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ORIGINAL ARTICLE

Controlled hypotension technology can improve patient recovery in the early postoperative period after total knee arthroplasty: A prospective, randomized controlled clinical study

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Knee osteoarthritis (KOA) is a degenerative disease, and the number of patients with KOA is increasing as the proportion of aging adults increases. Total knee arthroplasty (TKA) is an effective method for the treatment of KOA, and the number of surgical cases is also increasing annually. An electronic inflatable tourniquet is routinely used in TKA to reduce intraoperative bleeding and improve the visual clarity of the surgical field.[1] However, tourniquets have many drawbacks. For example, a tourniquet increases hidden blood loss during the TKA perioperative period, exacerbates postoperative pain,[2] and raises the risk of wound infection[3] and peripheral nerve damage.

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ABSTRACT

Objectives: The study aimed to analyze the application of controlled hypotension and tourniquets in total knee arthroplasty (TKA) to evaluate their early postoperative period effects in TKA.

Patients and methods: A total of 183 patients (43 males, 140 females; mean age: 67.8±6.4 years; range, 50 to 84 years) with knee osteoarthritis who needed TKA were recruited for this prospective, randomized controlled clinical study between August 2022 and May 2023. The study included a tourniquet group (group T, 94 patients) and a controlled hypotension group (group H, 89 patients). In group T, an inflatable tourniquet was used throughout the operation, with the pressure of the tourniquet set at 300 mmHg. In group H, controlled hypotension was used, with the mean arterial pressure controlled at 55-65 mmHg. The outcome measures of this study included blood loss, coagulation function, inflammatory mediators, knee joint function, permeation thickness of bone cement around the tibial prosthesis, and cognitive function.

Results: The baseline demographics and clinical characteristics of the two groups of patients were comparable ($p>0.05$). Intraoperative blood loss in group H was higher than that in group T ($p<0.05$), whereas hemoglobin decrease, postoperative drainage flow, hidden blood loss, and total blood loss in group T were higher than in group H ($p<0.05$). Fibrinogen, D-dimer, C-reactive protein, and interleukin-6 levels were higher in group T than in group H on the first and third postoperative days ($p<0.05$). The knee joint function of group H was significantly better than that of group T on the fifth day and one month after the operation ($p<0.05$). There was no significant difference in the penetration thickness of bone cement around the tibial prosthesis between the two groups ($p>0.05$). There was no significant difference in Mini-Mental State Examination scores between the two groups on the same day ($p>0.05$).

Conclusion: Controlled hypotension technology in TKA can reduce total blood loss by reducing hidden blood loss and can help to alleviate the postoperative hypercoagulable state, relieve inflammatory reactions, and facilitate early recovery of knee joint function after surgery.

Keywords: Controlled hypotension, early rehabilitation, total knee arthroplasty, tourniquet.

Controlled hypotension technology may avoid the disadvantages of tourniquet use in TKA. Controlled hypotension technology refers to use of drugs or anesthesia techniques to reduce the mean arterial blood pressure (MAP) to between 55 and 65 mmHg, the systolic blood pressure to between 80 and 90 mmHg, or the MAP to 70% of the baseline value. Controlled hypotension has advantages, including reducing intraoperative bleeding, ensuring clear surgical visibility, avoiding damage to important nerves and blood vessels, shortening the operation time, and lessening tissue edema; hence, it has been widely used in various clinical operations.[4,5] However, it is seldom used in TKA. Certainly, there are other reasons for the insufficient study of controlled hypotension technology in TKA. One is the convenience of tourniquet, and the other is the safety of controlled hypotension technology. It is undeniable that controlled hypotension will increase the risk of hypoperfusion injury of various organs. The disadvantages and complications include postoperative cognitive dysfunction, ischemic stroke, acute renal injury, myocardial injury, and postoperative hypotension.[6-8] However, many authors believe that in cases of controlled hypotension, sufficient blood and oxygen can be supplied to the organs, and in cases of extreme hypotension caused by excessively low intraoperative blood pressure levels, there is a significant risk of such complications.[9,10] Therefore, to avoid such serious complications, extreme hypotension should be avoided during surgery. Additionally, clinicians and anaesthesiologists must have a clear understanding of the contraindications for controlled hypotension technology. We excluded cases with contraindications for controlled hypotension technology.

