

Improved Primary Patency Rate of Hemodialysis Arterovenous Grafts Associated With Modified Stretch e-PTFE Vascular Grafts (Gore) by Compliant ePTFE Cuff

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Abstract

Purpose: The aim of this study was to value the performance of a modified commercially available longitudinal stretch expanded polytetrafluoroethylene (ePTFE) vascular Gore (W.L.Gore & Associates, Flagstaff, Arizona) graft (either Intering or heparin-bonded Propaten) with an added handmade compliant ePTFE cuff in arterovenous grafts (AVG) for hemodialysis, valuing the primary patency rate at 12 months.

Methods: 25 patients consecutively underwent AVG's with 8 modified stretch Intering grafts (mIG) and 17 modified stretch Propaten grafts (mPG). The modified grafts were obtained during surgical procedures assembling to the major host of a tapered stretch (longitudinal) ePTFE hemodialysis Gore graft, an hand-made cuff of the same material but turned at 90° to obtain a radial stretch (previously reported in experimental animal study). Primary patency rate of these modified grafts was evaluated at 12 months and the results compared with our previous experience: 60 consecutive cases with the same unmodified grafts (53 Intering and 7 Propaten grafts).

Results: In 25 patients with the modified grafts the cumulative primary patency rate of arterovenous grafts at 12 months was 91.3% with a one year mortality of 12%, while in our previous consecutive experience, primary patency and mortality rates in 60 patients with unmodified grafts were 60.4% and 11.7%, respectively. Valuing the overall combined primary patency rate of arterovenous grafts of the two groups (modified vs. unmodified grafts) with Kaplan Meyer curve and Logrank test the difference was statistically significant: Chi square=7.115, p=0.007. On the contrary analyzing the two subgroups with modified grafts (mIG vs. mPG) primary patency rates were 100% in both at 6 months, 87.5% and 94.1%, respectively at 12 months (statistically not significant).

Conclusions: The preliminary results of modified stretch ePTFE vascular grafts with compliant ePTFE cuff significantly seem to improve the vascular access graft patency, independently by the used stretch graft (heparin-bonded or not).

Keywords: Access stenosis; Access thrombosis; Arterovenous PTFE graft; ePTFE vascular graft; Intimal hyperplasia; Vascular access

Introduction

After the introduction of the "Fistula First" break through initiative [1] the primary vascular access of choice for hemodialysis (HD) is considered the autogenous arteriovenous fistula (AVF) [2,3]. However, this type of vascular access not always has a good hemodialysis efficiency for inadequate maturation of AVF or it is not possible for its creation for unsuitable vessels (arteries in diabetic or elderly patients; exhaustion of superficial veins after long-term HD, etc) [4]. In those cases the use of prosthetic arteriovenous grafts (AVGs) is mandatory even if these access modalities are associated with greater morbidity than with AVFs and they have inferior primary and secondary patency rate compared to AVFs [5]. Polytetrafluoroethylene (PTFE) is the main graft material used for AVG's in chronic hemodialysis but these AVG's are prone to failure caused by stenosis and occlusion. Stenosis occurred most commonly at the graft-venous anastomosis (50% at 1 year and 67% at 2 years after implantation) [6] and it mainly depend on neointimal hyperplasia (NH) development. Compliance mismatch between wall-graft and wall-vein [4,7] flow disturbance [8,9] and vein-wall vibration [10] at vein-graft anastomosis are retained as the main causes of NH development at that site. In the past to diminish the impact of these three causes various prevention strategies (vein cuff between graft and vein, precuffed grafts, etc) [11,12] have been used but the results have not been satisfactory. On the contrary as we showed in experimental animal study, by modifying commercially available stretch (longitudinal) PTFE Gore grafts with a compliant PTFE cuff (patent pending: PCT/IT2010/000146), it was possible to prevent NH and related stenosis [13]. For that reason AVG's were created with

these modified PTFE grafts in a group of hemodialysis patients to verify that supposed primary patency graft improvement also in humans.

Methods

In the period 2009-2010, 197 vascular accesses were created for patients in chronic hemodialysis: 172 (87.3%) were AVF's and 25 (12.7%) AVG's. All AVG's of that period were created using modified commercially available tapered (4-7 mm) longitudinal stretch ePTFE Gore grafts (8 modified standard-walled stretch Intering grafts called mIG and 17 modified stretch heparin-bonded Propaten grafts called mPG; W.L. Gore & Associates, Flagstaff, Ariz). These grafts were modified during the surgical procedures adding to their major host, an hand-made cuff obtained cutting a short segment of the same graft lengthwise which was then sewn crosswise (rotated 90°) [13]. The cuff had the same diameter of the major host of the graft (Figure 1). All 17 mPG and 5 mIG were implanted with J-loop shape (Figure 2a) between brachial artery (end-to-side 80°; 5 mm length) (Figure 2b) and

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Figure 1: Hand-made cuff with the same diameter of the major host of the graft.



