Shengxue Busui Decoction Combined with Low Molecular Weight Heparin for Preventing Deep Vein Thrombosis After Knee Arthroplasty

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Abstract: *Objective:* To investigate the effectiveness of Shengxue Busui Decoction combined with low molecular weight heparin (LMWH) in preventing deep vein thrombosis (DVT) after knee arthroplasty (KA) in elderly patients. *Materials and Methods:* Patients aged over 60 years who underwent KA at Xuanwu Hospital between October 2020 and June 2022 were prospectively enrolled. Participants were randomly assigned to an observation group or a control group. The control group received LMWH alone for postoperative DVT prophylaxis, while the observation group received Shengxue Busui Decoction in combination with LMWH. Routine coagulation parameters, plasma D-dimer levels, and thromboelastography (TEG) were assessed one day before surgery and three days after surgery. The occurrence of DVT was evaluated using lower limb venous ultrasound at 3 days, 1 week, and 1 month postoperatively. Pain intensity was assessed using the visual analogue scale (VAS), and knee function was evaluated using the Hospital for Special Surgery (HSS) score before surgery and at 1 week and 1 month after surgery. Bleeding events were recorded during the first postoperative month. *Results:* A total of 130 patients completed the study, with 65 patients in each group. There was no significant difference in baseline characteristics between the two groups. One week after surgery, the incidence of DVT was significantly lower in the observation group than in the control group (10.8% vs. 24.6%, $P < 0.05$). The observation group also showed a significantly lower incidence of bleeding events within one month postoperatively compared with the control group (10.8% vs. 29.2%, $P < 0.05$). Coagulation tests and TEG parameters indicated a relatively hypocoagulable state in the observation group compared with the control group three days after surgery. *Conclusions:* Shengxue Busui Decoction combined with LMWH is effective in reducing the incidence of postoperative DVT and bleeding events after KA, and may improve postoperative coagulation status.

Keywords: Knee Arthroplasty; Deep Vein Thrombosis of Lower Extremity; Shengxue Busui Decoction; Thrombelastogram

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1 Introduction

Knee Arthroplasty (KA) is a common treatment for end-stage knee osteoarthritis [1]. The procedure involves removing bones and cartilage that have been obviously diseased and implants artificial biological materials to replace the surface of the knee joint, so as to relieve pain, correct deformity, and improve the function of the knee joint. It is a highly effective treatment for end-stage arthritis and is widely recognized by orthopedic surgeons both domestically and internationally. More than 600,000 knee joint replacement operations are performed globally every year. The 10-year survival rate of prosthesis is 90%-95% [2]. However, it cannot be ignored that most patients with severe knee osteoarthritis are elderly patients, and the risk of complications for elderly patients increases with age after knee replacement, such as deep venous thrombosis (DVT) is a common and serious complication after KA surgery, which can lead to lower limb swelling in minor cases and affect patients' postoperative recovery and functional recovery. In severe cases, the thrombus may dislodge and travel to the pulmonary artery, causing a pulmonary embolism, which can be life-threatening and is a major factor impeding patient recovery after KA [3]. Studies have shown [4] that the incidence of DVT after KA exceeds 40%, which not only increases the duration of postoperative anticoagulant drug use, increases additional medical costs, but also increases the psychological burden of patients. At present, on the basis of physical prevention, subcutaneous injection of low molecular weight heparin (LMWH) and oral rivaroxaban are used to prevent DVT after KA in China, which can effectively reduce the occurrence of DVT, especially the occurrence of pulmonary embolism. However, these measures can not completely avoid the formation of DVT, and also increase the risk of gastrointestinal bleeding and subcutaneous ectasia. Studies have shown [5, 6] that the application of LMWH and rivaroxaban can increase the occurrence of bleeding and wound complications, and the incidence of wound ecchymosis is as high as 23%, which is considered to be the cause of local infection [7]. Currently, there is no standardized management for bleeding complications following anticoagulation; therefore, further research on DVT prevention after KA is warranted.

In recent years, more and more studies in China have begun to pay attention to the role of Traditional Chinese medicine (TCM) in the prevention and treatment of DVT. TCM has certain advantages over LMWH and oral anticoagulants in the prevention and treatment of DVT. The deficiency of kidney essence in elderly patients, combined with the trauma caused by KA surgery, intraoperative and postoperative bleeding, forming the syndrome of kidney deficiency and blood stasis, may be one of the reasons for the high incidence of thrombosis. The treatment of blood stasis in TCM is based on tonifying kidney and strengthening bone, and promoting blood circulation to remove blood stasis is the standard, so as to improve blood microcirculation [8]. The pathological mechanism of DVT after KA is mostly kidney deficiency and blood stasis. Shengxuebusui decoction has the effect of tonifying kidney and activating blood, which can improve local blood microcirculation to achieve the purpose of dredging collaterals and relieving pain. It plays an important role in preventing the formation of DVT and functional rehabilitation after KA.

