Cutting balloon angioplasty versus conventional balloon angioplasty in hemodialysis access stenoses: Multicenter prospective randomized comparison of primary patency rates.

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Purpose: *To compare primary patency rates of cutting balloon percutaneous transluminal angioplasty and conventional balloon percutaneous transluminal angioplasty in the treatment of different types of hemodialysis access stenosis.*

Patients and methods: *58 patients with different types of hemodialysis access stenosis in whom PTA was indicated were prospectively, randomized to have either conventional balloon percutaneous transluminal angioplasty or cutting balloon percutaneous transluminal angioplasty. The study was performed at 3 medical centers in Saudi Arabia (Al-Moosa Specialized hospital Al-Ahsaa, Tabuk University, & Saudi German Hospital Riyadh). The primary patency rates of conventional PTA group & cutting balloon PTA group were compared. The patients were followed up for 15 months. Primary patency rates for lesions were calculated with the Kaplan-Meier method according to the type of stenosis. We compared the two groups by using the log-rank test to determine statistical significance.*

Results: *In the cutting PTA group, 26 patients with 29 stenoses achieved clinical success. In the conventional PTA group, 25 patients with 30 stenoses achieved clinical success. In patients with graft-to vein anastomotic stenosis, the primary patency rate was significantly higher for cutting PTA than for conventional PTA (P = .037). In patients with autogenous venous stenosis, intragraft stenosis and arterial anastomotic stenosis, no significant difference in the primary patency rate was noted between groups (P = .360, .371 & .921 respectively).*

Conclusion: *Primary patency rates are significantly higher for cutting PTA in the treatment of graft-to-vein anastomotic stenosis, however, no significant differences in primary patency rates exist between these PTAs in the treatment of autogenous venous stenosis, intragraft stenosis, or arterial anastomotic stenosis.*

Introduction:

Autogenous arteriovenous fistulas (AVF) and prosthetic arteriovenous grafts (AVG) are necessary for chronic end-stage renal failure patients on hemodialysis. Hemodialysis accesses are prone to failure due to thrombosis, usually concomitant with stenosis over the anastomosis or outflow vein. Access thrombosis frequently requires semi-emergent salvage intervention. Patients eventually may require multiple salvage procedures to restore functionality or creation of a new access. The Dialysis Outcomes Quality Initiative guidelines of the National Kidney Foundation recommend that balloon percutaneous transluminal angioplasty (PTA) be performed to treat hemodialysis access stenosis. With use of PTA, it is not difficult to achieve the reasonable patency goals described in these guidelines.[1–5] Furthermore, secondary patency can typically be maintained with repeated PTA.[2] However, since patients undergoing long-term dialysis require hemodialysis access for long periods of time, improvement in primary patency rates would reduce the number of PTAs performed. Thus, the purpose of our study was to compare primary patency rates of cutting balloon PTA and conventional balloon PTA in the treatment of different types of hemodialysis access stenosis.

Patients and methods:

Study Design: From November 2011 to October 2013, 58 patients with different types of hemodialysis access stenosis in whom PTA was indicated were prospectively, randomized (using an internet randomization service[6]) to have either conventional balloon percutaneous transluminal angioplasty (conventional PTA) or cutting balloon percutaneous transluminal angioplasty (cutting PTA). The primary patency rates of conventional balloon PTA group & cutting balloon PTA group were compared. In the present study, primary subjects were those with stenoses in whom clinical success was achieved by using balloon angioplasty alone without stenting. The study was performed at 3 medical centers in Saudi Arabia (Al-Moosa Specialized hospital Al-Ahsaa, Tabuk University, & Saudi German hospital Riyadh). The vascular surgeon evaluated the indications for PTA; performed PTA, including conventional PTA and cutting PTA; measured vessel diameters; and monitored each patient's clinical course. Demographic **Table (1)** and procedural data were obtained; these data included access type and location, technical details of the procedure, complications, and procedure outcome. In some patients with thrombotic occlusion, balloon PTA was performed after surgical thrombectomy. All complications that occurred during PTA & post PTA follow-up were recorded and evaluated, including (balloon rupture, vascular injury, hemorrhage, hypotension, allergic reaction, and infection, and pulmonary embolism, ischemia of the hand, hypoxia, and death).

Patients: In all patients, an autogenous fistula or polytetrafluoroethylene (PTFE) graft (6 mm in diameter or 4-7mm tapered graft) was placed in either the forearm or the upper arm. None of the patients underwent previous PTA.

Criteria for PTA: According to Dialysis Outcomes Quality Initiative guidelines, all PTAs were performed in patients with more than 50% stenosis and clinical abnormalities.[1] Clinical abnormalities included abnormal physical examination findings (changes in bruits, thrills, pulse, etc.); abnormal urea recirculation measurements, as defined in the Dialysis Outcomes Quality Initiative protocol; elevated venous pressure during dialysis; decreased access flow; previous thrombosis in the access line; development of collateral veins; limb swelling; low arterial pressure during dialysis; and/or unexplained decreases in dialysis dose.[1]

Exclusion criteria: Previous PTA for the same lesion. PTA combined with stenting Associated significant (>50%) central venous stenosis. Positive pregnancy test within 7 days before enrollment. Patient scheduled for a kidney transplant. Life expectancy <6 months. Documented allergy to heparin or radiographic contrast material.

