ISSN:0975-3583,0976-2833 VOL12, ISSUE --, 2021

The effect of Permcath on cardiac function in patients with ESRD and mid-range ejection fraction.

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Abstract:

Background: Patients with chronic kidney disease (CKD) could present cardiac dysfunction. Recent studies have revealed that advanced CKD at baseline is associated with progressive worsening in cardiac structure and function. Furthermore, the left-to-right shunting of blood through an arteriovenous fistula (AVF) can significantly increase the preload on the heart.

Objectives: To answer for consultations about patients with mid-range ejection fraction (EF :40-50 %), who were candidates for renal dialysis, regarding which access of dialysis is more suitable for such patients and associated with better outcome. Due to a lack of definitive criteria that guide the selection of patients for different access routes, our study tried to identify which access for dialysis (AVF vs Permicath), was associated with better outcome with regard to cardiac function as judged by ejection fraction in such patients.

Patient and Methods: Patients dialyzing with a tunneled cuffed double-lumen central venous catheter (CVC) tend to experience higher rate of infection but less preload on the heart.

Results: In our study, dialysis via AVF & Permicath was associated with marked reduction of the systolic and diastolic blood pressure but no effect on heart rate. AVF significantly improved the LV systolic function but impaired the diastolic function. Permicath associated with significant improvement of LV systolic function with non-significant improvement of diastolic function.

Conclusion: We found that the AV type access contributed to a worsening of the diastolic heart function while permicath provided superior outcomes in patients with both heart failure and ESRD. While clinical guidelines for vascular access recommend avoiding CVC if possible, our findings reappraise the notion that an AVF may not be the optimal approach for each individual. Our study recommends permicath over AVF in patients with significant diastolic dysfunction and markedly dilated heart. Larger studies may be needed, to confirm our results.

Background:

An arteriovenous fistula (AVF) is the preferred method of hemodialysis access as it provides the safest, and most reliable and durable route (1,2). Conversely, patients dialyzing with a tunneled cuffed double-lumen central venous catheter (CVC) tend to experience an inferior outcome. Despite this evidence, many patients begin and chronically maintain regular hemodialysis via the CVC (3-5).

Patients with chronic kidney disease (CKD) could present cardiac dysfunction. Recent studies have revealed that advanced CKD at baseline is associated with progressive worsening in cardiac structure and function (6,7). Furthermore, the left-to-right shunting of blood through an AVF can significantly increase the preload on the heart (8).

Studies have shown that an AVF decreases systemic vascular resistance, causing increased stroke volume and cardiac output in order to maintain blood pressure, leading to left ventricular volume overload (9).

Due to a lack of definitive criteria that guide the selection of patients for different access routes, more research is necessary to identify patients whose heart failure might deem them intolerant to additional flow and volume overload from an AVF.

Aim of work:

The aim of this study is to assess the effect of Permcath versus AVF on cardiac function in patients with end- stage renal disease (ESRD) & mid-range systolic function as detected by left ventricular ejection fraction (LVEF) during follow-up.

Patients &Methods:

This is a prospective, controlled, randomized, observational study that included 80 patients who were admitted to Benha University Hospital with ESRD & mid-range ejection fraction (40-50 %). Patients divided into two groups according to hemodialysis access type; the first selected 40 patients underwent Permcath insertion & the latter selected 40 patients underwent AVF creation. Cardiac functions were assessed by echocardiography preoperative of vascular access creation &3 months postoperative, immediately after dialysis for both groups.

The study excluded patients with left ventricular systolic dysfunction (ejection fraction is less than 40%), ischemic heart disease, significant valvular heart disease, patients with previous AVF, patients who switched to peritoneal dialysis, or patients who had kidney transplantation during follow-up.