The detection of coagulation function is helpful to guide the postoperative medication of patients with KA. At present, the commonly used coagulation and thrombosis detection indicators are four items of coagulation and plasma D-Dimer (D-D), including Activated partial thrombin time (APTT), Prothrombin time (PT), thrombin time (TT), Fibrinogen (FIB), and D-D. However, the four coagulation tests and other indicators are detected by serum samples, and there is no blood cells involved in the coagulation process, which can only reflect a certain process in the coagulation process, and the reliability of coagulation information is poor. In contrast, thrombelastogram (TEG) is a method to detect blood viscosity in vitro first proposed by Hartert in 1948 [9]. The whole process from coagulation to thrombolysis of whole blood is simulated in vitro, and the collected electronic signals converted from kinetic energy are drawn into dynamic curve images by image sensors. Due to the limitation of technology, it has been used in the detection of clinical coagulation function in recent years, which can effectively reflect the function of platelets and coagulation factors. The main parameters of TEG included coagulation reaction time (R), clot formation time (K), coagulation Angle (α), and maximum amplitude (MA). Among them, R reflects the activity of coagulation factor, and R is negatively correlated with the activity of coagulation factor. The smaller the value of R, the stronger the activity of coagulation factor. K value and α Angle reflect fibrinogen function, K value is negatively correlated with fibrinogen function, α is positively correlated with fibrino-

gen function, the smaller the K value is, the larger the α is, the stronger the fibrinogen function is. MA reflects platelet function and is positively correlated with platelet function. The greater the value of MA, the stronger the platelet function.

In this study, Shengxuebusui decoction combined with LMWH was used in the prevention of complications after KA in elderly patients, and the effects on the occurrence of lower extremity venous thrombosis, coagulation function, postoperative pain (VAS) and knee joint function improvement (HSS) were explored.

2 Clinical Data

2.1 Source of Cases

KA patients admitted to the Department of Orthopedics of our hospital from October 2020 to June 2022 were selected and divided into observation group and control group according to the random number table method.

2.2 Inclusion Criteria

(1) 60 ≤ age ≤80 years old;
(2) severe knee osteoarthritis;
(3) severe or severe pain and functional limitation;
(4) in accordance with the indications for KA;
(5) conforming to the syndrome differentiation standard of kidney deficiency and blood stasis syndrome of TCM;
(6) willing to accept surgical treatment.

2.3 Exclusion Criteria

(1) patients with abnormal coagulation function or severe liver and kidney function damage;
(2) Lower extremity venous thrombosis detected by preoperative ultrasound;
(3) history of malignant tumor.
(4) The subjects asked to withdraw or had poor compliance;
(5) The subjects had serious adverse reactions during the treatment and needed to receive additional measures.

2.4 Ethical Review Requirements

This study was reviewed by the Ethics committee of Xuanwu Hospital, Capital Medical University, and the protocol was approved. Patients were informed of the purpose, nature, potential risks and benefits of the study before surgery, and informed consent was obtained from the patients.

2.5 Grouping Method

(1) The patients who met the inclusion criteria and agreed to participate in the study were numbered according to the order of admission, that is, 0-136.
(2) The Excel function RANDBETWEEN (1,136) was used to generate 68 random numbers assigned to the observation group (with replacement if duplicates occurred).
(3) The remaining 68 numbers in the observation group were removed and automatically included in the control group.

3 Research Methods

3.1 Preoperative Preparation

The surgical risk was evaluated by routine blood test, biochemical test, four coagulation tests, plasma D-Dimer, Thrombelastogram, deep venous ultrasound of lower limbs, X-ray of both lower limbs, and cardiopulmonary function test. The purpose and methods of the study were explained to the patients, and the precautions, possible complications and risks were explained to the patients. If discomfort occurred during the treatment, the doctor should be informed in time.

3.2 Thromboelastography

The probe and the reagent cup are the two main components of the thromboelastography (TEG) detector. After the assay was started, the reagent cup was rotated at a certain Angle. At the beginning, because the blood sample is liquid, the effect of the rotation of the reagent cup on the probe is negligible. With the activation of coagulation factors, the aggregation of platelets, the conversion of fibrinogen to fibrin, and the formation of blood clots on the probe, when the blood clots reach a certain strength, the probe is affected by the rotation of the reagent cup and rotates with the cup. When the blood clot reaches a certain intensity, the fibrinolytic system is activated, the fibrin is gradually dissolved, the blood clot gradually disappears, and its driving force on the probe is gradually weakened until it stops. The electronic system collects the kinetic

energy generated during the rotation of the probe to stop, analyzes and processes it, and finally forms the thrombelastogram such as Figure 1.

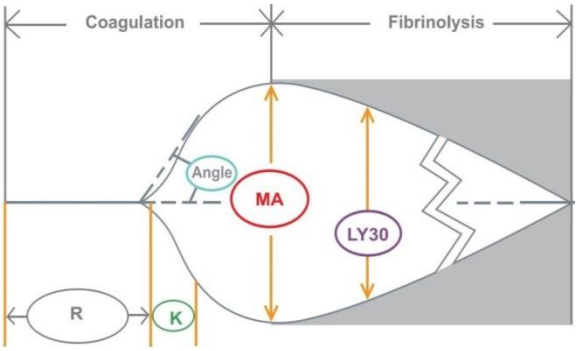

Figure 1 Thromboelastography and the meanings of various indicators in the graph. R: reaction time; K: kinetics time; Angle: kinetics of clot development; MA: maximum amplitude, maximum strength of clot; LY30: percent lysis 30min after MA

