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Cost-effectiveness analysis of duodenal–jejunal bypass sleeve device for people with obesity

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Abstract

Background Obesity has become major public health problem around the world. Lifestyle interventions, Pharmacotherapy and bariatric surgery are the common intervention to reduce weight in clinical practice. This study aims to conduct an economic evaluation of Duodenal–Jejunal Bypass Sleeve (DJBS) plus Intensive Lifestyle Intervention (ILI) compared with ILI only in people with obesity in China.

Methods A hybrid model using a Decision Tree and Markov model was used to compare 9-month and lifetime horizon cost-effectiveness between DJBS plus ILI and ILI only. The data on clinical effectiveness were based on a prospective, open-label, and randomized trial (NCT05938231). This study employed 1–3 times the Gross Domestic Product (GDP) per capita (¥85,498, exchange rate: \$1 US dollar = ¥6.73, 2022) and disposable income per capita (¥36,883, 2022) as the Willingness-To-Pay (WTP) thresholds. One-way, probabilistic sensitivity and scenario analysis were performed to test the robustness of the results.

Results The results of the 9-month decision tree model showed that compared to ILI only, DJBS plus ILI decreased body mass index (BMI) by 1.69 kg/m² (1.41 vs. 3.10), with an increasing cost of ¥28,963.98 yuan (¥29,111.06 vs. ¥147.08). The incremental cost-effectiveness ratio (ICER) was ¥17,138.45 per unit decrease of BMI. The lifetime horizon model showed that compared to ILI only, DJBS plus ILI had a higher cost of ¥13261.94 yuan (¥31,688.98 vs. ¥18,427.04), while with a life-year increase of 0.02 (9.43 vs. 9.41) and quality-adjusted life years (QALYs) increase of 0.15 (7.82 vs. 7.67) per people with obesity. The ICER was ¥88,412.93 per QALY gained. Probability sensitivity analysis showed the robustness of the economic evaluation results.

Conclusion The findings suggested that DJBS plus ILI was not a cost-effective strategy over a lifetime horizon when the WTP threshold was set at GDP per capita and disposable income per capita. However, it was considered cost-effective when the threshold was set at 1.03 times GDP per capita.

Keywords Cost-effectiveness analysis, Obesity, Weight management, Intensive lifestyle intervention, Duodenal–jejunal bypass sleeve

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Introduction

Obesity is a complex, chronic disease that has reached epidemic proportions around the world. Over 4 billion people may experience overweight and obesity by 2035, compared with over 2.6 billion in 2020 [1]. In China, more than 50% of adults and 19% of children and adolescents are already affected by overweight or obesity [2]. In 2019, the highest number of deaths were related to obesity, with 5.0 million deaths, followed by hyperlipidemia, type 2 diabetes mellitus (T2DM), hypertension, and non-alcoholic fatty liver disease (NAFLD) [3]. Obesity also shows a heavy economic burden around the world. From US\$1.96 trillion in 2020 to over US\$4 trillion in 2035, the impact is estimated to reduce global Gross Domestic Product (GDP) by 2.4%, rising to 2.9% by 2035 [1]. A study estimated that the medical costs attributed to overweight and obesity would reach ¥418 billion (approximately US\$61 billion), accounting for about 22% of total national medical costs by 2030 in China [4].

Lifestyle interventions (diet and physical activities) are the first-line treatment recommended in clinical guidelines [5–9]. Limited weight loss is achieved through lifestyle interventions, and weight regain often occurs after 6 months [10–13]. Bariatric surgery (BS), although recognized as the most effective and capable of achieving more than 20% in total weight loss [14, 15], is hindered by significant associated risks, high expenses, and low acceptance rates [16, 17]. The Duodenal–Jejunal Bypass Sleeve (DJBS, TONGEE®, TONGEE Medical, Hangzhou, China) is a novel nonsurgical device system. The DJBS is an impermeable sleeve placed via endoscopy to prevent nutrient absorption in the duodenum and proximal jejunum. It offers a new option for individuals dealing with obesity, particularly those who find traditional diet and exercise ineffective or who have comorbidities.

Health economics evaluations offer a comprehensive comparison of clinical outcomes and resource utilization across different interventions. These evaluations are often used to guide decisions on healthcare reimbursement and clinical practice. In many countries, including China, there is growing emphasis on using health economic evidence to support the regulatory approval of innovative drugs and medical devices [18, 19]. Given the increasing economic burden of obesity-related interventions, conducting cost-effectiveness analyses is essential for guiding resource allocation and prioritizing innovative treatments. Recent studies have highlighted the need for evidence-based methods to evaluate the value of emerging medical technologies [20–22]. To our knowledge, there is not yet evidence on the cost-effectiveness of DJBS compared to current interventions. To help fill existing research gaps, this study aimed to estimate the cost-effectiveness of DJBS plus intensive lifestyle

interventions (ILI) compared with ILI only in people with obesity in China.

Methods

Study design and target population

A prospective, randomized, multicenter, open-label clinical trial study (NCT05938231, Registration Date June 2, 2023) was conducted across seven tertiary hospitals in China (Beijing Friendship Hospital, Beijing, China; Beijing Shijitan Hospital, Beijing; Nanjing Drum Tower Hospital, Jiangsu; Affiliated Hospital of Inner Mongolia Medical University, Neimenggu; Tianjin Medical University General Hospital, Tianjin; Tang Du Hospital, Shanxi; The First Hospital of China Medical University, Liaoning). The trial compared the effectiveness of DJBS plus ILI to ILI only.

The trial involved adults with obesity (age ≥ 18 years old, body mass index (BMI) ≥ 30 kg/m², with or without metabolic comorbidities) (Supplementary Table 1). Initially, 99 participants were enrolled in the clinical trial, with 50 in the DJBS plus ILI and 49 in the ILI only. Finally, 92 patients completed the clinical trial, with 45 in the DJBS plus ILI and 47 in the ILI only (Supplementary Table 2). Of the patients with obesity, 92% had comorbidities with other related metabolic disorders, while 8% had obesity alone (Table 1). Population characters and clinical effectiveness data in our study were based on the trial. Asian BMI classification criteria were applied, categorizing patients as follows: No obesity (BMI < 25 kg/m²); Class I obesity (25.0 kg/m² \leq BMI ≤ 29.9 kg/m²), Class II obesity (BMI ≥ 30.0 kg/m²) [23]. At the 9-month follow-up, the BMI change in the DJBS plus ILI group was -3.10 ($-4.10, -0.40$), while the BMI change in the ILI group was -1.41 ($-2.60, 0.30$). The difference between the two groups was statistically significant ($p = 0.03$).

