The Maximum Threshold Value for HbA1c in Diabetic Patients Undergoing Elective Total Knee Arthroplasty

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ABSTRACT

Objective: To establish an optimal preoperative HbA1c threshold that enhances surgical outcomes and minimises postoperative complications in diabetic patients undergoing elective total knee arthroplasty (TKA).
Study Design: Prospective cohort study.
Place and Duration of the Study: Department of Orthopaedics, First People's Hospital of Lianyungang, China, from January 2021 to March 2024.
Methodology: A total of 152 diabetic patients scheduled for elective TKA were included. Data on preoperative HbA1c levels were collected and analysed to assess their impact on postoperative outcomes using the Oxford Knee Score (OKS). Patients were divided into groups based on HbA1c levels and compared for functional and pain recovery one year postoperatively. Statistical analyses included binary and multivariate logistic regression, with an emphasis on the minimum clinically important difference for OKS.
Results: Patients with a preoperative HbA1c below 7.35mmol/L exhibited significantly better functional and pain recovery outcomes at one-year post-TKA. The receiver operating characteristic curve (ROC) analysis confirmed the predictive power of HbA1c, with an Area Under the Curve of 0.734 for functional improvement and 0.721 for pain improvement.
Conclusion: The study identifies 7.35mmol/L as the optimal preoperative HbA1c threshold for diabetic patients undergoing elective TKA, with lower levels associated with improved functional and pain outcomes. Maintaining HbA1c below this level preoperatively can significantly enhance postoperative recovery and patient satisfaction.

Key Words: *Diabetes mellitus, Total knee arthroplasty, Haemoglobin A1c, Oxford knee score.*

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INTRODUCTION

Diabetes mellitus (DM) is a chronic disease affecting hundreds of millions of individuals worldwide, with its prevalence increasing from 108 million in 1980 to 537 million in 2019, and is projected to reach 643 million by 2030.[1] The prevalence of DM also shows an increasing trend with age, particularly among those over 65 years old.[2] Postoperative complications, including poor functional outcomes, reduced effectiveness of surgery, increased pain, decreased range of motion (ROM), and lower Forgotten Joint Score-12 (FJS-12) are common in DM patients following total knee arthroplasty (TKA).[3,4] Therefore, effective management of DM and optimisation of perioperative care in these patients are crucial.[4]

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Glycated haemoglobin (HbA1c), a form of haemoglobin chemically linked to glucose, used to monitor the average blood sugar levels over two to three months and to assess the effectiveness of diabetes treatment.[5,6] Studies indicate that higher preoperative HbA1c levels are associated with increased surgical site infections in patients undergoing elective colorectal surgery.[7] Additionally, postoperative peak glucose levels exceeding 250mg/dl are linked to increased 30-day readmission rates.[8] Compared to control groups and those with HbA1c levels between 6.5 - 8%, patients with HbA1c levels ≤6.5% and >8% tend to have significantly longer hospital stays.[9] For patients undergoing elective lumbar decompression, HbA1c levels of 7.8mmol/L and 7.5mmol/L correlate with worsening scores on the NRS Back and ODI, greatly affecting surgical outcomes.[5] From these precedents, the authors hypothesise that the preoperative control of HbA1c may impact the recovery outcomes post-TKA. Effective control of HbA1c levels could unexpectedly improve postoperative functional exercise and pain perception in TKA patients, playing a significant role in enhancing perioperative management for DM patients and reducing healthcare burdens. The objective of this study was to establish an optimal preoperative HbA1c threshold that enhances surgical outcomes and minimises postoperative complications in diabetic patients undergoing elective total knee arthroplasty TKA.

METHODOLOGY

Beginning in 2021, this study prospectively collected discharge data of diabetic patients undergoing elective TKA from the Department of Orthopaedics at the First People's Hospital of Lianyungang, China, with patient follow-ups continuing until March 2024. This study received approval from the Ethics Committee of the hospital. Two specialist physicians with over two years of clinical experience analysed the patient data. Over two years, a total of 173 elective TKA DM patients were initially considered, and after applying inclusion and exclusion criteria, data from 152 patients were ultimately included in the study.

