MMSG
ORIGINAL ARTICLE

Complication, patency and incidence rates of first-time vascular dialysis access fashioned in Malta

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Background

The aim of the study was to assess first-time arteriovenous fistulae (AVFs) and grafts fashioned over a 5 year period in Malta, and analyse their patency and complication rates. The study also investigates compliance with Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines for fistula incidence.

Methods

Patients who underwent surgery between January 1st 2012 and December 31st 2016 were identified through the vascular surgery database at Mater Dei Hospital - Malta and followed up until 31st December 2017. Complications, interventions and patency duration were recorded from patient notes. Patency rates were calculated with Kaplan-Meier curves and log-rank test was used to compare significance between the curves.

Results

A total of 258 vascular access (VA) procedures were analysed, only 242 of which were used for haemodialysis. The chance of a VA developing no complications was 38%, with stenosis and thrombosis rates of 36.8% and 24.8% respectively. There was no significant difference between the complication rates or intervention frequency when comparing different fistula types. Of the 207 patients who had AVFs created since January 2012, only 26.1% (n=54) had creation prior to initiation of haemodialysis. Primary patency survival rates for first-time AVFs were 58.7±7.1% at 1 year and 48.1±7.4% at 2 years. The assisted primary rates were 73.7±6.3% at 1 year and 67.6±6.9% at 2 years. The secondary patency rates were 76.4±6.1% (95% CI, 70.3%-82.5%) at 1 year and 70.8 ±6.9% at 2 years. There was no significant difference when comparing primary (p=0.539), assisted primary (p=0.634) or secondary patency (p=0.783) rates for the different AVF types.

Conclusion:

In Malta, AVF incidence lags behind the European average of 66%, but patency rates compare favorably with most other countries.

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Introduction

The number of patients receiving renal dialysis is steadily increasing, particularly in countries like Malta with a high prevalence of diabetes mellitus. Renal guidelines recommend the use of longer and more frequent haemodialysis (HD) sessions for which vascular access is required.[1] The aim of this study is to assess first-time arteriovenous fistulae (AVFs) and arteriovenous grafts (AVGs) fashioned over a 5 year period in Malta, and analyse their patency and complication rates. The study also investigates the time of fistula creation relative to haemodialysis start date, and compliance with Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines with regard to fistula incidence.[2]

Materials and Methods

Data Collection

All patients undergoing AVF or AVG creation surgery between January 1st 2012 and December 31st 2016 were identified through the vascular surgery database at Mater Dei Hospital, Malta. This hospital is the only centre in Malta were vascular access is fashioned surgically and is thus representative of the entire Maltese population. Vascular access procedures are performed by one vascular surgeon in Malta.

The vascular surgery history of this cohort was followed up until 31st December 2017. Complications, interventions and patency rates for all fistulae were recorded. For patients who passed away during the study period, records were reviewed till the date of death.

Data on patient age and gender, the type and site of fistula created, the date when created, number of days of patency, types of complications, types of interventions required, date of HD initiation and the date of death were collected.

Data for time of HD initiation was collected from records kept by the Mater Dei Hospital Renal Unit. The only digital records found available had only started being kept from January 2013 onwards. For earlier data, HD start date was taken as the date the patient was first registered to the renal unit on iSoft Clinical Manager. Dates from both sources were cross checked for accuracy.

Only patients above 18 years, who had a first-time AV fistula or graft created locally between the data collection period, were included in this study. Patients whose VA was not used for hemodialysis, were included in analysis of the fistula types created, however excluded from analysis of the complication and patency rates. This was done to eliminate bias from unused accesses.

Definitions

Definitions of vascular terms were as per standardized definitions by Lee et al. [3] The term vascular access (VA) was used to define any AVF or AVG. When referring to AVFs, we were including brachiocephalic, radiocephalic, ulnarcephalic, snuffbox and transposed brachiobasilic, ulnar basilica and radiobasilic fistulae. AVGs were defined as any artificial prosthetic segment used to contact the artery and vein. [3]

Complications were classified as thrombosis, stenosis, complete occlusion, infection, steal syndrome, aneurysmal dilation and non-maturation.[3] Only complications documented in the patient's notes were recognized. In some cases a fistula or graft may have

developed a recurrence of the complication after it was initially treated, and in other cases, more than one complication may have co-existed.