Cost-effectiveness analysis (CEA) was used to estimate the economics of 9-month and lifetime time horizon (the average life expectancy in China was 78.2 years old in 2022) in DJBS plus ILI compared with ILI only. The analysis was performed from the perspective of China's healthcare system and only direct medical costs were included. Costs were reported in 2022 Chinese Yuan (CNY ¥), with an annual average exchange rate of \$1 US dollar = ¥6.73 [24]. Costs and health outcomes were discounted at an annual rate of 5% [25]. The outcomes of the analysis were expressed as the difference in BMI from baseline (9 months), life years, Quality-Adjusted of Life Years (QALYs), and incremental cost-effectiveness ratio (ICER). This study employed multiple Willingness-To-Pay (WTP) thresholds to assess the cost-effectiveness of different interventions, using 1–3 times the Gross Domestic Product (GDP) per capita (¥85,498, 2022) [25] as the primary thresholds for the cost-effectiveness analysis [26]. Additionally, disposable income per capita (¥36,883, 2022)

Table 1 Study population characteristics and transition probabilities parameters inputs in model

parameters	Base value (range)	distribution	Distribution parameters	source
Discount rate	5% (0%~8%)	Uniform		[25]
Life expectancy	78.2	Uniform		Supplementary Table 4
Population				
Age	35 (26,44)	Uniform		Clinical trial
Male (%)	44% (39%,48%)	Uniform		Clinical trial
Baseline BMI	35.2 (27.8,43.5)	Uniform		Clinical trial
Patient composition (%)				
Class I obesity without comorbid	0%	Uniform		
Class II obesity without comorbid	8%	Uniform		
Class I obesity with T2DM	0%	Uniform		
Class II obesity with T2DM	17%	Uniform		
Class I obesity with NAFLD	0%	Uniform		
Class II obesity with NAFLD	62%	Uniform		
Class I obesity with ALD	0%	Uniform		
Class II obesity with ALD	13%	Uniform		
Epidemiological parameters				
Incidence of T2DM among class I obesity(per 1000 person-year)	16.4 (13.12,19.68)	Beta	$\alpha = 24.79; \beta = 3000.57$	[55]
Incidence of T2DM among class II obesity(per 1000 person-year)	32.23 (25.78, 35.45)	Beta	$\alpha = 24.58; \beta = 1513.09$	[55]
Incidence of NAFLD in obesity	0.52 (0.47, 0.56)	Beta	$\alpha = 19.09; \beta = 64.85$	[46]
Incidence of ALD in obesity	0.45 (0.39, 0.51)	Beta	$\alpha = 19.81; \beta = 79.36$	[56]
Incidence of CHD among class I obesity (per 1000 person-year)	5.44(4.35, 6.52)	Beta	$\alpha = 24.93; \beta = 9155.51$	[57]
Incidence of CHD among class II obesity (per 1000 person-year)	11.22(8.96, 13.46)	Beta	$\alpha = 24.85; \beta = 4416.51$	[57]
Incidence of stroke among class I obesity (per 1000 person-year)	11.96 (9.56, 14.35)	Beta	$\alpha = 24.85; \beta = 4143.42$	[57]
Incidence of stroke among class II obesity (per 1000 person-year)	16.17(12.93, 19.40)	Beta	$\alpha = 24.79; \beta = 3054.63$	[57]
Transition probabilities				
Remission rate of HbA1c in class I obesity(9months %)	0.50(0.40, 0.60)	Beta	$\alpha = 15.38; \beta = 26.18$	Clinical trial
Remission rate of HbA1c in class II obesity(9months %)	0.67(0.53, 0.80)	Beta	$\alpha = 11.49; \beta = 10.63$	Clinical trial
Probability of diabetes to uncontrol diabetes	0.014 (0.01, 0.02)	Beta	$\alpha = 24.63; \beta = 1727.94$	[58]
Remission rate of FLD(6months %)	0.44 (0.35, 0.53)	Beta	$\alpha = 13.74; \beta = 17.99$	[59]
Probability of ALD to CC	0.14(0.08, 0.2)	Beta	$\alpha = 23.24; \beta = 320.55$	[60]
Probability of NAFLD to CC	0.03(0.024, 0.036)	Beta	$\alpha = 24.95; \beta = 12437.26$	[61]
Probability of FLD to HCC among class I obesity	0.007 (0.0029, 0.0066)	Beta	$\alpha = 24.91; \beta = 7534.48$	[62]
Probability of FLD to HCC among class II obesity	0.009 (0.007, 0.01)	Beta	$\alpha = 24.88; \beta = 5409.75$	[62, 63]
Probability of CC to DC	0.316 (0.25, 0.37)	Beta	$\alpha = 24.01; \beta = 609.84$	[64]
Probability of CC or DC to HCC	0.03 (0.007, 0.053)	Beta	$\alpha = 24.61; \beta = 1628.59$	[64]
Probability of DC to LT	0.0003 (0.00002, 0.0011)	Beta	$\alpha = 25; \beta = 166628.17$	[65]
Probability of HCC to LT	0.003 (0.0015, 0.0045)	Beta	$\alpha = 24.96; \beta = 16628.21$	[65]
Probability of CHD to MI among class I obesity (per 1000 person-year)	5.8 (4.64, 6.96)	Beta	$\alpha = 24.92; \beta = 8582.27$	[66]
Probability of CHD to MI among class II obesity	0.0081 (0.0052, 0.012)	Beta	$\alpha = 24.79; \beta = 3032.49$	[23, 66]
From uncontrol diabetes to death (per 1000 person-year)	42.2 (32.5, 52.5)	Beta	$\alpha = 24.46; \beta = 1146.92$	[66]
From DC to death(6.8 years)	0.5 (0.4, 0.6)	Beta	$\alpha = 23.71; \beta = 453.41$	[61]
From HCC to death	0.368 (0.376, 0.375)	Beta	$\alpha = 20.63; \beta = 102.12$	[65]
From LT to death	0.22 (0.176, 0.264)	Beta	$\alpha = 22.29; \beta = 191.71$	[65]
From Post-LT to death	0.048 (0.0384, 0.0576)	Beta	$\alpha = 24.38; \beta = 1003.83$	[65]

Table 1 (continued)

parameters	Base value (range)	distribution	Distribution parameters	source
From MI to death (per 100,000 person-year)	60.29 (48.23, 72.34)	Beta	$\alpha = 25; \beta = 829286.43$	[67]
From stroke to death (per 100,000 person-year)	45.85 (36.68, 55.02)	Beta	$\alpha = 25; \beta = 1090474.04$	[67, 68]

Abbreviations: DJBS, duodenal–jejunal bypass sleeve; ILI, intensive lifestyle intervention; FLD, fatty liver disease; ALD, alcoholic fatty liver disease; NAFLD, non-alcoholic fatty liver disease; CC, compensatory cirrhosis; DC, decompensated cirrhosis; HCC, hepatocellular carcinoma; LT, liver transplantation; CHD, coronary heart disease; MI, myocardial infarction; T2DM, type 2 diabetes mellitus

was used as a supplementary threshold to provide further context and a broader perspective on the affordability of the interventions [27] A half-cycle correction was applied to the lifetime horizon to ensure accurate representation of costs and outcomes, as events were assumed to occur continuously within each modeled cycle [28].