The specific inclusion criteria were as follows: Patients aged 18 years or older scheduled for elective TKA, with a preoperative diagnosis of DM, and available preoperative HbA1c results. The exclusion criteria were as follows: Patients who underwent bilateral TKA within one year, those who died or were lost to follow-up for other reasons, those who experienced postoperative infection, or those who were affected by external forces or other surgeries impacting knee joint functionality. Figure 1 shows the study process. Using the hospital's electronic medical record system, this study collected preoperative HbA1c values and demographic characteristics of the patients, including age, gender, Kellgren-Lawrence (K-L) grading, body mass index (BMI), length of hospital stay, duration of surgery, and Oxford Knee Score (OKS), preoperatively and one year post-operatively. The OKS, devised by Dawson *et al.* in 1998,[10] consists of 12 questions scored from 0 to 4. Post-surgery, the attending physician was responsible for initiating rehabilitation exercises on the third day, with the rehabilitation department taking over for the following days until discharge, advising continued exercises after discharge. Follow-up visits at the orthopaedic outpatient clinic occurred at 1, 3, 6, and 12 months post-discharge, where the research team prompted rehabilitation and evaluated OKS.

Unified guidance included quadriceps exercises, straight leg raises, ankle pumps, knee extension exercises, and knee bending exercises.

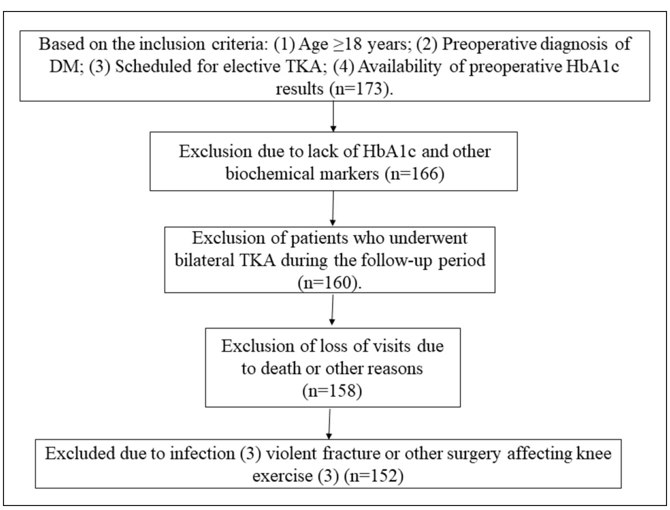

Figure 1: Final study subject inclusion and exclusion process.

The primary outcome measures are patient-reported outcomes (PROs). The PROs are based on the minimum clinically important difference (MCID) of the OKS, as per the research by Clement *et al.*,[11] where an improvement of 5.0 and 4.3 points in the pain and function sections of the OKS after one year postoperatively represents the MCID values, indicating patient satisfaction with functional and pain improvement.

Statistical analysis was performed using SPSS™ version 25.0 (IBM Corporation, Somers, NY, USA). The prospectively collected data were divided into OKS function satisfied and dissatisfied groups (postoperative 1-year OKS functional improvement >5.0 points as satisfied, otherwise as dissatisfied); OKS pain satisfied and dissatisfied groups (postoperative 1-year OKS pain improvement >4.3 points as satisfied, otherwise as dissatisfied) for analysis between the groups. Quantitative data were presented as mean ± standard deviation ($\bar{x} \pm s$) and median (IQR), with Independent-samples t-tests or Mann-Whitney U tests used to compare differences between two groups. Categorical variables were expressed as counts and frequencies and analysed using Chi-square test. MCID was defined as a postoperative one-year pain score improvement of 5.0 points and a function score improvement of 4.3 points.[11] HbA1c was evaluated as a predictor of OKS MCID using single-factor and multifactorial binary logistic regression. Receiver operator characteristic (ROC) curve analysis was conducted to determine the correlation of HbA1c with prognosis. Sensitivity, specificity, area under curve (AUC), and Youden's index were analysed. A p-value <0.05 was considered statistically significant.

