# Original Article Safety and clinical efficacy evaluation of warfarin anticoagulation with small balloon dilation for treating Budd-Chiari syndrome complicated with inferior vena cava thrombosis

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Abstract: Objective: This study aims to evaluate the safety and clinical efficacy of warfarin anticoagulation after small balloon pre-dilation for treating Budd-Chiari syndrome (BCS) complicated with inferior vena cava (IVC) thrombosis. Methods: This prospective study analyzed the consecutive clinical data of 53 patients with BCS complicated with IVC thrombosis, who were admitted in our hospital from January 2000 to October 2015. Patients were divided into three groups: group A, warfarin anticoagulation alone (n=11); group B, warfarin anticoagulation after 6-mm balloon pre-dilation (n=17); group C, warfarin anticoagulation after 10-mm balloon pre-dilation (n=25). Patients were followed-up after discharge at 1, 3, 6, 9 and 12 months after pre-dilation or warfarin anticoagulation therapy. IVC patency and morphologic changes of the thrombus were examined by ultrasound, while clinical symptoms and signs were determined during follow-up. Individualized treatment programs for each patient were made according to follow-up results. Results: Small balloon pre-dilation therapy was successful in all cases (groups B and C). IVC angiography confirmed the thrombus in the IVC, but no floating thrombus was found. IVC pressure was measured before and after percutaneous transluminal angioplasty (PTA). Anticoagulation with warfarin was well-tolerated by all patients after small balloon pre-dilation. No bleeding complications and pulmonary embolism occurred during the follow-up. Conclusion: Warfarin anticoagulation with small balloon dilation made interventional treatment possible for BCS with IVC thrombosis. Small balloon pre-dilation with warfarin anticoagulation therapy (control international normalized ratio of 2-3) is a safe, feasible and effective treatment. In particular, 10-mm balloon pre-dilation appears to be more significant, and IVC thrombosis can dissolve within 12 months. This provides a foundation for percutaneous angioplasty of the IVC.

Keywords: Budd-Chiari syndrome, inferior vena cava thrombosis, balloon pre-dilation, pulmonary embolism

#### Introduction

Budd-Chiari syndrome (BCS) is a rare form of hepatic venous outflow obstruction at the suprahepatic inferior vena cava (IVC), the hepatic veins, or both [1, 2]. BCS pathology type is complex. Hepatic vein thrombosis remains to be the cause of most BCS cases in Western countries. However, IVC obstruction is more prevalent in china [3]. IVC thrombosis can easily occur due to IVC obstruction, poor blood flow, blood stasis, vortexing and reversing. In a single center study, the incidence of BCS complicated with IVC thrombosis was 5.8% [4]. Treatment for BCS complicated with IVC thrombosis has been emphasized as a difficult topic. A great variety of therapeutic approaches have been reported including balloon dilation and stent placement [5, 6], infusion of thrombolytic agent [7, 8], TIPS [9], surgical shunting [10], and orthotopic liver transplantation [11, 12]. However, these approaches are complex, expensive and have a high risk of complication. BCS complicated with IVC thrombosis is considered the contraindication of PTA due to risk of acute fatal pulmonary embolism (PE). This study aimed to evaluate the clinical safety and efficacy of this method (Flow chart 1).

#### Materials and methods

A total of 53 consecutive patients, who were diagnosed BCS complicated with IVC thrombosis from January 2000 to October 2015 in our