Model structure and assumption

A hybrid model using a Decision Tree and Markov model was constructed in Microsoft Excel 2019 to assess the cost-effectiveness of DJBS plus ILI and ILI only. The model was developed to simulate the short- and long-term health and economic outcomes of obesity intervention using clinical trial data and real-world evidence. It integrated and expanded previous economic models by incorporating a broader range of disease states to better reflect the real-world progression of obesity-related conditions [29–35].

The decision tree part was based on the clinical trial design, which illustrated the possible deterministic pathways of the two groups during the 9-month after DJBS plus ILI and ILI only (Fig. 1A). The decision tree incorporated a 3-month DJBS placement period and a 6-month follow-up period after the removal of DJBS. After 3-month, patients could transition to different states, including no obesity, no obesity with comorbidity, class I obesity with or without comorbidity, and class II obesity with or without comorbidities states. Patients in the DJBS plus ILI group undergo 6-month of ILI, while those in the ILI only group receive constant lifestyle intervention over the 9-month study duration. At the end of the decision tree, patients would stay in no obesity, no obesity with comorbidity, class I obesity with or without comorbidity, and class II obesity with or without comorbidities states according to clinical trial outcomes (Supplementary Table 3).

After the decision tree stage, all patients with obesity, categorized by different obesity classes, transitioned into the Markov model. Based on the presence or absence of comorbidities, patients were further categorized into distinct health states: patients without comorbidities, T2DM remission, T2DM, T2DM uncontrolled, fatty liver disease (FLD), FLD/ compensatory cirrhosis (CC) remission, CC, decompensated cirrhosis (DC), hepatocellular carcinoma (HCC), liver transplantation (LT), Post-LT, coronary heart disease (CHD), myocardial

infarction (MI), Post-MI, stroke, post-stroke and death. After entering the Markov model with different states, patients could develop T2DM, liver disease, cardiovascular disease, or die (Fig. 1B). Over time, patients could transition between states, remain in their current state, or die. Given that the clinical trial had a 6-month follow-up period, which we consider to approximate a long-term simulation, the cycle length of the Markov model was set at 6 months.

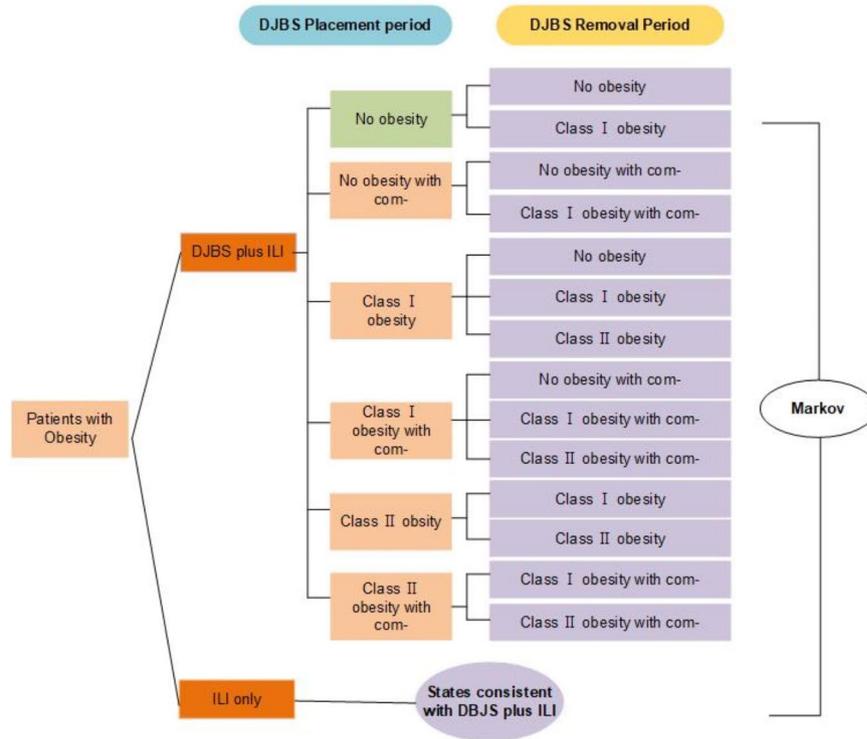
To clarify our hybrid model using Decision Tree and Markov model, we made some assumptions. Firstly, mortality in states such as patients with obesity and without comorbidities, T2DM remission, T2DM, CHD, FLD, CC, and FLD/CC remission was based on all-cause mortality. For the remaining disease states, disease-related mortality was applied. Secondly, our study did not account for situations where patients may switch to different interventions or undergo re-operations in the future. It assumed that the effectiveness was sustained in patients after receiving the intervention. Thirdly, all patients with comorbidities were supposed to be routinely treated with drugs. Finally, our model did not consider patients who may experience more than one comorbidity or patients who develop different disease states in various fields.

Model inputs

Clinical trial and transition probabilities

The efficacy data of DJBS plus ILI and ILI were derived from clinical trials. Improvement values in BMI, HbA1c, and FLD remission during the trial period were utilized to calculate the percentage of patients in different states at the 3-month and 9-month time points (Supplementary Table 3). Incidence rates of T2DM, CHD, and stroke in other obesity classes were estimated by adjusting the weighted average data from the literature. Due to insufficient evidence, it was assumed that the incidence rates of comorbidities with NAFLD, comorbidities with ALD, and transition probabilities between different disease states were the same across various BMI classes (Table 1). All-cause mortality rates for the total population and the entire national population in 2020 were derived from the World Health Organization (WHO) life table for China (Supplementary Table 4). Disease-related mortality rates were sourced from the literature (Table 1). All probabilities were converted into per-cycle rates (every 6 months).

