

Decreased Incidence of Clotted AV Access in Hemodialysis Patients after the Implementation of Follow up Program

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Received: December 24, 2015 Accepted: January 14, 2016 Online Published: February 24, 2016

doi:10.5539/gjhs.v8n10p81

URL: <http://dx.doi.org/10.5539/gjhs.v8n10p81>

Abstract

Background and Objectives: Access monitoring and pre-emptive angioplasty is known to decrease the incidence of AVF/AVG thrombosis. The effect on increase the longevity and functionality of Arterial-Venous access (AV access) in end-stage renal disease (ESRD) patients is not settled. Thrombosis is the leading cause of vascular access complications and is almost always associated with the presence of stenosis. Percutaneous transluminal angioplasty (PTA) is an accepted treatment of stenotic lesions in AV access (NKF 2001). The purpose of this study is to assess the effect of follow up of ESRD patients in the dialysis access center with preemptive angioplasty on access thrombosis.

Design, Setting, Participants, & Measurements: This is a single center observational interventional study extended over 9 years (Jan 1, 2006 to Dec 31, 2014) at the Dialysis Access Center of Pittsburgh, PA. The study is divided into 2 periods, period A (from Jan 2006 to December 2009), where follow up program was not in place. Period B extends from (January 1, 2011 to December 31, 2014). In this period, a follow up of patients with preemptive angioplasty of AV access has been implemented. We decided not to include 2010 as the program is implemented at the end of that year and including this year might skewed the data. All patients with ESRD on HD are seen in the Dialysis access center of Pittsburgh for access monitoring and interventional PTA if deemed necessary. Patients' data were abstracted from the electronic medical records. The study is approved by the IRB of Lifeline corp.

Results: During period A; a total of 4139 encounters with a mean of 1034, (1653 angioplasties with mean of 413/year, 375 angiogram, mean 94/year, and 303 thrombectomies of AVF/AVG with a mean 76/year) were carried out. Thrombectomies constituted (7.3%) of the total procedures performed.

Table 1 showed the mean distributions of AVG, AVF, and tunneled dialysis catheters (TDC) frequencies compared to national average in periods A & B.

In period B, a total of 6229 encounters with mean of 1557 encounter/year were performed, (3202 angioplasties, mean 801/year, 950 angiograms, mean 238/year, and 196 thrombectomies, mean 42/year) were done. Thrombectomies were decreased almost 2 folds in this period (7.3% to 3.15%).

The percentage of patients being dialyzed via TDC decreased in period B from 31.895% to 17.38%. The numbers of thrombectomies have also been decreased from average 76 to 42 /year (7.3% to 3.15%).

After implementing the program, as illustrated in period B, compared to the national average, the frequency of thrombectomies (3.15% vs. 9.6%) and TDC use (17.38% vs. 18%), have showed significant improvement. Meanwhile, the number of PTA has doubled from an average of (413 to 801/year) between the 2 periods. Our fistula rate has gone up from 48.7% to 66.2% between the 2 periods. Mild increase of the AVG use (12.07% to 18.07%) has also been observed. However, the use of TDC has decreased from (31.42% to 17.38%). These results are consistent with the motto of (fistula first and catheter last). The growth of PTA may explain the positive impact of this program on the number of thrombectomies as well as maintenance of access functionality in ESRD patients. The rate of PTA has gone up from (39.85% to 51.25%). This trade off may be acceptable if

access patency and functionality have to be maintained. It is not clear whether the follow up program with preemptive angioplasty would have a positive effect on the access expenditure and access longevity in this group of patients.

Conclusion: Follow up of ESRD patients in the dialysis access center and preemptive angioplasty if need be is an acceptable means to decrease the number of failed accesses, thrombectomies, as well as the use of TDC in ESRD patients.

Keywords: pre-emptive angioplasty, Arterial-Venous access, end-stage renal disease, thrombectomies

1. Introduction

There has been tremendous growth of end-stage renal disease (ESRD) in the United States with more than 600,000 patients in 2011 with around 400,000 patients on dialysis (USRDS, 2013). Patients with ESRD consume disproportionate health care resources, despite making up only 1.3% of the Medicare population. They accounted for 6.2% of the Medicare expenditures in 2011, (USRDS, 2013; Gorodetskaya, 2005; US census Bureau, 2012). Vascular access share accounts for approximately 10% of the total ESRD program costs (Feldman, 1996; Manns, 2005).

