

## FIRST BIORESORBABLE VASCULAR SCAFFOLD IMPLANTATION IN PATIENTS WITH ACUTE CORONARY SYNDROME IN THE REPUBLIC OF MACEDONIA

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### Abstract

**Background:** The term acute coronary syndrome (ACS) refers to any group of clinical symptoms compatible with acute myocardial ischemia. These high-risk manifestations of coronary atherosclerosis are important causes of the use of emergency medical care and hospitalization. We evaluated the feasibility and the acute performance of the everolimus-eluting bioresorbable vascular scaffolds (BVS) for the treatment of patients presenting with ACS.

**Methods and results:** The present investigation was a prospective, single-centre study. Clinical outcomes were reported at the 30-day, 6-month, 1 year and 2 years follow-up. The procedural success was 100.0%. After the BVS implantation a TIMI flow 3 was achieved in all 15 patients and the post-procedure percentage diameter stenosis was  $16.4 \pm 8.6\%$ . No patients had angiographically visible residual thrombus at the end of the procedure. Optical coherence tomography (OCT) analysis was performed in 8 patients (53.3%) and showed that the post-procedure mean lumen area was  $7.86 \pm 1.81 \text{ mm}^2$ , minimum lumen area  $5.51 \pm 1.58 \text{ mm}^2$ . At the 30-day, 6-month, 1 year (15 patients) and 2 years follow-up (5 patients) target-lesion failure rate was 0%. Non-target vessel revascularization and target vessel myocardial infarction were not reported. No cases of cardiac death or scaffold thrombosis were observed.

**Conclusion:** BVS implantation in patients presenting with ACS appeared feasible, with high rate of final TIMI-flow 3 and good scaffold apposition.

**Key words:** Bioresorbable vascular scaffold, Acute coronary syndrome, Optical coherence tomography

### Introduction

Coronary artery disease (CAD) is defined as myocardial ischemia as a result of irregularity between oxygen supply and myocardium consumption (less supply and/or more need). Obstructive coronary arteries (90–95%) are the most common reason for CAD and rarely some congenital anomalies, inflammation process, embolisation, systemic diseases (arteritis, systemic lupus erythematosus) [1]. Its epidemic character in the last few decades is characterised with high morbidity and mortality especially with high prevalence in developing countries, with expectation to widespread in developed countries in

2020. According to the World Health Organization it is the leading cause for mortality in the world among the people aged 60 and older. Patients with CAD have stenotic or occluded coronary arteries, resulting with chest pain, shortage of breath in rest or during exercise, electrocardiographic changes, heart attack or death [2].

CAD is characterized with variety of risk factors which can be defined as controlled and uncontrolled. The most common correlation is incidence of CAD with older age [3, 4]. But things are changing, moving towards younger population aged 45 and less exposed to higher risk for CAD especially in developing countries [5, 6].

Acute coronary syndrome (ACS) is one of the most difficult clinical manifestation of CAD, continuing to be a major health problem, despite of the impressive improvements in its diagnosis and therapy in last few decades. Because of the fact that the majority of population capable for working suffer from ACS, it is a serious social and economy problem [7]. The widespread use of aspirin and percutaneous coronary interventions (PCI) result in decreasing of the morbidity and mortality in ACS patients [8].

Percutaneous coronary intervention (PCI) is an optimal strategy to re-open the occluded or significantly narrowed coronary artery (culprit vessel) and improve the outcomes of patients with ACS [9]. Access-site selection is an important procedural issue in PCI. The transradial approach (TRA) has been associated with lower rate of access-site bleeding and vascular complications in comparison with the transfemoral approach. This has been evident with the aggressive use of antithrombotic and antiplatelet therapy in patients with ACS [10]. Vascular access-site complications have been shown to be associated with worse outcomes [11].

Bioresorbable vascular scaffold (BVS) is an interventional percutaneous device for treatment of the coronary artery disease. It is covered with bioresorptive polymer and cytostatic drug which is eluted in the coronary artery wall in the period of 1–2 months, preventing the uncontrolled neointimal hyperplasia. BVS introduction is the 4-th revolution in percutaneous coronary interventions after introducing balloon angioplasty in 1977, bare metal stents (BMS) in 1988 and drug eluting stents (DES) in 2001 year (Figure 1).

