

EDITORIAL COMMENT

Hemostatic Patch for Accelerated Hemostasis After Transradial Procedures



A Step Further?*

Olivier F. Bertrand, MD, PhD,^a Zoltan Ruzsa, MD, PhD^b

Like many trials and investigations studying the clinical impact of transradial access for diagnostic angiography and interventions, Safirstein et al¹ developed an original protocol, set up a network of enthusiastic collaborators, managed the multicenter randomized trial, and analyzed the results independently and without any industry support. In this issue of *JACC: Cardiovascular Interventions*, they report the results of the STAT-2 trial (Radial Hemostasis Is Facilitated With a Potassium Ferrate Hemostatic Patch [Statseal]: the Randomized Controlled Statseal With TR Band Assessment Trial II). The investigators should be congratulated for this accomplishment.

SEE PAGE 810

Although radial access has been widely used for more than 2 decades, Class Ia recommendation has only appeared recently in the American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions guidelines for revascularization.² Beyond clear benefits over standard femoral access in vascular complications and periprocedural bleeding, transradial access has paved the way to same-day discharge after uncomplicated percutaneous coronary interventions (PCIs), not only for elective procedures in stable

angina patients, but also after complex procedures in acute coronary syndrome patients.^{3,4} The current COVID pandemic has been a major impetus to shorten hospital stays, and this applies for many invasive medical procedures.

Hence, strategies to reduce hemostasis duration might lead to faster hospital discharge. Obviously, the superficial nature of the radial artery offers a unique and optimal situation to secure fast hemostasis, because it allows the patient to stand up and ambulate right after the procedure. This is also another reason why “radial lounges” built upon the concept of airport business lounges have started to spread around the globe. In these dedicated environments, free of hospital beds, patients use reclining chairs instead of beds, and spaces can also accommodate technologies for TV and Internet access in a cozier set-up.⁵ There is little doubt that radial lounges built as recovery rooms close to catheterization laboratories will continue to expand in the next decade.

Because significant cost benefit has been associated with outpatient practice, there is evidence that speeding up hospital discharge after diagnostic angiography and/or PCI can result in significant savings, regardless of the health care system environment.⁶⁻⁸ A prerequisite for a short hospital stay is to obtain a fast and safe hemostasis. Whereas for femoral access, there have been a flurry of suture-based and non-suture-based closure devices developed over the years, hemostasis devices for radial/ulnar access are less complex and less expensive. Basic single artery compression devices, usually divided into pneumatic or nonpneumatic, have remained the most popular. However, occlusive compression to hemostasis could be associated with the main drawback of radial artery access, that is, radial artery occlusion (RAO).⁸⁻¹¹ RAO is a multifaceted issue that results from the complex interplay between vessel injury, and local

*Editorials published in *JACC: Cardiovascular Interventions* reflect the views of the authors and do not necessarily represent the views of *JACC: Cardiovascular Interventions* or the American College of Cardiology.

From the ^aDepartment of Interventional Cardiology, Quebec Heart-Lung Institute, Laval University, Quebec, Quebec, Canada; and the ^bDivision of Invasive Cardiology, University of Szeged, Szeged, Hungary.

The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the [Author Center](#).

parameters such as spasm and flow disturbances and thrombosis. Although RAO has usually little clinical consequences, it is now commonly admitted that every effort should be made to minimize RAO. A recent consensus paper has specifically recommended that good clinical practice with radial access should be associated with a <5% risk of RAO.⁹

Beyond dedicated radial small-sized sheaths and catheters and intravenous anticoagulation, the 2 main factors linked to reduced RAO risk are: 1) the use of nonocclusive radial artery compression until hemostasis is completed; and 2) the limited compression time. “Patent-radial artery hemostasis” can be obtained in ~75% of the cases by early decompression and finger-oximetry monitoring with dedicated nursing protocols or >90% using prophylactic ulnar compression.¹¹ The optimal duration for radial artery compression is presently unknown. The tradeoff for reducing the compression time must be balanced against the risks of rebleeding, hematoma formation, and possibly pseudoaneurysm formation.

In the STAT-2 trial reported in this issue, the investigators¹ investigated the potential of using a potassium ferrate hemostatic patch (StatSeal, Biolife) as a topical prothrombotic agent to reduce hemostasis time after transradial diagnostic angiography and/or PCI. Compared with a standard deflation protocol using a commonly used pneumatic band (TR-band, Terumo), patch-assisted hemostasis was associated with a ~40% reduction in compression time, both after diagnostic and PCI procedures. Importantly, no differences in hematoma or RAO were observed between the 2 groups. Furthermore, rebleeding requiring repeat device inflation were observed significantly more often in the nonpatch group. No adverse reaction was observed with the use of the patch-assisted hemostasis.

In relative terms, reducing hemostasis time around 1 hour instead of 2 hours after transradial diagnostic angiography and/or PCI is a dramatic improvement. Significant reduction in hemostasis time has also been demonstrated with the same and other hemostatic patches by other investigators, which brings external validation for this study.¹²⁻¹⁴ It is worth

noting that a number of patients did not receive intravenous heparin. A word of caution remains because systematic intravenous anticoagulation is strongly recommended because it plays a substantial role in limiting the risks of RAO.⁹

Yet, a caveat should be mentioned. Indeed, obtaining an effective and safe hemostasis within 1 hour after diagnostic angiography might reduce use of hospital resources and allow very rapid discharge (~2 hours), however, this is less evident for patients having undergone PCI. For PCI patients, the safety parameter that is paramount is the risk of ischemic complications in relation with the coronary intervention itself. Based on numerous studies on same-day discharge after uncomplicated PCI, an observation period of 4 to 6 hours after PCI has been considered mandatory.^{3,4,15,16} Therefore, a 1-hour hemostasis time would not lead to earlier hospital discharge compared with a 2-hour compression time.

