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Systematic Case-Based Analysis of the Maurora® Drug-Eluting Stent in Vertebral Artery Intervention

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Abstract. Drug-eluting stent(DES) has reduced the rate of (ISR) and improved Vessel patency rate dramatically since it came out in 2002. However, the structure of vertebral artery is complex and has high rate of ISR, which causes a restriction of conventional bare-metal stent (BMS) and off-label coronary stents at this site. Maurora® sirolimus-eluting stent, as the first DES approved for vertebral artery indication all over the world, marked an important breakthrough in the field of neurointervention. This essay uses a systematic case-based approach to analyze the fluoropolymer coating design, drug-release mechanism, clinical performance, and practical challenges of the Maurora® stent. In a word, Maurora® deals with the challenges effectively in treating vertebral artery stenosis and provided a reference for the future optimization and development of DES in the neurovascular field, through the combined design of alloy material optimization, fluorinated coating, and drug-release system. Future direction may develop bioadaptive coatings and combination strategies to reduce restenosis and enhance neurovascular outcomes.

Keywords: Vertebral artery; drug-eluting stent; in-stent restenosis.

1. Introduction

DES has reduced the rate of ISR and improved Vessel patency rate dramatically since it was applied in 2002[1]. In the coronary field, the rate of restenosis was about 50% with balloon angioplasty, decreased to around 30% of ISR with BMSs, and then dropped to about 5% after the introduction of DESs. In contrast, the vascular structure at the origin of the vertebral artery is complex, which cause the procedure to be technically difficult, with a higher ISR rate and a higher rate of symptom recurrence compared with coronary cases. Epidemiological studies have shown that about 20% of posterior circulation ischemic strokes are caused by atherosclerotic stenosis of the vertebral artery, indicating the important role of vertebral artery lesions in stroke prevention and treatment [2]. In a long period, endovascular treatment of vertebral artery stenosis in the field of neurointervention has heavily relied on the off-label use of coronary, renal, and peripheral stents, with a lack of devices specifically designed for this indication [3]. This gap led to difficulties in stent delivery, poor adherence to the diseased vessel wall, and risks of postoperative restenosis recurrence, which may result in doctor–patient conflicts in clinical practice. In 2020, Maurora®, as the first sirolimus-eluting stent approved for vertebral artery indication worldwide, was officially launched, which marks an important breakthrough in the field of neurointerventional devices. This study is based on the registration clinical trial and post-market real-world follow-up data of the Maurora® stent, focusing on a systematic analysis of its drug-release design, postoperative efficacy, causes of restenosis, and market acceptance. Specifically: (1) analyzing the fluorinated coating and drug-release mechanism; (2) summarizing the efficacy and safety data from pre-market trials and post-market clinical follow-ups; and (3) identifying high-risk factors and potential improvements for restenosis based on related literature and studies.

This study systematically reviews its release mechanism, therapeutic efficacy, and intraoperative risk control with Maurora® as a representative case, providing the first high-quality DES case study framework in the neurointerventional field. It aims to fill the blank of specialized stent research for vertebral artery origin lesions and offer technical references for the future optimization, precise implantation, and multi-target therapeutic strategies of DESs.

2. Introduction to the Maurora®

2.1. Basic Information

In the development of coronary intervention, the earliest method was simple balloon angioplasty (1977), with a restenosis rate as high as 50%. In 1986, BMSs were introduced, reducing the incidence of restenosis to about 30%, which was still a considerable number. It was not until 2002 that DESs were introduced, bringing the restenosis rate down sharply to around 5%. Although the restenosis rate after vertebral artery stent implantation remains much higher than this figure, many studies have shown that DESs achieve significantly better outcomes than BMSs. Both European guidelines and Chinese expert consensus recommend DESs as the first choice, and DES-based intervention has become the mainstream treatment in coronary and neurointerventional fields [4,5,6]. However, the first-generation DESs still had many limitations. First, about drug selection, the first generation used paclitaxel. It can delay endothelialization. The second generation replaced it with mTOR inhibitors such as sirolimus and its derivatives, which can improve safety. Sirolimus inhibits the cell cycle of smooth muscle cells (G1–S phase) and reduces neointimal hyperplasia. Its drug release is well controlled, with over 50% released in 7 days and more than 90% in 90 days, matching the peak period of neointimal growth. Second, the second generation adopted a highly biocompatible permanent fluoropolymer coating. For example, the Maurora® stent uses a PVDF + PBMA fluorinated coating with good biocompatibility, stable drug release, and strong physical stability. Finally, the first-generation stents were made of stainless steel, which had thick struts, high rigidity, and tended to cause inflammation. The second generation uses alloy materials such as cobalt-chromium, platinum-chromium, or nickel-titanium. Maurora® uses an L605 cobalt-chromium alloy with thinner struts, providing strong support and better fatigue resistance. It adapts well to the dynamic environment of the vertebral artery and reduces the risk of stent fracture and restenosis.