Cutting PTA Group: Patients who underwent cutting PTA comprised 29 patients with 36 stenoses (17 men, 12 women). Included patients with significant dialysis access stenosis in whom clinical success was achieved by using cutting PTA alone. In this group, three of the 29 patients with thrombotic occlusion underwent surgical thrombectomy before PTA.

Conventional PTA Group: Conventional PTA was performed in 29 patients with 38 stenoses (13 men, 16 women). Included patients with significant dialysis access stenosis in whom clinical success was achieved by using conventional PTA alone. In this group, two of the 29 patients with thrombotic occlusion underwent surgical thrombectomy.

Assessment of Stenoses: Diagnostic fistulography was performed to identify and evaluate the target lesion and to evaluate the outflow veins. All lesions were characterized by location, length, and degree of stenosis. The angiographic criteria were assessed and satisfied before any treatment was performed. The target lesion was imaged in two orthogonal planes. The imaging plane that demonstrated the greatest degree of stenosis was used for subsequent anatomic measurements. Anatomic measurements were made with use of a calibrated reference marker or the computer- assisted edge detection software within the angiographic imaging system. The reference vessel was defined as an adjacent segment of normal vein located upstream from the target lesion. The degree of stenosis was reported as the maximum diameter reduction compared with the reference vessel diameter **Table (2)**.

Procedures and clinical success: All procedures were performed by the vascular surgeon under local anesthesia (lidocaine 2%) Anticoagulants (intravenous heparin, 2000 IU) were administered at the beginning of angioplasty procedures. Initial balloon size was determined with the same technique used to determine the expected vessel diameter in a fistula or the diameter of the adjacent graft. A 5–7-F introducer sheath was used as an access device for balloon angioplasty in all patients. In patients with an autogenous fistula, the introducer sheath was placed in the draining vein. In patients with a graft, the introducer sheath was placed in the graft or drainage vein. Clinical success of conventional or cutting balloon PTA was defined as an improvement in hemodialysis access failure and resumption of normal dialysis for at least one dialysis session after PTA.

Technique for cutting PTA: In cutting PTA, a 1-2 cm-long cutting balloon (Peripheral Cutting Balloon; Boston Scientific) rated as having a burst pressure of 10 atm and with inflation diameter of 5–8 mm was used. The lesion was crossed by using a 0.018- inch guidewire (Transend; Boston Scientific), over which the cutting balloon was introduced. First, the cutting balloon was inflated for 60 seconds at 4 atm. for two attempts. On the third inflation, if the balloon waist remained at the same pressure as on the second inflation, pressure was subsequently increased by 2 atm. & inflated repeatedly until the balloon waist disappeared. Once the balloon was completely inflated for 60 seconds on any attempt, the inflation procedure was stopped. Maximum pressure was set at 10 atm., even if the balloon waist remained after inflation at 10 atm., the inflation procedure was terminated. After inflation end, the deflated cutting balloon catheter was rolled before the next inflation. The reason for rolling the cutting balloon catheter was so the blade attached to the balloon would cut the vessel wall at a different site each time. At the end of the procedure, a final fistulogram was obtained **Figures (1-2)**.

Technique for conventional PTA: In conventional PTA, 2–4-cm long conventional balloons (Synergy; Boston Scientific) rated as having a burst pressure of 18 atm., and with an inflation diameter of 5–8 mm were used. The lesion was crossed by using a 0.035- inch guidewire (Terumo Medical Corporation, USA), over which the balloon was introduced. Each balloon was inflated to a level below the rated burst pressure recommended by the manufacturer until the balloon waist disappeared; then it was inflated for 60 seconds. If the balloon waist still remained when the rated burst pressure was reached, the balloon was inflated for 60 seconds for no more than three attempts until the balloon waist disappeared below the rated burst pressure. Even if the balloon waist remained after inflation at rated burst pressure the inflation procedure was terminated without further attempt. At the end of the procedure, a final fistulogram was obtained **Figures (3,4)**.

Total procedure time: The total procedure time was documented for each study patient. The start of the procedure was defined as the moment when the physician gained percutaneous access into the graft. The end of the procedure was defined as the completion of final postprocedural fistulography. The mean procedure times for conventional PTA and cutting PTA treatment were 49.6 minutes and 61.2 minutes, respectively (P= .642).

Follow-up: In both groups, clinical findings (change in bruits, thrills, pulse, etc) were noted at physical examination, venous dialysis pressure was recorded during each hemodialysis session, and monthly measurements of dialysis dose and urea recirculation were obtained. Access flow measurements were obtained with ultrasonography (US) every 2–3 months. Fistulography was performed when abnormal results were obtained. The mean duration of follow-up was 15 ±3 month.

