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RESEARCH PAPER

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Feasibility and safety of intracranial carotid implantation with covered stents for advanced head and neck squamous cell carcinoma involving the carotid artery: A preliminary investigation

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Abstract

Objective: The aim of this study was to assess the feasibility and safety of implanting covered stents in cases of advanced head and neck squamous cell carcinoma (ASCCHN) where the carotid artery was involved.

Methods: A total of 30 patients (29 males and one female) were included in this study, with ages ranging from 40 to 79 years. Among these patients, 28 patients had received radiotherapy and 17 received subsequent adjuvant therapy, while one was receiving treatment for the first time. Eighteen were treated with covered stent implantation in conjunction with surgery, and the remaining 12 received stent implantation alone. The study evaluated and compared the stent implantation's success rate, overall survival (OS), and associated complications.

Results: Successful implantation of covered stents was achieved in all 30 cases. No instances of significant hemorrhage or thromboembolic cerebral infarction occurred during surgery. Of the patients in the salvage surgical group, 15 underwent complete tumor resection with a success rate of 83.3% (15/18), of which four experienced tumor recurrence with a local recurrence rate of 26.7% (4/15). The OS rates at 6 months for all patients, the salvage surgical group, the 15 patients with complete tumor resection, and the nonsurgical group were 64.0%, 66.8%, 75.5%, and 58.6%, respectively. At 12 months, the OS rates were 21.4%, 29.3%, 43.2%, and 11.8%, respectively. Notably, the OS of the 15 patients who underwent complete tumor resection was significantly higher than that of the 12 patients who received stent implantation alone ($p = 0.044$). All cerebrovascular accidents occurred in patients with radiotherapy history, and subsequent adjuvant therapy had no significant effect on the OS time in the salvage surgical and nonsurgical groups ($p = 0.935$; $p = 0.526$).

Hai-Dong Zhang and Kai Sun contributed equally to this study.

Conclusion: In cases of ASCCHN involving the carotid artery, the implantation of covered stents is a safe and feasible procedure.

KEYWORDS
carotid artery involvement, covered stent, SCCHN

Key points

- All 30 cases of covered stents were successfully implanted, with a success rate of 100%.
- The OS of 15 patients with complete tumor resection was significantly higher than that of 12 patients with only covered stent implantation.
- Applying covered stent implantation in ASCCHN involving the carotid artery is safe and feasible.

INTRODUCTION

Carotid artery involvement represents a significant indicator of advanced head and neck tumors. The incidence rate among patients undergoing radical neck resection stands at 5.5%, with a higher proportion observed among those with recurrent or persistent diseases.[1,2] Active treatment interventions offer improved control over local diseases, leading to enhanced survival time and better quality of life for patients.[2,3] Nevertheless, the challenges posed by tissue fibrosis and scar adhesion after radiotherapy and/or surgery make locating the carotid artery a complex task, associated with a high risk of arterial rupture during surgical exploration and dissection. In cases where surgical feasibility is determined, conventional intraoperative management methods involve arterial ligation or arterial reconstruction.[4,5] Although arterial ligation or reconstruction can yield favorable margins, controversies persist due to the unpredictability of vascular invasion and the substantial surgical risks associated with this approach, including the potential for stroke and mortality. For instance, without prior assessment of the patency of the Willis loop in the brain, the incidence of neurological sequela ranges from 17% to 58%, with a mortality rate of 15%–20%.[6,7] Arterial rupture and hemorrhage, although rare complications, occur in approximately 5% of cases.[8] In situations where arterial rupture and massive hemorrhage do occur, the emergency rescue method is artery ligation. Previous studies have revealed higher rates of ischemic stroke and mortality associated with unassessed artery ligation.[8,9]

