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Does Technical Success of Angioplasty in Dysfunctional Hemodialysis Accesses Correlate with Access Patency?

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Abstract
Purpose To study if <30 % residual stenosis post angioplasty (PTA) correlates with primary access circuit patency, and if any variables predict technical success.
Materials and Methods A prospective observational study was performed between January 2009 and December 2012, wherein 76 patients underwent 154 PTA events in 56 prosthetic grafts (AVG) and 98 autogenous fistulas (AVF). Data collected included patient age, gender, lesion location and laterality, access type and location, number of prior interventions, and transonic flow rates pre- and postintervention. Impact of technical outcome on access patency was assessed. Univariate logistic regression was used to assess the impact of variables on technical success with significant factors assessed with a multiple variable model.
Results Technical success rates of PTA in AVFs and AVGs were 79.6 and 76.7 %, respectively. Technical failures of PTA were associated with an increased risk of patency loss among circuits with AVFs ($p < 0.05$), but not with AVGs ($p = 0.7$). In AVFs, primary access patency rates between technical successes and failures at three and 6 months were 74.4 versus 61.9 % ($p = 0.3$) and 53.8 versus 23.8 % ($p < 0.05$), respectively. In AVGs, primary access patency rates between technical successes and failures at three and six months were 72.1 versus 53.9 % ($p = 0.5$) and 33.6 versus 38.5 % ($p = 0.8$), respectively. Transonic flow rates did not significantly differ among technically successful or failed outcomes at one or three months.
Conclusion Technical failures of PTA had a significant impact on access patency among AVFs with a trend toward poorer access patency within AVGs.

Keywords Hemodialysis · Angioplasty · Dialysis fistula · Dialysis graft · Technical success

Abbreviations

CI	Confidence interval
KDOQI	Kidney disease outcomes quality initiative
SIR	Society of interventional radiology

Introduction

Multiple published studies, and the SIR reporting guidelines in dialysis interventions, define technical or anatomic success of percutaneous transluminal angioplasty (PTA) as <30 % residual stenosis following balloon angioplasty [1–6]. This endpoint that was initially adopted by three papers from the anatomic criteria used for arterial angioplasty [7–9]; however, there is a relative paucity of data validating its use for venous angioplasty in hemodialysis accesses. Additionally, there is a relative paucity of critical assessment of this endpoint with one retrospective study having analyzed the association of technical success with patency following PTA of dysfunctional dialysis AVFs [10].

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This observational prospective study examined the association between primary access circuit patency following technical failure or success of PTA, and factors that affect technical success among AVFs and AVGs.

Materials and Methods

Patients

Research ethics board approval was obtained for this prospective nonrandomized observational study, which was performed between January 2009 and December 2012. A total of 76 patients (44 males, 32 females) were consecutively enrolled who underwent 154 angioplasty events. Only patients with mature, autogenous hemodialysis fistulas or prosthetic grafts in use for delivery of HD were included. Thrombosed accesses, venous occlusions, and cases of in-stent stenosis were excluded. This dataset was analyzed previously in a study examining venous elastic recoil following angioplasty [11].

All patients were assessed in dialysis clinic by a designated dialysis nurse practitioner, where physical and transonic flow measurements were performed. Clinical indications for intervention referral included total access blood flow <500 mL/min by sonographic (US) dilution (Transonic Flow-QC; Transonic Systems, Incorporated, Ithaca, New York) or decrease in access blood flow by 20 % or greater from baseline blood flow, and one of the following occurred: (1) fistula recirculation was more than 5 % by sonographic dilution; (2) difficult cannulation; (3) dynamic venous pressures exceeded threshold levels three consecutive times. In addition, at least one clinical or hemodynamic finding that suggested access dysfunction according to the KDOQI guidelines, including—but not limited to—variable pump speeds, arm swelling, and extremity pain, was present.

Among 154 angioplasty events, 36 % (56/154) were performed on patients with prosthetic grafts and 64 % (98/154) on autogenous fistulas. Among the 54 patients with AVFs who underwent PTA, 60 % (32/54) were male and 40 % (22/54) were female. Among the 22 patients with AVGs who underwent PTA, 55 % (12/22) were male and 45 % (10/22) were female. The mean patient age was 59.6 years (SD 16.4). Other patient characteristics are summarized in Table 1.

