

# Fistuloplasty using a radiation-and-time-saving sheathless balloon catheter

Joel Crawford, Angela Kokkosis, Pamela Kim,  
Antonios Gasparis and Nicos Labropoulos

The Journal of Vascular Access  
2019, Vol. 20(3) 276–280  
© The Author(s) 2018



Article reuse guidelines:  
[sagepub.com/journals-permissions](http://sagepub.com/journals-permissions)  
DOI: 10.1177/1129729818804991  
[journals.sagepub.com/home/jva](http://journals.sagepub.com/home/jva)



## Abstract

**Introduction:** Sheath placement in dialysis access interventions is traditionally necessary to obtain imaging, guide percutaneous angioplasty, and evaluate results. The aim of this study was to assess the feasibility of performing sheathless Arterio-venous (AV) access interventions using a novel percutaneous angioplasty balloon catheter.

**Methods:** Between May and September 2017, data on all dialysis access interventions using a novel percutaneous angioplasty balloon with a dedicated injection port were collected. All procedures were performed without a sheath. Success was established as no conversion to sheath placement. Demographic data, location of lesion, time to perform procedure, amount of contrast used, radiation exposure, and access complications were recorded. Ultrasound was used to evaluate access site complications.

**Results:** Sheathless interventions were successful in 24 patients with the mean age of 62 years (29–94). There were 5 PTFE grafts and 19 native fistulas. Lesions were located anywhere from the arterial anastomosis to the cephalic arch. The average balloon size was 6 mm (5–7 mm), and the procedure time was 15.8 min (8–45 min). No access site complications were observed.

**Conclusion:** Sheathless intervention is feasible with several potential advantages, including short procedure time, minimal contrast volume, and reduced radiation exposure. Finally, the lower profile at the access site may result in fewer complications.

## Keywords

Angiography, angioplasty, fistula, phlebography, renal dialysis, ultrasonography

Date received: 9 May 2018; accepted: 9 September 2018

## Introduction

Placement of a sheath during percutaneous dialysis access interventions is traditionally necessary to obtain imaging, guide percutaneous transluminal angioplasty (PTA), and evaluate results. The availability of a novel PTA balloon with an injection port for contrast injection may eliminate the need for sheath placement. The aim of this study was to assess the feasibility of utilizing this novel high-pressure PTA balloon catheter (Chameleon, AV Medical) during sheathless dialysis access interventions.

## Methods

Data on dialysis access procedures performed using a novel (6-French OD) PTA balloon (Figure 1) were prospectively collected between May 2017 and September 2017.

Procedures were done by a single surgeon in an outpatient angiography suite without the use of a sheath. Success in performing the intervention was established as no conversion to sheath placement. Demographic data, location of lesion, time to perform procedure, amount of contrast used, radiation exposure, and access complications were collected prospectively. Duplex ultrasound was used to evaluate for any surrounding hematoma or stenosis at the access site during each procedure.

Previous ultrasound images were reviewed to evaluate location of lesion and determine access site. If necessary,

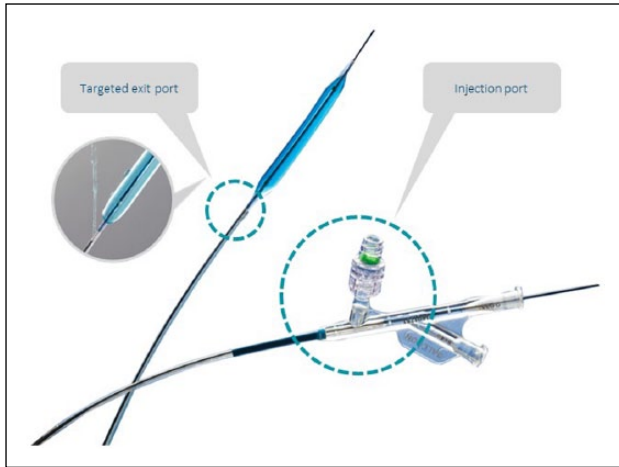
Stony Brook University Hospital, Stony Brook, NY, USA

### Corresponding author:

Nicos Labropoulos, Stony Brook University Hospital, Stony Brook, NY 11794, USA.

