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Original Article

A new double-lumen hemostatic device for treatment of intractable traumatic epistaxis induced by craniofacial basicranial fractures

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Abstract: Background and objective: Traumatic epistaxis is a complicated and sometimes life-threatening complication of skull-base fractures. The aim of the study was to observe the effect of a new hemostatic device on treatment of intractable traumatic epistaxis induced by craniofacial basicranial fractures. Methods: The study included 85 patients with intractable traumatic epistaxis induced by craniofacial basicranial fractures treated between January 2004 and December 2013 in our hospital. There were 58 males and 27 females between 18-66 years old with a mean age of (41.7±14.1) years and GCS score of (9.3±3.4) points (range, 3-15 points) on admission. The patients were treated with a new double-lumen hemostatic device together with a digital subtraction angiography (DSA) (Group A, 45 patients) or traditional anterior nasal packing with no use of DSA (Group B, 40 patients). The indices including hemostasis time, hemostasis success rate, infusion volume and hospitalization mortality were recorded and compared between the two groups. Results: In Group A, the success rate of hemostasis was 100%, with a mean hemostasis time of (13.1±2.9) min without obvious complications related to the operation or hemostatic device. Re-bleeding was found in 13 patients after the balloon deflation, all of whom were cured using an interventional therapy. The other 2 patients with negative DSA results were cured only with a prolonged compression time of the balloon. In Group B, the success rate of hemostasis was 62.5%, with a mean hemostasis time of (42.5±20.3) min, which was much longer than Group A ($P<0.05$). Group A had less blood transfusion with (600±244.9) ml and a lower hospital mortality (22.5%) compared with Group B ($P<0.05$). Conclusion: The new double-lumen hemostatic device combined with the DSA intervention is an effective treatment of traumatic epistaxis because of the shorter hemostasis time, higher hemostasis rate, lower blood transfusion volume and lower mortality rate compared with traditional anterior nasal packing.

Keywords: Epistaxis, hemostatic device, craniofacial basicranial fracture, digital subtraction angiography, nasal packing

Introduction

Traumatic epistaxis is a common complication resulting from a skull base fracture. The majority of patients can be cured using simple manual compression, cauterization or nasal packing [1]. However, some patients present with a complicated, and sometimes life-threatening, intractable epistaxis needing further treatment, such as cauterization, ligation of the external carotid artery, endovascular embolization, or endoscopic or microscopic surgeries [2]. How to quickly and effectively control the nasal bleeding remains a great challenge to clinicians.

There are various ways to stop bleeding, including posterior packing with a gel matrix [3] or using a device such as Foley catheter compression [4, 5], nasendoscope [6], Sengstaken-Blakemore tube [7], nasogastric [8, 9] and pneumatic nasal tamponade [10]. The success rate of posterior packing is 48%-83% [1]. Most reported patients need additional anterior nasal packing, even general anesthesia or tracheal intubation [11]. However, recurrence is commonly seen and many patients need a blood transfusion due to decreased blood pressure [12]. Moreover, there is no device that has the integrated function of ventilation, hemostasis and pedestal functions. In this study, we

Table 1. Baseline clinical and demographic characteristics of the patients

Group	Gender (M/F)	Age (years, $\bar{x}\pm s$)	GCS on admission		Open craniocerebral injury (case)	Craniotomy (yes/no)
			Average ($\bar{x}\pm s$)	GCS 3-5 (case)		
Group A	31/14	40.3±14.3	9.2±3.3	8 (17.8%)	5 (11.1%)	20/25
Group B	27/13	43.3±13.9	9.3±3.5	8 (20.0%)	6 (15.0%)	21/19
t/χ^2 value	0.019	-0.981	-0.109	0.000	0.284	0.55
P value	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05

Notes: Group A had the new double-lumen hemostatic device together with DSA. Group B only hadtraditional anterior nasal packing.

described a new double-lumen hemostatic device for controlling the nasal bleeding of intractable epistaxis to provide an alternative method for managing intractable traumatic epistaxis induced by craniofacial basicranial fractures.

