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Original Article

Physiotherapy Section

Content Validation of Total Knee Replacement Rehabilitation Protocol in Indian Population

P ANTONY LEO ASEER[1], G ARUN MAIYA[2], M MOHAN KUMAR[3], P V VIJAYARAGHAVAN[4]

ABSTRACT

Introduction: Total knee replacement (TKR) surgery has become the most successful surgery for patients with severe debilitating arthritis. The guidelines for rehabilitation progression should be tailored respecting the tissue healing parameters. Hence, the current literature states a need for protocol to mitigate these impairments and ultimately result in improved functional outcomes.

Objective: The present study aimed to validate the content of TKR rehabilitation protocol in Indian population.

Materials and Methods: The process of content validation involves development stage and expert judgment stage. The protocol was designed into three stages with extensive review of literature. After designing the protocol, nine experts in field of musculoskeletal Physiotherapy performed the judgemental process. The process of validation includes rating of experts in a 5 point likert grading on two parameters namely relevance and ease of performance. Based on expert's inputs on TKR protocol, the level of agreement, content validation index and kappa value was calculated.

Results: The three staged TKR protocol almost exhibited an excellent agreement on all stages. However, muscle activation exercises (except Vastus medialis obliques activation), stretching, strengthening program and functional training showed 100% agreement than other stages.

Conclusion: The structured TKR protocol exhibited excellent content validity to its use in Indian population.

Keywords: Joint replacement surgery, Osteoarthritis, Therapeutic exercises

INTRODUCTION

TKR is the most common surgical intervention, if the patient complains of severe tibiofemoral and patellofemoral pain, loss of knee joint functions mobility with severe deformity. During the past five years, the number of TKR performed in India has increased an average of 30% each year and the same growth rate is expected to continue in forthcoming decade [1]. Over the past four decades, joint replacement surgery has become the most successful surgery for patients with severe debilitating arthritis [2]. Patients who undergo TKR show marked improvements in function and reduction in pain compared with their preoperative condition [3,4]. However, recovery of functional ability is variable and not all patient experience significant improvements in pain and functions [5,6].

Therefore, rehabilitative efforts should focus on activities that help patients to improve performance of activities of daily living. The basic drawback in postoperative rehabilitation is adhering to a protocol or a "cookbook approach". The muscle impairments following TKR varies with different surgical approaches, but till date exercises are not designed according to the postoperative needs. The guidelines for rehabilitation progression should be tailored respecting the tissue healing parameters. It is believed that certain factors would best predict long term outcomes. Identification of these factors will aid in the creation of targeted therapeutic interventions to maximize postoperative functional ability [7].

The Orthopaedic Forum, National Institutes of Health (NIH) consensus statement on TKR in 2003 revealed that the rehabilitative services are the most under studied aspect of the postoperative management [8]. Although, there are several theoretical reasons to explain the postoperative impairments such as muscle weakness, atrophy, abnormal joint mechanics but there is no evidence supporting the generalised use of any specific preoperative or postoperative rehabilitation intervention. Finally, they concluded that there is no evidence –based guidelines exist for promoting or limiting post-TKR physical activity.

Despite major advances in the field of total joint arthroplasty, a standardised postoperative management protocol currently does not exist following TKR [9]. Despite the high incidence of TKR in recent years, there is no postoperative rehabilitation approach being incorporated correctly to address the muscular and functional deficits following surgery [10] and no studies have focused on evaluating the effects of tailored rehabilitation protocols [7] and yet not analysed in Indian population too.

Hence, the current literature states a need for protocol to mitigate these impairments and ultimately result in improved functional outcomes. The proposed protocol was designed based on principles of TKR rehabilitation as proposed by Zeni JA Jr and Snyder-Mackler L in 2010 [7]. The designed protocol requires a validation process for its relevance and ease of performance.

The term validity is referred to a test/protocol measuring what it intends to measure [11]. The content validity is also quiet similar to face validity using subjective judgement. Hence, an expert opinion is sorted to test the protocol for its intensions and practicality. The present study aimed to validate the content of TKR rehabilitation protocol in Indian population.

MATERIALS AND METHODS

The process of content validation involves development stage and expert judgment stage. The protocol was designed into three stages with extensive review of literature [7,12-16]. The staging of protocol is mannered in a progressive way, meeting the functional needs of patient. The staged rehabilitation of TKR protocol follows a set pattern of exercises in non weight bearing position followed by weight bearing exercises then with functional exercises. Totally ten experts were selected for the validation process but only nine experts in field of musculoskeletal physiotherapy gave consent to participate in the study. This validation study was approved by the Institutional Ethics Committee of Sri Ramachandra University, Chennai, Tamilnadu, India.