The purpose of this study was *(i)* to determine whether controlled hypotension technology can reduce perioperative bleeding in TKA, *(ii)* compare the difference in coagulation function and inflammatory mediators between groups, *(iii)* define whether controlled hypotension technology can contribute to the recovery of knee joint function, *(iv)* measure whether there is a difference in the penetration thickness of bone cement around the tibial prosthesis between the groups, and *(v)* evaluate whether there is a difference in cognitive function between groups.

PATIENTS AND METHODS

This single-center, randomized controlled trial was conducted at the Fuyang Hospital affiliated with Bengbu Medical College between August 2022 and May 2023. Patients who fulfilled the inclusion criteria (Table I) were randomly assigned to one of two groups: group T (the tourniquet group) and group H (the controlled hypotension group). Randomization was undertaken using a computer-generated randomization allocation table produced by a resident physician who was not involved in the recruitment phase.

Overall, 200 patients underwent unilateral TKA due to KOA (group T, n=100; group H, n=100). However, 17 patients were lost during follow-up at one month after the surgery (group T, n=6; group H, n=11). Thus, a total of 183 patients (43 males, 140 females; mean age: 67.8±6.4 years; range, 50 to 84 years) with TKA were included in the study, with 94 patients in group T) and 89 patients in group H. The study flowchart is shown in Figure 1.

Anesthesia and perioperative management

Both groups of patients were anesthetized with general anesthesia by the same group of anesthesiologists. In the operating room, the anaesthesiologist connected the electrocardiogram monitoring and blood oxygen saturation detection devices and performed radial artery puncture to

TABLE I
Eligibility criteria of the study population

Inclusion criteria	Exclusion criteria
Unilateral TKA due to KOA	Contraindications to anesthesia or serious impairment of heart, liver and kidney functions
General anesthesia	Concomitant bleeding disorder, coagulopathy or vein thrombosis of the lower limbs
Willing to participate the study	Concomitant hypovolemia, anaemia, or acute cerebral infarction
	Preoperative blood pressure above 160/100 mmHg
	Concomitant immune connective tissue disease
	Concomitant mental illness or cognitive impairment
	Unwilling to participate the study

TKA: Total knee arthroplasty; KOA: Knee osteoarthritis.

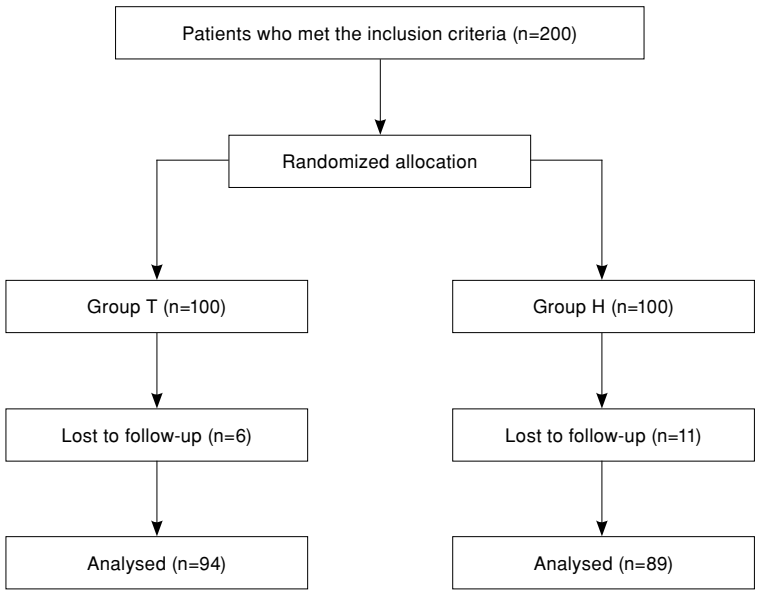

FIGURE 1. Study flowchart.

