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***Corresponding Author**
Gu Jianping
E-mail
cjr.gujianping@vip.163.com
Phone
+8613505171786

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Efficacy of Modified Pressure Cuff for Thrombolysis of Lower Limb Deep Vein Thrombus in Comparison with Traditional Sphygmomanometer Pressure Cuff

Mustafa Razi, Yan Li, Xu He, Mohammed Jameeluddin Ahmed, Janesya Sutedjo, Murtuza Razi, Jianping Gu*

Department of Interventional Radiology, Nanjing First Hospital Affiliated to Nanjing Medical University, Chang Le Road 68, Nanjing, Jiangsu, China

Abstract

The thrombolytic process for lower limb deep vein thrombosis (DVT) via locoregional infusion route involves infusion of a thrombolytic through the regional veins like the dorsalis pedis vein and great saphenous vein in combination with compression pressure so as to temporarily occlude the superficial veins of the region for the duration of the infusion process to direct the majority of drugs to the deep veins, leading to increase in the efficacy of the treatment. In this study, 80 patients with known cases of lower limb DVT were selected and randomly divided into two groups of 40 each. One group, the experimental group, received the compression via the modified pressure cuff, and the second group, the control group had compression via sphygmomanometer cuff. Both the groups received urokinase as the thrombolytic drug with the same dose being administered daily through the dorsalis pedis vein. The pressure required to compress the superficial veins and keep the deep veins patent was measured via digital subtraction angiography (DSA) at the time of patient's venography which was lower in experimental group patients. The data obtained from the study showed that the patients with the modified pressure cuff had a higher degree of thrombus clearance rate than patients with traditional sphygmomanometer cuff. The study showed an increase in efficacy of the antithrombotic therapy for lower limb DVT when used in combination with the modified pressure cuff. Further work needs to be done to better understand efficiency and shortcomings of the regime, as this study was a single center study.

Introduction

Venous thromboembolism (VTE) is a constellation of diseases consisting of deep vein thrombosis (DVT) and pulmonary embolism (PE) [1]. DVT is preventable as a disease and is a major cause of morbidity and mortality in VTE patients, with DVT accounting for about two-third of VTE cases [2]. DVT is also known as a major cardiovascular disease with a yearly rate of occurrence of about 0.1% and the mortality rate of about 6% [3]. Post-thrombotic syndrome (PTS) is a chronic and recurrent problem of acute proximal DVT, affecting around half of the number of patients with DVT within the first 1–2 years [4]. Multiple treatment options are available for the treatment of DVT ranging from pharmacological and interventional therapies to compression therapies and pharmacological and mechanical thrombolytics, which are administered according to the needs and requirements of the patients [5]. Delivery of the thrombolytic drugs is achieved via systemic, locoregional or catheter-directed thrombolysis (CDT) methods [6]. These methods have been shown to increase the therapeutic efficiency and also eliminate the side effects of the traditional oral anticoagulants [6]. A recent Cochrane study also depicts the superiority of thrombolysis over anticoagulation and also states that they increase venous patency, apart from diminishing the occurrence of post-thrombotic syndrome following proximal DVT by 1/3$^{rd.}$ [7]. The thrombolytic drugs available for use are tissue plasminogen activator, streptokinase and urokinase [8]. These fibrinolytic drugs have been shown to have better effects when they are administered directly into the affected vessels and also help in minimizing the rate of side effects due to these drugs [9]. The locoregional thrombolysis involves the administration of the thrombolytic drug through a vein in the foot, which is compressed with a firm bandage at just the right pressure so as to direct the drug towards the deep venous system and thus increasing the drug concentration in the occluded segment [10]. The main aim of quick clot clearance is to eradicate the thrombus from the occluded venous segment and establish unhindered blood flow, thus minimizing the complication of post-thrombotic syndrome (PTS) [11]. The thrombolytic agents used in acute DVT settings (onset <28 days old) show better outcome when compared to thrombolysis in patients with greater of the clot (onset >28 days) [12]. The major complication associated with thrombolytic therapy is bleeding, including major bleeding like intracranial bleeding [8].