RESULTS

Between 2021 and 2023, 173 DM patients scheduled for elective TKA were initially included. Of these, seven had missing biochemical markers, six underwent bilateral TKA during the follow-up period, two were lost to follow-up due to death or other reasons, three experienced infections, and three were excluded due to fractures from violence or other surgeries affecting knee joint exercise. Ultimately, 152 patients were followed up, comprising 58 males (38%) and 94 females (62%), with an average age of 71 (67-75) years. The majority had Grade III osteoarthritis (75 cases, 49%), and the average preoperative HbA1c was 6.60 (5.90-6.68) mmol/L. The average preoperative OKS was 21 (18-24), improving to 32 (28-35) one year postoperatively.

Table I shows the descriptive characteristics of the total patient cohort and compares those between the OKS function satisfied and dissatisfied groups. Age, gender, BMI, K-L grading, surgery duration, and hospital stay were relatively consistent between the groups, with p >0.05, indicating no statistical significance. However, significant differences were noted in preoperative OKS and HbA1c control levels, with p <0.05, suggesting statistical significance. Table II categorises patients based on one-year postoperative OKS pain recovery into satisfied and dissatisfied groups and performs a descriptive analysis of their characteristics and follow-up content, similar to Table I, where significant differences in preoperative OKS and HbA1c were observed.

Table I: Clinical and demographic data of the total patient cohort and the Oxford Knee Score functional satisfaction and dissatisfaction of groups during follow-up [n (%) / Mean ± SD / Median (IQR)].

Parameter	All Patients	Satisfied Group	Dissatisfied Group	p
Gender (male/female)	58/94 (38/62)	36/60 (37/63)	22/34 (39/61)	0.964[a]
Age (years)	71 (67 - 75)	71 (67 - 75)	71 (66 - 75)	0.732[b]
K-Lgrade (II/III/IV)	44/75/33 (29/49/22)	23/52/21 (24/54/22)	21/23/12 (38/41/21)	0.176[a]
HbA1c (mmol/L)	6.60 (5.90 - 6.68)	6.3 (5.80 - 7.00)	7.65 (6.35 - 9.15)	0.001[b]
BMI (kg/m^2)	25.64 ± 2.19	25.57 ± 2.39	25.76 ± 1.81	0.607[c]
Preoperative OKS	21 (18 - 24)	20 (17 - 23)	22 (20 - 26)	0.001[b]
Surgicalti (mins)	81 (76.00 - 88.00)	83 (76.00 - 88.00)	78.13 (75.00 - 87.75)	0.154[b]
Hospital stay (days)	7 (6 - 7)	7 (6 - 7)	7 (6 - 7)	0.099[b]

K-L: Kellgren-Lawrence; HbA1c: Haemoglobin A1c; BMI: Body mass index; OKS: Oxford Knee Score.[a] Chi-square test. [b]Mann-Whitney U test. [c]Independent-samples t-tests.

Table II: Clinical and demographic data of the Oxford Knee Score pain satisfaction and dissatisfaction groups [n (%) / Mean ± SD / Median (IQR)].

Parameter	Satisfied Group	Dissatisfied Group	p
Gender (male/female)	36/56 (39/61)	22/38 (37/63)	0.893[a]
Age (years)	71 (67 - 75)	71 (66 - 75)	0.768[b]
K-L grade (II/III/IV)	23 /48/21 (25/52/23)	21/27/12 (35/45/20)	0.413[a]
HbA1c (mmol/L)	6.30 (5.80 - 7.00)	7.50 (6.33 - 8.98)	0.001[b]
BMI (kg/m^2)	25.65 ± 2.55	25.60 ± 2.95	0.349[c]
Preoperative OKS	20 (17 - 23)	22 (20 - 26)	0.001[b]
Surgical time (mins)	83.50 (76.00 - 88.00)	78.00 (75.00 - 87.75)	0.154[b]
Hospital stay (days)	7 (6-7)	7 (6-7)	0.073[b]

K-L: Kellgren-Lawrence; HbA1c: Haemoglobin A1c; BMI: Body mass index; OKS: Oxford Knee Score ([a] Chi-square test. [b]Mann-Whitney U test. [c]Independent-samples t-tests).

Table III: Results of the multifactorial binary logistic regression analysis on the satisfaction group patients with pain and function Oxford Knee Score one year post-surgery.