(A) Decision tree Model



(B) Markov bubble diagram

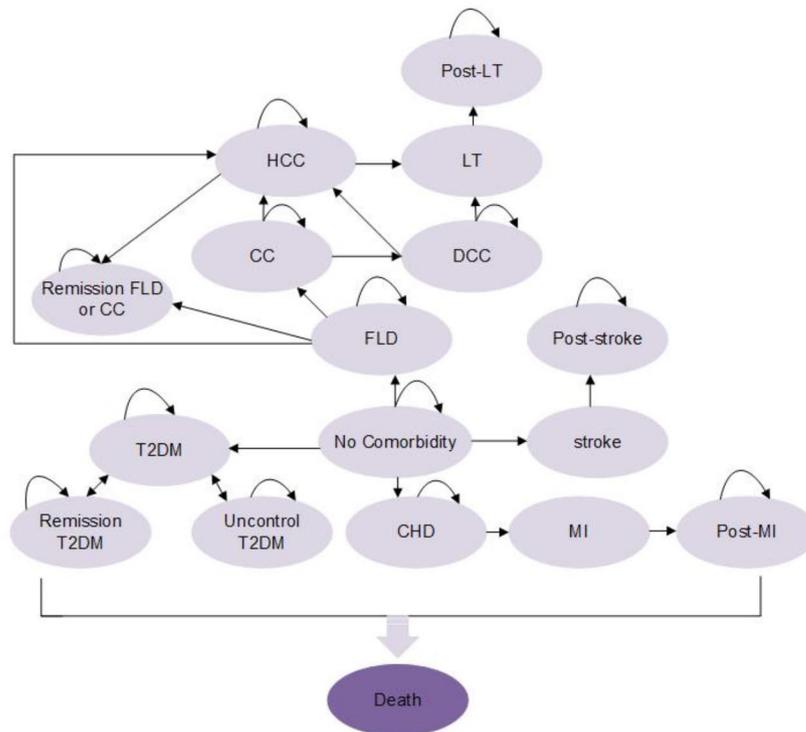


Fig. 1 Hybrid Decision Tree and Markov model. Abbreviations: with com-, with comorbidity; FLD, fatty liver disease; CC, compensatory cirrhosis; DC, decompensated cirrhosis; HCC, hepatocellular carcinoma; LT, liver transplantation; CHD, coronary heart disease; MI, myocardial infarction; T2DM, type 2 diabetes mellitus

Utility

We conducted searches in the China National Knowledge Infrastructure, Wan Fang Data, and Medline (PubMed) databases using the keywords “obesity,” “utility,” “health-related quality of life (HRQoL),” “EQ-5D,” “SF-36D,” and “cost.” The purpose was to retrieve literature related to obesity’s impact on health-related quality of life, cost analysis, and disease burden. To account for variations in quality of life among patients with obesity across different BMI classes, our study adjusted utilities for different classes of people with obesity. (Table 2).

Cost

Direct medical costs were calculated in this study, which included the DJBS placement/removal costs, comorbid disease pharmacotherapy costs, costs of adverse events, follow-up monitoring costs, and disease state management costs (Table 2). Medical service prices were derived from the price specifications issued by the clinical trial centers. Drug prices were obtained from the latest procurement prices of the six provinces through the YAOZHI medical database [36] (Supplementary Table 5). Information on comorbid disease pharmacotherapy and corresponding drug prices were sourced from the clinical trial and the YAOZHI medical database [36]. The adverse events costs and follow-up were calculated from clinical trials and public materials. Only adverse events requiring intervention and standard follow-up medical services were included in the calculation (Supplementary Tables 6, 7, 8). Disease state management costs were obtained from the literature review. All costs were adjusted to 2022 prices using the Consumer Price Index (CPI).

Sensitivity analysis

To identify the uncertainty of model parameters on calculated estimates, we conducted One-Way Sensitivity Analysis (OWSA) and Probabilistic Sensitivity Analysis (PSA) around critical parameters such as transition probabilities, costs, and utilities. The parameters were changed in a 95% confidence interval (CI). When the 95%CI could not be obtained, then the changed range was within $\pm 20\%$ of the baseline value. The discount rate used 0%~8% as the range of fluctuation [25]. A tornado diagram was used to present the results of OWSA. PSA was performed by drawing random samples out of their respective statistical distribution within 1000 Monte Carlo simulations. The results of PSA were presented through the Cost-effectiveness plane scatter plot, illustrating the distribution of cost and effectiveness outcomes. Additionally, the Cost-effectiveness acceptable curves (CEAC) were used to showcase the probability of cost-effectiveness across 1 to 3 times GDP per capita, and disposable income per capita.

Considering BS is the common and effective way in clinical practice. A scenario analysis was performed to compare cost-effectiveness between DJBS plus ILI and BS. Previous studies have shown that BS should be considered for patients with a lower BMI range (BMI ≥ 35 kg/m² or patients with a BMI of 30 to 34.9 who have concurrent metabolic disease) [7, 37]. While there are differences in BMI classification for obesity severity in Asian populations, the recommended indication for BS in Chinese guidelines is for adult patients with a BMI ≥ 32.5 kg/m² [38, 39]. This recommendation is consistent with international guideline thresholds [7]. Moreover, the baseline BMI in the clinical trial was 35.2 kg/m². Then, we assumed that all patients with obesity received surgery at the beginning of the model. No direct head-to-head comparison studies of DJBS plus ILI versus BS were available currently, so efficacy evidence for the DJBS plus ILI versus BS was obtained by indirect comparison using the Bucher method. We conducted a comprehensive literature search using both Chinese and English keywords, such as “metabolic surgery,” “bariatric surgery,” “gastric bypass,” “sleeve gastrectomy,” “lifestyle intervention,” and “dietary behavioral intervention.” Our search spanned several academic databases, including China National Knowledge Infrastructure (CNKI), Medline (PubMed), Embase, and Web of Science. We focused on clinical studies comparing BS with ILI. Based on clinical trial data comparing DJBS plus ILI with ILI alone—focusing on outcomes such as BMI and HbA1c—we performed an indirect comparison to estimate the results of BS versus DJBS plus ILI. Indirect treatment comparison results showed that, compared to DJBS plus ILI, BS had reduced BMI by 4.88 kg/m² and HbA1c by 0.31% (Supplementary Fig. 1, Supplementary Tables 9, and Supplementary Table 10). The results of the indirect analysis indicate that, currently, BS produces the most effective weight loss outcomes, consistent with existing literature [37, 40]. The cost of BS was ¥67,371.64, which was calculated from the literature [41]. The adverse events cost was ¥602.69 per patient (Supplementary Table 7). And other costs were the same as DJBS plus ILI.

