Mini moldable tunneler: a technical improvement for hemodialysis access

Mini tunelizador moldável: um avanço técnico no acesso vascular para hemodiálise

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Abstract

Background: Hemodialysis access fistula may involve creation of a tunnel for the accommodation of autologous vein or synthetic graft. The route and extent depend on the location of the anastomosis and fistula body.Currently, the tunnelers used are rigid metallic cylindrical structures. Various sizes and conformations may be necessary.
Objective: Testing the use of a mini universal moldable tunnel maker in hemodialysis access fistula surgical creation.
Methods: This is a pilot study. The tunneler developed consists of a cylindrical structure composed of stainless steel wire with a handle at the proximal end and dual interchangeable conical tip at the distal end. It is covered with a cylindrical sheath of polyethylene. Its technical surgical application and complications were studied during ten hemodialysis fistula creation.
Results: Characteristics of flexibility and conformability made possible the same mini tunnel maker to be used in various types of fistulas performed. The tapered distal tip with double diameter, interchangeable head, allowed the same apparatus to be used in autogenos and graft fistulas surgical creation.
Conclusion: The same mini malleable tunneler was used in all fistulas, regardless of the site of anastomosis and type of fistula performed without complications and with excellent patency rate.

Keywords: fistula; renal dialysis; surgery.

Resumo

Contexto: A confecção de fístula para hemodiálise pode envolver a criação de túnel para a acomodação do enxerto – veia autóloga ou prótese sintética. O trajeto e a extensão dependem do local escolhido para a realização das anastomoses e posicionamento do trajeto do enxerto. Na atualidade, os tunelizadores utilizados são constituídos de estruturas cilíndricas metálicas rígidas, que tornam necessário o uso de múltiplos tamanhos e conformações.
Objetivo: Testar a utilização de um único mini tunelizador universal metálico e moldável na cirurgia de confecção de fístula para hemodiálise.
Métodos: Trata-se de um estudo piloto. O tunelizador desenvolvido consiste de uma estrutura cilíndrica e modular composta de fio de aço inoxidável moldável interno, com manopla em extremidade proximal e dupla ponta cônica intercambiável em extremidade distal e bainha cilíndrica externa de polietileno. O tunelizador foi utilizado em dez cirurgias de confecção de fístulas para hemodiálise em membros superiores e inferiores, e o sucesso de sua aplicabilidade e a frequência de complicações precoces foram observados.
Resultados: Suas características de maleabilidade e conformibilidade permitiram a utilização do mesmo tunelizador nos diversos tipos de fístulas realizadas. A ponta cônica distal com duplo diâmetro, intercambiável, permitiu que o mesmo aparato fosse aplicado na utilização de veia autógena ou prótese sintética. Todas as cirurgias foram seguidas de sucesso e com baixos índices de complicações precoces.
Conclusão: A versatilidade do mini tunelizador metálico maleável e moldável permitiu sua utilização em todas as fístulas realizadas, independentemente do sítio das anastomoses e o trajeto de acomodação escolhido, sem complicações e com excelente índice de perviedade. Os dados sugerem que o mini tunelizador metálico maleável moldável pode ser utilizado com segurança e vantagens nas cirurgias de confecção de fístula para hemodiálise. Sua versatilidade e baixo custo de produção podem levá-lo a substituir os tunelizadores rígidos utilizados na atualidade e apontam para estudos mais elaborados e com casuística adequada para avaliação do real valor do novo instrumento.

Palavras-chave: fístula arteriovenosa; diálise renal; cirurgia.

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Introduction

The arteriovenous fistula surgically performed for hemodialysis may require the making of a tunnel to place the autologous vein or synthetic graft. The tunnel route and extension depend on the fistula location. The tunnelers currently in use are rigid metallic cylindrical structures. A set with tunnelers of,various sizes and conformations and even additional incisions may be necessary for graft placement. The available tunnelers can be a limiting factor for the making of such tunnels and predispose the patient to iatrogenic lesions and complications[1,2]. In a previously conducted study, we investigated the advantages of using a malleable tunneler in the revascularization of ischemic limbs[3].

This is a pilot study, which objective was to test the use of a universal malleable mini-tunneler in the surgical making of hemodialysis access fistulas.

Method

The metallic universal malleable tunneler was developed in the Bioengineering Laboratory of Instituto Dante Pazzanese de Cardiologia. It consists of a hybrid and modular cylindrical structure composed of: (1) an internal malleable stainless steel wire with a handle at the proximal end and dual interchangeable tapered tip at the distal end; (2) an external cylindrical sheath of transparent polyethylene (Figure 1).

