of all, we all agree with the authors regarding the adverse effects of smoking on cardiovascular disease (CVD), recognizing the importance of campaigns for smoking cessation as a preventable risk factor and prevention of passive smoking in preventing CVD (2). In addition, we recently demonstrated that smokers showed more impaired peripheral endothelial function than never smokers, resulting in a higher rate of in-stent restenosis in smokers (unpublished data). Furthermore, cigarette smoking has been known as a major risk factor in the development of atherosclerosis and has been shown to cause inflammation and modification of the lipid profile. These data seem to be theoretically compatible with the association with cigarette smoking and a higher burden of necrotic core in coronary lesions observed by a cross-sectional intravascular ultrasound (IVUS) study (3). Because coronary plaque progression/regression has been known as a multifactorial process, even in the precisely designed serial IVUS studies, it appears to be difficult to show the direct relationship between smoking and coronary plaque progression during a relatively short study period.

Considering the varying findings of the previous studies, the association between smoking status and coronary plaque progression has still been controversial. As the authors of letter noted, an appropriately designed serial IVUS study evaluating the impact of smoking on coronary plaque progression primarily is definitely warranted.

***Kenichi Tsujita, MD, PhD**
Seigo Sugiyama, MD, PhD
Hideki Shimomura, MD, PhD
Kenshi Yamanaga, MD
Koichi Kaikita, MD, PhD
Seiji Hokimoto, MD, PhD
Hisao Ogawa, MD, PhD
for the PRECISE-IVUS Investigators

*Department of Cardiovascular Medicine
Graduate School of Medical Sciences
Kumamoto University
1-1-1 Honjo, Chuo-ku
Kumamoto 860-8556
Japan
E-mail: tsujita@kumamoto-u.ac.jp

http://dx.doi.org/10.1016/j.jacc.2015.10.053

Please note: This work was supported in part by a Grant-in-Aid for Young Scientists B (22790713, 24790769) and a Grant-in-Aid for Scientific Research C (26461075) from the Ministry of Education, Science, and Culture, Japan (to Dr. Tsujita). Dr. Ogawa has received remuneration for lectures from Bayer, Boehringer Ingelheim, Daiichi-Sankyo, MSD, Pfizer, and Takeda; has received trust research/joint research funds from Bayer, Daiichi-Sankyo, and Novartis; and has received scholarship funds from AstraZeneca, Astellas, Bristol-Myers Squibb, Chugai, Daiichi-Sankyo, Dainippon Sumitomo Pharma, Kowa, MSD, Otsuka, Pfizer, Sanofi, Shionogi, and Takeda. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

REFERENCES

1. Tsujita K, Sugiyama S, Sumida H, et al. Impact of Dual Lipid-Lowering Strategy With Ezetimibe and Atorvastatin on Coronary Plaque Regression in Patients With Percutaneous Coronary Intervention: The Multicenter Randomized Controlled PRECISE-IVUS Trial. J Am Coll Cardiol 2015;66:495–507.

2. Anti-Smoking Promotion Committee of the Japanese Circulation Society. Anti-smoking declaration 2013. Circ J 2013;77:559–60.

3. Bolorunduro O, Cushman C, Kapoor D, et al. Comparison of Coronary Atherosclerotic Plaque Burden and Composition of Culprit Lesions Between Cigarette Smokers and Non-Smokers by In Vivo Virtual Histology Intravascular Ultrasound. J Invasive Cardiol 2015;27:354–8.

Outcomes After Transcatheter Aortic Valve Replacement With Balloon-Expandable Versus Self-Expandable Valves

CHOICE Trial Results

We read with interest the paper by Abdel-Wahab et al. (1) on 1-year outcomes of the CHOICE (Randomized Comparison of Transcatheter Heart Valves in High Risk Patients With Severe Aortic Stenosis: Medtronic CoreValve Versus Edwards SAPIEN XT Trial) randomized clinical trial comparing transcatheter aortic valve replacement (TAVR) with the balloon-expandable (BE) Edwards SAPIEN XT valve (Edwards Lifesciences, Irvine, California) versus self-expandable (SE) Medtronic CoreValve (Medtronic, Minneapolis, Minnesota). Of interest, the authors concluded that mortality was not statistically different between the 2 groups, but there were numerically higher stroke rates with BE valves. These data are interesting, but we suggest some caution in their interpretation. Indeed, important differences are present in the baseline characteristics between the 2 groups. First, significantly more women have been enrolled in the SE group. Of note, several studies (2,3) and a recently published meta-analysis (4) showed that mortality after TAVR is significantly lower in women compared with men. Second, patients in the BE group tended to be older (2.3 years older) and with a reduced left ventricular ejection fraction compared with SE patients, and both variables are important predictors of mortality after TAVR.