The interventions carried out on a VA were classified as angioplasty, thrombectomy and any surgical revision of the fistula or graft. Again, many repeat interventions may have been carried out on the same fistula or graft.[3]

Patency was defined as described by Sidawy et al.[4] Primary patency was defined as time of access placement to the time of first angioplasty. Assisted primary patency was defined as time of access to the time of first thrombectomy. Secondary patency was defined as the time of access placement to access abandonment. Fistula incidence rates refer to the amount of people starting dialysis with a functioning fistula. Survival rates refer to the amount of fistulas which maintained their patency.

*Statistics*IBM SPSS Statistics 20.0 software was used to analyse the collected data. Comparison between categorical variables was with the chi-squared test. Patency rates were calculated with survival analysis curves (Kaplan Meir curves), and log-rank test was used to compare significance between the curves. A p value of ≤0.05 was considered statically significant in all cases.

Results

The sample assessed included a total of 258 patients, 70.2% (n=181) of which were male, while 29.8% (n=77) were female. The mean patient age at the time of fistula creation was 63 years (SD=12.7).

The different types of VA created are shown in Table 1. The most common VA type was brachiocephalic, accounting for 53.1% (n=137) of VAs. Radiocephalic (n=41), prosthetic grafts (n=35), transposed (n=27) and snuffbox (n=12), and ulnar cephalic (n=6) accounted for the rest. A total of 162 fistulas were sited on the left, while 96 were sited on the right.

Table 1 Types of arteriovenous vascular access created

	Number (%)	
Total	258	(100)
Brachiocephalic	137	(53.1)
Radiocephalic	41	(15.9)
At the wrist	28	(10.9)
At the forearm	13	(5.1)
Prosthetic graft	35	(13.6)
Arm Loop	33	(12.8)
Ulnar Artery to Axillary Vein	1	(0.4)
External Iliac to Profunda Vein	1	(0.4)
Snuffbox	12	(4.7)
Transposed	27	(10.5)
Brachiobasilic	24	(9.3)
Ulnarbasilic	1	(0.4)
Radiobasilic	2	(0.8)
Ulnarcephalic	6	(2.3)

In cases were a prosthetic graft was fashioned, polytetrafluoroethylene (PTFE) was used in all cases. The majority of these grafts (12.8%, *n*=33) were arm loop fistulas.

Patient Outcome

Of the 258 patients assessed for VA creation in the 5 year period, a total of 121 patients had died before the 31st December 2017 cut off. Mean number of days between date of fistula creation and death was 510 days.

The majority of patients (82.9%, *n*=214) remained dialyzing until death or until the cut off period. The rest were either transplanted successfully (8.1%, *n*=21), found to not require haemodialysis despite fistula creation (6.2%, *n*=16), stopped renal replacement therapy completely (1.6%, *n*=4) or reverted to peritoneal dialysis (0.8%, *n*=2). One person had left the country and was thus lost to follow-up.

Complications

The breakdown of the different complications and their frequency, after excluding the 16 VAs which were never used for haemodialysis, are shown in Table 2. The chance of a VA not developing any complications was 38%, whilst the chances of stenosis or thrombosis at least once where 36.8% and 24.8% respectively. With regard to recurrent complications, the total number of stenotic events and thrombotic events were 138 and 102 respectively for 242 VAs.

Table 2 Complication Rates

	Number (%)	
Total VAs [1]	**242**	**(100)**
No Complications	91	(37.6)
Stenosis	89	(36.8)
Thrombosis	60	(24.8)
Occlusion	30	(12.4)
Aneurysm	27	(11.2)
Steal Syndrome	16	(6.6)
Infection	6	(2.5)
Non-maturation	4	(1.7)
Rupture	3	(1.2)
Other	4	(1.7)

[1] *16VAs were excluded from the original sample, in view of them not ever having been used for dialysis*

Table 3 Percentage of the most common complications according to each fistula type.