Variables	β	Standard Error	Wald-Value	OR	p	95% CI
Function						
HbA1c	0.646	0.143	20.492	1.908	0.001	(1.442, 2.523)
Age	0.040	0.029	1.911	1.041	0.167	(0.983, 1.101)
Gender	0.216	0.406	0.282	1.241	0.595	(0.560, 2.749)
BMI	0.125	0.09	1.942	1.133	0.163	(0.951, 1.350)
Hospital stay	0.047	0.129	0.133	1.048	0.716	(0.814, 1.349)
Surgical time	-0.02	0.019	1.128	0.980	0.288	(0.944, 1.017)
K-L grade (III)	-0.008	0.485	0.001	0.992	0.986	(0.383, 2.564)
K-L grade (IV)	0.224	0.562	0.159	1.252	0.690	(0.416, 3.769)
Pain						
HbA1c	0.623	0.140	19.742	1.865	0.001	(1.417, 2.455)
Age	0.040	0.028	2.064	1.041	0.151	(0.985, 1.100)
Gender (male)	0.381	0.401	0.900	1.463	0.343	(0.666, 3.213)
BMI	0.145	0.088	2.716	1.820	0.099	(0.973, 1.375)
Hospital stay	0.056	0.126	0.193	1.057	0.660	(0.825, 1.354)
Surgical time	-0.022	0.019	1.400	0.978	0.237	(0.943, 1.015)
K-L grade (III)	0.265	0.480	0.304	1.303	0.581	(0.509, 3.339)

HbA1c: Haemoglobin A1c; BMI: Body mass index; K-L: Kellgren-Lawrence.

Using HbA1c as an independent variable and OKS functional improvement satisfaction as the dependent variable, single-factor binary logistic regression analysis indicated that HbA1c is a strong predictor of OKS satisfaction, with a significant coefficient (Coefficient = 0.584), meaning that an increase in HbA1c is significantly associated with increased dissatisfaction. This was confirmed by the Wald test ($p < 0.05$), showing high statistical significance. Multifactorial binary regression analysis, controlling for age, gender, K-L grading, BMI, hospital stay, and surgery time, still showed significant results for OKS functional MCID, as seen in Table III. The odds ratio (OR) for HbA1c was 1.908, indicating that each unit increase in HbA1c increases the dissatisfaction with functional improvement by approximately 1.9 times. HbA1c's beta coefficient ($\beta = 0.646$, $\beta > 0$) indicates that higher HbA1c levels correlate with increased dissatisfaction chances, which means higher blood sugar control levels lead to poorer functional recovery one year postoperatively. The impacts of gender, age, hospital stay, and surgery time were not significant. The same logistic regression analysis method was applied to the OKS pain group, as seen in Table III, where single-factor and multifactorial results, similar to the functional group, showed significant positive correlations for HbA1c, indicating that increases in HbA1c is associated with higher chances of dissatisfaction with pain recovery. HbA1c's $\beta = 0.623$ implies that higher blood sugar control levels correlate with poorer pain improvement, for each unit increase in HbA1c, the likelihood of an event occurring increases by 1.865 times (OR=1.865).

As shown in Figure 2, HbA1c demonstrated strong predictive capability for determining whether OKS reached the MCID, with AUCs of 0.734 and 0.721 for functional and pain MCID, respectively. The optimal cut-off values for HbA1c were 7.35 (with sensitivities of 87.5% and 86.9%, and specificities of 64.3% and 60.0%, respectively). The 95% confidence intervals for the AUCs were (0.643 - 0.825) and (0.631 - 0.810), indicating reliable predictability of HbA1c for postoperative OKS MCID. In summary, HbA1c has strong predictive power for MCID in DM patients undergoing elective TKA, and controlling HbA1c levels below 7.35 can lead to ideal outcomes in terms of functional and pain recovery one year postoperatively, providing clinically meaningful guidance for alleviating postoperative pain and enhancing surgical satisfaction.