JACC VOL. 67, NO. 2, 2016
JANUARY 19, 2016:230–7

Another concern is that patients in the SE group presented a significantly higher incidence of more than mild aortic regurgitation, a well-known predictor of mortality after TAVR (5). However, the CHOICE trial failed to show any association between aortic regurgitation and mortality, possibly due to the previously described imbalance in baseline characteristics between the 2 groups.

Finally, patients in the BE group showed a trend for an increased rate of stroke compared with SE patients. Of interest, the authors reported an unexpected finding of 4 cases (3.4% of BE-implanted patients) of early prosthetic valve dysfunction in the BE group, possibly attributed to valve thrombosis, suggesting a possible link with the higher stroke rate. However, patients enrolled in the BE group at baseline compared with SE group also presented a higher incidence of atrial fibrillation, despite no difference in antithrombotic therapy, that might play a role in the higher stroke rate observed in the BE group.

*Rocco A. Montone, MD
Luca Testa, MD, PhD
Francesco Bedogni, MD

*Department of Interventional Cardiology
IRCCS Policlinico San Donato
P.zza Edmondo Malan
San Donato Milanese
Milan 20097
Italy
E-mail: rocco.montone@gmail.com

http://dx.doi.org/10.1016/j.jacc.2015.08.1133

Please note: Dr. Bedogni is a proctor for Medtronic, Boston Scientific, and St. Jude Medical. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

REFERENCES

1. Abdel-Wahab M, Neumann FJ, Mehilli J, et al. 1-Year outcomes after transcatheter aortic valve replacement with balloon-expandable versus self-expandable valves: results from the CHOICE randomized clinical trial. J Am Coll Cardiol 2015;66:791–800.

2. Hayashida K, Morice MC, Chevalier B, et al. Sex-related differences in clinical presentation and outcome of transcatheter aortic valve implantation for severe aortic stenosis. J Am Coll Cardiol 2012;59:566–71.

3. Ferrante G, Pagnotta P, Petronio AS, et al. Sex differences in post-procedural aortic regurgitation and mid-term mortality after transcatheter aortic valve implantation. Catheter Cardiovasc Interv 2014;84:264–71.

4. Stangl V, Baldenhofer G, Laule M, Baumann G, Stangl K. Influence of sex on outcome following transcatheter aortic valve implantation (TAVI): systematic review and meta-analysis. J Interv Cardiol 2014;27:531–9.

5. Athappan G, Patvardhan E, Tuzcu EM, et al. Incidence, predictors, and outcomes of aortic regurgitation after transcatheter aortic valve replacement: meta-analysis and systematic review of literature. J Am Coll Cardiol 2013;61:1585–95.

REPLY: Outcomes After Transcatheter Aortic Valve Replacement With Balloon-Expandable Versus Self-Expandable Valves

CHOICE Trial Results

We appreciate the thoughtful comments of Dr. Montone and colleagues concerning the 1-year clinical outcome of the CHOICE trial, but do not share their concerns about a differential impact of baseline characteristics on the observed mortality rates in a randomized setting. Among all baseline clinical and echocardiographic characteristics of the CHOICE population, only sex was statistically significantly different between the balloon-expandable (BE) and self-expandable (SE) groups (age and baseline left ventricular function were not significantly different) (1,2). As mentioned in the paper, we performed a logistic regression analysis to adjust for sex, and the results are essentially unchanged if sex is taken into account (2) (unadjusted p value for all-cause mortality at 1-year using the Fisher exact test = 0.37, adjusted p value for all-cause mortality at 1-year using logistic regression = 0.33).

The assumption of Dr. Montone et al. that more than mild prosthetic valve regurgitation was not associated with higher mortality in the CHOICE population is not correct. As briefly mentioned in the discussion section of our paper (2), device success (which was mainly driven by the absence of more than mild paravalvular leaks) was independently associated with improved survival at 1 year (adjusted odds ratio calculated by logistic regression = 0.16, 95% confidence interval: 0.04 to 0.67, p = 0.01). As previously discussed, the lack of a mortality difference between both devices despite differences in device success could be partially explained by the moderate sample size of this study as well as the numerically higher rate of thromboembolic events in the BE group, although this remains speculative.

Finally, a potential association between the numerically higher incidence of baseline atrial fibrillation (AF) and the occurrence of stroke in the BE group cannot be entirely excluded. In fact, 6 of 11 stroke events in the BE group occurred in patients with AF, but the rate of new-onset AF was nearly identical in the BE group (9.8%) and SE group (9.4%, p = 1.0) (2).

*Mohamed Abdel-Wahab, MD
Gert Richardt, MD

*Heart Center
Segeberger Kliniken GmbH
Academic Teaching Hospital of the Universities of Kiel, Hamburg, and Lübeck
Am Kurpark 1