**Table 1.** IVC patency and the changes of throm-<br/>bus were examined by ultrasound (IVC occlu-<br/>sion)

	1 M	3 M	6 M	9 M	12 M	Ρ
A n=11	0 (11)	0 (11)	0 (11)	1 (11)	3 (11)	27%
B n=17	0 (2)	1(5)	4 (9)	6 (10)	9 (10)	53%
C n=25	2 (1)	7 (2)	15 (3)	18 (3)	23 (3)	92%

hospital, were included into this study. Among these 53 patients, 28 were male and 25 were female; and average age of patients was 49 years (range, 32-77 years). Inclusion criteria: (1) chronic symptoms and signs for more than three months; (2) IVC color Doppler ultrasound examination, or contrast examination of IVC membranous occlusion, or short segment (<10 cm) occlusion combined with thrombus (mixed thrombus or fresh thrombus); (3) life expectancy >12 months. Exclusion criteria: (1) acute course or less than three months, (2) IVC floating thrombus or old thrombus, (3) anticoagulation contraindications. The types of IVC obstruction include membranous occlusion (32 patients) and segment type occlusion (21 patients). Among the 53 patients, five patients had hepatic venous occlusion, three patients had deputy hepatic vein occlusion, and one patient both occlusions. Clinical manifestations include abdominal wall varicosis, lower extremity varicose veins, lower limb skin pigmentation, leg ulcers, ascites, splenomegaly and mild jaundice. In all patients, BCS complicated with IVC thrombosis was confirmed by IVC and hepatic vein Doppler ultrasound examination. Furthermore, 33 cases had Child-Pugh grade A and 20 cases had Child-Pugh grade B. All patients had no contraindications to anticoagulation, such as hematemesis, hematochezia and active bleeding, ecchymosis, and blood system diseases. This study was approved by the Ethics Committee of our institution, and all patients provided written informed consent.

#### Procedure

## Pre-dilation treatment

All patients, procedures were performed in an interventional radiology suite. Intravenous heparin anticoagulation and vital signs were monitored during the operation. The patient was placed in the prone position, the neck and groin area were disinfected, and a sterile towel was spread on the disinfected area. The Seldinger technique was used to puncture the right femoral vein. Then, the blood vessel sheath was

introduced and the pigtail catheter was placed into the IVC. In the same way, the right jugular vein and vein sheath were introduced, and the pigtail catheter was placed into the IVC proximal end. Angiography were consistent with preoperative Doppler ultrasonography.IVC confirmed the thrombus in the IVC, but no floating thrombus was found. Using the femoral vein approach assisted by a road map, a 0.035-cm super-sliding guide wire was used through the IVC block section. If this method was unsuccessful, the right jugular vein was introduced into the RUPS100 by the right jugular vein; then, through the IVC occlusion section of the application of the hard wire. After the occlusion segment was successfully passed, a 6-mm or 10-mm balloon was used for dilation. Blood flow in the IVC was partially recovered, and no contrast agent spillover occurred. IVC pressure was measured and calculated before and after dilation. Finally, the catheter and blood vessel sheath was withdrawn and the puncture point was compressed. Vital signs were monitored after the patient returned to the ward. The patient was given low molecular weight heparin anticoagulation after IVC dilation at a dose of 5,000 U, which was administered by subcutaneous injection Q12H. At the first day after surgery, this was combined with warfarin anticoagulation with a starting dose of 2.5 mg/day. Blood coagulation was performed at the 4<sup>th</sup> day after the oral administration of warfarin, and dosage was adjusted according to blood coagulation. When INR reached 2.0-3.0, low molecular weight heparin was discontinued.

## Warfarin anticoagulation alone (group A)

A total of 11 patients underwent anticoagulation therapy with warfarin. Doppler ultrasound results revealed that IVC had a low echo and D-two was significantly higher than normal in one patient, while IVC Doppler ultrasound revealed that mixed echo and D-two polymer was slightly higher than normal in 10 patients. Low molecular weight heparin and warfarin anticoagulation was applied, and warfarin dose was adjusted to maintain INR between 2.0 and 3.0 during the course of the anticoagulation therapy. When INR reached 2.0-3.0, low molecular weight heparin was discontinued.

