Longterm Results After Surgical Thrombectomy and Simultaneous Stenting for Symptomatic Iliofemoral Venous Thrombosis

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Abstract *Objectives:* To evaluate the longterm outcome of venous thrombectomy and simultaneous stenting in patients with acute, symptomatic iliofemoral deep venous thrombosis (DVT).
Methods: Between January 1996 and December 2007, a total of 45 patients underwent venous thrombectomy at our institution. Thrombectomy results were classified by intraoperative phlebography as: TYPE I = complete, TYPE II = partial, TYPE III = complete with stenosis other than thrombus, TYPE IV = permanent occlusion. TYPEs I and IV were excluded from this analysis because no endovascular repair was performed.

25 patients underwent a venous hybrid operation comprising balloon-catheter thrombectomy, thrombolysis and stenting of residual stensosis. Three TYPE 2 and 22 TYPE 3 lesions were diagnosed. Three patients died during follow-up from causes unrelated to their treatment. Three were lost to follow-up. Hence, 19 patients were examined. A retrospective, non comparative single-centre study was performed.
Results: Median follow-up was 68 months (range 3—129). Primary and secondary patency rates were 74% (14/19) and 84% (16/19), respectively. Re-thrombosis occurred within seven days of operation in 26% (5/19). Procedure related mortality was zero. There was no case of late re-thrombosis. Four patients showed post-thrombotic sequelae (CEAP: C1, 2 or 3 s). No leg ulcer developed in any patient.
Conclusion: Venous thrombectomy with simultaneous stenting results in excellent longterm results in selected patients with symptomatic iliofemoral venous thrombosis.

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Introduction

Deep vein thrombosis (DVT) is a widespread disease with an incidence of 300:100,000 patients/year. The most important early complication is pulmonary embolism. Longterm complications include the development of a post-thrombotic syndrome (PTS) in 40—60% of conservatively treated patients after 10—15 years. Every 10th patient develops venous ulcers despite subsequent compression therapy.[1,2]

Venous thrombectomy is a treatment option that may be considered in selected patients. To avoid re-thrombosis, venous outflow should be re-established ensuring that there is no residual stensosis in the iliac veins or inferior vena cava. Performing intraoperative phlebography, outflow obstruction such as May-Thurner Syndrome[3] can be identified and treated in a ''one-step procedure'' by guide-wire directed thrombectomy or stenting.

This venous hybrid operation has been performed since 1996 at our institution. Good mid-term results were published by our group in this journal previosly.[4] This study evaluates the longterm outcome in a consecutive series with follow-up until 2007. It is to our knowledge the longest follow-up ever published.

Methods

Study population

Between January 1996 and December 2007, a total *of* 45 consecutive patients underwent surgery for iliofemoral/caval thrombosis. 25 patients were treated by endovascular techniques (balloon-catheter thrombectomy, thrombolysis, angioplasty, with or without stent deployment) in a one-step procedure. These patients comprise the study group reported in this paper. There were 22 female patients, median age 32 years (range 16—63) and 3 male, median age 61 (56—70) years. 23 thromboses occurred on the left, one in the right lower limb vessels (cancer-induced phlegmasia caerulea dolens), and one presented with bilateral thrombosis (hypoplasia of the inferior vena cava). Indications for surgical venous thrombectomy are shown in Table 1. Thrombectomy only was performed in cases of acute onset of (<10 days) thrombosis[5] although in young patients treatment was sometimes attempted after longer periods of venous occlusion. Bed-ridden patients, patients with a short life expectancy or with underlying malignancy were excluded from surgical treatment. Graduated elastic compression stockings with a pressure of 23—32 mmHg and anticoagulation for at least 6—12 months were recommended for all patients. The duration of oral anticoagulation was determined for each patient individually in cooperation with a medical specialist in thrombophilic diseases. In most cases the duration of anticoagulation was in the range 6—12 months.

Table 1 Indications for surgical venous thrombectomy (number in this series; modified from reference[17]).

