






TRI 30th Anniversary Newsletter Vol. 2

The future brought by radial approach — Same-Day Discharge

What is SDD?

Do you know the abbreviation “SDD”? This stands for *Same-Day Discharge*, namely, it refers to same-day catheterization where the patient completes catheterization and then goes home without being hospitalized on the same-day. Use of a transradial approach to increase the rate of conduct of this same-day discharge is now being discussed as one of the latest topics. Looking back at the history of discussion, SDD has been reported since the early 2000s triggered by the emergence of vascular closure devices that greatly reduced the duration of hemostasis in the femoral approach.¹ In the late 2000s, same-day catheterization with the radial approach was reported, and the number of reports of SDD steeply increased along with the popularization of the radial approach in the late 2010s.² This was related to the radial approach’s benefit of the greatly reduced incidence of post-procedural hemorrhagic complications to shorten the stay in hospital.



	<p>Patient</p> <ul style="list-style-type: none"> • Patient has less exposure to hospital environment allowing for alleviation of fear and improved patient satisfaction
	<p>Physician</p> <ul style="list-style-type: none"> • Studies have shown same-day discharge improves patient satisfaction with comparable outcomes to overnight stay²
	<p>Hospital Administrator</p> <ul style="list-style-type: none"> • Same-day discharge increases hospital bed availability³ and can save U.S health care system between \$200-\$500 million per year³ • Increased hospital efficiency, allowing for more elective procedures

Why SDD?

The greatest benefits from same-day discharge after PCI are improved patient satisfaction, reduced hospitalization time, and efficient use of medical costs.² Particularly these days, an increasing number of patients wish to stay in hospital for a shorter period due to the

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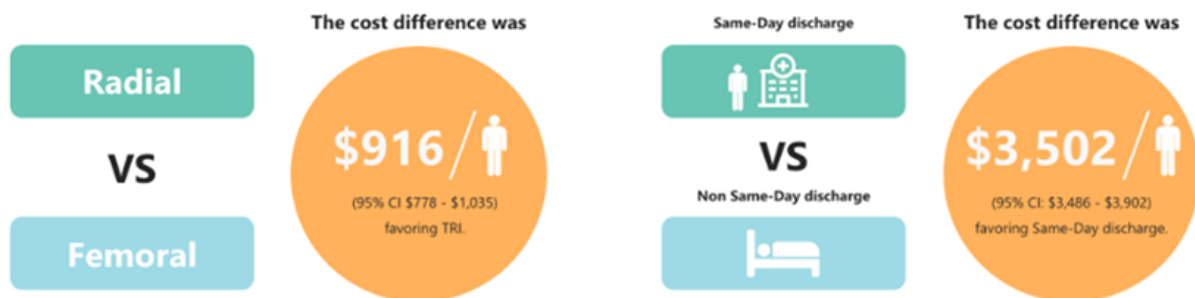




COVID-19 pandemic. In addition, it has been confirmed that SDD has no significant difference from inpatient care in the incidence of complications of bleeding, repeat coronary procedures, death, or rehospitalization, as well as procedure outcome.²

In addition, the background to the increasing attention to SDD includes cost benefits. Hospitals can efficiently obtain profits by increasing bed turnover, and medical costs are reduced by SDD in some regions. In the US, for example, Dr. Amit Amin et al. reported in 2017 that switching of the approach site from the femoral artery to the radial artery reduced medical costs by \$916 per capita. Furthermore, the SDD group had the medical cost reduced by \$3,502/person compared with the hospitalization group.⁴

Cost impacts reported in Dr. Amit P Amin's study ⁴



How to start SDD?

So, what conditions are required to conduct SDD? According to the latest SCAI Guidelines⁵, cases can be classified into cases suitable and cases unsuitable for SDD from the viewpoint of the 3Ps: Patient, Procedure, and Program (see the figure below). Based on this classification, many patients benefit from SDD. SDD can be conducted not only based on consent from individual patients and doctors but requires a great change involving all organizations related to patient's flow in the hospital. To embark on this journey, you should understand patient safety above all else.

