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Excessive Rotational Speed May Be Associated With the Transection of Guidewires in Rotational Atherectomy

Among several specific devices for calcified lesions, rotational atherectomy (RA) has been a cornerstone for severely calcified coronary lesions. Unique complications such as burr entrapment were observed in percutaneous coronary intervention with RA, and one of unique complications was the transection of the RotaWire (Boston Scientific, Marlborough, MA), which might result in fatal complications such as vessel perforation.[1] There were few reports mentioning the incidence of transection. Our group previously reported the incidence of transection of the RotaWire as 0.8% from the analysis of 250 RA cases.[2] However, the reasons or the specific risk factors for the transection have not been systematically analyzed.

Although manufacturer recommended the rotation speed <19,000 rotation per minute (rpm), the maximum rotational speed greater than 190,000 rpm is sometimes used in clinical practice.[3] Our group revealed that the RotaWire may be spinning under the maximum rotational speed in a bench test,[4] whereas the RotaWire theoretically would not spin during high-speed mode because of the internal brake and WireClip Torquer (Boston Scientific, Marlborough, MA). If the RotaWire was spinning during RA, the RotaWire would be fatigued, which might be a risk of the transection of the guidewire. Our group conducted a randomized control study regarding the rotational speed (high speed vs low speed),[5] which started at November 2014. This randomized control study served as a trigger to reconsider the rotational speed in our catheter laboratory. Our group had adopted a liberal rule regarding the rotational speed ranging 140,000 to 220,000 rpm until November 2014 (beyond 200,000 rpm was occurred frequently), whereas our group has adopted a conservative rule regarding the rotational speed ranging 140,000 to 190,000 rpm (beyond 190,000 rpm was tried only occasionally) since November 2014. We retrospectively compared the incidence of the transection of the RotaWire between the period of liberal rotational speed (April 2007 to November 2014) and that of conservative rotational speed (November 2014 to May 2020). This study was approved by the institutional review board of Saitama Medical Center, Jichi Medical University (S20-029), and written informed consent was waved because of the retrospective study design. The incidence of the transection of the RotaWire was significantly higher in the period of liberal rotational speed than in the period of conservative rotational speed, while the incidence of burr entrapment or vessel perforation due to burrs were not different between the 2 periods (Table 1). Although we did not register each rotational speed before December 2009, the rotational speed was significantly faster in the period of liberal rotational speed than in the period of conservative rotational speed. Of 4 cases with the transection of the RotaWire, each rotational speed was not available in 2 cases before December 2009, but was available in 2 cases after December 2009 (211,800 rpm and 197,700 rpm, respectively). Since the incidence of transection was only 1% even in the period of liberal rotational speed, the excessive rotational speed would not be an only reason for the transection of the RotaWire. Moreover, only 4 events out of 901 RA cases would not allow us to perform a multivariate logistic regression analysis to adjust confounding factors, which usually require at least 20 events for 2 variables and at least 30 events for 3 variables. However, our analysis would provide a hypothesis that the excessive rotational speed might fatigue the RotaWire. Previous large-scale registries regarding RA did not provide each rotational speed. Our preliminary data suggest that future large-scale registries should include each rotational speed to analyze the association between the excessive rotational speed and adverse events.

Disclosures

Dr Sakakura has received speaking honoraria from Abbott Vascular, Boston Scientific, Medtronic Cardiovascular, Terumo, OrbusNeich, Japan Lifeline, and NIPRO. He has served as a proctor for Rotablator for Boston Scientific and has served as a consultant for Abbott Vascular and Boston Scientific. Prof. Fujita served as a consultant for Mehergen Group Holdings, Inc.