measure blood pressure. The general anesthesia induction drugs used included intravenous injection of etomidate 0.15-0.2 mg/kg, midazolam 0.05-0.1 mg/kg, rocuronium 0.6 mg/kg, and sufentanil 0.1-0.5 μg/kg. Anesthesia maintenance drugs included intravenous propofol 3-12 mg/(kg·h), remifentanil 6-30 μg/(kg·h), and continuous inhalation of sevoflurane (1-2%). During surgery, the patient's blood pressure was controlled by adjusting the pump speed of propofol and remifentanil, intermittently administering sufentanil, intermittently administering antihypertensive drugs, and using vasoactive substances. In group T, a tourniquet was used throughout the operation; the pressure of the tourniquet was set at 300 mmHg. After the wound was sutured and bandaged, the tourniquet was released. In group H, intraoperative MAP was controlled at 55-65 mmHg, and a tourniquet was not used.

All patients underwent surgery by the same team of surgeons. The patient was placed in the supine position, and the operation was performed in a standard manner using a midline skin incision and a medial patellar approach. The drainage tube was clamped for 4 h, opened for the first time at 4 h after the operation, and removed two days after the operation. All patients underwent the same postoperative fluid replacement, pain relief, anti-inflammatory, anticoagulant, and rehabilitation exercise strategies. We measured the penetration thickness of bone cement at different positions around the tibial prosthesis on the second day after surgery. All patients received thromboembolism prophylaxis with low-molecular-weight heparin and rivaroxaban after surgery. During hospitalization, 4,000 IU of low-molecular-weight heparin was injected subcutaneously every day after surgery. After leaving the hospital, 10 mg of rivaroxaban was orally administered every day until 35 days after surgery.

Data collection

The collected demographic data included age, sex, height, weight, and body mass index. Blood loss data included hemoglobin, intraoperative blood loss, drainage volume, dominant blood loss, total blood loss, and hidden blood loss. Intraoperative blood loss was calculated with the following formula: intraoperative blood loss=weight of bloody gauze-weight of dry gauze + suction volume of aspirator-amount of saline rinse (with a weight of 1 g calculated as 1 mL). Postoperative drainage volume was calculated with the following formula: postoperative drainage volume=postoperative drainage device blood volume + weight of gauze around the wound-weight of dry gauze (1 g weight is calculated as 1 mL). Dominant blood loss was calculated with the following formula: dominant blood loss = intraoperative blood loss+postoperative drainage volume. The Gross equation was used to calculate the patient's total blood volume: total blood volume=K1×Height (m) 3 +K2×weight

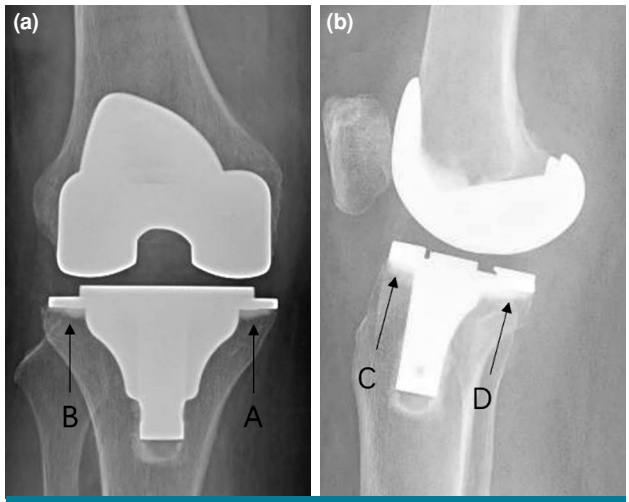

FIGURE 2. Measurement position of the bone cement penetration thickness **(a)** knee joint anteroposterior position; **(b)** knee joint lateral position; point A, midpoint between the medial platform of the tibial prosthesis and the bone surface; point B, midpoint between the outer platform of the tibial prosthesis and the bone surface; point C, midpoint between the anterior platform of the tibial prosthesis and the bone surface; point D, midpoint between the posterior platform of the tibial prosthesis and the bone surface).