Figure 2A: Arteriovenous graft All 16 mPG with J-loop shape between brachial artery and axillary vein.

axillary vein (end-to-side 45°; 12 mm length) (Figure 2c) while 3 mIG were implanted with U-loop shape between femoral artery and great saphenous vein. Anastomosis were created using 6/0 polypropilene continuous sutures. In all patients AVG's have been created by one author (G). All patients had the same clinic characteristics (sex, age, diabetes etc) with previous vascular access (range 4 - 10, mean 6) and without any suitable native veins for a new autogenous AVF's. All the patients received ASA 100 mg a day for life and Ticlopidine 250 mgr twice a day for one month. Primary patency graft rate of AVGs with modified grafts was analyzed at 12 months and compared with our previous experience (2005-2009) of a consecutive series of AVG's [60 cases (11.7%) of 512 vascular access], created by the same author (G) with the same unmodified grafts (53 consecutive Interling grafts and following 7 consecutive heparin bonded Propaten grafts) (55 AVGs in the upper arm and 5 in the lower limb with the same surgical modalities of the group with modified grafts) .

The primary patency rates were calculated with Kaplan-Meier survival curves for the two groups and Log-rank test was used to assess the statistical significance of the difference between the two groups (modified vs. unmodified) and between the two subgroups of modified grafts (mIG vs. mPG). Primary patency rate was defined as the percentage of grafts that functioned well without any surgical or endovascular intervention after implantation. All cases considered, out of the patients with events or censored during follow-up, had a minimum of 12 months of follow-up, but primary patency rate times longer than 12 months were censored at 12 months from the date of AVG creation.

Results

One patient with mIG and two patients with mPGs have died with one year mortality of 13.6%.in the group with modified graft. The

primary patency rate for all 25 modified stretch PTFE grafts was 91.3% at 12 months, while in our previous consecutive experience, primary patency and mortality rates in 60 patients with unmodified grafts were 60.4% and 11.7% respectively. Valuing the overall combined primary patency rate of arteriovenous grafts of the two groups (modified vs. unmodified grafts) with Kaplan Meyer curve and Logrank test the difference was statistically significant: Chi square=7.115, p=0.007 (Figure 3). On the contrary analyzing the two subgroups with modified grafts (mIG vs. mPG), primary patency rates were 100% in both at 6 months, and 87.5% and 94.1%, respectively , at 12 months (statistically not significant) (Figure 4). Nevertheless in the mIG group the only case

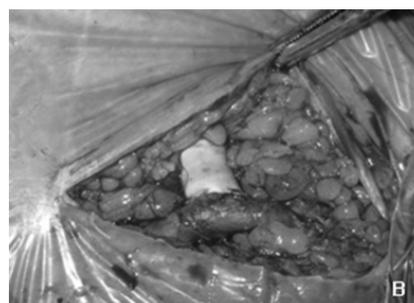


Figure 2B: Arterio-graft anastomosis (end-to-side 80°; 5mm length).



Figure 2C: Vein-graft anastomosis (end-to-side 45°; 12 mm length).

ArteroVenous Graft Primary Patency Rate, 12 Months

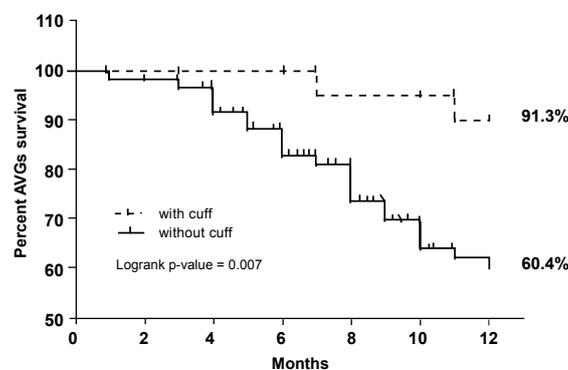
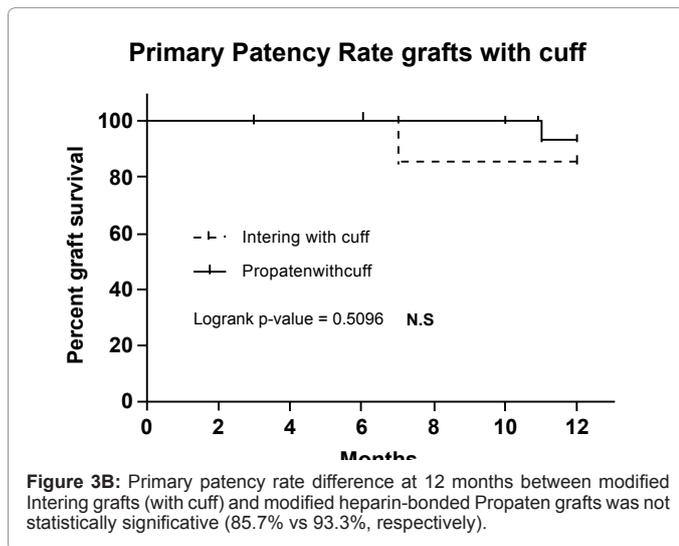