Email: [nlabrop@yahoo.com](mailto:nlabrop@yahoo.com)

on-table ultrasound was performed by the surgeon to obtain this information. Access of the arteriovenous fistula on all procedures was obtained with a micropuncture kit using ultrasound guidance (Figure 2(a)). Exchange of the microsheath with the novel balloon catheter was facilitated over a Benson or similar wire (Figure 2(b)). A fistulogram could be performed at this time using the novel sheathless PTA balloon.

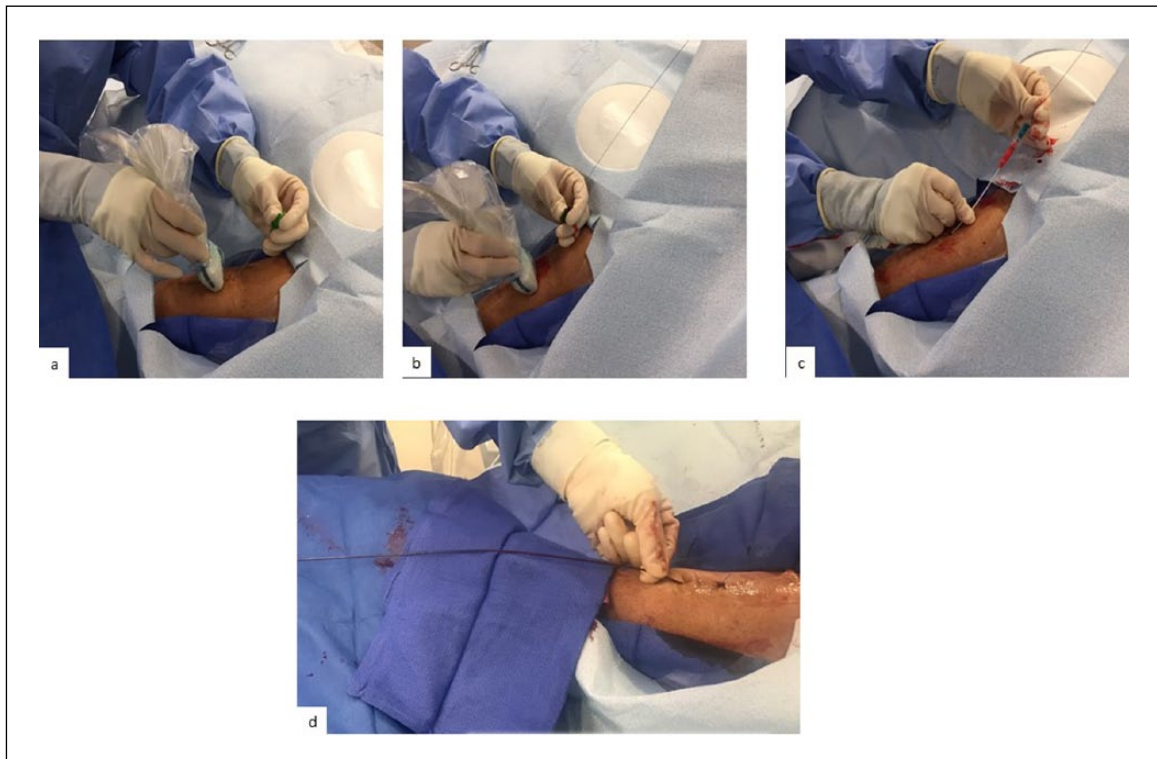


**Figure 1.** Novel PTA balloon with dedicated injection port and proximal exit port.

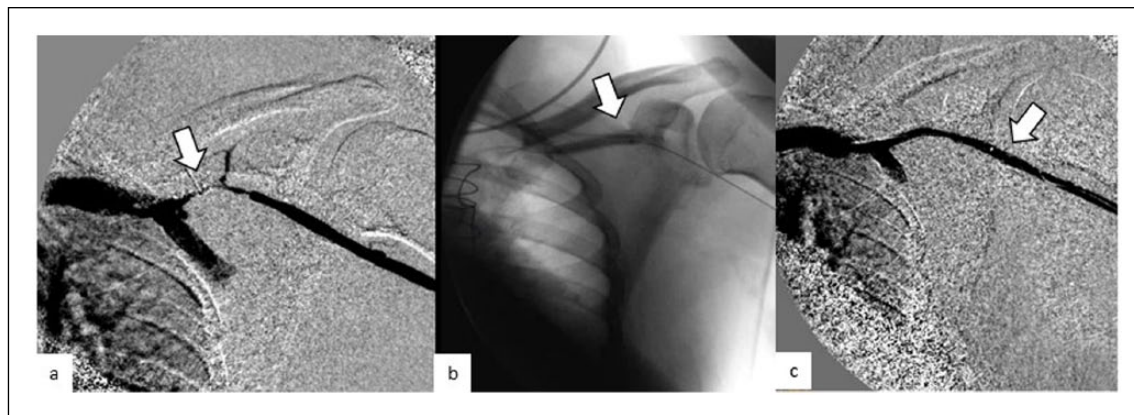
The PTA balloon is a plain, moderately high-pressure balloon (25 atm) which has a dedicated infusion port that allows injection of contrast through an exit port located just behind the balloon (Figure 1). This provides the interventionalist to image and treat using one catheter and minimizing catheter exchanges. By positioning the catheter close to the lesion, it also allows imaging with lower contrast volume.

Antegrade intervention included balloon advancement proximally with the flow of the fistula (away from the arterial anastomosis) to the area of the lesion and PTA. Post-intervention images were obtained after pulling the balloon back through the injection port (Figure 3). If re-intervention was necessary, the balloon was advanced to the lesion and retreated. Evaluation of the arterial anastomosis was done while the balloon was inflated with retrograde contrast infusion through the injection port (Figure 4).