Statistical analysis: Balloon diameter, percent diameter stenosis before PTA, residual percent diameter stenosis after PTA, and percent diameter dilatation (ie, residual percent diameter stenosis after PTA minus percent diameter stenosis before PTA) in the cutting PTA group and the conventional PTA group were compared by using the Mann-Whitney U test. Hemodialysis access stenosis was divided into the following four types: (a) autogenous venous stenosis (stenosis of venous runoff from arterial-venous anastomosis to central veins), (b) graft-to-vein anastomotic stenosis, (c) intragraft stenosis, and (d) arterial anastomotic stenosis. For these four types, the patency rates were assessed with the Kaplan-Meier method and compared with the results of log-rank statistics in the cutting and conventional PTA groups.

Primary patency for the lesion was defined as uninterrupted patency of the treated site after balloon PTA. The end point of patency was decided at the time of treatment for hemodialysis access failure due to restenosis of the treated site. However, when a lesion other than that at the treated site caused hemodialysis access failure, primary patency for the lesion was not interrupted.

As the sample size was small, the X^2 test or Fisher exact test was used to compare patency rates for various time points (3rd, 6th, 9th, 12th, and 15th months) between cutting and conventional PTA groups for the four types of stenosis. P values of less than .05 were considered to indicate a statistically significant difference. All analyses were performed by using Stat- View, version 5.0, software (SAS Institute, Cary, NC).

Results

Cutting PTA: From November 2011 to October 2013, 29 patients (17 men, 12 women; mean age, 60.4 years ±10.1) with 36 stenoses, underwent cutting PTA. 26 patients 89% with 29 stenoses achieved clinical success with cutting PTA. Clinical success could not be achieved with cutting PTA alone in three patients with seven stenoses; these patients required additional stent implantation (1 patient) or surgical reconstruction (2 patients). Of the 29 stenoses, (18 were autogenous venous stenoses, 5 were graft-to-vein anastomotic stenoses, 4 were intragraft stenoses, and 2 were in arterial anastomotic stenosis). Two patients with thrombotic occlusion were included among the 26 patients in whom clinical success was achieved. The inflation diameter of the cutting balloons used, the mean loaded maximum pressure used are illustrated in **Table (3)**. the mean percent diameter stenosis before PTA, after PTA, and mean percent diameter dilatation after PTA, respectively, were 80.9 ±12.0, 30.8 ±15.5, and 50.1 ±18.5 for autogenous venous stenosis; 82.1 ±16.2, 34.9 ±12.7, and 47.2 ±11.0 for graft-to-vein anastomotic stenosis; 68.1 ±18.9, 38.9 ±16.0, and 29.2 ±13.3 for intragraft stenosis; and 74.8 ±5.5, 34.9 ±11.2, and 40.9 ±11.0 for arterial anastomotic stenosis **Table (2)**.

Conventional PTA: Of the 29 patients who had 38 stenoses. 25 patients 86% with 30 stenoses (13 men, 16 women; mean age, 61.9 years ± 10.2) achieved clinical success with conventional PTA. Clinical success could not be achieved with conventional PTA alone in four patients who required additional stent implantation (one patient) or surgical reconstruction (2 patients) graft insertion (one patient). Of the 30 stenoses, (17 were autogenous venous stenoses, 7 were graft-to-vein anastomotic stenoses, 3 were intragraft stenoses, and 3 were in arterial anastomotic stenosis). The inflation diameter of the cutting balloons used, the mean loaded maximum pressure used are illustrated in **Table (3)**. The mean percent diameter stenosis before PTA, after PTA, and mean percent diameter dilatation after PTA, respectively, were 74.1 ±14.3, 26.8 ±13.0, and 47.3 ±17.7 for autogenous venous stenosis; 67.9 ±13.4, 32.0 ±12.3, and 35.9 ±14.3 for graft-to-vein

Figure (1): Dilatation of cephalic venous stenosis of mid-forearm radio-cephalic fistula using cutting balloon angioplasty. a. Stenosis, b. cutting balloon inflation to dilate the stenosis without waist, c. completion venography after balloon dilatation.

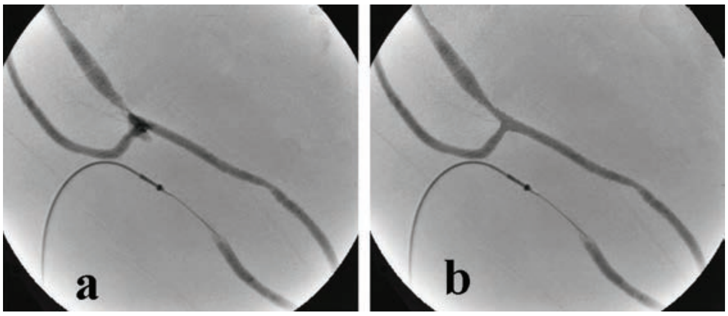

Figure (2): Forearm loop graft with graft-to-vein anastomotic stenosis. a. before and b. after cutting balloon dilatation.

