Cardiovascular Revascularization Medicine 20 (2019) 598–602

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

A Novel Patent Hemostasis Protocol - Prevention of Pseudoaneurysm after Tibiopedal Arterial Access for Evaluation and Treatment of Peripheral Arterial Disease☆,☆☆,★

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ARTICLE INFO

Article history:
Received 14 May 2018
Received in revised form 20 August 2018
Accepted 30 August 2018

Keywords:
Tibiopedal arterial access
Pseudoaneurysm
Vascular complication
Peripheral arterial disease

ABSTRACT

Background: Pseudoaneurysm (PSA) is a rare complication (0.2%) after transpedal arterial access (TPA) for endovascular treatment of peripheral arterial disease, occurring only in the posterior tibial artery (PTA) likely related to the anatomy of the vessel leading to unfavorable circumstances for adequate hemostasis. We describe a novel patent hemostasis protocol for TPA access to avoid PSA.

Methods: We prospectively studied 586 patients with symptomatic PAD who underwent 1038 peripheral procedures between 02/2016 and 02/2017 via TPA (dorsalis pedis artery (DP)/anterior tibial artery (ATA), PTA or peroneal artery (PA)). Hemostasis for the DP/ATA was achieved with the Vasostat™ device, while TR Band™ was used for PTA/PA, as per our new protocol (figure). Patent hemostasis technique was confirmed using Doppler.

Results: Of the 1038 procedures, 733 (88% interventional) were done via the DP/ATA, 176 (92% interventional) were done via the PTA and 129 (64% interventional) were via the PA. The incidence of PSA related to any access site was 0.0%. All access sites were patent on Doppler ultrasound at 30 day follow up.

Conclusion: PSA associated with TPA is very rare, it can be easily prevented with the above described patent hemostasis protocol while preserving the patency of the access site.

Condensed abstract: Pseudoaneurysm (PSA) is a rare complication (0.2%) after transpedal arterial access (TPA). We describe a novel patent hemostasis protocol for TPA access to avoid PSA. We prospectively studied 586 patients with symptomatic PAD who underwent 1038 endovascular procedures via TPA (dorsalis pedis artery (DP)/anterior tibial artery (ATA), PTA or peroneal artery (PA)). Hemostasis for the DP/ATA was achieved with the Vasostat™ device, while TR Band™ was used for PTA/PA, as per our new protocol (figure). Patent hemostasis technique was confirmed using Doppler. The incidence of PSA related to any access site was 0.0%. All access sites were patent on Doppler ultrasound at 30 day follow up. PSA associated with TPA is very rare, it can be easily prevented with the above described patent hemostasis protocol while preserving the patency of the access site.

1. Introduction

In the current era, endovascular intervention (PVI) is undertaken as the initial approach to treat symptomatic peripheral arterial disease over surgical intervention. The traditional transfemoral approach is associated with vascular complications like hematoma, retroperitoneal bleed and arteriovenous fistula [1,2]. In order to avoid these complications and facilitate early patient ambulation, discharge and potential enhanced patient comfort, certain operators have switched to the use of primary tibiopedal approach for PVI [1,3,4]. However it has its own risks mainly consisting of pseudoaneurysm and access vessel closure [3,5,6]. In a large series by Patel et al., the incidence of PSA was 0.2%, occurring only in the posterior tibial artery (PTA) access after an intervention, while using traditional patent hemostasis technique [3,7]. We describe a novel patent hemostasis protocol for TPA access using the current available equipment to avoid PSA.

2. Methods

We prospectively studied consecutive patients, referred for symptomatic peripheral arterial disease who underwent peripheral endovascular procedures between February 2016 and February 2017

Abbreviations: TPA, tibiopedal arterial access; TFA, transfemoral approach; PAD, peripheral arterial disease; PSA, pseudoaneurysm; DPA, dorsalis pedis artery; ATA, anterior tibial artery; PTA, posterior tibial artery; PA, peroneal artery.

☆ Patel et al. Novel hemostasis protocol for tibiopedal arterial access.

☆☆ Authorship declaration: All authors listed meet authorship criteria. They have read and are in agreement with the manuscript.

★ Disclosures: None.