(kg)+K3; K1=0.3669, K2=0.03219, and K3=0.6041 for males ; K1=0.3561, K2=0.03308, and K3=0.1833 for females. Total blood loss was calculated with the following formula: total blood loss=total blood volume×(preoperative hematocrit-postoperative smaller hematocrit)/mean hematocrit; mean hematocrit=(preoperative hematocrit+postoperative smaller hematocrit)/2. Hidden blood loss was calculated with the following formula: hidden blood loss=total blood loss-dominant blood loss.

Laboratory data collected included coagulation function and partial inflammatory mediators. Knee joint function data collected included the range of motion of the knee joint and the Hospital for Special Surgery (HSS) knee score. Other relevant data collected included the American Society of Anesthesiologists score, surgical time, number of cases of deep-vein thrombosis (DVT), permeation thickness of bone cement around the tibial prosthesis (the measurement position is shown in Figure 2), and the Mini-Mental State Examination (MMSE).

Statistical analysis

Data were analyzed using IBM SPSS version 25.0 software (IBM Corp., Armonk, NY, USA). Descriptive data are expressed as the mean ± standard deviation (SD), median (interquartile range), or number and frequency, where applicable. Intergroup comparisons were performed using a t-test or one-way analysis of variance for continuous variables and the Pearson chi-square test, Fisher exact test, or the Fisher-Freeman-Halton exact test for categorical variables. A p value of <0.05 was considered statistically significant.

RESULTS

The baseline demographic and clinical characteristics of the patients are shown in Table II. There was no significant difference in these data between the groups ($p>0.05$).

None of the patients in this study received a blood transfusion. There was no significant difference between the two groups in surgical time or dominant

TABLE II
Demographic and clinical characteristics of the study population

	Group T		Group H		
	n	Mean±SD	n	Mean±SD	*p*
Age (year)		68.13±6.34		67.45±6.54	0.477
Sex					0.281
Male	19		24		
Female	75		65		
Height (cm)		159.81±6.78		158.90±7.10	0.376
Weight (kg)		67.38±10.50		68.29±10.02	0.550
BMI (kg/m^2)		26.37±3.74		27.01±3.23	0.218
ASA score					0.704
II	73		67		
III	21		22		

SD: Standard deviation; BMI: Body mass index; ASA: American Society of Anesthesiologists.

TABLE III
Comparison of blood loss

Variables	Group T Mean±SD	Group H Mean±SD	*p*
Hb (g/L, preoperative)	126.99±12.25	127.17±13.15	0.924
Hb (g/L, POD 1)	102.20±14.10	108.21±13.33	0.003
Hb (g/L, POD 3)	91.35±14.02	98.75±13.51	<0.001
Hb decrease value (g/L)	36.52±12.17	28.57±12.62	<0.001
Surgical time (min)	79.90±8.19	81.65±8.36	0.155
Intraoperative bleeding (mL)	59.26±12.72	89.66±17.22	<0.001
Drainage volume (mL)	161.28±39.25	123.60±41.95	<0.001
Dominant blood loss (mL)	220.53±40.66	213.26±44.19	0.248
Hidden blood loss (mL)	645.91±224.00	474.04±194.80	<0.001
Total blood loss (mL)	866.44±222.86	687.30±189.16	<0.001

Hb: Hemoglobin; POD 1: Postoperative Day 1; POD 3: Postoperative Day 3.

blood loss (p>0.05). Intraoperative blood loss in group H was higher than that in group T (p<0.05); hemoglobin decrease, postoperative drainage volume, hidden blood loss, and total blood loss in group T were higher than in group H (p<0.05, Table III).