TKR Protocol

The structured rehabilitation protocol [Annexure-1] is staged into three comprising early function phase (protective phase) from day 1 to two weeks, progressive function phase (transitional phase) from three weeks to six weeks and advanced function phase (activity phase) from seven weeks to 12 weeks. Each phase has several categories including: prerequisite, goals, precautions, therapeutic exercise with frequency and duration, functional activities, criteria for progression and outcomes measured.

In phase 1, therapeutic exercise has specific components as like general exercises, mobility exercises, stretching, muscle activation and functional training. The progressive function phase and in advanced function phase has mobility, stretching, strengthening, closed chain activities, balance training, functional training and aerobic conditioning components. Phase1 is considered as inpatient phase and discharge planning is made, whereas phase 2 and 3 are home based under supervision and minimal supervision phases respectively. The TKR protocol is aimed to reduce joint pain, swelling, promote scar healing, remodelling and improve pain free knee mobility in accordance to prosthetic kinematics. Further aimed to improve key muscle strength of quadriceps muscle and hamstrings muscle in varied types of contraction, regaining a normal gait pattern and neuromuscular coordination for walking. Finally, the protocol concludes in regaining complex weight bearing activities like stair ascent, descent, proprioception, balance and coordination for complex activities.

The protocol is developed based on current literature and muscle impairments following TKR [10,12-16]. On analysis of protocol, it was found many exercises as like closed chain exercise and balance exercises are not commonly incorporated amongst TKR patients. Hence, the protocol requires content validation by experts.

Procedure of Validation

The primary investigator invited 10 independent experts with minimum 10 years of experience in musculoskeletal physiotherapy. As per recommendations by Lynn MR [17] a minimum of five and a maximum of 10 experts are required for the validation process. Out of 10, nine experts agreed to participate and were diversely placed in Southern parts of India. All experts were practicing musculoskeletal physiotherapy including five Professors and four senior Physiotherapists. The process of validation included rating of experts in a 5 point likert grading on two parameters namely relevance and ease of performance. The scale was scored as 1=strongly disagree, 2=mildly disagree, 3=neutral, 4=agree, 5=strongly agree. The score 4 and 5 were acceptable for calculation, if scored less than 3, experts were requested for suggestions. The key exercise components were listed in three stage manner with likert scale being measured for its relevance and ease of performance. The prepared content was sent through electronic media and basic instructions were given. Based on expert's inputs on TKR protocol, the level of agreement, content validation index and kappa value was calculated.

The content validation index was calculated by dividing number of experts who scored 4 or 5 by total number of experts participated. The cut off level for acceptance if >0.78 as in accordance to a study [18], thus seven out of nine agree for an exercise. This further highlights that if level of agreement is greater than 78%, the exercise is considered with good agreement among experts and to be included in protocol. A modified kappa was calculated to confirm the relevance of exercise protocol. The interpretation of kappa values were proposed as: fair= 0.40 to 0.60, good= 0.60 to 0.74 and excellent= 0.75 to 1.00.

RESULTS

Based on the reports of nine experts, the Content Validity Index (CVI) is tabulated in [Table/Fig-1]. The protocol has eight components namely general exercises, mobility, stretching, muscle activation, strengthening, closed chain activity, balance training and functional training.

The 29 item TKR rehabilitation protocol was graded by all experts with good agreement among them. Apart from 27 items, two exercises were rated with poor agreement namely upper extremity strength training (CVI-67%) and lap stool exercises to improve knee mobility (CVI-44%). The experts suggested that upper extremity strength training was not specific to the protocol and lap stool exercise are not commonly prescribed and it may produce more forces on replaced knee joint. Hence as per expert's suggestion, these two exercises were excluded from protocol.

The CVI of > 78% is considered to exhibit excellent level of agreement; those exercises with CVI less than 78% are not included in the protocol as described above. Expert's opinion in use of Continuous passive motion is CVI-89% and its ease of performance was rated 67%.

The three staged TKR protocol almost exhibited an excellent agreement on all stages. However, muscle activation exercises(except Vastus medialis oblique activation), stretching, strengthening program and functional training showed 100% agreement than other stages. In general group of exercises, both chest physiotherapy and bed mobility exercises, the CVI is 100%. All exercises in joint mobility program has CVI >89%, except CPM. The ease to perform scar tissue mobilization was rated as CVI 78%. All the exercises used to activate major muscles following TKR have excellent agreement of 100% except VMO activation (Relevance CVI-89% and Ease of performance-78%).

