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Comparitve study between synthetic brachio - axillary and brachio - vena comitans grafts for haemodialysis

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***Abstract*---**Background: Hemodialysis is dependent upon the construction, maintenance and preservation of a good vascular access. Objectives: To compare between brachio venacomittant graft and brachio Axillary graft in patients with chronic renal failure with exhausted upper extremity superficial venous accesses, for the purpose of regular haemodialysis, as regard to patency, function criteria (fistula thrill) and complications. Subjects and methods: This prospective randomized study was being conducted on 50 patients with end stage renal disease. It was being carried out at the department of vascular surgery, Al-Azhar University Hospitals (Al-Hussein and Bab-Alsheryah University Hospitals). Cases were being divided into two groups: Group (A): 25 patients were undergone Brachio axillary graft and Group (B): 25 patients were undergone Brachio venacomittant graft. Results: Regarding Access failure, 12.0% at 6 m, in group A. 32.0% at 6 m, in group B, regarding Primary patency, 68.0% at 6 m, in group A. 56.0% at 6 m, in group B, regarding secondary patency, 72.0% at 6 m, in group A. 56.0% at 6 m, in group B. There was insignificant difference between both groups as regard Access failure, primary and secondary patency. Conclusion: In patients with poor preservation of all veins of the upper limb, B-Ax AVG showed superiority in functionality and safety compared to AVG using other upper limb veins. The complication rates in both study groups were non statistically significant difference. Therefore,

considering the age, underlying disease, and expected lifespan of the patient group, B-Ax AVG creation is an acceptable surgical method for select patients.

***Keywords*---**fistula, axillary vein, renal dialysis, brachio venacomittant graft.

Introduction

End stage renal disease (ESRD) is a huge public health problem with significant morbidity, mortality, and cost. Creation and maintenance of dialysis access are of special concern. Vascular surgeons are predominantly involved in the care of patients with ESRD in terms of establishing and maintaining access for haemodialysis.[1] Hemodialysis remains the commonest mode of renal replacement therapy for end stage renal disease patients (ESRD) worldwide. Nearly 80% of ESRD patients in Singapore were on hemodialysis. The Kidney Disease Outcome Quality Initiative (KDOQI) guidelines recommended autogenous arteriovenous radiocephalic (RC AVF) or a brachiocephalic fistula (BC AVF) as the first-line options for vascular access.[2]

Successful hemodialysis relies on the selection of an optimal site and conduit for vascular access (VA). The arteriovenous fistula (AVF) is considered the gold standard of VA due to its superior patency, lower complication rates and reduced costs.[3] The arteriovenous fistula (AVF) remains the best vascular access for patients on hemodialysis (HD), showing better survival and lower complication rates than arteriovenous grafts (AVG) and tunneled dialysis catheters (TDCs).[4] Ideally, having a mature AVF created before initiating renal replacement therapy will avoid the need for a central venous catheter (CVC) associated with increased complications, morbidity, and mortality.[2,5,6]

Unfortunately, the anatomy and the vessel conditions in chronic kidney disease (CKD) patients are not always conducive to autologous AVF creation. In the absence of suitable veins for AVF creation, the remaining access options are either a TDC or AVG creation, with AVGs being the more favorable option. TDCs are problematic for multiple reasons, including the commonly encountered long-term complications of infection, stenosis, and catheter dysfunction.[6] Compared to AVFs and AVGs, TDCs are associated with the greatest all-cause and infection-related mortality. As a result, the aforementioned are the least desirable choice for long-term vascular access.[7]

AVGs can be created in a variety of anatomical locations. Still, the two most common configurations are the forearm loop graft using the brachial artery and a suitable vein in the antecubital fossa, and the straight upper arm graft using the brachial artery to either the axillary, proximal brachial, or proximal basilic veins.[8] Lower extremity thigh grafts are possible but should only be considered if no other access option exists, as thigh grafts have higher morbidity than upper extremity AVGs.[9] The main aim of this study was to compare between brachio venacomittant graft and brachio Axillary graft in patients with chronic renal failure with exhausted upper extremity superficial venous accesses, for the purpose of regular

hemodialysis, as regard to patency, function criteria (fistula thrill) and complications.

Patients and Methods

This prospective randomized study was conducted on 50 patients with end stage renal disease. It was carried out at the department of vascular surgery, Al-Azhar University Hospitals – Cairo (Al-Hussein and and Bab- Alsheryah University Hospitals).

