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Clinical application value of bioabsorbable stent in percutaneous coronary intervention for non-left main lesion

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Abstract: *Non-left main coronary artery disease is a common coronary artery disease, and about 1/5 patients need percutaneous coronary intervention (PCI). This article reviews the advantages, safety and limitations of using bioabsorbable stents in clinical treatment of non-left main coronary artery disease.*

Keywords: *bioabsorbable scaffold (BRS)*

1. Introduction

Percutaneous coronary intervention (PCI) for non-left trunk lesions is the main method to treat non-left trunk lesions, and drug-coated metal stent is the most widely used device in PCI. However, stent has some disadvantages, such as it is not conducive to coronary CT angiography and treatment of target vessels. How to maintain the patency of blood vessels safely and permanently, the excessive proliferation of vascular endothelium and reduce the rate of vascular restenosis is the of clinical attention. The development from metal stent to drug-eluting stent has become one of the choices of vascular reconstruction therapy. Bioabsorbable stent (BRS) is a safe and effective material at present, which can improve the prognosis of patients and become a milestone in percutaneous coronary intervention. BRS can support coronary arteries like traditional stents, and keep them normal. Most can release active drugs and inhibit cell proliferation like drug-eluting stents, but BRS has better biocompatibility and avoids adverse events caused by stent structure propping up in blood vessels [1]. This article reviews the value of BRS in the treatment of non-left main lesion by PCI.

2. Advantages of Bioabsorbable Stent

2.1 Reduce the risk of late stent thrombosis

A large number of studies have shown that the incidence of stent thrombosis is less than 1% one after drug elution, but the risk of stent thrombosis is significantly increased in the late stage and extremely late stage. The mechanism of stent thrombosis is not completely clear, which may be related chronic inflammation of blood vessels caused by stent structure, and some scholars think it is related to immunization and epidemic prevention. The polymer coating by drug elution may lead to hypersensitivity of blood vessels, and this hypersensitivity will cause thrombosis. BRS, as a bioabsorbable material, can be degraded and absorbed in about 3 years, leaving no foreign body avoiding the long-term exposure of the internal structure of the stent, thus helping to reduce the risk of thrombosis in the late and extremely late stent. Studies have also shown that magnesium alloy, as a skeleton BRS, can produce negative charges in its degradation, and negative charges have an aggregation effect.

2.2 Little influence on vascular structure and physiology

Compared with the metal skeleton used in traditional stents, the skeleton material of BRS has elasticity and high adhesion to the blood vessel wall, which can reduce the occurrence of stent adhesion defects and reduce the stent adhesion accidents caused by various factors in the later stage. Stent implantation is an interventional operation, which will lead to high shear stress and low shear stress

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at the edge of stent, which can cause hemodynamic disorder, and hemodynamic disorder will further cause restenosis in stent. Stent structure exists in blood vessels for a long time, and abnormal shear stress will damage local vascular endothelium, while the ability of synthesizing vasodilators such as nitric oxide and adenosine will be damaged, resulting in contradictory vasoconstriction of coronary artery and increasing the incidence of myocardial ischemia. BRS has good biocompatibility, high elasticity and biodegradability, which can greatly reduce the damage to the structure and function of blood vessels, avoid affecting the vasomotor function of blood vessels, and is beneficial to the recovery of blood supply. Studies have shown that after BRS stent implantation, after follow-up, the vascular bending rate and angle change are lower than those of metal stent.

2.3 Covering and transforming unstable plaques

After traditional metal stent implantation, atherosclerotic plaques can cause vascular restenosis and thrombosis in the late stent, and even drug elution technology cannot avoid thrombosis. Therefore, in order to ensure the safety of patients after placing BRS. Some studies have pointed out that the new intima of blood vessel covered with unstable plaque on the surface after BRS implantation, and some scholars believe that BRS can turn unstable and easy-to-rupture plaque into stable atherosclerotic plaque covered with fibrous cap. In the process of BRS degradation, certain products will also be produced, which can alleviate chronic inflammatory reaction, thus reducing the risk of vascular disease revascularization after stent implantation.

2.4 The restrictions on other treatment methods are small

In recent years, with the extensive use of BRS in clinic, it has strong flexibility. For example, patients with BRS stents can undergo coronary artery bypass grafting through the distal end of the diseased coronary artery with permission; BRS has little influence on some non-invasive small examinations such as magnetic resonance imaging and CT angiography. Patients with BRS need to take aspirin+clopidogrel antiplatelet therapy for a long time. After the stent is completely degraded, patients can stop preventive medication or reduce dual antiplatelet therapy, so as to reduce the vascular adverse events caused by long-term use of antiplatelet drugs. Moreover, BRS also plays a certain role in the treatment of in-stent restenosis after PCI. Compared with drug-eluting balloon, BRS can provide more lasting drug release and support. In the treatment of diseased blood vessels, the implantation of BRS can also reduce the influence on the structure and function of local blood vessels. For some patients with acute coronary syndrome caused by the occlusion of coronary artery branches caused by the implantation of metal stents, BRS can reduce the occurrence of such events [2].

