FULLY BIORESORBABLE SCAFFOLDS FOR CORONARY ARTERY DISEASE

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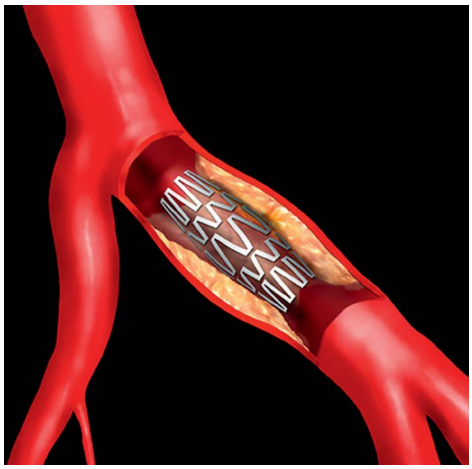
KEY MESSAGES

Percutaneous coronary intervention (PCI) with stents is the most common procedure to restore blood flow in the management of obstructive coronary artery disease. Recently, Bioresorbable Vascular Scaffolds/stents, made from a naturally resorbable material, have been presented as an alternative to other PCI techniques.

According to a systematic review published by Ludwig Boltzmann Institute[a] for Health Technology Assessment in March 2015[1], the available evidence is currently insufficient to show that Bioresorbable Vascular Scaffolds/stents are at least as effective and safer than drug eluting stents in coronary artery disease. The authors recommend to re-assess the evidence in 2018, when results from some of the ongoing trials are expected to become available.



SUMMARY OF THE PUBLICATION

- *Zechmeister-Koss I, Rothschedl E. Fully bioresorbable scaffolds for coronary artery disease. Decision Support Document Nr. 81; 2015. Vienna: Ludwig Boltzmann Institute for Health Technology Assessment.*

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Quality of the publication

Two KCE researchers independently appraised the quality of this review using the AMSTAR tool. The score obtained by the review is 7/11.

Context

Despite a decreasing prevalence over the last decades, coronary artery disease (CAD) is still the leading cause of death in Europe and worldwide[2]. Percutaneous coronary intervention (PCI) is the most common procedure to restore blood flow and has contributed to substantial improvements in the management of obstructive CAD.

The most common PCI technique in the mid-1990s consisted of introducing permanent metallic coronary stents (BMS) which relieved obstruction to coronary flow. A decade later, the more effective and safer drug eluting stents (DES) were launched. These stents are coated with a drug, gradually released over a prolonged period of time, which helps further prevent the arteries from re-closing.

More recently, fully bioresorbable vascular scaffolds/stents (BVS), made from a material resorbed naturally by the body overtime, have been presented as an alternative treatment modality which could provide better or similar outcomes, but with less complications than the currently used DES.

The objective of the review was to assess whether the implantation of fully BVS in adults with CAD is at least as effective but safer than other revascularization approaches (permanent stents). The studied outcomes were: cardiac and all-cause mortality, morbidity (angina and myocardial infarction), revascularisation rates and quality of life (QoL), as well as safety (scaffold/stent-thrombosis; periprocedural mortality and mortality from bleeding/stroke and other serious adverse events such as stroke).

What is KCE has read for you?

KCE has read for you synthesises a recently published high-quality systematic review or health technology assessment with relevance for the Belgian health system.
The original publication was appraised and contextualised by KCE researchers.
KCE has read for you is not based on original research conducted by KCE.
More details on methodology can be found on the KCE website

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This document includes:

- **Key findings** of the publication under evaluation
- **A contextualisation** within the Belgian healthcare system

Not included:

- Recommendations
- Detailed descriptions

Trustworthy original publication

The methodological quality of the systematic review was assessed with the AMSTAR tool

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Methods

A systematic review of several bibliographic databases (Medline, Embase, The Cochrane Library and CRD) was performed in January 2015 and completed by hand searches and a request for data from manufacturers of CE-marked BVS. Study types were limited to clinical trials and systematic reviews.
The quality of the evidence was assessed using GRADE[b].

Results

Interim results from two randomized controlled trials (RCTs), comparing one BVS (ABSORB®) with drug eluting stents (DES) on 741 patients overall, were used to evaluate the efficacy of BVS on CAD in adults. No evidence was available to compare efficacy between different BVS. The safety was assessed based on these two RCTs and ten observational studies (nine on ABSORB® and a very small size study on DESolve®). Overall safety data was available for 1290 patients.