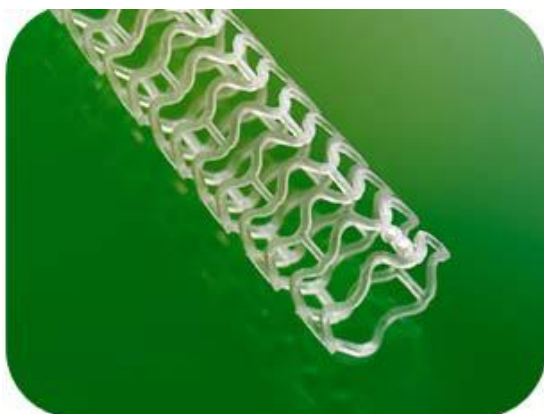


Figure 1 – Absorb bioresorbable vascular scaffold

## Methods

**Study population.** Patients with ACS scheduled for PCI and stenting regardless to indication were eligible to be included in this prospective study. The study was conducted in accordance with our local internal review board regulations and written informed consent was obtained from all the patients prior the procedures. The intention is 100 consecutive patients to be treated with ACS.

**Study protocol.** Patients were divided in two groups:

**Group 1** – consisting of 50 patients with ACS, with PCI through transradial approach and BVS implantation (Absorb Bioresorbable Vascular Scaffold System, Abbott Vascular);

**Group 2** – consisting of 50 patients with ACS, with PCI through transradial approach and second generation DES implantation.

**Vascular access.** The radial artery was accessed after local infiltration with 1–1.5 ml 2% lidocaine, using puncture technique with a 20 G plastic intravenous cannula and 0.025" mini guidewire (45 cm) and followed by 5 Fr or 6 Fr hydrophilic introducer sheath (Terumo corporation) placement. Spasmolytic cocktail (5 mg verapamil) was given intraarterially through the radial sheath.

**Interventional procedures.** Standard guide catheters were used to perform PCI (standard shapes like Judkins, Extra Back Up, Amplatz) mostly 6 Fr. Standard guidewires for PCI, mostly Balance Middle Weight (Abbott Vascular) were used according to case specificity. Manual thrombus aspiration was performed in the cases with high thrombus burden. Stent choice was performed with sealed envelope randomization.

**Anticoagulation and antiplatelet treatments.** Before the PCI, patients were treated with intravenous bolus of unfractionated heparin (100 IU/kg), aspirin (300 mg followed by 100 mg/day) and clopidogrel loading dose (600 mg followed by 75 mg/day for at least 1 year). After completion of PCI, weight-adjusted dosage protocol of heparin infusion was continued for 24 hours.

**Hemostasis management.** The radial artery sheath was removed immediately after the procedure and hemostasis was achieved by a simple bandage compression or the TR band

(Terumo Corporation). Simple bandage compression was applied with 4–6 small elastic bands, at the puncture site. The TR band was applied by inflating 13–15 ml of air and after each hour the TR band was gradually deflated and totally removed after 4 hours. The patient has no mobility restriction after the procedure.

**Study endpoints.** The primary endpoint of the study was target lesion failure (TLF) at 30 days, 1 and 2 years of follow up, defined as the composite of cardiovascular death, target vessel myocardial infarction (MI), or target vessel revascularization (TLR). The secondary endpoints are MI, TLR and definite stent thrombosis (ST) in both groups, comparing the survival rate between the patients in BVS and DES group.

**Definitions.** The criteria for TLF, MI and ST are consistent with the Academic Research Consortium (ARC). *Target lesion failure* is defined as the composite of cardiovascular death, target vessel myocardial infarction (MI), or target vessel revascularization (TLR). *Cardiovascular death* is defined as acute myocardial infarction, sudden cardiac death, death due to heart failure, death due to stroke, death due to cardiovascular procedures, death due to cardiovascular hemorrhage (intrapericardial bleed with cardiac tamponade) or death due to other cardiovascular causes after the index procedure. *Procedural success* is determined by angiographic success, defined as the achievement of a minimum stenosis diameter reduction to < 20% in the presence of grade 3 TIMI flow.

