Health Technology Assessment of Total Knee Replacement in Patients with Osteoarthritis (OA) Knee in India

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Policy Brief

Executive Summary:

- Osteoarthritis (OA), a slowly progressive, degenerative disease of the joints involving their cartilages and surrounding tissues, is highly prevalent throughout the world.(1,2). The knee joint is among the most commonly OA affected joints and is often disabling depending on its severity which are measured using Kellgren-Lawrence (K-L) classification system(3-5).
- Cost-utility analysis (CUA) and budget impact analysis (BIA) were conducted, on individuals ≥ 50 years with Osteoarthritis(OA) knee Kellgren-Lawrence (K-L) grades 2 and 3. Three scenarios were considered, varying the age at which TKR is administered while assuming a 20-year lifespan for the implant. Markov model was used to determine Incremental Cost-effectiveness Ratio (ICER).

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- Total Knee Replacement (TKR) is most effective when the individual is 50 years old, suffering from KL Grade 3 OA knee with only one-time replacement followed by conservative management after the expiry of the implant. However all ICER estimates are below the willingness-to-pay threshold, that it should be offered to every individual whoever is clinically eligible for it.

Policy Recommendations:

1. TKR is cost-effective in the age groups of 50 and above and all ICER estimates are below WTP threshold. Therefore this needs to be covered under the existing financing system to provide financial risk protection to the population currently suffering from OA Knee.
2. BIA suggests covering 40% of the population who are vulnerable will cost around 1% of the union and state budget together in the year 2023 and will remain 1% till 2028. We recommend increasing coverage gradually with increase resource envelope.
3. Prioritize equity as a central principle in the pricing strategy for ensuring fairness and accessibility.

Background

An increasingly aging population and demand for higher functional activity levels among the elderly will further keep escalating the need for TKR, worldwide. There will be also greater demand for TKR in the middle-aged group as well because with increasing obesity across the globe, the age of onset of OA requiring surgery has shifted to the younger side. Hence, in the face of this increasing demand for TKR, there is a need for increasing global availability and accessibility to knee arthroplasty (6). Around 1,50,000 TKRs are performed every year (7) in India. But the demand for surgical procedures like TKR will grow exponentially in the fast-growing economy that India is, as the aging Indian population will keep on further aspiring to live a life of better quality, leveraging their ever-burgeoning affordability and growing political clout to demand social and health security from the state. An indigenous economic evaluation study estimating the cost-effectiveness of TKR in India and its implications on the health expenditure of the nation can be a good starting point for this purpose.

Aims and Objective

This policy brief addressed the policy question of cost-effectiveness of Total Knee Replacement in comparison with non-surgical management among population aged 50 and above in Indian context. The study was conducted by the HTAIn Resource Hub at Indian Institute of Public Health Hyderabad.

Methods and Approach

We considered a decision-analytic model-based CUA of TKR in patients of various age groups suffering from OA knee in India with different severities and accounting for multiple scenarios using the provider's perspective. Markov model was the chosen methodology for this purpose as it can model the risk of recurrent events in a straightforward fashion as compared to other decision analytic methods. Our methodological principles are consistent with the Indian reference case for conducting economic evaluations used by the agency for Health Technology Assessment in India (HTAIn).

TKR Intervention Scenarios:

1. TKR implant expires in 20 years (cycles) and all live patients continue with non-surgical treatment up to death.
2. First TKR implant expires in 20 years and then a second repeat TKR is conducted on those patients who are likely to live for another 20 years or more. The second TKR implant expires in another 20 years following which all live patients continue with non-surgical treatment up to death.
3. First TKR implant expires in 20 years and a second repeat TKR is conducted on those patients who are likely to live for another 20 years or more. The second TKR implant expires in another 20 years and a third repeat TKR is conducted on those patients who are likely to live for another 20 years or more. The third TKR implant expires in another 20 years following which all live patients continue with non-surgical treatment up to death.

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The analysis was performed under the following components:

- The cost and the outcome of the TKR (intervention arm) and Non-surgical management (Comparator arm) was calculated using Markov model. Two Markov models were developed: TKR (intervention arm) and Non-surgical (comparator arm).
- Lifespan of the implant used in TKR is 20 years (8), we envisioned three different scenarios, each representing different combinations of TKR, repeat TKR (up to two repeats), and non-surgical management. Also, as the average age of onset of OA knee of sufficient severity (KL grade 2 onwards) where TKR may be applied is 50 years, we modelled the outcomes of three different cohorts, the starting age of which were 50, 60 and 70 years respectively.
- Transition probabilities and Quality of Life (QOL) values for each state in both the Markov model were extracted from the existing literature (9-11).
- Cost data for TKR intervention arm and non-surgical arm were extracted from National costing database (12).
- After incorporation of all values of cost and effectiveness, the Incremental Cost effectiveness Ratio (ICER) was calculated from the TKR (intervention arm) and non-surgical (comparator arm).

Results:

- Net Quality Adjusted Life Years(QALY) gained per OA knee treated with TKR were superior when performed at the age of 50, regardless of OA severity and across all scenarios. The lowest ICER was ₹36,107/QALY gained, observed at 50 years while the highest was ₹61,363/QALY gained at 70 years for grade-2 severity.
- TKR intervention was costlier than non-surgical management but all ICERs were under the WTP threshold for all grades, age groups and scenarios
- TKR is cost-effective when compared to non-surgical management in patients with OA knee in India irrespective of age, the severity of the disease, and the types of implants used.