Clinical data and methods

General information

Inclusion Criteria: (1) The patients at age range of 18-65 years old; (2) Patients with active nasal bleeding caused by craniofacial basicranial fracture on admission. Exclusion criteria: (1) Patients with a history of diabetes, hypertension, severe hepatic disease, severe kidney disease or malignant tumor; (2) Patients with severe thoracic and abdominal organ injury at admission; (3) Patients with a history of severe trauma or space-occupying lesions in the nasal cavity, in the menstrual period, with a history of hematological diseases or long-term use of an anticoagulant drug. The study involved 85 patients with intractable traumatic epistaxis treated from 2004 to 2013, including 58 males and 27 females with ages of 18-66 years. The patients were divided into groups using the new double-lumen hemostatic device with a DSA (Group A, 45 patients) or traditional anterior nasal packing with no use of a DSA (Group B, 40 patients). Group A included 45 patients with a male to female ratio of 31:14, mean age of (40.3±14.3) years, and GCS scores of (9.2±3.3) points on admission, including 8 patients (17.8%) with 3-5 points. There were 5 patients (11.1%) with an open craniocerebral injury, and 20 patients (44.4%) received craniotomy. Group B consisted of 40 patients, with a male to female ratio of 27:13, at mean age of (43.3± 13.9) years, GCS score of (9.3±3.5) points on admission, including 8 patients (20.0%) with GCS of 3-5 points. There were 6 patients (15.0%) with an open craniocerebral injury, and 21 patients (46.67%) received a craniotomy. There was no significant difference in aspects of gender, age, GCS scores, percentage of open craniocerebral injury or proportion of craniectomy between the two groups. See **Table 1**. All the patients signed an informed consent. The study was supervised and approved by the Institutional Ethics Committee of the Zhuji Hospital of Zhejiang University (200402).

Surgical methods

Basic life support and treatment were given immediately after patient admission. This treatment includes three priorities: (1) Open the airway to remove foreign bodies and blood clots, when tracheal intubation or a tracheal incision could be used, if necessary; (2) Quickly establish a vein passage for prompt blood transfusion if a patient's hemoglobin was below 70 g/L; (3) Use of a hemostatic device to control nasal bleeding. The double-lumen hemostatic device is 5-6 cm long and 4-5 mm in diameter and has two cavities. The large cavity is for ventilation and support of the nasal structure. The small cavity is for inflating a balloon with air. The front end of the catheter is wrapped with a hemostatic sponge and is approximately 2 cm long (**Figures 1**, **2**). Group B was hemostased with traditional anterior nasal packing with Vaseline gauze using the following steps: a petroleum-impregnated catheter was inserted into the posterior pharynx through the bleeding nostrils, and a balloon was inflated to a final volume of 5 ml. The catheter was then slowly pushed into the posterior nasopharynx and fixed. After the tube was properly fixed, a small amount of a saline solution was added into the anterior nasal passage to dilate the hemostatic sponge. By controlling the bleeding in a few minutes, a blood pressure examination and CT scan for head or cervical vertebra was subse-

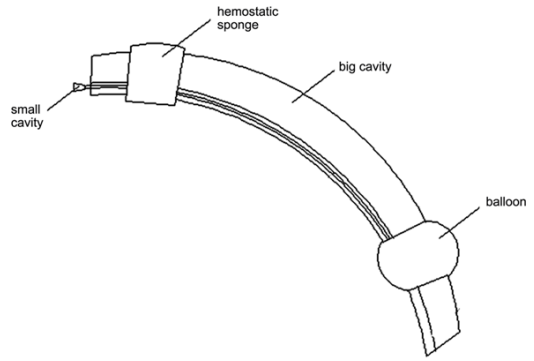

Figure 1. Schematic illustrations of thedouble-lumen hemostatic device. The device has two cavities. The large cavity has a function for ventilation and supports the nasal structure, while the small one is used to inflate the air to the balloon.

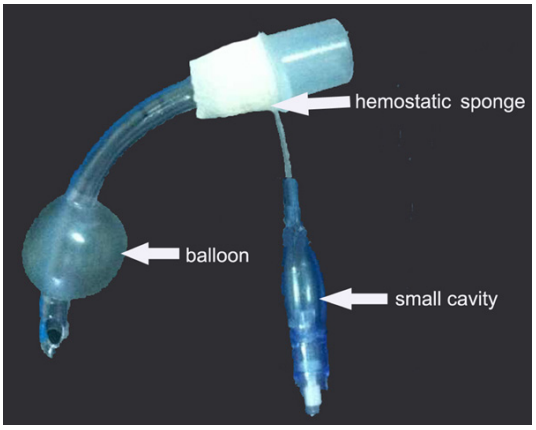

Figure 2. The structure of the double-lumen hemostatic device. The small cavity is used for inflating the air into the balloon, and the balloon is inflated.

quently performed. The catheter could be maintained for 36-48 hours. The balloon should be deflated to ensure hemostasis of the nasal bleeding. If homeostasis has not be obtained or if progressive proptosis, blindness orintracranial vascular murmur appears, the balloon should be inflated again, and a further DSA examination should be conducted. See **Figure 3**.