All patients in the study subjected to the following; complete medical history taking (with special emphasis on; detailed history regards age, gender, body weight), past history of; diabetes mellitus (known diabetic treated by diet therapy or hypoglycemic medications), hyperlipidemia (fasting total cholesterol >200 mg/dl or low-density lipoprotein cholesterol ≥ 130 mg/dL or on treatment with a lipid-lowering agent) (10), and history of other risk factors for coronary artery disease (CAD) including: hypertension and received medications, smoking status and family history of CAD, and physical examination will be performed with special emphasis on; cardiac examination, chest examination with identifying patients with systemic hypertension (systolic blood pressure(SBP) ≥ 140 mm Hg and/or diastolic pressure(DBP) ≥ 90 mm Hg, and/or known hypertension treated with antihypertensive medication) (11), and identifying the presence of obesity by measuring waist circumference and body mass index(BMI). The diagnosis of obesity is based on the Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults (12).

All patients had, before and after the intervention, 12 lead ECG; a transthoracic echocardiogram study to identify the estimated ejection fraction (EF), regional wall motion abnormalities (RWMA), cardiac chambers dimensions and associated valvular lesions as per American Society of Echocardiography guidelines and recommendations (13).

Statistical analysis:

The collected data were tabulated and analyzed using the computer programs Statistical Package for Social Science (SPSS) version 26.0 for windows, (SPSS Inc, Chicago, IL). The collected data were summarized after establishing their non -normality by K-S test (One-Sample Kolmogorov-Smirnov Test) of normality, in terms of median, inter-quartile range (IQR) for quantitative data and frequency and proportion for qualitative data. Statistical comparisons between the different study groups were carried out using univariate tests including the Chi-square test ($\chi 2$), Fischer exact test, Student t test, Man-Whitney U test, Wilcoxon, and Mc Nemar-Bowker tests as appropriate. A P-value < 0.05 was considered statistically significant.

Ethical considerations:

All the participants were requested to sign a written informed consent regarding the procedure according to the study protocol.

Results:

Between January 2019 and March 2020, a total of 80 patients with mid-range ejection fraction (40-50%), were selected from 250 patients with end-stage renal disease, underwent new hemodialysis access creations at Benha University Hospital. The study investigated the changes in cardiac function in both groups of patients before and 3-months after creation of AVFs or insertion of Permcath.

Clinical records of 80 patients were available for this study, including 36 men and 44 women with the median age of 52 for AVF and 59.5 for the Permcath group. Tables 1 summarize the clinical characteristics of patients of the two different types of access, i.e., CVC (n = 40; 50%), AVA (n = 40; 50%). Most baseline characteristics and preoperatively echocardiographic parameters were identical between groups with median follow-up time from access creation was 3 months. Echocardiographic scans were available both before and 3 months after intervention during follow up in all patients.

Table 1: Comparing the studied groups regarding their characters.

	Pt with AVF (40)		Pt with Permcath (40)		Statistical test	P value
	No	%	No	%		
Age median (IQR)	52.0(40.5-59.5)		59.5 (57.0-64.5)		Z_{MWU}= 4.22	<0.001**
Sex Male Female	 12 28	 30.0 70.0	 24 16	 60.0 40.0	X^2= 7.27	0.007**