The strengthening program of major muscles of Knee joint had excellent agreement amongst experts but ease of performing resistance exercises has been rated CVI-78%. Closed chain activities relevance of performing VMO activation in standing and step up exercises is 89%. The stable base standing with arm reaches and in diagonal reaches has excellent agreement of 100%, whereas foam pad and wobble board standing balance training has 89% relevance and 78% ease to perform it. In functional training, the ease to perform full weight bearing standing, symmetrical weight shifting in standing and unsupported ambulation was rated 89%, 89% and 78% respectively.

DISCUSSION

The main finding of the present study is that 27 exercises out of 29, exhibited excellent agreement. The process of validation includes development of protocol, initial review of few experts, expert judgment process and analysis. The proposed structured TKR rehabilitation protocol was considered to possess excellent content validity and applicable to primary TKR in Indian population.

Before the validation process, a group of experts evaluated the face validity of the protocol, in which few exercises were not considered by the members. This includes Neuromuscular Electrical Stimulation (NMES) for quadriceps, prone leg hang to encourage knee extension and strengthening of knee rotators. A Cochrane review in 2010 has concluded the use of NMES after TKR is unclear and poor evidence exists on its use [19], moreover its use for activation may be applicable in poor quadriceps strength. It was considered by the experts that adopting prone positions in acute postoperative period to perform prone leg hang was not found to be feasible. Whereas, strengthening the key stabilizers of knee joint is required rather considering knee rotators, which is not found in literature. Hence before validation process, these three exercises were excluded from the protocol.

The role of chest physiotherapy and early bed mobility exercises on postoperative day one was rated to be the most crucial step to start the rehabilitation process. Continuous passive motion is considered to be an early intervention following TKR, despite various

Contents of TKR protocol	Relevance		Ease of performance	
	CVI	Kappa	CVI	Kappa
General				
Chest Physiotherapy	100	1.00	100	1.00
Bed mobility	100	1.00	100	1.00
Mobility				
Continuous passive motion	89	0.89	67	0.60
Heel slides in supine lying	89	0.89	89	0.89
Hip abduction in supine lying	100	1.00	89	0.89
Passive patellar glides	89	0.89	89	0.89
Stretching				
Knee extension stretch	100	1.00	100	1.00
Scar tissue mobilization	100	1.00	78	0.76
Muscle Activation				
Isometrics of key muscles	100	1.00	100	1.00
SLR, Short arc knee extension	100	1.00	100	1.00
Seated knee extension	100	1.00	100	1.00
Hamstring curl	100	1.00	100	1.00
Vastus medialis oblique activation	89	0.89	78	0.76
Strengthening				
Hip abduction in side lying	100	1.00	100	1.00
Multi angle hip movements in standing	100	1.00	100	1.00
Resistance exercises to quadriceps and hamstring	100	1.00	78	0.76
Closed Chain Activity				
Vastus medialis oblique contraction in standing	89	0.89	100	1.00
Wall slides	100	1.00	89	0.89
Forward and lateral step up	89	0.89	100	1.00
Balance Training				
Standing-arm raise and diagonal reach	100	1.00	100	1.00
Standing on foam pad	89	0.89	78	0.76
Standing on wobble board	89	0.89	78	0.76
Obstacle walking	89	0.89	100	1.00
Functional Training				
Full weight bearing standing	89	0.89	89	0.89
Symmetrical weight shift in standing	100	1.00	89	0.89
Unsupported ambulation	100	1.00	78	0.76
Stair ascent and descent	100	1.00	100	1.00

[Table/Fig-1]: Content Validity Index (CVI) and kappa (K*) of TKR protocol.

controversies of its use, experts agreed the relevance of using CPM but not the ease of performance in acute postoperative care. Hence, the use of CPM is left out to be optional in TKR rehabilitation. This finding is in accordance to a very recent study in 2014 [20] concluded that there is no high quality studies in CPM and its use need to be reconsidered. The stretching program comprises knee extension stretch in acute postoperative days to prevent flexion contractures as it is a normal tendency for patients to maintain in minimal knee flexion to ease pain. However, the importance of scar tissue mobilization during remodeling phases was also considered to be significant in preventing tissue tightness.