3. Limitation and safety of bioabsorbable stent

Although BRS has many advantages, its clinical application time is still short, and there are still some limitations and safety problems. Abbott's ABSORB BRS has received enough clinical data. Although the absorption rate of major adverse cardiovascular events in the initial small single-group trial was low for 5 years, the incidence rate was only 3.4%, mainly cardiac death, myocardial infarction and revascularization of target lesions. However, compared with DES, a larger randomized controlled study (ABSORBII) showed no significant difference in 1-year follow-up. Some studies exclude patients who have recently suffered from acute myocardial infarction or whose levels of myocardial infarction markers have not returned to normal, and the impact of BRS on these patients is difficult to predict. At the same time, some scholars suspect that BRS can not completely prevent late stent thrombosis, and may cause more late lumen injury than DES [3].

At present, the raw materials and manufacturing technology of BRS have some limitations. Firstly, the stent size is limited, and some stent materials have insufficient expansion force, which limits the application of thicker blood vessels, especially the left main coronary artery lesions; Secondly, the thickness of BRS is thicker than that of the new generation DES, which may lead to poor stent passability and difficult implantation, especially in the case of severe local calcification and tortuous blood vessels. The increase of stent thickness may increase the risk of thrombosis in the stent and may also cause restenosis after PCI [4]. If BRS wants ideal expansibility and thickness, it needs to design its structure and material, and put forward higher requirements. Using magnesium and rare earth alloy as BRS can ensure strong expansibility and thickness. However, BRS with magnesium alloy as skeleton degrades too fast, and the released substances become the biggest defect. The first generation of AMS-1 stent with magnesium alloy as the skeleton has some problems. The stent loses its supporting

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ability prematurely, resulting in restenosis of diseased blood vessels. The new generation of DREAMS stent, although modified, is made of magnesium alloy material and structure, which supports blood vessels more permanently, but it is still in the clinical trial stage [5].

BRS implantation requires sufficient balloon as dilation for pretreatment. After stent implantation, high-pressure post-dilation is needed to ensure that the stent can be completely released and adhered to the wall. Imaging equipment such as intravascular ultrasound and optical correlation imaging are also needed as auxiliary interventional therapy to confirm the complete degree of release. In order to improve the accuracy of release, it is necessary to eliminate vascular endothelial injury at the edge of the stent and poor adhesion of the stent. This process increases the time of vascular recanalization, misses the best PCI opportunity, aggravates myocardial ischemia and myocardial necrosis in patients with acute coronary syndrome, and the post-expansion of high pressure can also lead to the destruction of BRS itself. At present, compared with metal stents, the overall price of BRS in the market is higher, and the storage of some BRS requires special equipment and environment, such as ABSORB stents, which need to be stored at MINUS 20℃ to avoid the aging of polymer materials, thus increasing the use cost [6]. Whether the drug release and degradation process of newly implanted BRS have an impact on the original implanted DES needs further study. At present, there are many improved BRS stents, and these products have been greatly improved in degradation speed and pressure resistance compared with the previous generation, but most of them are in the clinical trial stage, and a few products on the market have not been widely promoted [7].

4. BRS treatment of non-left main lesion

4.1 BRS treatment status

Coronary bifurcation lesion is a complex vascular lesion, in which 15%-20% patients need interventional therapy. Bifurcation lesion refers to the lesions of main branches and branches of coronary artery, which are adjacent to or located at the opening of sequential branches, and there are more than half of the stenosis in the lumen, and the lesions of non-left main branches are the most common. BRS is the main stent for PCI in the treatment of non-left main lesions, and it has unique physiological characteristics, which makes the implantation of BRS have a good therapeutic effect [8].

4.2 BRS near-end optimization technology

The proximal optimization technique is to use a large diameter short non-compliant balloon to dilate the blood vessel near the bifurcation ridge after high pressure, so as to obtain a good adhesion technique. In the treatment process, in order to ensure the good stent on the blood vessel wall and assist the operation of guidewire implantation, the pressure of releasing the stent balloon is gradually increased during the operation. During use, in order to avoid stent rupture, the expansion of the operator should not exceed the maximum BRS expansion. Many studies have found that BRS implantation has more benefits [9].

5. Prospect

As a new type of vascular stent device, BRS is favored by doctors and patients because of its complete biodegradability. It has the advantages of reducing thrombosis in stents, having little influence on vascular structure and function, and also having little influence on hemodynamics. It is helpful to restore vascular structure at an early stage and transform unstable plaques. These advantages make the popularization and application of BRS have great development space. However, there is no convincing clinical evidence at present, and its effectiveness and safety need to be corroborated and supported by larger-scale randomized controlled experiments. Due to some reasons of raw materials and manufacturing technology, BRS is not arbitrary in performance, and its price is high in loudness. Special equipment and processes are needed for storage and use to increase its safety and effectiveness, which increases its cost. In the future, BRS may replace the traditional DES and become one of the main devices of PCI [10].

6. Conclusion

At present, PCI is the main method to treat coronary artery stenosis of coronary heart disease.

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Compared with the mature and widely used drug-eluting stents of the previous generation, the use of BRS is considered as the fourth revolution of PCI. Although drug-eluting metallic stents can be better used at present, and the restenosis rate of stents is lower, the long-term persistence of coatings will cause long-term chronic inflammatory stimulation to blood vessels, leading to adverse events such as incomplete stent endothelialization and platelet aggregation, and there is still a high risk of late stent thrombosis. In this case, BRS can be a better choice, which has the advantages of being absorbable and degradable, can restore the function of vasoconstriction and relaxation, reduce or avoid the vascular inflammatory reaction caused by long-term indwelling stent, and plays an important role in the treatment of non-left main artery lesions. Many clinical randomized controlled studies also confirmed the safety and effectiveness of BRS.

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