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https://doi.org/10.1016/j.carrev.2018.08.023
1553-8389/

via TPA (dorsalis pedis artery (DP)/anterior tibial artery (ATA), posterior tibial artery (PTA) or peroneal artery (PA)). TPA was chosen as the primary approach in these cases, as per institutional protocol. Under ultrasound guidance, the flow in the DPA/ATA, PTA and/or PA was demonstrated by Doppler in the long-axis and short-axis views. Vascular access was obtained with a 21 × 19 tapered gauge echogenic tip needle (Terumo Corporation, Somerset, NJ) with an anterior wall puncture technique followed by a 4 Fr Pinnacle Precision (Terumo Corporation, Somerset, NJ). Systemic heparin was administered to maintain activated clotting time > 300 s. An intra-arterial antispasmodic cocktail of 100 μg of nitroglycerine and 2.5 mg verapamil was injected. If a significant lesion requiring intervention was identified, the intervention was performed via a 4 Fr sheath (Terumo Corporation, Somerset, NJ) or upsized to a 6 Fr Glidesheath Slender (Terumo Corporation, Somerset, NJ), which employs a smaller outer diameter that is equivalent to a standard 5 Fr sheath, from the retrograde approach. Post intervention, prior to sheath removal, an additional dose of 100 μg of nitroglycerine was injected [1,3,8]. Hemostasis was achieved using the novel patent hemostasis protocol (Fig. 1).

3. Novel patent hemostasis protocol (Fig. 1)

With extrapolation from the radial experience, to prevent access vessel occlusion, patent hemostasis has been the conventional approach for hemostasis for TPA [1,3,6,7]. With improvisation and modification, we devised this approach. As per the new protocol, for the DP or ATA, VasoStat™ device, which is FDA approve for tibiopedal access was used (Fig. 2). In the Vasostat™ device, a central plunger is ratcheted to apply sufficient compression to the puncture site in the skin and the underlying entry point in the pedal/tibial artery, the device is secured by adhesive pads, with confirmation of a positive distal Doppler pulse and the sheath is removed. After 2 h the VasoStat™ device was checked by a nurse by disengaging the ratchet mechanism to reduce the compressive pressure. If there was continued oozing, the device was retightened for an additional 15–20 min prior to removal. The device was then removed by gently peeling the adhesive surfaces from the skin [6]. For PTA (Fig. 3) and PA (Fig. 4), TR Band™ was used for patent hemostasis with certain modifications. The TR Band™ was inflated to around 30 cc air at the site of TPA with a positive distal Doppler pulse, after which the sheath was removed. The TR band™ was deflated by 2 cc of air every 15 min for up to 2 h. After 2 h, TR Band™ was completely deflated. If there is bleeding, inflate TR Band with air as needed to stop bleeding and deflate slowly. All patients were observed for another 15–20 min for bleeding and hematoma, with recheck of pulses using Doppler prior to discharge. All patients were discharged within 2–2.5 h of intervention. The patients were discharged on antiplatelets/anticoagulation post procedure at the discretion of the