Cases were divided into two groups: Group (A): 25 patients were undergone Brachio axillary graft, and Group (B): 25 patients were undergone Brachio venacomittant graft.
Inclusion criteria: Patients with end stage renal disease in need for permanent access for haemodialysis, and exhausted upper extremity superficial venous accesses.
Exclusion criteria: Patients with suitable superficial venous system for fistula creation, patients with previous ligation of the brachial artery, and patients with central venous obstruction at the same side.

Patients were subjected to the following

- Full history taking.
- Full clinical examination.
- General examination.
- Local examination of the upper limbs
- Chest X-ray.
- Duplex Ultrasound for the venous and arterial systems in both upper limbs.

Data was collected and maintained regarding to: age, gender, other chronic diseases such as diabetes mellitus, hypertension, ischaemic heart disease, cerebrovascular accident, dyslipidemia. In addition to full details of duplex scanning.

Pre-operative Assessment

Doppler/duplex scan was performed for all patients. The duplex scan protocol included visualization of both arterial and venous systems. In addition to detection of the occluded vessels in the upper limbs as a result of previous multiple operations or obliterated or unsuitable small veins.

Operative procedure: Group (A): 25 patients were undergone Brachio axillary straight graft under local or general anaesthesia, and Group (B): 25 patients were undergone Brachio venacomittant loop graft also under local or general anaesthesia. Expanded PTFE graft was used. This graft is less prone to steal syndrome, more resistant to infection and long term patencies.

Follow up of the patients

Patients was evaluated and followed up immediately at the first postoperative day then at one week, 1 month, 3 months and 6 months as regard to patency, functioning of the graft, resistant to infection, primary patency, the validity period of the process, blood flow rate during hemodialysis, as well as incidence of complications as thrombosis, infection, steal syndrome, pseudoaneurysm formation, venous congestion.

Statistical analysis

The collected data was collected, tabulated, and statistically analyzed using SPSS program (Statistical Package for Social Sciences) software version 26.0, Microsoft Excel 2016. Descriptive statistics were done for numerical parametric data as mean± SD (standard deviation) and minimum & maximum of the range and for numerical non parametric data as median and 1st& 3rd inter-quartile range, while they were done for categorical data as number and percentage. Inferential analyses were done for quantitative variables using independent t-test in cases of two independent groups with parametric data and Mann Whitney U in cases of two independent groups with non-parametric data. Inferential analyses were done for qualitative data using Chi square test for independent groups. Wilcoxon Rank test was used to assess the statistical significance of the difference of a non - parametric variable between related samples. The level of significance was taken at P value <0.05 is significant, otherwise is non-significant. The p-value is a statistical measure for the probability that the results observed in a study could have occurred by chance.

Results

Table (1): Demographic and anthropometric characteristics among the studied groups

		Group (A) (n = 25)		Group (B) (n = 25)		Test value	P-value
		N	%	N	%		
Sex	Male	14	56 %	15	60%	X^2= 0.08	0.77
	Female	11	44 %	10	40%		
Age		51.3± 5.3		52.7± 5.8		1.19	0.66
BMI (kg/m2)	Mean± SD	26.2± 2.22		26.50± 2.3		X^2= 1.07	0.86
Weight	Mean± SD	77.4± 6.2		77.6± 5.9		Z= MWU 1.10	0.81

P value< 0.05 is significant, P value< 0.01 is highly significant, SD: Standard deviation, ZMWU = Mann- Whitney U test, X^2= Chi- Square test

Table (1) showed demographic characteristics among the two studied groups. The mean age 51.3± 5.3 in group A, The mean age 52.7± 5.8 in group B. There were 56% male in group A, 60 % were male in group B. There were no significant difference between both groups as regard demographic characteristics. There were insignificant difference between both groups as regard anthropometric characteristics.