DM	24	60.0	28	70.0	X^2= 0.88	0.35
HTN	12	30.0	12	30.0	X^2= 0.0	1.0
Smoking	12	30.0	8	20.0	X^2= 1.07	0.30
Obesity	6	15.0	4	10.0	X^2= 0.46	0.50
Dyslipidemia	8	20.0	10	25.0	X^2= 0.29	0.59
PRE						
SBP median (IQR)	147.5 (131.25-168.75)		157.5 (131.25-163.75)		Z_{MWU}=0.19	0.85
DBP median (IQR)	90.0 (85.0-98.75)		90.0 (85.0-95.0)		Z_{MWU}=0.08	0.94
Pulse median (IQR)	75.0 (65.0-80.0)		74.0 (65.25-80.0)		Z_{MWU}= 0.08	0.94
LA size median (IQR)	4.55 (4.3-5.08)		4.65 (4.3-5.18)		Z_{MWU}=0.41	0.69
IVSd median (IQR)	1.0 (0.9-1.0)		1.0 (0.93-1.1)		Z_{MWU}=1.29	0.20
PWDd median (IQR)	1.0 (0.9-1.0)		1.0 (0.9-1.0)		Z_{MWU}=0.10	0.92
LVEDDs median (IQR)	5.45 (5.03-5.78)		5.65 (5.4-6.08)		Z_{MWU}=2.63	0.009**
LVESDs Mean ±SD	4.29±0.52		4.58±0.38		St t= 2.88	0.005**
MR Trivial Mild Moderate	 8 16 14	 21.1 42.1 36.8	 12 14 10	 33.3 38.9 27.8	 X^2=1.55	 0.46
AR Mild	4	100	4	100	-	-
Diastolic dysfunction Grade I Grade II Grade III	 26 12 2	 65.0 30.0 5.0	 24 14 2	 60.0 35.0 5.0	 FET= 0.37	 0.93
EF% median (IQR)	44.0 (41.0-46.75)		44.5 (42.0-46.75)		Z_{MWU}= 0.21	0.83
PHTN None Mild HTN Moderate HTN	 36 4 0	 90.0 10.0 0.0	 36 2 2	 90.0 5.0 5.0	 FET= 2.29	 0.44
POST						
SBP median (IQR)	140.0 (125.0-150.0)		140.0 (120.0-145.0)		Z_{MWU}=1.44	0.15
DBP median (IQR)	82.5 (76.25-90.0)		85.0 (76.25-90.0)		Z_{MWU}=0.69	0.49
Pulse median (IQR)	72.5 (70.0-80.0)		74.5 (67.75-79.0)		Z_{MWU}=0.19	0.85
LA size median (IQR)	4.75 (4.43-5.38)		4.3 (4.0-4.78)		Z_{MWU}=3.69	<0.001**
IVSd median (IQR)	1.0 (0.9-1.0)		1.0 (0.93-1.0)		Z_{MWU}=1.29	0.20
PWDd median (IQR)	1.0 (0.93-1.0)		1.0 (0.9-1.1)		Z_{MWU}=0.19	0.85
LVEDD median (IQR)	5.6 (5.3-5.9)		5.4 (5.2-5.58)		Z_{MWU}=2.38	0.017*
LVESDs median (IQR)	4.5 (3.93-4.83)		4.2 (3.8-4.48)		Z_{MWU}=1.74	0.08
MR Trivial Mild Moderate Severe	 4 18 12 4	 10.6 47.4 31.6 10.6	 20 14 2 0	 55.6 38.9 5.6 0.0	 FET= 17.76	 <0.001**
AR Mild Moderate AR	 2 2	 50.0 50.0	 4 0	 100 0.0	 FET= 0.67	 0.41
Diastolic dysfunction Grade I Grade II Grade III	 10 24 6	 25.0 60.0 15.0	 26 12 2	 65.0 30.0 5.0	 FET= 13.03	 0.001**
EF% Mean ±SD	45.7±4.98		48.05±3.99		St t= 2.33	0.023*
Arrhythmia Atrial tachycardia PACS PVCS None	 2 2 0 36	 5.0 5.0 0.0 90.0	 0 4 4 32	 0.0 10.0 10.0 80.0	 FET= 6.23	 0.065
PHTN post None Mild HTN	 34 2	 85.0 5.0	 36 2	 90.0 5.0	 FET= 1.93	 0.73

