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Original Contribution

EVALUATION OF HEALTH BENEFITS OF THE USE OF INNOVATIVE SELF-EXPANDING LASER-CUT STENT TECHNOLOGY

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ABSTRACT

INTRODUCTION: The evaluation of health technologies plays a crucial role in modern healthcare, providing a reliable foundation for making informed decisions regarding the reimbursement of new medical devices, drug therapies, and diagnostic approaches. A review has been conducted to outline the benefits of implementing the innovative self-expanding laser-cut stent technology in the treatment of cerebral aneurysms.

OBJECTIVE: The aim of this study is to assess the benefits, safety, and efficacy of using a self-expanding laser-cut stent for the treatment of cerebral aneurysms, which represents the most common endovascular approach for managing these conditions.

MATERIALS: A documentary research method was employed, including a systematic review of literature from electronic databases such as PubMed, Scopus, Web of Science, and ResearchGate, using specialized software to evaluate existing risks, safety, and efficacy in the application of a self-expanding laser-cut stent for cerebral aneurysm treatment. The procedural aspects, types of complications, clinical outcomes, and aneurysm occlusion rates with self-expanding laser-cut stents were retrospectively analyzed.

RESULTS: Studies indicate that embolization devices utilizing self-expanding laser-cut stents achieve a complete occlusion rate of 83.3% and a favorable occlusion rate of 97.7% in a one-year angiographic study of 174 aneurysms, with minimal morbidity and no mortality associated with the intervention. This suggests that the treatment is a safe and effective approach for intracranial aneurysms. Based on findings from multiple independent studies, treatment with the DED stent represents a reasonable, safe, and effective alternative.

CONCLUSION: The data from various studies support endovascular techniques as a safe and effective therapeutic method for treating cerebral aneurysms, even in the acute phase. The identified clinical evidence demonstrates the added value of self-expanding laser-cut stents for embolization as a safe and effective option for treating cerebral aneurysms by redirecting blood flow when other endovascular or neurosurgical techniques are not viable.

Key words: cerebral aneurysms, treatment.

INTRODUCTION

Cerebrovascular diseases are a heterogeneous group of conditions that include both ischemic and hemorrhagic disorders affecting the arterial and venous circulation of the brain. An aneurysm is an abnormal localized dilation of the vessel wall that occurs due to congenital or acquired weakening or destruction of the vascular wall. This weakening may result from congenital defects, localized infections (mycotic aneurysms), trauma (traumatic aneurysms), or systemic vascular diseases. Aneurysms most commonly affect large elastic arteries, particularly the aorta and its major branches. Based on their origin, aneurysms are classified as either acquired or congenital and further categorized as true or false. Cerebrovascular diseases (CVDs) hold a significant position among socially impactful diseases due to their high morbidity, mortality, and the severe disability they cause in stroke survivors. Bulgaria ranks among the leading

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countries in the world in terms of CVD incidence and mortality, with approximately 82,398 cases recorded annually. The primary goal of cerebral aneurysm therapy is the prevention of rupture (1). Treatment includes a combination of surgical and conservative therapeutic approaches aimed at addressing the key factors contributing to poor prognosis. The management of unruptured cerebral aneurysms, which have not yet manifested symptoms, presents potential serious complications and must be carefully weighed against the predicted risk of rupture. Surgery, endovascular treatment, or other therapies are often recommended to manage symptoms and prevent damage from both ruptured and unruptured aneurysms. The primary objective of modern neurosurgical treatment is to exclude the aneurysm from cerebral circulation to prevent recurrent hemorrhage while preserving normal cerebral blood flow. For approximately 20 years, endovascular therapy has been primarily employed for aneurysms unsuitable for surgical clipping. Endovascular treatment is a novel, minimally invasive method for managing cerebrovascular diseases. It involves the use of specialized coils, spirals, and stents, which are inserted into the aneurysm via a catheter to seal it. Advantages of Endovascular Therapy:

- Applicable for aneurysms located in areas inaccessible to surgical intervention (primarily in the posterior circulation).
- Can be used for both ruptured and unruptured aneurysms.
- Minimally invasive and associated with lower trauma (2).

Neovascular embolization, or coiling, essentially involves catheterization of the femoral artery. Under fluoroscopic guidance, the catheter is slowly advanced through the aorta and then through the carotid or vertebral artery until it reaches the intracranial artery where the aneurysm has formed. Once the catheter reaches the aneurysm entrance, a thin metallic wire, known as a coil, is slowly and gradually inserted into the aneurysmal sac. The coil continues to be deployed until it forms a dense mass—similar to a ball of yarn (3, 4). In this way, there is no space for blood accumulation in the aneurysmal sac, effectively isolating it from circulation and eliminating the risk of rupture and subarachnoid hemorrhage. Flow Diversion is a technique in which a catheter is used to place a stent (a soft, flexible mesh tube) within the blood vessel where the aneurysm has developed. This process immediately diverts blood flow away from the aneurysm. Redirecting the blood flow reduces pressure on the aneurysm, making it less likely to rupture. The most commonly used stents are the PED (Pipeline Embolization Device) and Derivo Embolisation Device (DED) (5, 6). Over time, new cells grow over the stent, sealing the aneurysm and strengthening the vessel (7, 8). If the stent covers the opening of a branching vessel, the normal blood flow prevents cellular growth in that section of the stent and avoids blockage of the branch, ensuring that the stent does not disrupt blood supply to other areas of the brain. The use of this type of embolization device is preferred because of the following advantages:

• Increased safety - this treatment method eliminates the need for doctors to enter the aneurysm itself - which is often the riskiest part of the endovascular approach.