In this study, 80 patients were selected and divided into 2 groups of 40 each to compare the efficacies and the thrombus clearance rates of thrombolysis while using the sphygmomanometer cuff and the modified pressure cuff to compress the superficial veins while keeping the deep veins patent. From January 2015 to October 2016, patients presenting with complaints of unilateral lower limb swelling with edema and having disease history limited to 28 days were selected. The diagnosis of the common iliac vein, external iliac vein, popliteal vein or femoral vein DVT was confirmed after a digital subtraction angiography (DSA). The patients were explained about the benefits of thrombolysis through the locoregional veins like the dorsalis pedis vein. The possible complications associated with the locoregional therapy, including the possibility of hemorrhage were explained and consent forms were signed after accepting the treatment method.

Materials and Methods

The experimental group patients were given the modified sphygmomanometer pressure cuff. The modification was done in the conventional sphygmomanometer cuff by XJ-B Jiangsu Yuanyan medical equipment Co. Ltd. (Fig. 1A). The cuff was lengthened from 45cm to 65cm, the airbag lengthened from 22cm to 35cm and the width of the cuff and airbag was reduced from 12cm to 7cm so as to make it narrower. These modifications helped in keeping the air pressure in the cuff uniform and also to fit more tightly to the calf. The control group was administered the conventional sphygmomanometer cuff (XJ-B Jiangsu Yuanyan medical equipment Co. Ltd.). The dimensions of the cuff were: width of the cuff and airbag: 12cm, the length of the cuff: 45cm and the length of the airbag was 22cm.

The place of the positioning of the pressure cuff was in the lower calf region, 15cm above the medial malleolus and the cuffs were inflated in an alternating fashion for 15 min each in both the groups (Fig 1B). The average age of the patients was a 58.4±11 year with the all patients falling in the range of 18-75 years. Around 56 patients had left lower limb DVT and 24 patients were presented with right lower limb DVT. The experimental group consisting of 40 patients was given compression via the modified pressure cuff and the control group consisting of 40 patients were given the conventional sphygmomanometer cuff. The patients in both the control and experimental groups were explained in detail about the benefits and side effects of the study, to which they consented wilfully and this study was

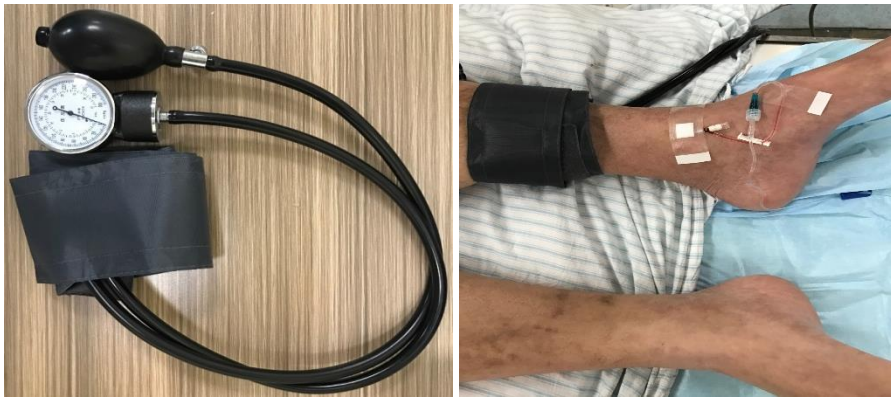

Fig. 1 Modified pressure cuff (A) and the usage method of the compression cuff (B).

also approved by the ethics committee of the Nanjing first hospital. The patients were divided into these groups randomly. The optimal pressure for compression, so as to compresses the superficial veins and keeping the deep veins patent was measured during the venography procedure. The duration of inflation and deflation was 15 minutes in both the groups. These patients were administered Urokinase 500,000 U/day (250,000 U/vial, China Livzon Pharmaceutical Group inc.) along with 500ml normal saline via an intravenous infusion pump set (ZNB-XD, Beijing Kellymed Co. Ltd). The access was obtained through the dorsalis pedis vein in the lower limb and the flow rate was maintained at 20 ml/hr. All the patients were also administered a subcutaneous injection of nadroparin calcium, fraxiparine (GlaxoSmithKline (Tianjin) Co., Ltd.) 4100 U/12 hours of anticoagulation therapy. The patients were screened with bleeding parameters like aPTT, fibrinogen, red blood cell count and platelet levels on a daily basis for the duration of the infusion therapy. The infusion duration ranged from 5 days to 10 days depending on thrombus clearance. This screening was stopped after the discontinuation of the drug infusion.