• Phlegmasia coerulea dolens	($n = 1$)
• Iliofemoral thrombosis	($n = 23$)
• Thrombosis of the inferior caval vein	($n = 1$)
• Acute thrombosis (<10 days)	($n = 22$)
• Embolizing thrombus	($n = 2$)
• Ascending thrombosis	($n = 0$)
• Free-floating thrombus	($n = 0$)
• Pregnancy-associated thrombosis	($n = 1$)

Aetiology of iliac vein obstructions

Stenosis or obstruction of the common iliac vein was observed in 88% (22 out of 25) patients. In two patients, the external iliac vein and in one patient the inferior venous cava was also affected. In 68% (17 patients), thrombosis was caused by a spur. One patient presented with a retroperitoneal fibrosis three years after surgery and radiotherapy for curative treatment of a rectal carcinoma. A compressive obstruction of the common iliac vein was caused by a prevertebral haematoma after an orthopaedic operation of the spine. One patient presented with phlegmasia caerulea dolens caused by local spread of a bladder tumour. One thrombosis was caused by a metastasising prostate carcinoma which was diagnosed in the course of further investigations and one by a congenital hypoplasia of the inferior vena cava. The three TYPE II patients showed residual thrombotic narrowing (Table 2).

Classification of venous stenosis

The results of surgical thrombectomy were assessed intraoperatively by ascending phlebography. We have previously published our classification of these findings.[4] Surgical thrombectomy clearing all thrombotic material was defined as TYPE I ($n = 19$). Residual thrombotic stenosis after surgical thrombectomy was referred as TYPE II ($n = 3$). Venous wall obstructions other than residual thrombus (e.g. May-Thurner syndrome, hypoplasia or extraluminal compression) were defined as TYPE III ($n = 22$) (Fig. 1A). Residual total venous obstruction of the iliofemoral junction after thrombectomy were defined as TYPE IV lesions ($n = 1$). Patient classification is summarised in Table 3.

Hybrid procedure

Our operative protocol also has been published before.[4] In brief, patients were operated on under with 15 mmHg positive end-expiratory pressure (PEEP) ventilation and 30° chest elevation. Transfemoral thrombectomy of the iliac veins was performed with a wire-guided Fogarty balloon-catheter under fluoroscopy. Thrombotic material from below the inguinal ligament was evacuated by manual compression augmented by wrapping with elastic bandages. No Fogarty catheter was passed distally from the femoral vein in order to preserve venous valve function.

Ascending phlebography was routinely performed in all patients. If residual venous obstruction was detected an appropriate endovascular treatment was indicated depending on location, morphology, and nature of the lesion. In TYPE II lesions, wire-guided thrombectomy alone or in combination with local thrombolysis was performed using a pulse-spray catheter (multi-side-hole) with 250,000—500,000 IU

Table 2 Summary of TYPE II and III lesions identified in our series of 25 patients.

TYPE II patients ($n = 3$)	
• Obstruction/Stenosis of the common iliac vein	
- Residual thrombotic stenosis	$n = 2$
• Stenosis of the external iliac vein	
- Residual thrombotic stenosis	$n = 1$
TYPE III patients ($n = 22$)	
• Obstruction/Stenosis of the common iliac vein	
- Stenosis by spur	$n = 17$
- Actinic/Radiogenic stenosis	$n = 1$
- Compressive prevertebral hematoma	$n = 1$
- Compressive carcinoma (bladder)	$n = 1$
• Stenosis of the external iliac vein	
- Compressive carcinoma (prostate)	$n = 1$
• Obstruction of the inferior vena cava	
- Congenital Hypoplasia	$n = 1$

urokinase. Venous hypoplasia or a spur was treated by stenting the affected region. Stents were placed using an introducer sheath guided through the venotomy and positioned using a guide-wire (Vascutek®-Terumo, Glasgow, Scotland). Both, phlebography and stenting was performed under guidance of a mobile digital subtraction angiography unit. When positioning the stent in the common or external iliac vein care was taken not to occlude the internal iliac vein or the contralateral common iliac vein (Fig. 1B). For TYPE I, no further treatment was necessary. In TYPE IV lesions treatment was impossible because the occluded vein could not be passed.