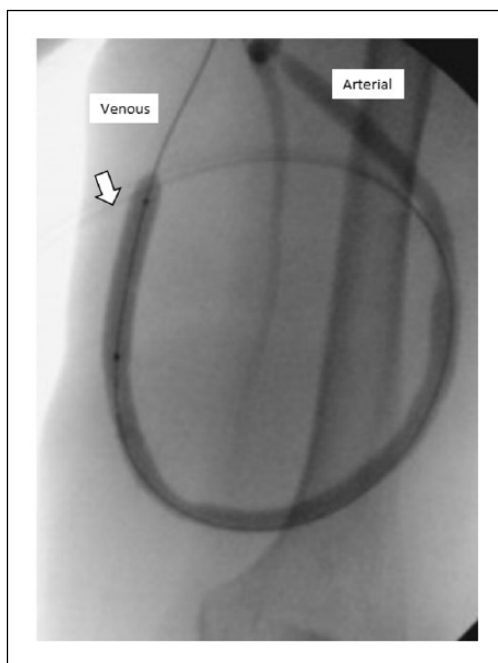
With retrograde interventions (lesions located at or near the arterial anastomosis), access of the fistula was performed in a retrograde fashion (against the flow of the fistula) (Figure 5(a)). The balloon catheter was then advanced to the area of the lesion and PTA performed (Figure 5(b)). Post-intervention imaging was obtained through the injection port after advancing the balloon catheter through the arterial anastomosis and into the



**Figure 2.** (a) Ultrasound-guided access with a micropuncture needle, (b) advancement of microwire through micropuncture needle, (c) placement of microsheath over wire after removal of micropuncture needle, and (d) sheathless PTA balloon placement over 0.35 wire, access site is hemostatic even without the presence of a sheath.



**Figure 3.** (a) Fistulograms performed through novel PTA balloon with high-grade stenosis in cephalic arch (arrow), (b) PTA of cephalic arch lesion (arrow), and (c) post-intervention fistulogram through injection port after pulling back PTA catheter (arrow). This allows imaging with minimal use of contrast rather than injecting from a sheath.



**Figure 4.** While PTA of venous outflow stenosis (arrow), a retrograde fistulogram can be obtained to evaluate the arterial anastomosis.

inflow artery over a wire (Figure 5(c)). Procedures on patients with residual renal function or with iodine allergy were guided by ultrasound and fluoroscopy without contrast.