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Table 1
Comparison of frequency of complications in the period of liberal rotational speed versus in the period of conservative rotational speed

	Period of liberal rotational speed (April 2007 to November 2014, n = 418)	Period of conservative rotational speed (November 2014 to May 2020, n = 483)	p Value
RotaWire transection- n, (%)	4 (1.0)	0	0.046
Perforation due to burr- n, (%)	0	2 (0.4)	0.502
Burr entrapment- n, (%)	2 (0.5)	1 (0.2)	0.600
Mean rotational speed x 1,000 rpm (n = 685)	197.8 ± 12.9 (n = 202)	170.3 ± 14.8 (n = 483)	<0.001*

Fisher exact test for RotaWire transection, perforation due to burr, burr entrapment.
Student *t* test for mean rotational speed.
* No mean rotational speed data before December 2009.

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Retraction of Studies on Potential Drug Therapies for COVID-19: A Call for Reliability and Scientific Integrity

The author of this paper recently discussed the findings on cardiovascular safety of the controversial use of chloroquine and hydroxychloroquine for the treatment of COVID-19 reported in observational studies, stressing the need of high quality large randomized controlled trials in order to assess the effectiveness and safety of these drugs and other potential therapies for COVID-19.[1] One of the commented studies,[2] which reported a decrease in the in-hospital survival and an increased frequency of de-novo ventricular arrhythmias with the use of chloroquine or hydroxychloroquine, was recently retracted by 3 of the 4 authors, causing controversy in the scientific community and raising serious concerns on the reliability of published papers and the transparency and accountability of researchers particularly in the midst of this global health crisis. The reasons that lead the retraction of the aforementioned study as well as the analysis of other studies with implications for cardiovascular safety that have also been retracted or subjected to an expression of concern, are worthy of consideration.

In a recent comment, Mehra et al[2] stated that after an unsuccessful attempt to conduct an independent peer review of the database on which their findings were based, they can no longer assure the veracity of their conclusions thus, they requested the retraction of their publication. Likewise, a different study conducted by Mehra et al[3] assessed the relationship of cardiovascular disease and drug therapy with in-hospital mortality among patients with COVID-19. In this study the authors reported no increased risk of in-hospital mortality associated with the use of angiotensin-converting−enzyme inhibitors and angiotensin-receptor blockers. However, in a subsequent letter the authors argued that they were unable to access to the raw data and the database was not available to a third-party auditor validation therefore, the authors asked for retraction of the paper.[3] At this time, 15 studies about COVID-19 have been retracted, 2 temporarily retracted and 1 subjected to an expression of concern.[4]

The rush for showing results and publishing papers despite its lack of validation, as health professionals and patients desperately seek treatment options, illustrate the obvious need for strengthening the review process of papers for accuracy and reliability before publication and a call to follow the standards of the International Committee of Medical Journal Editors and the Committee on Publication Ethics. Considerations regarding veracity and scientific integrity are of utmost importance. As previously stated by the author of this paper, the current findings on efficacy and safety of the potential therapies for COVID-19 require validation from high-quality large randomized controlled trials.[1]

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The Era of Point-of-Care Ultrasound Has Arrived: Are Cardiologists Ready?

Dear editor,

Point-of-Care Ultrasound (POCUS) has become a vital tool for bedside diagnosis and management in patient care. Accordingly, POCUS is becoming an important educational component in medical school and residency training programs. Although POCUS protocols can be generalized and involve multiorgan assessment, the fundamental component of bedside ultrasound assessment is cardiac POCUS, or similarly termed "focused cardiac ultrasound." A recent publication by Kirkpatrick et al defined three forms of focused cardiac ultrasound: Ultrasound-assisted physical examination, cardiac POCUS, and critical care echocardiography.[1] However, with significant overlap between these forms of focused cardiac ultrasound, distinguishing between them may be of lesser importance from a practical standpoint.

Traditionally, the providers involved in obtaining and interpreting bedside cardiac POCUS have been predominantly non-cardiologists, including specialists in critical care medicine, emergency medicine, and anesthesia. This emphasis on cardiac POCUS by non-cardiologists is reflected by the increasing number of publications and training courses on cardiac POCUS, which are almost exclusively led by various non-cardiology professional societies.[2,3] In particular, cardiac POCUS in the setting of critical care is increasingly perceived as its own entity with a separate term "critical care echocardiography." In fact, critical care echocardiography has been advocated as an essential component of training and is