The covered stent, characterized by its flexible and self-expanding intra-cavity design, combines the properties of a metal stent and an artificial blood vessel. This unique design allows it to adapt to the surrounding environment, providing effective support and coverage within the targeted area. The metal stent is typically constructed from stainless steel or a nickel–titanium alloy, while the artificial blood vessel consists mainly of a tubular membrane composed of polytetrafluoroethylene (PTFE) or polyester fiber, lined within the metal stent structure. The stent is implanted into the diseased blood vessel through image-guided intervention, serving to safeguard the integrity of the blood vessel wall, maintain stable hemodynamics, and prevent rupture in diseased arteries. In cases of arterial rupture, it can be employed for emergency hemostasis. The utilization of covered stents has been increasingly recognized in the management of peripheral benign vascular diseases.[10–14] However, limited studies have explored its applicability in the context of head and neck malignant tumors.

This article aims to investigate the feasibility and safety of employing covered stents in cases of advanced head and neck squamous cell carcinoma (ASCCHN) involving the carotid artery, based on clinical experiences drawn from the cases within our department.

METHODS

Patient selection

Between June 2019 and May 2023, our department treated a cohort of 30 patients (29 males and one female) diagnosed with ASCCHN involving the carotid artery. The age range of the patients was between 40 and 79 years, with a median age of 58 years. Among these individuals, 28 patients had received radiotherapy and 17 received subsequent adjuvant therapy, while one was undergoing treatment for the first time. Enhanced neck CT scans showed that the tumors encompassed the carotid artery by ≥180°. All patients were classified as stage IVb based on clinical evaluation. Out of the 30 cases, 60.0% (18/30) received combined treatment involving covered stent implantation and surgery (salvage surgical group), while the remaining 40.0% (12/30) underwent covered stent implantation alone (nonsurgical group) (Table 1).

TABLE 1 Baseline data of advanced head and neck squamous cell carcinoma patients(*n*).

Characteristic	Salvage surgical group (*n* = 18)	Nonsurgical group (*n* = 12)	*p*-Value (Fisher's)
Sex			0.400
Male	18	11	
Female	0	1	
Age			1.000
≥65 years	7	4	
<65 years	11	8	
Primary tumor site			0.657
Nasopharynx	4	4	
Oral and oropharynx	4	1	
Larynx	4	5	
Laryngopharynx and cervical esophagus	3	2	
Thyroid	1	0	
Unknown primary	2	0	
Surgical history			0.102
Yes	15	6	
No	3	6	
Radiotherapy history[a]			0.503
Yes	16	12	
No	2	0	
Subsequent adjuvant therapy[b]			0.170
Yes	12	5	
No	6	7	
Immediate complications[c]			0.054
Yes	0	3	
No	18	9	
Intraoperative vascular complications			/
Yes	0	/	
No	18	/	
En blac resection			/
Yes	15	/	
No	3	/	
Invasion of carotid adventitia			/
Yes	2	/	
No	16	/	
Delayed complications[c]			0.622
Yes	4	1	
No	14	11	
Local recurrence[d]			/
Yes	4	/	
No	11	/	
CBS type			/
I	/	4	
II	/	5	
III	/	3	

Note: "/" means no data. Abbreviation: CBS, carotid blowout syndrome.

[a]Radiotherapy history before covered stent implantation (with or without salvage surgery).

[b]Adjuvant treatment after covered stent implantation (with or without salvage surgery), including chemotherapy, immunotherapy, and palliative radiotherapy.

[c]Immediate and delayed complications associated with covered stent implantation.

[d]Including only patients with complete tumor resection.

Inclusion criteria

This study included only patients who met the following criteria:

1. Pathological diagnosis of squamous cell carcinoma.
2. Imaging indicating tumor encasement of the carotid artery by ≥180°.
3. Absence of distant metastasis.
4. An Eastern Cooperative Oncology Group physical condition score of 0–3 points.
5. Life expectancy of ≥6 months.