Budget Impact Analysis

We extrapolated the population suffering from OA knee based on the cumulative prevalence of OA knee. It was found that 4.77 crore population above the age of 50 years is likely to have OA knee in 2023, which will increase to 6.08cr in 2028. Approximately, 2% of this sub-population (9.54 lakhs) will be prescribed or will access TKR surgery which will increase to 12.14 lakh people or patients in the year 2028. We assumed three different scenarios for BIA.

1. The government may not bear expenses of the entire population requiring TKR and may cover up to 40% of the population who are vulnerable. This 40% vulnerable population is decided as per the Ayushmann Bharat-Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) eligibility criteria. Accordingly, total expenditure commitment will be INR 5013 crores (cr) in the year 2023 and will increase to INR 8444 cr in 2028, which is around 1% of the state and national government budget together in the year 2023 and will remain around the same 1% over the next 5 years.
2. If the government covers expenses of the entire population that are supposed to undergo TKR surgery, total expenditure required will vary from INR 12532 cr in 2023 to INR 21109 cr in 2028 and as a share in total union and state government budget, this will vary from 2.7% in 2023 to 2.4% in 2028. The resources required to cover the entire expenditure of TKR patients decreases as a share of total state and union government budget over the years.
3. We have also made an attempt to understand the share of TKR expenditure in the National Health Mission (NHM) budget considering the cost of 40% of the vulnerable population to be covered under NHM like in scenario1. In this case, total expenditure required for TKR will vary from 17% of NHM budget in 2023 to 25% in 2028.

Willingness to Pay Threshold

The per capita GDP of India was INR 1,28829/- at current price in 2020-21. Normally, three times of per capita GDP is assumed to be the WTP threshold value. All ICERs for all scenarios (all grades, all age groups, all combinations of treatment) were much less than WTP threshold value. All input parameters were inflated or reduced to 50%, the net QALY gained is less than PCGDP

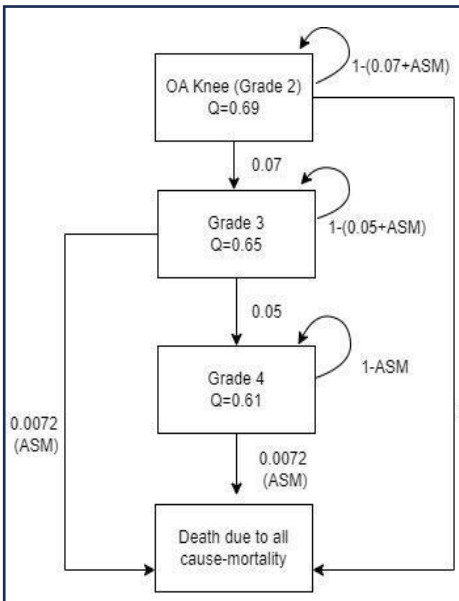

Figure 1: Markov Model of Intervention

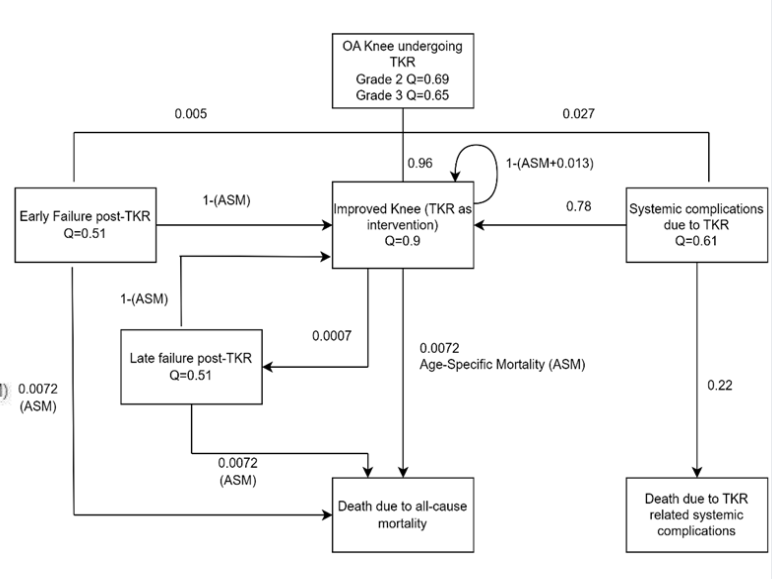

Figure 2: Markov Model for Comparator

Table 1: Incremental Cost Effectiveness Ratio (ICER)

Patient's Age (in years)	Grade-2			Grade-3		
	Scenario- 1 (Single TKR)	Scenario- 2 (Double TKR)	Scenario- 3 (Triple TKR)	Scenario- 1 (Single TKR)	Scenario- 2 (Double TKR)	Scenario- 3 (Triple TKR)
	Net QALY gain			Net QALY gain		
50	3.1	3.8	3.8	3.4	4.2	4.3
60	2.6	2.8		2.9	3.2	
70	1.9			2.1		
	Extra cost (in INR)			Extra cost (in INR)		
50	111158	174182	177894	111158	174182	177894
60	112175	149635		112175	149635	
70	113766			113766		
	ICER (INR per QALY gained)			ICER (INR per QALY gained)		
50	36108	46136	46912	32284	41051	41735
60	43518	52943		38386	46609	
70	61363			53458		

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