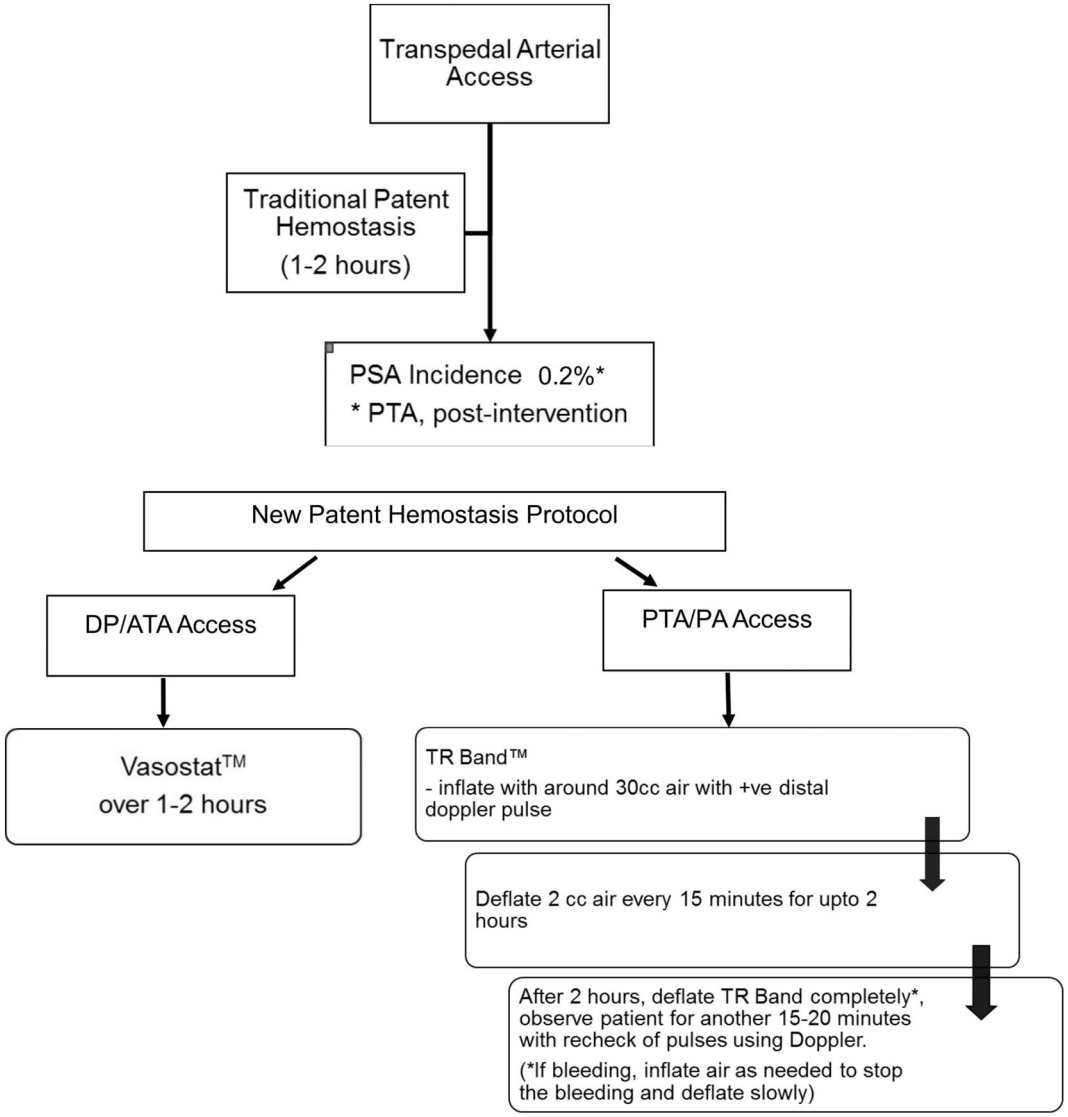

Fig. 1. New patent hemostasis protocol – transpedal arterial access. PSA: pseudoaneurysm; DP: dorsalis pedis artery; ATA: anterior tibial artery; PTA: posterior tibial artery; PA: peroneal artery.

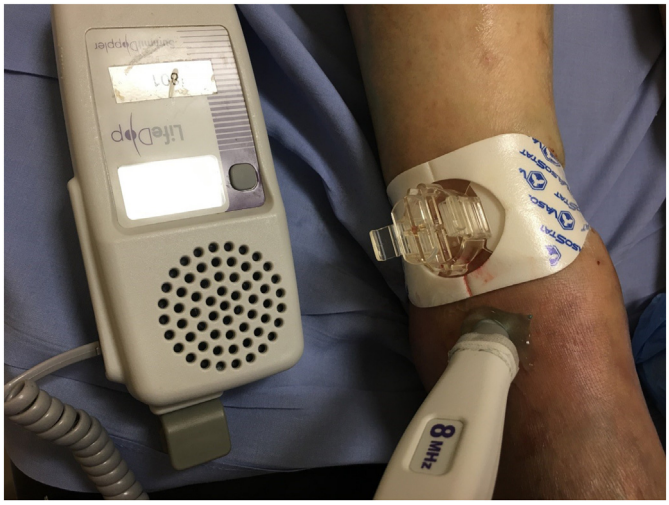

Fig. 2. Novel patent hemostasis technique for dorsalis pedis/anterior tibial artery using VasoStat™.