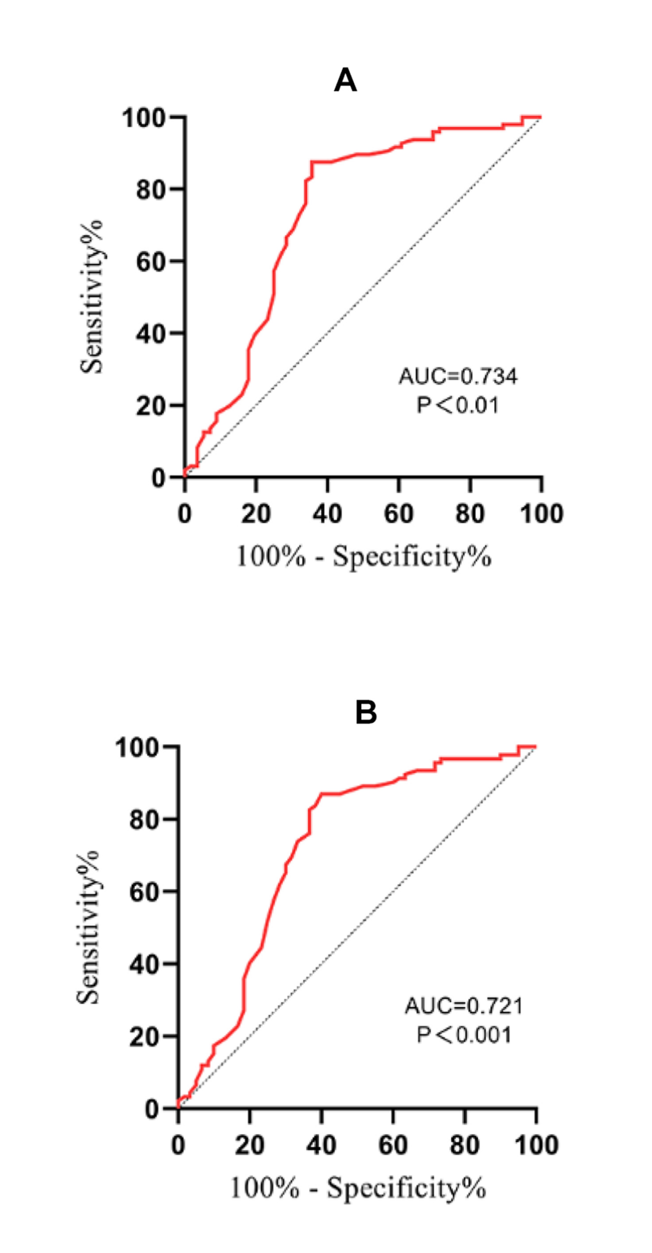

Figure 2: HbA1c prediction of post-TKA OKS MCID using receiver operating characteristic curve (ROC). (A) ROC of function group (B) ROC of pain group.

DISCUSSION

Adverse outcomes following TKA have always garnered significant attention. A study by the Australian Clinical Outcomes Registry reported that the overall incidence of adverse outcomes in TKA patients was 53.6%, with 14.4% of patients reporting major complications and 46.6% reporting minor complications.[12] These complications primarily include knee stiffness or arthrofibrosis, where excessive scar tissue forms within the knee joint, severely limiting the mobility of the new joint.[13] Other common complications include anaesthesia risks, thrombosis, prosthesis infection, persistent pain,[14] transfusion complications, metal component allergies, wound and bleeding complications, and arterial damage. These postoperative outcomes underscore the importance of careful patient selection and the optimisation of pre- and postoperative plans to reduce the incidence of these complications. Clinicians must be aware of these risks and manage them effectively to ensure the best therapeutic outcomes for patients.

The OKS was introduced in 1998 and has been validated for measuring pain and function after total knee replacement.[10] Although originally developed for patients undergoing knee replacement, it has also been used to assess the effectiveness of pharmacological treatments, osteotomies, rehabilitation, and post-fracture outcomes. The advantages of OKS include its multifunctionality: Patients can fill out the questionnaire on paper or digitally, and studies show no clinical differences between data collected orally and in writing before and after TKA.[15] Its predictive nature is useful for forecasting the need for revision six months post-replacement[16] and serves as a reliable indicator for patients with poor health status awaiting TKA.[17] Its capacity for tracking improvement allows surgeons to monitor joint conditions and keeps patients informed about their recovery, boosting postoperative confidence.[18]