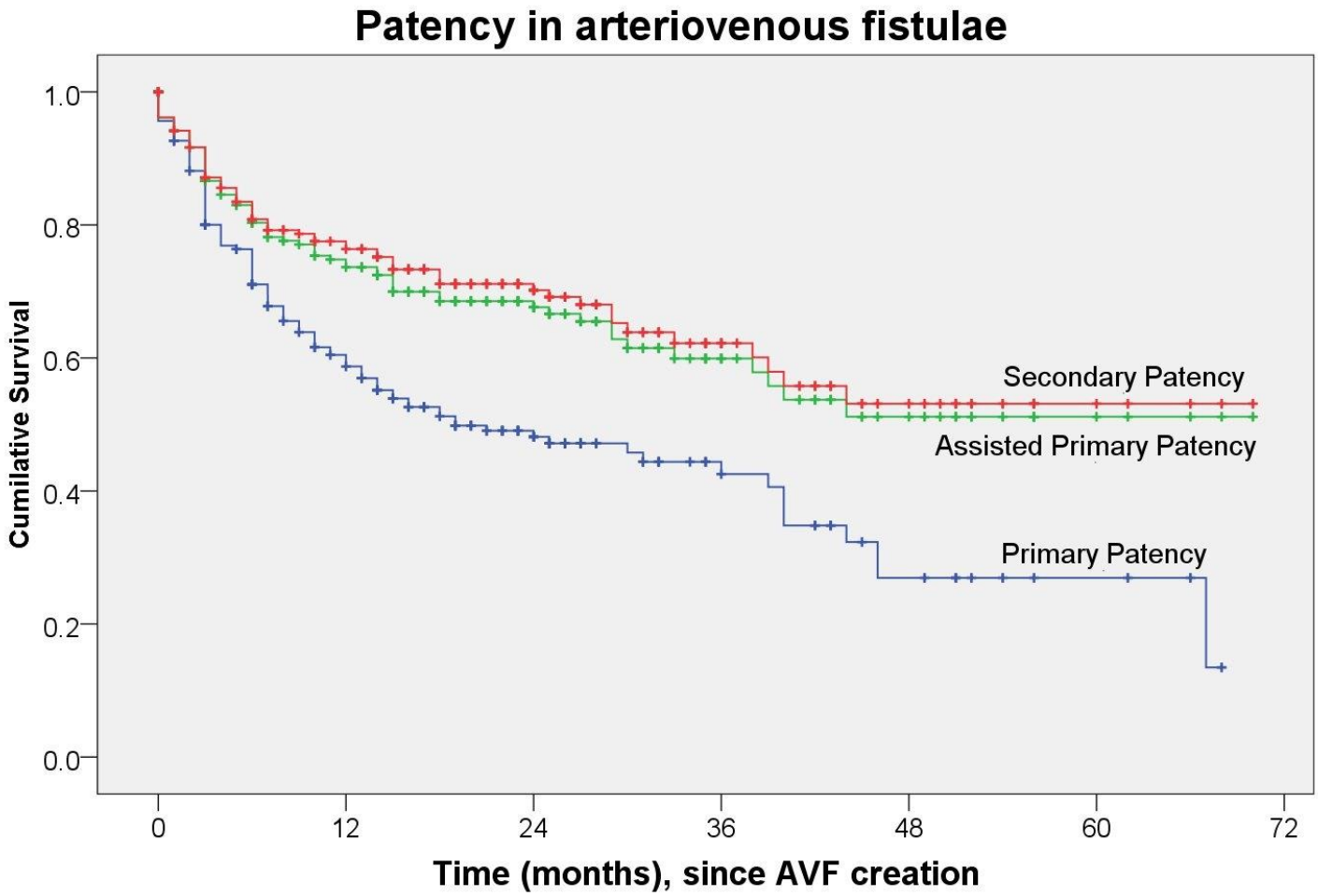
Fistula Type	N of Fistulas	No Complications		Thrombosis		Stenosis	
		n	%	n	%	n	%
All	242	91	37.6	60	24.8	89	36.8
BC	126	53	42.1	24	19.0	41	32.5
RC	39	15	38.5	8	20.5	13	33.3
Graft	35	4	11.4	24	68.6	19	54.3
TP	26	11	42.3	3	11.5	11	42.3
SB	11	4	36.4	1	9.1	5	45.5
UC	5	4	80.0	0	0.0	0	0.0