Access monitoring and pre-emptive angioplasty is known to decrease the incidence of AVF/AVG thrombosis (Schwab, 1995; Besarab, 1995; Safa, 1992; Smits, 2001). The results on increasing the longevity and functionality of Arterial-Venous access (AV access) in ESRD patients are still not settled. Different studies have demonstrated reduced thrombosis (Ram, 2003; Allon, 2007; Whittier, 2011) and perhaps prolongation of the cumulative patency of AV fistula and grafts (Tessitor, 2008), while others fail to yield significant effects (Moist, 2003; Dember, 2004). Thrombosis is the leading cause of vascular access complications and is almost always associated with the presence of stenosis. Percutaneous transluminal angioplasty (PTA) is an accepted treatment of stenotic lesions in AV access (NKF, 2001). The purpose of this study is to assess the effect of follow up of ESRD patients in the dialysis access center with preemptive angioplasty on access thrombosis.

2. Material and Methods

2.1 Participants and Study Design

We analyzed the effect of follow up program on the number of thrombectomies and angioplasties on a cohort of adults hemodialysis patients who had fistula or graft between January 1, 2006 and December 31, 2014 at the Dialysis Access Center of Pittsburgh, PA. A total of 6082 patients with 10368 encounters were included in the study. The age range is 23 to 92 years with mean age of 64 years. There were 50.92% males and 57.25% diabetics. Patients' data were abstracted from the electronic records of Lifeline data base.

This is a single center observational interventional study extended over 9 years at the Dialysis Access Center of Pittsburgh, PA. The study is divided into 2 periods, period A (from January 1, 2006 to December 31, 2009) where follow up program was not in place. Period B is from (January 1, 2011 to December 31, 2014) where a follow up of patients with preemptive angioplasty of AV access has been implemented. We decided not to include 2010 as the program is implemented at the end of that year and including this year might skewed the data. All patients with ESRD on HD are seen in the Dialysis access center of Pittsburgh for access monitoring and interventional PTA if deemed necessary. The study is approved by the IRB of Lifeline corp.

The follow up program entails the following:

- The patients are brought to the dialysis access center for clinical examination and/or ultrasound evaluation of their access. The treating interventionalists is reviewing the clinical and dialysis data of the patients and incorporates the results of the US and clinical examinations of the access and forms an educated decision. This information decides whether to take the patient to the procedure room for angiogram of the access and/or angioplasty.
- For patients who had thrombectomy or angioplasty performed- post-operative visit scheduled;
 - Thrombectomy in 1 month.
 - Central vein angioplasty in 2 months.
 - Regular angioplasty in 3 months.

Notes on subsequent post operative visit- Assumptions made in modeling protocol:

- Central vein angioplasty patients who have a post op angioplasty performed continue to be scheduled 2 months out for subsequent post op visit.

- Thrombectomy patients who have a post op angioplasty performed are subsequently scheduled one month and then 3 months out for a post op visit (similar to regular angioplasty patient).
- Any patients that have a good flow and normal angiogram will be scheduled for a clinical examination in 6 months.
- In the following visit if medically necessary angiogram is performed and angioplasty is done then the patient is scheduled for upcoming visit to the DAC which depends on the following:
 - o Nature of the lesion
 - o Site of the lesion
 - o Natural history of the lesion and the time interval of recurrence of the symptoms and signs relevant to the access.
 - o The interval between visits can be increased or decreased depending on the above factors.

The decision to take the patient to the operating room is entirely left to the discretion of the treating interventionalist. The treating interventionalist incorporates all data from clinical examination of the access, the ultra-sound evaluation, and the clinical and dialysis data from the Vasc-alert, flow studies, clearance and pressure studies of the monitoring modality used by the dialysis unit before forming an educated decision.

2.1 Measures and Definitions

All procedures of angioplasties, angiograms, thrombectomies, catheter exchanges and catheter placements that were done at the Access center of Pittsburgh from January 1, 2006 to December 31, 2014 were compared in the 2 periods (A and B). Physical examination of the AV access along with ultra-sound evaluation was carried out at the Access by the interventionalists. Thrombectomy, angioplasty or angiogram were done at the discretion of the interventionalists. Thrombosis of the access is diagnosed if there was no flow in the access and or the presence of intra-vascular clot on ultra-sound evaluation. Successful thrombectomy is defined as one dialysis session via the access following the procedure. Angioplasty is successful if the residual after angioplasty is <30%.

