD are prone to get affected more than men before the age of 50.

The World Health Organization (WHO) has estimated 9.6% men and 18% women globally with symptomatic osteoarthritis of age greater than 60 years (WHO, 2017). The United Nations report predicts that by 2050, people aged over 60 accounts for more than 20% of population worldwide, of which a conservative estimate of 15% will have symptomatic OA and one third of group is expected to
be severely disabled. The epidemiology of osteoarthritis in India has been studied sporadically. In Indian population KDJD older than 60 years is estimated to be 43% in women and 25% in men. The prevalence of knee DJD in four major zones of India is estimated to be 28.7%. The prevalence was noted to be higher in big cities (33.1%) and villages (31.1%) than compared to small cities and towns (Chandra Prakash et al. 2016).

The most common cause of Knee DJD is the ageing process and it is strongly associated with a wide variety of modifiable and non-modifiable risk factors including obesity, genetic predisposition, reduced bone mineral density, poor work ergonomics, trauma and gender (Haq et al. 2003). The World Health Organization recommends a symptom based grading system for disease progression in DJD and presently there is no validated tools available (WHO report in 2003).

The clinical classification criteria for knee DJD (KDJD) is knee pain, joint stiffness more or equal to 30 minutes, crepitus, bony enlargement, bony tenderness and no palpable warmth. This classification has 95% sensitivity and 69% specificity. Apart from diagnostic testing of X-rays and MRI scan, physical examination is required to confirm the diagnosis.
The cyclic pattern of pain, swelling and instability compromise joint sensation and interfere with reflexive motor co-ordination of the joint. Joint motion and position sense also has an important role in maintenance of balance. These balance deficits are associated with a loss of joint function and can be used to predict falls in elderly, thus posing a serious health risk. The pain pattern and reduced functional mobility are the key disabling factors reducing the quality of life and further increases the risk of morbidity.

The four major treatment options of KDJD are non-pharmacological, pharmacological, intra-articular therapy and surgical intervention. The conservative management (non-pharmacological) includes patient education, application of physical modalities for pain reduction, orthotic devices and manual physical therapy.

All clinical practice guidelines and a recent Cochrane review (Fransen et al. 2015) recommend the use of therapeutic exercise in KDJD (Nelson et al. 2014). The pharmacological management includes the role of analgesics, non-steroidal anti-inflammatory therapy, corticosteroids and visco-supplementation. In spite of vigorous conservative treatment, if the patient has intractable pain, loss of functional capacity and poor quality of life than they are expected to be candidates
for surgical intervention. Moreover for patients with advanced disease process that is not yielding to conservative measures, joint replacement surgery becomes the most recommended plan of care.

Total knee Replacement (TKR) surgeries are highly successful, commonly performed orthopedic procedure for individuals with end stage knee osteoarthritis (OA) in relieving pain, improving physical functions and quality of life. A total of 45,000 knee replacements were performed in India (2010) and this may translate to more than 350,000 TKR per year by the end of the decade (Bharat S. Mody, 2010). The Indian society of Hip and Knee Surgeons (ISHKS) joint registry has a record of 34,478 TKR performed in India from 2006 to 2012 contributed by 42 surgeons (Jawahir et al. 2013).

Total knee replacement surgery decreases pain, restores joint mobility and functions, improves health-related quality of life (HRQoL) which is associated with a high patient satisfaction rate. The outcomes of TKR are rated based on implant survivorship, clinical outcomes of joint mobility, muscle strength and ability to perform activities of daily living (ADL).
Figure 1.1: TKR Surgical procedure

Intramuscular plane  Patella everted, joint exposed  Removal of osteophytes

Vastus medialis  Patella  Posterior osteophyte

Release of PCL, capsule  Tibia cut precision  Femoral fitting
Trial reduction & alignment

Cementing

Cam and post assembled

Wound closure
Patient satisfaction following TKR is an integral outcome being considered, however discrepancy between the satisfaction levels of patient and surgeon was noticed among Indian population (Balaji Zacharia et al. 2016) citing drawbacks in postoperative care. The key to success in TKR is by achieving pain free range of motion (ROM), stability, durability, independent ADL that which is devoid of complications.

The rehabilitation Outcomes reported in literature is classified as patient reported physical function or pain; physiological tests; physical performance tests and generic health related quality of life measures. The outcomes are focused towards short term and long term effects on pain severity, joint mobility functions, muscle performance, physical functions and enhanced quality of life.

The most frequent patient reported measure is the pain severity on activity and limited joint functions reporting on physical functions. The physiological tests include range of motion (ROM) testing, isometric muscle strength testing and performance measures of six minute walk test (6MWT) or time taken to accomplish a functional task. A systematic review (Marie et al. 2010) reveals that
more than twenty five types of outcome tools in various trials being used without a fixed nomenclature.

The expected format of measuring outcomes should be based on the International Classification of Functions (ICF) to measure body functions, ability to perform physical activities and performance measures. The categorization of outcome measures based on ICF model are as follows: postoperative pain, knee joint mobility and muscle strength (ICF level: body functions); physical functioning (ICF level: activity) that includes walking distance in six minutes and self report tools i.e; Knee Osteoarthritis Outcome Survey (KOOS) and health related quality of life (HRQOL) dimensions (ICF level: Participation restrictions).

**Figure 1.2: ICF conceptual framework: study outcome measures**
The factors influencing the outcomes following TKR rehabilitation include preoperative parameters, operative methods and postoperative care. The preoperative variables like advancing age, female gender, co-morbidities, obesity, preoperative mobility and muscle strength are noted to negatively influence the QOL (Robson et al. 2014).