Table (2): Comparison between past history of medical diseases, heart rate, SBP and DBP among the studied groups

		Group (A) (n = 25)		Group (B) (n = 25)		Test value	P-value
		N	%	N	%		
Hypertension		15	60.0%	14	56.0%	X^2= 0.08	0.77
DM		11	44%	10	40%	0.082	0.77
Smoker		12	48.0%	11	44%	X^2=0.08	0.77
IHD		10	40.0%	9	36.0%	0.08	0.77
Cerebrovascular accident		6	24.0%	5	20%	0.11	0.73
Dyslipidemia		8	32%	7	28%	0.095	0.75
Heart rate (bpm)	Mean± SD	80.60± 6.20		80.50± 6.35		^{Z}= MWU 1.19	0.54
SBP, mm Hg	Mean± SD	135.65±13.41		135.96± 13.22		^{Z}= MWU 1.39	0.25
DBP, mm Hg	Mean± SD	85.60± 6.20		84.50± 6.35		^{Z}= MWU1.022	0.93

P value< 0.05 is significant, P value< 0.01 is highly significant, SD: Standard deviation, X^2= Chi- Square test

There were insignificant difference between both groups as regard past history of medical diseases. Also, there were no significant difference between both groups as regard Heart rate, SBP or DBP (Table 2).

Table (3): Comparison between the studied groups regarding time taken for graft maturation, operative time, blood loss, and hospital stay

		Group (A) (n = 25)	Group (B) (n = 25)	Test value	P-value
Hospital stay (days)	Mean±SD	1.3 ± 0.24	1.28 ± 0.21	^{Z}= MWU 1.30	0.51
Time for graft maturation (days)	Mean±SD	22.9 ± 2.5	39.9 ± 4.5	^{Z}= MWU 3.24	0.005
Operative time (min)	Mean±SD	121.2 ± 12.5	95.5 ± 10.5	1.41	0.39
Blood loss (ml)	Mean±SD	150 ± 10	200 ± 13	1.69	0.20

P value< 0.05 is significant, P value< 0.01 is highly significant, SD: Standard deviation, ^{Z}MWU = Mann- Whitney U test

There were high significant difference between both groups as regard Time for graft maturation (days) (Table 3).

Table (4): Comparison between the studied groups regarding graft thrombosis and access failure

	Group (A) (n = 25)		Group (B) (n = 25)		Test value	P-value
	N	%	N	%		
Further thrombosis at 6 m	3	12%	5	20%	0.59	0.44
Access failure at 6 m	3	12%	8	32%	2.91	0.08

P value< 0.05 is significant, P value< 0.01 is highly significant, SD: Standard deviation, X^2= Chi- Square test

Table (4) showed that regarding graft thrombosis, 12.0% with further thrombosis at 6 m, in group A. 20.0% with further thrombosis at 6 m, in group B. There were insignificant difference between both groups as regard graft thrombosis**.** Regarding access failure, 12.0% at 6 m, in group A. 32.0% at 6 m, in group B. There were insignificant difference between both groups as regard Access failure**.**

Table (5): Comparison between the studied groups regarding primary patency

	Group (A) (n = 25)		Group (B) (n = 25)		Test value	P-value
	N	%	N	%		
Primary patency at 6 m	17	68%	14	56%	2.91	0.08

P value< 0.05 is significant, P value< 0.01 is highly significant, SD: Standard deviation, X^2= Chi- Square test

Table (5) showed that regarding Primary patency, 68.0% at 6 m, in group A. 56.0% at 6 m, in group B. There were insignificant difference between both groups as regard primary patency**.**

Table (6): Comparison between the studied groups regarding secondary patency

	Group (A) (n = 25)		Group (B) (n = 25)		Test value	P-value
	N	%	N	%		
Secondary patency at 6 m	18	72%	14	56%	2.91	0.08

P value< 0.05 is significant, P value< 0.01 is highly significant, SD: Standard deviation, X^2= Chi- Square test

Table (6) showed that regarding secondary patency, 72.0% at 6 m, in group A. 56.0% at 6 m, in group B. There were insignificant difference between both groups as regard Secondary patency**.**

Discussion

Regarding the demographic data of the studied groups, the current study showed that the mean age 51.3± 5.3 in group A, The mean age 52.7± 5.8 in group B. There were 56% male in group A, 60 % were male in group B. There was no significant difference between both groups as regard demographic characteristics. The current study showed also that the mean BMI 26.2± 2.22 in group A, The mean BMI 26.50± 2.3 in group B. The mean weight 77.4± 6.2 in group A, The mean weight 77.6± 5.9 in group B. There was insignificant difference between both groups as regard anthropometric characteristics.