Efficacy

Mortality

No statistically significant differences on cardiac or all-cause mortality were found between BVS or DES at 9 months (one trial, 240 patients) or 12 months (one trial, 501 patients). The quality of the evidence was assessed as moderate by the authors of the review.

Cardiac mortality:
- at 9 months: 1% with BVS vs 0% with DES (p=0.33);
- at 12 months: No cardiac mortality in any of the two groups.

All-cause mortality:
- at 9 months: 1% with BVS vs 2% with DES (p=1.00);
- at 12 months: 0% with BVS vs 1% with DES (p=0.33).

Revascularisation rates

No significant differences at 9 months (moderate quality of evidence) or 12 months (low quality of evidence).
- at 9 months: 24% with BVS vs 24% with DES (p=0.99);
- at 12 months: 4% with BVS vs 7% with DES (p=0.08).

Morbidity

No statistically significant differences were found in occurrence of myocardial infarction at 9 or 12 months and in angina-free at 12 months. However, the angina rate was significantly lower in patients treated with BVS compared to DES. The quality of the evidence was rated as moderate.

Myocardial Infarction:
- at 9 months: 1% with BVS vs 1% with DES (p=0.55);
- at 12 months: 4% with BVS vs 1% with DES (p=0.06).

Angina:
- Angina-free rates at 12 months: No statistically significant difference.
- Angina rates at 12 months: 22% for BVS vs 30% for DES (p=0.04).

Health related QoL

The limited available evidence on QoL (moderate quality of evidence) did not show any significant differences between BVS or DES (p=0.55).

Safety

Scaffold/stent thrombosis

Evidence from the two RCTs (moderate quality of evidence) showed no statistically significant differences at 9 and 12 months.
- at 9 months: 1% with BVS vs 0% with DES (p=0.33);
- at 12 months: 1% with BVS vs 0% with DES (p=0.55).

The quality of evidence for all other adverse events was very low and there was a lack of long-term term outcome measurements.

Conclusions

The Ludwig Boltzmann Institute review concludes that there is insufficient evidence to show that Bioresorbable scaffolds are at least as effective but safer than other stents in CAD treatment. They recommend to revisit the situation in 2018 when results from some of the ongoing trials (more than 14 RCTs underway) are expected to become available. These conclusions appear to be in line with a recently published systematic review[3], including evidence from new RCTs, but having a lower quality (AMSTAR 4/11), than the one here summarised.

BELGIAN CONTEXT

In Belgium, cardiovascular disease remains the most common cause of death[4]. At present DES are commonly used and reimbursed. Only one BVS (ABSORB) is reimbursed since May 2013 and its use appears to remain limited. From July 2014 to June 2015, 1.6 % of stents used in the management of CAD were BVS (BVS=554). In contrast, DES were used in 72.0 % of the cases (DES=24 612) and bare metallic stents in 26.4% of the cases (BMS 9 033) over the same period.

REFERENCES

- *1. Zechmeister-Koss I. Decision Support Document Nr. 81. Vienna: Ludwig Boltzmann Institute for Health Technology Assessment. Fully bioresorbable scaffolds for coronary artery disease. 2015.*
- *2. Nichols M, Townsend N, Scarborough P, Rayner M. Cardiovascular disease in Europe 2014: epidemiological update. Eur Heart J. 2014; 35(42):2950-9.*
- *3. Keh YS, Yap J, Yeo KK, Koh TH, Eeckhout E. Clinical Outcomes of Bioresorbable Scaffold in Coronary Artery Disease: A Systematic Literature Review. J Interv Cardiol. 2016. doi: 10.1111/joic.12260*
- *4. Statbel 2012 (www.statbel.fgov.be).*

a. Ludwig Boltzmann Institute ?

Ludwig Boltzmann Institute for Health Technology Assessment is an Austrian academic non-profit institution that provides research to support health care decision-making.

b. GRADE ?

GRADE (Grading of Recommendations Assessment, Development and Evaluation) offers a system for rating quality of evidence in, amongst other, systematic review.

More information on GRADE can be found
- in the GRADE website
- and in the KCE process book