Follow-up and observation indices

The hemostasis time, success rate of hemostasis, clinical blood transfusion volume and mortality rate during hospitalization were compared between the two groups. All the patients were followed for more than 6 months to observe the progress.

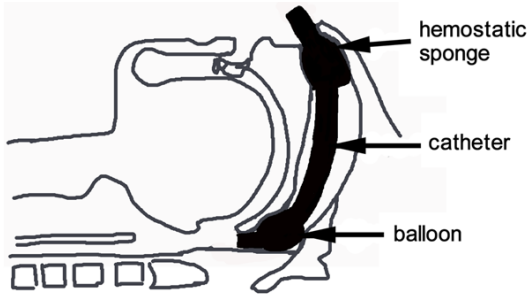

Figure 3. Drawing of how to use the hemostatic device. The petroleum-impregnated catheter is inserted through the bleeding nostrils into the posterior pharynx. The balloon is inflated with air from a small cavity with a final volume of 5 milliliters. A small amount of saline solution is added into the anterior nasal to make the hemostatic sponge expand and tightly pack the anterior nasal cavity.

Statistical analysis

SPSSPASW Statistics V18.0 was employed for statistical analyses. Enumeration data including intracranial infection rate, hospitalization mortality rate and success rate of hemostasis were processed using a *Chi-square* test. Measurement data including average time of hemostasis and clinical blood transfusion volume were assessed using a *t* test. A *P* value of <0.05 was considered statistically significant.

Results

Comparison on hemostasis success rate, time of hemostasis, rebleeding and infection between two groups

The average time of hemostasis, clinical blood transfusion volume, intracranial infection rate and hospitalization mortality rate were (13.1± 2.9) min, (350±151.7) ml, 6.7% and 6.67% respectively in Group A. Group A had a hemostasis success rate of 100%, with no obvious complications related to the operation or hemostasis device. After the release of the balloon, an emergency DSA examination found rebleeding in 13 patients, including 6 patients with a carotid cavernous fistula, 2 with anterior ethmoidal artery bleeding and 3 with sphenopalatine branch bleeding of the external carotid artery and the formation of a false aneurysm. All of these patients were treated with an interventional therapy. Another two patients with negative DSA results were cured only by prolonging the balloon compression duration. In

Table 2. Comparison of the treatment outcomes between the two groups

Group	Hemostasis duration (min, $\bar{X}\pm s$)	Successful rate of hemostasis	Transfusion volume (ml, $\bar{X}\pm s$)	Blood transfusion (case)	Intracranial infection (case)	Endovascular intervention (Y/N)	Hospital mortality
Group A	113.1±2.9	100%	350±151.7	6 (13.3%)	3 (6.7%)	11/34	3 (6.67%)
Group B	442.5±20.3	62.50%	600±244.9	13 (32.5%)	2 (5.0%)	9/31	9 (22.5%)
t/χ^2 value	1-9.502	-20.491	-2.286	4.482	0.106	0.044	4.279
P value	4<0.05	<0.05	<0.05	<0.05	>0.05	>0.05	<0.05

Notes: Group A had the new double-lumen hemostatic device together with DSA. Group B had the traditional anterior nasal packing.

Group B, the average time of hemostasis was (42.5±20.3) min. The success rate of hemostasis was 62.5%. Ten patients were treated with emergency interventional therapy due to combined symptoms including a carotid cavernous fistula, external carotid artery false aneurysm or maxillary artery branch bleeding. The clinical blood transfusion volume was (600±244.9) ml, and the hospitalization mortality rate was 22.5%, which were significantly different compared with Group A. The intracranial infection rate was 5% in the Group B, lower than 6.7% in the Group A, but the difference was not significant between the two groups.

After 36-48 hours, the bleeding was controlled in 32 patients and the devices were then removed when the balloon was deflated. Four patients with progressive proptosis and decreased visual acuity underwent a whole brain DSA examination. Three of these patients had a unilateral carotid cavernous fistula and they were cured using a successful balloon embolization. The other patient had a bilateral carotid cavernous sinus fistula and had a failed balloon embolization. This patient had to receive a bilateral stent coverage treatment several times. Unfortunately, visual impairment still persisted.