operator. Our standard of care included use of dual antiplatelet therapy (Aspirin + P2Y12 inhibitor (operator's choice of agent)) post intervention and if anticoagulation is required for any other medical reason (Atrial fibrillation, deep venous thrombosis/pulmonary embolism, intracardiac clot, other thrombogenic medical conditions) then the patient was discharged on a P2Y12 inhibitor and anticoagulation (Warfarin/Direct oral anticoagulation). For the patients who didn't receive any intervention, the choice/combination of antiplatelets were at the operator/physician's discretion depending on the patient's medical

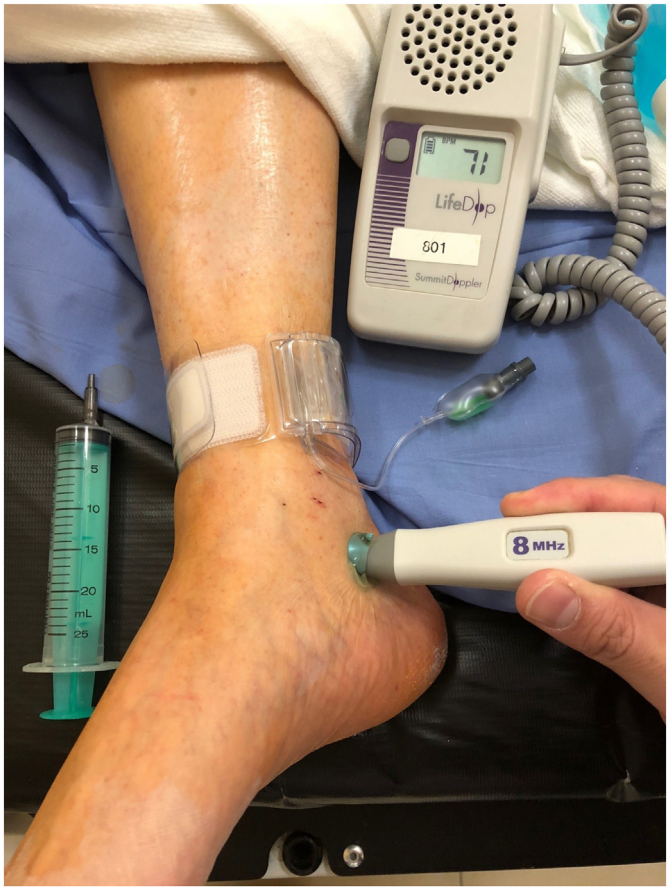

Fig. 3. Novel patent hemostasis technique for posterior tibial artery using TR band™.

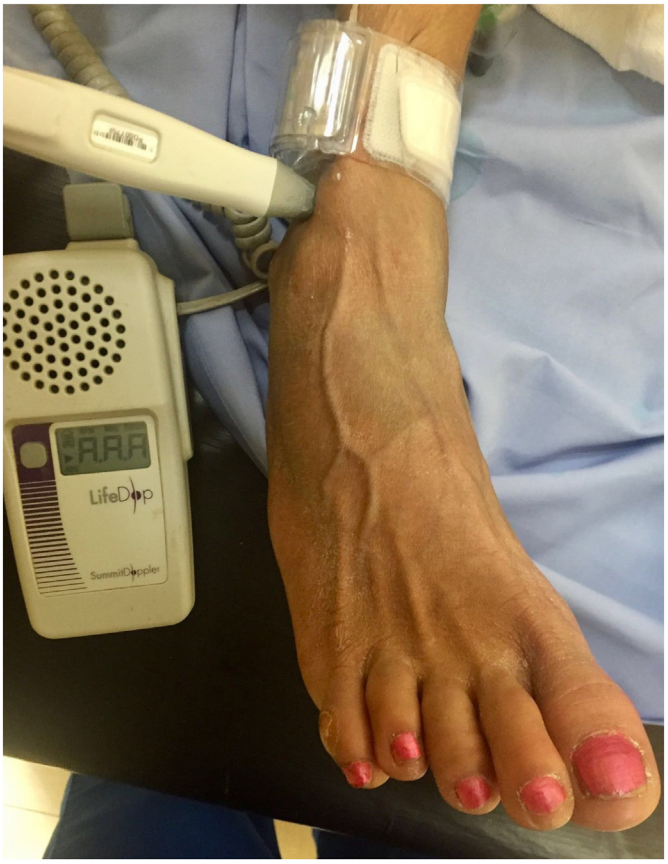

Fig. 4. Novel patent hemostasis technique for peroneal artery using TR band™.

problems and necessity. A clinical assessment was performed prior to the discharge and at follow-up visits 1-week post intervention. At 1-month after the intervention, a clinical assessment and lower extremity duplex ultrasound was performed to assess for access site complications like pseudoaneurysm and patency of the access site vessel.