3. Results

There were 10,368 encounters during the entire follow up study. The total numbers of cohort patients with ESRD included in the study, from (January 1, 2006 to December 31, 2014), are 6082 patients. The demographic data are shown in Table 1.

Table 1. Demographic data of ESRD patient

Total encounters	10,368
Number of Patients	6082
Age range,	23 to 92 years
Mean	64 years
Diabetes	57.25%
Male: female	50.92 :49.08
Percentage of access type	
AVF	66.15%
AVG	13.09%
TDC	24.64%

During the follow up period, the incident rate of AVF and to a lesser extent the AVG have been increased compared to the national average, Table 2.

Table 2. Percentage of AVF, AVG, and TDC compared to the national average.

Access type	Pre-follow up program				Post-follow up program			
	2006	2007	2008	2009	2011	2012	2013	2014
AVF	46.82(32.92)	47.62(35)	47.35(35.23)	50.85(36.61)	63.55(41.78)	68.25(44.08)	70.85(44.91)	70.30(44.57)
AVG	12.85(37.05)	13.01(27.97)	10.53(25.87)	11.87(25.17)	13.72(25.01)	14.83(23.59)	13.80(21.52)	14.07(21.55)
TDC	32.57(26.40)	31.67(31)	33.82(32.25)	29.52(30.74)	22.20(24.96)	16.75(22.54)	15.20(21.08)	15.38(19.90)

AVF-arterial-venous fistula, AVG- arterial-venous graft, TDC- tunneled dialysis catheter;

Numbers represent the percentage, the number between the parentheses are the national average.

The reasons for referral to the Access center of Pittsburgh are shown in Table 3. The reason for inadequate blood flow as a referral has decreased from 18.69% to 7.32% in period B. The incident rate of clotted access decreased from 7.3% in period A to 3.15% after follow up program implementation. The incident of bleeding has gone up in period B to 11.32% from 5.43%. The reason for this increase is not entirely clear. The percentage of follow up visits has also gone up to 23.15% from 1.47%.

Table 3. Reason for referral to the access center

Reason for referral	Pre-follow up program				Post-follow up program			
	2006	2007	2008	2009	2011	2012	2013	2014
Inadequate blood flow to the dialysis machine	24.43%	10.52%	9.33%	10.48%	9.54%	7.76%	4.65%	
Malfunction catheter	13.23%	10.75%	7.62%	3.97%	4.83%	3.45%	2.22%	1.55%
Clotted access	10.31%	8.60%	7.45%	8.79%	3.61%	3.43%	1.67%	1.67%
Determination of access placement	9.8%	8.48%	10.10%	8.74%				
Mature access/catheter removal	5.73%	7.92%	6.68%	8.67%	8.46%	7.08%	4.44%	4.46%
Increase venous or arterial pressure	5.22%	7.01%	6.08%	5.65%	3.47%	6.01%	6.91%	5.08%
Unable to cannulate	4.96%	5.88%	5.82%	4.60%	4.80%	5.21%	3.45%	3.41%
bleeding	3.44%	4.64%	6.42%	7.21%	11.40%	13.36%	12.08%	8.43%
Swollen extremity	2.67%	4.07%	3.60%	2.93%	3.47%	2.95%	2.31%	1.80%
Follow up	1.53%	1.36%	0.60%	2.39%	25.65%	27.04%	21.48%	18.41%

Thrombectomy number has decreased dramatically in period B. Table 4. The numbers of angioplasty in the same period have increased, (51.25% from 39.86%). as shown in Table 4.

Table 4 the TDC use showed a significant decrease in period B, 31.89% to 17.38%. These are of course welcoming news.

