VOL. 11, NO. 13, 2018
ISSN 1936-8798/$36.00

Letters

RESEARCH CORRESPONDENCE

The IMPACTOR-CTO Trial

Despite concordant outcome data from a thousand registries comparing successful versus unsuccessful CTO PCI (1), recent randomized trials did not support the impact on survival of CTO PCI compared with OMT (2). In contrast, more certainty exists about its importance in improving QoL (2).

The IMPACTOR-CTO (Impact on Inducible Myocardial Ischemia of PercutAneous Coronary InTervention versus Optimal Medical TheRapy in Patients with Right Coronary Artery Chronic Total Occlusion) trial is a single-center randomized trial powered to investigate the impact on inducible ischemia burden of PCI versus OMT (≥2 antianginal agents) on functional status and QoL in patients with isolated RCA CTO.

From October 2010 to April 2014, patients with isolated dominant RCA CTO and stable angina were screened. After baseline adenosine stress cardiac magnetic resonance, patients were randomly assigned (1:1) to either CTO PCI associated with OMT or OMT alone. Patients who underwent unsuccessful CTO PCI attempts and those noncompliant with OMT were excluded from the study. Adenosine stress cardiac magnetic resonance was performed at baseline (before randomization) and at 2 and 12 months. MIB was estimated as a percentage as previously described (3). Functional status was evaluated using the 6-minute walk test, and QoL was measured using the Short Form-36 Health Survey.

The primary endpoint was the ΔMIB, defined as the decrease in MIB from baseline to 12-month control. The secondary endpoints were changes in 6-min walk distance, QoL, and MACE occurrence (defined as the composite endpoint of all-cause death, myocardial infarction, and unplanned revascularization) at 12 months.

Among 317 patients with CTO screened, a total of 94 eligible patients with isolated RCA CTO (29.6%) were randomly allocated to either the PCI or the OMT. In the PCI group, failed CTO PCI was observed in 8 patients, for an overall angiographic success rate of 83%. In the OMT group, 14 patients were excluded for noncompliance with OMT. Thus, 39 and 33 patients were included in the PCI and OMT arms, respectively. The mean age of the study population was 56.6 ± 8.1 years, and 83.3% were men. No difference was observed in baseline clinical and angiographic characteristics between the PCI and OMT groups.

In the PCI group, MIB significantly decreased from 27.7 ± 8.5% at baseline to 16.1 ± 8.6% at 12 months ($p < 0.01$), whereas no significant changes were observed in the OMT group (from 28.4 ± 8.6% at baseline to 27.0 ± 8.0%; $p = 0.83$). Hence, ΔMIB was significantly higher in the PCI group in comparison with the OMT group (13.9 ± 6.1% vs. 0.3 ± 4.2%; $p < 0.01$) (**Figure 1A**).

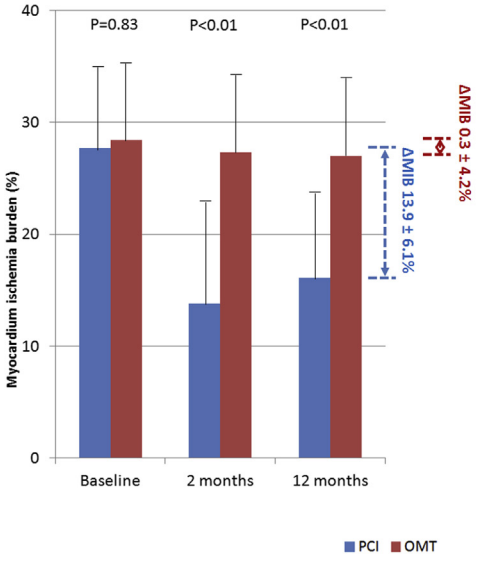
Six-minute walk distance significantly increased in the PCI group from 295 m (interquartile range [IQR]: 261 to 363 m) at baseline to 430 m (IQR: 360 to 452 m) at 12 months ($p < 0.01$). Conversely, no improvement was observed in the OMT group (356 m [IQR: 286 to 425 m] and 378 m [IQR: 290 to 420 m] at baseline and 12 months, respectively, $p = 0.71$). At 12 months, patients who underwent successful CTO PCI showed an improvement in each item of the Short Form-36 Health Survey compared with baseline. Conversely, no QoL parameters improved in the OMT group (**Figure 1B**).

