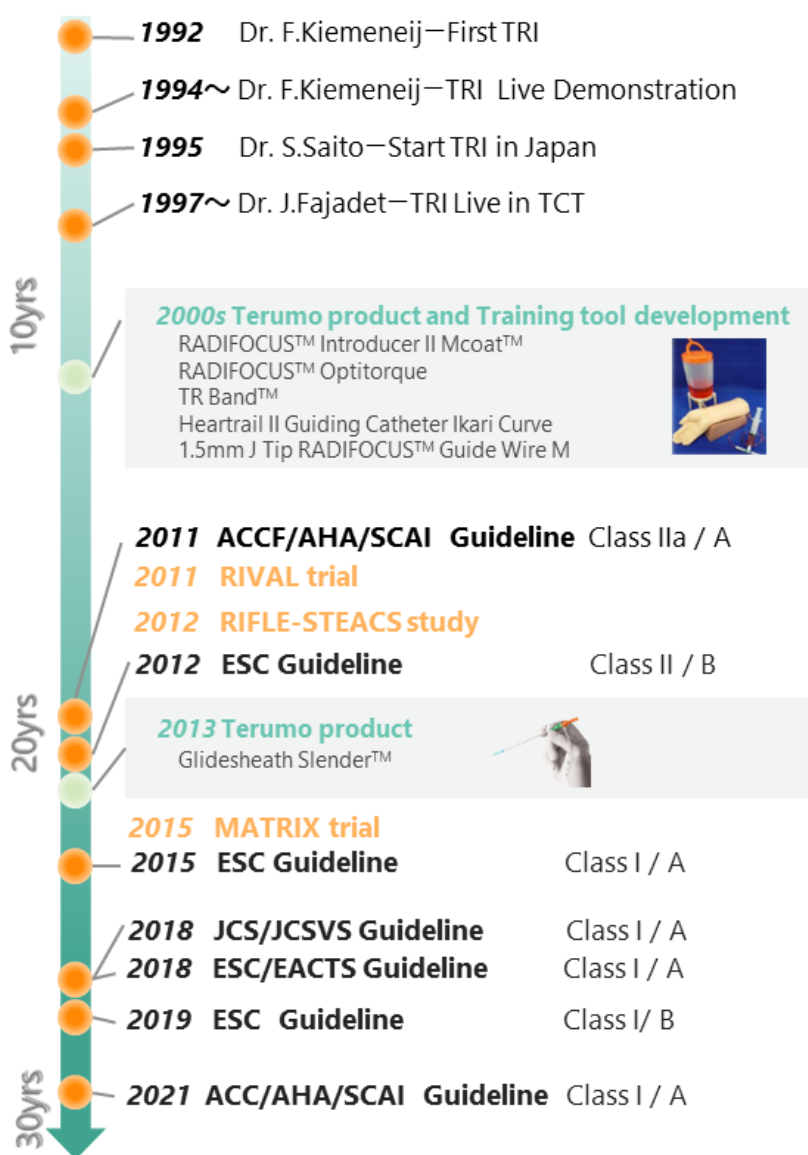




TRI 30th Anniversary Newsletter Vol. 4

Latest Evidence and Guidelines for Radial Access



2022 marks 30 years since Dr. Kiemeneij performed the world's first radial access PCI. In this issue we look at how guideline indications for radial access have changed, and at recent trends in radial access research.

Radial access guidelines through the years

In 2011, around 20 years after the first transradial intervention (TRI) by Dr. Kiemeneij, ACCF/ AHA/ SCAI Guidelines for Percutaneous Coronary Intervention in the US stated that radial access was effective in reducing access-site complications. However, the recommendation and evidence levels remained unrevised at Class IIa/Level A.

