

ORIGINAL ARTICLE

EVIDENCE BASED COMPARISON OF BASILIC VEIN SUPERFICIALIZATION VERSUS SYNTHETIC POLYTETRAFLUOROETHYLENE (PTFE) GRAFTS FOR HEMODIALYSIS.

By

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Aim: To use evidence based data to compare basilic vein superficialization & synthetic graft for hemodialysis.

Patients and methods: Two groups of patients:

Group 1: 50 patients with basilic vein superficialization .

Group 2: 50 patients with synthetic PTFE graft.

The comparison includes: indications, patency rates using and complications

Results: Statistical analysis of the results for both groups was done to determine the indications, type of anesthesia used, time consumed in operation theatre primary & secondary patency rate & complications.

Functional patency rate at one & two years was better in group 1 than group 2 ($P < 0.05$) which is statistically significant.

In group 1 local anesthesia was more used than group 2 and with less need for additional sedation, but the difference was not significant.

The mean time consumed for operation of prosthetic graft is (54.6+10.6 min) which was shorter than that used for superficialization of the basilic vein but this was not statistically significant.

As regarding complications: Infection, thrombosis and pseudoaneurysms were statistically significant higher in group 2 than group 1, while the rate of bleeding, venous hypertension & steel were also higher in group 2 but the difference was not statistically significant.

The role of successful endovascular management of segmental stenosis was statistically significantly higher in group 1.

Conclusion: Superficialization of the basilica vein provides superior patency and less complication rates compared to synthetic PTFE graft.

Keywords: Renal failure, Arterio-venous fistula, Synthetic grafts.

INTRODUCTION

Long term vascular access has become more important as patients live longer on hemodialysis. Improved survival has resulted in an increasing number of patients with failed vascular access so an increasing number of options for vascular access should be added to the surgeon's experience.⁽¹⁾

Superficialization of the basilic vein means mobilization and transposition to a more superficial position, basilica

vein is usually not accessible to routine venipuncture or phlebotomy but it needs more dissection and time than do other angioaccess. The long term patency is good with fewer complications than artificial grafts, it also leaves a chance to use the ipsilateral axillary vein for implantation of a synthetic graft after failure of basilica vein superficialization.^(2,3) Synthetic PTFE grafts were considered in some studies as the best secondary angioaccess. Being placed for almost any artery to any vein of sufficient size to permit an anastomosis and are readily available in various lengths, diameters, and configurations.

It could be used early without a higher incidence of complications.⁽⁴⁻⁶⁾

Aim: The lack of compelling evidence in the literature to support the use of either basilica vein superficialization or synthetic PTFE grafts as a secondary angioaccess was initiating factor to compare them in this study.

PATIENTS AND METHODS

100 patients with chronic renal failure on hemodialysis after failure or unreconstructable primary radiocephalic fistula were included in this study.

They were randomly divided into 2 groups.

Group I: 50 patients were subjected to superficialization of the basilic vein. Technique is shown in (Figs. 1a,b).