Results

The data were collected and analysed for the clearance rate of thrombus in both the groups (Fig. 2 and Fig. 3). The thrombus clearance rate was classified into 3 grades. Grade I: <51%, Grade II: 50%-95%, Grade III: 95%. The statistical calculations of the collected data were done with SPSS 2.0 to estimate the thrombus clearance rates in the two groups after the treatment via the paired sample T-test and the P value was assumed as <0.05.

The lower limb deep vein venography of the experimental group patients showed the pressure required to keep the deep veins open and collapse the superficial veins was measured between 65 mmHg to 75 mmHg (average value 70 mmHg ± 5 mmHg). The lower limb deep vein venography of the control group patients demonstrated the sphygmomanometer pressure value within 60 mmHg to 85 mmHg (average value 70 mmHg ± 10 mmHg).

During the study, complications of minor bleeding were associated with the urokinase blood oozing from the puncture site in two patients, two patients developed haematuria, and one patient developed gingival bleed. One patient developed secondary sheath thrombus, three patients developed decreased fibrinogen levels and one patient developed abdominal wall hematoma. The complications were managed appropriately by observing the aPTT, red blood cell levels, fibrinogen levels and the treatment was continued along with the above-mentioned blood screening to prevent any major bleeding or complications. The average thrombus clearance rate in the two groups with the same dose of urokinase administration at different time intervals was higher (P<0.05) in the experimental group than the control group (Table 1).

Discussion

In this study, 80 patients with known cases of acute DVT with the onset of symptoms less than 28 days were selected. These patients had DVT in the common iliac, external iliac, femoral or popliteal veins. The diagnosis was confirmed via a digital subtraction angiography (DSA). The patients in the study were administered thrombolytic agent, i.e., urokinase via the locoregional administration route through the dorsalis pedis vein in the foot of the affected limb. The urokinase was administered in low dose (250000U-500000U) for long duration (4-10 days). As per the procedure, a compression pressure was applied in the lower calf region, 15 cm above the medial malleolus, so as to compress the superficial

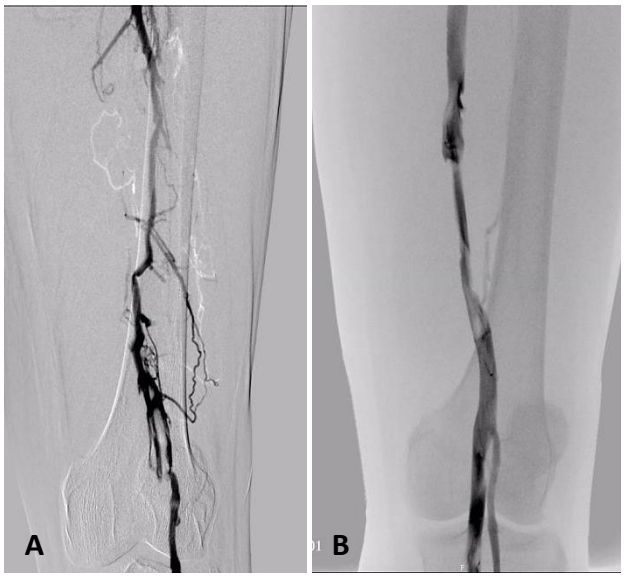

Fig. 2 Pre-procedural (A) and post-procedural (B) digital subtraction angiography of a patient in the control group.

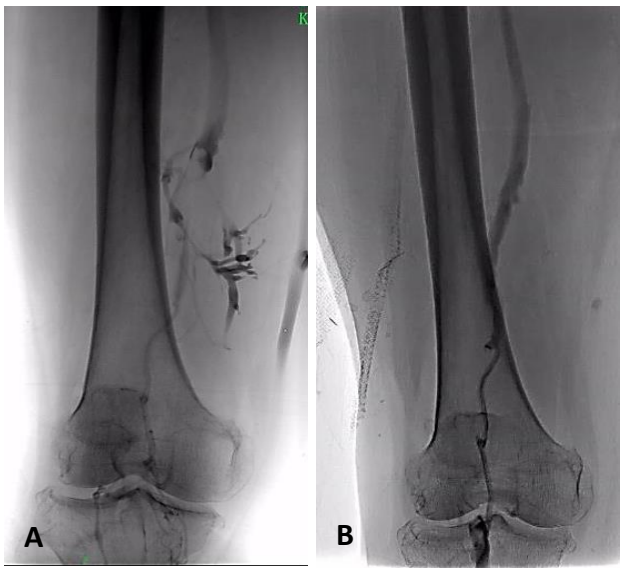

Fig. 3 Pre-procedural diagnostic angiography taken for the patient in the experimental group (A); the digital subtraction angiography demonstrates lower femoral segment thrombus and post-thrombolysis of the same patient (B) using urokinase and the modified pressure cuff for compression banding in the lower part of the affected limb. The venography clearly depicts efficient clearance of the thrombus using the proposed method.