In 2012, the following year, radial

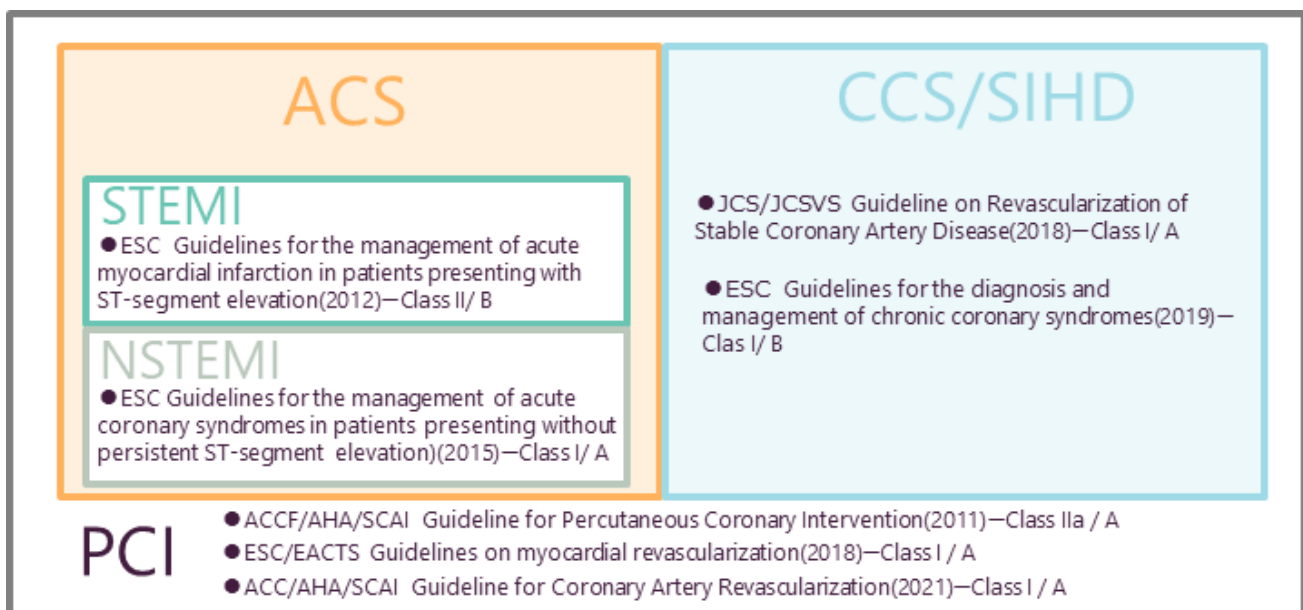
PUSHING BOUNDARIES





access was included in the European ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation. This came on the back of the RIVAL (2011) and RIFLE STEACS (2012) trials which showed a reduction in major bleeding events when radial access was used in patients with acute coronary syndrome (ACS).

The 2015 publication of ESC Guidelines for the management of ACS in patients presenting without persistent ST-segment elevation indicated a Class I recommendation for radial access. Based on the results of a meta-analysis which included the MATRIX trial (2015) and other evidence, radial access became recommended for non-STEMI ACS cases.



Radial access was later given a Class I indication in Japan too, and then in 2021, the ACC/AHA/SCAI Guidelines for Coronary Artery Revascularization gave radial access a Class I/Level A indication for reducing the risk of access-site complications and bleeding, both in ACS patients and in SIHD patients.



Recent research trends in radial access

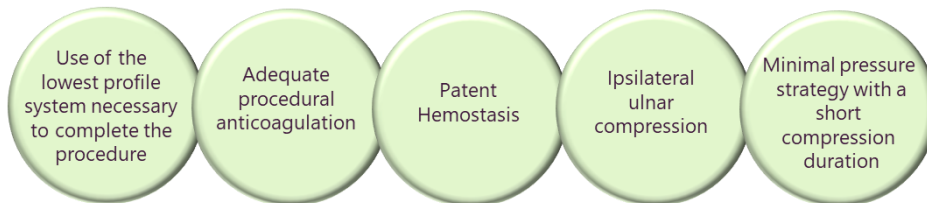
As radial access becomes widely adopted as the preferred approach, recent research is shifting focus to radial artery occlusion (RAO), a complication specific to radial access. For patients who undergo multiple angiography and PCI procedures, RAO can limit their radial access options. Recent studies explore how to reduce the risk of RAO with a focus on hemostasis techniques, and in particular “patent hemostasis”: hemostasis without occlusion of blood vessels (see table below). Recommendation in the global consensus paper published in 2019 included methods for hemostasis and using the smallest possible diameter stent.⁶ It is clear that reducing RAO is a popular trend in radial access research.

RAO

Radial artery occlusion

Title	Year	Compared hemostasis method		
PROPHET study¹	2008	Conventional pressure	vs	Pressure application confirming radial artery patency using Barbeau's test
PROPHET II study²	2016	Standard patent hemostasis protocol	vs	Prophylactic ipsilateral ulnar compression in addition to patent hemostasis
RACOMAP trial³	2009	Compression with TR Band guided by the mean artery pressure (MAP)	vs	Standard compression procedure (15 cm ³ of air in TR Band)
CRASOC I⁴	2012	Compression with 13 cc of air into TR Band for 4 hours	vs	Compression with 10 cc of air into TR Band for 4 hours
CRASOC II⁴	2017	Compression with 10 cc of air for 3 hours	vs	Compression with 10 cc of air for 2 hours
CRASOC III⁴	2017	Compression with 10 cc of air for 2 hours	vs	Compression with 10 cc of air for 1.5 hours
MEMORY Trial⁵	2018	Manual compression	vs	Patent hemostasis with mechanical compression device

Best Practices for the Prevention of Radial Artery Occlusion
 International Consensus Paper(2019)⁶