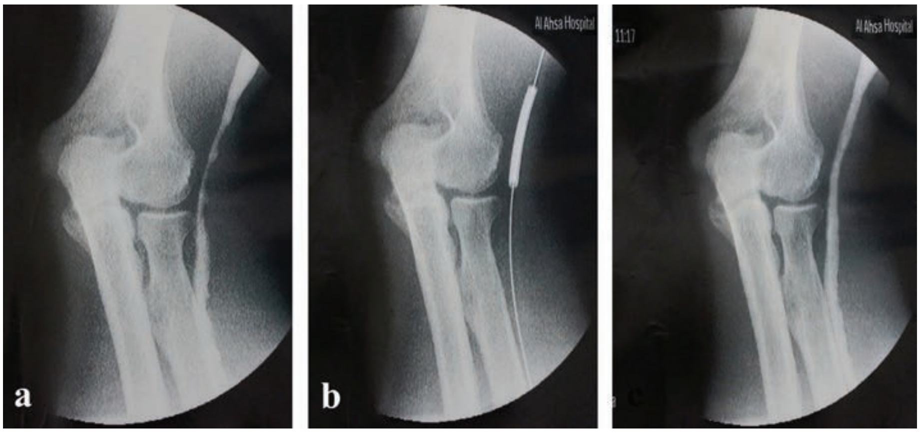

Figure (3): Conventional balloon angioplasty of cephalic venous stenosis in radiocephalic fistula. a. Fisulogram showing the stenotic segment of the cephalic vein at the level of the elbow, b. Conventional balloon inflation dilating the stenotic sement without waist, c. Completion venography after conventional balloon dilatation.

anastomotic stenosis; 63.0 ±9.5, 27.9 ±8.7, and 35.1±14.1 for intragraft stenosis; and 72.1 ±6.1, 24.1 ±15.0, and 48.0 ±13.7 for arterial anastomotic stenosis **Table (2)**.

Cutting PTA and conventional PTA groups: No significant differences in balloon diameter between cutting PTA and conventional PTA groups were seen for any type of stenosis **Table (3)**. No significant differences in percent diameter stenosis were seen between cutting PTA and conventional PTA groups before PTA for graft-to-vein anastomotic stenosis (P =.060), intragraft stenosis (P =.858), or arterial anastomotic stenosis (P =.328). A significant difference in percent diameter stenosis was seen between the groups for autogenous venous stenosis (P =.011) **Table (2)**. No significant differences

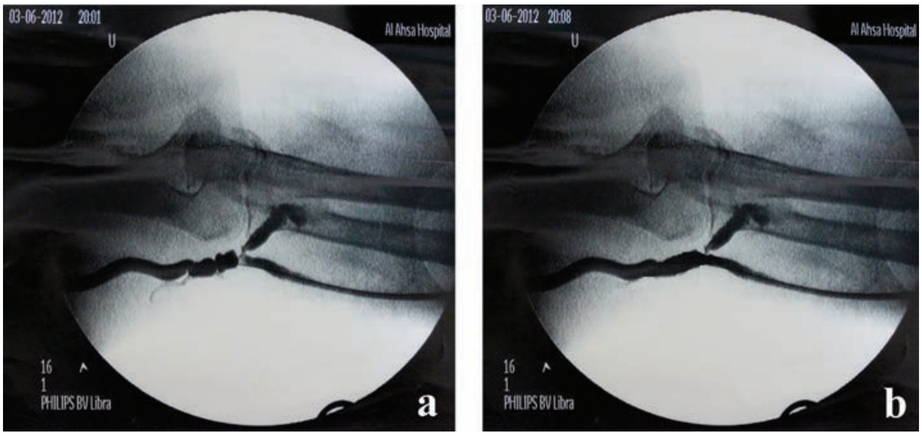

Figure (4): Brachiocephalic fistula with arterial anastomotic stenosis.
a. Before and b. After conventional balloon dilatation.

Table (1): Demographic characteristics of the study population.

Characteristic	Cutting Balloon (%)	Conventional (%)	P Value
Age (y)	60.4 ± 10.1	61.9 ± 10.2	.205
Male sex	58	55	.826
Diabetes mellitus	56	49	.232
Hypertension	85	82	.559
Coronary artery disease	24	26	.796
Congestive heart failure	7	9	.553

Table (2): Percent diameter stenosis before PTA and residual percent diameter stenosis after PTA.