Implantation process of covered stent

The procedure involved the percutaneous puncture of the right femoral artery, performed under local anesthesia. Initial angiography was conducted to evaluate the patency of the main cerebral artery and communicating branches. The length of the carotid artery involved in the tumor was determined based on preoperative imaging examination and real-time intraoperative imaging localization. After systemic heparinization with 3000 units of unfractionated heparin, a covered stent (GORE VIABAHN, 8 × 10 cm) was accurately guided into position using a guidewire and subsequently deployed. The stent was designed to extend at least 1 cm beyond both the upper and lower ends of the affected arterial segment, ensuring complete coverage. Postimplantation angiography confirmed proper stent expansion and unobstructed blood flow (Figure 1).

FIGURE 1 After the implantation of covered stent (right common carotid artery/internal carotid artery, white arrow), the angiography showed that the stent was fully open and blood flow was unobstructed.

Surgical resection process

The procedure was performed within 1 week after implanting the covered stent in the artery. The main challenge of the procedure was to identify and dissect the carotid artery. Notably, the presence of the covered stent greatly facilitated this step. To expose the carotid artery for localization purposes, the sternocleidomastoid muscle was dissected from its origin at the sternum head and above the clavicular head. This allowed for a smooth and systematic exploration from the base to the top. In all 18 cases, arterial dissection occurred beneath the carotid artery adventitia, revealing intact arterial walls. Tissue suspected of carotid artery involvement was collected for pathological examination. Following successful artery exposure, the tumor was resected, and any resultant surgical defects were repaired using a pectoralis major myocutaneous flap. This approach provided protective coverage for the exposed carotid artery, both internally with the covered stent and externally by forming a dual protective barrier.

Statistics

Data analysis was conducted using SPSS 23.0. The success rate and complications of stent implantation were assessed using the χ^2 test to compare baseline data. Kaplan–Meier survival curves were retrospectively employed to analyze patients' overall survival (OS) at 6 and 12 months. A significance level of $p < 0.05$ was considered statistically significant.

RESULTS

Patient characteristics

There were no statistically significant differences between the two groups in terms of age, gender, primary tumor site, surgical history, radiotherapy history, subsequent adjuvant therapy, immediate complications, and delayed complications (Table 1). All 30 cases underwent successful implantation of covered stents. In the salvage surgery group, none had intraoperative hemorrhage or ischemic stroke, and the success rate of complete tumor resection was 83.3% (15/18).

Follow-up

A comprehensive follow-up was conducted for all patients over a duration ranging from 1 to 24 months, with a median follow-up period of 9 months. The OS rates at 6 months were as follows: for all patients—64.0%, for the salvage surgical group—66.8%, for the 15 patients who underwent complete tumor resection—75.5%, and for the nonsurgical group—58.6%. At the 12-month mark, the OS rates were recorded as follows: for all patients—21.4%, for the salvage surgical group—29.3%, for the 15 patients with complete tumor resection—43.2%, and for the nonsurgical group—11.8%. Importantly, the OS rate of the 15 patients who underwent complete tumor resection demonstrated a statistically significant improvement compared to that of the nonsurgical group ($p = 0.044$) (Figure 2).

Association between treatment history and outcome

Before covered stents implantation, 89% (16/18) of the patients in the salvage surgery group and 100% (12/12) in the nonsurgical group received radiotherapy. The patients who had vessel wall thrombus detachment during implantation (three cases), hemiparesis (three cases), and hemorrhage (two cases) after implantation had the radiotherapy history. In addition, we found that subsequent adjuvant therapy (palliative radiotherapy, immunotherapy, and chemotherapy) did not significantly affect the OS time, either in the salvage surgical and nonsurgical groups, after statistical analysis ($p = 0.935$; $p = 0.526$).