Re-bleeding was found in 9 patients when the balloon was deflated. The later treatment included re-inflating the balloon and a DSA examination. Two patients with negative results were cured after being treated with prolonged packing for another 48 hours. Two patients with a unilateral carotid cavernous fistula were treated using a balloon embolization. Two patients had anterior ethmoidal artery bleeding, and 3 patients had a pseudoaneurysm formation on the sphenopalatine branch of the external carotid artery. All of these patients were cured using a treatment with PVA particles (polyvinyl alcohol).

Prognosis of Group B

Three out of 45 patients were died of severe traumatic brain injury. Two patients were in vegetative state and 5 had severe disability 6 months after trauma. However, no patients were died from hemorrhagic shock. During 6 months of follow-up, 12 patients were reexamined with a DSA, and 20 patients underwent a CTA examination in Group B, which showed no obvious vascular abnormity.

Hemostasis success rate, rebleeding and outcome in Group B

In Group B, the nasal bleeding was successfully stopped in 25 patients but not stopped in 15. Five patients with a small amount of nasal bleeding received no special treatment, and the bleeding was finally controlled. Ten patients had a large amount of bleeding when the nasal packing was completed. Three patients were found with a carotid cavernous fistula, and 2 patients had anterior ethmoidal artery bleeding. Four patients had a pseudoaneurysm formation on the branch of the external carotid artery. All of them were treated using interventional therapy. However, 1 case with a carotid cavernous fistula had bilateral visual impairment after the treatment. One case with a pseudoaneurysm developed a large area cerebral infarction and was discharged with unstable breath and blood pressure. Another case with negative results was treated with prolonged packing, blood transfusion and a hemostatic agent. Moreover, no unexpected serious adverse reactions, such as intracranial infection or intracranial hematoma, were found. See **Table 2**.

Typical case

A 72-year-old woman was admitted to our hospital 30 min after a severe head injury caused by a traffic accident. A physical examination revealed unconsciousness with a massive epi-