Mild to moderate HTN Moderate HTN	2 2	5.0 5.0	0 2	0.0 5.0		
EF% Changes Decreased EF% No change Increased EF%	 4 2 34	 10.0 5.0 85.0	 2 4 34	 5.0 10.0 85.0	 FET= 1.32	 0.59
EF% diff [(Pre-post) *100/pre]	-4.3(-4.91) -(-2.35)		-7.38(-15.89) -(-2.73)		Z_{MWU}=2.77	0.006**
SBP diff [(Pre-post) *100/pre]	7.18(3.55-9.96)		9.38(7.85-14.49)		Z_{MWU}=3.82	<0.001**
DBP diff [(Pre-post) *100/pre]	6.07(1.25-11.11)		7.78(5.26-12.5)		Z_{MWU}=1.08	0.28
Pulse diff [(Pre-post) *100/pre]	0.0(-7.02-6.47)		0.0(-3.02-2.59)		Z_{MWU}=0.99	0.32

HTN: hypertension, DM: diabetes mellitus, SBP: systolic blood pressure, DBP: diastolic blood pressure, LA: left atrium, LVESD: left ventricular end-systolic dimension, LVEDD: left ventricular end-diastolic dimension, EF: ejection fraction, PAC: premature atrial contraction, PVC: premature ventricular contraction, PHTN: pulmonary hypertension, MR: mitral regurgitation, AR: aortic regurgitation.

The study showed statistically significant reduction in SBP after creation of AVF (147.5 vs 140 mmHg) and after insertion of Permcath (157.5vs 140 mmHg) with superiority of Permcath in the reduction of SBP (7.18 for AVF vs 9.38 for Permcath group), however, there was highly significant reduction in DBP after creation of AVF (90 vs 82.5 mmHg) and after insertion of Permcath (90 vs 85 mmHg) with no difference between the two groups (6.07 for AVF vs 7.78 for Permcath group), and no significant change in pulse rate was shown after intervention in both groups (Table 2 and 3).

Table 2: Comparing different variables before and after intervention among AVF group.

Pt with AVF (40)	**PRE**		**POST**		Statistical test	P value
	No	%	No	%		
SBP median (IQR)	147.5 (131.25-168.75)		140.0 (125.0-150.0)		$Z_{wilcoxon}$ test= 5.27	<0.001**
DBP median (IQR)	90.0 (85.0-98.75)		82.5 (76.25-90.0)		$Z_{wilcoxon}$ test= 4.17	<0.001**
Pulse median (IQR)	75.0 (65.0-80.0)		72.5 (70.0-80.0)		$Z_{wilcoxon}$ test= 0.06	0.96
LA size median (IQR)	4.55 (4.3-5.08)		4.75 (4.43-5.38)		$Z_{wilcoxon}$ test= 5.07	<0.001**
IVSd median (IQR)	1.0 (0.9-1.0)		1.0 (0.9-1.0)		$Z_{wilcoxon}$ test= 0.0	1.0
PWDd median (IQR)	1.0 (0.9-1.0)		1.0 (0.93-1.0)		$Z_{wilcoxon}$ test= 1.41	0.16
LVEDDs median (IQR)	5.45 (5.03-5.78)		5.6 (5.3-5.9)		$Z_{wilcoxon}$ test= 5.12	<0.001**
LVESDs median (IQR)	4.3 (3.8-4.78)		4.5 (3.93-4.83)		$Z_{wilcoxon}$ test= 4.44	<0.001**
MR Trivial Mild Moderate Severe	 8 16 14 0	 21.1 42.1 36.8 0.0	 4 18 12 4	 10.6 47.4 31.6 10.6	 FET= 3.07	 0.38
AR Mild Moderate AR	 4 0	 100 0.0	 2 2	 50.0 50.0	 FET= 0.67	 0.41
Diastolic dysfunction Grade I Grade II Grade III	 26 12 2	 65.0 30.0 5.0	 10 24 6	 25.0 60.0 15.0	 FET= 10.74	 0.005**
EF% median (IQR)	44.0 (41.0-46.75)		46.0 (42.0-48.75)		$Z_{wilcoxon}$ test= 3.65	<0.001**
PHTN None Mild HTN Mild to moderate HTN	 36 4 0	 90.0 10.0 0.0	 34 2 2	 85.0 5.0 5.0	 FET= 1.18	 0.76