N, number; BC, brachiocephalic; RC, radiocephalic; SB, snuffbox; TP, transposed; UC, ulnarcephalic.

Table 4 Frequency of required interventions by fistula type

Fistula Type	Number of fistulas	Number of Interventions			
		None	Thrombectomy	Angioplasty	Surgical Revision
Brachiocephalic	126	60	6	38	39
Radiocephalic	39	19	2	11	12
Graft	35	6	25	20	12
Transposed	26	12	0	10	5
Snuffbox	11	5	0	5	1
Ulnarcephalic	5	4	0	1	1
Total	**242**	**106**	**33**	**85**	**70**

Figure 1 Kaplan-Meier survival curves for patency rates of total AVFs, showing primary patency, assisted primary patency and secondary patency



No significant difference between having no complications (p=.507), or having thrombosis (p=.808), or stenosis (p=.513) was observed between the different AVF types (Table 3). However, a significant difference was observed between the rate of no complications (p<.001), thrombosis (p< .001) and stenosis (p=.020) for PTFE grafts when compared to the rest of the AVFs.

The frequency of interventions carried out according to VA type are shown in Table 4. Over the analysis period, a total of 85 angioplasties and 33 thrombectomies were carried out. Surgical revision of the VA was required 70 times. 43.8% (n=106) of the VAs created required no intervention. When looking at the various fistula types, only 16.6% of grafts required no intervention while 47.6% of brachiocepahlic, 48.7% of radiocephalic and, 46.1% of transposed fistulae required no intervention. When looking at the interventions carried out, we found that AVGs had an intervention rate of 0.27 per VA per year, when compared to AVFs with an intervention rate of 0.11 per VA per year.There was no significant difference between the different fistula types (p=.713) however there was significant difference in the rate of intervention between fistula and grafts (p<.001).

AVF Incidence

Out of the 207 patients who had AVFs created since January 2012, only 26.1% (*n*=54) had AVF creation prior to initiation of HD. When calculating incident AVFs after May 2014, the end point of the local study by Caruana et al., the incident rate of AVFs was 28.6%, showing no significant difference (*p*=.584) and hence no significant improvement since the previous study.[5]

Patency

The primary patency rates for first-time AVFs were 58.7% (95% CI, 51.7%-65.7%) at 1 year and 48.1% (95% CI, 40.7%-55.5%) at 2 years respectively. The assisted primary rates were 73.7% (95% CI, 67.4%-80.0%) at 1 year and 67.6% (95% CI, 60.7%-74.5%) at 2 years., while the secondary patency rates were 76.4% (95% CI, 70.3%-82.5%) at 1 year and 70.8 %(95% CI, 63.9%-77.7%) at 2 years. (Figure 1)

The patency rates according to the different type of VA are shown in Table 5. There was no significant difference when comparing primary patency (*p*=.539), assisted primary patency (*p*=.634) or secondary patency rates (*p*=.783) for the different types of fistulas (Figure 2).