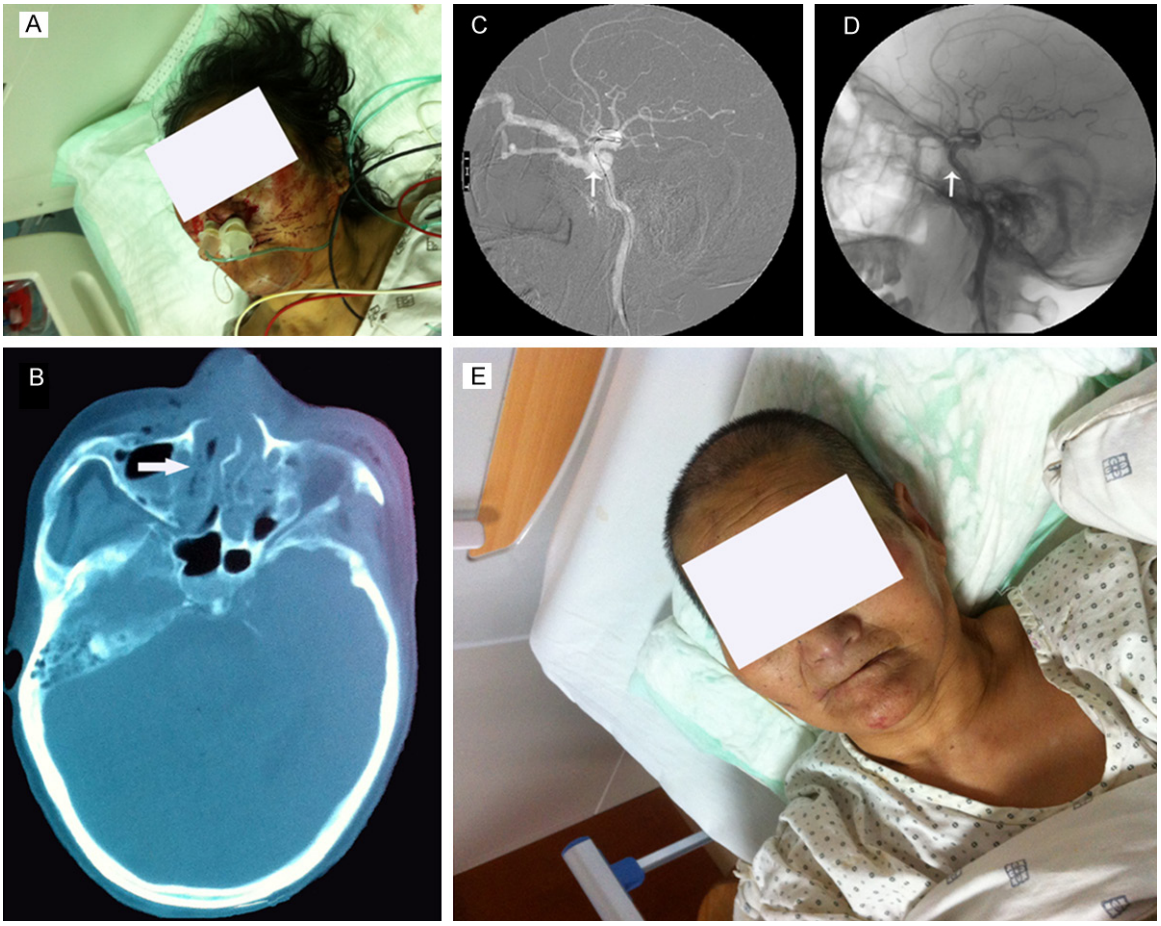

Figure 4. Illustrative case of a 72-year-old woman. A. The hemostatic device has been inserted into the patient's nostrils, and the nasal bleeding stopped; B. The CT scan revealed multiple facial fractures and a cranial base fracture. The antrum highmori and antrum ethmoidale were filled with a massive clot (white arrow); C. A digital subtraction angiography revealed a traumatic carotid-cavernous fistula and arterial blood was flowed that into the vena ophthalmica (white arrow indicates the orificium fistulae of TCCF); D. The fistula was successfully totally occluded (white arrow) after the endovascular implantation of a covered stent; E. The patient had a good outcome without any obvious complications.

staxis but with independent breath, a normal heart rate and a blood pressure of 110/70 mmHg. Swelling and bruising were observed in the bilateral eyelid, but the pupil reaction was normal. After cleaning the clot in the mouth, we inserted a petroleum-impregnated catheter through the bleeding nostrils into the posterior pharynx and inflate the balloon to the final volume of 5 milliliters (**Figure 4A**). The patient's nasal bleeding stopped immediately. A subsequent CT scan revealed multiple facial fractures and a cranial base fracture affecting the sphenoid and ethmoid bones. The antrum highmori and antrum ethmoidale were filled with a massive clot (**Figure 4B**). She was conservatively managed for the cerebral contusion. Unfortunately, although much slighter than pre-treatment, the patients' nasal bleeding began again when we deflated the balloon after 48 hours. We then inflated the balloon again and sent her for a DSA examination **Figure 4C**, **4D**. An emergency diagnostic angiography showed a traumatic carotid-cavernous fistula (TCCF). An endovascular covered stent was then immediately implanted. The fistula was successfully totally occluded. Two weeks later, the patient was discharged from our hospital with good recovery **Figure 4E**.

Discussion

Epistaxis is a common clinical problem. Although the majority of patients can be managed conservatively, some patients will develop

hemorrhagic shock due to extensive bleeding. Clinically, epistaxis can be classified as anterior or posterior bleeding based on its location. Intractable epistaxis is considered mainly the posterior bleeding that predominately originates from the sphenopalatine [13] and maxillary arteries [12]. The pathology may involve direct trauma and disruption of vessel or the formation of a pseudoaneurysm [12]. The main causes for life-threatening epistaxis caused by skull fracture are the direct damage to the arteriovenous venous sinus of the skull, mainly involving the carotid artery, sphenopalatine artery, or ethmoid artery. The main form of bleeding is a ruptured vessel or the formation of a pseudoaneurysm [14].

Epistaxis caused by a skull fracture may lead to massive blood loss after a short time. Many patients will develop hemorrhagic shock. Thus, transferring them from one place to another for examination or operation is risky. Therefore, stopping the bleeding quickly and effectively is much more important. Historically, the treatment for posterior epistaxis has consisted of anti-shock treatment, compression of the carotid artery and nasal packing. If the bleeding cannot be adequately controlled, a transantral surgical ligation of the branches of the internal maxillary artery may be used. However, this procedure may result in some complications and sometimes have no effect on bleeding control due to blindness [12].