3.3 Treatment Methods and Interventions

KA was performed by the same group of orthopedic surgeons. After 24 hours of postoperative antibiotic prophylaxis, ankle pump training, active lower limb muscle strength exercise, lower limb ice compress were started after anesthesia disappeared, and the first day after operation, the patients began to get out of bed with the assistance of walking AIDS. Subcutaneous injections of LMWH were started 12 hours after surgery and continued for 14 days at a dose of 0.4ml/ day. In the observation group, Shengxuebusui decoction was added on the first day after operation, including: Shengdi 15g, dipsacus 15g, Eucommia 12g, Chuanxiong 12g, safflower 12g, Niuxi 9g, Angelica 12g, Radix paeoniae 12g, Danpi 6g. On the day of surgery, Chinese medicine prescriptions were prepared by the TCM preparation room, vacuum packed 100ml/ bag, and taken warm one bag in the morning and evening for 14 days.

3.4 Postoperative Detection Indicators

On the 3rd day after operation, fasting venous blood was collected for routine blood test, four tests of blood coagulation, plasma D-dimer and TEG test. On the 3rd day, 14th day and 1 month after operation, deep venous ultrasound examination of the lower extremities was performed to evaluate the occurrence of DVT.

3.5 Observation Indicators

3.5.1 Parameters of TEG

R value, K value, α Angle, MA value, CI. R represents the time from coagulation factor activation to the time when blood clot intensity reaches 2mm and is related to the function of coagulation factors. The K value is the time for clot strength to go from 2mm to 20mm, and the α Angle is the elastograph cut Angle at a clot strength of 20mm, which together reflect the rate of fibrin cross-linking and are highly correlated with fibrinogen function. MA records the maximum amplitude of the curve, which is related to platelet concentration, function, and strength of interaction between platelets and fibrin, and mainly reflects platelet function. CI is a coagulation parameter calculated based on R, K, α and MA (CI= -0.6516R-0.3772K+0.1224MA+0.0759α-7.7922), and the normal value is -3 to +3, which describes the overall coagulation function of patients [10].

3.5.2 Four Coagulation Tests and Plasma D-dimer Values

APTT, PT, TT, FIB, D-D.

3.5.3 Blood Loss

The Nadler formula was used to calculate the total blood loss: blood volume =k1* height (m)+ K2*body weight (kg) +k3, k1=0.3669, k2=0.03219, k3=0.6041 for males; k1=0.3561, k2=0.03308 and k3=0.1833 in females [11]. Total blood loss = patient's blood volume *(preoperative HCt-postoperative HCT) + transfusion volume.

3.5.4 Pain and Improvement of Knee Joint Function

VAS score and HSS score of knee joint function were used to evaluate the patients before operation and at 1 week and 1 month after operation.

3.5.5 Occurrence of DVT

deep venous ultrasound examination of the lower extremities was performed 3 days, 1 week and 1 month after KA to evaluate whether the patient had DVT after operation.

3.5.6 Comparison of Bleeding Complications

the occurrence of bleeding complications such as he-

matemesis, positive fecal occult blood and skin ecchymosis within 1 month after operation was observed.

3.6 Statistical Methods

The measurement data were expressed as mean ± standard deviation. The TEG parameters, coagulation indexes, and HSS scores were compared between groups by independent sample t test, and within the group by paired sample t test. The rank sum test was used to compare the pain scores between groups, and the X2 test was used to compare the incidence of DVT and bleeding complications between groups. $P < 0.05$ was considered statistically significant.

4 Results

4.1 Baseline Data

A total of 136 patients were included, of which 6 patients were lost to follow-up, and 130 patients had complete data, 65 in the observation group and 65 in the control group. General preoperative data are shown in Table 1. There were no significant differences in gender, age, height, weight, intraoperative blood loss, hypertension, diabetes, and coronary heart disease between the two groups ($P> 0.05$).

Table 1 Demographic Characteristics of the Observation and Control Groups (Mean ±SD)

	Observation	Control	P
Age	70.18 ±7.16	68.74 ±7.80	0.273
F/M	10/55	12/53	0.640
height	159.98 ±7.29	159.72 ±7.10	0.836
weight	73.78 ±12.75	73.14 ±10.52	0.756
bleeding	137.98 ±79.09	133.56 ±91.40	0.769
hypertension	46	40	0.266
diabetes	17	16	0.84
heart disease	7	5	0.545
TKA	26	26	-
UKA	39	39	-

4.2 Comparison of Postoperative Coagulation Parameters Between Groups

There was no significant difference in coagulation function between the two groups before operation. Three days after operation, APTT, PT and TT in the observation group were longer than those in the control group, and FIB was lower than that in the control group, and the differences were statistically significant (Table 2). Plasma D-dimer levels showed no significant difference between groups. These results suggest that the observation group was in a relatively hypocoagulable state compared to the control group. For intra-group comparison, in the observation group, APTT, PT, TT and D-D were higher than those before operation, and FIB was lower than that before operation, indicating that the observation group was in a relatively hypocoagulable state 3 days after operation. In the control group, D-D was higher than that before operation, APTT and TT were lower than those before operation, and PT and FIB were not statistically different from those before operation (Table 2), indicating that the observation group was in a relatively hypercoagulable state 3 days after operation compared with that before operation. Among the TKA patients, there was no significant difference in preoperative coagulation function between the control group and the observation group. At 3 days after operation, APTT, PT, and TT in the observation group were longer than those in the control group, FIB was smaller than that in the control group, and there was no significant difference in D-D (Table 3), indicating that the TKA patients in the observation group were in a hypocoagulation state compared with the control group. Among the UKA patients, there was no statistically significant difference in preoperative coagulation function between the control group and the observation group. At 3 days after surgery, APTT, PT, and TT in the observation group were higher than those in the control group, FIB was lower than that in the control group, and there was no statistically significant difference in D-D (Table 4), indicating that the UKA patients in the observation group were in a hypocoagulation state compared with the control group.