Control angiogram will be performed after 2 or 3 years from the index procedure to document the process of biodegradation of BVS with intravascular ultrasound (IVUS) or optical coherence tomography (OCT) and measurements of minimal lumen diameter (MLD) of the vessel, minimal lumen area (MLA), minimal stent diameter (MSD) and minimal stent area (MSA).

**Statistical analysis.** The data were expressed as mean  $\pm$  standard deviation for normally distributed numeric variables, or reported as median (min/max) when the data did not fit a normal distribution. Percentages were used to express categorical variables.

**Acute coronary syndrome.** ACS is caused by acute thrombosis induced by ruptured atherosclerotic plaque with or without vasocon-

striction, resulting in sudden and critical reduction in blood flow [12].

Because of the fact that this situation can be life threatening condition, the criteria for risk stratification are performed so that the clinician can make decisions for patient treatment and to individualize them to every different patient. Main symptom is chest pain, but classification is based on electrocardiographic changes. There are two category of patients:

1) Patients with acute chest pain and ST segment elevation > 20 min (STE-ACS)

2) Patients with acute chest pain and non ST segment elevation (NSTEMI-ACS)

The incidence of NSTEMI-ACS is higher and it is about 3 cases per 1000 population [13, 14]. In hospital, mortality is higher in STE-ACS (7%) comparing to NSTEMI-ACS (3–5%), but after 6 months the mortality rate is almost the same (12% comparing to 13%) [15, 16]. Patients with NSTEMI-ACS are older, having more comorbidities, especially diabetes and renal failure. Epidemiology perception showed that treatment of NSTEMI-ACS should not be directed only to acute phase, but with the same intensity on long term period [17–23].

There are several diagnostic criteria for ACS:

- Chest pain in rest lasting more than 20 minutes, "de novo" chest pain, or recent destabilization of exertional angina [24–28].

- electrocardiographic changes with ST segment depression > 1 mm (NSTEMI), transitory (less than 30 minutes) ST segment elevation > 1mm in at least two contiguous leads or ST segment elevation > 1mm in two standard leads or > 2mm in two contiguous precordial leads (STEMI) [29–31].

- positive enzyme status – elevated cardiac markers in a period of 24 hours, defined as elevated troponin T, troponin I, creatinine kinase (CK) and its cardiac isoenzyme (CK-MB) above the referent values [32–35].

- coronary angiography, with coronary artery stenosis more than 70% or occlusion ("culprit lesion").

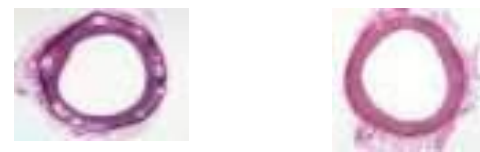
The recanalisation of the culprit coronary artery is the basis of the ACS therapy. The first choice is mechanical recanalisation – percutaneous coronary intervention (PCI) through transradial approach (TRA) because of the less ble-

eding events compared to the transfemoral approach (TFA) and the significant lower mortality and major adverse cardiac events [36–39].

**Bioresorbable vascular scaffold.** Bioresorbable vascular scaffold (BVS) – ABSORB (Abbott Vascular) is an interventional percutaneous device for treatment of coronary artery disease. It is covered with bioresorptive polymer and cytostatic drug everolimus eluting in the coronary artery wall in the period of 1–2 months, preventing the uncontrolled neointimal hyperplasia. It is the 4th revolution in the percutaneous coronary interventions after introducing the balloon angioplasty in 1977, the bare metal stents in 1988 and the drug eluting stents in 2001 year.

After BVS implantation the process of its resorption is starting through natural metabolic