PUSHING BOUNDARIES



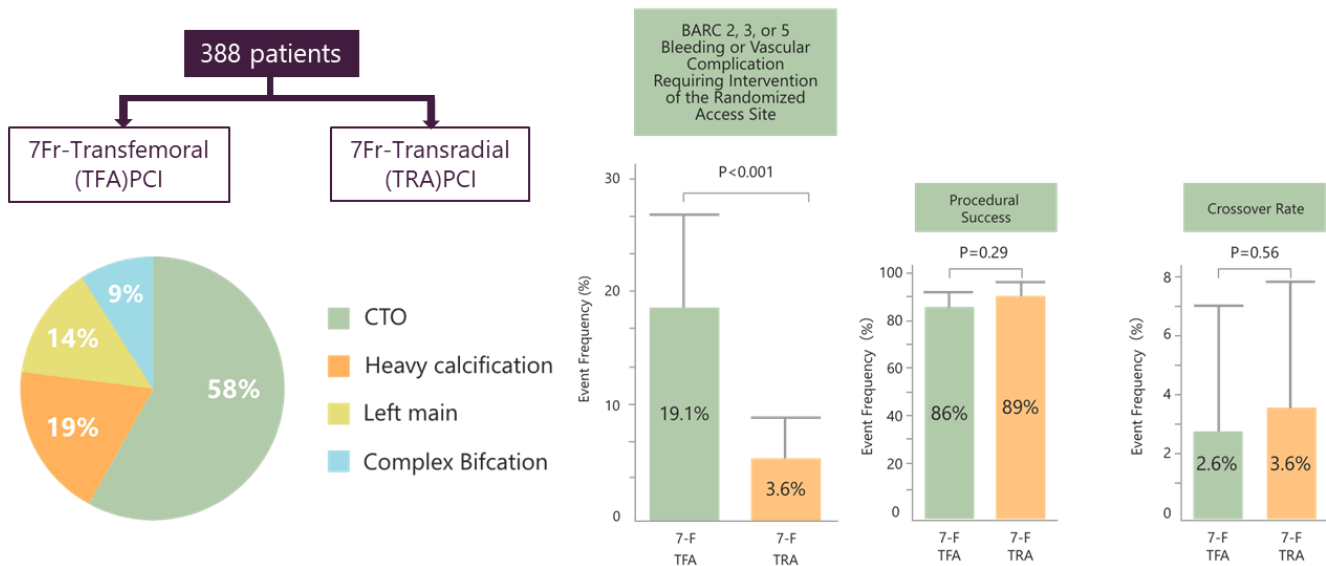


Radial 30th TRANSFORM LIVES WITH TRANSRADIAL

Complex PCI

In addition to reducing the risk of RAO, another trend seen in radial access research is in proving the effectiveness of radial access in complex PCI cases, with the COLOR trial (2021) being the most recent. The COLOR trial compared the incidence of major bleeding and vascular complications in complex PCI (chronic total occlusion, left main, heavy calcification, complex bifurcation), at the access site at time of hospital discharge, when using a 7Fr Glidesheath Slender for TRA and a 7Fr sheath for TFR. The results showed a significant lower incidence of BARC 2,3, or 5 bleeding and vascular complications in TRA.⁷

The COLOR (Complex Large-Bore Radial Percutaneous Coronary Intervention) trial⁷



Other evidence includes the results of a meta-analysis of seven randomized clinical trials, including COLOR and MATRIX, announced at ESC2022. Prompted by the fact that not all previous studies had shown the impact of radial access on mortality rates, the analysis verified radial access as reducing mortality, with radial access results showing a reduction in 30-days mortality and major bleeding events.⁸

Going forward, we expect to see continued research into the clinical efficacy of choosing radial access for complex lesion PCI.

PUSHING BOUNDARIES





Terumo's commitment to the advancement of radial access

While radial access has made much progress in the area of global guidelines, and as a subject for research, in clinical practice there is still room for advancement. At Terumo, we will continue to ensure that radial access, shown to produce better patient outcomes compared to femoral, will be performed safely, and expanded to more cases. We will also provide evidence-based information to enable our Glidesheath Slender, designed to provide easier radial access even in the smallest of arteries, to be applied in the treatment of complex lesions. To increase the rate of patent hemostasis and reduce RAO, it is crucial that clinical evidence and information on patent hemostasis techniques and methods are made more easily available. As the manufacturer of the TR Band, we will continue to provide training to those involved in hemostatic management, and explore hemostatic protocol options that reduce the burden for patients and healthcare professionals.