Table 2 Comparison of routine Coagulation Parameters between Observation Group and Control Group (* indicates P<0.05 compared with preoperative value).

group	D-D		APTT		PT		TT		FIB	
	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation
observation	0.84 ±1.81	2.97 ±2.97*	35.16 ±3.32	36.55 ±3.30*	12.80 ±0.72	13.54 ±0.84*	16.31 ±1.10	16.64 ±0.98*	3.63 ±0.73	3.30 ±0.56*
control	0.86 ±1.78	3.01 ±2.59*	35.57 ±3.81	34.72 ±2.98*	12.85 ±0.61	12.74 ±0.67	16.63 ±0.84	15.92 ±0.88*	3.58 ±0.79	3.74 ±0.88
P	0.949	0.943	0.507	0.001	0.685	0.000	0.062	0.000	0.694	0.001

Table 3 Comparison of routine coagulation Indexes between Observation group and Control Group undergoing TKA (* indicates P<0.05 compared with preoperative).

group	D-D		APTT		PT		TT		FIB	
	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation
observation	0.84 ±1.19	3.40 ±2.84*	34.84 ±2.70	36.07 ±3.51*	12.73 ±0.53	13.63 ±0.62*	16.28 ±0.75	16.53 ±0.76*	3.67 ±0.80	3.32 ±0.50*
control	0.89 ±1.69	2.92 ±1.72*	35.19 ±2.52	34.19 ±2.29*	12.84 ±0.61	12.69 ±0.69	16.54 ±0.76	15.75 ±0.84*	3.55 ±0.73	3.71 ±0.85
P	0.911	0.469	0.635	0.027	0.487	0.000	0.224	0.001	0.656	0.048

Table 4 Comparison of conventional coagulation parameters between the observation group and the control group in Patients undergoing UKA (* indicates P<0.05 compared with preoperative values).

group	D-D		APTT		PT		TT		FIB	
	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation
observation	0.84 ±2.14	2.69 ±3.06*	35.37 ±3.69	36.70 ±3.47*	12.84 ±0.82	13.49 ±0.92*	16.33 ±1.30	16.61 ±1.12*	3.61 ±0.69	3.29 ±0.20*
control	0.84 ±1.86	3.07 ±3.06*	35.8 3 ±4.49	35.08 ±3.35*	12.86 ±0.62	12.77 ±0.66	16.70 ±0.90	16.03 ±0.91*	3.60 ±0.84	3.75 ±0.91
P	0.994	0.590	0.619	0.039	0.975	0.000	0.148	0.015	0.973	0.009

4.3 Comparison of Postoperative TEG Indexes Between the Two Groups

There was no significant difference in R, K, α, MA and CI between the two groups before operation. At 3 days after operation, the R and K values of the observation group were higher than those of the control group, and the α Angle, MA and CI values were lower than those of the control group (P<0.05) (Table 5), indicating that the observation group was in a relatively hypocoagulable state compared with the control group. For intra-group comparison, in the observation group, R and K were longer than those before operation, and α Angle, MA value and CI value were lower than those before operation, indicating that the observation group was in a hypocoagulation state 3 days after operation. In the control group, K was smaller than that before surgery, MA was larger than that before surgery, and R and α angles were not statistically different from those before surgery (Table 5), indicating that the control group was in a hypercoagulable state 3 days after surgery compared with that before surgery. Among the TKA patients, there were no significant differences in R, K, α, MA and CI between the control group and the observation group before operation. At 3 days after operation, the R and K values of the observation group were longer than those of the control group, and the α Angle, MA and CI values were smaller than those of the control group (Table 6), indicating that the TKA patients in the observation group were in a relatively hypocoagulable state compared with the control group at 3 days after operation. Among the UKA patients, there was no significant difference in preoperative TEG indexes between the control group and the observation group. At 3 days after surgery, the R value and K value of the observation group were higher than those of the control group, and the α Angle and MA value were lower than those of the control group (Table 7), indicating that the UKA patients in the observation group were in a relatively hypocoagulation state compared with the control group at 3 days after surgery.