	Percent Diameter Stenosis before PTA			Residual Percent Diameter Stenosis after PTA			Percent Diameter Dilatation after PTA		
Stenosis Type	Cutting PTA	Conventional PTA	P Value*	Cutting PTA	Conventional PTA	P Value*	Cutting PTA	Conventional PTA	P Value*
Autogenous venous	80.9 ±12.0	74.1 ±14.3	.011	30.8 ±15.5	26.8 ±13.0	.328	50.1 ±18.5	47.3 ±17.7	.311
Graft-to-vein anastomotic	82.1 ±16.2	67.9 ±13.4	.060	34.9 ±12.7	32.0 ±12.3	.372	47.2 ±11.0	35.9 ±14.3	.100
Intragraft	68.1 ±18.9	63.0 ±9.5	.858	38.9 ±16.0	27.9 ±8.7	.028	29.2 ±13.3	35.1±14.1	.287
Arterial anastomotic stenosis	74.8 ± 5.5	72.1 ±6.1	.327	34.9 ±11.2	24.1 ±15.0	.096	40.9 ±11.0	48.0 ±13.7	.141

**P* values were derived from comparisons between cutting and conventional PTA groups and were calculated with the Mann-Whitney U test.

between cutting PTA and conventional PTA groups were seen in residual percent diameter stenosis after PTA for autogenous venous stenosis (P =.328), graft-to-vein anastomotic stenosis (P =.371), or arterial anastomotic stenosis (P =.096). A significant difference in residual percent diameter stenosis was seen between the groups for intragraft stenosis (P =.028). No significant differences between cutting PTA and conventional PTA groups were seen in percent diameter dilatation after PTA for autogenous venous stenosis (P

Table (3): Diameter and loaded maximum pressure of balloons.

	Inflation diameter of balloon (mm)			Loaded maximum pressure (atm)	
Stenosis Type	Cutting PTA	Conventional PTA	P Value*	Cutting PTA*	Conventional PTA*
Autogenous venous	5.6 ± 0.6	5.4 ± 0.5	.862	6.0 ± 4.0	15.1 ± 2.2
Graft-to-vein anastomotic	5.2 ± 0.2	5.1 ± 0.4	.480	6.1 ± 2.2	15.5 ± 3.2
Intragraft	5.4 ± 0.3	5.5 ± 0.6	.487	8.2 ± 2.0	16.7 ± 2.6
arterial anastomotic stenosis	5.3 ± 0.4	5.5 ± 0.7	.775	8.4 ± 2.6	15.0 ± 2.0

**P* values were derived from comparisons between cutting and conventional PTA groups and were calculated with the Mann-Whitney *U* test

Table 4: Patency rates for autogenous venous stenosis.

	Patency Rate (%)		
Time after PTA (mo.)	Cutting PTA	Conventional PTA	P Value*
3	94	94	.668
6	83	53	.013
9	67	53	.003
12	56	47	.271
15	44	41	.291

**P* values were derived from comparisons between cutting and conventional PTA groups and were calculated with the X^2 test or Fisher exact test.

Table (5): Patency rates for graft-to-vein anastomotic stenosis.

	Patency rate (%)		
Time after PTA (mo.)	Cutting PTA	Conventional PTA	P Value*
3	100	86	.533
6	80	71	>.99
9	80	57	.032
12	60	42	.071
15	60	42	.352

**P* values were derived from comparisons between cutting and conventional PTA groups and were calculated with the X^2 test or Fisher exact test.

=.312), graft-to-vein anastomotic stenosis (P =.100), intragraft stenosis (P =.287), or arterial anastomotic stenosis (P =.141).

Primary patency rates for autogenous venous stenosis: For cutting PTA group, the 6-month patency rate was 83% and the 1-year patency rate was 56% according to Kaplan-Meier analysis results. For conventional PTA group, the 6-month patency rate was 53% and the 1-year patency rate was 47%, as calculated with the Kaplan-Meier method. No significant differences (P =.360) in primary patency rates were identified between the two groups by using Kaplan-Meier analysis. With use of the X^2 or Fisher exact tests, patency rates in the cutting PTA group were found

Table (6): Patency rates for intragraft stenosis.

	Patency rate (%)		
Time after PTA (mo.)	Cutting PTA	Conventional PTA	P Value*
3	100	100	>.99
6	75	67	>.99
9	50	33	.270
12	50	33	.246
15	25	33	.246

**P* values were derived from comparisons between cutting and conventional PTA groups and were calculated with the X^2 test or Fisher exact test.

Table (7): Arterial anastomotic stenosis.

	Patency Rate (%)		
Time after PTA (mo.)	Cutting PTA	Conventional PTA	P Value*
3	100	100	>.99
6	100	100	.412
9	50	67	.350
12	50	67	.246
15	50	33	>.99

**P* values were derived from comparisons between cutting and conventional PTA groups and were calculated with the X^2 test or Fisher exact test.

to be significantly higher than those in the conventional PTA group in the 6th, and 9th months (P =.013, and P =.003, respectively) **Table (4)**.