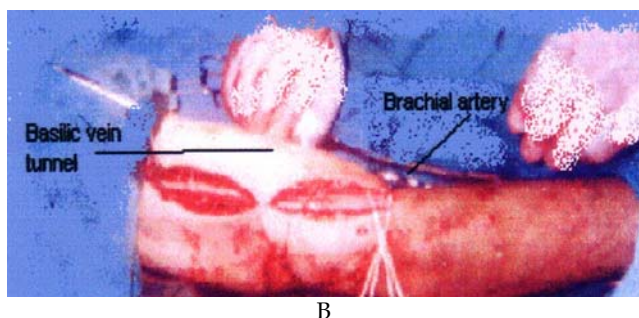
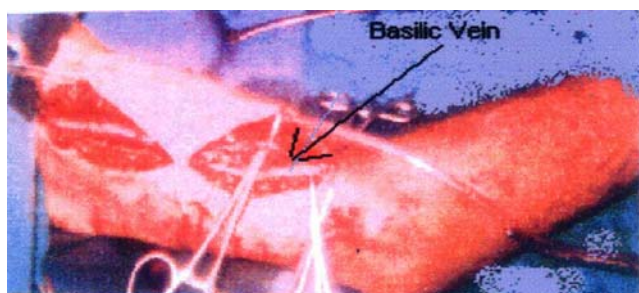
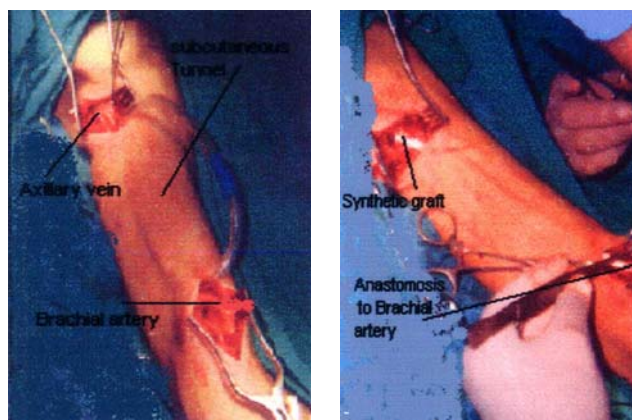


Fig 1a,b. Superficialization of The Basilic Vein.

Group II: 50 patients were subjected to insertion of synthetic PTFE grafts.

Technique is shown in Figs. (2a,b,c).



A

B



C

Fig 2.a,b,c. Prosthetic graft.

In all patients, an informed consent was obtained.

Preoperative assessment was done for all patients in the form of;

Preoperative laboratory investigations (blood picture, kidney function coagulation profile). Preoperative assessment of upper limb using Duplex ultrasonography for vein mapping and arterial flow at the targeted site for angioaccess.

In this study strict instructions were given to the nephrologists to delay the puncture of the vein or graft until the period of maturation required for dilation and thickening of the vein or incorporation of the prosthetic graft material into the surrounding subcutaneous tissues is reached.

Follow up: Patients were followed up for assessing the primary and secondary patency rates and complications, in both groups.

The secondary patency should be accurately calculate at the time of correction of a defect in an Arterio venous fistula or synthetic graft by intervention leading to restoration of normal blood flow.

In addition to the routine access examination in the hemodialysis unit for monitoring of the venous pressure and access flow, duplex ultrasonography was performed every 3 months (up to 2 years) for early detection of complications and access surveillance.

Finally statistical analysis was used to incorporate the evidence based data to compare the results in both groups following a set of pre-specified test to compare the patency rates (using log rank test) and the incidence of complications (using chi-squared test) for proper surgical decision making.

RESULTS

The demographic data in both groups are shown in Table 1.

Table 1. Demographic data in both groups.

Patient characteristics	Group I	Group II
Age	48(17-66 years)	46 (20-64 years)
Sex ratio (male/female)	23/27	26/24
Diabetes mellitus	26 (52%)	24 (48%)
Coronary heart disease	12 (24%)	10 (20%)
Hypertension	16 (32%)	18 (36%)
Previous A-V fistula	30 (60%)	34 (68%)

The aetiology of performing secondary angioaccess in both groups is shown in Table 2.

Table 2. Causes for secondary angioaccess.

Reasons for secondary angioaccess	Group I (50 patients)	Group II (50 patients)
Thrombosed cephalic vein.	15(30%)	16(30%)
Unsuitable cephalic vein for anastomosis.	10(20%)	8(16%)
Failure of primary fistula	20(40%)	18(36%)
Early cannulation of primary fistula.	5(10%)	8(16%)

Type of anesthesia used in both groups is shown in Table 3.

Table 3. Type of anesthesia used in both groups.

Type of anesthesia	Group I	Group II
Local infiltration	40(80%)	36(72%)
Local +Sedation	8(16%)	11(22%)
General	2(4%)	3(6%)

In both groups the operation could be performed under local infiltration anesthesia (80%) in group I and (72%) in group II, while 16% in group I and 22% in group II required additional sedation by intravenous agents. the incidence of general anesthesia was 4% in group I and 6% in group II, The difference in both groups was not statistically significant.

The mean time consumed for each operation is shown in Table 4.