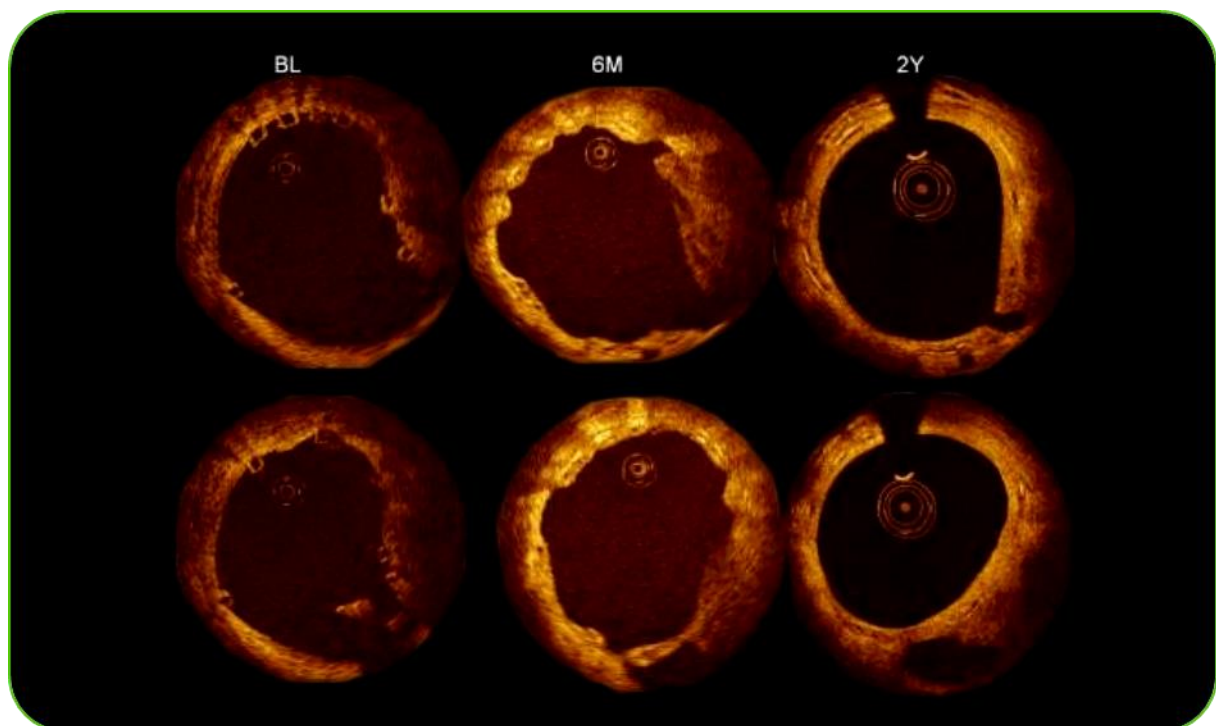
process in the period of 2–3 years and after that period the BVS is fully resorbed from the coronary artery (Figure 2). The bioresorption of the scaffold stops the mechanical pressure on the coronary artery, allowing the return of the vasomotoric function and the lumen of the vessel itself. It is very important to emphasize the fact that there is no more structure which is mechanically caging the coronary vessel and normal vasomotoric response to physiologically stimulus is allowed (Figure 3).



After BVS implantation

After BVS resorption

*Figure 2 – Bioresorbable vascular scaffold after the implantation and resorption*



*Figure 3 – Complete BVS resorption after 2 years from the implantation (OCT images)*

ABSORB Cohort A, [40, 41] Cohort B, [42] и ABSORB EXTEND [43] clinical trials demonstrated excellent safety and efficacy.

– The great advantage of this vascular reparative therapy appears during the return of the vasomotoric function of the coronary vessel itself and the resorptive phase are visible after the first year of its implantation. With these advantages BVS enables life acquisitions for the patients which were not possible up to now in interventional

cardiology. The revascularisation is equal to best in class second generation DES treatment in the first three months, but with BVS drug releasing and vessel caging are temporary and are present during the healing of the coronary vessel.

– Expansion of the strategies for up to date treatment of the patients include widespread use of invasive imaging techniques like IVUS, OCT and non invasive techniques like computed tomography (CT) [43].



– Extremely compatibility to the patients prone to allergic reactions with nickel and molybdenum which are releasing from the metallic stents and could be trigger mechanism for "in stent" restenosis [44, 45]. It is also very important to emphasize that the first implantations of BVS were limited to patients with stable angina, one vessel coronary artery disease, lesions type

A, lesions without calcification. Today, their use is safe and spread even in very complicated cases with left main stenosis, tortuous coronary arteries, diabetic patients (Figure 4), patients with ACS including acute myocardial infarction with ST segment elevation and present thrombotic burden (Figure 5).