DISCUSSION

Feasibility and safety of combined covered stent implantation with surgical resection

Patients diagnosed with local advanced head and neck tumors involving the carotid artery often face a challenging prognosis with

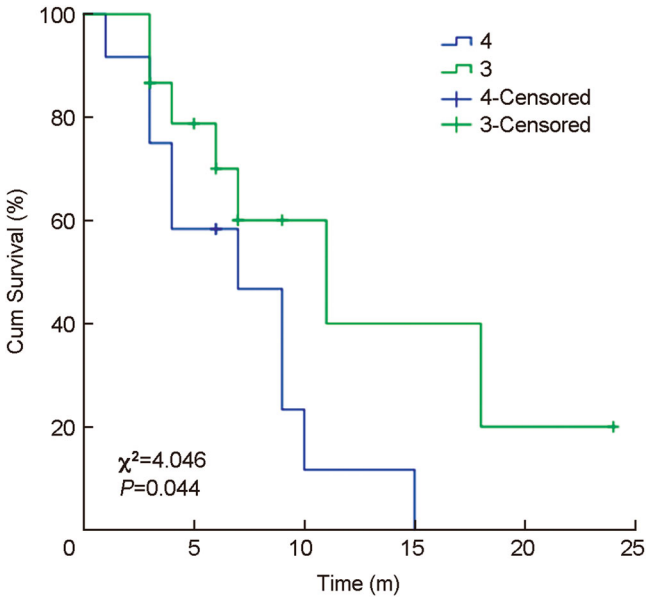

FIGURE 2 Comparison of survival rates between patients who underwent combined surgery with covered stents (complete tumor resection, 15 cases; Represented by the number 3) and patients with only covered stents implantation (12 cases; Represented by the number 4)(Log-Rank).

lower survival rates. Prior research has demonstrated that radical resection surgery can significantly enhance the quality of life and prolong survival rates for such patients.[1,15] This study reaffirms this finding, as patients who underwent covered stent implantation combined with surgical intervention had substantial short-term survival gains. These data show that the survival rate of patients with tumor complete resection is higher than that of patients without surgery ($p = 0.044$).

Managing carotid artery involvement during surgery poses substantial difficulties, particularly for patients with a history of radiation therapy or postoperative recurrence. Local tissue fibrosis and surgical scar adhesions further complicate the identification and dissection of the carotid artery. Furthermore, radiation therapy generates free radicals that can lead to various vascular complications, including thrombosis, fibrosis, atherosclerosis, and weakening of the arterial wall.[16,17] These factors increase the risk of arterial rupture during or after surgery. Covered stent implantation plays a pivotal role in protecting the carotid artery, maintaining stable hemodynamics, and preventing intraoperative arterial rupture and hemorrhage, thereby reducing the likelihood of severe complications such as postoperative ischemic cerebrovascular events. In 2017, Markiewicz et al.[18] introduced the concept of using covered stents in conjunction with early carotid artery implantation combined with surgical resection to treat ASCCHN involving the carotid artery. Although their study involved a small sample size and a short median follow-up period of 3.5 months, it highlighted the safety and effectiveness of this approach. Nevertheless, long-term follow-up studies are necessary to fully assess the long-term advantages of this technique.

Our study included 18 ASCCHN patients with carotid artery involvement who underwent covered stent implantation combined with surgical resection. The presence of the covered stent facilitated the complete removal of the carotid artery from the arterial adventitia without any instances of massive hemorrhage or ischemic cerebrovascular events during surgery. Of the 18 patients, 15 had complete tumor resection, and three experienced incomplete tumor resection (one case suspected of involving the upper mediastinum and two suspected of involving the skull base). During the surgical procedure, the pectoralis major myocutaneous flap was utilized to repair the defect following tumor resection, effectively safeguarding the detached carotid artery.