## Postoperative monitoring

Twenty-four hours after the surgery, blood oxygen saturation and vitalsigns of all patients

	А	В	С
n	11	17	25
Gender (M/F)			
Μ	4	10	14
F	7	7	11
Average age	45	49	47
Course			
Child-Pugh grade			
A	8	12	13
В	3	5	12
Clinical signs and symptoms			
Abdominal varicose veins	11	17	23
6 M	10	15	14
Lower limb varicosity	10	15	22
6 M	10	13	17
Lower limb skin pigmentation	5	9	16
6 M	5	7	8
Lower limb ulcer	1	3	5
6 M	1	2	2
Esophageal gastric varices	9	15	20
6 M	9	13	12
Ascites	0	0	1
6 M	0	0	1

**Table 2.** Clinical signs and symptoms (6months)

were monitored by ECG. If chest tightness, cough, sputum blood, blood pressure drop and other clinical manifestations occurred, CTA examination was performed in a timely manner to confirm the presence of PE.

# All pre-dilation procedures were successful

All patients were successfully treated by interventional therapy. IVC angiography confirmed IVC stenosis or segmental stenosis and IVC thrombosis infive patients with hepatic venous occlusion, three patients with deputy hepatic vein occlusion, and one patient with both occlusions. All patients were successfully pre-dilated by a 6-mm or 10-mm balloon.

## Follow up

After discharge, patients were followed-up at 1, 3, 6, 9 and 12 months after pre-dilation or warfarin anticoagulation therapy, respectively. Follow-up included two-dimension and color-Doppler ultrasound examinations, as well as the determination of clinical manifestations. IVC patency and morphologic changes of the thrombus were examined by ultrasound, and clinical symptoms and signs were determined by clinical examinations during follow-up. A target international normalized ratio of 2-3 was applied to limit the period of warfarin anticoagulation. If clinical symptoms and bleeding symptoms were found during the treatment period (such as digestive tract, urinary tract bleeding, cerebral hemorrhage, etc.), the patient was sent to hospital timely (**Tables 1, 2**; **Figure 1**).

# IVC percutaneous angioplasty

During the follow-up period, percutaneous transluminal balloon angioplasty (PTBA) or stent placement was performed in the IVC, when IVC color Doppler ultrasound examination and angiography results confirms that the IVC thrombus disappeared. Anticoagulation was continued when the thrombus was not dissolved and IVC no occlusion. If the thrombus did not disappear and IVC re-occlusion (B/C), 6-mm or 10-mm balloon dilation and anticoagulation therapy continued. All cases were treated with PTBA or stent placement therapy after warfarin anticoagulation therapy within 12 months. All operations were successful and no complications occurred.

# Statistical analysis

Quantitative data were expressed as mean  $\pm$  standard deviation. IVC pressure was performed before and after the operation using a paired-sample *t*-test. A *P*-value <0.05 was considered statistically significant. All statistical analyses were performed using SPSS version 16.0 (**Table 3**).

# Results

In group A, thrombosis in three patients were completely or close to completely dissolved (n=11), and the average time of thrombolysis was 11 months; while blood clots in eight patients were partly dissolved or insoluble, and the rate of thrombus dissolution was 27%. In group B, thrombosis in nine patients were completely or close to completely dissolved (n=17), and average time of thrombolysis was 8.33 months; while blood clots in eight patients were partly dissolved or insolubleand IVC re-occlusion occurred in 10 patients (IVC re-occlusion occurred in one patient in one month, in three patients in three months, in four patients in six months, and in one patient in nine months).



**Figure 1.** A 45 year old male patients diagnosed with BCS inferior vena cava thrombosis. The diagnostic and therapeutic procedures are shown in the chart. A. Doppler ultrasound examination showed that IVC occlusion with thrombus. B. Angiography confirmed BCS complicated with thrombosis. C, D. Through block section and pre-dilation with small balloon. E, F. In follow up period, Doppler ultrasound examination and angiography showed thrombus dissolution. G. Dilation of the IVC using large balloon (30 mm, 26 mm). H, I. Doppler ultrasound examination and angiography shows complete normalization of diameter and flow after dilation.