Anatomic variables analyzed in addition to technical success included lesion location and laterality, and access type and location. Clinical variables analyzed included patient age, gender, diabetic status, number of prior interventions, time to next intervention, access age, and pre- and postintervention transonic flow rates whenever possible. Patient age was stratified as <60 and ≥60 years. Patients were also grouped according to the location of their arteriovenous fistula or prosthetic graft.

Table 1 Baseline characteristics of the study patients and dialysis accesses

Characteristic	Fistulas (%)	Grafts (%)
Patients ($n = 76$)	54 (71.0)	22 (29.0)
Gender[a]		
Male	32 (59.3)	12 (55)
Female	22 (40.7)	10 (45)
Patient age (years)	58.2 ± 16.6	61.9 ± 16.1
Age stratification[a]		
<60	56 (56.6)	17 (30.4)
≥60	43 (43.4)	39 (69.6)
Angioplasty events ($n = 154$)	98 (63.6)	56 (36.4)
Number of prior events[b]		
1	48 (49.0)	22 (39.3)
>1	50 (51.0)	34 (60.7)
Arm side[b]		
Right	28 (28.6)	12 (21.4)
Left	70 (71.4)	44 (78.6)
Diabetes[b]		
No	81 (82.7)	22 (39.3)
Yes	17 (17.3)	34 (60.7)
Fistula type[b]		
Radiocephalic	35 (35.7)	
Brachiocephalic	63 (64.3)	
Graft type[b]		
Upper arm graft		18 (32.1)
Upper am loop		9 (16.1)
Forearm loop		28 (50.0)
Thigh graft		1 (1.8)
Stenosis location in AVFs[b]		
Arterial anastomosis	2 (2.0)	
Juxta-anastomosis	27 (27.6)	
Outflow vein	34 (34.7)	
Cephalic arch	26 (26.5)	
Central veins	9 (9.2)	
Stenosis location in AVGs[b]		
Arterial anastomosis		12 (21.4)
Graft		10 (17.9)
Perigraft anastomosis		22 (39.3)
Outflow vein		8 (14.3)
Central vein		4 (7.1)

[a] Denotes baseline metrics based on total number of patients

[b] Denotes baseline metrics based on total number of angioplasty events

Technique/Procedure

Informed consent was obtained from all individual participants included in the study. Angioplasty was performed by five fellowship-trained, board-certified

interventional radiologists with between 7 and 35 years of experience. Intravenous sedation and heparin were administered at the discretion and supervision of the treating physician.

After access was obtained, digital subtraction fistulography was performed and those found to be having any venous stenotic lesions >50 % within the access circuit (from the arterial anastomosis to the heart) and a clinical indicator of access dysfunction underwent PTA. No vasodilators were administered. Balloon type was at the discretion of the interventionist with high or ultra-high pressure balloons used, and cutting or drug eluting balloons were excluded. Balloon size was 0–2 mm larger than the closest normal adjacent diameter vein or graft. Balloon inflation time was at least 45 s with complete effacement of the stenotic lesion. Pre- and post-PTA fistulography was obtained, with different obliquities obtained on an unstandardized individual patient basis of at least 45 degrees apart. No further intervention was performed in case of technical failures of PTA (i.e., observed recurrent stenosis >30 %).

Image Analysis

Pre- and post-PTA lesion stenosis was measured with electronic callipers from stored DICOM images. Lesion stenosis was measured against the diameter of the adjacent normal vein segment or graft (Fig. 1). No lesions were exactly at the anastomosis. In these cases, where stenosis was juxta-anastomotic, the vein segment preceding the stenosis or the size of the anastomosis was used.