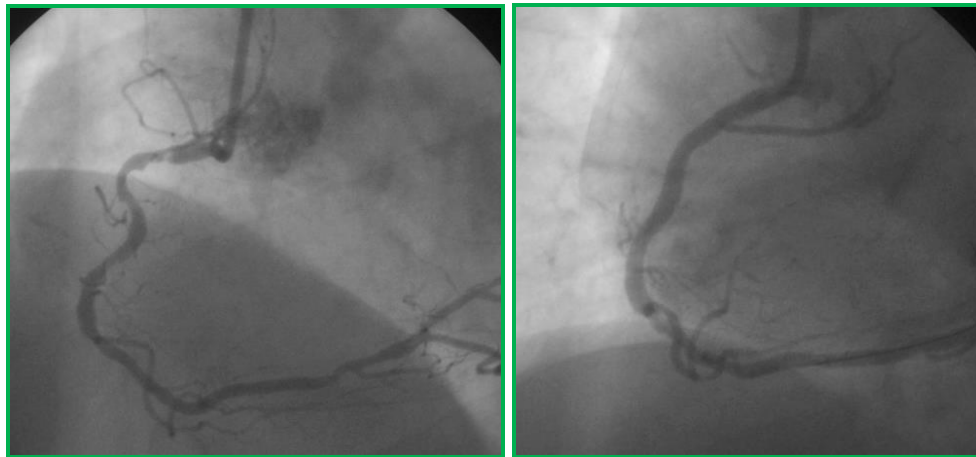


Figure 4 – BVS implantation in diabetic patients

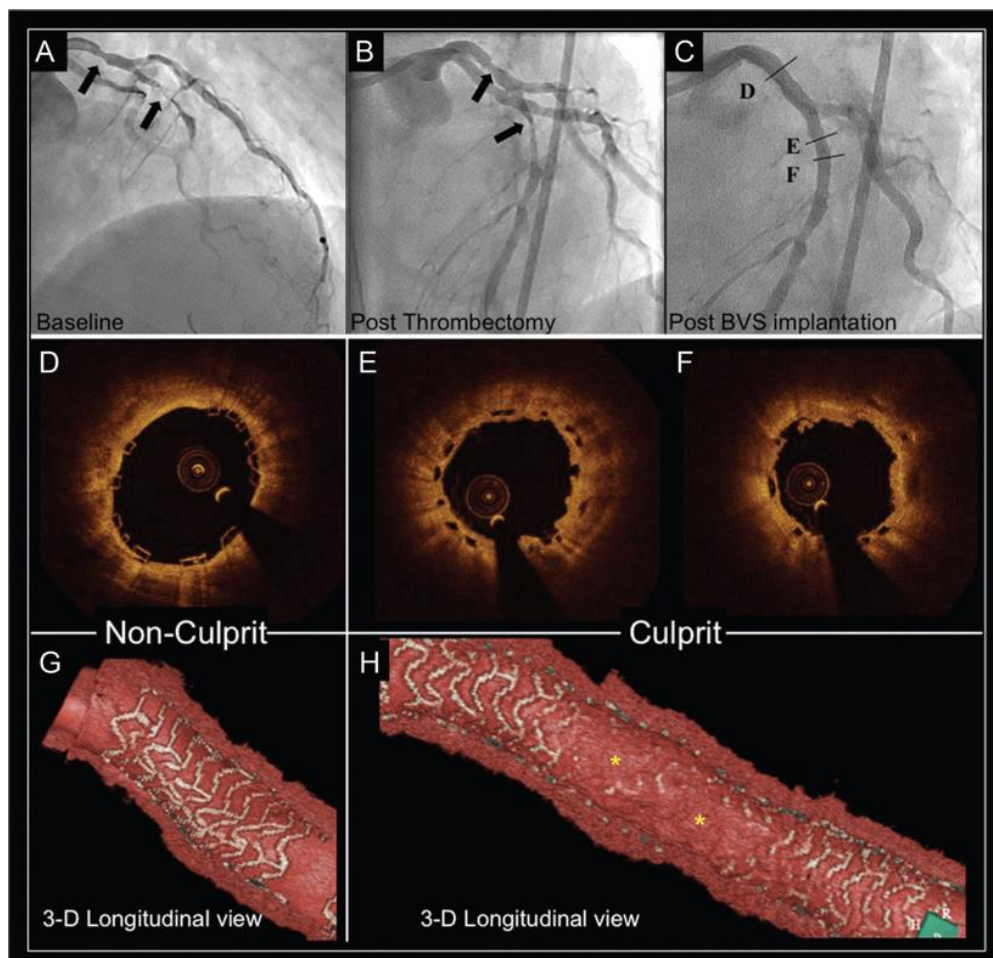


Figure 5 – BVS implantation in patients with acute myocardial infarction with OCT imaging

## Results

Until January 2015, 32 patients were enrolled in the study from both groups.