Table 5 Comparison of Thrombelastograms between the Observation Group and the Control Group (* indicates P<0.05 compared with pre-operative value)

group	R		K		α		MA		CI		ΔCI
	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation	
observation	6.39 ±1.29	6.87 ±1.10*	1.61 ±0.39	1.80 ±0.40*	61.39 ±9.80	58.61 ±11.40*	61.47 ±5.43	59.38 ±5.48*	-0.38 ±1.59	-1.21 ±1.81*	-0.83 ±1.41
control	6.31 ±1.44	6.07 ±1.04	1.60 ±0.44	1.39 ±0.34*	62.40 ±8.99	64.71 ±7.55	59.57 ±7.90	65.39 ±5.42*	-0.48 ±1.97	0.64 ±1.37*	1.12 ± 1.67
P	0.744	0.000	0.832	0.000	0.543	0.000	0.113	0.000	0.753	0.000	0.000

Table 6 Comparison of TEG in Patients Undergoing TKA between Observation Group and Control Group (* indicates P<0.05 compared with preoperative value).

group	R		K		α		MA		CI		ΔCI
	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation	
observation	6.08 ±1.19	6.55 ±1.11*	1.53 ±0.36	1.73 ±0.34*	61.83 ±10.08	58.29 ±12.35*	61.59 ±5.29	59.11 ±5.78*	-0.10 ±1.67	-0.05 ±1.10*	-0.96 ±1.49
control	6.11 ±1.12	5.87 ±0.80	1.60 ±0.46	1.27 ±0.33*	63.44 ±8.52	64.36 ±8.58	58.83 ±8.31	66.04 ±4.83*	-0.36 ±1.99	0.87 ±1.29*	1.23 ± 1.73
P	0.924	0.016	0.505	0.000	0.537	0.045	0.161	0.000	0.606	0.000	0.000

Table 7 Comparison of TEG between the observation group and the Control group in Patients undergoing UKA (* indicates P<0.05 compared with preoperative value).

group	R		K		α		MA		CI		ΔCI
	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation	Pre-operation	Post-operation	
observation	6.59 ±1.32	7.04 ±1.04*	1.67 ±0.39	1.84 ±0.43*	61.10 ±9.73	58.83 ±10.88*	61.40 ±5.59	69.57 ±5.33*	-0.57 ±1.53	-1.32 ±1.69*	-0.75 ±1.36
control	6.44 ±1.62	6.20 ±1.16	1.59 ±0.43	1.47 ±0.33*	61.70 ±9.33	64.94 ±6.88*	60.07 ±7.69	64.96 ±5.81*	-0.55 ±1.97	0.49 ±1.42*	1.05 ± 1.64
P	0.653	0.001	0.413	0.000	0.781	0.004	0.387	0.000	0.978	0.000	0.000

4.4 Comparison of Pain and Knee Joint Function Improvement Between the Two Groups

There was no significant difference in VAS score and HSS score of knee function between the two groups before operation, 1 week and 1 month after operation (Table 8). Among TKA patients, there was no significant difference in VAS score and HSS score of knee joint function between the observation group and the control group before operation and at 1 week after operation. At 1 month after operation, the VAS score of the observation group was lower than that of the control group (Table 9). Among the UKA patients, there was no significant difference in VAS score and HSS score of knee joint function between the observation group and the control group before surgery and at 1 week and 1 month after surgery (Table 10).

Table 8 Comparison of VAS score and HSS score between observation group and control group

Group	VAS			HSS		
	Pre-operation	1 week after operation	1 month after operation	Pre-operation	1 week after operation	1 month after operation
Observation	6 (6,7)	2 (2,3)	0 (0,1)	45.08±7.40	75.89±4.10	89.12±3.09
Control	6 (5,6)	2 (2,3)	1 (0,1)	45.69±4.91	76.42±4.22	88.63±3.34
P	0.192	0.122	0.198	0.578	0.474	0.385

Table 9 Comparison of VAS score and HSS score between observation group and control group undergoing TKA

Group	VAS			HSS		
	Pre-operation	1 week after operation	1 month after operation	Pre-operation	1 week after operation	1 month after operation
Observation	6 (6,7)	2 (2,3)	0 (0,1)	44.77±5.76	75.54±3.77	88.77±3.09
Control	6 (6,6)	2 (2,3)	1 (1,1)	46.65±4.43	75.77±4.07	88.27±3.79
P	0.054	0.336	0.011	0.192	0.833	0.604

Table 10 Comparison of VAS scores and HSS scores between the observation group and the control group undergoing UKA

Group	VAS			HSS		
	Pre-operation	1 week after operation	1 month after operation	Pre-operation	1 week after operation	1 month after operation
Observation	6 (5,7)	2 (2,3)	0 (0,1)	45.28±8.39	76.13±4.34	89.36±3.10
Control	5 (5,6)	2 (2,3)	1 (0,1)	45.05±5.17	76.85±4.31	88.87±3.04
P	0.063	0.241	0.185	0.363	0.465	0.485

4.5 The Incidence of Postoperative DVT Was Compared Between the Two Groups

There was no significant difference in the incidence of DVT between the two groups at 3 days and 1 month after surgery. One week after operation, the incidence of DVT in the observation group was 10.8%, and that in the control group was 24.6%. The difference was statistically significant (Table 11), indicating that Shengxuebusui decoction can reduce the incidence of DVT after joint replacement.

Table 11 Incidence of Postoperative DVT in the Observation and Control Groups

	Observation Group	Control Group	P
3 days after surgery	15 (23.1%)	20 (30.8%)	0.323
1 week after surgery	7 (10.8%)	16 (24.6%)	0.039
1 month after surgery	1 (1.6%)	2 (3.1%)	0.559

4.6 Comparison of Bleeding Events Between the Two Groups

In the observation group, the incidence of subcutaneous ecchymosis was 9.2%, and the overall incidence of bleeding events within 1 month postoperatively was 10.8%, which were lower than those in the control group ($P<0.05$) (Table 12), indicating that Shengxuebusui decoction could reduce the occurrence of bleeding events after KA.