Subsequent analysis of the 15 patients who underwent complete tumor resection yielded favorable clinical outcomes. Although two cases exhibited rapid pathological positive carotid adventitia, no further carotid artery resection was deemed necessary during surgery. Postoperative follow-up revealed that four patients experienced local recurrence, including those with tumor invasion of the carotid adventitia. Complete tumor resection significantly improved the survival rate, with a 6-month OS rate of 69.5% and a 12-month OS rate of 37.0%. Summarizing our center's surgical experience, during the process of finding and peeling off the artery, it is easy to cause arterial rupture and bleeding. Once carotid hemorrhage occurs, rapid artery ligation is required, which limits the opportunity for arterial reconstruction since arterial reconstruction requires finding and freeing at least 1 cm of the unaffected proximal and distal arterial segments. Without preoperative evaluation of ligation, ischemic cerebrovascular events can reach an incidence rate of up to 79%.[19] Even if the balloon occlusion test (BOT) during the preoperative evaluation shows no neurological dysfunction, 5%–20% of patients may still experience strokes following permanent carotid artery occlusion.[20] Radiation therapy can damage the transplant bed and weaken the arterial wall, increasing the risk of anastomotic rupture and bleeding post-artery reconstruction. In contrast, the implantation of covered stents before surgery significantly reduces the probability of bleeding during the procedure. Even when minor artery damage occurs during dissection, the presence of the covered stent offers critical protection, maintaining normal blood flow without hindrance (Figure 3). This beneficial outcome prevents common carotid artery ligation and significantly reduces the risk of ischemic cerebrovascular events. Furthermore, the covered stent's certain elasticity and firmness enhances its utility during surgery by facilitating more efficient artery localization and minimizing surgical complexity. The elasticity imparted by the covered stents also provides structural support to the arterial wall, highlighting the gap between the arterial wall and the tumor and allowing for more thorough dissection (Figure 4). Consequently, our study demonstrates a significantly lower local recurrence rate compared to simple arterial dissection, as reported in existing literature.[5]

Additionally, as covered stent implantation occurs preoperatively by experienced interventional physicians, it is a highly safe procedure. By eliminating the need for intraoperative arterial reconstruction, the total surgical time for tumor resection is shortened, and the

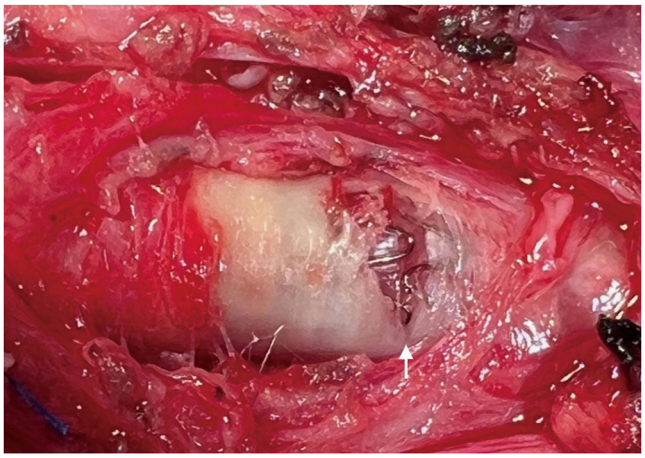

FIGURE 3 During the stripping, there was minor damage to the arterial wall and the covered stent was exposed (white arrow), but no massive hemorrhage occurred.

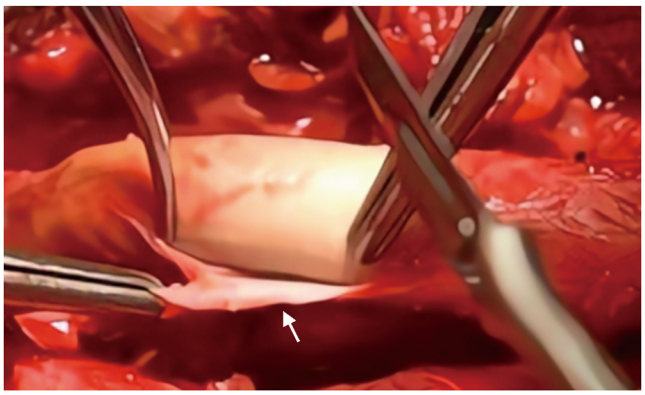

FIGURE 4 After the implantation of covered stent, the arterial adventitia (white arrow) was more thoroughly peeled off.

associated complications are reduced. Nonetheless, in cases of rapid pathological positive carotid artery outer membrane dissection, the risk of local recurrence post-surgery rises, necessitating a "window" or circular resection of the entire affected arterial wall layer.