**Group 1** – In this group 15 patients with ACS were enrolled with BVS implantation. 11 patients were male (73.3%), 4 patients were female (26.7%). In 8 patients (53.3%) BVS was implanted on the left anterior descending artery (LAD), in 4 patients (26.7%) on right the coronary artery (RCA) and in 3 patients (20.0%) on the circumflex artery (Cx). The pre-procedural TIMI flow was 0 in 7 patients (46.7%), and TIMI 2-3 flow in 8 patients (53.3%). After the BVS implantation TIMI 3 flow was achieved in all 15 patients. No patients had angiographically visible residual thrombus at the end of the procedure. Post-procedural diameter stenosis was  $16.4 \pm 8.6\%$ . OCT analysis was performed in 8 patients (53.3%) and it showed that the post-procedure mean lumen area was  $7.86 \pm 1.81 \text{ mm}^2$ , minimum lumen area  $5.51 \pm 1.58 \text{ mm}^2$ . In all 15 patients BVS were successfully implanted without any complications, device and procedural success were 100%. At the 30-day, 6-month, 1 year and 2 years follow-up (5 patients) target-lesion failure rate was 0%.

**Group 2** – In this control group 17 patients with ACS were enrolled with second generation DES implantation. 14 patients (82.4%) were male, 3 patients (17.6%) were female. In 11 patients (64.7%) DES was implanted on the left anterior descending artery (LAD), in 4 patients (23.5%) on the right coronary artery (RCA) and in 2 patients (11.8%) on the circumflex artery (Cx). The pre-procedural TIMI flow was 0 in 8 patients (47.1%), and TIMI 2-3 flow in 9 patients (52.9%). After the DES implantation TIMI 3 flow was achieved in all 17 patients. No patients had angiographically visible residual thrombus at the end of the procedure. Post-procedural diameter stenosis was  $15.6 \pm 8.4\%$ .

In all 17 patients DES were successfully implanted without any complications, device and procedural success were 100%. At the 30-day, 6-month, 1 year and 2 years follow-up (6 patients) target-lesion failure rate was 0%.

Non-target vessel revascularization, target vessel myocardial infarction (MI) or cerebrovascular insult were not reported in both groups. No episodes of cardiac death, scaffold or DES

thrombosis were observed. All patients received dual antiplatelet therapy with Aspirin and Clopidogrel for 12 months.

## Discussion

The present study is the first single centre report for BVS implantation in the Republic of Macedonia, investigating the safety and clinical outcomes of BVS in patients with acute coronary syndrome.

Results of ABSORB Cohort A study report 5-year follow up at 29 patients with BVS implantation with major cardiovascular event (myocardial infarction without significant Q wave presence) at only one patient (3.4%). No episodes of cardiac death or scaffold thrombosis were observed [40, 41].

ABSORB Cohort B study report 2-year follow up at 100 patients with BVS implantation with major cardiovascular events in 9 patients (9.0%) (3 patients with non Q wave myocardial infarction and 6 patients with target lesion revascularisation). No episodes of cardiac death or scaffold thrombosis were observed [42].

ABSORB EXTEND study report 6-month follow up at 269 patients with BVS implantation with major cardiovascular events in 7 patients (3.0%) (4 patients with non Q wave myocardial infarction and 3 patients with Q wave myocardial infarction). The incidence of target lesion revascularisation was very low (0.4%), scaffold thrombosis in 1 patient (0.4%) cardiac death in 1 patient (0.4%) [43].

All three studies revealed excellent safety and efficacy.