The overall patency of AVGs was found to be lower at 17.1% (95%CI 4.6%-29.6%) primary patency, 17.1% (95%CI 4.6%-29.6%) assisted patency and 48.6% (95%CI 32.1%-65.1%) secondary patency. Comparing to the patency of AVFs (Figure 3.), there was a statistically significant difference between primary patency (*p*<0.001), assisted primary patency (*p*<0.001) and secondary patency (*p*=.010)

Table 5 Patency Rates According to Different Type of VA

VA Type	Overall			1 Year			2 Years		
	P (%)	AP (%)	SP (%)	P (%)	AP (%)	SP (%)	P (%)	AP (%)	SP (%)
Grafts	17.1	17.1	48.6	17.8	25.7	67.4	0	10.4	45.2
All Fistulas	47.8	66.2	68.6	59.7	74.3	76.9	48.9	68.1	70.8
BC	47.6	64.3	68.3	61	73.3	77.6	46.1	63.7	67.7
RC	48.7	61.5	61.5	58.4	71.5	71.5	53	68.8	68.8
SB	36.4	81.8	81.8	45.6	90.9	90.9	45.6	90.9	90.9
TP	46.2	73.1	73.1	58.4	75.1	75.1	49.3	75.1	75.1
UC	80	80	80	80	80	80	80	80	80

VA, Vascular Access; P, primary patency; AP, assisted primary patency; SP, secondary patency; BC, brachiocephalic; RC, radiocephalic; SB, snuffbox; TP, transposed; UC, ulnarcephalic.

Figure 2 Kaplan-Meier survival curves for secondary patency rates, according to the different types of fistulas