Demographics and clinical variables for these patients were obtained from electronic medical records. The Institutional review board approved this study and all patients signed an informed consent prior the procedure.

4. Results

During the study period between February 2016 and February 2017, 586 consecutive patients with symptomatic PAD despite maximum medical therapy underwent 1038 endovascular procedures. Patient demographics and clinical history are depicted in Table 1. The mean age of the study population was 73 years and 52% were women. There was a high prevalence of hypertension (91%), tobacco use (46%), hyperlipidemia (81%) and diabetes mellitus (51%). All the patients had Rutherford class III or worse symptoms.

Of the 1038 procedures, 733 were done via the DPA/ATA of which 88% were interventional procedures. There were 176 procedures done via the PTA (92% interventional procedures), and 129 were done via the PA (64% interventional procedures) (Fig. 5).

A 4 Fr sheath (Terumo Corporation, Somerset, NJ) was used in 55% of the procedures, while 6 Fr slender sheath (Terumo Corporation, Somerset, NJ) was used in 19% of the procedures. Of the total 845 interventions in 455 patients, both SFA and tibial disease was treated in 70.8% cases. Balloon angioplasty and atherectomy (CSI Diamondback 360® Orbital atherectomy: 1.25 mm diamond or 1.50 mm diamond or Turbohawk™ directional atherectomy (Medtronic, USA) as deemed appropriate for

Table 1
Patient characteristics.

Patient characteristics	N = 586
Age (years)	72.8 ± 11.0
Female, %	52.6
H/o hypertension, %	90.7
H/o hyperlipidemia, %	81.1
Tobacco use, %	46.0
H/o coronary artery disease, %	44.3
H/o cerebrovascular accident, %	3.9
H/o diabetes mellitus, %	50.6
H/o prior PVD INTERVENTION, %	33.1
Rutherford classification, %	
III	46.2
IV	49.0
V	3.4
VI	1.4

Data given as mean ± standard deviation or number (percentage).
H/o - history of; PVD – peripheral vascular disease.

Table 2
Procedural characteristics.

Procedural characteristics	N = 1038
Sheath	
4 Fr, %	55.1
4/5 s Fr, %	25.0
5 Fr, %	0.6
4/6 s Fr, %	19.3
Activate clotting time (ACT) (s)	>300
Interventions	N = 845
SFA, %	4.5
SFA/tibial, %	70.8
Tibial, %	24.7
Balloon angioplasty, %	100.0
Atherectomy, %	100.0

the lesion) was done in all the procedures for appropriate lesions. The ACT was maintained >300 s in all cases (Table 2).

Post removal of the hemostasis devices prior to discharge, all access vessel pulse was present with Doppler ultrasound and there was no incidence of access site hematoma. The patients were discharged on antiplatelets/anticoagulation combination as deemed appropriate (Supplementary Table 1). At 30 day follow up, the incidence of PSA related to any access site was 0.0%. There was no access site vessel closure, confirmed with a complete vascular Doppler ultrasound. All the patients followed up, there was no death or amputation at 30 days.

5. Discussion

There are currently no other studies describing the tibiopedal access site hemostasis methods or protocols to prevent complications. This is a unique patent hemostasis protocol described for tibiopedal access. In our study of 1038 peripheral vascular procedures, after implementing the new protocol, the incidence of PSA was down to 0.0%, compared to our prior experience of 0.2% [3] and the access sites remained patent at 1 month follow up.