During the conception phase of the device, some characteristics were sought,, such as a metallic alloy that could offer a balance between rigidity, flexibility and conformability to allow bending in several curved shapes, and utilization of the same tunneler, regardless of the type of fistula performed. Its dual interchangeable tapered tip allows to use the same device in fistulas made either of prosthesis or vein (Figure 2).

After this study was approved by the Research Ethics Committee, the universal mini-tunneler that had been developed was used in several types of fistulas performed by the principal investigator. (Figure 3) We observed the occurrences of early perioperative complications (30 days), as well as the fistula patency in the same time period.

Result

The initial experience with the mini-tunneler that has been designed was obtained with the following fistulas performed between September 2009 and November 2010 by the main author (Table 1).

The flexibility and deformation capability characteristics enabled to adapt and use the same mini-tunnel maker in various types of fistulas. The dual interchangeable tapered tip at the distal end allowed the same device to be used in both autogenous or synthetic fistulas.

The rate of complications was low (2%). A case of superficial surgical wound infection was treated with oral antibiotics and one superficial hematoma was followed up, without intervention. After an average follow-up period of 9.9 months (minimum: 2.0; maximum: 16.0 months), the patency index was 100%.

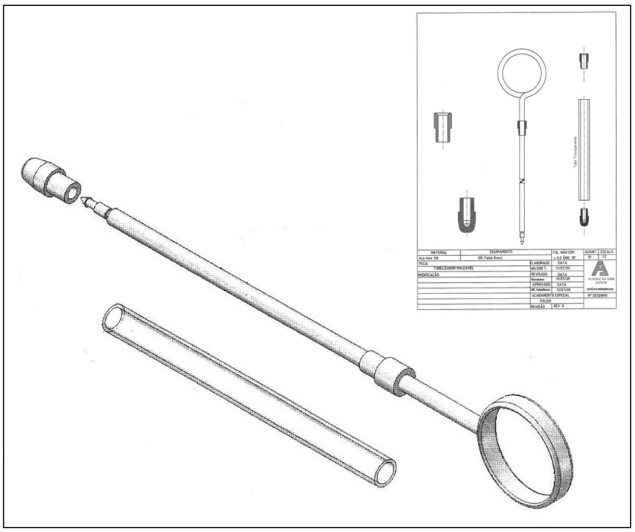

Figure 1. Industrial design of the mini universal tunneler.

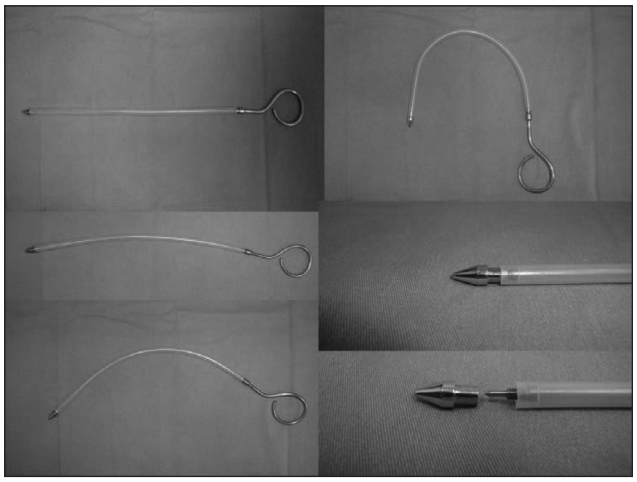

Figure 2. Mini universal tunneler in various curvatures and dual interchangeable tapered tip.

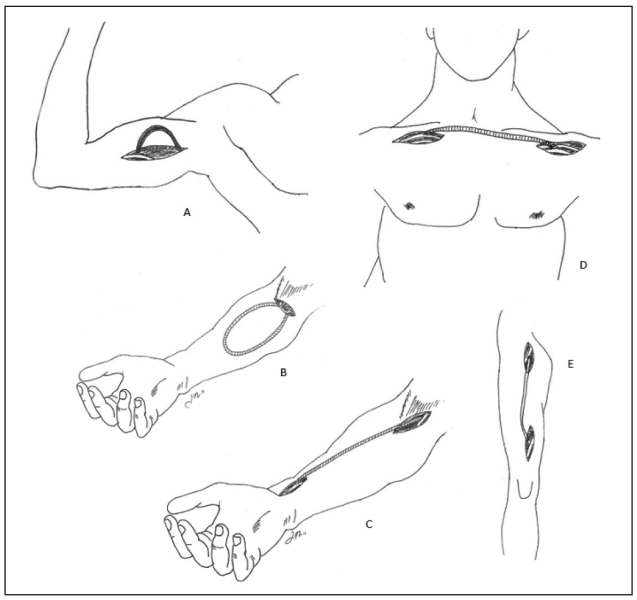

Figure 3. Examples of types of fistulas performed with the same mini universal tunneler: (A) basilic vein transposition; (B) brachio-basilic 6-mm PTFE forearm loop fistula; (C) straight radio-basilic, 6-mm PTFE forearm fistula; (D) axillo-axillary straight 6-mm PTFE fistula; (E) saphenous vein to superficial femoral artery fistula.