The muscle activation program was considered to possess excellent agreement amongst experts. Muscle impairments are the most crucial parameter to be addressed following TKR, hence muscle activation program will address those needs [10]. Of all the muscle activation exercises, Vastus medialis Obliques muscle activation was rated less, as no studies reported its use in TKR. The protocol further explains the need for resistance exercises and methods to implement strengthening program. This stage also exhibits excellent validation index, as studies reported that resistance exercises will show better improvements if muscle impairments are resolved through muscle activation programs [12]. The optimal resistance ranges from 0.5 kg to 1 kg as prescribed in a TKR outpatient protocol, however in later stages, 60% of one Repetition Maximum (1RM) can be employed.

Closed Chain Activities (CCA) are not so commonly incorporated in TKR protocols because of its kinematic loading characteristics. The key important mechanical principle behind closed chain exercises is co-contraction of muscle groups; however lateral step up exercises will recruit/train quadriceps to a greater extent. Studies analysing the effects of CCA are sparse apart from a case report in bilateral TKR [13].

Mostly rehabilitation programs are designed to increase range of motion and strengthening muscles but measures to improve balance is neglected [15]. Even though the CVI of staged balance training was found to be excellent, careful administration of methods is required in acute stages. In this present study, basic balance training like forward arm reaches; diagonal arm reaches in standing are incorporated. This stage of training is expected to promote early return of functional activities and weaning of assistive device. Further, the balance training is progressed in standing using foam pad with eyes open and followed by eyes closed and use of wobble board is optional. The benefits of additional balance training will significantly impact early functional recovery following TKR [15].

Thus the structured, staged TKR rehabilitation protocol was well appreciated by majority of experts and the functional training and aerobic conditioning was considered to be the most integral part of rehabilitation.

LIMITATION

The limitations of the present study include experts were recruited only from the Southern parts of India for the validation process.

CONCLUSION

The structured TKR rehabilitation protocol exhibited excellent content validity to its use in Indian population. The protocol is safe and can be administered from initial postoperative day till full functional recovery. In future, the effectiveness of validated TKR protocol in Indian population to be analysed and next levels of validation testing to be carried out.

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ANNEXURE-1

Structured Total Knee Replacement (TKR) Rehabilitation Protocol in Indian Population.

Stage 1-Early Function Phase (Protective Phase) from Day 1-2 Weeks.	
Pre-requisite	Immediate postoperative day following TKR (0-1 day) Patient on room air, conscious ,oriented and ability to obey commands Patient with or without knee mobilizer (brace)
Goals	Facilitate airway clearance Reduce pain Educate on postoperative rehabilitation process Allow surgical site healing Initiate bed mobility and assisted/self transfers Educate and initiate weight bearing using assistive device Initiate and improve knee joint mobility Recruit firing of inhibited muscles Maintain flexibility of muscles
Precautions	Check for signs of inflammation and deep vein thrombosis Positioning knee in extension with towel roll under ankle joint

Therapeutic exercise	Frequency	Duration
General • Chest physiotherapy. • Bed mobility. • Ankle pumps	Twice /day as much as possible	
Mobility • CPM 0-30 degrees (progress 5-10 degree a day as tolerated)-optional • Heel slides in supine lying-to achieve 90 degree of flexion • Gentle patellar glides • Hip abduction in supine lying	Twice /day	20-30 minutes
Stretching • Patient education-during sleep, replace the knee immobiliser • Place a pillow under the ankle to help passive knee extension. • Knee extension stretch gentle manual over pressure on the knee	Twice/day	3 sets x 30 second hold (5-10 minutes)
Muscle Activation • Isometrics of gluteals, hamstring and quadriceps. • Straight leg raise • Short arc terminal knee extension • Seated knee extension (90° - 0°) • Isolated hamstring curl in prone lying • McConnell method of VMO contraction in high sitting	Thrice/day	
Strengthening • Upper extremity weight training using dumb bells • Hip abductor strengthening in side lying	Twice/day	3 sets x 20 reps
Functional training • Full weight bearing standing with walker. • Symmetrical weight shift training within parallel bars • Single arm raise, diagonal raise in standing(balance training)	Twice /day	3 sets x 10 reps
Modalities-cold packs(optional)	As needed	10-15 minutes
Functional activities	Ability to transfer from lying to sitting ,sit to stand from chair Walking with assistive device	
Criteria for progression	Minimal or no pain Ability to walk with or without assistive device Ability to perform phase 1 exercises with ease Ability to perform 0 degree knee extension and 80-90 degree knee flexion	
Outcomes measured	Visual analog scale, Joint mobility using universal goniometry Walking distance using six minute walk test	