Results

Base case analysis

The results of the 9-month decision tree model showed that compared to ILI only, DJBS plus ILI decreased in BMI by 1.69 kg/m² (1.41 vs. 3.10), with an increasing cost of ¥28,963.98 (¥29,111.06 vs. ¥147.08). The ICER was ¥17,138.45 per Δ BMI improved (Table 3).

The results over the lifetime horizon indicated (Table 4), compared to ILI only, DJBS plus ILI has improved life years by 0.02 (9.41 vs. 9.43), and QALYs by 0.15 (7.67 vs. 7.82), with increasing cost ¥13,261.94 (¥18,427.04 vs. ¥31,688.98), respectively. The ICER was

Table 2 Utilities and costs parameters input in model

parameters	Base value (range)	distribution	Distribution parameters	source
Health Utilities				
Class I obesity without comorbidities	0.95 (0.85, 1)	Beta	$\alpha = 30; \beta = 2$	[69]
Class II obesity without comorbidities	0.94 (0.84, 1)	Beta	$\alpha = 31; \beta = 2$	[69]
Diabetes (BMI ≥ 25 kg/m ²)	0.86 (0.69, 1)	Beta	$\alpha = 16; \beta = 3$	[70]
Remission diabetes	0.95 (0.76, 1)	Beta	$\alpha = 26; \beta = 1$	[71]
Uncontrol diabetes	0.77 (0.69, 0.84)	Beta	$\alpha = 92; \beta = 28$	[72]
FLD	0.85 (84, 0.86)	Beta	$\alpha = 4162; \beta = 735$	[73]
CC	0.76 (0.68, 0.83)	Beta	$\alpha = 94; \beta = 30$	[74]
DC	0.63 (0.56, 0.69)	Beta	$\alpha = 133; \beta = 77$	[75]
HCC	0.41 (0.36, 0.44)	Beta	$\alpha = 235; \beta = 343$	[75]
LT	0.65 (0.52, 0.78)	Beta	$\alpha = 33; \beta = 18$	[76]
Post-LT	0.71 (0.57, 0.85)	Beta	$\alpha = 28; \beta = 11$	[76]
remission-FLD	0.85 (0.84, 0.86)	Beta	$\alpha = 16,652; \beta = 2939$	[73]
remission-CC	0.85 (0.84, 0.86)	Beta	$\alpha = 16,652; \beta = 2939$	[73]
CHD	0.78 (0.24, 1)	Beta	$\alpha = 32; \beta = 9$	[77]
MI	0.65 (0.58, 0.71)	Beta	$\alpha = 134; \beta = 72$	[78]
Post-MI	0.8 (0.72, 0.88)	Beta	$\alpha = 76; \beta = 19$	[79]
Stroke	0.65 (0.73, 0.76)	Beta	$\alpha = 2524; \beta = 1359$	[80]
Post-stroke	0.74 (0.66, 0.81)	Beta	$\alpha = 96; \beta = 34$	[80]
Utility decrements among class I obesity	0.02 (0.01, 0.03)	Beta	$\alpha = 15; \beta = 737$	[81]
Utility decrements among class II obesity	0.06 (0.03, 0.08)	Beta	$\alpha = 25; \beta = 427$	[81]
Costs (CNY ¥)				
Intervention costs				
DJBS placement and removal costs (Excluded DJBS)	2,007.20 (704.9, 5,242.51)	Gamma	$\alpha = 3; \beta = 668$	Supplementary Table 5
DJBS device	26,500.00 (25,500, 27,500)	Gamma	$\alpha = 2689; \beta = 10$	TONGEE Medical estimate
Comorbidities related drug costs	96.70 (44.92, 254.71)	Gamma	$\alpha = 3; \beta = 30$	Clinical trial
Costs of adverse events				
ILI group	32.54 (27.44, 63.02)	Gamma	$\alpha = 13; \beta = 3$	Supplementary Table 6
DJBS group	497.37 (378.00, 668.81)	Gamma	$\alpha = 8; \beta = 177$	
Follow-up monitoring costs	46.05 (25.50, 113.00)	Gamma	$\alpha = 9; \beta = 46$	Supplementary Table 8
Disease state management costs				
T2DM	5,914.27 (4,629.28, 6,9432.92)	Gamma	$\alpha = 96; \beta = 62$	[55]
Remission T2DM	5,277.86 (4131.14, 6943.92)	Gamma	$\alpha = 96; \beta = 55$	[55]
Uncontrol T2DM	6,277.48 (4,913.57, 7,370.35)	Gamma	$\alpha = 96; \beta = 65$	[55]
CC	21,876.57 (7,585.82, 35,222.79)	Gamma	$\alpha = 9; \beta = 2373$	[82]
DC	48,723.56 (28,965.52, 66,377.95)	Gamma	$\alpha = 25; \beta = 1953$	[82]
HCC	102,845.01 (72,364.59, 128,893.28)	Gamma	$\alpha = 49; \beta = 2112$	[82]
LT	446,172.99 (315,422.36, 630,836.52)	Gamma	$\alpha = 29; \beta = 15,158$	[83]
Post-LT	70,927.01 (63,081.19, 77,555.75)	Gamma	$\alpha = 353; \beta = 201$	[83]
FLD	2,019.32 (1,580.58, 2,370.87)	Gamma	$\alpha = 96; \beta = 21$	[84]
CHD	11,445.68 (8,958.87, 13,438.31)	Gamma	$\alpha = 96; \beta = 119$	[85]
MI	51,179.98 (13,898.97, 180,640.08)	Gamma	$\alpha = 1; \beta = 36,929$	[86]
Post-MI	825.36 (139.77, 1,389.90)	Gamma	$\alpha = 6; \beta = 129$	[86]
Stroke	22,607.04 (16,806.20, 36,451.90)	Gamma	$\alpha = 19; \beta = 1161$	[87]
Post-stroke	3,985.64 (3,430.32, 6,369.83)	Gamma	$\alpha = 27; \beta = 147$	[87]

Note, all costs were calculated in 2022 Chinese Yuan Renminbi

Abbreviations: DJBS, duodenal–jejunal bypass sleeve; ILI, intensive lifestyle intervention; FLD, fatty liver disease; ALD, alcoholic fatty liver disease; NAFLD, non-alcoholic fatty liver disease; CC, compensatory cirrhosis; DC, decompensated cirrhosis; HCC, hepatocellular carcinoma; LT, liver transplantation; CHD, coronary heart disease; MI, myocardial infarction; T2DM, type 2 diabetes mellitus

Table 3 Base case cost-effectiveness results (9 months)

	Total cost (CNY ¥)	Incremental cost (CNY ¥)	Δ BMI	Incremental QALY	ICER (CNY ¥/ΔBMI)
ILI	147.08	-	1.41	-	-
DJBS plus ILI	29,111.06	28,963.98	3.10	1.69	17,138.45

Abbreviations: DJBS, duodenal–jejunal bypass sleeve; ILI, intensive lifestyle intervention; CNY, Chinese Yuan; ΔBMI, the decrease in BMI from baseline; ICER, Incremental cost effectiveness ratio

¥88,412.93 per QALY gained. Therefore, when the WTP threshold was set at GDP per capita or disposable income per capita, DJBS plus ILI was not considered cost-effective compared to ILI alone. However, when the WTP threshold exceeded 1.03 times GDP per capita, DJBS plus ILI was deemed more cost-effective than ILI only.