A total of 25 stent-devices were implanted. Of these 52% were self-expanding *[Easy-Wallstent® endoprothesis (n = 11) (Boston scientific, USA) Symphony® stent (n = 1), Smart stent® (n = 1) (Cordis, Johnson and Johnson, USA)] and 48% balloon*-expanding stents [Palmaz® XXL ($n = 11$), Corinthian® ($n = 1$) (Cordis, Johnson and Johnson, USA)].

Follow-up

Follow-up included recording details of the medical history (duration of anticoagulation, and compression therapy, symptoms suggesting thrombotic recurrence and post-thrombotic symptoms), clinical examination and colour duplex sonography.

Swelling was assessed by measuring the circumference of both legs. Skin changes such as reticular or varicose veins, trophic skin changes and ulceration were documented. Duplex ultrasonography was performed with a special focus on patency of stents, patency and competence of deep and superficial veins, and signs of PTS. The colour duplex ultrasound system (Xario, Toshiba, Tokyo, Japan) with equipped with a linear array probe (frequency, 7.5 MHz; range, 5—10 MHz) to investigate the lower limbs and a phased array probe (frequency, 3.5 MHz; range, 2.25—5 MHz) to investigate the abdomen and pelvis. All deep and superficial veins in both lower extremities were examined from the vena cava to the calf veins. The patient was seated in an upright position with his or her legs dependent to examine the calf veins. Duplex ultrasonography of the thigh and iliac veins was performed with the patient lying supine. The diagnosis of DVT was based on both incompressibility of the vein on B-mode and lack of spontaneous flow on colour duplex imaging. Venous reflux was defined as the presence of reverse blood flow greater than 0.5 seconds following the release of a firm manual calf or thigh compression.[6] Patients were categorized according to the CEAP classification.[7] In addition the ''Venous Clinical Severity Scoring'' (VCSS) for longitudinal studies was used.[8]

Statistical analysis

Data were collected in an Excel database (Excel Microsoft Corporation, Redmond, WA, USA). Data consistency checks

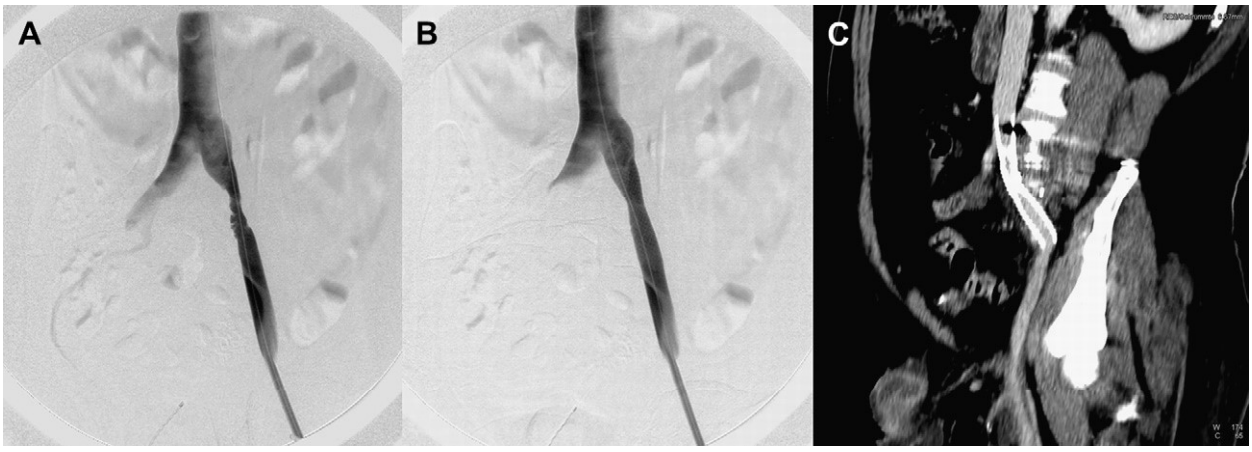

Figure 1 22-year-old female who underwent transfemoral thrombectomy with subsequent ascending venography. It shows a persistent narrowing (May-Thurner Syndrome) of the common iliac vein (TYPE III thrombectomy) (**A**) which was treated by the deployment of a 16/60 mm Wall-stent (**B**). A postoperative CT-angiography (sagittal reconstruction with center-line measurement) showed a patent stentgraft (**C**). Eight years after treatment the reconstruction was still patent and the patient showed no symptoms of post-thrombotic syndrome.

