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MGuard™ stent... We beg to differ. Commentary to the article "Long-term follow-up of mesh-covered stent implantation in patients with ST-segment elevation myocardial infarction"

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We read with interest the article published in the February edition of your journal by Dudek et al. [1] about the long term follow up results of the mesh-covered stent (MGuard™ Coronary Stent System, InspireMD Ltd., Israel) in patients with ST elevation myocardial infarction.

We report a higher major adverse cardiac and cerebrovascular event (MACCE) complication rate in our tertiary centre where high volume operators perform around 1,700 percutaneous coronary intervention (PCI) cases/year.

In the period between July and November 2013, 21 MGuard™ stents were deployed in 16 patients. The average age was 65 (range 44–85) years, with the majority (13 patients) being males. The average diameter stent used was 3.6 (range 3–4) cm and average length was 22.6 (range 18–28) mm.

Eleven cases were primary PCI, three were urgent acute coronary syndrome, and two were elective. Radial access was used in the majority of patients (ten cases). Seven cases involved saphenous vein grafts, six involved the right coronary artery, and three involved the left anterior descending artery (LAD). The average Thrombosis In Myocardial Infarction prior to the procedure was 0.7 (range 0–3).

One case had cardiogenic shock and died shortly after the procedure. Fourteen cases had confirmed thrombus on angiography. Thrombus aspiration was used in the majority of cases. One case had a distal embolic protection device deployed. Glicoprotein IIb/IIIa inhibitors were used in four cases. Seven cases received predilation prior to deploying the MGuard™ stents and nine cases had post dilation.

Five (31%) cases had acute PCI complication in the form of no reflow which resolved with intra coronary nitrates/adenosine. Three of them were in the setting of primary PCI. Two cases were in saphenous vein grafts of elective cases.

Excluding the case with cardiogenic shock and death, 13 patients had an average follow up of 79 (3–149) days. Nine (69%) patients experienced MACCE during the follow up period. Six (46%) had repeat angiography. Three (23%) patients had definite stent thrombosis and presented with myocardial infarction (two were elective PCI to saphenous vein grafts within three and 63 days), and one within 96 days (primary PCI LAD). Three patients had instent restenosis (within 63, 77 and 96 days). Three patients had target lesion revascularisation: one with drug eluting stent, one with drug eluting balloon and one with coronary artery bypass grafting. One patient had cerebrovascular accident during follow up.

We appreciate that the numbers reported here are small and the nature of this retrospective review carries all the limitations related to this type of analysis; however, our experience suggests that the effectiveness of the MGuard™ stent in the setting of a thrombus laden lesion is not entirely as expected, and that there is more to the pathophysiology than just mechanically trapping the thrombus.

Conflict of interest: *none declared*

References

1. Dudek D, Dziewierz A, Kleczyński P et al. Long-term follow-up of mesh-covered stent implantation in patients with ST-segment elevation myocardial infarction. Kardiol Pol, 2014; 72: 140–145.

Ahmed Farag, Grahame Goode, Jonas Eichhöfer
Blackpool Victoria Hospital, United Kingdom

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Authors' response

We appreciate the concerns raised by Farag et al. [1] about our recent paper on the long-term performance of MGuard™ stent in patients with ST-segment elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI) [2]. In general, it is hard to compare results of the MAGICAL study [2, 3] and the registry from Farag et al. [1], as they included different subsets of patients with different risk profiles. In the MAGICAL study [2, 3], consecutive, non-shock patients with STEMI < 12 h were enrolled. The study population was preselected based on inclusion and exclusion criteria, and thus may be a lower risk group. The use of atherectomy and/or thrombectomy catheters and/or embolic protection

devices was not permitted before stent implantation in the MAGICAL study; thus patients with a very large thrombus burden and potentially the highest risk of distal embolisation were not included. After enrollment of 30 patients, the protocol of the study was changed and the use of simple aspiration catheters before stenting was possible at the discretion of the operator. Also, patients with saphenous vein grafts (SVG) stenosis were not enrolled in the MAGICAL study. The long-term event rates were low, but were comparable to those reported for patients treated with a stent during primary PCI for STEMI [4, 5]. Importantly, all clinical events were adjudicated by an independent clinical events committee.

Findings from the MAGICAL study are supported by the results of the MASTER study [6]. This randomised, multicentre study reported that among patients with STEMI < 12 h, the MGuard™ stent resulted in superior rates of epicardial coronary flow and complete ST-segment resolution compared to conventional metallic stents. Similarly to the MAGICAL study, patients with cardiogenic shock and SVG stenosis were not included in this study. In the MASTER study, the risk of intraprocedural thrombotic events, defined as the development of new or increasing thrombus, abrupt vessel closure, no reflow, slow reflow, distal embolisation, side branch closure, or intraprocedural stent thrombosis at any time during the procedure for MGuard™ stent was 21.7%, but similar to that reported for a control group (22.3%; p = 0.83). Most importantly, a trend towards lower 30-day cardiac and all-cause mortality was noted for patients treated with the MGuard™ stent. Recently presented 12-month data [7] has confirmed similar trends persisting throughout a 12-month follow-up. Twelve-month rates of ischaemic target-lesion revascularisation in the MGuard™ group were higher than in the control stent group, but were comparable to those expected from bare-metal stents. No difference in the rate of definite or probable stent thrombosis was observed at 30 days (MGuard™ vs. control: 1.4% vs. 0.9%; p = 1.0) and at 12 months (2.3% vs. 0.9%; p = 0.26). These rates are far lower than those reported by Farag et al. [1].