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Post-PCI Procedure Discharge criteria*

Favorable Same-Day Discharge		
PATIENT <ul style="list-style-type: none"> <input type="checkbox"/> Patient is clinically stable <input type="checkbox"/> Patient is at baseline functional and mental status <input type="checkbox"/> Baseline comorbidities such as diabetes, CHF, COPD, PAD and ESRD are stable 	PROCEDURE <ul style="list-style-type: none"> <input type="checkbox"/> Adequate hemostasis achieved <input type="checkbox"/> Successful procedure¹ <input type="checkbox"/> Effective dual-antiplatelet therapy administered (Pretreatment not required) 	PROGRAM <ul style="list-style-type: none"> <input type="checkbox"/> Meets PCI program operational requirements for postprocedure care <input type="checkbox"/> Adequate caregiver support <input type="checkbox"/> Patient and caregiver education <input type="checkbox"/> Provision of P2Y12 inhibitor and medication instruction <input type="checkbox"/> Contact information and follow-up appointment
Considerations for Overnight Observation		
PATIENT <ul style="list-style-type: none"> <input type="checkbox"/> Chronic kidney disease requiring prolonged hydration <input type="checkbox"/> Decompensated CHF or fluid overload <input type="checkbox"/> Decompensated COPD <input type="checkbox"/> Continuing angina <input type="checkbox"/> Contrast reaction with ongoing symptoms 	PROCEDURE <ul style="list-style-type: none"> <input type="checkbox"/> Angiographic complexities¹ (Prolonged no reflow, side branch closure, dissection, perforation), Inability to deliver stent/balloon angioplasty only, last remaining coronary artery PCI <input type="checkbox"/> Bleeding complication <input type="checkbox"/> Vascular complication; <input type="checkbox"/> Large contrast volume <input type="checkbox"/> Need for GP IIb/IIIa Infusion <input type="checkbox"/> Periprocedural MI <input type="checkbox"/> Left ventricular support device used <input type="checkbox"/> Large-bore (≥9 French) or brachial access 	PROGRAM <ul style="list-style-type: none"> <input type="checkbox"/> Inadequate home support <input type="checkbox"/> No transportation home <input type="checkbox"/> Discomfort of patient, caregiver, or physician with same-day discharge <input type="checkbox"/> Inadequate access to emergency medical care following PCI

* This checklist provides recommendations that are supported by current guidelines.¹ These recommendations do not replace healthcare facility's protocols and are meant to be individualized to each facility program.

References

1. Seto, Arnold H., et al. "Length of Stay Following Percutaneous Coronary Intervention: An Expert Consensus Document Update from the Society for Cardiovascular Angiography and Interventions." *Catheterization and Cardiovascular Interventions*, vol. 92, no. 4, 2018, pp. 717–731.

A number of studies have already been performed on safety of SDD (see the figure below). We, Terumo, will continue to promote the recognition of these study results as listed below and support the popularization of the radial approach. The transradial approach, for which Terumo has made a great effort with you for many years, is

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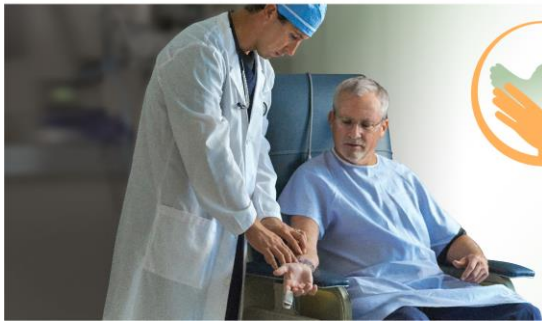


also a key to enable the practice of SDD. We would like to make every effort to support you in the future so that more patients and medical professionals can benefit from the transradial approach and SDD.