DM patients face more challenges in their recovery process after TKA than non-diabetic patients.[19] They are more prone to complications such as infections and bleeding and typically have longer hospital stays and reduced joint mobility.[4] In a five-year follow-up of the Forgotten Joint Score-12 (FJS-12), DM patients scored lower than non-DM patients, struggling to achieve "joint forgetfulness," and their preoperative OKS and functional outcomes at two years were significantly poorer.[20]

As the global diabetic population grows, so do the challenges faced by DM patients undergoing TKA, including numerous complications and more difficult management post-surgery. To date, few studies have explored how to optimise preoperative and postoperative plans for DM patients, particularly in perioperative management. Most of the researchers have focused on managing DM patients undergoing general surgery, with fewer guidelines specific to TKA management. For example, research by Grant *et al.* indicates that elective surgery patients with DM should have their preoperative glucose levels identified and optimised, and personalised insulin plans formulated, aiding in crafting individualised diabetes care plans for admission, surgery, and postoperative periods.[21] Additionally, Muermann *et al.* suggests that preoperative serum ketone body screening is a cost-effective way to provide secondary prevention of diabetic ketoacidosis (DKA) and other DM emergencies, allowing for early detection and intervention.[22] However, these are general guidelines, and specific treatments may vary based on the surgical conditions and patient glucose levels. Liu *et al.* argued that effective blood sugar control is crucial for preventing postoperative complications in DM patients undergoing TKA. Timely use of antibiotics and thrombosis prevention measures are necessary to ensure surgical success and smooth recovery, although this study is retrospective and may not represent a broader population of TKA patients due to its smaller sample size and older data. Livshetz *et al.* emphasised the importance of maintaining good glucose control and minimising DM-related perioperative risks through surgical screening, suggesting HbA1c level screening for all surgical candidates to detect DM and recommending maintaining blood glucose levels between 80 to 180 mg/dL to minimise postoperative complications.[23] However, this recommendation is based on a consensus article and lacks a consistent HbA1c threshold for predicting postoperative complications, thus its results are somewhat limited. Ferrera suggests reducing postoperative glucose levels and improving the incidence of TKA complications and infection rates through a carbohydrate-restricted diet,[24] but this does not consider other variables that affect glucose levels, such as surgical duration and individual patient characteristics. Moreover, the study focuses on short-term glucose management post-surgery without addressing long-term outcomes.

This study, through a prospective cohort of 152 diabetic patients incorporating surgical time, BMI, hospital stay, and other parameters, examines important clinical outcome indicators such as MCID, and explores the impact of HbA1c control on postoperative functional improvement and pain recovery. It provides an optimal cut-off value for OKS MCID, with logistic regression analysis showing a high correlation between HbA1c and OKS MCID ($p < 0.05$). Higher glucose control levels correlate with lower patient satisfaction with postoperative functional and pain improvement, and an HbA1c of 7.35mmol/L correlates with achieving OKS MCID one year postoperatively, significantly improving both function and joint pain perception. However, the main outcome indicator of this study is relatively narrow, focusing only on OKS MCID and not considering other knee joint scoring systems, primarily because research on MCID following knee replacement is still limited and the computational models are only beginning to mature. Thus, future research directions for managing DM patients post-TKA have signifi-cant room for improvement.

CONCLUSION

In DM patients undergoing elective TKA, an HbA1c level above 7.35 mmol/L is associated with worsened scores in both the functional and pain groups one year post-operatively. When HbA1c exceeds this threshold, physicians should intervene early inpatient glucose levels to improve postoperative recovery and enhance surgical satisfaction.

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ETHICAL APPROVAL:
This study has been approved by the Ethics Committee of the First People's Hospital of Lianyungang City.

PATIENTS’ CONSENT:
All patients participating in the study were informed of the risks and signed informed consent.

COMPETING INTEREST:
The authors declared that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this manuscript.

AUTHORS' CONTRIBUTION:
DS, SS, ZM: Study’s conception and design, material preparation, data collection, and analysis.
DS: Manuscript writing.
DY: Study conception and design.
All authors approved the final version of the manuscript to be published.

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