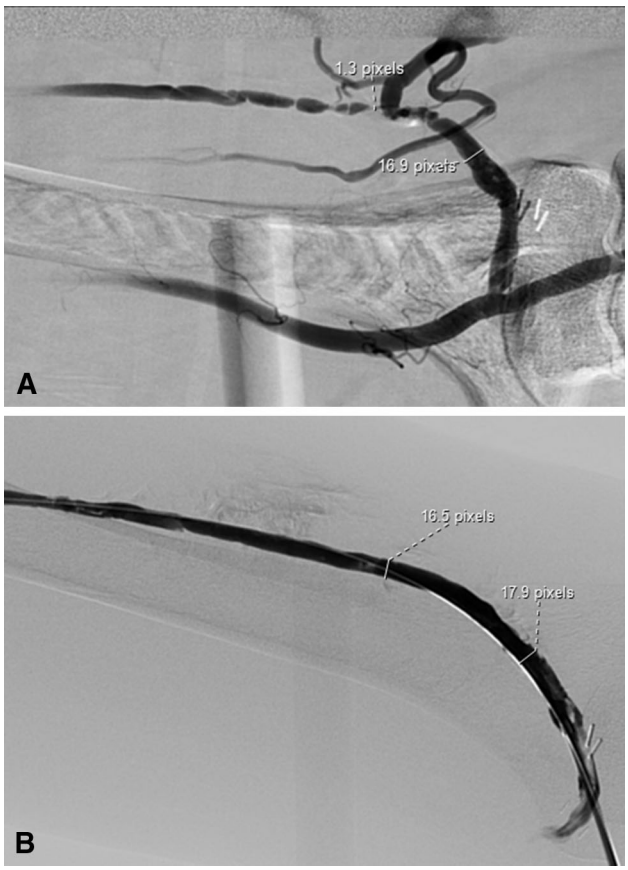

Fig. 1 Fistulogram of the left arm brachiocephalic fistula which presented with decreased transonic flows. **A** Within the cannulation zone, there is 92 % venous stenosis [100 × (1−[1.3/16.9])]. **B** Following angioplasty with a 6-mm balloon, residual stenosis is 8 % [100 × (1−[16.5/17.9])]

Follow-Up

Surveillance was conducted after percutaneous therapy with the use of ultrasound dilution technique (Flow-QC; Transonic Systems) at monthly intervals whenever possible during routine dialysis treatment sessions and by observing dialysis flow rates. Patients were referred for repeat angiography using the aforementioned criteria for intervention.

Statistics and Definitions

Technical success was defined according to the SIR reporting guidelines as <30 % residual stenosis following PTA with full effacement of the angioplasty balloon [4]. Clinical success was resumption of dialysis for at least one session. Primary access circuit patency was defined from time of original intervention until the next access thrombosis or reintervention of a lesion anywhere within the access circuit, or until access abandonment. Access patency censure occurred with loss to follow-up, death, or renal transplantation.

Classification of complications followed SIR reporting guidelines, with minor complications including events that involved nominal therapy of no consequence including overnight admission for observation only [4]. Major complications included events that required therapy with a short hospitalization (<48 h), major therapy with an unplanned increased in care and prolonged hospitalization (>48 h), or permanent adverse sequelae or death.

Loss of patency over survival times was estimated using Kaplan–Meier survival method. The association of technical failure (residual stenosis >30 %) of PTA with the risk of loss of patency was assessed using a univariate Cox proportional hazards model. If observed to have a univariate p-value <0.20, then technical failure of PTA was analyzed with a multiple variable Cox model utilizing backward selection with an alpha of 0.05 included in the final model. The association of variables with technical

success of PTA was assessed using a univariate logistic regression model.

Each PTA event was considered an independent event, with statistical interdependence among patients with repeat interventions and those with more than one treated lesion accounted for using a generalized estimating equations model. Results are reported as hazard ratio (HR) and 95 % confidence interval (CI).

The association of technical success and transonic flow at 1 and 3 months was assessed using analysis of covariance, including the preprocedure transonic flow as a covariate in the model. The alpha-level was set at 0.05 for statistical significance. All analyses were done using SAS version 9.3 (SAS Institute, Cary, NC).

Results

Overall technical success rate of PTA with <30 % residual stenosis was 78 % following full effacement of the balloon in all cases. Four minor complications of PTA occurred constituting a complication rate of 2.6 %. All four cases involved focal venous rupture, where in one case the angioplasty balloon was inflated for one minute to successfully tamponade the ruptured segment. The remaining three cases required no intervention. No major complications were encountered.