There was no significant difference in coagulation function between the two groups before the operation (p>0.05), but D-dimer and fibrinogen levels were higher in group T than in group H on the first and third postoperative days (p<0.05). The incidence of postoperative DVT in group T was higher than in group H, but there was no significant difference in the incidence of DVT between the two groups (p>0.05). There was

TABLE IV
Comparison of coagulation function and inflammatory mediators

Variables	Time points	Group T n	Group T Mean±SD	Group H n	Group H Mean±SD	*p*
PT (S)	Preoperative		12.52±0.59		12.50±0.73	0.810
APTT (S)	Preoperative		33.36±2.64		33.16±3.01	0.621
Fibrinogen (g/L)	Preoperative		3.32±0.49		3.28±0.52	0.574
Fibrinogen (g/L)	POD 1		3.56±0.52		3.32±0.48	0.001
Fibrinogen (g/L)	POD 3		3.67±0.51		3.42±0.51	0.001
D-dimer (mg/L)	Preoperative		0.63±0.39		0.62±0.39	0.873
D-dimer (mg/L)	POD 1		4.88±1.88		3.66±1.95	<0.001
D-dimer (mg/L)	POD 3		5.43±1.91		4.06±1.96	<0.001
DVT	Postoperative					0.246
Yes		3	3	0		
No		91	91	89		
CRP (mg/L)	Preoperative		2.39±0.98		2.34±1.08	0.750
CRP (mg/L)	POD 1		57.41±20.79		46.45±20.53	<0.001
CRP (mg/L)	POD 3		100.39±35.76		77.34±23.31	<0.001
IL-6 (pg/mL)	Preoperative		2.47±1.50		2.56±1.67	0.686
IL-6 (pg/mL)	POD 1		125.98±35.34		81.18±29.84	<0.001
IL-6 (pg/mL)	POD 3		82.88±26.51		47.10±20.60	<0.001

SD: Standard deviation; PT: Prothrombin time; APTT: Activated partial thromboplastin time; DVT: Deep venous thrombosis; CRP: C-reactive protein; IL-6: Interleukin-6; POD 1: Postoperative Day 1; POD 3: Postoperative Day 3.

TABLE V
Comparison of range of motion of the knee joint and HSS score

Variables	Time points	Group T Mean±SD	Group H Mean±SD	*p*
ROM (°)	Preoperative	91.90±10.04	92.54±12.47	0.704
ROM (°)	POD 5	94.99±6.28	100.80±7.17	<0.001
ROM (°)	POM 1	105.21±8.02	109.80±7.70	<0.001
HSS score	Preoperative	47.60±8.57	48.58±7.33	0.402
HSS score	POD 5	67.14±5.78	71.02±7.02	<0.001
HSS score	POM 1	81.41±4.73	83.48±4.07	0.002

SD: Standard deviation; ROM: Range of motion of the knee joint; POD 5: Postoperative Day 5; POM 1: Postoperative month 1; HSS: Hospital for Special Surgery.

TABLE VI
Comparison of permeation thickness of bone cement around tibial prosthesis

Variables	Group T Mean±SD	Group H Mean±SD	*p*
Point A (mm)	2.32±0.30	2.32±0.32	0.972
Point B (mm)	2.47±0.35	2.43±0.34	0.404
Point C (mm)	2.17±0.28	2.12±0.27	0.224
Point D (mm)	2.46±0.38	2.43±0.30	0.486

SD: Standard deviation.