PSA is a rare complication after arterial puncture for endovascular intervention. It is characterized by localized rupture of the arterial wall leading to blood extravasation, which is then walled off by the surrounding layers of connective tissue but maintains its communication with the arterial lumen through a neck [2,3,9,10]. When transfemoral and transradial approach were studied, the common factors associated with PSA are multiple punctures, anticoagulation, larger sheath size, female sex, obesity, and calcified arteries amongst others [3,9,11,12]. In regards to tibiopedal approach, our prior study showed an incidence of 0.2% [3], where we observed that all the PSA was related to PTA access, and only after an interventional procedure. However no PSA were seen in the ATA/DPA or the PA. This is likely related to anatomical course of the PTA, possibly the sheath size, malapposition/failure of hemostasis device and/or the duration of hemostasis. We also feel that the extra need of anticoagulation, burden of disease and use of atherectomy device during interventional procedures, may be some factors which would contribute in the occurrence of PSA after an interventional procedure, as compared to diagnostic procedures.

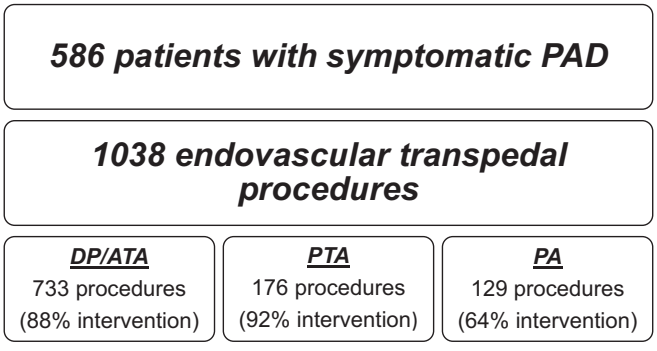

Fig. 5. Patient flow chart. PAD: peripheral arterial disease; DP: dorsalis pedis artery; ATA: anterior tibial artery; PTA: posterior tibial artery; PA: peroneal artery.

Though we cannot currently modify the sheath size and the interventional equipments, which are appropriately being used. By learning from the limitations from our prior experience, we feel that modifying the patent hemostasis technique using the already available equipment may help in reducing the incidence of PSA. For the PTA, it was felt that there was a lack of bony support in the depressed fossa beneath the medial malleolus to provide adequate compression. As per the protocol devised, we apply high compression pressure (up to 30 cc of air) using TR band™ with maintenance of the pulse, confirmed with the help of Doppler, as opposed to the routine radial method of seeing the flash of blood to decide the amount of air to be injected. We felt this approach provided adequate compression to the surrounding tissue which in turn compressed the PTA access site. We also felt that a similar approach should work for peroneal artery as well which is deeper lying vessel above the inferior tibiofemoral joint. This problem of lack of bony support was not encountered with the DPA/ATA, which are more superficial lying over the lower end of tibia and tarsal bones, hence we felt that using VasoStat™ which has a curved bottom and would fit appropriately to the anatomy of the leg/dorsal foot to provide adequate compression to the underlying vessel.

Using this protocol, there was adequate compression provided for sufficient time, in turn causing no incidence of PSA. Also maintenance of pulse, distal to the point of compression is confirmed by Doppler, ensuring that there was no vessel occlusion, which was similarly noted at 1 month follow up. Furthermore using adequate amount of nitroglycerin during the procedure and maintaining high ACT (>300 s) helped.

6. Limitations

This was a single center observational cohort study, so it has its related biases. The transpedal technique was done at a center with high volume transradial operators, the results may not be extrapolated to centers with operators who are not familiar with similar equipment, puncture technique and patent hemostasis techniques. We have data with the traditional patent hemostasis technique for TPA learnt from the radial experience, published by Patel et al. [3]. However, we did not use manual compression or other technique like balloon tamponade and hence data is not available for comparison. All the patients were followed at 1 month – clinically and limited Doppler ultrasound examination was performed to check for any complication using color Doppler flow and presence of a pulsed wave Doppler waveform, however there is a possibility that a clinical/subclinical PSA or vessel closure may have developed after 1 month, however we are not aware of any such cases. The information on the Doppler velocities and ratios at

every arterial segment post intervention up to the tibiopedal access site is not available for assessment. We are not able to provide follow up on the long-term outcomes on repeat revascularization for these patients, so it will be difficult to comment that how having no access site pseudoaneurysms affects the interventional outcomes.

7. Conclusion

PSA following TPA is very rare and can be easily prevented with the above described patent hemostasis protocol, while preserving the patency of the access site.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.carrev.2018.08.023.

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