Negative pressure wound management system for inguinal wounds after venous hybrid procedures

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Primary Objective: Assess the incidence of wound infections in patients treated with venous stenting and AV fistula and Prevena negative pressure wound therapy (NPWT).Secondary Objective(s): Assess the incidence of lymph leakage in patients treated…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON43445

Source
ToetsingOnline

Brief title
Vacuumtherapy after venous hybrid procedures

Condition

- Bacterial infectious disorders
- Vascular therapeutic procedures

Synonym
lymph leakage, wound infection

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: hybrid procedures, inguinal wound, negative pressure, wound therapy

Outcome measures

Primary outcome

Main study parameter/endpoint

Incidence of wound infections in patients treated with AV fistula and stenting

and Prevena vacuum therapy.

Secondary outcome

Secondary study parameters/endpoints (if applicable)

Incidence of lymph leakage in patients treated with AV fistula and stenting and

Prevena negative pressure management system

Other study parameters (if applicable)

Evaluate the clinical appearance and quality of the scar by filling out the

Patient Observer Scar Assessment Scale v2.0 Nl and photos

Study description

Background summary

Annually about 1-2 per 1000 people in Western European countries develop deep venous thrombosis (DVT). The most frequent long-term complication of DVT is development of a Post thrombotic syndrome (PTS). (1)
PTS consists of a range of symptoms that can occur in patients following a deep vein
thrombosis. The definition of PTS is difficult to quantify but can be measured best by the Villalta score. The higher the Villalta score, the more severe complaints are. A score >15 indicates a severe PTS.
The pathological pathway of PTS is not completely understood but can be found in altered haemodynamics. Virchow*s triad consisting of hypercoagulable state, vascular wall damage and venous stasis explains the development of a deep vein thrombosis. The first two mentioned causes are encountered in standardised

treatment nowadays. For the venous stasis no good treatment existed until recently percutaneous angioplasty (PTA) and dedicated venous stents became available. (2)
Patients with PTS experience symptoms related to chronic venous insufficiency caused by obstruction and valve impairment leading to venous hypertension. These symptoms may include pain, tired legs, venous claudication and cramps, oedema, pigmentation or other skin changes finally leading to ulcera.
Patients with established PTS experience a significant impact on QoL with, in several cases,
daily disabilities comparable to an impaired QoL in Chronic Obstrucive Pulmonary Disease (COPD), congestive heart disease and diabetes. (3, 4)
PTS develops in 40-50 % of all patients with a history of a DVT depending on anatomic position of deep venous thrombosis and involvement of collateral system.(5-7) Whenever DVT occurs in iliofemoral or caval veins with obstruction of collateral systems the outflow obstruction is greater than DVT*s in the calf veins. One can understand this outflow obstruction will present more clinical and invalidating symptoms. Other risk factors for severe PTS, found in a large prospective trial, are morbidity included severity of venous symptoms at 1 month, recurrent ipsilateral DVT, high body mass index and higher age. Some of these risk factors are modifiable while others are not. (8, 9)
Venous outflow obstruction is caused by inadequate recanalization, extravascular compression or congenital abnormalities.
Conventional treatment of DVO to minimalize complaints consists of the use of elastic compressions stockings, exercise, lymph drainage therapy and the use of (pain) medication. For most patients the physician selects one or a combination of the treatment modalities mentioned above in an attempt to reduce symptoms. However this is not always effective.(10)
A definitive solution for DVO patients may be a revascularisation procedure and stenting of
the affected tract. This can be achieved by endovascular or hybrid procedures in which a
PTA is performed and a dedicated venous stent is placed. This procedure is already being performed in various hospitals around the world with good results on an individual basis. The goal of PTA and stenting is to prevent PTS (whenever placed in acute settings) or recurrent DVT and associated expected decrease in quality of life.
Patients with a severe PTS with extension of post thrombotic changes (stenosis or occlusion) below the sapheno-femoral junction sometimes require a so-called hybrid procedure. Because of the difficulty in predict which patients need this so-called procedure we sometimes experience occlusion of stents in patients treated solely by percutaneous recanalization and stent placement. This second group will have to be hospitalized to receive urokinase by thrombolysis and afterwards creation of an AV-fistula to maintain flow through the previously stented traject.
This procedure is performed under general anesthesia in which recanalization and stenting is performed and a possible endoflebectomy with creation of arterio-venous fistula (AVF) will be created to guarantee preferential and

significant flow. The vein is opened in a longitudinal way and the synechiae and scars will be removed. Afterwards the vein will be sutured primairily or with a patch to guarantee an acceptable diameter of the vessel. Because of the idiopatic damage at the vessel there is an increased risk of thrombogenetic events and all of these patients receive an AVF. This AVF is created by connecting the common femoral vein to the common femoral artery with a PTFE loop of 5-6 mm. (11)
To gain access to the femoral vein and artery, a longitudinal groin incision of 5-10 cm has to be made. This will result in restriction of daily activities during a couple of weeks. The main reason can be found in the fact that the incision will be made in a mobile area. Besides this, patients with venous obstruction mostly have impaired lymphatic drainage.
Our experience is that venous patients have important postoperative morbidity because of leakage of seroma and possible infections associated with this.
In our own population, currently consisting of 86 patients treated by the aforementioned hybrid procedure have a surgical site infection rate of 35% and lymph leakage of 27%.
Hereby 4.7 % (4 patients) of our own population had an additional surgical procedure because infection proceeded and gave an infection of the PTFE AV-fistula. In this additional surgical procedure the fistula needed to be removed with the chance of occlusion of the stents.
In order to reduce these numbers, untill now, patients received a gentamycin mesh and low-vacuum drain to drainage seroma. This drain is removed whenever production of fluid is less than 50cc/ 24 hours.
To treat these patients more optimal and prevent infections and lymphatic leakage we want to give all patients a negative pressure incision management system (Prevena) during 7 days.