Table 12 Incidence of Bleeding Events after Surgery in the Observation Group and the Control Group

	Observation Group	Control Group	P
haematemesis	0	0	-
tarry stool	1 (1.6%)	4 (6.2%)	0.171
ecchymosis	6 (9.2%)	15 (23.1%)	0.032
total	7 (10.8%)	19 (29.2%)	0.009

5 Discussion

KA is an important method for the stepwise treatment of knee osteoarthritis, which can effectively reduce pain, improve knee function, and improve the quality of life of patients [1]. With the development of medical technology, many studies have reported the long-term survival rate of prosthesis and high patient satisfaction after KA [12, 13]. However, there are still a series of complications after KA, such as DVT, infection, prosthesis loosening and periprosthetic fracture, among which DVT is a common complication after KA [3]. It has been reported in literature that despite the routine use of LMWH prevention, about 30% of patients are still accompanied by different degrees of lower extremity venous thrombosis after surgery [4]. The vascular intima is damaged, the blood return

is slowed, and the blood hypercoagulable state is the three elements of thrombosis. Intraoperative pulling, separation and other operations often lead to damage to the intima of blood vessels, release coagulation factors, and start the coagulation process. In addition, postoperative bed rest, reduced lower limb activity, and loss of muscle pump function slow down the venous blood return of lower limbs. The hypercoagulable state of blood is the cause of high incidence of DVT after KA in elderly patients with knee joints. DVT of the lower extremities can lead to limb swelling, increased inflammatory response, and affect functional recovery. The most serious is pulmonary embolism caused by embolus detachment, which is life-threatening. The drug treatment of lower extremity DVT requires doubling of LMWH, which significantly increases the risk of bleeding. The most common complications are tissue intravasation and sungestion, gastrointestinal bleeding, and even anemia. Therefore, effective prevention of lower extremity DVT after KA is very important.

In TCM, lower extremity DVT falls under categories such as "swelling of the thigh," "Bi syndrome," and "blood stasis." In the concept of TCM, "if the limb is damaged on the outside, the qi and blood are injured on the inside". In addition, the elderly kidney essence deficiency, zangfu function is low, during the perioperative period, the degree of tolerance is reduced, "the qi deficiency, will not reach the blood vessels, blood vessels without qi, will stay and stasis", the elderly kidney deficiency, qi deficiency, Yin and Yang deficiency, easy to form venous thrombosis. Therefore, after KA in the elderly, deep vein thrombosis may form due to kidney deficiency and blood stasis.

Shengxue-busui Decoction comes from the third volume of the Compendium of Traumatic Diseases. It is mainly used for nourishing pulp by nourishing blood. After luxation, qi and blood deficiency, liver and kidney insufficiency are found. It was consistent with the symptoms of kidney deficiency and blood stasis in elderly patients undergoing knee replacement. It is pointed out in Classic Chinese Materia Medica that Chuanxiong herb pair can be used to treat diseases of blood stasis type. Some studies have shown that Chuanxiong herb pair can promote blood circulation, inhibit inflammation repair, relieve pain and enhance the immune system through a variety of signaling pathways [14]. It is recorded in Shennong Bencao Jing (Shennong's Classic of Materia Medica) that Diopecia ulmoides has the effect of strengthening and strengthening muscles and bones, and some cellular and molecular experimental studies have proved that diopecia ulmoides has a good synergistic effect in the treatment of osteoporosis [15]. Dipsacus can promote bone formation related bone metabolic process in osteoblasts to achieve the effect of treating osteoporosis. Carthamus tinctorius is a TCM for promoting blood circulation and removing blood stasis. It is often used to treat cardiovascular and cerebrovascular diseases in clinic. The latest research shows that safflower is rich in antioxidant active ingredients, including flavonoids, polysaccharides and alkaloids, which can promote blood circulation and remove blood stasis by anti-oxidant enzymes, scavenging free radicals and antagonizing the mechanism of nitric oxide [16]. The functions of Chuanniuxi include removing blood stasis and clearing meridians, promoting joint function, diuresis and diuresis. It is often used in the treatment of falls and injuries, rheumatic arthralgia, muscular spasm, hematuria and blood and other diseases. Modern medical studies have shown that the main chemical components of Chuanniuxi are steroids, triterpene saponins and polysaccharides, which can effectively enhance the deformability of red blood cells, inhibit platelet aggregation, and promote wound healing [17]. It is recorded in the Benjing that Paeony regulates evil qi and abdominal pain, removes blood obstruction, shatts accumulation, treats cold and heat hernia conglomeration, relieves pain, promotes urination, and benefits qi. It has been widely used in clinical research in traditional Chinese and western medicine. According to the analysis of modern pharmacological research, the main active ingredients in paeony are total glucosides of paeony, which have a variety of effects such as anti-inflammation, immune regulation and cardiovascular protection [18]. In this study, the Shengxuebusui decoction in Shangke Buyao was used, in which the original tonifying kidney was filled with essence, and the disyllabic tonifying kidney and strengthening bone was the key. Eucommia ulmoides tonifying kidney and relaxing sinew, Chuanxiong, safflower and Chuanniuxi promoting blood circulation, Angelica sinensis and Baishao peony nourishing blood and activating blood circulation, soft sinew and promoting blood circulation are the main drugs, Shaozuo Danpi cooling blood circulation, so that the tonic is not stagnating. The whole prescription nourishing blood and activating blood, tonifying kidney and strengthening bone. It can effectively improve the internal environment of the body, reduce the possibility of thrombosis, achieve the effect of early rehabilitation, and improve the quality

of life of patients.

