Rev Port Cardiol. 2013;32(12):1013–1018

Revista Portuguesa de
Cardiologia
Portuguese Journal of Cardiology
www.revportcardiol.org

POSITION STATEMENT

Position Statement on bioresorbable vascular scaffolds in Portugal☆

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Received 24 May 2013; accepted 29 May 2013
Available online 10 January 2014

KEYWORDS
Bioresorbable vascular scaffolds;
Coronary angioplasty;
Percutaneous coronary intervention;
Diabetic;
Stent

Abstract
Background: Bioresorbable vascular scaffolds (BVS) were recently approved for percutaneous coronary intervention in Europe. The aim of this position statement is to review the information and studies on available BVS, to stimulate discussion on their use and to propose guidelines for this treatment option in Portugal.
Methods and Results: A working group was set up to reach a consensus based on current evidence, discussion of clinical case models and individual experience. The evidence suggests that currently available BVS can produce physiological and clinical improvements in selected patients. There are encouraging data on their durability and long-term safety. Indications were grouped into three categories: (a) consensual and appropriate – young patients, diabetic patients, left anterior descending artery, long lesions and diffuse disease; (b) less consensual but possible – small collateral branches, stabilized acute coronary syndromes; and (c) inappropriate – left main disease, tortuosity, severe calcification.

☆ Please cite this article as: Campante Teles R, Pereira H, Cyrne de Carvalho H, et al. Posição sobre suportes vasculares restaurativos transitórios coronários em Portugal. Rev Port Cardiol. 2013;32:1013–1018.

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Conclusion: BVS are a viable treatment option based on the encouraging evidence of their applicability and physiological and clinical results. They should be used in appropriate indications and will require technical adaptations. Outcome monitoring and evaluation is essential to avoid inappropriate use. It is recommended that medical societies produce clinical guidelines based on high-quality registries as soon as possible.

PALAVRAS-CHAVE
Suportes vasculares restaurativos transitórios;
Angioplastia coronária;
Intervenção coronária percutânea;
Diabetes;
Stent

Posição sobre suportes vasculares restaurativos transitórios coronários em Portugal

Resumo
Introdução: Os suportes vasculares restaurativos transitórios (sVRT) foram recentemente aprovados para intervenção coronária percutânea (ICP) na Europa e possuem propriedades muito inovadoras. O objetivo desta declaração de posição é rever criticamente a informação e os estudos com os sVRT disponíveis e contribuir para uma reflexão científica que promova o seu uso racional com orientações estruturadas para a sua aplicação inicial em Portugal.
Métodos e resultados: Foi constituído um grupo de trabalho para alcançar um consenso com base na evidência científica conhecida, na discussão de casos clínicos modelo e na experiência individual. A evidência reunida sugere que os sVRT disponíveis podem produzir uma melhoria fisiológica e clínica em doentes selecionados. Os dados relativos à sua durabilidade e segurança a longo prazo são animadores. As indicações iniciais foram agrupadas em três categorias: a) consensuais e apropriadas – jovens, diabéticos, descendente anterior, lesões longase doença difusa, b) menos consensuais mas possíveis – lesões com pequeno colateral, síndromas coronárias agudas estabilizadas; c) inapropriadas – tronco comum, tortuosidade, calcificação grave.
Conclusão: Os suportes vasculares restaurativos transitórios constituem uma terapêutica válida pela evidência científica encorajadora da sua aplicabilidade, da melhoria fisiológica e clínica. Devemos privilegiar as indicações aconselhadas e adequar as técnicas de angioplastia coronária, bem como monitorizar e avaliar os resultados para evitar uma adoção inapropriada. É recomendável o desenvolvimento expedito de normas de orientação clínica pelas sociedades científicas apoiada em registos de elevada qualidade.

Preamble

Andreas Gruntzig performed the first coronary balloon angioplasty in 1977,[1] and since then there have been continual advances in the percutaneous treatment of coronary artery disease by cardiac catheterization.

A major development occurred in 1986 with the introduction of stents, which reduced the rate of subacute coronary artery occlusion to 1.5%, considerably decreasing the need for emergency coronary artery bypass grafting.[2]

The next advance was in 2001 with the advent of drug-eluting stents (DES), which, by lessening neointimal hyperplasia, dramatically reduced the restenosis rate seen with bare-metal stents by 39–61%, and hence the need for secondary revascularization.[3–5]

The introduction of DES sparked a wealth of research on coronary devices that included registries and high-quality randomized trials, contributing to evidence-based medicine in this area. This demonstrated that the increasingly widespread use of DES had limitations, particularly in terms of late thrombosis, which has now been thoroughly studied and controlled.[5,6]

Despite the good clinical outcomes obtained with DES, these stents have a fixed, rigid metal structure that cannot be removed and that hinders the adaptive biological process of remodeling. Furthermore, the polymers and drugs involved cause local inflammation, which inhibits physiological recovery of the artery and contributes to late thrombosis and neoatherosclerosis.

After a decade of intense pre-clinical research, there was a third revolutionary advance, that of bioresorbable vascular scaffolds (BVS), which are designed to provide temporary radial support to the vessel, to facilitate administration of antiproliferative drugs and to promote recovery of the artery's normal structure and physiological function by gradual removal of the scaffolding through a process of biodegradation.

BVS have several advantages, including physiological recovery of the vessel, reduced stent thrombosis and need for antiplatelet therapy, fewer constraints on future interventions in the vessel and its collaterals, and the possibility of using noninvasive diagnostic exams, particularly computed tomography angiography.[7–11] These devices afford all the benefits of a stent, plus the added advantage of being absorbed by the body, ideally after they have fulfilled their