One-way sensitivity analysis

The tornado diagram highlights the ten model parameters that had the largest association with the ICER. The utility decrement in class II obesity has the most significance on the ICER. Other crucial parameters include the discount rate, prevalence of alcoholic fatty liver disease,

and the utility decrement of class I obesity (Fig. 2). We found that when the WTP threshold was above twice the GDP per capita (¥171,396.00/QALY), DJBS plus ILI remained cost-effective despite variations in all model inputs (Fig. 2).

Probabilistic sensitivity analysis

In the PSA, model parameters were varied simultaneously 1000 times, and ICER values were calculated. According to our PSA results, each dot represents the lifetime discounted incremental cost and QALYs of one bootstrap sample. The dotted lines indicated different WTP thresholds in this study, respectively. The scatter points in the scatter plot diagram were concentrated in the first quadrant, meaning that compared to ILI, DJBS plus ILI could yield more QALYs, but it needed to pay more costs at the same time (Fig. 3A). CEAC showed the cost-effective probability of different groups. The dotted vertical lines represent the WTP thresholds (Fig. 3B). With the gradual increase in the WTP thresholds, the probability of cost-effectiveness for DJBS plus ILI increased. When the WTP threshold was set to disposable income per capita, the probability of ILI only being

Table 4 Base case cost-effectiveness results (lifetime)

	Total cost (CNY ¥)	Incremental cost (CNY ¥)	Total LYs	Incremental LY	Total QALYs	Incremental QALY	ICER (CNY ¥/LY)	ICER (CNY ¥/QALY)
ILI	18,427.04	-	9.41	-	7.67	-	-	-
DJBS plus ILI	31,688.98	13,261.94	9.43	0.02	7.82	0.15	663,096.9	88,412.93

Note, half-cycle correction results were presented in table

Abbreviations: DJBS, duodenal–jejunal bypass sleeve; ILI, intensive lifestyle intervention; CNY, Chinese Yuan; LY, life years; QALY, quality adjusted life years; ICER, Incremental cost effectiveness ratio

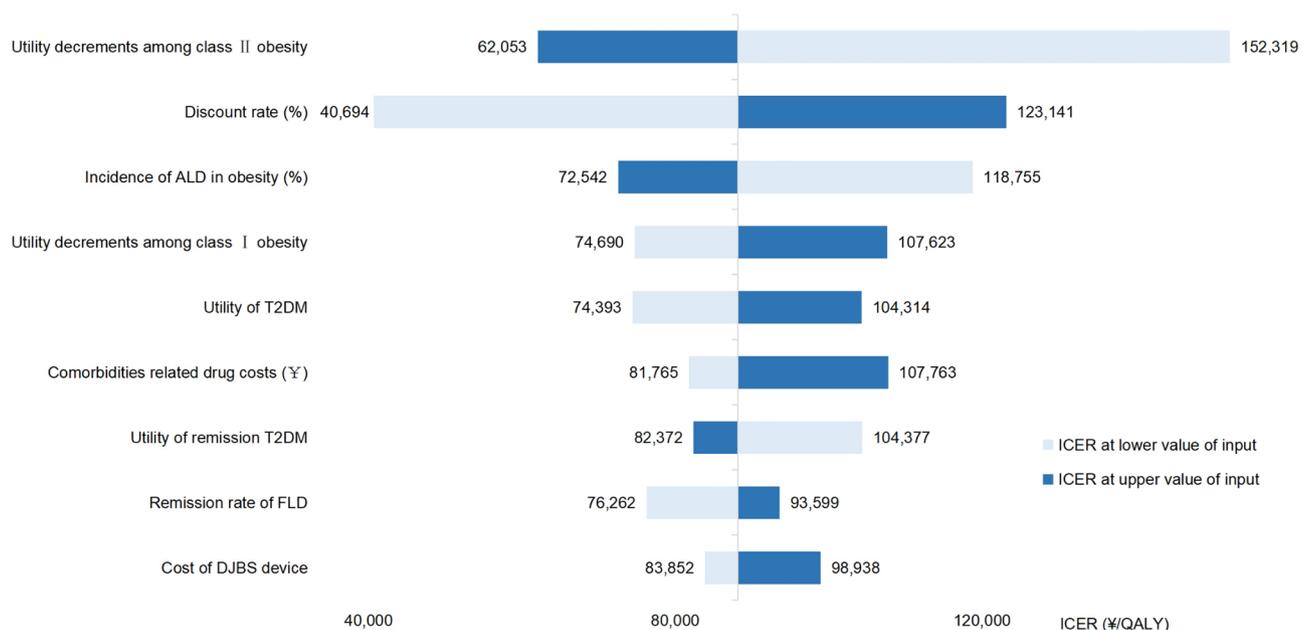


Fig. 2 Tornado Diagram for One-way Sensitivity Analysis. Abbreviations: DJBS, duodenal–jejunal bypass sleeve; ILI, intensive lifestyle intervention; ALD, alcoholic fatty liver disease; FLD, fatty liver disease; T2DM, type 2 diabetes mellitus

