

# Clinical Outcomes of Warfarin Anticoagulation after Balloon Dilation Alone for the Treatment of Budd–Chiari Syndrome Complicated by Old Inferior Vena Cava Thrombosis

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**Background:** To evaluate the safety and clinical efficacy of warfarin anticoagulation after balloon dilation alone for the treatment of Budd–Chiari syndrome (BCS) complicated by old inferior vena cava (IVC) thrombosis.

**Methods:** From January 2008 to November 2013, 19 BCS patients complicated with old IVC thrombosis were treated with balloon dilation followed by oral administration of anticoagulant warfarin. Follow-up was performed at 1 week, then 1, 2, 3, 6, and 12 months after balloon dilation, and then annually thereafter. IVC patency and morphologic changes of the old thrombus were examined by ultrasound, and clinical symptoms and signs were determined by clinical examinations during follow-up.

**Results:** Successful IVC balloon dilation was achieved in the 19 patients (100%). Inferior vena cavography demonstrated the patency of IVC lumen, and the size of the old thrombus was not altered. The mean pressure gradient between IVC and the right atrium was reduced from  $27.5 \pm 3.0$  cm H<sub>2</sub>O (range, 22–35) before treatment to  $5.4 \pm 1.3$  cm H<sub>2</sub>O (range: 2–7) after treatment ( $t = 41.6$ ,  $P < 0.05$ ; 1 cm H<sub>2</sub>O = 0.098 kPa). Patients were followed up as outpatients for an average of  $15.9 \pm 14.4$  months (range, 3–66). Anticoagulation with warfarin was well tolerated in all patients after balloon dilation alone. Of the 19 patients, complete resolution of the old thrombus was achieved in 12 patients and partial resolution was achieved in 7 patients. Color Doppler ultrasound showed that 17 patients had IVC lumen patency, and 2 patients had IVC reocclusion. None of the patients had recurrence of thrombosis, symptomatic pulmonary embolism, and bleeding complications throughout the follow-up period.

**Conclusions:** Our results indicate that warfarin anticoagulation after balloon dilation alone is a safe and effective therapy for BCS patients with old IVC thrombosis.

## 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.<sup>1,2</sup> In western countries, hepatic vein thrombosis remains to be responsible for most of the BCS cases.<sup>3</sup> However, IVC obstruction is more prevalent in China.<sup>4</sup> After IVC occlusion, blood flow distal to the occlusion site is slow and even reverse. Due to the hypercoagulable state in BCS,

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thrombosis can easily occur in the IVC. There are many therapeutic approaches for BCS complicated with fresh IVC thrombosis. These include thrombolytic agents, agitation thrombolysis, and retrieval stent filter.<sup>5–9</sup> Treatments of BCS with old thrombus are different from those with fresh thrombus. It has been reported that BCS with old IVC thrombosis can be treated by urokinase thrombolysis after predilation, thrombolytic therapy before IVC dilation, and placement of retrieval stent filter.<sup>10–13</sup> However, anticoagulation with warfarin after balloon dilation alone has not been reported for the treatment of BCS with old IVC thrombosis. The purpose of this study was to evaluate the initial clinical safety and efficacy of this method.

## MATERIALS AND METHODS

### Patients

This retrospective study has been approved by the Ethics Committee at the Affiliated Hospital of Xuzhou Medical College (Jiangsu Province, China). Written informed consent was obtained from all subjects.

From January 2008 to November 2013, 130 consecutive BCS patients with IVC thrombosis underwent endovascular treatment in our center. Inclusion criteria were (1) patients with chronic symptoms and signs of IVC obstruction over 3 months; (2) preoperative two-dimensional and color Doppler ultrasound, magnetic resonance angiography, or computer tomography (CT) angiography confirmed the presence of BCS with old IVC thrombosis; and (3) the old IVC thrombus was diagnosed by transcatheter aspiration. Exclusion criteria were (1) BCS patients with fresh or mixed thrombosis; (2) after balloon dilation of the IVC in BCS patients with old thrombus, luminal diameter retraction was >50%, which required stent placement; (3) IVC was completely filled with old thrombus and stent placement was necessary; and (4) absolute contraindications to anticoagulation were present. Based on these criteria, 19 BCS patients with old IVC thrombosis were actually included in this study. The general features of the 19 patients at initial presentation were summarized in Table I. Underlying etiologic factors for BCS with old thrombosis were identified in 3 patients. Two patients had hyperhomocysteinaemia, and 1 had positive anticardiolipin IgG antibodies. JAK2 V617 F mutation was not present in all the 19 patients. The levels of

antithrombin-III, protein C, and protein S were not examined.

### Procedures

**Inferior vena cavography and transcatheter aspiration.** Under local anesthesia, a 6F sheath was inserted into the right femoral vein. A 5F pigtail catheter was advanced into IVC via the sheath for angiography. The location of IVC occlusion, the scope, and morphology of the IVC thrombus were determined by inferior vena cavagram. After withdrawal of the pigtail catheter, a 6F Judkins right guiding catheter (Cordis Corp., FL) was advanced to the level of the IVC thrombus. The catheter connected to a 20 mL syringe was pushed back and forth (each movement <1 cm) and rotated for at least 3 times to facilitate aspiration of the thrombus at the same time. Each patient underwent 3 times of transcatheter aspiration. When no thrombus or only a small amount of white thrombus was obtained from the aspiration, it was determined to be an old thrombus.

**IVC balloon dilation.** As localizer, a pigtail catheter was advanced into the distal end of the IVC occlusion via the right femoral vein. A 6F sheath was inserted into the right internal jugular vein. A 5F angiographic catheter (Cordis Corp., FL) was then advanced to the proximal end of the IVC to perform angiography. A steel needle with a curved head (China Patent No.: 201120361170.4) was advanced through the 5F angiographic catheter and penetrated the IVC occlusion under the fluoroscopic guidance. The 5F angiographic catheter was then advanced to the distal end of the IVC along the steel needle track. The needle was withdrawn and a 260 cm long, 0.035 inch guiding wire was advanced through the 5F angiographic catheter to the distal end of IVC. Subsequently, a balloon catheter (25, 26, or 28 mm in diameter and 40 mm in length, Optimed, Ettlingen, Germany) was inserted to dilate the obstruction of IVC. After the dilation, inferior vena cavography was performed immediately to evaluate the extent of IVC patency and the features of the old thrombus.

**Anticoagulation therapy.** Low-molecular-weight heparin (Nadroparin Calcium, 5000 U/12 hr) was given for 3–4 days by subcutaneous injection after balloon dilation. Warfarin was administered orally at a dose of 5 mg/day from the second day after angioplasty. Warfarin dose was adjusted to maintain the international normalized ratio (INR) between 2.0 and 3.0 during the course of anticoagulation therapy. The duration of warfarin administration was at least 1 year.

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