Moderate HTN	0	0.0	2	5.0		

HTN: hypertension, DM: diabetes mellitus, SBP: systolic blood pressure, DBP: diastolic blood pressure, LA: left atrium, LVESD: left ventricular end-systolic dimension, LVEDD: left ventricular end-diastolic dimension, EF: ejection fraction, PAC: premature atrial contraction, PVC: premature ventricular contraction, PHTN: pulmonary hypertension, MR: mitral regurgitation, AR: aortic regurgitation

Table 3: Comparing different variables before and after intervention among permcath group.

Pt with Permcath (40)	**PRE**		**POST**		Statistical test	P value
	No	%	No	%		
SBP median (IQR)	157.5 (131.25-163.75)		140.0 (120.0-145.0)		$Z_{wilcoxon}$ test= 5.56	<0.001**
DBP median (IQR)	90.0 (85.0-95.0)		85.0 (76.25-90.0)		$Z_{wilcoxon}$ test= 5.18	<0.001**
Pulse median (IQR)	74.0 (65.25-80.0)		74.5 (67.75-79.0)		$Z_{wilcoxon}$ test= 0.03	0.98
LA size median (IQR)	4.65 (4.3-5.18)		4.3 (4.0-4.78)		$Z_{wilcoxon}$ test= 5.56	<0.001**
IVSd median (IQR)	1.0 (0.93-1.1)		1.0 (0.93-1.0)		$Z_{wilcoxon}$ test= 0.0	1.0
PWDd median (IQR)	1.0 (0.9-1.0)		1.0 (0.9-1.1)		$Z_{wilcoxon}$ test= 0.0	1.0
LVEDd median (IQR)	5.65 (5.4-6.08)		5.4 (5.2-5.58)		$Z_{wilcoxon}$ test= 4.68	<0.001**
LVESDs median (IQR)	4.55 (4.33-4.9)		4.2 (3.8-4.48)		$Z_{wilcoxon}$ test= 5.08	<0.001**
MR						
Trivial	12	33.3	20	55.6	X^2= 7.33	0.026*
Mild	14	38.9	14	38.9		
Moderate	10	27.8	2	5.6		
AR						
Mild	4	100	4	100	-	-
Moderate AR	0	0.0	0	0.0		
Diastolic dysfunction						
Grade I	24	60.0	26	65.0	FET =0.31	0.86
Grade II	14	35.0	12	30.0		
Grade III	2	5.0	2	5.0		
EF% median (IQR)	44.5 (42.0-46.75)		49.0 (45.25-51.0)		$Z_{wilcoxon}$ test= 5.14	<0.001**
PHTN						
None	36	90.0	36	90.0	FET= 0.0	1.0
Mild HTN	2	5.0	2	5.0		
Moderate HTN	2	5.0	2	5.0		

HTN: hypertension, DM: diabetes mellitus, SBP: systolic blood pressure, DBP: diastolic blood pressure, LA: left atrium, LVESD: left ventricular end-systolic dimension, LVEDD: left ventricular end-diastolic dimension, EF: ejection fraction, PAC: premature atrial contraction, PVC: premature ventricular contraction, PHTN: pulmonary hypertension, MR: mitral regurgitation, AR: aortic regurgitation

The left ventricular end diastolic dimension (LVEDD) increased from 5.45 cm to 5.6 cm (p-value <0.001), left ventricular end systolic dimension (LVESD) increased from 4.3 cm to 4.5 cm (p-value <0.001), the size of left atrium (LA) increased from 4.55cm to 4.75cm (p-value <0.001) after AV fistula, however, these parameters were significantly reduced after Permcath insertion (Table 2 and 3).