Stage 2-Progressive Function Phase (Transitional Phase) From 3-6 Weeks.	
Pre-requisite	Ability to walk with or without assistive device Ability to perform 0 degree knee extension and 80-90 degree knee flexion Minimal or no pain in knee joint
Goals	Reduce pain related to activities Educate on progressive rehabilitation process Mobilize scar in all directions Mobilize patella in all directions Improve knee joint flexion mobility from 90° - 100° Strengthen Quadriceps in specific to activation of vastus medialis obliques and Hamstring muscles Initiate closed chain activities Monitor and correct gait deviations Improve balance reactions
Precautions	Check for scar healing and remodeling Check for muscle tightness Check for signs of wound infection

Therapeutic exercise	Frequency	Duration
Mobility • Passive patellar glides-four planes. • Prone lying knee bending to achieve 100° knee flexion	Twice /day	2 sets x 20 reps
Stretching • Hamstring, Gastroc soleus stretches. • Scar tissue mobilization	Twice /day	3 sets x 30 secs hold (5-10 minutes)
Strengthening (with cuffed weights-0.5 to 1 Kg) • Multi angle hip movements in all planes (standing) • Straight leg raise • Short arc Terminal knee extension • Seated knee extension (90° - 0°) • Hamstring curl in prone lying • McConnell method of VMO contraction in high sitting • Leg press	Thrice /day Twice/day	3 sets x 30 reps 3 sets × 20 reps
Closed Chain Activity • VMO contraction in standing • Unsupported standing training within parallel bars • Wall slides • Lateral step up and forward step up (2"-4" block) • Mini squats	 Twice/day	
Balance Training • Balance training in standing (foam pad)-with eyes open and closed • Balance training in standing (tilt board)-with eyes open and closed • Single leg stance	Twice/day Twice/day	 3 sets × 30 reps
Functional Training • Unsupported ambulation • Stair climbing and descent using handrail		
Aerobic Conditioning • Stationary cycling (high seat with nil/ less resistance		

Functional activities	Independent ambulation Stair ascent and descent
Criteria for progression	Ability to walk without assistive device Ability to perform phase 2 exercises with ease Ability to perform 0 degree knee extension and 100 degree knee flexion Independent ADL Improved voluntary control of quadriceps
Outcomes measured	Joint mobility using universal goniometry Isometric muscle strength testing using dynamometer Walking distance using six minute walk test Joint specific outcome measure Quality of life –SF36

Stage-3 Advanced Function Phase (Activity Phase) From 7-12 Weeks.	
Pre-requisite	Ability to have pain free walk without assistive device Ability to perform 110 degree knee flexion Ability to perform basic community related activities
Goals	Educate on full functional recovery phase Improve knee joint flexion mobility >110° Improve quadriceps and hamstring muscle endurance Improve balance and coordination Improve aerobic fitness

Therapeutic exercise	Frequency	Duration
Stretching		
• Hamstring, Gastroc soleus and iliotibial band stretches in standing	Twice /day	3 sets x 40 sec hold (10minutes)
Strengthening (with cuffed weights- 2 Kg or 60% of 1 RM)		
• Exercises as in previous phase		
Closed Chain Activity		
• Front lunge and partial squats	Thrice /day	3 sets x 30 reps
Balance Training		
• Obstacle walking		
• Tandem walking, shuttle walking		
• Figure of 8 walk	Thrice /day	3 sets x 30 reps
• Perturbation training		
Functional Training		
• Reciprocal stair ascent/descent		
Aerobic Conditioning		
• Walking	Twice/day	
• Stationary cycling with resistance		

Functional activities	Independent ambulation Reciprocal Stair ascent and descent
Outcomes measured	Walking distance using six minute walk test Joint specific outcome measure Quality of life –SF36 Balance test measures

PARTICULARS OF CONTRIBUTORS:
1. Professor and Vice Principal, Faculty of Physiotherapy, Sri Ramachandra University, Chennai, Tamilnadu, India.
2. Professor, Department of Physiotherapy, School of Allied Health Sciences, Manipal University, Manipal, Karnataka, India.
3. Professor, Department of Orthopaedics, Sri Ramachandra University, Chennai, Tamilnadu, India.
4. Professor, Department of Orthopaedics, Sri Ramachandra University, Chennai, Tamilnadu, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. P. Antony Leo Aseer,
Professor and Vice Principal, Faculty of Physiotherapy, Sri Ramachandra University, Chennai-600116, Tamilnadu, India.
E-mail: viceprincipal.physiotherapy@sriramachandra.edu.in

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