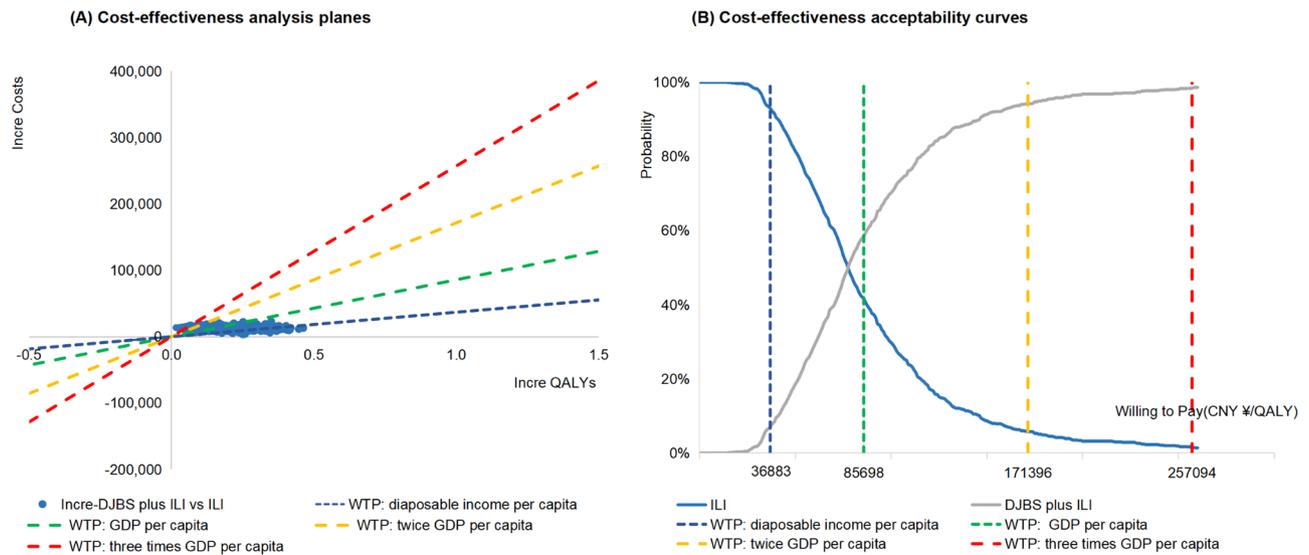


Fig. 3 The Cost-effectiveness planes and cost-effectiveness acceptability curves. Abbreviations: DJBS, duodenal–jejunal bypass sleeve; ILI, intensive lifestyle intervention

Table 5 Scenario analysis cost-effectiveness results (lifetime)

	Total cost (CNY ¥)	Incremental cost (CNY ¥)	Total QALYs	Incremental QALY	ICER (CNY ¥/QALY)
DJBS plus ILI	31,688.98	-	7.82	-	-
BS	49,475.14	17,786.16	7.94	0.12	148,218.00

Note, half-cycle correction results were presented in table
 Abbreviations: DJBS, duodenal–jejunal bypass sleeve; ILI, intensive lifestyle intervention; BS, bariatric surgery; CNY, Chinese Yuan; LY, life years; QALY, quality adjusted life years; ICER, Incremental cost effectiveness ratio

cost-effective was 93%. However, when the WTP threshold was 1 to 3 times the GDP per capita, the probability of DJBS plus ILI being cost-effective increases to 58.4%, 94.2%, and 98.4%, respectively (Fig. 3B).

Scenario analysis

Compared to DJBS plus ILI, BS was associated with an increase in QALY of 0.12 and, simultaneously, increased costs of ¥17,786.16 yuan. The ICER for BS was ¥148,218.00 per QALY gained, exceeding the WTP threshold of GDP per capita (¥85,498) but under the WTP threshold of twice GDP per capita (¥171,396) (Table 5). Moreover, compared to ILI only, the ICER for BS was ¥115,931.50 per QALY gained. BS is more cost-effective than ILI only when the threshold is up to 1.4 times GDP per capita. BS involved higher costs than DJBS plus ILI; thus, decreasing the cost of surgery or improving the WTP threshold would result in cost-effectiveness. When the threshold was set to disposable income per capita, BS was never deemed cost-effective.

Discussion

In this study, we explored the cost-effectiveness of DJBS plus ILI in people with obesity using a decision tree-Markov model. The 9-month results showed that compared to ILI only, DJBS plus ILI had improved BMI by 1.69 kg/m² (1.41 vs. 3.10), with an associated increase in cost of ¥28,963.98yuan (¥147.08 vs. ¥29,111.06). The ICER was ¥17,138.45 per ΔBMI improved. Compared to ILI only, the ICER for DJBS plus ILI was ¥88,412.93 per QALY gained over the lifetime horizon. When WTP thresholds were more than 1.03 times GDP per capita, DJBS plus ILI was more cost-effective than ILI only. However, when the WTP threshold was disposable income per capita, DJBS plus ILI was not cost-effective compared to ILI only. OWSA indicated that utility decrement in class II obesity and discounted rate significantly affected ICER values. PSA results suggested that when the WTP threshold is above GDP per capita, the probability of DJBS plus ILI is more cost-effective than ILI only. Scenario analysis results indicated that compared to DJBS plus ILI, the ICER for BS was ¥148,218.00 per QALY.

There are some challenges and emerging opportunities for the clinical management of obesity in China [17]. ILI, as noted in most patients, does not result in long-term sustained weight loss. The pharmacotherapy of obesity has limited options and a lack of long-term safety evidence in China. BS is regarded as an essential alternative treatment option for people with severe obesity. However, bariatric surgery is related to low acceptance and high expenses in China [16]. Therefore, an unmet clinical need exists. DJBS device is a novel and minimally invasive device. The device significantly reduces body weight by 4.9%~12.9% at 3 months and improves metabolic

parameters in patients with obesity and NAFLD [42]. To date, weight loss medical devices have not yet been utilized in current clinical practice in China. Our findings provided evidence for medical devices in clinical practice in China.

For patients with obesity, DJBS plus ILI remained cost-effective way than BS in scenario analysis. These findings are important because the weighing of the risks and benefits of BS in the setting of people with obesity may not appear obvious when the WTP threshold is under GDP per capita to patients or physicians. Due to the lack of direct comparative evidence between BS and DJBS plus ILI, an indirect comparison was performed using available literature. The clinical studies comparing BS and ILI included patients with obesity and comorbidities, which is consistent with the population in the clinical trials underlying the study. However, the literature used for this indirect comparison assessed the effects of BS and ILI at a 1-year follow-up, with some studies reporting optimal efficacy of BS at this time [43–45]. In contrast, the clinical trial in this study had a follow-up period of 9 months. In the Markov model analysis, it was assumed that efficacy remains constant over time, which may have resulted in an overestimation of the clinical benefit of BS. While the indirect comparison provides useful insights, the absence of direct trials introduces some uncertainty in the results. Furthermore, variation in follow-up duration across studies may impact the generalizability of the findings.

Furthermore, previous cost-effectiveness analysis studies have already compared intensive diet and life with BS. Most of them found that surgery was to be cost-effective or cost-saving [41, 46]. However, in our study, BS was a cost-effective intervention only when the WTP threshold exceeded 1.4 times GDP per capita in people with obesity compared to ILI only. The major reason for these differences may be attributed to variations in the target population differences and comparators. Previous studies often focused on patients with obesity and T2DM, and the comparators were pharmacotherapy [47–49]. The intensive diet and life group have higher medication costs, making the BS group more cost-effective [41, 46]. In our study, 83% of patients were comorbid with FLD or obesity alone, resulting in lower comorbidity-related costs compared to those studies. Additionally, two studies comparing BS with ILI found that the economic outcomes of BS were linked to the grading of comorbidities and BMI levels in obesity [50, 51].