Autogenous Fistulas

Lesion stenosis was found to occur at the juxta-anastomosis in 27.6 % (27/98) of cases, and most commonly in the upper extremity outflow veins in 34.6 % (34/98) of cases. Overall primary access patency rates for autogenous fistulas at 3 and 6 months were 71.7 % (95 % CI 63.2–81.3) and 24.1 % (95 % CI 16.5–35.2), respectively.

Technical success rate of PTA among AVFs was 79.6 % (78/98), and the clinical success rate was 100 %. Three-month access primary patency rate was 74.4 % (95 % CI 65.1–85.0) among technically successful PTA events compared to 61.9 % (95 % CI 44.3–86.6) in technical failures ($p = 0.3$). Six-month access primary patency rate among technically successful PTA events was 53.8 % (95 % CI 43.4–66.5) compared to 23.8 % (95 % CI 11.1–51.2) in failures ($p = 0.006$). Median circuit survival of technical successes was 212 days as compared to 139 days in technical failures of PTA ($p = 0.08$). Technical failure of PTA was associated with a borderline risk of patency loss (HR = 1.6, 95 % CI 1.0–2.7, $p = 0.08$), which became significantly associated with the risk of patency loss in the final multiple variable model (HR = 1.9, 95 % CI 1.1–3.2, $p = 0.02$).

Table 2 Patient and access characteristics in predicting technical success among AVFs

Characteristic	Hazard ratio (95 % CI)	*P*-value
Gender		
Male	1.6 (0.4–3.0)	0.8
Female	1 (reference)	
Age		
≥60 years	1.7 (0.5–5.6)	0.4
<60 years	1 (reference)	
Age, per 10 years	1.4 (1.0–2.1)	0.07
Length of stenosis		
≥60	1.1(0.4–2.9)	0.8
<60	1 (reference)	
Number of prior events		
>1	0.7 (0.3–1.8)	0.5
1	1 (reference)	
Fistula type		
Brachiocephalic	0.5 (0.2–1.7)	0.3
Radiocephalic	1 (reference)	
Side of arm		
Right	1.0(0.3–3.8)	1.0
Left	1 (reference)	
Diabetes		
Yes	2.3 (0.5–11.3)	0.3
No	1 (reference)	
Location of stenosis		
Arterial anastomosis	1.4 (0.03–61.5)	0.9
Juxta-anastomosis	1.5 (0.4–6.0)	0.6
Cephalic arch	0.6 (0.2–2.0)	0.4
Central veins	1.0 (0.2–5.3)	1.0
Fistula	1 (reference)	

The only change in odds for an increase of 10 years in age was borderline associated with predicting technical success (HR = 1.4, 95 % CI 1.0–2.1, $p = 0.07$; Table 2). Patient age greater than 60 years however did not predict technical success ($p = 0.3$). No other anatomical or clinical variable significantly impacted technical success of PTA among AVFs.

Transonic flow measurements were available for 41 lesions up to 3 months following PTA. The mean transonic flow rates at 1 and 3 months were not statistically significant between technically successful and failed PTA events ($p = 0.1$ and $p = 0.2$, respectively).

Prosthetic Grafts

Lesion stenosis was found most commonly at the venous anastomosis or immediately adjacent to it in 57.1 % (32/56) of cases. Overall primary access patency rates for

prosthetic grafts at 3 and 6 months was 67.9 % (95 % CI 56.3–81.3) and 34.9 % (95 % CI 24.3–50.0), respectively. Among patients with prosthetic grafts, eight patients (36 %) did not lose patency over the entire follow-up duration.

Technical success rate of PTA among AVGs was 76.7 % (43/56), and clinical success rate was 100 %. Three-month access primary patency rate was 72.1 % (95 % CI 59.3–86.8) among technically successful PTA events compared to 53.9 % (95 % CI 32.6–89.1) in technical failures ($p = 0.5$). Six-month access primary patency rate among technically successful PTA events was 33.6 % (95 % CI 22.0–51.5) compared to 38.5 % (95 % CI 19.3–76.5) in technical failures ($p = 0.8$). Median survival of technical successes was 146 days compared to 92 days for technical failures of PTA ($p = 0.7$). Technical failure of PTA was not significantly associated with risk of patency loss (HR = 0.9, 95 % 0.5–1.8, $p = 0.7$).