Regarding the left ventricle (LV) function, the AVF group associated with highly significant deterioration of the diastolic function, however there was no significant improvement in the diastolic function after the insertion of Permcath, while LV systolic function was improved with highly significant increase in EF in both groups (Table 2 and 3) (Figure 1&2). The study also showed significant improvement in the magnitude of the mitral regurgitation (MR) after the insertion of Permcath, and no significant deterioration in the magnitude of the MR after creation of AVF (The severity of MR is determined by regurgitant volume & regurgitant fraction). (Table 2 and 3), Fig: 3

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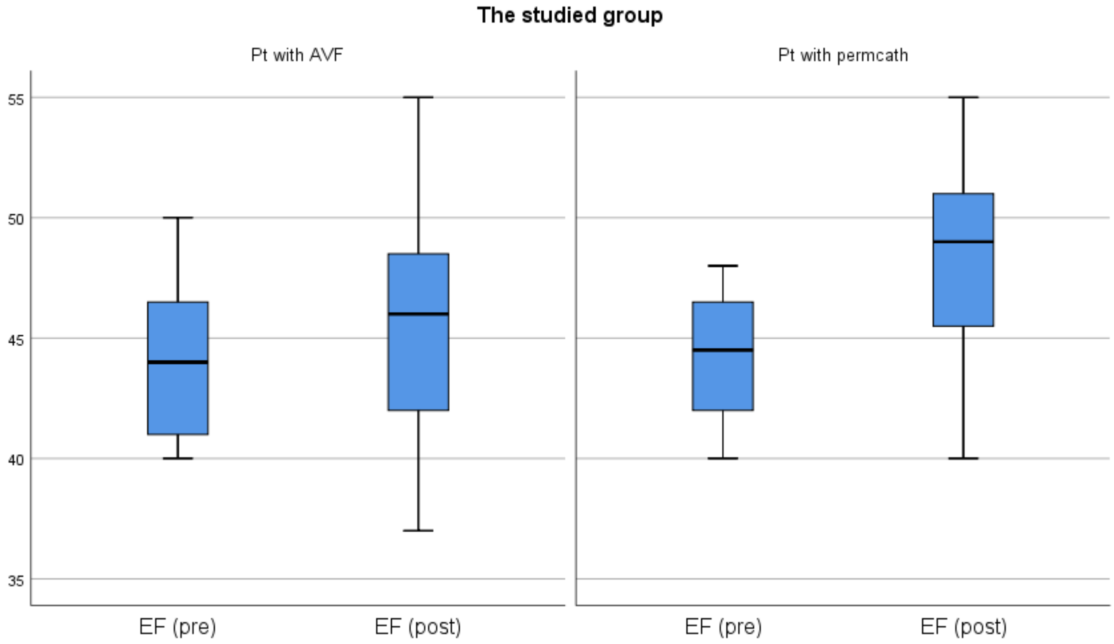

Fig 1: Comparing the EF between the 2 groups.