Literatures	Results																																				
<p>Same versus next day discharge after elective transradial PCI: The RADial SAME Day DischArge after PCI trial. (The RASADDA-PCI trial)</p> <p>Rodriguez-Araujo G et al</p> <p>Cardiovasc Revasc Med. 2018 Sep;19(6S):7-11.</p> <p>https://www.sciencedirect.com/science/article/pii/S1553838918302422?via%3Dihub</p>	<table border="1"> <thead> <tr> <th data-bbox="884 712 1023 779">Same day discharge (N=245)</th> <th data-bbox="1023 712 1246 779">No significant difference</th> <th data-bbox="1246 712 1385 779">Over night discharge (N=245)</th> <th data-bbox="1385 712 1465 779"></th> </tr> </thead> <tbody> <tr> <td data-bbox="884 779 1023 831">3.7%</td> <td data-bbox="1023 779 1246 831">Procedural complications</td> <td data-bbox="1246 779 1385 831">2.5%</td> <td data-bbox="1385 779 1465 831">p=0.43</td> </tr> <tr> <td data-bbox="884 831 1023 882">4.1%</td> <td data-bbox="1023 831 1246 882">Re-hospitalization</td> <td data-bbox="1246 831 1385 882">4.1%</td> <td data-bbox="1385 831 1465 882">p=0.92</td> </tr> <tr> <td data-bbox="884 882 1023 934">2.5%</td> <td data-bbox="1023 882 1246 934">Re-intervention</td> <td data-bbox="1246 882 1385 934">2.1%</td> <td data-bbox="1385 882 1465 934">p=0.77</td> </tr> <tr> <td data-bbox="884 934 1023 985">0%</td> <td data-bbox="1023 934 1246 985">Myocardial infarction</td> <td data-bbox="1246 934 1385 985">0.08%</td> <td data-bbox="1385 934 1465 985">p=0.15</td> </tr> <tr> <td data-bbox="884 985 1023 1037">0%</td> <td data-bbox="1023 985 1246 1037">Stroke</td> <td data-bbox="1246 985 1385 1037">0%</td> <td data-bbox="1385 985 1465 1037">p=1.0</td> </tr> <tr> <td data-bbox="884 1037 1023 1088">0%</td> <td data-bbox="1023 1037 1246 1088">All-cause mortality</td> <td data-bbox="1246 1037 1385 1088">0%</td> <td data-bbox="1385 1037 1465 1088">p=1.0</td> </tr> </tbody> </table>	Same day discharge (N=245)	No significant difference	Over night discharge (N=245)		3.7%	Procedural complications	2.5%	p=0.43	4.1%	Re-hospitalization	4.1%	p=0.92	2.5%	Re-intervention	2.1%	p=0.77	0%	Myocardial infarction	0.08%	p=0.15	0%	Stroke	0%	p=1.0	0%	All-cause mortality	0%	p=1.0								
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<p>Same Day Discharge versus Overnight Stay in the Hospital following Percutaneous Coronary Intervention in Patients with Stable Coronary Artery Disease: A Systematic Review and Meta-Analysis of Randomized Controlled Trials.</p> <p>Bundhun PK, Soogund MZ, Huang WQ.</p> <p>PLoS One. 2017 12(1): e0169807.</p> <p>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5222585/</p>	<p>During this 30-day follow up mortality, the following items were not significantly different between same day discharge and overnight stay following PCI.</p> <table border="1"> <thead> <tr> <th data-bbox="916 1128 1075 1151">Outcomes analyzed</th> <th data-bbox="1091 1128 1235 1151">OR with 95% CI</th> <th data-bbox="1267 1128 1347 1151">P value</th> <th data-bbox="1362 1128 1426 1151">I²(%)</th> </tr> </thead> <tbody> <tr> <td data-bbox="916 1162 1075 1184">Any adverse event</td> <td data-bbox="1091 1162 1235 1184">0.42 [0.05–3.97]</td> <td data-bbox="1267 1162 1347 1184">0.45</td> <td data-bbox="1362 1162 1426 1184">71</td> </tr> <tr> <td data-bbox="916 1196 979 1218">Death</td> <td data-bbox="1091 1196 1235 1218">0.22 [0.04–1.35]</td> <td data-bbox="1267 1196 1347 1218">0.10</td> <td data-bbox="1362 1196 1426 1218">0</td> </tr> <tr> <td data-bbox="916 1229 1059 1252">Major bleeding</td> <td data-bbox="1091 1229 1235 1252">0.73 [0.15–3.54]</td> <td data-bbox="1267 1229 1347 1252">0.69</td> <td data-bbox="1362 1229 1426 1252">72</td> </tr> <tr> <td data-bbox="916 1263 948 1285">MI</td> <td data-bbox="1091 1263 1235 1285">0.68 [0.33–1.41]</td> <td data-bbox="1267 1263 1347 1285">0.30</td> <td data-bbox="1362 1263 1426 1285">25</td> </tr> <tr> <td data-bbox="916 1296 979 1319">MACEs</td> <td data-bbox="1091 1296 1235 1319">0.45 [0.20–1.02]</td> <td data-bbox="1267 1296 1347 1319">0.06</td> <td data-bbox="1362 1296 1426 1319">0</td> </tr> <tr> <td data-bbox="916 1330 1075 1352">Blood transfusion</td> <td data-bbox="1091 1330 1235 1352">0.64 [0.13–3.21]</td> <td data-bbox="1267 1330 1347 1352">0.59</td> <td data-bbox="1362 1330 1426 1352">0</td> </tr> <tr> <td data-bbox="916 1364 1075 1386">Repeated revascularization</td> <td data-bbox="1091 1364 1235 1386">0.67 [0.14–3.15]</td> <td data-bbox="1267 1364 1347 1386">0.61</td> <td data-bbox="1362 1364 1426 1386">54</td> </tr> <tr> <td data-bbox="916 1397 1075 1420">Re-hospitalization</td> <td data-bbox="1091 1397 1235 1420">1.53 [0.88–2.65]</td> <td data-bbox="1267 1397 1347 1420">0.13</td> <td data-bbox="1362 1397 1426 1420">0</td> </tr> </tbody> </table> <p><small>Abbreviations: MI: myocardial infarction, MACEs: major adverse cardiac events, OR: odds ratio, CI: confidence intervals</small></p>	Outcomes analyzed	OR with 95% CI	P value	I ² (%)	Any adverse event	0.42 [0.05–3.97]	0.45	71	Death	0.22 [0.04–1.35]	0.10	0	Major bleeding	0.73 [0.15–3.54]	0.69	72	MI	0.68 [0.33–1.41]	0.30	25	MACEs	0.45 [0.20–1.02]	0.06	0	Blood transfusion	0.64 [0.13–3.21]	0.59	0	Repeated revascularization	0.67 [0.14–3.15]	0.61	54	Re-hospitalization	1.53 [0.88–2.65]	0.13	0
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Hydrophilic Coated Sheath



