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”
published in “Kardiologia Polska” 2014; 72, 2: 140–145

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. 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. 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).

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%) repeated 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 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%) repeated 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 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.

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

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

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 MGuardTM 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 intra-procedural thrombotic events, defined as the development of new or increasing thrombus, abrupt vessel closure, no reflow, slow reflow, distal embolisation, side branch closure, or intra-procedural stent thrombosis at any time during the procedure for MGuardTM 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 MGuardTM 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 MGuardTM 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 (MGuardTM 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], MGuardTM 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 MGuardTM as an alternative to metallic stents in patients with STEMI.

Conflict of interest: Dariusz Dudek, Jacek Legutko, Stanisław Bartuś — research grant from InspireMD.

References

Dariusz Dudek1, Artur Dziewierz2, Paweł Kleczyński1, Dawid Giszterowicz2, Tomasz Rakowski1, Danuta Sorysz3, Łukasz Rzeszutko1, Jacek Legutko1, Stanisław Bartuś1, Jacek Dragan1, Artur Klecha1, Zbigniew Siudak1, Krzysztof Żmudka1, Tomasz Rakowski1
1Department of Interventional Cardiology, Jagiellonian University Medical College, Krakow, Poland
2Department of Interventional Cardiology, Nowy Sacz, Poland
3Department of Interventional Cardiology, Nowy Targ, Poland

www.kardiologiapolska.pl