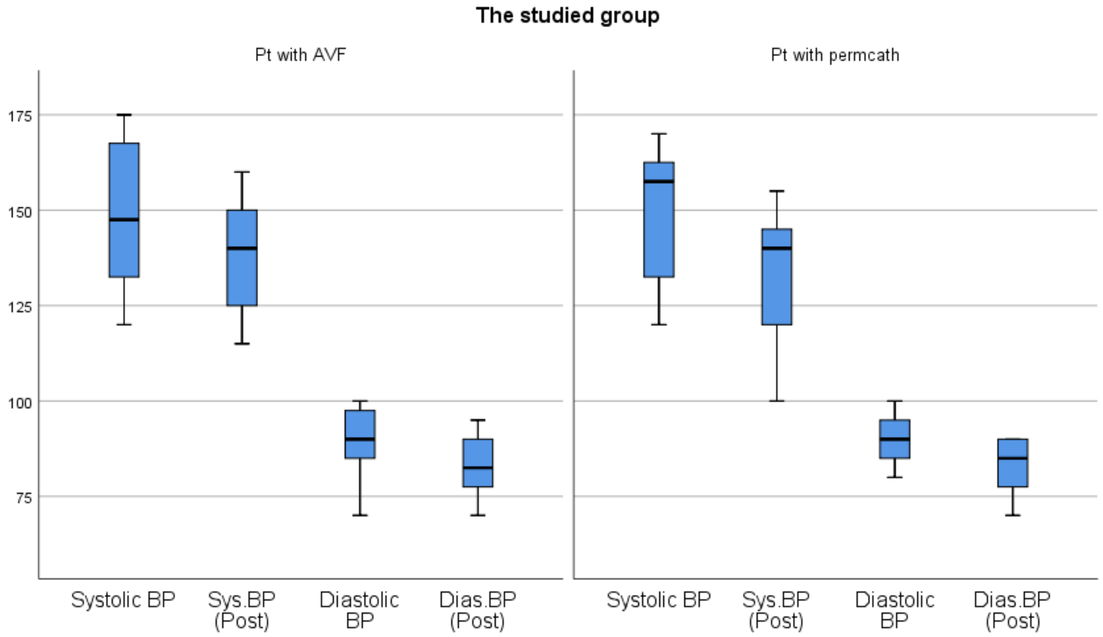

Fig 2: Comparing the SBP and DBP between the 2 groups.

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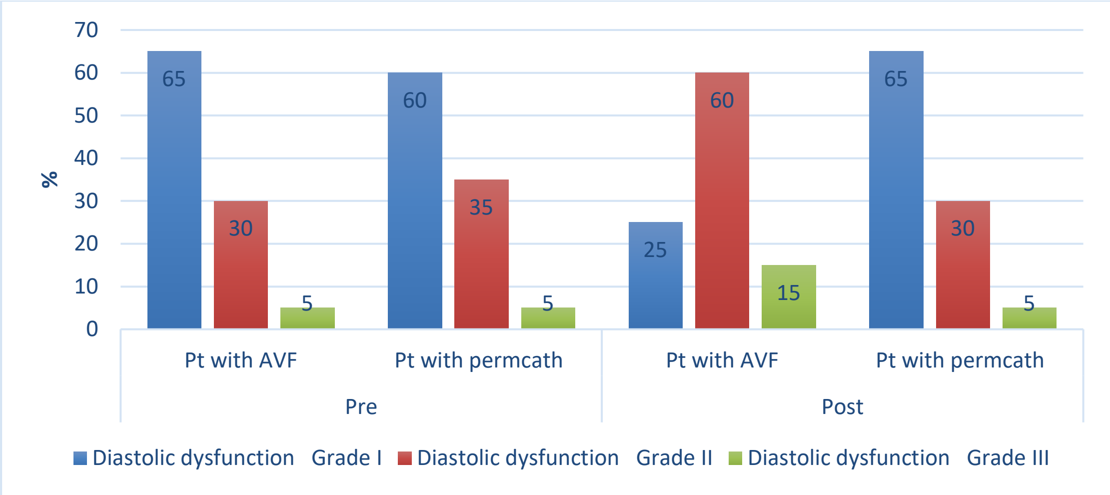

Fig 3: Comparing the diastolic function between the 2 groups.

The study did not show any significant change in the pulmonary artery systolic pressure (PASP), nor significant effect on the cardiac arrhythmia after the creation of AVF or the insertion of Permcath. (Table 2 and 3)

Discussion:

Arterio-venous fistulas (AVFs) have superior longevity, lower cost and hence has become the vascular access of choice for patients needing dialysis. Despite their association with a lower mortality, AVFs has a significant effect on cardiac functions pre-dominantly related to increase in pre-load and decrease in after-load with consequent increase in cardiac output (15), for this purpose, 80 patients with ESRD and mid-range ejection fraction were evaluated before and 3month after creation of AVF or Permcath insertion, clinically, ECG and by echocardiography to compare the impact of each intervention on cardiac function.