With multiple pre-operative factors underlying, most studies concluded the strongest predictors were preoperative pain, joint functions and diagnosis of OA/Rheumatoid Arthritis (RA) (Andy Judge et al. 2012).

The intra-operative factors depend on the precision and accuracy of prosthetic design, which offer a great chance of survival but it is still further dependent on the surgical procedures. The most standard prosthetic design with good durability and stability is the Posterior Stabilized (PS) prosthesis.

The posterior stabilized prosthesis design comprises a tibial post and femoral cam to substitute the posterior cruciate ligament and allows femoral roll back mimicking the normal knee joint mechanics.
There are five contemporary TKR surgical approaches namely medial parapatellar, subvastus, midvastus, trivector and lateral parapatellar. The medial Para-patellar is the historical gold standard and the most commonly used approach. The functional recovery of muscle strength and post-operative pain was noted to be better in midvastus than medial parapatellar approach.
Mostly these studies have analyzed the functional outcome in comparing the effects of surgical approaches rather not on the effects of therapeutic interventions between approaches. Irrespective of these approaches, post-operative rehabilitation is not focused to the needs.

Postoperative physiotherapy and rehabilitation greatly influences the outcome in TKR individuals. Therefore rehabilitative efforts should focus on activities that help patients to improve performance of activities of daily living. The basic drawback in post-operative rehabilitation is adhering to a “cookbook approach” which doesn’t address muscle impairments and balance disorders following surgery.

Mostly rehabilitation programs are designed on increasing range of motion and strengthening muscles but measures to improve balance is neglected (Schwartz et al. 2012). The muscle impairments following TKR varies with different surgical approaches, but till date exercises are not designed according to the post operative needs. The guidelines for rehabilitation progression should be tailored to individual patient’s postoperative need, respecting the tissue healing parameters. Muscle impairments are not well defined and remain understudied aspect of post-operative
management in TKR (The Orthopedic Forum, NIH consensus statement on TKR, 2003).

It is believed that certain factors would best predict long-term outcomes and identifying these factors will aid in creation of targeted therapeutic interventions to maximize the postoperative functional abilities (Zeni JA et al. 2010). Although pre-operative predictors may aid in the identification of people at risk for post-operative difficulties, it is also important to recognize the operative and postoperative factors that may predict long-term outcomes.

Despite the high increase in TKR surgeries in recent years, there is no post-operative rehabilitation approach being incorporated correctly to address the muscular and functional deficits following surgery (Meier W et al. 2008) and no studies have focused on evaluating the effects of tailored rehabilitation protocols (Zeni JA et al. 2010) and hence not yet analyzed in Indian population too. The recommendation made from a systematic review warrants an optimal Physical therapy protocol addressing strengthening program and intensive functional training to meet the demands.
A systematic review of controlled trials with respect to physical exercise after TKR (Pozzi et al. 2013) enlists the required components of rehabilitation for optimal care. Moreover in available controlled trials and studies based on Physiotherapy Evidence Database (PEDro) ranking on quality reveal that the information related to intensity, frequency, dose of exercises and criteria for progression weren’t considered (Pozzi et al. 2013).

The most cited reason of reduced efficacy in postoperative exercise regimen is that none of the trials have incorporated high intensity long duration rehabilitation program within the first postoperative month (Michael et al. 2011). The protocols need to be designed to meet the long term outcomes; moreover the review recommends the need for intense functional training and following of the principles of FIT (frequency, intensity and duration).

A very recent meta-analysis by Neil Artz et al. (2015) on effectiveness of physiotherapy exercise following TKR highlights the absence of long term benefits and powered trials. They also highlighted the lack of national guidance in facilitating early recovery using exercise based rehabilitation. Further the available protocols are designed to provide short term effectiveness and not towards long
term recovery. A few randomized trials have addressed the effectiveness of exercise rehabilitation showing short term improvements in physical domains. However the systematic review highlights the need for integrating the key components of exercise rehabilitation on the long term benefits in TKR population.

Globally, there is no evidence-based practice guidelines that exist to inform the best practice for post-acute rehabilitation following TKR, therefore specific rehabilitation practices vary greatly among providers. The American Physical Therapy Association (APTA) have listed that Physical Therapy management of patients with TKR in the acute post-operative phase (7 days) is in the development stage (APTA, 2016). Furthermore, little or no guidance exists on recommended activities following discharge from the acute care set-up.

The therapeutic interventions are largely based on clinical experience, preferential approaches and facility based protocols (Hawker et al. 2009). There are a number of reports stating that some patients do not reach their physical functions and demands following TKR and that post-operative pain, physical impairments and functional limitations are still issues persist even two years after surgery (Meier et al. 2008 and Mizner et al. 2005). The series of evidence based reviews dating from
2003 to 2016 warrants the need for structured protocol with required components of mobility, strength, balance and functional training in acute postoperative phase.

1.2 Need for the study:

There are very limited numbers of studies available globally with structured TKR rehabilitation program addressing the possible impairments. No single study has been conducted in TKR rehabilitation in Indian population with a randomized controlled trial design. Globally, studies using multiple outcomes are scarce and also due to cultural differences between countries, results of studies from other countries should always be applied with caution in Indian scenario.

The present study intends to design a protocol based on social, cultural requirements of Indians and to address the muscle strength and balance impairments following TKR procedure. Therefore this proposed research is focused on larger RCT in three phases of rehabilitation with multiple outcome measures as per the concept of International classification of functions. Hence this study intends to analyze the effectiveness of structured total knee replacement rehabilitation program on the quality of life and functional outcome in Indian population.