At present, coagulation status is mainly monitored by four coagulation tests and plasma D-dimer. These coagulation detection methods are detected by serum samples without blood cells, so the detection accuracy of coagulation status is low, and some coagulation abnormalities cannot be timely and effectively reflected. To a large extent, TEG has solved the shortcomings of traditional coagulation detection indicators. TEG uses whole blood as a test sample, which can record the process of blood coagulation from the beginning to the complete dissolution of blood clots. By simulating coagulation in vitro, TEG can intuitively and dynamically reflect the whole process of coagulation and fibrinolysis, including the activation of coagulation factors, the conversion of fibrinogen to fibrin and cross-linking into fibrin to form a network, the interaction between reticular fibrin and platelets, the activation of fibrinolytic system, and the dissolution of thrombus. TEG comprehensively evaluates platelet function, coagulation factors, fibrinogen function and fibrinolysis [19], which can accurately, rapidly and comprehensively reflect the coagulation state of the body, and provide correct medication guidance for anticoagulant and hemostatic therapy [20]. With the development of technology, TEG monitoring of coagulation function has been widely used in the field of orthopedics [10, 21]. Some studies have shown that TEG is an effective method to measure the coagulation function after TKA [10]. In this study, on the basis of the traditional coagulation test, the use of TEG to monitor the coagulation function of patients can more accurately reflect the coagulation status of patients. Traditional coagulation function tests mainly include APTT, TT, PT, FIB, D-D, etc., which can more accurately determine whether patients have hypercoagulable state and risk of thrombosis, but the sensitivity is relatively low.

This study found that there was no significant difference in preoperative routine coagulation test indexes between the observation group and the control group, which was comparable. Three days after the operation, the APTT, PT, TT of the observation group were longer than those of the control group, FIB was smaller than that of the control group, and there was no significant difference in D-D, indicating that the observation group was in a low coagulation state than the control group. Shengxuebusui decoction can improve the coagulation state of the body after KA and improve the anticoagulant effect of the body. This is consistent with the results of Wang Jing [22] used Chai Huang Huoxue decoction for the prevention of DVT after hip replacement, indicating that the TCM of kidney tonghuoxue can improve the coagulation function after hip replacement and play a good effect on the prevention of DVT. In the observation group, the D-D, APTT, PT and TT on the 3 days after operation were higher than those before operation, and FIB was lower than that before operation, indicating that the patients were still in a hypercoagulable state under the condition of LMWH DVT on the 3 days after joint replacement. In accordance with the purpose of anticoagulant therapy after KA, the observation group was in a hypocoagulable state compared with that before operation, indicating that Shengxuebusui decoction is helpful to improve the hypercoagulable state of the body in the early stage after joint replacement. Among them, the D-D of the observation group and the control group was increased compared with that before operation. Considering that the specificity of D-D in the detection of coagulation status was low, trauma, blood loss, infection, etc. could lead to D-D increase, and postoperative D-D increase was caused by trauma and blood loss of KA surgery.

This study found that there was no significant difference in preoperative TEG indicators between the observation group and the control group, which was comparable. Three days after operation, the R value and K value of the observation group were higher than those of the control group, and the α Angle, MA value and CI were lower than those of the control group, indicating that the observation group was in a relatively hypocoagulable state compared with the control group. In the intra-group comparison, the K value of the control group decreased, and the MA value and CI increased, indicating that the control group was in a hypercoagulable state. The R value and K value of the observation group were higher than those before operation, and the α Angle, MA value and CI were lower than those before operation, indicating that the observation group was in a relatively low coagulation state. The R value reflects the function of coagulation factors, and the use of anticoagulants or the deficiency of coagulation factors can lead to the increase of R value. The R value decreased when the activity of coagulation factors increased and the function was hyperactive. The K value reflects the function of fibrinogen, which increases with the use of anticoagulants or low fibrinogen and shortens with hyperfibrinogenemia. The α Angle reflects the rate of increase in the strength of blood clots formed by the combination of platelets and reticular fibrin, and the α Angle increases when the blood is in a hypercoagulable state. MA value