Table 3 Classification of phlebographic findings after venous thrombectomy (modified[4]).

• TYPE I	complete restoration of venous inflow
• TYPE II	residual stenosis due to remaining thrombus
• TYPE III	residual stenosis due to other reasons than thrombus (e.g. May-Thurner Syndrome, extrinsic compression)
• TYPE IV	complete obstruction

were performed, in case of missing values or obvious entry mistakes, patient charts were reviewed to minimise incomplete data sets. For continuous variables, means and standard deviations were calculated. Wilcoxon signed-rank test was used for statistical analysis of VCSS. Patency rates and actuarial re-thrombosis were estimated by Kaplan-Meier life table analysis using XLstat (Addinsoft, New York, USA). A p-value <0.05 was defined statistically significant.

Results

Follow-up

During follow-up three male patients died (all TYPE III) due to cancer. Two TYPE II patients and one TYPE III patient were lost to follow-up. Therefore 19 of 25 patients (one TYPE II and 18 TYPE III patients) were examined. The median follow-up of all patients examined was 68 months (range 3—129 months).

Duplex ultrasonography revealed that 14 of 19 patients had no abnormal findings in any part of the venous system. Two stents were permanently occluded. In one stent the thrombosis partially recanalised spontaneously within two years of the operation. We could find no evidence of progressive stenosis in the patent stents during the follow-up period.

Incompetence of the common femoral vein was found in one patient and in four cases the great saphenous vein was incompetent.

Risk factors and thrombophilic disorders

In addition to anatomical obstruction all patients had risk factors for thrombosis (table 4). 50% of patients had more than one (up to three) risk factors. Nine patients had thrombophilic disorders, and five patients had more than one thrombophilia. Except for one homozygous PAI (plasminogenactivator-inhibitor 1)-gene mutation all the other gene mutations were heterozygous (Table 5).

Table 4 Risk factors for thrombosis in this series (50% had more than one risk factor).

• Operation	($n = 4$)
• Immobilisation other than operation	($n = 3$)
• Gravidity/postpartum	($n = 3$)
• Metastasising Carcinoma	($n = 2$)
• Oral contraceptives	($n = 9$)
• Thrombophilic disorders	($n = 9$)

Table 5 Thrombophilic disorders were found in 9 patients (Five patients had more than one risk factor).

• Factor-V-Leiden	($n = 5$)
• Protein S deficiency	($n = 1$)
• Protein C deficiency	($n = 1$)
• Prothrombin mutation	($n = 3$)
• PAI-gene mutation	($n = 4$)
• Elevated factor VIII activity	($n = 1$)
• Hyperhomocysteinaemia	($n = 1$)

Feasibility and clinical outcome

Technical feasibility of the surgical thrombectomy procedure was 100% (25/25) from which the operative mortality was 0%. Endovascular reconstruction was accomplished *with one complication*. One stent (Palmaz XXL®) was dislodged into the inferior vena cava by the introducer sheath during deployment of a second stent *and* was corrected by retraction and repositioning with a balloon-catheter. *Procedure-related* pulmonary embolism was not studied by CT scanning since no patient showed any clinical sign of pulmonary embolism.

Early re-thrombosis in the first seven days after operation occurred in five TYPE III patients. In three a spur was undiagnosed initially (two patients underwent stening and patient one refused a second operation). One re-thrombectomy was not successful (the re-thrombosis was diagnosed 10 days after the initial thrombectomy), but the thrombosis partially recanalised spontaneously within two years. One re-thrombosis occurred due to post-thrombotic lesions in the venous system due to residual wall roughness. In this setting, prospects of success by another operation seemed poor and therefore conservative treatment was preferred.

In summary, two of five re-thromboses were successfully recanalised by a second operation and there was no late re-thrombosis.