Primary Patency Rates for Graft-to-Vein Anastomotic Stenosis: For cutting PTA alone, the 6-month patency rate was 80% and the 1-year patency rate was 60% according to Kaplan-Meier analysis results. For conventional PTA alone, the 6-month patency rate was 71% and the 1-year patency rate was 42% according to Kaplan- Meier analysis results. With use of Kaplan-Meier methods, the primary patency rate was significantly higher for cutting PTA than for conventional PTA (P =.037). With use of the X^2 or Fisher exact tests, the patency rate was significantly higher for cutting PTA than for conventional PTA in the 9th month (P =.032) **Table (5)**.

Primary Patency Rates for Intragraft Stenosis: For cutting PTA alone, the 6-month patency rate was 75% and the 1-year patency rate was 50% according to Kaplan-Meier analysis results. For conventional PTA alone, the 6-month patency rate was 67% and the 1-year patency rate was 33%, as calculated with the Kaplan-Meier method. With use of Kaplan-Meier analysis, no significant differences in primary patency rates were identified between the groups (P =.371). With use of the X^2 or Fisher exact tests, no significant differences in patency rates were identified between the groups at any follow-up point **Table (6)**.

Primary Patency for arterial anastomotic stenosis: For cutting PTA alone, the 6-month patency rate was 100% and the 1-year patency rate was 50% according to Kaplan-Meier analysis results. For conventional PTA alone, the 6-month patency rate was 100% and the 1-year patency rate was 67%, as calculated with the Kaplan-Meier method. No significant differences in primary patency rates were noted between the groups with use of the Kaplan-Meier method (P =.921). With use of the X^2 or Fisher exact tests, no significant differences in patency rates were identified between the groups at any time point **Table (7)**.

Complications in cutting PTA: Balloon rupture occurred in one of 36 stenoses, but subsequent angiography revealed no extravasation, but angiography performed 3 months after cutting PTA revealed aneurysmal dilatation at the site of balloon inflation. Diameter of aneurysmal dilatation was less than 2 cm. Follow-up testing conducted 1 year after PTA showed no aneurysmal diameter increase, and aneurysmal dilatation did not affect hemodialysis. Cutting PTA did not cause any other complications.

Complications in conventional PTA: Balloon rupture occurred during inflation in two of the 38 stenoses, but angiography revealed no extravasation. Extravasation occurred immediately after balloon inflation in one patient, and hemostasis was achieved by inflating the same balloon with 2 atm of pressure in the same location to apply compression from inside the vessel and by manually applying external compression for 5 minutes. Extravasation disappeared and clinical success was achieved. Conventional PTA did not cause any other complications.

Discussion:

Percutaneous transluminal angioplasty (PTA) is the main stay of treatment in hemodialysis access stenosis. PTA is a safe and useful intervention to restore access patency and preserve venous capital for future AVF or AVG creation.[7] PTA restores the luminal diameter of venous fistula by stretching and dissection of the vessel wall. This induces vascular damage and may cause subsequent restenosis.[8] whether the mechanism of venous restenosis is similar to arterial restenosis is uncertain. However, venous restenosis seems to recur more frequently than that of its arterial counterpart. Cutting balloon angioplasty reduces the amount of arterial wall damage by inducing a controlled fracture of atherosclerotic plaque. It is uncertain if cutting balloon angioplasty will reduce the recurrence rate of venous stenosis as compared to conventional balloon angioplasty.[9]

The cutting balloon was designed to decrease the local vascular trauma caused by conventional balloon angioplasty. In 1991, Barath and colleagues[10] described their experience with use of the cutting balloon in normal porcine arteries. By creating longitudinal incisions into the medial layer of the vascular wall while simultaneously dilating the lesion, the cutting balloon causes less stretching and less injury to the surrounding vascular smooth muscle. These investigators suggested that limiting the extent of angioplasty induced injury could reduce the expression of proliferative growth factors and thereby decrease the neointimal hyperplasic response.[10] This concept was clinically verified by Kondo and colleagues,[11] who used the coronary cutting balloon to treat 127 atherosclerotic lesions in the coronary arteries of 110 patients. In the subgroup of patients who were treated with only the cutting balloon, there was a significant decrease in the degree of restenosis. In addition, the acute gain in luminal diameter was greater when the cutting balloon was used compared with conventional angioplasty.

Vorwerk and colleagues[12] were the first group to report the use of the cutting balloon for treatment of hemodialysis related venous stenoses. Fifteen patients with 19 venous stenosis underwent treatment with use of 3-mm, 5-mm, and 6-mm cutting balloons. However, 68% of these lesions were also treated with conventional angioplasty balloons during the same procedure. Vorwerk et al[12] achieved a 6-month primary patency rate of 64%, but these results are confounded by the concurrent use of conventional angioplasty. This is a widespread problem that is found in other published reports describing the use of the cutting balloon for treatment of vascular access–related venous stenosis.[13-17] The results of these studies include patients who underwent concurrent treatment with the cutting balloon and conventional angioplasty. Singer-Jordan et al[15] described the use of the cutting balloon as “primary” treatment for fistula- related venous stenoses. However, 40% of the 42 study patients also underwent conventional angioplasty immediately after use of the cutting balloon and two patients received stents. Sreenarasimhaiah et al[17] reported the results of treatment with the cutting balloon in three patients, all of whom also underwent conventional angioplasty and stent placement after use of the cutting balloon. In the majority of these published reports, the cutting balloon was used to treat stenoses that failed to respond to high pressure balloon angioplasty. However, under these circumstances, the long-term patency rate is not necessarily reflective of the cutting balloon. As previously described, the cutting balloon is designed to reduce vascular trauma and thereby reduce neointimal hyperplasia and improve long-term patency of the vascular access. One could theorize that concurrent use of a high-pressure angioplasty balloon would negate these conceptual benefits.