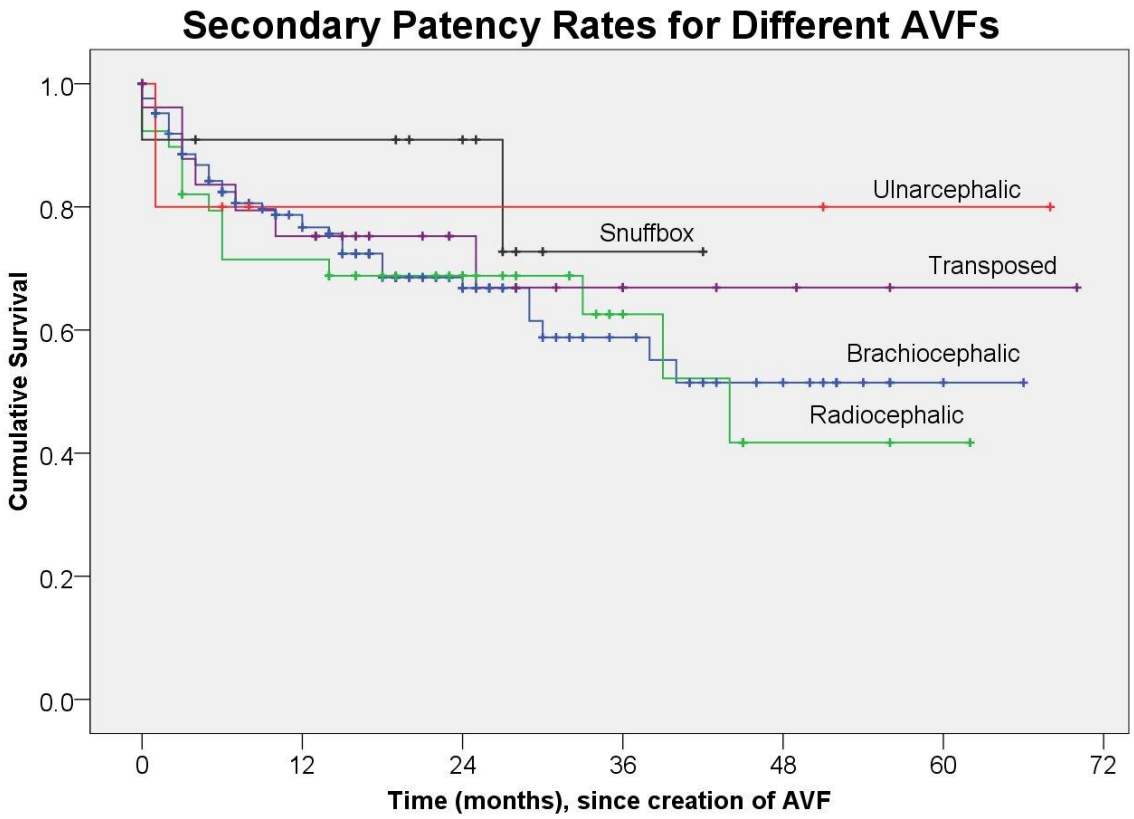
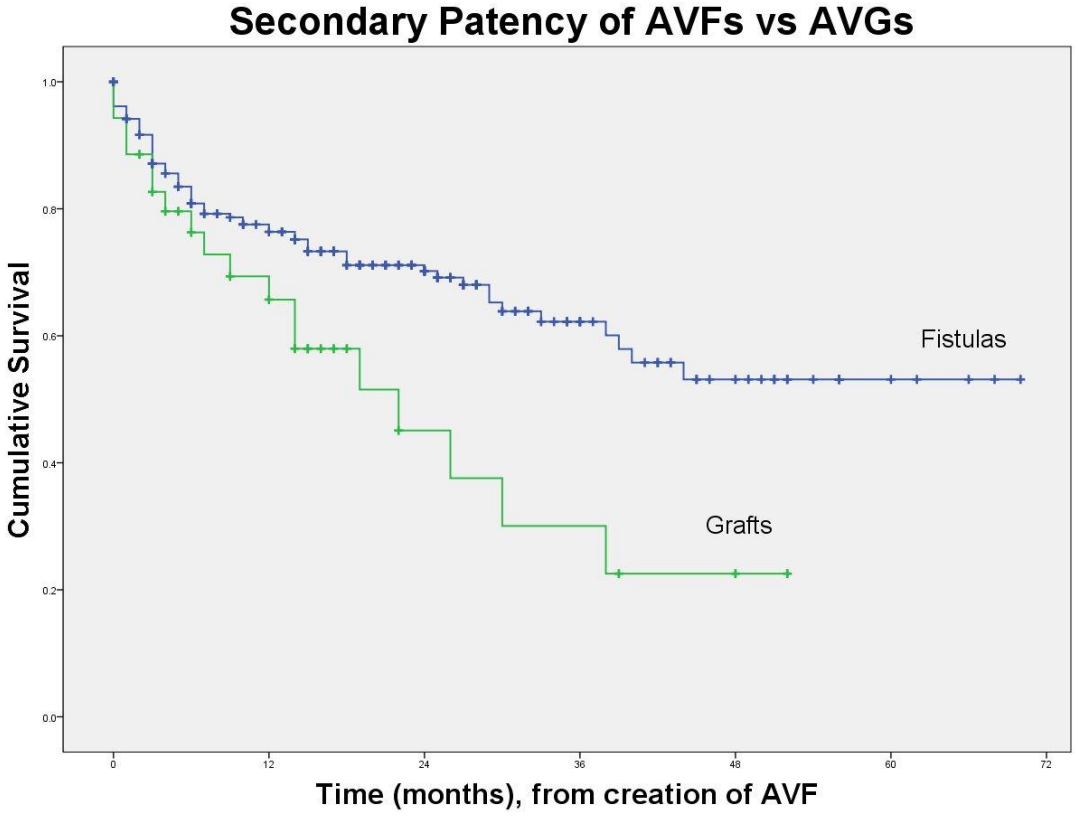


Figure 3 Kaplan-Meier survival curves comparing the secondary patency between AVFs and AVGs



Discussion

The patency rates of AVFs fashioned in Malta over a 5 year period are similar to those reported in international literature.[5-7] Al-Jaishi et al. who carried out a metaanalysis of 12,838 fistulas over a 12 year period, concluded that one may expect a primary patency rate of 60±4% (1 year) and 51±7% (2 years), and a secondary patency of 71±7% (1 year) and 64±9% (2 years).[6] These rates are very similar to patency rates achieved locally over the analysis period. In our study, the 1 year secondary patency rate of 76.4±6.1% is also similar to the 83.1% 1 year patency rate reported locally by Caruana et al. [5]

While McGrogan et al. had noted inferior primary and secondary patency rates of radiocephalic fistulas compared to brachiocephalic,[8] we found no significant difference between primary or secondary patency rates between the two (p=.812 and p=.765 respectively). Similarly we found no significant difference when comparing all the different fistula types.

