

Normal P axis. PR, rate & rhythm
p V1 - 10 mV or more negative
Q/S in V1 & V2
ST-T negative ANT/LAT/INF
T > -30 mV. ST > -0.5 mV

GlobalData»
MediPoint

**DRUG-ELUTING BALLOONS –
CURRENT AND FUTURE PLAYERS**

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SAMPLE

Introduction

2 Introduction

Coronary artery disease (CAD) and peripheral artery disease (PAD) are global public health and socioeconomic issues that affect millions of lives each year. Percutaneous coronary interventions (PCI) and endovascular therapies, such as stenting and angioplasty, have been widely adopted to treat CAD and PAD in the lower extremity. Vascular stents, such as bare metal and drug-eluting stents are often used in clinical practice to treat coronary and peripheral artery lesions. However, for indications such as in-stent restenosis (ISR), small-vessel disease, coronary bifurcations, and femoropopliteal artery and below-the-knee (BTK) lesions, stenting is associated with poor clinical outcomes, reiterating the need for alternative therapies. In addition, implanting permanent stents, such as drug-eluting stents (DES) and bare metal stents (BMS), into the vessel can increase the risk of chronic inflammation, restenosis, and thrombosis.

Emerging technologies, such as drug-eluting balloons (DEB), address the challenges and complications of stenting in these subsets of lesions. DEB provide fast, short-term, homogenous, local drug delivery, preserve the anatomy of the vessel, promote enhanced vessel healing, and reduce the need for prolonged dual antiplatelet therapy without leaving any metal behind. Medical device companies have developed a range of DEB for coronary and peripheral applications in the lower extremity. The majority of these DEB have paclitaxel as the antiproliferative drug of choice, with different drug coating technologies and balloon/catheter designs. In this report, DEB are defined as drug-coated angioplasty balloon catheters.

This report focuses on the global DEB market for treating CAD and PAD in the lower extremity. The global DEB market is determined for the 10 countries covered in the report, which are the US, France, Germany, Italy, Spain, the UK, Japan, Brazil, China, and India. The report identifies and analyzes the key companies shaping and driving the global DEB market. The report provides insight into the competitive DEB landscape, including new companies entering the market and pipeline products in development. From GlobalData's analysis, it is evident that the current adoption of DEB for coronary and peripheral applications is slow. However, the DEB market for peripheral applications is larger compared with that for coronary applications. DEB are currently not commercially available in the US or Japan. Large-scale, long-term, cost-effectiveness studies need to be conducted to demonstrate their clinical efficacy and DEB need to be integrated appropriately into the existing reimbursement systems.

DEB provide fast, short-term, homogenous, local drug delivery, preserve the anatomy of the vessel, promote enhanced vessel healing, and reduce the need for prolonged dual antiplatelet therapy without leaving any metal behind

Introduction

To successfully market DEB, companies need to design novel platforms that address the challenges in treating femoropopliteal and infrapopliteal artery lesions, coronary bifurcations, and small-vessel disease, and show that they have superior clinical performance to the stents that are used to treat these lesions.

2.1 Catalyst

Minimally-invasive techniques, including stenting and angioplasty, have become the standard of care for patients with CAD and PAD in the lower extremity. Modern developments in endovascular interventions have led to a paradigm shift in the treatment of PAD in the lower extremity towards endovascular therapy. Although vascular stents, including bare metal, drug-eluting, and covered stents, offer treatment solutions for patients, they do not provide sustained clinical outcomes in lesions such as ISR, small-vessel disease, coronary bifurcations, and superficial femoral artery (SFA) and BTK lesions. In the peripheral vasculature, the femoropopliteal and infrapopliteal arteries are challenging to treat, given the diffuse nature of the atherosclerotic disease and long and heavily-calcified lesions. In the femoropopliteal arteries, the high plaque burden, slow vascular flow, and exposure to high mechanical forces increase the risk of stent compression and fracture. Alternative effective technologies need to be designed to address these unmet needs.

Compared with the coronary and peripheral vascular stent markets, the DEB market is a much smaller market. However, it is a dynamic market that allows device manufacturers to develop a range of platforms to target different coronary and peripheral indications. Low-profile DEB technologies are being developed to reduce the risk of complications of stenting such as restenosis and thrombosis, improve long-term vessel patency, and reduce barotrauma to the vessel. DEB-only and DEB as an adjunct therapy can be used to treat complex and challenging lesions and optimize stenting. Given the lack of effective therapies, DEB can become the gold standard of treatment for coronary/peripheral artery ISR. In addition, DEB may become a primary therapy for treating peripheral lesions in the lower extremity, where stenting can be used as a “bailout” strategy.

Introduction

As more long-term clinical data that demonstrate the superior therapeutic benefits of DEB and reimbursement become available, the adoption of DEB by the medical community will increase slowly in the future. As CAD and PAD present enormous global public health and socioeconomic issues, and use of stents continues to increase, it is important to find effective treatment modalities that ensure long-term quality results for patients.

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Appendix

6.7 About MediPoint

MediPoint is the flagship product for GlobalData's Medical team. Each MediPoint report is built from the ground up by our team of healthcare analysts in the US and UK. Each report includes input from experienced physicians and leading key opinion leaders (KOLs). Running throughout each report in the series, "What Physicians Think" quotes provide a unique insight into how healthcare professionals are reacting to events within the industry, and what their responses could mean for industry strategists.

6.8 About GlobalData

GlobalData is a leading global provider of business intelligence in the healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports, and forecasts. Our analysis is supported by a 24/7 client support and analyst team. GlobalData has offices in New York, Boston, London, India, and Singapore.

6.9 Disclaimer

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