Nowadays, Maurora® is the first DES approved for vertebral artery indication. It offers a wide range of models, with diameters from 2.5 to 5.0 mm and lengths from 8 to 20 mm, including 24 sizes. These options better meet clinical needs, especially for lesions at the vertebral artery origin. The most important thing is that the stent uses advanced fluoropolymer coating technology with high biocompatibility, providing better safety and lower long-term thrombosis risk.

2.2. Clinical Application

Before launching, Maurora® had a clinical trial. It was a randomized controlled study conducted at ten centers across China. A total of 188 patients were enrolled, including 92 in the DES group and 96 in the BMS group. The mean age of the participants was 61.6 years (range, 38–75 years), and 152 (80.9%) was male. The study compared the clinical efficacy and safety of sirolimus-eluting stents and BMS in patients with symptomatic intracranial and vertebral artery stenosis.

The primary endpoint of the trial was the rate of ISR at 180 days. The rate was 14.5% in the DES group and 43.8% in the BMS group, with a risk difference of 29.3% ($P = 0.001$). These data showed that Maurora® significantly reduced the risk of restenosis in high-risk patients. The secondary endpoints included ischemic stroke or transient ischemic attack (TIA) events in the target lesion area within 30 days to one year after the procedure, as well as the stent implantation success rate. The incidence of ischemic stroke or TIA was 2.2% in the DES group and 5.2% in the BMS group, showing a better trend for DES. The implantation success rate was 97.8% in the DES group and 99.0% in the BMS group. Some cases of failed implantation were related to the tortuous vertebral artery, which may be improved by using intermediate catheters in the future. The safety endpoint included perioperative events within 30 days, such as any stroke, all-cause death, and adverse events. There were three cases (3.3%) of stroke or death in the DES group and five cases (5.2%) in the BMS group, showing no significant difference. This suggests that DES has comparable or even better safety than BMS. The overall adverse event rate was 64.1% in the DES group and 75.0% in the BMS group, most of which were unrelated to the device, such as mild infection or blood count changes, reflecting the real clinical situation.

In a word, the results showed that Maurora® performed better than BMS in both safety and efficacy, providing a safer and more effective treatment option for patients.

3. Analysis and Evaluation

3.1. Drug-Release Profile

Maurora® uses a high-biocompatibility permanent fluoropolymer coating composed of PVDF and PBMA. PBMA serves as the inner adhesive layer, ensuring stable drug release. During the first week after implantation, when tissue proliferation is most active, more than 50% of the drug is released, providing strong support during the early critical period against smooth muscle overgrowth. As tissue proliferation slows, the cumulative release exceeds 80% within 90 days and reaches over 90% at 120 days, which covers the peak period of smooth muscle cell proliferation.

PVDF forms the outer layer and has strong albumin adsorption ability, which reduces platelet and inflammatory cell adhesion. This helps lower the risks of acute, subacute, and late thrombosis while maintaining uniform drug release and coating integrity. Even under balloon expansion pressure, the coating remains intact without cracking or detaching. The drug used is sirolimus, an mTOR inhibitor, and it can suppress cell proliferation. Based on these features, the Maurora® controlled-release system provides timely and stable drug delivery. Its benefits patients with vertebral artery stenosis and helps reduce long-term restenosis risk.