Table 1. Arteriovenous fistulas performed with mini universal tunneler and complications observed within max. 30 days after the surgery.

Patient	Age	Fistula	Complication
1	27	Brachio-basilic arteriovenous, 6-mm PTFE forearm loop fistula	-
2	34	Basilic vein transposition	-
3	65	Saphenous vein to common femoral artery arteriovenous fistula	-
4	36	Basilic vein transposition	-
5	70	Straight brachio-axillary arteriovenous, 6-mm PTFE fistula	-
6	77	Basilic vein transposition	Superficial infection of operative injury
7	25	Saphenous vein to superficial femoral artery arteriovenous fistula	
8	89	Axillo-axillary straight bridge arteriovenous, 8-mm PTFE fistula	-
9	56	Basilic vein transposition	-
10	67	Saphenous vein to superficial femoral artery arteriovenous fistula	Superficial hematoma
11	72	Straight radio-basilic arteriovenous, 6-mm PTFE forearm fistula	-

Discussion

Hemodialysis is the type of treatment relatively well tolerated by the patient with end-stage renal failure. It is estimated that 373 patients in the United States and 171 in Europe *per* one million inhabitants, are on hemodyalisis[4]. Around 40% of Medicare's funding for renal disease - i.e., US$6 billion - are spent annually with these patients[5].

In Brazil, according to data from DATASUS, the number of patients that develop end-stage renal failure has increased. In 2008, 87,000 patients were on hemodialysis, which means an 87% increase over year 2000 figures.

For a patient to start a hemodyalisis treatment program, it is essential to have a working AV fistula. Fistula failure and complications are the main causes of hospital admission and and overall costs (in the USA, US$500,000/year) of patients in a hemodialysis program[5,6].

Operative wound infection and necrosis are the most frequent early complications of access fistula operations [7,8] and graft tunneling can an important factor in the occurrence of these complications. It is widely known that the fistula should be placed neither very deeply, as it can make puncture difficult, nor very superficially, which may increase the risk of operative wound necrosis and infection. The number of incisions and extent of surgical dissection required for graft tunneling can influence the incidence rate of infection[9]. Using the device presented in this study may reduce the number of incisions and probably the rate of infection. The location[9], configuration[10] and material[11] used in making the access fistula are factors that can affect the frequency of complications.

Indications for hemodialysis have been extended. Patients undergoing hemodyalisis are increasingly older, diabetic, immunodepressed, clinically unstable and sometimes have been submitted to multiple accesses in the past, increasing the complexity of the operation. It is not uncommon to see graft tunneling in extra-anatomical positions, with long prosthesis and even with partial utilization of previous fistulas.

In our study, new fistulas were performed in two patients with partial utilization of previous fistulas. In the first case, the patient developed an infected pseudoaneurysm in the middle segment of a previous basilic vein transposition. After local drainage, debridement and sterile isolation of the site of infection, a new 6-mm PTFE fistula was performed between the remaining basilic vein segment anastomosed in the brachial artery and the axillary vein, as the patient did not have any autogenous veins in the reoperated limb.

In the second patient, a fistula performed with the saphenous vein in the distal superficial femoral artery developed early obstruction, and a new loop fistula was made with anastomosis to the ipsilateral common femoral artery.

Currently available rigid tunnelers molded in pre-determined curves can be of limited use or may even cause injuries to structures and organs present in the alternative fistula routes.

There is no description in the literature of a malleable tunneler similar to the model presented here. Our initial experience in performing fistula operations for hemodialysis, using the same concept of a malleable tunneler that had been used in revascularization of ischemic lower limbs[3], showed only two cases of mild complications (superficial infection, hematoma), which were treated conservatively. These results, combined with the universal mini-tunneler easy maintenance, low cost and versatility, indicates that it can replace with advantages the currently used rigid models.

Conclusion

Data from this study suggest that the metallic malleable mini-tunneler can be used with safety and advantages in fistula operations for hemodialysis. Its versatility and low production costs may lead it to replace currently used rigid tunnelers and indicate that further studies with larger number of cases are requiredto assess the real value of this new device.

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