The results of the univariate logistic regression analysis of clinical and anatomic variables predicting technical success of PTA among AVGs are summarized in Table 3. Accesses that were a forearm loop graft were significant in predicting technical success (HR = 10.6, 95 % CI 1.6–107.6, $p = 0.03$), while left arm laterality was borderline significant at predicting technical success (HR = 5.3, 95 % CI 0.9–30.3, $p = 0.06$). No other anatomical or clinical variable significantly predicted technical success among AVGs.

Transonic flow measurements were available for up to 28 lesions up to three months following PTA. The mean transonic flow rates at 1 and 3 months were not statistically significant between technically successful and failed PTA events ($p = 0.5$ and $p = 0.4$, respectively).

Table 3 Patient and access characteristics in predicting technical success among AVGs

Characteristic	Hazard ratio (95 % CI)	*P*-value
Gender		
Male	2.0 (0.3–13.1)	0.5
Female	1 (reference)	
Age		
≥60 years	2.5 (0.4–16.6)	0.4
<60 years	1 (reference)	
Age, per 10 years	1.4 (0.8–2.3)	0.3
Length of stenosis		
≥60	2.2 (0.6–8.2)	0.3
<60	1 (reference)	
Number of prior events		
>1	1.0 (0.4–2.2)	0.9
1	1 (reference)	
Graft type		
Upper arm loop	3.0 (0.3–45.4)	0.3
Forearm loop	10.6 (1.6–107.6)	0.03
Thigh graft	3.0 (0.03–304.3)	0.6
Upper arm graft	1 (reference)	
Side of arm		
Left	5.3 (0.9–30.3)	0.06
Right	1 (reference)	
Diabetes		
Yes	2.3 (0.5–10.8)	0.3
No	1 (reference)	
Location of stenosis		
Arterial anastomosis	0.8 (0.007–82.4)	0.9
Graft	0.9 (0.2–5.0)	0.9
Outflow vein	0.7 (0.09–5.2)	0.7
Central veins	0.07 (0.003–1.6)	0.09
Graft anastomosis	1.0 (0.1–9.4)	1.0
Perigraft anastomosis	1 (reference)	

Discussion

Technical failure of balloon angioplasty was associated with significantly poorer AVF patency. Although significance was not observed for other endpoints of patency for AVGs, there was an observed trend towards poorer access patency following technically unsuccessful angioplasty suggesting that <30 % residual stenosis following PTA may be a suitable angiographic endpoint.

The current study utilizes a dataset that was recently published on elastic recoil following angioplasty [11]. That study specifically looked at venous elastic recoil defined as >50 % venous narrowing within 15 min following angioplasty, if its occurrence impacted overall access patency and factors associated with its occurrence [11]. In this investigation, technical success defined as <30 % angiographic stenosis immediately following angioplasty was specifically assessed as a predictor of AVF and AVG primary patency only and factors associated with technical success.

Our observed technical success rates of 80 and 77 % in AVFs and AVGs, respectively, are comparable to those reported in the past using the same definition. Technical success rates within several retrospective studies defined as <30 % residual stenosis post-PTA have ranged from 75 to 89 % for autogenous fistulas [12–14]. In a prospective study evaluating balloon angioplasty within prosthetic grafts [5], technical success of 73 % was achieved where proper core lab determination was performed rather than an "eye-ball" assessment.

Three-month access circuit patency rate among AVFs in our study was observed at 71.7 %, which is consistent with prior studies [6, 12, 14]. Our observed three-month access patency rate in AVGs at 67.9 % is similar to the 63.4 %

primary patency rate in a prior prospective study evaluating the efficacy of balloon angioplasty on HD grafts [15]. Six-month access circuit patency rates among AVFs and AVGs in our study were observed at 47.1 and 34.9 %, respectively. Prior published studies reported 6-month access primary patency rates between 40 and 57 % among AVFs [6, 12, 14] and 20 and 40 % among AVGs [5, 6, 15]. Our findings are comparable to these aforementioned studies.