The current study was the first study compared the Brachio axillary graft and Brachio venacomittant graft in end-stage renal disease patients. So, we will compare our results with studies presenting each technique separately. The

present study can be supported by Yousef et al.[10] who compared two graft types (Saphenous Vein Versus Synthetic Graft) for Brachioaxillary Hemodialysis access. Thirty patients were operated upon by saphenous graft for brachio-axillary shunt (group I) while the other thirty patients were operated upon by synthetic graft (PTFE) for brachio-axillary shunt (group II). Also, Belczak et al.[11] aimed to compare different types of grafts used for brachioaxillary access in hemodialysis patients in terms of their patency and complication rates. The study enrolled 49 patients underwent brachioaxillary bypass with implantation of autologous saphenous vein, polytetrafluoroethylene (PTFE), or PROPATEN® grafts. There were 26 men and 23 women with mean age of 57 years.

As well Davoudi et al.[12] aimed to compare the primary patency time of basilic vein transposition and prosthetic brachioaxillary access grafts in hemodialysis patients. In this randomized clinical trial, 60 hemodialysis patients were recruited and randomly assigned to two intervention groups; Basilic vein transpositions (BVT) or Arteriovenous access grafts (AVG). 30 BVts and 30 AVG were performed in each group studied. the groups were well matched for age and sex. The mean age of AVG group was 60.10 ± 16.53 years of them 13 (43.3%) males. The mean age of BVT group was 64.93 ± 15.42 years of them 8 (26.7%) males.

Furthermore, Fumagalli et al.[13] aimed to evaluate outcomes of forearm brachial-brachial AVGs (BB-AVGs) placed in patients with poor superficial veins. The study analyzed 105 BB-AVGs created in 105 consecutive patients, using standard-walled polytetrafluoroethylene grafts, The median age of the patients was 69 years (range, 22-87 years), and most patients were male and elderly. Regarding comorbidities among the studied groups, the present study showed that there were 60.0% patients with Hypertension, 44.0% with DM, 48.0% with Smoker, 40.0% with IHD, 24% cerebrovascular accident, 32% with Dyslipidemia in group A. 56.0% patients with Hypertension, 40.0% with DM, 44.0% with Smoker, 36.0% with IHD, 20% cerebrovascular accident, 28% with Dyslipidemia in group B. There was insignificant difference between both groups as regard past history of medical diseases.

Yousef et al.[10] reported that the most common comorbidities in the studied groups were DM, HTN, IHD and Smoking with no significant difference. As well, Fumagalli et al.[13] revealed that Hypertension (66.7%) and peripheral vascular disease (43.8%) were the main comorbidities. Approximately one-third of patients were suffering from diabetes and coronary artery disease. Hypertension affected 25 patients initiating dialysis and 45 patients on chronic dialysis (86.2% vs 59.2%; P < .01). Regarding vital signs among the studied groups, we found that the mean Heart rate 80.60± 6.20 in group A, The mean Heart rate 80.50± 6.35 in group B. The mean SBP 135.65± 13.41 in group A, The mean SBP 135.96± 13.22 in group B. The mean DBP 85.60± 6.20 in group A, The mean DBP 84.50± 6.35 in group B. There was no significant difference between both groups as regard Heart rate, SBP or DBP.

Blood pressure variability (BPV) is significantly associated with cardiovascular diseases (CVD) and mortality in hemodialysis patients. However, the relationship between blood pressure and CVD in hemodialysis patients is complex and affected by many factors.[14] Strategies to reduce blood pressure variability might be

beneficial for hemodialysis patients. Comparison between the studied groups regarding time taken for graft maturation, operative time, blood loss, and hospital stay, showed that the mean Hospital stay (days) was 1.3 ± 0.24 in group A, the mean Time for graft maturation (days) was 22.9 ± 2.5 in group A, the mean Operative time (min) was 121.2 ± 12.5, The mean Blood loss (ml) was 150 ± 10 in group A. The mean Hospital stay (days) was 1.28 ± 0.21 in group B, the mean Time for graft maturation (days) was 39.9 ± 4.5 in group B, the mean Operative time (min) was 95.5 ± 10.5, The mean Blood loss (ml) was 200 ± 13 in group B.