TABLE VII
Comparison of cognitive function

Variables	Time points	Group T Mean±SD	Group H Mean±SD	*p*
MMSE score	Preoperative	28.47±1.03	28.38±1.06	0.579
MMSE score	POD 1	28.31±1.10	28.13±1.06	0.278
MMSE score	POD 3	28.32±1.13	28.35±1.09	0.859

SD: Standard deviation; MMSE: Mini-Mental State Examination; POD 1: Postoperative Day 1; POD 3: Postoperative Day 3.

also no significant difference in C-reactive protein (CRP) and interleukin (IL)-6 levels before the operation (p>0.05), but CRP and IL-6 levels were significantly higher in group T than in group H on the first and third days after the operation (p<0.05, Table IV).

There was no significant difference in the knee joint range of motion or HSS score between the two groups before the operation (p>0.05). The knee joint function of group H was significantly better than that of group T on the fifth day and at one month after the operation (p<0.05, Table V).

There was no significant difference in the penetration thickness of bone cement around the tibial prosthesis between the two groups (p>0.05, Table VI).

There was no significant difference in the MMSE scores between the two groups of patients on the same day (p>0.05, Table VII).

DISCUSSION

In the present study, we investigated whether the clinical effects of TKA under controlled hypotension and tourniquet differed. The main finding of the present study is that TKA under controlled hypotension is more conducive to early rehabilitation of knee joint function compared to tourniquet use, as revealed by the blood loss, coagulation function,

inflammatory factors, and knee joint function in the two groups.[11]

There is much blood loss during the TKA perioperative period due to frequent osteotomy. A previous study has suggested that total blood loss can reach 1,470-2,500 mL in TKA, including 900-1,140 mL of hidden blood loss and 570-1,360 mL of dominant blood loss.[12] With improvements in perioperative management and the application of hemostatic drugs, the total amount of perioperative bleeding in TKA has decreased,[13] but it remains higher than 400 to 800 mL. A previous study reported that reducing hidden blood loss can be achieved by reducing the use time of a tourniquet.[14] Our results suggest that using controlled hypotension technology in TKA increases intraoperative bleeding but reduces the postoperative drainage volume, hidden blood loss, and total blood loss. The increase in intraoperative bleeding under controlled hypotension is due to the higher local blood pressure of the affected limb than in the tourniquet group during surgery, which may cause an increase in the operation time, but in our study, there was no difference in operation time between the two groups. The reasons for the higher postoperative drainage volume, hidden blood loss, and total blood loss in group T than in group H may include the following points. First, when using a tourniquet, bleeding points are not easily found, and hemostasis operations, such as electrocautery, are less common. When the surgery is completed, complete release of the tourniquet can cause local blood pressure to recover, leading to joint cavity bleeding and increased drainage volume. Second, long-term use of a tourniquet may cause venous stasis and produce a hypercoagulable state[15] and small thrombi, leading to increased red blood cell consumption. Third, long-term use of a tourniquet also leads to limb ischemia-reperfusion injury,[16] local hypoxia, aggravated inflammatory reaction, increased red blood cell injury, vascular endothelial injury, and increased interstitial bleeding.

Postoperative DVT is a rare complication that may pose serious harm to patients. During the perioperative period of TKA, venous stasis, endothelial injury, and postoperative hypercoagulable state jointly increase the risk of postoperative venous thromboembolism. The present study showed that D-dimer and fibrinogen levels in group T were higher than those in group H on the first and third postoperative days. This may be because using a tourniquet in TKA can lead to ischemia-reperfusion injury, vascular endothelial damage, and venous stasis, which contribute to the formation of small emboli. These factors may increase the incidence of DVT.[17] Hence, replacing tourniquets with hypotension control technology can relieve the postoperative hypercoagulable state. In addition, clinicians can use white blood cell count and CRP[18] and IL-6[19] levels as markers to evaluate surgical stress. Our results indicate lower CRP and IL-6 levels in the controlled hypotension group than in the tourniquet group on the first and third days after surgery. We believe that the replacement of a tourniquet with controlled hypotension can relieve inflammatory reactions, which may be related to ischemia-reperfusion injury caused by a tourniquet.