ABSORB II study which is the first randomized trial of the Absorb BVS (Abbott Vascular), enrolled 501 patients, 335 patients (with 364 lesions) received bioresorbable scaffold and 166 patients (182 lesions) received the metallic stent. The one year follow up indicates that the scaffold has similar clinical outcomes to an everolimus-eluting metallic stent (Xience, Abbott Vascular) at one year. There were no significant differences between groups in either the rate of the device-oriented clinical endpoint between groups (5% for the bioresorbable scaffold vs. 3% for the metallic stent;  $p = 0.35$ ), or the rate of the patient-oriented clinical endpoint (7% vs. 9% respectively;  $p = 0.47$ ). Also one year angina rates were significantly lower with

bioresorbable scaffold compared with the metallic stent: 22% vs. 30%, respectively ( $p = 0.04$ ). Neither the overall rate of definite stent thrombosis (0.6% for the bioresorbable scaffold vs. 0% for the metallic stent;  $p = 1$ ) nor the overall rate of definite/probable stent thrombosis (0.9% vs. 0%, respectively;  $p = 0.55$ ) was significantly different between groups [46–48].

Recent studies have investigated the clinical outcome of BVS in the setting of the novo coronary artery lesions, mostly limited to type A lesions in patients presenting with stable angina. Theoretical advantages of BVS over metal stents include the fact that the bioresorption of the scaffold allows the recovery of physiological processes of endothelial vasomotor function, vascular remodelling and at a distance of time after implantation, lumen enlargement [49].

It is important to emphasise that all interventions were performed through transradial approach, which lead to lower rate of bleeding events and consequently lower mortality rate [50].

The results in our study correlate with already published results from several relevant multicenter trials with bioresorbable scaffolds, especially with ABSORB II study. Our data apparently suggest that the outcome after the implantation of BVS is comparable to that of the second generation drug-eluting stents. This study includes consecutive patients in a non-randomised design and further data are needed to provide a more definitive demonstration of safety and efficacy of this strategy.

### Conclusion

BVS implantation in patients presenting with ACS appeared feasible is safe and effective with high rate of final TIMI-flow III and good scaffold apposition and very low rate of major adverse cardiovascular events. Larger studies are currently needed to confirm these preliminary data.

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## Резиме

### **ПРВА ИМПЛАНТАЦИЈА НА БИОРЕСОРПТИВЕН ВАСКУЛАРЕН СКАФОЛД КАЈ ПАЦИЕНТИ СО АКУТЕН КОРОНАРЕН СИНДРОМ ВО РЕПУБЛИКА МАКЕДОНИЈА**

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*Основа:* Терминот акутен коронарен синдром (АКС) се однесува на група клинички симптоми изразени во вид на акутна миокардна исхемија. Овие високоризични манифестации на коронарната атеросклероза се важни причини за примена на итна медицинска заштита и болничко лекување. Евалуирани се успешноста и исходот од првата имплантација на биоресорптивни васкуларни скафолди (БВС) во третманот на пациенти со АКС во Република Македонија.

*Методи и резултати:* Трудот претставува проспективна студија од еден центар. Клиничкиот исход е прикажан по следење во период од 30 дена, шест месеци, една и две години. Процедуралниот успех изнесува 100,0%. По БВС-имплантацијата, ТИМИ 3 протокот беше постигнат кај сите 15 пациенти. Постпроцедуралната дијаметар стеноза изнесуваше  $16,4 \pm 8,6\%$ . Кај ниеден пациент не беше регистриран видлив резидуален тромб на крајот на процедурата. Анализа со оптичка кохерентна томографија беше направена кај 8 пациенти (53,3%), која покажа постпроцедурална средна лумен ареа од  $7,86 \pm 1,81 \text{ mm}^2$ , минимум лумен ареа  $5,51 \pm 1,58 \text{ mm}^2$ . Периодот на следење беше направен на 30 дена, шест месеци, една година (15 пациенти), две години (5 пациенти). Потребата за повторна интервенција на местото на лезијата изнесуваше 0%. Во досегашниот период на следење не беа регистрирани смртен исход, појава на интракоронарна БВС-тромбоза и нов миокарден инфаркт.

*Заклучок:* Имплантацијата на БВС кај пациенти со акутен коронарен синдром е сигурна и успешна метода, со постпроцедурален ТИМИ 3 проток кај сите пациенти и добра скафолд-апозиција во коронарната артерија.

**Клучни зборови:** биоресорптивен васкуларен скафолд, акутен коронарен синдром, оптичка кохерентна томографија