There are varying patency rates reported when it comes to PTFE grafts. Our secondary patency rates of grafts are similar to those reported in studies by Ravari et al.[9] and Disbrow et al. [10] When it comes to primary patency rates, while our local rates do compare to some studies eg. 19.5% (1 year)[11], there are other studies which record considerably higher patency rates of 42-43% after a year.[12-13]

With transposed fistulas we noted similar patency rates at 1 and 2 year intervals, when compared to non-transposed fistulas. This differs to the study by Choi et al. which noted superiority of transposed patency rates after 2 years, despite similar rates after 1 year.[14]

With regards to snuffbox fistulas, we reported very satisfactory assisted and secondary patency rates up to 2 years follow up. Our 1 year secondary patency rates (90.9%) are in keeping with the 93±4% quoted in literature however we lag behind in primary patency (45.6%) when comparing to patency rates quoted from 65%-83%.[15-16] Despite this, it should be noted that our snuffbox fistula sample was relatively small (5.3%, n=11), and may therefore not be thoroughly representative. Snuffbox fistulas have the advantage of easier anastomosis due to closer proximity between artery and vein, as well as a reduced risk of steal in view of narrower artery caliber, which makes them an attractive option for fistula creation.[15]

Incidence of complications in fistulae were in keeping with reported incidence published by Stolic et al, with thrombosis 17-25% and stenosis 14-42%.[17] Although no difference in complication rates were noted between fistula types locally, it must be said that the ulnarcephalic and snuffbox fistula samples were small, and may not be fully representative. We did note that 43.8% of AVFs and AVGs created required some sort of intervention, be it surgical or endovascular. This highlights the high demand of stress placed on, not only the health service, but also on the physical and mental wellbeing of already vulnerable patients.

In 2006, the National Kidney Foundation (NFK) through the Kidney Disease Outcomes Quality Initiative (KDOQI) released updated guidelines which recommends incident fistula rates of 50% and at least 40% prevalent rates in patients undergoing haemodialysis. The Centers for Medicare & Medicaid Services (CMS) implemented a Fistula First Breakthrough Initiative (FFBI) in an attempt to

achieve these rates. In 2009, the target incidence rate was increase to 65%. In the study carried out by Caruana et al, which reviewed fistulae in Malta from October 2012 to May 2014 showed that only 25% of people had a functioning fistula before haemodialysis.[5] This is in keeping with our findings of 26.1% Even when analyzing our data from May 2014 onwards, the rate showed no significant improvement since the last local study carried out indicating that recommended targets are far from being reached.

When comparing this to countries across the world, we find that Malta lags behind the European average (66%) and most of the major countries such as Germany (72%), Japan (69%), Italy (61%), Spain (64%) and UK (37%). Our fistula incidence rates are comparable to Belgium (26%) and Canada (26%) while surpassing those of the USA (16%).[18] While the FFBI initiative had brought on a welcome improvement in fistula rates, it also led to increase in AVF failure rates and procedures required to salvage them.

In conclusion, we found that in Malta the AVF incidence lags behind the European average, but patency rates are comparable with most other countries. Efforts should be made for earlier referral to vascular surgeons and close liaison with the attending nephrologist to ensure the best possible patient-centered care.

Summary Box

What is known about this subject?

- Need for arteriovenous fistulae and grafts are increasing with more frequent and longer haemodialysis sessions
- Fistula should be created prior to initiation of haemodialysis
- In Malta, incidence rates of fistulas prior to haemodialysis were at 25% in 2014

What are the new findings?

- Patency and complication rates of Maltese fistulas are comparable with European standards
- No increase in fistula incidence over the past 3 years since last local study
- We lag behind European counterparts in fistula incidence

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