Table 4. Procedures performed in the Access center

Procedure performed	Pre-follow up program				Post-follow up program			
	2006	2007	2008	2009	2011	2012	2013	2014
Angioplasty	39.44%	40.27%	39.13%	40.58%	51.04%	53.19%	50.32%	50.46%
angiogram	8.56%	8.26%	9.42%	9.82%	14.76%	14.51%	16.19%	16.80%
Dialysis access	7.25%	7.58%	6.51%	7.97%	1.64%	1.55%	2.68%	2.48%
Thrombectomy								
Hemodialysis catheter exchange	13.61%	9.84%	12.5%	10.27%	6.94%	4.81%	3.40%	3.29%

Pre-follow up program	Post-follow up program							
Procedure performed	2006	2007	2008	2009	2011	2012	2013	2014
Hemodialysis catheter removal	7.12%	9.50%	8.74%	10.29%	9.93%	8.05%	6.68%	8.43%
Hemodialysis catheter placement	5.47%	5.54%	4.02%	2.29%	1.72%	0.97%	1.44%	0.62%
Office visit	1.78%	2.6%	2.14%	5.08%	7.02%	6.37%	5.96%	11.10%
Ultrasound	2.55%	1.7%	1.54%	0.58%	2.21%	6.52%	11.31%	5.39%

4. Discussion

The concept of prospective monitoring with elective intervention to maintain patency of AV access has been carried out in multiple clinical studies (Schwab, 1999; Besarab, 1995; Kanterman, 1995; Vaiji, 1991; Safa, 1995; Sands, 1995; Turmel-Rodrigues, 1993; Besarab, 1998). This study confirms previous data that preemptive angioplasty of the AV access has benefits on decreasing the incidence of thrombectomies, access failure and missed dialysis sessions (Schwab, 1995; Besarab, 1995; Safa, 1995).

Different methods for access monitoring are used in our ESRD population (transonic, static & venous pressure along with blood flow monitoring, and Vasc-alert), but the utility of this methods differ in the different dialysis centers. Owing to multiple logistic factors it is not possible to rely on busy dialysis staff to monitor the accesses and refer patients in timely manner to the access center for PTA intervention, thrombosis prevention, and access maintenance. These constraints prompted us to implement a follow up program to these patients in the dialysis access center. Starting in October 2010, all patients on HD are followed up prospectively on different intervals according to the nature of their underlying lesion on initial angiograms. Their AV accesses are examined by experience interventionalists with ultrasound evaluation and PTA if deemed necessary. The follow up evaluation of the accesses are performed in the access center and the intervals ranging from one to twelve months.

Our results are clearly showed decreased thrombosis rate overall in AVF and AVG following the implementation of the program. This study confirms the previous findings of other workers (Schwab, 1989; Smits, 2001). The reason for this remarkable improvement is not entirely clear. We speculated that close follow up of these patients with attentions to preemptive PTA have significantly decreased the rate of access thrombosis and may have improved the number of patients who are TDC dependent. It is clear that angioplasty rate have increased in the same period. This may be an acceptable trade off to maintain access functionality and patency.

The take home message is the value of close follow up, monitoring, and prospective PTA in AV access management. Not only does it appear that thromboses are avoided, but the use of TDC have significantly decreased, thereby, preventing the attended complications, e.g. blood stream infection and central vein stenosis.

The appropriate criticism of this program is that monitoring of AV access to prevent thrombosis merely replaces one intervention with another. The numbers of PTA interventions have doubled (average of (413/year to 801/year, 39.85% to 51.25%) to maintain patency of the AV access. Nonetheless, the use of an elective intervention appears to extend access patency and diminish the need for urgent thrombectomies. The increased incidence of referral because of increased bleeding may reflect the awareness of the dialysis staff to send patients promptly for angiograms. Can these results translate into positive gains? The impact on access longevity and expenditure are not clearly known at this time.

The limitations of this study are that it was carried out in one center and may not be applied in other facilities. The follow up periods is also limited. In addition, a concurrent control group is not used. However, the results of low thrombectomies and decrease rate of TDC use are striking. Replications of this study in multiple centers would increase the authenticity and gives larger confirmatory results to the robustness of the study.

In summary, close follow up of HD patients with preemptive PTA to the AV access prevents thrombosis; maintain access patency, and decrease the missed dialysis sessions. The issue of increase longevity and functionality of these vital conduits are not settled at this time. Active follow up of these patients with pre-emptive angioplasty measures are worthy of further investigations. The ideal long-term therapy in the treatment of AV access is the prevention of fibromuscular and intimal hyperplasia rather than correction of an existing pathological process. This aim remains an aspiration for future endeavor.

Conflict of Interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

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