Editor's Perspective

Diffusion of Innovations and Adoption of Transradial Intervention

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A doption of scientific innovations, including drugs, devices, and techniques, is critical to the advancement of safe and efficacious healthcare. Often, however, disconnects between scientific evidence and clinical practice are observed with less supported innovations being widely adopted and those with stronger data underused. Popularized by the sociologist Rogers in 1962, the diffusion of innovations theory is used to explain the spread of ideas or practices among social systems, including academic disciplines. The attractiveness of diffusion theory is that it goes beyond the innovation to understand the influence of communication channels, time, and the social system. In healthcare, adoption of a new innovation or technology depends heavily on the interaction between the innovation and the adoption system. The complexities of how an innovation is introduced into clinical practice are exemplified by the story of transradial intervention (TRI). Several aspects of TRI have contributed to the relatively slow rate of uptake in the United States.

One of the main reasons that TRI has not been widely adopted is that the relative advantages of the technique, as compared with the current standard of femoral access, have not always been evident. In general, innovations that have a clear relative advantage either in effectiveness or cost-effectiveness are more often adopted. In the 1990s, technological advances in interventional equipment allowed techniques to be performed through smaller sheaths and the feasibility of TRI was reported. During the next decade, there were several pioneers who had the foresight to understand the value in TRI and develop the necessary skills to apply the technique to a broader base of patients. As a result of the efforts of the very early adopters, the procedure was not abandoned, and benefits of the technique began to emerge in the literature, including a reduction in peri-procedural bleeding, cost-effectiveness, and patient preference. Other attributes of the innovation, however, were slowing adoption. Physicians did not have a formal way to acquire the necessary procedural skills and equipment specifically designed for radial catheterization was not available. In additional, initial studies in aggregate failed to show that TRI resulted in improved cardiovascular outcomes compared with transfemoral but did show longer fluoroscopic time and higher procedural failure. The balance of the relative advantages compared with the complexity and potential risk stalled adoption of the innovation. By 2007, 14 years after the initial reports of the feasibility of TRI, only 1% of PCI was performed by the radial approach.

Commonly, evidence for innovations is contemplated for long periods, may be challenged, or the relevance may be viewed differently on the basis of other available data. The motivation to design large trials to compare transradial and femoral PCI came when the association between PCI-related bleeding and mortality was reproducibly demonstrated. Early studies of TRI suggested that this procedural approach had the potential to reduce mortality by decreasing bleeding. The challenge in studying procedural innovations lies in the need for physicians with sufficient experience, which may be hard to define. Although a general learning curve can be assumed, determining the criteria for participation in a trial is difficult. In the largest randomized controlled trial of TRI, RadIAL Versus femorAL (RIVAL) access for coronary intervention which enrolled from 2006 to 2010, operators were required to have performed a minimum of 50 radial procedures within the previous year. The trial demonstrated that in patients with acute coronary syndromes, the composite cardiovascular outcome was similar in the radial versus femoral access groups. Favoring TRI, vascular access site complications were significantly lower in the radial group, and symptomatic radial occlusion was rare. Several important observations were made in the RIVAL trial, including different outcomes in high- and low-volume radial PCI centers, with benefit for the primary outcomes for radial access in high-volume centers and in patients with ST-segment–elevation myocardial infarction. The RIVAL trial reminds us of the paradox that occurs with procedural innovations. Evidence about the benefits and appropriate patients for the procedure cannot be determined until learning occurs, which requires a period of experimentation.

At the time RIVAL was published, the uptake of TRI in the United States was on the rise at 11% on the basis of CathPCI National Cardiovascular Data Registry. After the publication continued, adoption has occurred but wide variation still exists. In our institution, for example, the TRI rate is 34.2% according to our 2012 third-quarter NCRD report, compared with a national average of 16.2%. Looking at the TRI rate on a regional or hospital level may give us false reassurance that diffusion of TRI is going beyond the early adopters to the early majority. An even wider gap in adoption is observed, however, among operators. Again, using my institution as an example, there are interventionalists that perform TRI on a routine basis (>80%), including ST-segment–elevation myocardial

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infarction, operators who do selective cases, and those who do not perform TRI at all. On the basis of these observations, I am of the opinion that TRI is underadopted for the current level of evidence.

Continued impediments to TRI adoption are several but are decreasing over time. Physicians still concerned about radiation can be assured that with expertise and high TRI volume radiation does not differ between the radial and the femoral approach. Those awaiting demonstration of a reduction in hard clinical end points with TRI should be satisfied with the Radial Versus Femoral Randomized Investigation in ST-Elevation Acute Coronary Syndrome study, which showed that in high-volume centers, TRI was associated not only with a reduction in bleeding, but also cardiac mortality. Concern for radial occlusion should be lessened by the practice of patent hemostasis. The remaining obstacles cannot be overcome easily and include the learning curve and the need for system level support. These aspects, however, are not specific to TRI and are components of many interventional innovations. Although TRI is simple compared with innovations, such as transcatheter aortic valve replacement, it still requires physician training, and administrative and catheterization laboratory staff support. For physician training proctoring by competent operators is a resource that can be used.

In 2013, 20 years after the first report of TRI, there is a critical mass of TRI-capable operators, a scientific evidence based, incorporation of TRI into practice guidelines, availability of regional society-sponsored courses, and more formal dissemination of the technique through fellowship training programs. External pressures for TRI exist and will continue to increase. From a socioeconomic standpoint, the cost of training programs exist and will continue to increase. From a socioeconomic standpoint, the cost benefits of TRI compared with transfemoral PCI have been described and same-day PCI and the potential for differential reimbursement or incentives based on PCI outcomes will favor TRI. Public awareness of the technique must also be considered and patient preference will drive educated consumers to seek out competent interventionalists. The innovation of TRI has become a self-sustaining technique that will not be abandoned.

What can we learn from examining the diffusion of TRI that can be applied to future procedural innovations to optimize the rate of adoption and align clinical practice with scientific evidence? New innovations must be assessed not only for the outcomes examined in clinical trials, but also for physician training requirements and system readiness. With this approach a more formal dissemination process can be developed that will minimize risk and prevent the market from driving the uptake of procedures prematurely. Professional societies and physicians in leadership positions need to assume a dominant role in this process so that regulatory and payer groups do not take the responsibility from us.

Disclosures

None.

References


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