



## BIOABSORBABLE CORONARY ARTERY STENTS: PATIENT FOLLOW-UP AFTER TWO YEARS OF TREATMENT

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### ABSTRACT

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**Background:** Bioabsorbable vascular scaffolds (BVS) are a relatively new technology in interventional cardiology and it has many upsides when comparing it to metallic stents. After performing its main function – revascularization, it also repairs the wall of the artery and then absorbs and disappears completely. Basically it overcomes all of the downsides which metallic stents have. This study was done to evaluate results and complications of two-year treatment and also the need of revascularization for patients that have been treated with BVS. **Methods:** This follow up is done performing a retrospective survey. There were 46 consecutive patients who have suffered from ischemic heart disease in our survey (this includes stable and unstable chest angina and myocardial infarction). First of all, risk factors of our patients were collected (diabetes, hypertension, smoking). Coronary artery angiography and stenting with bioabsorbable stents were performed on all of these patients. Patients were observed while still in hospital, after six months, after one year and after two years after discharge from the hospital in case of complications - major adverse cardiac events (MACE - death, thrombosis, myocardial infarction, stroke). Also, we evaluated length of hospitalization and the need for repeated revascularization. **Results:** Age mean of patients which participated in the study was 58 years of which 26 were males and 20 were females. More than half (73.9%) of participants had stable angina pectoris with one vessel disease (47.8%), two vessel disease (23.9%), three vessel disease (28.3%). To determine the complexity of coronary artery disease we used the Syntax score and 47.8% of study participants had a score of more than 10 points. Risk factors - such as arterial hypertension (95.6%), diabetes (4.3%), smoking (15.2%), and dyslipidemia (76%) were also evaluated. The study analyzed the most suitable technique aspects: 47.8% of patients had a long 28 x 3.5 mm stent. During the one year period there were no complications whatsoever. During the second year - there were 3 myocardial infarctions and 1 revascularization. The mean of hospitalization time was  $6.25 \pm 2.58$  days.

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## Introduction

Since cardiovascular diseases are one of the leading causes of death all over the world, ischemic heart disease is certainly a big problem. For example, U.S. Department of Health and Human Services in 2014 reported 614,348 deaths from heart diseases, which surpasses other leading causes, for example: cancer with 591,699 deaths per year, and chronic lower respiratory diseases with 147,101 deaths per year.<sup>[1]</sup> Ischemic heart disease is a narrowing of coronary arteries, which means that with time, less and less blood and oxygen reach the myocardium. This can cause a major complication – myocardial infarction, which results in worsening of the quality of life and in some cases can even result in death. To prevent such thing happening, stents were invented to keep coronary arteries open and to keep a continuous flow of blood and oxygen to the myocardium. Metallic stents have been used most of the time, then drug eluting stents were made to stop cell proliferation, thrombosis and restenosis. Then, a new type of stent was presented – a bioabsorbable stent or in other words – bioabsorbable vascular scaffold. This type of stent was made to avoid the downsides of a metallic stent. Metal stents are associated with acute and late thrombosis, also there is a need for long-term dual antiplatelet therapy. Also, metallic stents can interfere with diagnostic tests such as CT and MRI. They can disturb vascular remodeling and coronary vasomotion. Metallic stents also make coronary artery bypass graft procedures difficult, should the patient need one in the future.<sup>[2]</sup> Objectives of this study were to evaluate the rate of complications for patients that have been treated with bioabsorbable stents and to evaluate the need for a repeated revascularization for patients with bioabsorbable stents.

## Methods

This follow up is done performing a retrospective survey. All of the patients had suffered from ischemic heart disease (this includes stable and unstable chest angina and myocardial infarction) in our survey. Various risk factors of our patients that add to higher risk of ischemic heart disease were collected, such as diabetes, arterial hypertension, smoking. They all were hospitalized, coronary

artery angiographies and stenting with bioabsorbable stents were performed. The patients were observed while hospitalized, after six months, after one year and after two years after discharge from the hospital in case of complications - major adverse cardiac events - MACE. MACE includes death, thrombosis, myocardial infarction, and stroke. Also, we have evaluated the average length of hospitalization and the need for repeated revascularization for these patients.

## Results

We had 46 patients, 26 were male and 20 were female, all of them Caucasian. First of all, we collected risk factors and calculated the age mean of the patients. As statistics have shown, ischemic heart disease is more common in males and people of older age.<sup>[3]</sup> Age mean of patients, which participated in this study, was 58 years. Risk factors – 44 patients (95.6%) had arterial hypertension, 2 patients (4.3%) had diabetes, 7 patients (15.2%) were smokers, and 35 patients (76%) had dyslipidemia. More than half - 34 patients (73.9%) had stable angina pectoris. Of which: angina pectoris with one vessel disease – 22 patients (47.8%), with two vessel disease – 11 patients (23.9%), and with three vessel disease – 13 patients (28.3%). To determine the complexity of coronary artery disease, the Syntax score was used and 47.8% of study participants (22 patients) had a score of more than 10 points. Others – 52.2% of study participants, had a score of more than 20 points. In this study it was also analyzed, what would be the most suitable technique aspect: 47.8% of patients had a long 28 x 3.5 mm stent. The mean of hospitalization time was  $6.25 \pm 2.58$  days. During six-month period and one year period there were no complications whatsoever. During the second year - there were 3 myocardial infarctions and 1 revascularization procedure, because of restenosis. To conclude, out of the 46 patients, 4 (1.8%) had a repeated hospitalization and a PCI procedure. There were no other MACE events occurring during the two-year period.

## Discussion

The results of our study suggest that bioabsorbable stents might be more effective than traditional stents and produce less side effects on a two-year period. Of course, to truly determine its effectivity a bigger study and a longer follow up for MACE events is needed. A study published in 2014 has done just that. In that study there were 89 trials including 85,490 patients in that study. Results from that study were that after a one year follow up, usage of bioabsorbable stents was associated with lower rates of cardiac death/myocardial infarction, myocardial infarction when compared to bare metal stents and lower rates of target vessel

revascularization, when compared to zotarolimus-eluting stents. Bioabsorbable stents had similar rates of cardiac death/MI and myocardial infarction and target vessel revascularization, when compared to second generation drug eluting stents, but higher risk of stent thrombosis than cobalt-chromium everolimus eluting stents.<sup>[4]</sup> Bioabsorbable vascular scaffold technology is a big step forward in interventional cardiology. It certainly is not flawless, but looking at current results of various studies it certainly is surpassing other stent technologies with lower rates of complications, which means better life quality for patients.

### Conclusion

Patients of this study have had none of the MACE complications neither during six month nor one year period. Also there was no need for repeated revascularization for patients who had been treated using bioabsorbable stents during the first year. During the second year, 4 patients had complications (3 had suffered a myocardial infarction and 1 needed a revascularization, because of restenosis). This study suggests that the bioabsorbable vascular scaffold technology might be more effective than the traditional metallic stents or drug eluting stents, but still, a longer patient follow up is needed to get more precise results of late outcomes.

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