In a time of increased pressure for cost containment, further cost analysis will be required. Compared with closure devices used for femoral access, radial hemostatic devices are much less expensive, but the cost of these hemostatic patches is not trivial. Ultimately, it will be worth studying the detailed impacts of patch-assisted radial hemostasis on patient safety and comfort, and reduction in use of hospital resources and, ultimately, costs.

FUNDING SUPPORT AND AUTHOR DISCLOSURES

Prof Bertrand holds the International Chair on Interventional Cardiology and Transradial Approach at University Laval. He also holds patents on radial artery hemostasis devices (unrelated with technologies used in this study). Dr Ruzsa has reported that he has no relationships relevant to the contents of this paper to disclose.

ADDRESS FOR CORRESPONDENCE: Prof Olivier F. Bertrand, Department of Interventional Cardiology, Quebec Heart-Lung Institute, Faculty of Medicine, Laval University, 2725, Chemin Ste Foy, Quebec City, G1V 4G5, Canada. E-mail: Olivier.bertrand@fmed.ulaval.ca.

REFERENCES

1. Safirstein JG, Tehrani DM, Schussler JM, et al. Radial hemostasis is facilitated with a potassium ferrate hemostatic patch: the STAT2 trial. *J Am Coll Cardiol Interv*. 2022;15(8):810-819.
2. Lawton JS, Tamis-Holland JE, Bangalore S, et al. 2021 ACC/AHA/SCAI guideline for coronary artery revascularization: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2022;79(2):e21-e129. <https://doi.org/10.1016/j.jacc.2021.09.006>
3. Abdelaal E, Rao SV, Gilchrist IC, et al. Same-day discharge compared with overnight hospitalization after uncomplicated percutaneous coronary intervention: a systematic review and meta-analysis. *J Am Coll Cardiol Interv*. 2013;6:99-112.
4. Bertrand OF, De Larochelliere R, Rodes-Cabau J, et al. A randomized study comparing same-day home discharge and abciximab bolus

- only to overnight hospitalization and abciximab bolus and infusion after transradial coronary stent implantation. *Circulation*. 2006;114:2636-2643.
5. Brewster S, Khimdas K, Cleary N, et al. Impact of a dedicated "radial lounge" for percutaneous coronary procedures on same-day discharge rates and bed utilization. *Am Heart J*. 2013;165:299-302.
 6. Amin AP, Pinto D, House JA, et al. Association of same-day discharge after elective percutaneous coronary intervention in the United States with costs and outcomes. *JAMA Cardiol*. 2018;3:1041-1049.
 7. Rinfret S, Kennedy WA, Lachaine J, et al. Economic impact of same-day home discharge after uncomplicated transradial percutaneous coronary intervention and bolus-only abciximab regimen. *J Am Coll Cardiol Interv*. 2010;3:1011-1019.
 8. Shroff AR, Gulati R, Drachman DE, et al. SCAI expert consensus statement update on best practices for transradial angiography and intervention. *Catheter Cardiovasc Interv*. 2020;95:245-252.
 9. Bernat I, Aminian A, Pancholy S, et al. Best practices for the prevention of radial artery occlusion after transradial diagnostic angiography and intervention: an international consensus paper. *J Am Coll Cardiol Interv*. 2019;12:2235-2246.
 10. Hahalis G, Aznaouridis K, Tsigkas G, et al. Radial artery and ulnar artery occlusions following coronary procedures and the impact of anticoagulation: ARTEMIS (Radial and Ulnar ARTERY Occlusion Meta-Analysis) systematic review and meta-analysis. *J Am Heart Assoc*. 2017;6(8):e005430. <https://doi.org/10.1161/JAHA.116.005430>
 11. Pancholy SB, Bernat I, Bertrand OF, Patel TM. Prevention of radial artery occlusion after transradial catheterization: the PROPHET-II randomized trial. *J Am Coll Cardiol Interv*. 2016;9:1992-1999.
 12. Achim A, Kakonyi K, Jambrik Z, et al. Distal radial artery access for coronary and peripheral procedures: a multicenter experience. *J Clin Med*. 2021;10(24):5974. <https://doi.org/10.3390/jcm10245974>
 13. Anchan R, Venturini J, Larsen P, et al. Safe and rapid radial hemostasis achieved using a novel topical hemostatic patch: results of a first-in-human pilot study using hydrophobically modified polysaccharide-chitosan. *Catheter Cardiovasc Interv*. 2022;99(3):786-794. <https://doi.org/10.1002/ccd.29529>
 14. Ayyaz Ul Haq M, Nazir SA, Rashid M, et al. Accelerated patent hemostasis using a procoagulant disk; a protocol designed to minimize the risk of radial artery occlusion following cardiac catheterization. *Cardiovasc Revasc Med*. 2019;20:137-142.
 15. Heyde GS, Koch KT, de Winter RJ, et al. Randomized trial comparing same-day discharge with overnight hospital stay after percutaneous coronary intervention: results of the Elective PCI in Outpatient Study (EPOS). *Circulation*. 2007;115:2299-2306.
 16. Shroff A, Kupfer J, Gilchrist IC, et al. Same-day discharge after percutaneous coronary intervention: current perspectives and strategies for implementation. *JAMA Cardiol*. 2016;1:216-223.
-
- KEY WORDS** cost, health care, hemostasis, occlusion, patch, radial, transradial