A single superficial horizontal mattress suture (U-stitch), which avoided incorporating the fistula conduit, was placed after the balloon was removed and pressure applied for 2 min. The access site was evaluated for any hematoma or other complications on all patients with ultrasound.

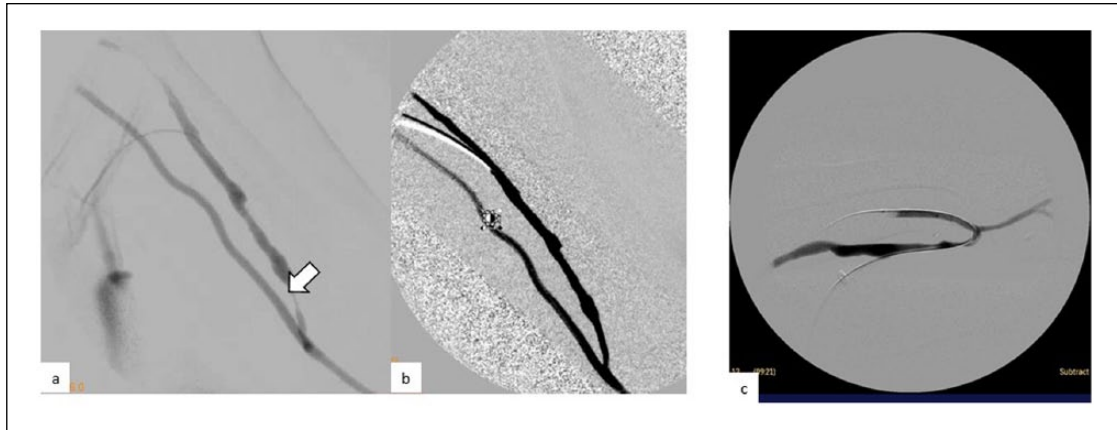
## Results

A total of 24 dialysis-dependent patients, 22 males and 2 females, with the mean age of 62 years (range: 29–94 years) were included in the study. Sheathless intervention was successful in all patients. There were 5 patients with PTFE grafts and 19 with native fistulas. Lesions were located anywhere from the arterial anastomosis to the proximal outflow vein. The average balloon size was 6 mm, with the smaller being 5 mm and the larger being 7 mm. The mean procedure time was 15.8 min ranging from 8 to 45 min. Six interventions were performed solely with duplex ultrasound and fluoroscopic guidance (three of the lesions were near the anastomosis, while three were proximal in the outflow vein). For all other interventions, the average amount of contrast volume used was 24.9 mL (range: 2–44 mL). The average radiation exposure time was 3.29 min, Defined Air Product (DAP) was 1.113 Gy/cm<sup>2</sup> and Cumulative Air Kinetic Energy (cum Air Kerma) was 4.28 mGy. DAP indicates the total radiation emitted by the X-ray tube, while cum Air Kerma indicates the total radiation delivered to the patient. There were no peri-procedural complications. All patients were successfully dialyzed within 24 h of the procedure.

## Discussion

The purpose of this study was to evaluate the feasibility of sheathless interventions using a novel PTA balloon with a dedicated injection port, evaluate for peri-procedural complications, and describe the technique. The study was not designed to evaluate the long-term results of PTA.

Sheathless AV access PTA is feasible with several potential advantages, including decreased radiation exposure, less contrast utilization, and reduced procedure time by eliminating wire/catheter exchanges (Table 1).



**Figure 5.** (a) Juxta-anastomotic high-grade stenosis (arrow) and (b) post-intervention imaging with PTA catheter advanced in the arterial system. (c) This allows to obtain a fistulogram without having to exchange for a diagnostic catheter which requires multiple steps, or inject from a sheath while compressing the venous outflow which may lead to sub-optimal imaging.