We primarily sought to investigate the impact of technical success of PTA on access circuit primary patency. Access patency loss was significant among circuits with AVFs if angioplasty was technically unsuccessful, which achieved significance by multivariate analysis ($p < 0.05$). In a prior study corroborating our findings, outcomes of PTA in de novo AVFs demonstrated a negative correlation between early HD access dysfunction and technical success of PTA [13]. Other studies evaluating patency at alternative time points have shown no significant association between residual stenosis >30 % and 12-month access patency in AVFs following PTA [10, 12]; however 6-month access patency was never assessed. Atkas et al. [10] assessed impact of residual stenosis following angioplasty on patency at 1–3 years among accesses with fistulae where residual stenosis was found to be significantly associated with secondary but not primary patency. It is plausible that if access patency was evaluated at 6 months or if a pooled access patency was assessed, as in our study, a significant impact on patency may have been observed. Balloon inflation times in the aforesaid study also ranged from 1 to 3 min, a potential confounder as longer inflation times have been suggested to negatively impact intermediate patency secondary to greater vessel trauma [16].

In a randomized study, one- and three-minute inflation times were assessed to determine impact on technical success. Although 3-min inflation time was found to result in better technical success than one-min inflation, postintervention access patency was no different between groups [17]. However, the authors did not assess if technical success or failure was associated with a significant change in primary access patency as demonstrated in this study.

Technical failures of PTA performed on AVGs did not significantly impact access circuit patency nor did it impact access patency at three or six months when compared to technical successes, but a trend toward poorer patency was observed. Although the small sample size of our population may limit interpretation of significance, a prior randomized prospective study with larger sample size ($n = 93$) demonstrated similar results [5].

None of our documented anatomic or clinical variables significantly predicted technical success of PTA among circuits with AVFs. Increasing patient age was predictive of technical success in access circuits with fistulae, but this was not significant when accounting for interdependence in patients with repeat interventions and those with more than one treated lesion. Forearm loop configuration in prosthetic grafts was the only variable significant for predicting technical success ($p < 0.05$). We cannot provide any reason or hypothesis for this observation.

Transonic flow measurements were available in up to 41 patients with AVFs and 28 patients with AVGs in our study. Technical success of PTA was not significantly associated with mean follow-up transonic flow measurements up to 6 months following balloon angioplasty. However, we observed limited patient follow-up occurring primarily because a majority of patients were referrals from other centers. Consequently, this remains a limitation to interpretation and possible nonsignificance.

The findings observed within our study suggest the use of 30 % residual stenosis as the angiographic endpoint of a successful outcome following angioplasty within access circuits is applicable and relevant to primary access patency. The clinical importance of technical success defined as <30 % residual stenosis of PTA has been deliberated on multiple prior occasions [2, 12]. In a recent retrospective study comparing angiographic and pressure measurements in central venous PTA, technically successful events alone did not predict access patency, however when grouped together with pressure measurements access patency was predicted in synergistic fashion [18]. Another retrospective series found that postprocedural access blood flow demonstrated a stronger correlation with immediate postinterventional angioflow than with angiography results, with no significant correlation observed between access blood flow and residual stenosis following angioplasty [19]. Intraprocedural flow measurements have also been postulated to help discern the need for repeat intervention when angiography results are equivocal in clinical significance [20].

There are several strengths to our study, including that the study was performed prospectively, procedural technique was conducted under conventional and recommended clinical practice guidelines, and we included both AVGs and AVFs with their outcomes examined independently. Furthermore, we accounted for the statistical interdependence among patients with repeat interventions and those with more than one treated lesion and areas of angioplasty were analyzed with electronic callipers from DICOM images. However, the study is limited by a relatively small sample that may limit interpretation and possible nonsignificance of other influencing factors on the results. Adding real time access flow measurements would have strengthened the study, although at a considerable cost surplus. Further, the flow data were incomplete and limited by referrals from outside centers, and the effect of inflation time was not studied nor controlled beyond 45 s.

Conclusion

Our findings suggest that technical failures of PTA have a significant negative impact on primary patency of access circuits with AVFs with an observed but insignificant trend toward poorer AVG access patency overall. Residual measured stenosis <30 % post-PTA may be a suitable angiographic outcome.

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Compliance with Ethical Standards

Conflict of Interest All authors declare that they have no relevant conflicts of interest or financial disclosures.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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