Four patients reported minor symptoms including telangiectases, swelling or varicosities. No ulcer occurred. The CEAP clinical stage is shown in Table 6. The VCSS showed a decrease in all patients but one ($p = 0.0001$) in the course of the follow-up. The median of the VCSS

Table 6 CEAP clinical stage.

C0a:	$n = 11$ (no symptoms)
C1a:	$n = 3$ (asymptomatic telangiectases and reticular veins)
C2a:	$n = 1$ (asymptomatic varicosities)
C3s:	$n = 1$ (symptomatic edema)
C1, 2s:	$n = 2$ (symptomatic telangiectases and reticular veins and varicosis)
C2, 3s:	$n = 1$ (symptomatic varicosities and edema)

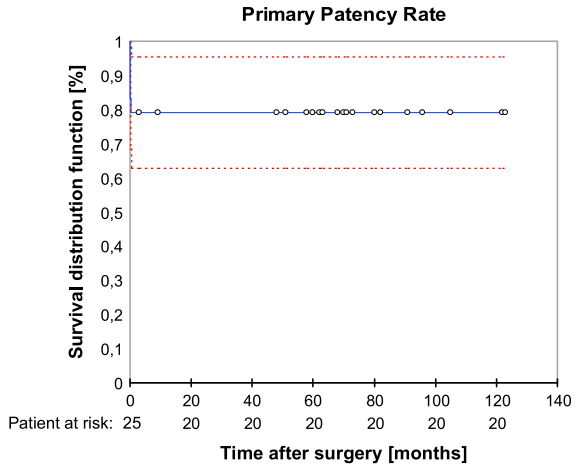

Figure 2 Kaplan-Meier estimates of primary patency rate after venous thrombectomy.

decreased from 6 points preoperatively to 0. In one patient the score increased from 6 to 7 points.

During a median follow-up of 68 months the primary and secondary patency rates of the endovascular reconstruction were 74% ($n = 14$ of 19) and 84% ($n = 16$ of 19), respectively (Figs. 1C, 2 and 3).

Discussion

In this study we found that venous thrombectomy with simultaneous stenting shows excellent longterm results in selected patients with symptomatic iliofemoral venous thrombosis.

In recent decades surgical treatment of deep vein thrombosis (DVT) was rarely been mentioned. Haller and Lansing described venous thrombectomy in the 1960s with excellent early results.[9,10] However, the follow-up results showed high rates of re-thrombosis probably due to a flawed study design and a lack of intraoperative phlebography. With intraoperative phlebography anatomical obstruction of the iliac veins such as May-Thurner Syndrom

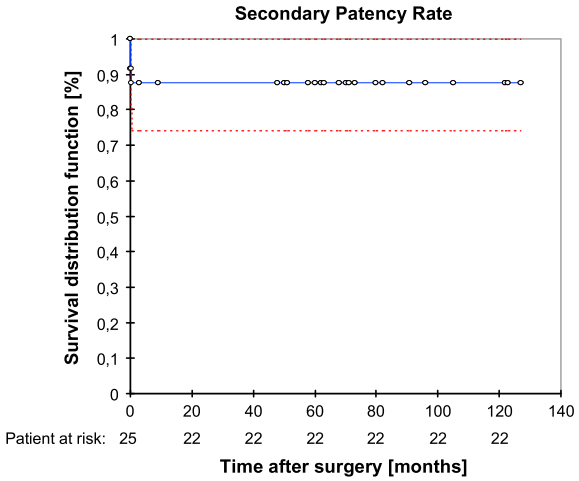

Figure 3 Kaplan-Meier estimates of secondary patency rate after venous thrombectomy.

can be easily detected. Current literature provides much more encouraging results with patency rates after endovascular treatment of 70% and more.[5,11–13]

However, in the current guidelines of the ''American Heart association'' (AHA) for treatment of venous thromboembolism operative treatment of iliofemoral venous thromboembolism is only recommended in impending acute limb loss. On the other hand, the American College of Chest Physicians (ACCP) guidelines advise operative venous thrombectomy in selected patients with acute iliofemoral DVT to reduce acute symptoms and post-thrombotic morbidity if appropriate expertise and resources are available.[14]