Regarding knee joint function, we believe that using controlled hypotension technology is beneficial for early functional recovery in TKA patients. This may be because of the following. First, a low incidence of venous thrombosis is beneficial for patients' rehabilitation exercise, as the first treatment to consider after venous thrombosis is thrombolysis rather than exercise to avoid causing embolism in other parts of the body. Second, controlled hypotension technology can alleviate inflammatory reactions. It is generally believed that the presence of fewer inflammatory factors results in reduced pain, which is conducive to rehabilitation.[20] Third, long-term use of a tourniquet will cause atrophy of the quadriceps femoris muscle,[21] which is not conducive to the recovery of muscle strength and affects the recovery of knee joint function.[22] Our results are similar to those of a randomized controlled experiment conducted by Wang et al.,[23] who shortened the duration of tourniquet use to enable patients to achieve good and early recovery. Moreover, less total blood loss under controlled hypotension is also conducive to the recovery of patients' overall function, which conforms to the concept of rapid recovery.

In addition, bone cement penetration thickness and cement-bone interface strength are critical for successful primary TKA, and aseptic loosening of knee joint prostheses generally occurs on the tibial side; thus, the penetration thickness of bone cement around the tibial side of the prosthesis can be an effective method for predicting the survival rate of the prosthesis.[24] Overall, increasing the penetration thickness of bone cement can help increase the stability of the prosthesis. There is controversy about whether a tourniquet has an impact on the infiltration thickness of bone cement around the prosthesis,[25,26] and not using a tourniquet may affect

the fixation strength of the joint prosthesis due to high intraoperative bleeding.[27] Nevertheless, we emphasize that TKA under controlled hypotension will not affect the penetration thickness, even without the use of a tourniquet.

Furthermore, the complication of controlled hypotension is caused by extreme hypotension during anesthesia and surgery. Wang et al.[28] evaluated the intraoperative blood loss and postoperative hypotension in TKA patients and concluded that controlling the systolic blood pressure between 90 and 100 mmHg is the most ideal approach, which can effectively reduce perioperative blood loss without increasing the incidence of postoperative hypotension. Walsh et al.[7] believes that the risks of acute renal injury and myocardial injury increase significantly when the MAP is below 55 mmHg for a long time under anesthesia. It is obvious that due to consideration for patient safety, our patients' intraoperative MAP was higher than 55 mmHg. None of the patients in this study experienced severe complications during the perioperative period. Postoperative cognitive dysfunction is a postoperative disorder that affects a patient's directional function, attention, judgment ability, and execution ability. Since cerebral blood flow remains unchanged in cerebral blood vessels despite changes in perfusion pressure (MAP 50-150 mmHg), many studies suggest that intraoperative blood pressure control at lower levels is not significantly correlated with the occurrence of postoperative cognitive dysfunction.[29,30] For example, Zhang et al.[31] used controlled hypotension techniques in functional endoscopic sinus surgery and concluded that there was no significant difference in cognitive function scores between the hypotensive group and the nonhypotensive group. Zhao et al.[6] grouped different blood pressure levels during TKA surgery and believed that different intraoperative blood pressure levels did not cause significant differences in postoperative cognitive function. The results of these studies are similar to ours.

There are some limitations to this study. This was a single-center study with a small number of cases, and multicenter studies or more cases are needed to validate our conclusions. Another limitation of this study is its short follow-up and lack of long-term follow-up.

In conclusion, our study results suggest that controlled hypotension technology in TKA can decrease total blood loss by reducing hidden blood loss and help alleviate the postoperative hypercoagulable state, relieve inflammatory reactions, and facilitate early recovery of knee joint function after surgery.

Ethics Committee Approval: The study protocol was approved by the Fuyang People's Hospital Medical Ethics Committee (date: 18.01.2022, no: 2022-8). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Idea/concept, control/supervision, critical review, design, references: H.W., Y.D.; Data collection and/or processing, literature review, writing the article: X.L., J.L.; Analysis and/or interpretation: X.L., J.L., H.W., Y.D.

Conflict of Interest: The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

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