**Table 3.** IVC pressure (cmH<sub>2</sub>O)

	2		
	С	В	Statistic
	n=25	n=17	Р
Before dilatation $(cmH_2^0)$	29.92+3.463	29.94+3.682	0.985
After dilatation ( $cmH_2O$ )	23.84+3.520	26.29+3.197	0.025
After dilatation ( $cmH_2O$ )	23.84+3.520	26.29+3.197	0.025

The rate of IVC thrombus dissolution and reocclusion were 53% and 59%, respectively. In group C, thrombosis in 23 patients were completely or close to completely dissolved, and average time of thrombolysis was 6.61 months: while blood clots in two patients were partly dissolved or insoluble and IVC re-occlusion occurred in three patients (IVC re-occlusion occurred in one patient in one month, in one patient in three months, and in one patient in six months). The rate of IVC thrombus dissolution and re-occlusion were 92% and 12%, respectively. Dissolution rate of the IVC thrombus was significantly lower than that in the small balloon dilation combined with warfarin anticoagulation. Anticoagulant therapy after 10mm balloon pre-dilation anticoagulant thrombolytic rate was significantly higher than the 6-mm balloon pre-dilation group and the IVC low re-occlusion rate. In addition, symptoms and signs of patients obviously improved in six months after 10-mm balloon pre-dilation anticoagulant thrombolysis.

# Complications

All patients had no symptoms of PE after intervention, and liver and renal functionswere normal. During the follow-up, all patients were stable and underwent symptomatic treatment. During warfarin anticoagulation, two patients appeared to have systemic subcutaneous hemorrhagic ecchymosis. Coagulation evaluation revealed an INR of 6.92. The patient was immediately given vitamin K1 confrontation, and warfarin dose was adjusted. The remaining patients had no control of the digestive tract, urinary bleeding and fatal intracerebral hemorrhage.

## Discussion

Our study evaluates the safety and clinical efficacy of warfarin anticoagulation after small balloon pre-dilation for the treatment of BCS complicated with IVC thrombosis. Patients were given standard anticoagulation of warfarin after small balloon predilation, which controlled the international normalized ratio within 2-3. This method was safe and effective, and no complications occurred. The IVC thrombosis was dissolved or was close to complete

dissolution in one year. The longer the warfarin anticoagulation therapy, the higher the rate of thrombosis in IVC became. To our knowledge, this is the first study to report on small balloon dilation combined with warfarin in the treatment of BCS complicated with IVC thrombosis.

BCS complicated with IVC thrombosis is regarded as an interventional treatment contraindication. There are several reports on the endovascular treatment for BCS complicated by a thrombus. In recent years, a relevant literature for the treatment of BCS complicated with IVC thrombosis with catheter embolectomy has been reported [13]. The disadvantage of this method is that it is accompanied by a large amount of blood loss, the thrombus could not be easily cleaned, and thrombus is formed again after operation. Furthermore, the surgical process is complex and technological requirements are high. Catheter thrombolysis is one of the methods used, in which a thrombolysis catheter is inserted into the IVC for continuous urokinase infusion to treat the thrombolysis [8]. This method is effective for treating fresh thrombus, and most of these can be successfully treated with early thrombolytic therapy. Since BCS is a chronic course of disease. IVC thrombi consist of mixed thrombus or old thrombus; in which thrombus dissolution rate is not high and thrombolytic therapy has a higher risk of bleeding. Furthermore, this method requires a long treatment period, requiring more cost. Chun-Qing Zhang reported on IVC stent placement and the implantation of stents, and reports on the fracture and displacement of the IVC are also common [13]. However, the cost of this method is higher. A retrieval stent filter is used to prevent PE in treating BCS complicated thrombus [14-16]. However, complications related to the retrieval of the stent filter such as migration, fracture and failure of removal are not rare. In this study, small balloon dilatation of the IVC was performed. The opening of the IVC is small and is equivalent to the IVC filter, which can avoid a large thrombosis. Even if smaller fragments would fall off, these did not result in symptomatic PE; and subsequent thrombolytic therapy gradually lysed these fragments [8]. Clinical symptoms were relieved by the reduction in IVC pressure. Patients were given warfarin anticoagulation, and PBA treatment was implemented after the IVC thrombus was dissolved, which cleared the way and fully opened the IVC.