Nasal packing is another conventional treatment to stop bleeding. Nasal packing is usually useful for anterior nasal bleeding but often fails in posterior nasal bleeding because the front part of the nose is small and the back part is large, or trumpet-shaped. The hemostatic gauze cannot reach the posterior part of the nose from the nostril. Other flaws of this method include that it is time-consuming, laborious, causes evident mucosal damage, and is more painful.

The presenting signs and symptoms of a traumatic carotid cavernous fistula include proptosis [15], chemosis [16], orbital bruits [6] and is associated with life-threatening epistaxis or intracranial hemorrhage [17]. The conventional nasal packing for traumatic epistaxis is anterior nasal packing. However, most nasal bleeding comes from the posterior nasal cavity. Methods used prior to posterior nasal packing caused many complications, such as leading to new damage to the nasal structure, vasovagal reaction, infection, intracranial hematoma, cerebrospinal fluid fistula, etc [5]. The operation process is often complicated, and some patients even need general anesthesia [10]. The success rate of posterior packing is between 48% and 83% [1].

The new device is simple. With this device, posterior nasal packing takes 5-6 min to complete with a success rate of 100% for bleeding hemostasis without serious complications. Moreover, the device has ventilation and pedestal functions. No anterior nasal packing was needed with this device, which often make the patients feel uncomfortable. Compared to the traditional anterior nasal packing, the new device shortened the time of hemostasis, decreased the blood transfusion volume [(350±151.7) ml vs (600±244.9) ml] and reduced the hospitalization mortality rate (6.67% vs 22.5%). The conventional nasal packing for traumatic epistaxis is anterior nasal packing. However, there was little effect with the anterior nasal packing because most nasal bleeding comes from the posterior nasal cavity. Previously used methods for posterior nasal packing cause many complications, such as leading to new damage to the nasal structure, vasovagal reaction, infection, intracranial hematoma, cerebrospinal fluid fistula, etc [5]. The process was often complicated, and some patients even need general anesthesia [10]. The success rate of posterior packing is between 48 and 83% [1].

In our group, there were six patients with a carotid cavernous fistula cured by an interventional treatment. Five patients had a rupture of the external carotid artery and were treated by PVA particles. Two patients had a negative angiography. The reason for the bleeding was thought to be the rupture of small branches of the external carotid artery. No special treatment was given to these patients, only a prolonged compression time. Their bleeding finally stopped. The nasal bleeding of 9 patients stopped when the hemostatic device was removed. All the patients were clinically followed for 6 months. Most of them were also followed with an angiography or CTA. On the contrary, the new device we designed (patent No.: ZL201420067243.2) has the advantages of being fast, convenient and less painful when inserting a balloon catheter into the front nostrils (usually within 5 min). The posterior cavity

can be adequately filled when the balloon is inflated. Moreover, no anterior nasal packing was needed. Only a small amount of saline solution was added to the hemostatic sponge and with little damage to the nasal mucosa. After 36-48 hours, the balloon was deflated to observe the status of the bleeding. If the bleeding was not well controlled, the balloon was deflated again. In the study, the nasal bleeding in all the patients was immediately controlled after using this new device. The blood pressure returned to normal, and the hemorrhagic shock was corrected. The blood transfusion volume was also significantly reduced. In the meantime, the surgeons may have enough time to do whole-brain DSA examinations or operations. A DSA can directly display a bleeding site and is a quick, safe, reliable, and less invasive medical treatment with minimal complications [13]. The rupture of an artery or the formation of a pseudoaneurysm on the branch of the external carotid artery caused by severe skull base fracture can be treated using a DSA intervention.

Traumatic carotid-cavernous fistula are usually treated by an endovascular balloon embolization. However, an endovascular covered stent is a safer, more feasible and life-saving procedure and a prudent mode of therapy [18]. In this study, one patient with a carotid-cavernous fistula was not cured using a balloon embolization. Instead, the patient was successfully treated using an endovascular-covered stent. None of the patients died of nasal bleeding, indicating the effectiveness of this new double-lumen hemostatic device combined with an endovascular intervention in the emergency treatment of an intractable traumatic epistaxis caused by skull base fracture.

In conclusion, the new double-lumen hemostatic device combined with an endovascular intervention is a fast, easy and effective method for intractable traumatic epistaxis caused by skull base fracture, which is available in pre-hospital care in poorly equipped institutions, even without DSA. Patients will have more opportunity for further treatment in other higher level hospitals if their bleeding can be well controlled. However, the exact clinical effect still needs to be proved by further clinical studies.

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Disclosure of conflict of interest

None.

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