Table 4. mean operative consumed time in both groups.

Group I	Mean Time:(62,2 +12.4)minute
Group II	Mean Time:(54,6+10.8) minute

The mean time for prosthetic PTFE grafts is shorter than that required for basilic vein superficialization ,but this was not statistically significant.

Functional patency was defined as the ability to cannulate and hemodialyse the patient successfully. Primary and secondary cumulative patency of both groups were analysed using the Log-rank test at one and two years, and are shown in Table 5.

Table 5. Primary and secondary patency rates at 1 and 2 years.

Patency Rate	Group I	Group II
1ry patency rate at 1 year	86%	70%
2ry patency rate at 2 years.	82%	60%
2ry patency rate at 1 year	92%	82%
2ry patency rate at 2 years.	84%	68%

The primary and secondary functional patency rates at 1and2 years for group I were better than in group II ,which is statistically significant. (p <0.05)

The complications in both groups are shown in Table 6.

Table 6. Complications in both groups.

Complications	Group I	Group II	P value
Infection	3(6%)	9(18%)	P<0.05
Bleeding	3(6%)	4(8%)	NS
Venous hypertension	3(6%)	4(8%)	NS
Vascular steel	3(6%)	3(6%)	NS
Thrombosis	5(10%)	9(18%)	P<0.05
Pseudoaneurysm	5(10%)	11(22%)	P<0.05

P<0.05 is of significance
NS=Non Significant.

Examples of complications of both groups are shown in (Figs. 3a,b,c).

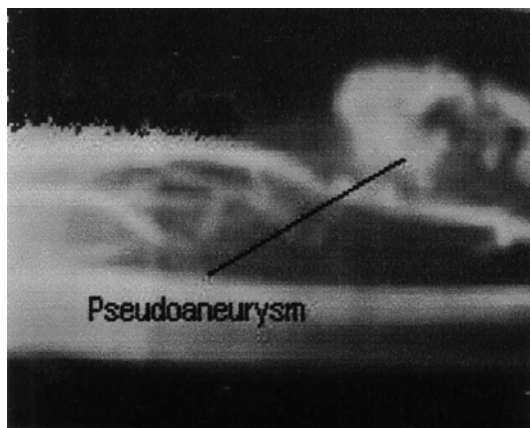
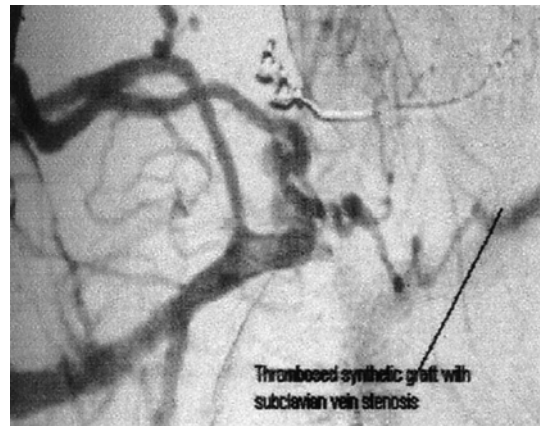


Fig 3a. Pseudoaneurysm



Fig 3b. Steel syndrome



C

Fig 3c. Thrombosed graft

The role of endovascular management of segmental stenosis during the surveillance of both groups is shown in Table 7.

Table 7. Endovascular management.

Endovascular procedures	Group I	Group II
Successful	4 (8%)	1 (2%)
Failed	1 (2%)	8(16%)

The role of endovascular management was more successful in group I,

which is statistically significant P<0.01.