Feasibility and safety of only implantation of covered stent

Carotid blowout syndrome (CBS) is a rare but severe complication encountered in approximately 3%–4.5% of cases involving head and neck malignant tumors. Which typically arises from factors such as radical neck lymph node dissection, radiotherapy, local infections, or direct tumor invasion. Research shows that patients receiving a total radiation exposure >70 Gy in the neck have a nearly 14-fold increased risk of CBS.[21] Furthermore, when substantial bleeding occurs, the mortality rate can soar to as high as 75%.[22] The optimal treatment method for CBS is still controversial, with surgical interventions such as arterial reconstruction or ligation being commonly accepted as the preferred methods.[17] However, in cases of acute bleeding where the patient is unable to undergo the BOT, both the mortality rate and the incidence of neurological sequela remain alarmingly high. Covered stents offer a multifaceted solution as they not only serve to reconstruct the arterial wall but also enhance its mechanical integrity, maintain blood flow patency, and reduce the risk of ischemic cerebrovascular events. The application indications for covered stents primarily target patients at risk of permanent carotid artery occlusion. These include individuals who cannot tolerate the BOT procedure, are unsuitable for emergency BOT, exhibit poor compensation in the Willis ring, or have severe stenosis or complete occlusion of the contralateral carotid artery.[21] Wong et al.[23] conducted a study encompassing patients with head and neck malignant tumors complicated by CBS to investigate the safety and efficacy of intravascular embolization and covered stents implantation. Their data showed that both embolization and stent transplantation were secure methods for managing acute CBS. However, the incidence of postoperative stroke following carotid artery embolization was higher compared to that of stent transplantation (10.3% for embolization; 2.5% for stent transplantation; $p < 0.02$). In this study, 12 patients underwent sole stent implantation. Among them, three patients with nasopharyngeal carcinoma underwent immediate hemostasis after stent implantation, while the remaining nine patients did not experience carotid artery rupture or major bleeding events. Nevertheless, the OS rate among the group was not notably high, with a 6-month OS rate of 58.0% and a 12-month OS rate of 11.8%. These findings collectively demonstrate that covered stents represent a straightforward, safe, and effective approach for addressing CBS in patients with head and neck malignant tumors.

Complications of covered stent implantation

The utilization of covered stents, classified as "allogeneic grafts," has sparked ongoing debate regarding their safety during implantation. Patients with a history of neck radiotherapy often exhibit damage to vascular endothelial cells due to the radiation's effects, culminating in a vascular inflammatory response, atherosclerosis, and mural thrombosis.[24] During the implantation process of covered stents, there is a potential risk of detaching mural thrombi, resulting in an immediate complication—acute cerebral infarctions. The six patients in this study who developed cerebrovascular accidents (three cases of incidental wall thrombus detachment during stent implantation and three cases of thromboembolism and contralateral limb hemiparesis during subsequent follow-up) had the radiotherapy history, which also proved the damage to arterial vessels caused by radiotherapy. Two of the three patients with hemiplegia due to vessel wall thrombus detachment improved their symptoms, and one patient eventually died of multiorgan failure. Thus, it is important to thoroughly assess the carotid artery's condition before proceeding with covered stent implantation, especially in those patients with the radiotherapy history, for which carotid ultrasound and angiography can provide an important reference.[25]