This experiment was inspired by the clinical experience of warfarin anticoagulation treatment for deep venous thrombosis [17]. During follow-up, warfarin dissolved the recanalization of deep venous thrombosis of the lower extremity. Losi et al. reported that a patient with a very large and old thrombus in the left atrium was treated by warfarin. After two years of therapy, the thrombus was completely resolved without clinical evidence of PE [18]. Tianxiao Li et al. reported that BCS with IVC thrombus treated with warfarin anticoagulant therapy alone had a certain effect [19]. It has been also reported that BCS combined with IVC thrombosis, stent implantation, and postoperative warfarin anticoagulation therapy have certain effects [20]. Warfarin is widely used in clinical treatment for anticoagulant therapy, and the drug mechanism for vitamin K antagonist mainly inhibit the formation of the coagulation factor; thus, achieving the effect of anticoagulation. Previous studies have shown that anticoagulation with warfarin can reduce thrombus propagation, prevent further clot formation, and allow the body's natural fibrinolytic system to dissolve the existing clot spontaneously [21]. Thrombus dissolution efficiency of pure warfarin anticoagulation is lower than small balloon dilatation and anticoagulation. Anticoagulation therapy with partial patency of the IVC, in addition to the above mentioned warfarin thrombolysis mechanisms and after small balloon pre-dilation of the IVC, restores blood flow towards the heart; thereby improving the efficacy of thrombolytic treatment [8]. The physical erosion of blood flow is very important. Compared with these results, the stronger the physical scour is, the higher thrombolysis rate.

To our knowledge, this is the first study that described warfarin anticoagulation treatment after small balloon pre-dilation for BCS with IVC thrombosis. Our study first proposed the idea of phase treatment BCS with IVC thrombosis. Under small balloon pre-dilation combined with warfarin anticoagulant therapy, the IVC thrombus is expected to dissolve or undergo organization to reduce the rate of stent implantation can reduce cost and avoids the incidence of stent-related complications such as stent migration and fracture; resulting in hepatic vein and accessory hepatic vein occlusion [20, 21]. Based on the present study, small balloon predilation alone followed by warfarin anticoagulation is a safe and effective treatment for a selected group of BCS patients with IVC thrombosis. No bleeding complication and symptomatic PE was reported during the follow-up examinations.

We can safely draw some conclusions from our study that the greater the diameter of the IVC pre-dilated, the more clinical symptoms were relieved; and the patency rate of IVC and thrombus dissolution rate were also higher. When a thing reaches its extreme, it reverses its course. The greater the diameter of the pre-dilation balloon, the greater the physical stimulation of the thrombus in the IVC, and the higher the risk of PE. In this experiment, we found that the effect of a 10-mm balloon was significant. We look forward to further studies on whether a 12-mm or 14-mm balloon would be more effective without reducing the level of safety.

Although 10-mm balloon pre-dilation combined with warfarin for the treatment of BCS with IVC thrombosis is a safe and effective treatment strategy, some limitations still exist. (1) The subjects were confined to the patients with chronic diseases, disease stability can be tolerated. (2) During the follow-up, IVC re-occlusion even after 10-mm balloon pre-dilation. This study is a single center, prospective study. Thus, more clinical evidence is needed to confirm these results.

In summary, although we needed more clinical evidence and long-term follow-up studies, this study revealed that small balloon pre-dilation with warfarin anticoagulation therapy for BCS with IVC thrombosis formation is a safe, effective and economic treatment method. At the same time, it lays the foundation for the next step in treating of BCS complicated with IVC thrombosis.

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#### Disclosure of conflict of interest

None.

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