Among patients who underwent CTO PCI attempts, 4 of 47 (8.5%) experienced periprocedural complications: 2 vascular complications and 2 tamponades. No death was observed in either group. In the PCI group, 2 patients underwent target vessel revascularization 5 and 6 months following the index procedure. No significant difference was found in MACE-free survival between the PCI and OMT groups at 12 months (94.9% vs. 100%; $p = 0.19$).

There is a growing need to understand whether a reduction in pre-PCI ischemic burden, particularly in the setting of CTO, relates to a subsequent improvement in QoL and clinical outcome. The DECISION-CTO and the EuroCTO trials are yet unpublished randomized studies comparing CTO recanalization and OMT (2). The majority of patients included in both studies had multivessel disease

FIGURE 1 Changes in Inducible Myocardial Ischemia Burden and Quality-of-Life Parameters in the Percutaneous Coronary Intervention and Optimal Medical Therapy Groups

A



B

	Baseline			At 2 months			At 12 months		
	PCI group (n=39)	OMT group (n=33)	p	PCI group (n=39)	OMT group (n=33)	p	PCI group (n=39)	OMT group (n=33)	p
Physical Functioning, median (IQR)	40 (23; 45)	40 (30; 45)	0.42	45 (45; 75)*	41 (31; 45)	<0.01	45 (45; 70) *	40 (30; 45)	<0.01
Role Physical Functioning, median (IQR)	25 (0; 50)	25 (0; 75)	0.17	75 (50; 75) *	25 (25; 75)	<0.01	75 (50; 75) *	25 (25; 50)	<0.01
Bodily pain, median (IQR)	41 (22; 41)	41 (22; 51)	0.15	62 (41; 62) *	40 (40; 51)	<0.01	51 (41; 62) *	41 (32; 51)	<0.01
General Health, median (IQR)	25 (20; 45)	40 (25; 50)	0.07	50 (35; 57)	45 (20; 50)	0.02	50 (45; 55) *	40 (20; 50)	<0.01
Vitality, median (IQR)	30 (20; 38)	33 (25; 45)	0.22	45 (35; 50) *	35 (25; 45)	<0.01	45 (40; 50) *	33 (25; 40)	<0.01
Social Functioning, median (IQR)	50 (25; 54)	50 (25; 63)	0.43	75 (50; 75) *	50 (38; 75)	<0.01	63 (50; 75) *	50 (37; 63)	<0.01
Role-Emotional, median (IQR)	36 (33; 67)	38 (36; 69)	0.57	100 (67; 100) *	40 (34; 68)	<0.01	100 (66; 100) *	67 (33; 67)	<0.01
Mental Health, median (IQR)	40 (30; 46)	40 (32; 52)	0.22	52 (44; 62) *	40 (32; 52)	<0.01	52 (48; 60) *	40 (32; 48)	<0.01

(A) Inducible myocardial ischemia burden (MIB) at baseline and 2 and 12 months. **(B)** Short Form-36 Health Survey parameters at baseline and 2 and 12 months. *In comparison with baseline values ($p < 0.05$). IQR = interquartile range; OMT = optimal medical therapy; PCI = percutaneous coronary intervention.

(72% and 51.5%, respectively) (2). In both studies, the composite clinical outcome was similar between the PCI and OMT groups at 5- and 1-year follow-up. Whereas DECISION CTO showed no difference in QoL between the 2 groups, the EuroCTO trial suggests favorability of CTO PCI (2). This difference between the 2 randomized studies might be because randomization was done before non-CTO PCI in DECISION-CTO. Hence, the improvements in QoL parameters observed in the OMT arm of this latter trial could be related not to OMT prescribed for untreated CTO but to PCI of non-CTO lesions. The IMPACTOR-CTO trial confirmed the results of the EuroCTO trial by showing the importance of CTO PCI in improving functional status and QoL in the setting of single-vessel disease, with no impact on clinical outcome.

Our study had some limitations. In addition to its single-center design, the comparisons between the PCI and OMT groups were made per protocol and not intention-to-treat. Further randomized trials with larger samples should be performed to better determine the most appropriate strategy to adopt in the presence of isolated RCA CTO.

Anton A. Obedinskiy
Evgeny I. Kretov
Marouane Boukhris
Vladislav P. Kurbatov
Alexander G. Osiev
Zied Ibn Elhadj
Nataliya R. Obedinskaya
Sami Kasbaoui
Igor O. Grazhdankin
Alexey A. Prokhorikhin
Dmitry D. Zubarev
Alexey Biryukov
Evgeny Pokushalov
Alfredo R. Galassi
***Vitaly I. Baystrukov**

*E.N. Meshalkin National Medical Research Center
Rechkunovskaya Strasse 15
Novosibirsk, 630055
Russia
E-mail: vet-007700@mail.ru

https://doi.org/10.1016/j.jcin.2018.04.017

Please note: The authors have reported that they has no relationships relevant to the contents of this paper to disclose.