Several studies compared the use of high-pressure balloon angioplasty versus the Peripheral Cutting Balloon for treatment of stenoses in autogenous fistulas & reported equivalent immediate results.[18-20] T. Vesely et al[21] in 2005 comparing use of the cutting balloon PTA versus Conventional balloon PTA for treatment of hemodialysis-related venous stenoses & demonstrated that the cutting balloon PTA provides equivalent 6-month patency to PTA for stenotic and thrombosed grafts. Kariya S, et al compare primary patency rates of cutting balloon percutaneous transluminal angioplasty (PTA) with their older experience in the use of conventional balloon PTA in the treatment of different types of hemodialysis access stenosis, & reported higher primary patency rates for cutting PTA in comparison with conventional PTA in the treatment of graft-to-vein anastomotic stenosis,[22] which is similar to our results. Some investigators reported the, safety, high technical success rate, low complication rates & lower restenosis rate when cutting balloon PTA used in resistant venous stenoses of dialysis access,[23-25] others reported that cutting balloon PTA did not improve patency compared to published results of conventional PTA, but may lower the frequency of required re-interventions.[26]

We found that in patients with autogenous venous stenosis and those with graft-to-vein anastomotic stenosis, the primary patency rate for cutting PTA was higher than that for conventional PTA. As our results of log-rank testing show, a longer period of primary patency achieved by performing cutting PTA might be expected only in patients with graft-to vein anastomotic stenosis; however, the sample size was insufficient to determine if there was a significant difference. However, Kaplan-Meier and the results of X^2 testing indicate a possibility that longer periods of primary patency achieved by performing cutting PTA could be expected for autogenous venous stenosis and graft to-vein anastomotic stenosis after PTA. Despite the prospective randomized nature our study was limited by the small number of subjects, future larger studies are warranted.

When cutting PTA was performed to treat intragraft stenosis, primary patency was not significantly improved, and residual percent diameter stenosis was greater for cutting PTA than for conventional PTA. The reasons for this may be because of the presence of a circumferential artificial structure in the vascular wall, no structurally weak areas were present, even when high pressure was applied, and minimal vascular damage resulted from dissection and vessel stretching. As a result, no advantage was obtained by using a cutting balloon in the treatment of intragraft stenosis. In the cutting PTA group, aneurysmal dilatation at the site of inflation was seen during follow-up in one stenosis. However, aneurysmal dilatation did not increase in size and did not cause any dialysis failure. Aneurysmal dilatation could have been caused by an incision in the vascular wall created by a blade; thus, patients need to be monitored for a certain period of time after cutting PTA. In conclusion, primary patency rates are significantly higher for cutting PTA than for conventional PTA in the treatment of graft-to-vein anastomotic stenosis. However, no significant differences are apparent in primary patency rates between cutting PTA and conventional PTA groups in the treatment of autogenous venous stenosis, intragraft stenosis, or arterial anastomotic stenosis. These data suggest that cutting PTA could be performed to treat graft-to-vein anastomotic stenosis.

Reference

1- NKF-DOQI: Clinical practice guidelines for vascular access: National Kidney Foundation-Dialysis Outcomes Quality Initiative. *Am J Kidney Dis* 1997; 30(4 suppl 3): 150–191.

2- Turmel-Rodrigues L, Pengloan J, Blanchier D, et al: Insufficient dialysis shunts: Improved long-term patency rates with close hemodynamic monitoring, repeated percutaneous balloon angioplasty, and stent placement. *Radiology* 1993; 187: 273–278.

3- Gmelin E, Winterhoff R, Rinast E: Insufficient hemodialysis access fistulas: Late results of treatment with percutaneous balloon angioplasty. *Radiology* 1989; 171:657–660.

4- Glanz S, Gordon DH, Butt KM, Hong J, Lipkowitz GS: The role of percutaneous angioplasty in the management of chronic hemodialysis fistulas. *Ann Surg* 1987; 206: 777–781.

5- Beathard GA: Percutaneous transvenous angioplasty in the treatment of vascular access stenosis. *Kidney Int* 1992; 42: 1390–1397.

6- Sealed Envelope: Randomisation Services. http://www.sealedenvelope.com

7- Beathard GA: Fistula salvage by endovascular therapy. *Adv Chronic Kidney Dis* 2009; 16: 339–351.