WTP thresholds play a critical role in determining the economics of different interventions. Previous studies on the cost-effectiveness of weight loss interventions have typically relied on fixed thresholds [47, 52, 53] or conducted threshold analyses [54]. In the absence of specific willingness-to-pay thresholds for patients with obesity in

China, we adopted the 1–3 times per capita GDP range as the primary cost-effectiveness threshold for this study. This range aligns with the guidelines set forth by China's medical insurance policies and the Chinese Pharmacoeconomic Evaluation Guidelines. Obesity is not widely recognized as a disease among the general public in China, and medical insurance reimbursement primarily covers patients with obesity-related comorbidities. As a result, weight loss interventions for patients are generally paid out-of-pocket. To address this, we also considered disposable income per capita as a supplementary threshold to evaluate the cost-effectiveness of different interventions. Based on the probabilistic sensitivity analysis, when the threshold was set at per capita GDP, DJBS plus ILI was found to be cost-effective compared to ILI only. However, when the threshold was based on disposable income per capita, DJBS plus ILI was not considered cost-effective relative to ILI only. We also look forward specific international guideline on WTP threshold.

This study was conducted in parallel with the randomized clinical trial to obtain the best available evidence at this stage to compare the economics of DJBS with ILI. Our findings have several implications for policy and clinical practice. First, it offers evidence to optimize clinical weight loss strategies. Our study suggested that DJBS plus ILI was a cost-effective strategy when the WTP threshold was above 1.03 times GDP per capita compared to ILI only. Second, DJBS treatment is non-invasive and reversible. Thus, it is likely to be of interest to patients who do not have BS due to fear of surgery-related risk. Third, DJBS can be placed and removed in repetition. This flexibility is particularly valuable for patients who may not meet expected weight loss outcomes or for those experiencing weight regain.

This study had some limitations. Firstly, we used weight loss data from a clinical trial involving 92 patients and a limited follow-up duration of 6 months. Although the trial represents the best available evidence to date, long-term follow-up and larger sample studies need to prove the effectiveness and safety of DJBS. Secondly, in addition to the incidence and prevalence rates, the data on the probability of disease state transfer are from the general population, and there is heterogeneity between general populations and people with obesity. However, OWSA and PSA results suggested the robustness of our findings. Thirdly, this analysis assumed consistent incidence rates of NAFLD and ALD and transition probabilities between disease states across BMI classes due to insufficient stratified evidence. This assumption may oversimplify the impact of obesity severity on disease progression and should be revisited as more robust data become available. Finally, we assumed in our model that the efficacy of all patients would continue to be maintained after intervention until the end of the model. Although we analyzed

the short-term cost-effectiveness in DBJS plus ILI and ILI only, this assumption should be viewed with some caution. The available evidence suggests even intensive surgery intervention will cause weight regain [43]. Fourth, due to a lack of evidence comparing the efficacy of BS and DJBS plus ILI, we developed an indirect comparison treatment in scenario analysis. Heterogeneity, such as patient characteristics study designs, were among the included studies, which affected the quality of the combined results. Finally, our model did not consider the situation of patients with more than two different comorbid diseases. However, the disease states of patients are often complex in the real world, which affects the extrapolation of the results to a certain extent.

Conclusion

This study established evidence of the cost-effectiveness of a novel duodenal–jejunal bypass sleeve in managing obesity. The 9-month and lifetime simulation results showed that DJBS plus ILI was a cost-effective way. The lifetime horizon results have suggested that when the WTP threshold was set GDP per capita or disposable income per capita, compared to ILI only, DJBS plus ILI was not cost-effective. However, when the WTP threshold exceeded 1.03 times GDP per capita, DJBS plus ILI was deemed more cost-effective than ILI only. Compared to ILI only, BS intervention was cost-effective only when the WTP threshold was above 1.4 times GDP per capita. Only when the WTP threshold was greater than 1.7 times per capita GDP was BS likely to be more cost-effective than DJBS plus ILI. When the WTP threshold was set to the disposable income per capita, both DBJS PLUS ILI and BS failed to exhibit cost-effectiveness when compared to ILI only. However, considering DJBS is a novel device in clinical practice, further trials and studies of the DJBS intervention are needed to optimize clinical treatment strategies.

Abbreviations

DJBS	Duodenal–jejunal bypass sleeve
ILI	Intensive lifestyle intervention
BMI	Body mass index
ICER	Incremental cost-effectiveness ratio
QALYs	Quality-adjusted of life years
T2DM	Type 2 diabetes mellitus
NAFLD	Non-alcoholic fatty liver disease
GDP	Gross domestic product
BS	Bariatric surgery
WTP	Willingness-to-pay
FLD	Fatty liver disease
CC	Compensatory cirrhosis
DC	Decompensated cirrhosis
HCC	Hepatocellular carcinoma
LT	Liver transplantation
CHD	Coronary heart disease
MI	Myocardial infarction
WHO	World health organization
HRQoL	Health-related quality of life
CPI	Consumer price index

OWSA	One-way sensitivity analysis
PSA	Probabilistic sensitivity analysis
CI	Confidence interval
CEAC	Cost-effectiveness acceptable curves

Supplementary Information

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Supplementary Material 1

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Author contributions

QX conceptualized the research idea, constructed a decision tree-Markov model, collected and analyzed data, wrote the first draft, and revised the manuscript. WY contributed to the literature review and data analysis. LL contributed to data collection and data analysis. BL conceptualized the research idea and contributed to manuscript writing and revisions. All the authors read and approved the final manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The study was approved by the Human Research Ethics Committees of Beijing Friendship Hospital Affiliated to Capital Medical University (2019-P1-X-028-05); Beijing Shijitan Hospital Affiliated to Capital Medical University (<2022> Ethics Fast Approved No.<55>); Nanjing Drum Tower Hospital (2020-175-10); Affiliated Hospital of Inner Mongolia Medical University (SY.2020032); Tianjin Medical University General Hospital (IRB2020-039-07); Tang Du Hospital (No. K202210-03) and the First Hospital of China Medical University (2020QL005-2). Written informed consent were obtained from study participants.

Consent for publication

Written informed consent was obtained from every participant for publication of this study. The participant had the right and chance to withdraw the clinical trial at any time. The decision not to participate or to withdraw from the clinical trial did not involve any penalty.

Competing interests

The authors declare no competing interests.

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