In the small registry of 16 patients described by Farag et al. [1], MGuard™ stents were probably selected for the highest risk patients, when operators expected a high risk of distal embolisation and angiographic complications. Also, unlike the MAGICAL and MASTER studies, patients with SVG stenosis were included. It is well known that PCI of SVG stenosis carries an increased risk of angiographic complications, including the occurrence of no-reflow phenomenon [8]. Thus the events rate reported by Farag et al. [1] is very high, but is somewhat to be expected from this high risk group of patients, as the outcomes of patients with acute coronary syndromes are strongly related to baseline risk profile (i.e. presence of cardiogenic shock/haemodynamic compromise, comorbidities) and angiographic characteristics (i.e. thrombus load, extent of coronary artery disease, SVG involvement) [9, 10]. We could expect similar event rates in this small and highly selected cohort of patients with the use of conventional bare-metal stents or drug-eluting stents.

Case reports, cases series, and registries all add to our knowledge; however, randomised clinical trials with head-to-head comparison are still the most appropriate tool for the assessment of new technologies. Data from ongoing randomised clinical trials, like the MASTER II trial, powered for clinical endpoints, is needed to weigh the competing risks and benefits of the MGuard™ as an alternative to metallic stents in patients with STEMI.

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References

1. Farag A, Goode G, Eichhöfer J. MGuard™ stent... We beg to differ. Commentary to the article "Long-term follow-up of mesh-covered stent implantation in patients with ST-segment elevation myocardial infarction". Kardiol Pol, 2014; 72: 476.
2. Dudek D, Dziewierz A, Kleczyński P et al. Long-term follow-up of mesh-covered stent implantation in patients with ST-segment elevation myocardial infarction. Kardiol Pol, 2014; 72: 140–145.
3. Dudek D, Dziewierz A, Rzeszutko Ł et al. Mesh covered stent in ST-segment elevation myocardial infarction. EuroIntervention, 2010; 6: 582–589.
4. Dziewierz A, Siudak Z, Rakowski T et al. Drug-eluting versus bare-metal stents in ST- segment elevation myocardial infarction: a mortality analysis from the EUROTRANSFER Registry. Clin Res Cardiol, 2011; 100: 139–145.
5. Kübler P, Jankowska EA, Ferenc M et al. Comparison of drug-eluting stents to bare-metal stents in ST-elevation myocardial infarction in long-term follow-up. Kardiol Pol, 2013; 71: 25–31.
6. Stone GW, Abizaid A, Silber S et al. Prospective, Randomized, Multicenter Evaluation of a Polyethylene Terephthalate Micronet Mesh-Covered Stent (MGuard) in ST-segment elevation myocardial infarction: the MASTER Trial. J Am Coll Cardiol, 2012; 60: 1975–1984.
7. Dudek D, Abizaid A, Silber S et al. TCT-41 One-year results from the MASTER trial, a Prospective, Randomized, Multicenter Evaluation of an Embolic Protection Stent (MGuard) in Patients with STEMI Undergoing Primary PCI. J Am Coll Cardiol, 2013; 62 (suppl. 1): B14.
8. Grygier M, Araszkiewicz A, Lesiak M, Grajek S. Intracoronary adenosine administered during aortocoronary vein graft interventions may reduce the incidence of no-reflow phenomenon. A pilot randomised trial. Kardiol Pol, 2014; 72: 126–133.
9. Filipiak KJ, Kołtowski L, Grabowski M et al. Comparison of the seven-year predictive value of six risk scores in acute coronary syndrome patients: GRACE, TIMI STEMI, TIMI NSTEMI, SIMPLE, ZWOLLE and BANACH. Kardiol Pol, 2014; 72: 155–165.
10. Kul S, Uyarel H, Turfan M et al. A new prognostic evaluation of patients with acute ST-elevation myocardial infarction undergoing primary angioplasty: combined Zwolle and Syntax score. Kardiol Pol, 2014; 72: 146–154.

Dariusz Dudek[1], Artur Dziewierz[1], Paweł Kleczyński[1], Dawid Giszterowicz[2], Tomasz Rakowski[1], Danuta Sorysz[1], Łukasz Rzeszutko[1], Jacek Legutko[1, 3], Stanisław Bartuś[1], Jacek Dragan[2], Artur Klecha[3], Zbigniew Siudak[1], Krzysztof Żmudka[1]
[1]Department of Interventional Cardiology, Jagiellonian University Medical College, Krakow, Poland
[2]Department of Interventional Cardiology, Nowy Sacz, Poland
[3]Department of Interventional Cardiology, Nowy Targ, Poland