REFERENCES

1. Galassi AR, Brilakis ES, Boukhris M, et al. Appropriateness of percutaneous revascularization of coronary chronic total occlusions: an overview. Eur Heart J 2016;37:2692–700.

2. Di Mario C, Sorini Dini C, Werner GS. Thousand registries are not worth a randomized trial: also true for chronic total occlusions? J Am Coll Cardiol Intv 2017;10:1535–7.

3. Rossello X, Pujadas S, Serra A, et al. Assessment of inducible myocardial ischemia, quality of life, and functional status after successful percutaneous revascularization in patients with chronic total coronary occlusion. Am J Cardiol 2016;117:720–6.

RESEARCH CORRESPONDENCE

Procedural Success and Clinical Outcome of the Portico Transcatheter Aortic Valve Using the Left Subclavian Artery as Primary Access

Transcatheter aortic valve replacement (TAVR) is becoming the standard of care in high-risk patients with severe aortic stenosis and has proven to be a valid alternative also in patients with intermediate surgical risk (1,2). The Portico valve (St. Jude Medical, St. Paul, Minnesota) is a second-generation self-expanding, resheathable intra-annular TAVR device. Its delivery system has a low profile and a flexible delivery catheter enabling passage through small and tortuous vessels. The valve has been evaluated in 2 smaller, nonrandomized trials using transfemoral access (3,4). However, results on alternative access routes remain scarce.

The preferred access in our center is the left subclavian artery (LSA) because of the shorter working distance and potential avoidance of aortic arch scraping during passage toward the ascending aorta. We describe the outcome of 120 consecutive patients treated between September 2015 and July 2017 with the Portico device using the LSA as primary access. During this period, we performed a total of 257 TAVR, with LSA access in 59% of patients and self-expanding devices (either Portico or CoreValve/Evolut R [Medtronic, Minneapolis, Minnesota]) in 87% of patients.

Transfemoral (TF) access was used in the first proctored cases and whenever the LSA was considered inaccessible because of diameter, tortuosity, or extensive calcification. The left internal mammary artery as a coronary bypass conduit was considered a relative contraindication for LSA.

Electrocardiogram-triggered computed tomography scanning was used for sizing of the aortic annulus and the femoral and subclavian arteries. All procedures were performed under general anesthesia, and access was obtained by surgical cut-down using purse-string sutures for closure. An inflatable sheath (Solopath, Terumo Medical Corporation, Somerset, New Jersey) was used in all patients, allowing nontraumatic passage through both the femoral artery and the potentially tortuous proximal part of the LSA.

There were no significant differences in baseline characteristics between patients in the LSA versus the TF cohort, except for a higher EuroSCORE I and a higher prevalence of the left internal mammary artery as bypass conduit in the TF cohort (**Table 1**).

Ninety-one patients (75.8%) were treated using LSA access. In these patients, device success was obtained in 96.7%. All-cause mortality at 30 days was 4.4% (4 patients); causes were subacute coronary obstruction, sequelae of ischemic stroke, tamponade, and intracerebral hemorrhage (**Table 1**).

Major and minor vascular complications occurred in 2.2% and 14.3%, respectively. The latter consisted mainly of dissection of access (12.1%), which was either treated conservatively (5.5%), surgically (1.1%), or by endovascular stenting (5.5%), all without clinical sequelae. Life-threatening and major bleeding occurred in 2.2% and 3.3%, respectively. Periprocedural infarction occurred in 2.2%. Transient ischemic attack or stroke occurred in 5.5%. Outcome in the LSA cohort did not statistically differ from the TF cohort (**Table 1**). There was no significant learning curve effect comparing the first 45 patients (early cohort) with the last 46 patients (later cohort) with the exception of the rate of permanent pacemaker implantation.

The observed rates of the aforementioned adverse outcomes are comparable to rates described for competing first- and second-generation devices using TF as well as alternative access (5).

In conclusion, implantation of the Portico bioprosthesis with the LSA as primary access proved to be feasible and safe with excellent short-term outcomes. The flexibility of the delivery system and the low insertion profile enable safe passage through the potentially challenging, tortuous anatomy of the LSA. A shorter working distance when using a dedicated (shorter) alternative access delivery system might further improve deliverability. Further data on using the Portico device via alternative access routes, including direct aorta ascending approach, will be provided by the currently enrolling Portico ALT study.