Figure 3A: Kaplan Meyer survival curves to estimate primary patency rate at 12 months for all 25 cases with modified grafts (with cuff) (91.3%) and all 60 cases with unmodified grafts (without cuff)(60.4%). Difference statistically significant : Logrank test p-value 0.007. Each tick marks on curves represents an event i.e, patient death, time of graft occlusion or endovascular o vascular adjunctive procedures.



with graft failure did not depend on stenosis at vein-graft anastomosis but it depended on acute graft thrombosis after myocardial infarction and cardiac failure, which was solved with thrombolytic therapy. In the lower limb all 3 cases with mIG were patent at 12 months, while all 5 with unmodified Intering Grafts were failure after 2,5,6,6 and 7 months, respectively. Any cases with modified graft showed bleeding or pseudoaneurysm at graft-cuff-vein anastomosis.

Discussion

AVF is the first option for the patients in chronic hemodialysis but in some cases after the AVF's failure or in patients with unsuitable superficial veins or in obese or diabetic patients it is mandatory for the use of AVG's. Although AVG's are easier to create and can be used more quickly, the results were not satisfactory in the time with a mean primary patency rate less than 60% at 12 months [6,12]. The major cause of failure of synthetic grafts depend on irreversible thrombosis, superimposed on hemodynamically significant vascular stenosis at vein-graft anastomosis due a progressive neointimal hyperplasia (NH) development. The PTFE is the material more used for AVG's but neither the grafts with different shapes (tapered vs. non tapered) [14], nor with vein cuff at one side [11], precuffed graft [12], different structures of ePTFE grafts (stretch vs. non stretch) [15] solve or reduce that complication. Davidson et al. [16], in 2009 using heparin bonded hemodialysis ePTFE grafts, reported better clot free survival benefit than standard ePTFE vascular hemodialysis grafts (78% vs. 58% respectively) at 12 months, but 38% of his cases had a follow-up time of less than 6 months and it is well know [6] that the most dangerous time for the NH development and followed stenosis and occlusion of the grafts is the period between six and twelve months. In our previous experimental study in swine [13], we showed any differences on NH development between standard ePTFE graft and heparin bonded ePTFE grafts used as AVGs, while on the contrary using the same modified grafts with a compliant ePTFE cuff at vein-graft anastomosis we were able to inhibit NH in both graft types. For that reason, we used these modified ePTFE grafts in humans, and we valued their performance in terms of primary patency rate at 12 months. Our preliminary results showed high primary patency benefit of AVGs created with these modified grafts, and confirming our experimental data. In fact though the number of the evaluated patients was little and longer time for follow-up should be necessary, the preliminary results of this clinic study confirm a lesser graft failures using these compliant grafts compared with commercially available ePTFE grafts, independently by the stretch ePTFE Gore grafts

used (Intering or heparine-bonded Propaten graft). Unfortunately the AVG failure in hemodialysis patients does not only depend on progressive stenosis at vein-graft anastomosis but also for acute or recurrent systemic blood hypotension and therefore the mPG could play an additional role in the prevention of graft thrombosis and in cumulative patency rate of AVG's in long time. Anyway these data could open a great scenario about new strategy on vascular access. In fact though in recent years, there has been a great push called "Fistula First" to promote arteriovenous fistulas as the first line of treatment vs. AVGs, many authors, especially in USA, reported various cases with immature AVF's and other the high incidence of patients with unsuitable vessels for AVF's (diabetes, obesity) [4,5]. In these cases these modified grafts would provide a superior alternative to the native fistula as hemodialysis vascular access.

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