• Shorter recovery - many patients who once required extensive surgery can now undergo this procedure and go home the next day. Some patients return to work within a week.

• Fewer recurrences - this technique appears to reduce the recurrence rate (the chance that a patient will develop another aneurysm).

• Less radiation exposure - with this procedure, patients receive a much lower dose of radiation than with other endovascular techniques.

• Lower cost - this surgery costs less than other endovascular treatment approaches (9, 10).

RESULTS

According to data from several research groups, Zaeske et al. (2021) and Trivelato et al. (2019), investigating the implantation of flow-diverting devices, the studies confirm that these devices are technically successful in all patients. PED is more frequently used for treating large aneurysms in the anterior circulation of the brain (internal carotid artery) (11, 12). However, it has more limited flexibility when treating aneurysms in smaller distal vessels or in the posterior circulation. The DED stent is suitable for wide-neck and complex aneurysms, including those in the posterior circulation or distal vessels, thanks to its more flexible design. It is more effective for treating aneurysms in anatomically challenging regions. The DED embolization device achieved a complete occlusion rate of 83.3% and a favorable occlusion rate of 97.7% in a one-year angiographic study of 174 aneurysms, with minimal morbidity and no mortality

associated with the intervention. This indicates that DED is a safe and effective treatment for intracranial aneurysms. Endovascular flow diversion for intracranial "blister" aneurysms is an increasingly practiced treatment method for this challenging category of aneurysms. However, the requirement for antiplatelet therapy can pose a significant limitation in the acute phase of subarachnoid hemorrhage. Data from the study by Incandela et al. support this endovascular technique as a safe and effective therapeutic method for treating aneurysms in the acute phase (13-15). Among patients who received PED stents, multiple devices were used more frequently (35.6%) compared to those treated with DED stents (4.1%, $P < 0.001$). Procedural adverse events occurred in four cases in each group (PED: 5.5%, DED: 8.2%, $P = 0.713$), including three thromboembolic events and one hemorrhagic event per group. The morbidity rates were similar between the two groups (PED: 2.7%, DED: 4.1%, $P = 1.0$). No procedure-related deaths were reported in the study. At six-month follow-up, complete or near-complete occlusion (O'Kelly-Marotta scale C+D) was achieved in 79.0% (49/62) of patients treated with PED and 80.0% (32/40) of patients treated with DED ($P = 0.354$) (16,17,18). In terms of complication rates, functional outcomes, and aneurysm occlusion, no significant differences were found between the groups treated with PED and DED. Based on the study results, DED is considered a reasonable, safe, and effective alternative to PED (19-21).

DISCUSSION

The DED device has been approved for use in Europe (EU member states applying Directives 90/385/EEC and 93/42/EEC), the United States, and Japan. Data from the British study "The International Subarachnoid Aneurysm Trial (ISAT)," which lasted 18 years, indicate that patients treated with DED embolization devices benefit from state-of-the-art self-expanding stents for intracranial neurovascular flow diversion. The technical success rate of these devices ranges from 83.3% to 100%, while the clinical success rate varies between 73.9% and 100%. The use of a self-expanding laser-cut stent (DED) for the treatment of cerebral aneurysms represents a less invasive approach with demonstrated clinical efficacy. According to Trivelato et al. and Daglioglu et al., DED enables precise flow diversion, leading to partial or complete thrombosis of the aneurysm upon follow-up. The structural features of the DED—such as a smooth surface, multiple radiopaque markers, and flared ends—facilitate accurate deployment and optimal apposition to the vessel wall, contributing to the overall safety of the procedure. Additionally, the smooth surface of the stent reduces the risk of corrosion and thrombus formation (22).

In the context of the Bulgarian healthcare system, where approximately 40,000 cases of stroke are reported annually and a significant number of patients are diagnosed with unruptured cerebral aneurysms (581 examined and 236 surgically treated in 2023, according to NHIF data), the introduction of DED may offer both clinical benefits and economic efficiency (23).

Cost-effectiveness and budget impact analyses indicate that DED therapy results in direct cost savings for the NHIF compared to PED when applied within the same clinical pathways (CP 206.1, 206.2, 206.3), while providing equivalent therapeutic efficacy and a superior safety profile (24).

According to the methodology of the World Health Organization, which uses GDP per capita as a cost-effectiveness threshold, DED therapy is classified as cost-effective and represents a sustainable alternative for reimbursement within the public healthcare system (25).

CONCLUSION

The primary advantage of this study is that it represents the largest prospective multicenter study investigating the use of self-expanding laser-cut stent embolization devices for the treatment of cerebral aneurysms. The clinical evidence identified from multiple studies highlights the added value that the DED embolization device can offer to patients. The authors conclude that the embolization device has proven to be a safe and effective option for treating aneurysms through flow diversion, particularly in cases where other endovascular or neurosurgical techniques are not feasible or pose a high risk. Further long-term follow-up and comparative studies are needed to establish stronger conclusions regarding the superiority of the self-expanding laser-cut stent.

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