Thus, the rationale of this study is to assess the incidence of wound infections and secondary lymph leakage in patients treated with venous hybrid procedure and Prevena vacuum therapy.

Study objective

Primary Objective:
Assess the incidence of wound infections in patients treated with venous stenting and AV fistula and Prevena negative pressure wound therapy (NPWT).

Secondary Objective(s):
Assess the incidence of lymph leakage in patients treated with venous stenting and AV fistula and Prevena NPWT.

Evaluate the clinical appearance and quality of the scar by filling out the Patient Observer Scar Assessment Scale v2.0 Nl and photos

Study design

This is a cohort study in patients with deep venous obstruction after a venous hybrid procedure (primary or secondary) to assess wound infection (and lymph leakage rate) after treatment with negative pressure incision management system. Subjects will visit the hospital with routine control moments and do not have to make an additional visit for this study.
As in standard care all patients will be seen on the outward patient clinic before treatment, after 1-2 weeks, 6 weeks, 3 months, 6 months and 12 months. On the first visit (pre-operative) all patients undergo duplex ultrasound and magnetic resonance venography as in standard care. The medical history, allergies and medication use will be recorded. Special attention will be paid to patients with prednisone because quality of skin and wound management is altered in these patients. In medical history special attention will be paid to diabetic disease, chronic obstructive pulmonary disease and collagen deficits because of the known wound healing problems in these patients. Body mass index and intoxications with especially smoking will be recorded. All of the above mentioned parameters are already scored in standard care. If by chance one of the factors of medical history is not scored, the general practitioner will be asked to provide this after inclusion of the patient.
Whenever a patient has post thrombotic changes below the sapheno-femoral confluents, a hybrid procedure is offered whenever complaints are severe. All patients will be informed about the standard treatment and addition of the negative pressure incision management system.
Whenever patients present after solely percutaneous recanalization and stenting with occluded stents, a thrombolysis is offered whenever complaints are heavy. If an additional AV-fistula is needed to guarantee stent flow these patients will also be informed about the study of the NPWT.
All patients receive 1-2 gram Kefzol 30 minutes before incision like our hospital policy explains. The hybrid procedure will be performed by recanalization and stenting with additional endoflebectomy by a longitudinal incision in the vein. The vein will be cleared and an arterio-venous fistula will be created between the common iliac vein and common iliac artery by using a PTFE loop. All patients have a gentamycin mesh and drain placement before wound closure because of the large lymphatic and seroma leakage during the first few days postoperative. Whenever drain production of the additional drain is below 50cc/ 24 hours this drain will be removed.

The only addition to aforementioned standard treatment is the use of the Prevena system. This will be placed on the operation theatre under sterile conditions (after disinfection with chlorhexidin and possible shaving of the inguinal area). The system will be placed on a closed inguinal wound. The negative pressure incision management system will be installed with a negative pressure of 120 mmHg during 7 days. Afterwards the first (out)ward patient clinic follow up will take place and wound evaluation will be performed. Whenever it is not possible to see the patient within 1 week the wound

management system will be asked to be removed by the general practitioner. This is possible because the system is attached like a plaster. Patients will be seen for their first postoperative visit within 2 weeks.
The goal of the study is to evaluate wound infections 3 months postoperative. Evenso the evaluation of the Patient and Observer Scar Assessment scale. Photos of the inguinal area will be taken at dismission, 7,15 and 30 days postoperative.
Whenever there is system failure and the patient is experiencing wound problems like redness, fever or purulent leakage oral antibiotic treatment will start. Whenever redness will increase or fever will be continuous patients need to be admitted to the hospital for intravenous antibiotic treatment like standard care.

Intervention

The Prevena system will be placed on the operation theatre like prescribed in user manual.

Study burden and risks

All patients will receive the Prevena negative pressure incision management system during 7 days postoperative. This system is used as a plaster with negative pressure vacuum and has no negative side effects besides possible errors in creating negative pressure or allergic reaction to ingredients of the used products. Another minor possible negative effect can be the fact that patients need to wear an extra (small) bag to save the canister. The advantage is this canister is lightweight and portable.
Patients will meet routine follow up moments (like all of our treated patients on 1-2 weeks, 6 weeks, 3 months, 6 months and 12 months postoperative) on the outward patient clinic and no additional visits will be necessary. At dismission, 7,15 and 30 days a photograph of the inguinal area will be taken. Patients and physician will be asked to fill out the Patient Observer Scar Assessment Scale v2.0 Nl on 3, 6 months and 12 months follow up to analyze the quality and clinical appearance of the wound.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-All patients with deep venous obstruction below the sapheno-femoral junction primary elective for hybrid procedure with creation of an AV-fistula in the MUMC.
-All patients with occluded stents treated by thrombolysis and in need of an additional AV-fistula in the MUMC.
-Patient must be able to fill in Dutch questionnaires and be able to communicate in Dutch
-Life expectancy >1 year

Exclusion criteria

-Patients with allergies for the components of the used negative pressure incision management system (Prevena)
-Known to be, or suspected of being unable to comply with the study protocol (e.g. no permanent address, known to be non-compliant or presenting an unstable psychiatric history)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-09-2016
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Prevena NPWT
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	20-07-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL56603.068.16