Related Products

Glidesheath Slender™

Hydrophilic Coated Sheath



The proprietary thin-wall technology and Terumo Mcoat™ hydrophilic coating

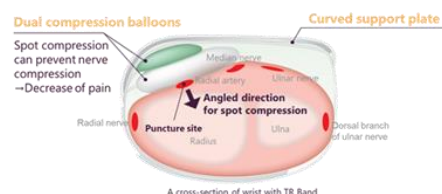


TR Band™

Radial Artery Compression Device



Transparent structure designed for visual control and selective compression of the radial artery



PUSHING BOUNDARIES





tis.terumo.com

<https://tis.terumo.com/featured/radialedge>



Customer Support

<https://tis.terumo.com/form/contact/radialedge>

Reference

1. Pancholy S, Coppola J, Patel T, Roke-Thomas M. Prevention of radial artery occlusion-patent hemostasis evaluation trial (PROPHET study): a randomized comparison of traditional versus patency documented hemostasis after transradial catheterization. *Catheter Cardiovasc Interv.* 2008 Sep 1;72(3):335-340. doi: 10.1002/ccd.21639. PMID: 18726956.
2. Pancholy SB, Bernat I, Bertrand OF, Patel TM. Prevention of Radial Artery Occlusion After Transradial Catheterization: The PROPHET-II Randomized Trial. *JACC Cardiovasc Interv.* 2016 Oct 10;9(19):1992-1999. doi: 10.1016/j.jcin.2016.07.020. PMID: 27712733.
3. Cubero JM, Lombardo J, Pedrosa C, Diaz-Bejarano D, Sanchez B, Fernandez V, Gomez C, Vazquez R, Molano FJ, Pastor LF. Radial compression guided by mean artery pressure versus standard compression with a pneumatic device (RACOMAP). *Catheter Cardiovasc Interv.* 2009 Mar 1;73(4):467-72. doi: 10.1002/ccd.21900. PMID: 19229978.
4. Dangoisse V, Guédès A, Chenu P, Hanet C, Albert C, Robin V, Tavier L, Dury C, Piraux O, Domange J, Jourdan K, Bihin B, Schroeder E. Usefulness of a Gentle and Short Hemostasis Using the Transradial Band Device after Transradial Access for Percutaneous Coronary Angiography and Interventions to Reduce the Radial Artery Occlusion Rate (from the Prospective and Randomized CRASOC I, II, and III Studies). *Am J Cardiol.* 2017 Aug 1;120(3):374-379. doi: 10.1016/j.amjcard.2017.04.037. Epub 2017 May 10. PMID: 28577752.
5. Petroglou D, Didagelos M, Chalikias G, Tziakas D, Tsigkas G, Hahalis G, Koutouzis M, Ntatsios A, Tsiafoutis I, Hamilos M, Kouparanis A, Konstantinidis N, Sofidis G, Pancholy SB, Karvounis H, Bertrand OF, Ziakas A. Manual Versus Mechanical Compression of the Radial Artery After Transradial Coronary Angiography: The MEMORY Multicenter Randomized Trial. *JACC Cardiovasc Interv.* 2018 Jun 11;11(11):1050-1058. doi: 10.1016/j.jcin.2018.03.042. PMID: 29880098.
6. Bernat I, Aminian A, Pancholy S, Mamas M, Gaudino M, Nolan J, Gilchrist IC, Saito S, Hahalis GN, Ziakas A, Louvard Y, Montalescot G, Sgueglia GA, van Leeuwen MAH, Babunashvili AM, Valgimigli M, Rao SV, Bertrand OF; RAO International Group. Best Practices for the Prevention of Radial Artery Occlusion After Transradial Diagnostic Angiography and Intervention: An International Consensus Paper. *JACC Cardiovasc Interv.* 2019 Nov 25;12(22):2235-2246. doi: 10.1016/j.jcin.2019.07.043. PMID: 31753298.
7. Meijers T, Aminian A, van Wely M, et al. Randomized Comparison Between Radial and Femoral Large-Bore Access for Complex Percutaneous Coronary Intervention. *J Am Coll Cardiol Intv.* 2021 Jun, 14 (12) 1293–1303.
8. Giuseppe Gargiulo, MD, PhD, Daniele Giaccoppo, MD, MSc, PhD, Sanjit S. Jolly, MD, PhD, John Cairns, MD, Michel Le May, MD, Ivo Bernat, MD, Enrico Romagnoli, MD, Sunil V. Rao, MD, PhD, Maarten A.H. van Leeuwen, MD, PhD, Shamir R. Mehta, MD, MSc, Olivier F. Bertrand, MD, PhD, George A. Wells, MD, Thomas A. Meijers, MD, George C.M. Siontis, MD, Giovanni Esposito, MD, PhD, Stephan Windecker, MD, Peter Jüni, MD, Marco Valgimigli, MD, PhD, for the Radial Trialists' Collaboration. Effects on Mortality and Major Bleeding of Radial Versus Femoral Artery Access for Coronary Angiography or Percutaneous Coronary Intervention: Meta-Analysis of Individual Patient Data From 7 Multicenter Randomized Clinical Trials. *Circulation.* 2022;146:1329–1343

PUSHING BOUNDARIES