reflects the maximum intensity of blood clots, and the change of MA is affected by platelets and fibrin, among which platelets play a major role. Studies have confirmed that an elevated MA value is closely associated with hyperfibrinogenemia and platelet hyperfunction [23]. Studies have shown that the blood flow state of the body changes after joint replacement, and the body is in a hypercoagulable state, which is easy to lead to the occurrence of DVT [24]. LMWH plays an anticoagulant role by binding to antithrombin III, changing its structure, and then inhibiting the activity of coagulation factor Xa, thereby improving the hypercoagulable state of blood after KA and reducing the risk of thrombosis [25]. In this study, compared with before operation, the K value of the control group decreased, CI increased, and there was no significant difference in R value, α Angle and MA value, mainly because the traction or blunt separation operation during the operation led to venous vascular endothelial injury, endothelial cell exposure, activated platelets, induced platelet adhesion and aggregation, and activated intrinsic and extrinsic coagulation pathways [26]. After platelet aggregation and activation, a large amount of thromboxane A2 (TXA2) is released. TXA2 further promotes platelet aggregation and vascular contraction, accelerates the coagulation cascade reaction, and makes the blood in a hypercoagulable state. Although anticoagulation with LMWH was used 12 hours after operation to prevent the occurrence of DVT, the patient was still in a hypercoagulable state compared with that before operation, which may be related to the continuous release of coagulation factors. This further indicated that the patient had early hypercoagulation after joint replacement, and the risk of DVT was high, and postoperative anticoagulation therapy was needed. The R value and K value of the observation group were higher than those before operation, and the α Angle, MA value and CI were lower than those before operation. Compared with before operation, the observation group was in a hypocoagulable state. The R value and K value of the observation group were longer than those of the control group, and the α Angle, MA value and CI were smaller than those of the control group. The observation group showed better anticoagulant effect, which was closely related to the efficacy of Shengxuebusui decoction. CI is a comprehensive indicator of coagulation function. Some studies have shown that CI value can be used to predict the occurrence of bleeding events after KA. When ΔCI is lower than 0.1805, it indicates that the body is in a hypocoagulation state and the incidence of bleeding complications increases significantly [27]. In this study, the mean ΔCI of the observation group was -0.83, and the mean ΔCI of the control group was 1.12. We found that the incidence of bleeding complications in the observation group was 10.8%, while the incidence of bleeding complications in the control group was 29.2%. The incidence of bleeding complications in the observation group was significantly lower than that in the control group, which was inconsistent with the results of previous studies. On the one hand, it is related to the effect of ShengxueBusui Decoction in promoting blood circulation and removing blood stasis, and promoting the absorption of blood ooze in tissue space. On the other hand, the ΔCI in this study is the maximum difference between the postoperative and preoperative CI, and the CI value 3 days after surgery in this study is not the maximum postoperative CI, so further research is needed to determine its effectiveness.

In addition, this study also found that there was no statistically significant difference in the incidence of DVT between the two groups 3 days after surgery. The incidence of DVT in the observation group was lower than that in the control group at 1 week after operation, and there was no difference between the two groups at 1 month after operation. These results indicate that Shengxue Busui Decoction can ameliorate the patients' coagulation profile, mitigate the early postoperative hypercoagulable state, potentially promote thrombus dissolution, help restore coagulation balance, and demonstrates beneficial effects in preventing and treating DVT. We also found that the incidence of bleeding events in the observation group was 10.8%, and that in the control group was 29.2%. The application of Shengxuebusui decoction reduced the incidence of bleeding events, which was contradictory to the relatively hypocoagulable state in the observation group. We hypothesize that this is related to the mechanism of action of Shengxue Busui Decoction, which aligns with the principles of TCM syndrome differentiation and treatment. In line with the idea of dialectical treatment of TCM. It not only improves the hypercoagulable state of blood and blood stasis, but also accelerates the absorption in the tissue space before ecchymosis formation, thereby reducing the occurrence of subcutaneous ecchymosis and bleeding events. In addition to bleeding complications, no other adverse events were found in the study, indicating that the application of Shengxuebusui decoction in the prevention and treatment of DVT after KA can not only reduce the incidence of postoperative DVT, but also reduce the incidence of postoperative bleeding

complications, play its role in promoting blood circulation and removing blood stasis, and do not increase the incidence of adverse events, with good safety.

The main limitation of this study is the small number of patients enrolled. There was no TCM group for comparison; Due to the short study time, coagulation function and TEG were not performed repeatedly after surgery and during follow-up to further explain the changes in coagulation status after KA.

6 Conclusion

The combination of Shengxue Busui Decoction with LMWH can effectively improve coagulation function following joint replacement, reduce the incidence of postoperative DVT and bleeding events, demonstrates beneficial effects in promoting blood circulation and resolving blood stasis, and plays an important role in the prevention and treatment of postoperative DVT. The efficacy of Shengxue Busui decoction combined with LMWH is better than that of LMWH alone.

Author Contributions

All authors have contributed to the conceptualization and design of this study. Xiang Zhang, Hongchen Ren, Hui Feng, and Haicheng Tao conducted material preparation, data collection, and analysis. The initial manuscript was written by Xiang zhang and Hongchen Ren. Jingbo Cheng, and Lei Zhang are responsible for article quality control, with Mingli Feng as the corresponding author, Yuchen Wang contributed to the revision of the manuscript. All authors have read the final manuscript and agreed to publish it.

Ethics Statement

We promise that all relevant ethical documents have been submitted to the Ethics Committee Office of Xuanwu Hospital, Capital Medical University for signature and seal. We have obtained informed consent from all patients participating in this study and signed informed consent forms.

Conflicts of Interest

All authors have approved the manuscript for submission and without any potential competing interests. In addition, I promise that the paper is not submitted to any other journals.

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