8- Davidson CJ, Newman GE, Sheikh KH, Kisslo K, Stack RS, Schwab SJ: Mechanisms of angioplasty in haemodialysis fistula stenoses evaluated by intravascular ultrasound. *Kidney Int* 1991; 40: 91–95.

9- Tan TL, May KK, Robless P, Ho P: Outcomes of endovascular intervention for salvage of failing haemodialysis access. *Annals of Vascular Diseases.* 2011; 4(2): 87–92.

10- Barath P, Fishbein MC, Vari S, Forrester JS: Cutting balloon: a novel approach to percutaneous angioplasty. *Am J Cardiol* 1991; 68: 1249–1252.

11- Kondo T, Kawaguchi K, Awaji Y, et al: Immediate and chronic results of cutting balloon angioplasty: A matched comparison with conventional angioplasty. *Clin Cardiol* 1997; 20: 459–463.

12- Vorwerk D, Adam G, Muller-Leisse C, Guenther RW: Hemodialysis fistulas and grafts: Use of cutting balloons to dilate venous stenoses. *Radiology* 1996; 201: 864–867.

13- Bittl JA, Feldman RL: Cutting balloon angioplasty for undilatable venous stenosis causing dialysis graft failure. *Cathet Cardiovasc Intervent* 2003; 58: 524–526.

14- Ryan JM, Dumbleton SA, Smith TP: Using a cutting balloon to treat resistant high-grade dialysis graft stenosis. *AJR Am J Roentgenol* 2003; 180: 1072–1074.

15- Singer-Jordan J, Papura S: Cutting balloon angioplasty for primary treatment of hemodialysis fistula venousstenoses: Preliminary results. *J Vasc Interv Radiol* 2005; 16: 25–29.

16- Song HH, Kim KT, Chung SK, et al: Cutting balloon angioplasty for resistant venous stenoses of Brescia-Cimino fistulas. *J Vasc Interv Radiol* 2004; 15: 1463–1467.

17- Sreenarasimhaiah VP, Margassery SK, Martin KJ, et al: Cutting balloon angioplasty for resistant venous anastomotic tenosis. *Semin Dialysis* 2004; 17: 523–527.

18- Aftab SA, Tay KH, Irani FG, Gong Lo RH, Gogna A, Haaland B, Tan SG, Chng SP, Pasupathy S, Choong HL, Tan BS: Randomized clinical trial of cutting balloon angioplasty versus high-pressure balloon angioplasty in hemodialysis arteriovenous fistula stenoses resistant to conventional balloon angioplasty. *J Vasc Interv Radiol* 2013; 4.pii:S1051-0443(13)01541-8. Article in Press.

19- Kundu S, Clemens R, Aziza J, Tam P, Nagai G, You J, Au V: Ultrahigh-pressure angioplasty versus the Peripheral Cutting Balloon™ for treatment of stenoses in autogenous fistulas: Comparison of immediate results. *J Vasc Access* 2010; 11(4): 303–311.

20- Wu CC, Lin MC, Pu SY, Tsai KC, Wen SC: Comparison of cutting balloon versus high-pressure balloon angioplasty for resistant venous stenoses of native hemodialysis fistulas. *J Vasc Interv Radiol.* 2008; 19(6): 877–883.

21- Vesely TM, Siegel JB: Use of the peripheral cutting balloon to treat hemodialysis-related stenoses. *Journal of Vascular and Interventional Radiology* 2005; 16(12): 1593–1603.

22- Kariya S, Tanigawa N, Kojima H, Komemushi A, Shomura Y, Shiraishi T, Kawanaka T, Sawada S: Primary patency with cutting and conventional balloon angioplasty for different types of hemodialysis access stenosis. *Radiology*. 2007; 243(2): 578–587.

23- Wu CC, Wen SC: Cutting balloon angioplasty for resistant venous stenoses of dialysis access: Immediate and patency results. *Catheter Cardiovasc Interv* 2008; 1:71(2): 250–254.

24- Bhat R, McBride K, Chakraverty S, Vikram R, Severn A: Primary cutting balloon angioplasty for treatment of venous stenoses in native hemodialysis fistulas: Long-term results from three centers. *Cardiovasc Intervent Radiol.* 2007; 30(6): 1166–1170. Discussion 1171–1172.

25- Carrafiello G, Laganà D, Mangini M, Recaldini C, Mancassola G, Frattini G, Colussi G, Dionigi G, Fugazzola C: Cutting Balloon angioplasty for the treatment of haemodyalisis vascular accesses: Midterm results. *Radiol Med.* 2006; 111(5): 724–732.

26- Heerwagen ST, Lönn L, Schroeder TV, Hansen MA: Cephalic arch stenosis in autogenous brachiocephalic hemodialysis fistulas: results of cutting balloon angioplasty. *J Vasc Access.* 2010; 11(1): 41–45.