There was no mortality in both groups during the period of follow up (2 years)

DISCUSSION

The improved survival of patients on hemodialysis has resulted in an increasing number of patients with a need for secondary angioaccess, both transposed basilic vein and synthetic PTFE grafts are common angioaccess operations. However there was no universal standard choice for one operation supported by evidence based data. The superiority of basilica vein superficialization in the literature is based on its protected position in the arm being deep and usually not visible and is usually a relatively large conduct. The patency rates at one year in different studies ranged from (69-90%).^(1,7-10) while the patency rate for synthetic PTFE grafts at one year in other studies ranged from (60-85%).⁽¹¹⁾In the literature there is no compelling evidence to support the priority of performing either basilic vein superficialization or synthetic PTFE

grafts. The advocates of basilic vein superficialization reported long term patency rate with fewer complications.^(2,12,13) while others reported that complications were higher in basilic vein superficialization (20%) versus PTFE grafts (5%)⁽¹⁰⁾ and the patency rate is comparable to basilic vein superficialization with available various lengths, diameters and configurations to be placed for any anatomy to any vein of sufficient size.⁽⁴⁻⁶⁾ Evidence based medicine is a systematic structure of non-consensus method employed to define the best scientific available therapeutic interventions ultimately, the goal is to improve both surgical decision making and patient outcomes. In this study a specific question regarding the use of either basilic vein superficialization or PTFE grafts as a secondary angioaccess is to be answered following a set of pre-specified test to compare the patency rates (using log rank test) and the incidence of complications (using chi-squared test). The statistical analysis revealed that in both groups the operation could be performed under local infiltration anesthesia and a minority required either additional sedation or general anesthesia (4% in group I and 6% in group II). The use of local infiltration anesthesia in group I (80%) needed 16% additional sedation and in group II (72%) needed 22% additional sedation. But the difference in both groups was not statistically significant.

In the literature, basilic vein transposition was recorded to be performed under general anesthesia in the majority of patients.⁽¹⁴⁾

There was no statistical significant cause among the reasons for secondary angioaccess in both groups.

The mean time consumed for operation in group II (54.6±10.8 minutes) was shorter than that of group I (62.2±12.4 minutes), but this was not statistically significant.

The functional primary patency rates at one and two years in group I were 86% and 82%, and in group II were 70% and 60%. The secondary patency rates at one and two years in group I were 92% and 84%, and in group II were 82% and 68%.

Analysis of the functional patency rates using the Log-Rank test showed that primary and secondary functional patency rates at one and two years for group I were better than group II, which is statistically significant. ($P < 0.05$).

As regarding complications in both groups: Infection rate after the period of follow up in group I was 6% and 18% in group II.

The incidence of infection in PTFE grafts in the literature

ranged from 5% to 12% per year.⁽¹⁵⁻¹⁷⁾ The incidence of infection in this study and in the literature is significantly higher in prosthetic PTFE grafts than that in basilic vein superficialization. In this study the incidence of thrombosis was 10% in basilic vein superficialization and 18% in PTFE grafts which was statistically significant ($p < 0.05$). In the literature the incidence of graft thrombosis was also significantly higher than autogenous fistula (64% versus !%).⁽¹⁸⁾ In another study the risk of thrombosis was reported to be 2.6 times in PTFE grafts than basilic vein superficialization.⁽¹⁷⁾ The role of endovascular management of segmental stenosis during the surveillance of both groups showed significant response in patients with basilic vein superficialization 4:1 in comparison to PTFE graft 1:8 ($P < 0.01$). The incidence of pseudoaneurysm formation secondary to graft infection or trauma in this study was significantly higher in PTFE grafts 22% versus 10% in basilic vein superficialization. The incidence of pseudoaneurysm formation in prosthetic graft was found to be higher than basilic vein superficialization in other studies.^(12,18) In this study the incidence of vascular steal due to reversal of arterial flow distal to the anastomosis was 6% in group I and II, and it was also reported in literature for both proximally based autogenous or prosthetic fistulae and the incidence ranged from 4-10%.⁽¹⁸⁻²⁰⁾ In this study the venous hypertension was recorded in 6% in patients of group I and in 8% of group II with no statistical significance. Also the incidence of bleeding in group I was 6% and 8% in group II with no statistical significance. The cost of operation is double with PTFE grafts.

In conclusion basilic vein superficialization provided better cumulative patency rates than PTFE grafts with fewer surgery related complications. So, there is a strong evidence to support the use of basilic vein superficialization as a secondary angioaccess before the placement of prosthetic PTFE grafts. Further national meta-analysis is required to support this evidence based study.

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