The LVEDD increased from 5.45 cm to 5.6 cm (p-value <0.001), LVESD increased from 4.3 cm to 4.5 cm (p-value <0.001), the size of LA increased from 4.55cm to 4.75cm (p-value <0.001) after AV fistula, however, these parameters were significantly reduced after Permcath insertion. In the previous studies as Reddy et al. (2017) showed that, AVF/AVG creation was associated with significant dilatation in the left atrium and RV dimensions (16).

Iwashima et al. (2002) study, showed that LA and LV dimensions increased significantly days 7 and 14 after AV fistula creation (16).

In our study, there was high significant increase in the EF in both groups, AVF:(44 before vs 46 after) & Permcath :(44.5 vs 49), in agreement with the present study Iwashima et al. (2002) study showed that creation of the AV fistula produced a significant increase in FS and CO after 3 to 14 days. Maximal increases in these parameters concerning LV systolic function were obtained day 7 (FS, 8%; CO, 15%) (17).

Unal et al. (2010) study showed that there was no significant difference between 2 time periods in ejection fraction (18), while in Reddy et al. (2017) study showed that there was a slight reduction in LV systolic function, evidenced by decreases in LV EF (16).

In our study, there was highly significant deterioration of the diastolic function after creation of the AVF with no significant improvement in the diastolic function after the insertion of Permcath.

Savage et al. (2002) study showed that Diastolic filling parameters (E to A ratio), in the AVF patients, were impaired, indicative of worsening diastolic functions (19). While in Reddy et al. (2017) study showed that there was no change in LV diastolic function (16).

In our study, there was no significant change in the pulmonary artery systolic pressure after the creation of AVF or the insertion of Permcath and that result can be explained by small volume of the study. In the previous studies Saleh et al. (2018) study showed that the HFA group had significantly increase PASP as compared with non-HFA group (20).

Paneni et al. (2010) study showed increase in systolic pulmonary artery pressure in patients receiving hemodialysis with radial and brachial AVFs (21)

Our study, showed significant reduction in SBP after creation of AVF (147.5 vs 140 mmHg)) and after insertion of Permcath (157.5vs 140mmHg) with superiority of Permcath in the reduction of SBP (7.18 for AVF vs 9.38 for Permcath group), and at the same time, showed highly significant reduction in DBP after creation of AVF (90 vs 82.5 mmHg) and after insertion of Permcath (90 vs 85 mmHg) with no significant difference between the two groups (6.07 for AVF vs 7.78 for Permcath group).

Iwashima et al. (2002) study showed that diastolic and systolic blood pressure decreased significantly days 7 and 14 after AV fistula creation (17).

In our study, there was no significant difference in heart rate after intervention in both groups, while in

ISSN:0975-3583,0976-2833 VOL12, ISSUE --, 2021

Reddy et al. (2017) study showed that Heart rate increased by an average of 5 bpm (P = 0.003)16 and in similar study Iwashima et al. (2002) showed that heart rate did not change in the study (16).
The study showed significant improvement in the magnitude of the MR after the insertion of Permcath with no significant deterioration in the magnitude of the MR after creation of AVF & Cheung et al. (2004) study showed that valvular heart disease is common among patient on hemodialysis with a prevalence of 39–43%. The majority of valvular abnormalities (mitral regurgitation and tricuspid regurgitation) (22). Acarturk et al. (2008) study showed that there was no direct relationship between AV access flow and development of TR (22).

Conclusion:
We found that the AV type access contributed to a worsening of the diastolic heart function while permicath provided superior outcomes in patients with both heart failure and ESRD, while clinical guidelines for vascular access recommend avoiding CVC if possible, our findings reappraise the notion that an AVF may not be the optimal approach for each individual. Our study recommends permicath over AVF in patients with significant diastolic dysfunction and markedly dilated heart. Larger studies may be needed, to confirm our results.

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