veins and keep the deep veins patent. This helps in increasing the concentration of the thrombolytic drug in the target veins. From January 2014 till December 2014, as per the protocols, our department used sphygmomanometer cuffs for applying pressure in the thrombolytic therapies via the locoregional routes. It was observed that the conventional sphygmomanometer cuffs are designed for use on the forearm, thus ensuring that the cuff covers the forearm properly and tightly adhere to the skin of the forearm. Their use in the calf represented a scenario where, due to the obvious difference in the shape and the circumference of the two regions, it was difficult for the sphygmomanometer cuff to be placed in the calf region as tightly and without any gaps as in the forearm, resulting in difficulty in distributing air bag pressure to the whole surface of the calf. This resulted in the ineffective blocking effect of superficial venous blood flow. This was evident in the lower extremity venography where even with a pressure of more than 80 mmHg - 85 mmHg, superficial venous blood flow was still evident a few. After deliberating on the above shortcomings of using the conventional sphygmomanometer cuff as a pressure band for thrombolytic therapy, a modified cuff was designed. The length of the cuff was increased; the width of the airbag is narrowed, so as to make the width of the airbag 15%-25% of the calf length. After these alterations, the modified pressure cuff closely attached to the calf, so that the air pressure in the superficial venous compression is very uniform.

The results of the experimental group study showed that the angiography of patients with narrow pressure cuff had a significant effect in blocking the superficial venous blood flow. The pressure range was 65-75 mmHg with an average of 70mmHg ± 5 mmHg. The thrombus clearance rate depicted significant efficiency when compared to the control group. When the width of the airbag was reduced to 7 cm, it could fit closely with the calf. The results showed that the experimental group had less influence on the skin; it was not easy to cause local skin redness, wrinkles, pain and other complications and gave a higher comfort degree. A similar study, which focused on the use of loco-regional therapy via the great saphenous vein using the pressure tourniquet for the treatment of Ilio-femoral thrombosis depicted better outcomes when compared with catheter-directed thrombolysis. The study follows the patients for two years after the treatment and the patients treated via the loco-regional route showed better outcomes and lesser side effects like PTS [13]. Another study which was undertaken by our department focusing on the nursing aspect of the use of the two types of pressure cuffs depicted that the patients with the modified pressure cuffs were relatively more comfortable than the patients in the other pressure cuff group. The patients in the

Table 1 Comparison of average thrombus clearance rate after thrombolytic therapy up to ten days between the experimental and control groups. The data are expressed mean ± standard deviation.

Groups	Cases	Urokinase dosage (U/d)	Thrombus clearance rate (%)			
			3d	5d	7d	10d
Experimental group	40	250000	34.25±8.05	63.25±14.07	89.50±6.96	94.38±5.33
Control group	40	250000	28.88±9.16	54.38±13.06	79.38±10.07	85.38±6.54
T value			-2.409	-2.924	-5.218	-7.477
P value			0.021	0.006	0.000	0.000

modified pressure group experienced a lesser degree redness of legs and also shows that the degree of inflation required for collapsing the superficial vessels was also lesser than the rate at which the vessels collapse in the patients with regular sphygmomanometer [14].

Conclusions

The modified pressure cuff shows a notable increase in the thrombus clearance rate when compared to the use of conventional sphygmomanometer cuff for pressure banding to augment the effect of thrombolytic therapy. The pressure required to compress the superficial veins also showed a notable decrease, leading to decreased discomfort in patients. Though the results are significant, this was a single center trial with a fairly small experimental group. Further study in a multicentre setting with a larger patient group needs to be undertaken to completely estimate the efficacy and study the drawbacks if evident.

Conflict of Interest

The authors declare that we have no conflict of interest to declare.

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