In the study presented here, the clinical outcome during the follow-up period was excellent, although we acknowledge that this is based on limited numbers. Only four patients suffered from minor signs of post-thrombotic syndrome in our series. One patient increased in the VCSS because she wore compression stockings permanently. The intensity of her pain diminished. This fits with the majority of recent surgical studies.[5,11,12,15–20] The accepted method of treating DVT is the use of heparin in combination with compression therapy. These measures are effective at preventing acute complications such as ascending DVT or pulmonary embolism. Late sequelae, such as PTS, can be reduced by wearing compression stockings,[21] but despite this up to 60% of all conservatively treated DVT-patients develop a PTS, every 10th patient suffers venous leg ulceration.[1,2]

There is evidence that early thrombectomy can prevent longterm venous damage and PTS. See-Tho et al. showed that inflammatory changes that lead to venous valve destruction are reversible if the thrombus dissolves early.[22] Caps et al. previously described that the proximal thrombotic occlusion remaining in human leg veins will lead to progressive distal valvular incompetence.[23]

Although surgical thrombectomy is an invasive treatment it is associated with a low rate of peri- and post-procedural risk compared to the alternative ''less invasive'' approaches. Catheter-directed thrombolysis results in a mean infusion time of ~53 h and major bleeding complications of 11% have been described.[1] Catheter-directed thrombolysis plus mechanical thrombectomy has mean infusion times of ~23 h and major bleeding complications of 14%.[24] Systemic fibrinolysis should be used with great caution due to the high rate of complication associated with this treatment.[25]

Groin lymphatic fistulas are a troublesome finding after surgery. Local morbidity was low in this study and in international literature (≤1%).[26–28] Local complications included one lymphatic fistula and one seroma. Both were treated conservatively.

Creation of arteriovenous fistulas (AVF) after thrombectomy[17–19] or stent deployment[5,11,12] is proposed by some authors. Both methods are effective and show good longterm results. Some even advise a combination of both techniques.[29] In our opinion, AVF is only indicated in ascending thrombosis but not necessary in descending thrombosis if any stenosis is completely removed. A disadvantage of AVF is an obligatory second operation after ~6 weeks.[29] A long-standing AVF can lead to distal common femoral vein stenosis.[30]

Venous stenoses are prone to elastic recoil after balloon dilatation, so stent placement considerably improves patency.[5] We observed good stent patency rates in our study and similar findings have been reported in other larger clinical series.[5,11—13]

Re-thrombosis in our patients only occurred if stenosis was not treated adequately at the initial operation. This is in line with findings of a multi-centre registry of 473 patients who were treated with catheter-directed thrombolysis without further reconstruction. A one-year primary patency rate of 79% could only be achieved if no residual stenosis was persistent. Residual stenosis of 1—50% had a one-year patency rate of only 58% and residual stenosis of more than 50% of only 32%.[1] If a residual stenosis occurred after catheter-directed thrombolysis stent deployment led to patency rates over 80%.[31] Mickley et al. had rates of re-thrombosis of 73% if a spur was not treated, 13% after treatment and 6% in patients without any stenosis.[11]

As in our series, re-thrombosis only occurred in the first few days after thrombectomy.[5,11,12,17—19] This was mainly due to missed residual stenoses (mainly spurs) or in some cases because of acute thrombosis of post-thrombotic lesions. Surgical thrombectomy is not appropriate in such cases.

Some authors describe good results after treatment of chronic symptomatic stenosis and occlusion with angioplasty and stent deployment. Juhan et al. described a primary and secondary patency rate of 88% and 100% after 22 months, respectivly.[5]

Neglén et al. treated 447 patients with stenosis and stenosis plus reflux affected by chronic venous insufficiency (swelling, pain, venous claudication, ulcers). By treating the venous outflow with angioplasty and stent deployment 50% were completely relieved of pain, 33% were relieved of swelling and 55% of ulcerated limbs healed.[12]

Conclusion

This study shows that residual stenoses of the iliac veins after venous thrombectomy can be reconstructed in a one-stage venous hybrid operation with excellent longterm patency and resolution of clinical symptoms in selected patients with symptomatic iliofemoral venous thrombosis.

Conflict of Interest/Funding

None.

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