**Table 1.** Comparison of procedures.

Standard technique	Novel balloon
Local anesthesia	Local anesthesia
Micro-puncture access	Micro-puncture access
Guide wire placement	Guide wire placement
Sheath exchange	Novel balloon exchange
Fistulogram	Fistulogram <sup>a</sup>
Exchange balloon	No need for exchange
Advance balloon	Advance balloon
Perform angioplasty	Perform angioplasty
Manually compress outflow vein and perform retrograde fistulogram	Perform retrograde fistulogram while balloon inflated <sup>a</sup>
Exchange balloon for catheter	Advance balloon centrally <sup>a</sup>
Perform central venogram	Perform central venogram <sup>a</sup>
Remove catheter and sheath	Remove balloon
Close puncture	Close puncture

<sup>a</sup>In patients with residual renal function or with iodine allergy, the procedure is performed under ultrasound guidance and these steps are eliminated.

A multi-operator study in 2012 reported radiation and procedure time for over 2000 cases. It showed an average exposure time of 7.8 min (range: 2.1–31.7 min), procedure time of 52.7 min (range: 25–110 min), DAP of 10.60 Gy/cm<sup>2</sup> (0.33–59.16 Gy/cm<sup>2</sup>), and Reference point Air Kerma was 46.42 mGy (5.10–163 mGy).<sup>1</sup> In our study, the procedure time and radiation exposures were drastically lower. Direct comparison, though, cannot be done as this was single operator using a technique which may not be applicable to everyone. Reduced procedure time has the potential to increase utilization of the angio suite. In this experience, the procedure time on average was about one-third that of the standard technique. This could allow the operator to perform more procedures.

Patients and operators benefit from radiation reduction. Retrograde fistulogram using this device with the described technique without the need of manual compression can result in higher success rate and better imaging. It also

allows the operator to be further away from the X-ray source. Steps like this have been recommended and are being addressed by groups such as the Joint Inter-Society Task Force on Occupational Hazards in the Interventional Laboratory.<sup>2</sup> Another concern addressed by a hands-free method of retrograde fistulogram is hand radiation. Significant exposure occurs during many procedures not requiring such a proximity of the operator hands.<sup>3</sup>

Improved access to lesions close to the access site is another benefit. Even with a short 5-cm sheath, there is a limitation to how close the balloon may be inflated to the access site. By utilizing the novel balloon, we were able to perform angioplasty to the taper of the balloon at the access site.

An additional benefit is the reduced profile of the sheathless balloon. There were no access site complications seen during these interventions. The novel balloon we used has a taper, which is significantly shallower

than the sheath. One possible access complication during the traditional fistulogram is losing sheath access when trying to angioplasty lesions close to the access site. This risk is completely eliminated.

Limitations of this study include that this is a single operator study using a technique which may not be applicable to everyone. The technique does have a learning curve before routine application. The study does not have a comparative arm using a sheath or a regular balloon to make direct comparisons. It also lacks long-term data on fistula patency. Finally, the availability of drug-coated balloons (DCBs) may result in better long-term outcomes<sup>4</sup> reducing the number of interventions in the life of the access and result in overall lower radiation exposure.

Sheathless interventions in our experience have certain advantages, which need to be further evaluated with larger studies. The availability of an infusion port on a device allows the device to act not just as an interventional device but a diagnostic device. Adaptation of such technology on other devices (i.e. DCBs, stents, etc.) may be beneficial for the interventionalist.

## Conclusion

Sheathless intervention using this novel balloon catheter is feasible with several potential advantages, including short procedure time, minimal contrast volume, and reduced

radiation exposure. Finally, the lower profile at the access site may result in fewer access site complications.

## Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

## Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

## References

1. Heye S, Maleux G, Oyen RH, et al. Occupational radiation dose: percutaneous interventional procedures on hemodialysis arteriovenous fistulas and grafts. *Radiology* 2012; 264(1): 278–284.
2. Klein LW, Miller DL, Balter S, et al. Occupational health hazards in the interventional laboratory: time for a safer environment. *Catheter Cardiovasc Interv*. Epub ahead of print 4 January 2018. DOI: 10.1002/ccd.21772.
3. Attigah N, Oikonomou K, Hinz U, et al. Radiation exposure to eye lens and operator hands during endovascular procedures in hybrid operating rooms. *J Vasc Surg* 2016; 63(1): 198–203.
4. Khawaja AZ, Cassidy DB, Al Shakarchi J, et al. Systematic review of drug eluting balloon angioplasty for arteriovenous haemodialysis access stenosis. *J Vasc Access* 2016; 17(2): 103–110.