3.2. Effectiveness of Product

The effectiveness of the Maurora® has been confirmed in both registered clinical trials and post-market follow-ups. In the registration study, the 180-day ISR rate was 14.5%, which is much lower than 43.8% in the BMS group ($P = 0.001$). This shows that the drug-release system and stent structure effectively suppressed smooth muscle growth in the short term. In the real-world follow-up, the ISR rate further decreased to 5.6%, and the symptomatic ISR rate was only 2.0%. These results show that Maurora® achieved stable long-term outcomes in a broader clinical population, maintaining vessel patency and reducing symptom recurrence. However, these good results were not entirely due to the stent itself. Later analyses showed that postoperative ISR was related to anatomical factors such as calcification, tortuosity, and proximal stenosis, as well as procedural strategies like stent sizing and pre-dilation. The performance of Maurora® still depends greatly on the operator's judgment and experience. Studies have also shown that abnormal vascular structure and hemodynamic changes play an important role in the development of atherosclerotic stenosis. Procedural strategies, such as stent size selection and pre-dilation, further influence stent apposition and the risk of restenosis[7]. Previous studies have also shown that the occurrence of restenosis is not only affected by stent apposition and structural design but is also closely related to local hemodynamic disturbances and inflammatory proliferation of smooth muscle cells [8]. Earlier guidelines recommended a stent diameter ratio of 1:1.1. However, recent coronary DES studies found that angiographic measurements often underestimate the true vessel diameter. Choosing a stent with a diameter ratio of 1:1.1 to 1:1.3 to the normal vessel is more helpful for proper apposition and full expansion, which can reduce the risk of restenosis and symptom recurrence [9]. Therefore, its effectiveness essentially depends on both platform performance and operator technique. In a word, the core value of the Maurora® stent is beyond doubt. As the only DES currently approved for vertebral artery indication in China, it provides a standardized solution highly matched in structure, coating, and release mechanism for complex vertebral artery origin lesions. It has filled a long-standing technical blank in the field of neurointerventional devices [10].

3.3. Market Position

Maurora® is the first sirolimus-eluting stent approved for vertebral artery indication in China. It now holds more than 70% of the market share in regions capable of neurointerventional procedures nationwide. The fluoropolymer coating is Sinil Pharmaceutical's proprietary technology, and it is the

only one in China that applies this coating to cerebrovascular stents. The main advantage of Maurora® records its wide range of 24 models, with diameters from 2.5 to 5.0 mm and lengths from 8 to 20 mm, allowing it to meet the needs of more patients. The 4.0 mm diameter model is the most commonly used. Competing stents may have similar prices and performance but face limitations in size options. In addition, both European and international consensus support the replacement of BMS with DES. Experts in neurointervention, both in China and abroad, also recommend DES as the first choice. Since the restenosis rate of the vertebral artery is much higher than that of the coronary artery, bare-metal stents can no longer meet clinical needs, and DESs will become the mainstream treatment.

4. Challenge and Outlook

Although Maurora® has significantly reduced the ISR rate to 14.5% compared with 43.8% in the BMS group, restenosis still occurs. This problem is especially seen in high-risk vascular beds such as the vertebral artery. Data show that sirolimus elution has not completely solved the ISR issue, which remains a challenge for Maurora® in the future. Studies have shown that some patients with recurrent ISR responded to paclitaxel-coated balloon (DCB) angioplasty. In the future, a combined use of DES and DCB may become a new treatment option for vertebral artery stenosis.

Sirolimus can inhibit smooth muscle cell migration and reduce the ISR rate, but it may delay endothelial healing and cause chronic inflammation to some extent. Future optimization of the drug-release system may include targeted drug combinations, intelligent responsive release, and the use of biodegradable or bioactive coatings instead of permanent polymers or fluoropolymers to reduce inflammation and promote healing.

5. Conclusion

Maurora®, as the first sirolimus-eluting stent approved for vertebral artery indication in China, shows clear advantages in drug-release design, clinical performance, and intraoperative adaptability. Its highly biocompatible fluoropolymer coating and stable drug-release mechanism effectively reduce early smooth muscle cell proliferation, providing a physical basis for prevention in complex anatomical conditions. Both the 180-day ISR reduction observed in the registration trial and the 5.6% overall ISR rate with 2.0% symptomatic ISR in real-world data confirm the safety and effectiveness of Maurora® in treating vertebral artery origin stenosis. Although postoperative ISR and stent fracture remain challenges, the launch of this product has filled the gap of dedicated stents in the neurointerventional field and provided a clinical foundation for future optimization and standardization of DES design and implantation.

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