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RADIFOCUS™

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- Designed for good torque control and high flow
- One catheter strategy (for radial approach) has benefit on procedure time and direct cost



↓ -40%

Procedure time⁶

199.6±50.2 s vs 331.5 s, p=0.001



↓ -13%

Direct cost per procedure⁷

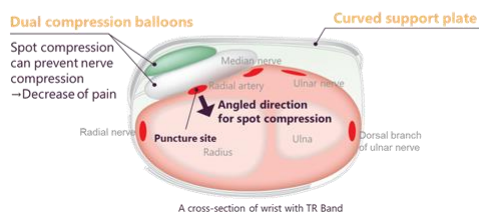
149 (140-160) vs 171 (160-183) p<0.001

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Radial Artery Compression Device



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



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Reference

1. Yee KM, Lazzam C, Richards J, et al. "Same-day discharge after coronary stenting: a feasibility study using a hemostatic femoral puncture closure device." *J Interv Cardiol.* 2004 Oct;17(5):315–20.
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3. Groves, Elliott, and Mladen I Vidovich. "Length of Stay After PCI." *American College of Cardiology*, 5 Aug. 2019.
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6. Seong-Man Kim et al., "Novel diagnostic catheter specifically designed for both coronary arteries via the right transradial approach. A prospective, randomized trial of Tiger II vs. Judkins catheters." *Int J Cardiovasc Imaging.* Jun-Aug 2006;22(3-4):295-303.
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