These results were comparable with Yousef et al.[10] who revealed that in Brachioaxillary access technique the mean total operation time was 120.7± 9.51 minutes and 91.0±2.04 minutes for the saphenous and synthetic group respectively that showed significant statistical difference (p value <0.001).The time for graft maturation was within a mean interval of 39.9± 7.71 days and 14.0± 2.04 days after the intervention for the saphenous and synthetic group respectively that showed significant statistical difference (p value <0.001).Median blood loss was 200 ml and 125 ml in saphenous and synthetic group respectively which is statistically significant (p value <0.001).There was no significant difference could be detected between both groups in hospital stay with P-Value >0.05. Regarding graft thrombosis among the studied groups, the current study showed that 12.0% with Further thrombosis at 6 m, in group A. 20.0% with Further thrombosis at 6 m, in group B. There were insignificant difference between both groups as regard graft thrombosis.

This can be supported by Yousef et al.[10] who reported that PTFE Brachioaxillary graft thrombosis had occurred in three cases (10%) within 1 month, for which thrombectomy was done and regained patency in one case , three cases of further thrombosis within 6 months with failure of trial of thrombectomy to regain patency (one case associated with pseudoaneurysm and infection so graft is removed) and another three cases at 12 months follow up and thrombectomy was successful in two out of the three cases. In addition, Fumagalli et al.[13] reported that most complications and interventions were due to thrombosis (0.527 per person-year) or stenosis (0.381 per person-year) and related interventions (0.490 per person-year). Of the 80 thromboses that underwent declotting procedures, 57 (71.3%) had underlying venous anastomotic stenoses. Such cases were treated in conjunction with angioplasty or revision of the venous anastomosis. The other 23 thromboses (28.7%) occurred without underlying stenoses.

Regarding Access failure, the current study showed that 12.0% at 6 months, in group A. 32.0% at 6 m, in group B. There was insignificant difference between both groups as regard Access failure. However, the study by Yousef et al.[10] revealed that in PTFE Brachioaxillary graft access failure at 1, 6 and 12 months occurred in 10, 20 and 26% respectively. While, the study by Yousef et al.[10] revealed that in PTFE Brachioaxillary graft access failure at 3, 6 and 12 months occurred in 8.7, 20 and 6.3% respectively. The study by Fumagalli et al.[13] reported that Rates of primary failure and surgical revisions of PTFE brachial-comitans grafts, before cannulation, was 7.8% and 5.9%. Median access survival, after excluding primary failures, was 12.7 and 44.5 months, for primary and secondary patency, respectively.

Also, Fumagalli et al.[13] reported that BB-AVG rates of primary failure and revision before cannulation were 7.6% and 5.7%, respectively. Regarding Primary patency the present study showed that 68.0% at 6 m, in group A. 56.0% at 6 m, in group B. There was insignificant difference between both groups as regard Primary patency. Also, regarding Secondary patency, 72.0% at 6 m, in group A. 56.0% at 6 m, in group B. There was insignificant difference between both groups as regard Secondary patency. Yousef et al.[10] reported that Primary patency rate is higher in group II (PTFE for brachio-axillary shunt) as it was 86.7%,76.7 and 63.3% at 1, 6 and 12 months in comparison to 66.7%, 53.3% and 40% in group I (saphenous join for brachio-axillary shunt) however it isn't statistically significant. Assisted primary patency rate is also higher in group II as it was 86.7%,76.7 and 70%at 1, 6 and 12 months in group II in comparison to 66.7%, 53.3% and 40% in group I however it isn't statistically significant in 1 and 6 months follow up but significant in 12 months follow up (P value< 0.05). Secondary patency rate is higher in group II as it was 90%,80 and 73.3%at 1, 6 and 12 months in group II in comparison to 70%, 60% and 46.7% in group I however it isn't statistically significant at 1 and 6 months follow up but significant at 12 months follow up (P value< 0.05).

The study by, Fumagalli et al.[13] reported that in PTFE brachial-comitans grafts Primary patency rates at 12, 24, and 36 months were 49.5%, 29.5%, and 19.5%. Secondary patency rates at 12, 24, and 36 months were 76.3%, 62.7%, and 54.6%. In addition, Davoudi et al. [12] showed that the mean primary patency time in the Basilic vein transpositions (BVt) and Arteriovenous access grafts (AVG) groups was 244.13 ± 103.65 and 264.97 ± 149.28, respectively and there was no statistically significant difference between the two groups studied (P=.533).

Conclusion

In patients with poor preservation of all veins of the upper limb, B-Ax AVG showed superiority in functionality or safety compared to AVG using other upper limb veins. The complication rates in both study groups were non statistically significant difference. Therefore, considering the age, underlying disease, and expected lifespan of the patient group, B-Ax AVG creation is an acceptable surgical method for select patients.

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