Delayed complications, such as thrombosis, vascular endothelial damage during stent placement, and the release of vasoactive factors, leading to platelet adhesion and aggregation, are common. Previous studies have shown that poor stent adhesion and incomplete dilation can precipitate hemodynamic fluctuations. Furthermore, tumor cells' secretion of coagulation factors and the elevation of antitumor immunoglobulin levels in the bloodstream can foster a hypercoagulable state. Research suggests that irregular use of anticoagulants and premature discontinuation thereof may exacerbate thrombotic events.[8,23,26] The PTFE membrane inside the currently covered stent has strong biocompatibility, its negative charge can inhibit the aggregation of thrombin on the tissue surface and platelet aggregation, thereby inhibiting thrombosis. Moreover, the PTFE membrane's coating with heparin provides an additional anticoagulant effect. During the follow-up of this study, three patients experienced thromboembolism and contralateral hemiplegia (one patient developed thromboembolism and contralateral hemiplegia on the second day postoperation, potentially related to controlled hypotension during operation and thrombosis caused by blood flow slowdown), with an incidence of 10% (3/30). Two additional patients who experienced thromboembolism did not adhere to standardized antiplatelet drug regimens, potentially contributing to the heightened occurrence of thrombosis. Consequently, despite the inherent antiplatelet aggregation properties of covered stents, this study's follow-up results underscore the ongoing necessity of anticoagulant treatment following covered stent implantation. In this study, there were two cases of surgical patients who suffered from postoperative massive hemorrhage, and one case of hypopharyngeal cancer with suspected involvement of the upper mediastinum. In this case, the tumor was not completely removed during the operation, leading to massive hemorrhage that occurred 40 days after the operation. Angiography was performed when a massive hemorrhage occurred. Considering the rupture of the left subclavian artery, the bleeding stopped after the implantation of another covered stent, which may be related to the dissection of the subclavian artery and may also be related to the invasion of the tumor. Another patient with massive bleeding from laryngeal cancer (occurring 32 days postsurgery) developed a pharyngeal fistula. In this instance, the common carotid artery became infected, causing the stent to become exposed. However, the source of bleeding resided below the proximal end of the stent. Tragically, the patient's family opted to forgo further medical intervention, and the patient ultimately succumbed to complications, potentially linked to arterial rupture stemming from infection.

We observed that subsequent adjuvant therapy (palliative radiotherapy, immunotherapy, and chemotherapy) after covered stent implantation did not significantly affect the OS time of the patients in this study. A possible explanation is that the available adjuvant treatments were not effective in improving survival in patients with this extremely advanced stage of head and neck cancer.[27] This may indicate that subsequent adjuvant therapy was not a critical factor in this study sample. Meanwhile, we also have to take into account that there are some methodological limitations of the study that may have affected the results. For example, a higher risk of death, a smaller sample size or a shorter follow-up period may have caused a bias in the results. To obtain more accurate and reliable conclusions, there is still a need to expand the sample size, extend the follow-up period, and standardize adjuvant therapy.

CONCLUSIONS

In summary, applying covered stent implantation in ASCCHN involving the carotid artery is safe and feasible. For surgical patients, this approach facilitates the precise location, dissection, and protection of arteries, resulting in more thorough tumor resection. For patients afflicted by CBS, it offers effective prevention and treatment options for carotid artery rupture and hemorrhage.

AUTHOR CONTRIBUTIONS

Hai-Dong Zhang: Writing—original draft/editing; performing surgery; data analysis. **Kai Sun**: Data collection; article writing and revision. **Zhen-Kun Yu**: Conceptual design; performing surgery; modification; reviewing/editing. **Shan-Chun Gong**: Performing surgery. **Kai Liu**: Modification; reviewing/editing. **Xian-Jun Lyu**: Implanted stent.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest

DATA AVAILABILITY STATEMENT

Data are available via source literature, for which all citations are included in the manuscript.

ETHICS STATEMENT

This study was approved by the institutional review board of BenQ Medical Center Affiliated to Nanjing Medical University (ethics No.: 2020041401).

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