

ENDOVASCULAR TREATMENT OF CAROTID-CAVERNOUS FISTULAS WITH LONG-TERM FOLLOW-UP: FROM BALLOON DEPLOYMENT TO STENT-GRAFT PARENT ARTERY RECONSTRUCTION

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ABSTRACT

Introduction: The long-term effect of endovascular treatment for traumatic direct carotid-cavernous fistulas (CCF) and this study served this purpose with the focus on the initial balloon deployment to stent-graft parent artery reconstruction.

Materials and methods: Between 1999 and 2012, 32 patients with traumatic direct CCFs were treated endovascularly at our institution and retrospectively analyzed. All patients had cerebral angiography for the diagnosis of CCF. Treatment modalities included balloon occlusion of the CCF, sacrifice of the ipsilateral internal carotid artery (ICA) with detachable balloons, coil embolization of the CCF and secondary pseudoaneurysms, and covered-stent reconstruction of the parent artery.

Results: All patients were successfully managed endovascularly. Three patients were initially treated with ICA sacrifice, 19 with detachable balloons or coils, and the remaining 10 with a covered stent. At angiographic follow-up (2-24 months), four (21.1%) of the 19 patients treated with detachable balloons and coils developed a pseudoaneurysm after occlusion of the CCF, and four (21.1%) patients recurred and were retreated with ICA sacrifice in three and coil embolization in one. In total, 29 embolization procedures were performed for the 19 patients with detachable balloons or coils, and six (27.3%) patients experienced permanent ICA occlusion before the application of the covered stent. Of 10 patients with covered stents, four patients initially failed detachable balloon deployment. Clinical follow-up (12-72 months) revealed complete occlusion of all the CCFs with no recurrence of CCF symptoms and signs.

Conclusion: Traumatic direct CCFs can be successfully managed endovascularly with increasingly better effects from detachable balloons to covered stent reconstruction of ICA.

Keywords: Direct carotid-cavernous fistula, Endovascular treatment, Detachable balloon, Covered stent, Follow-up.

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Introduction

Cavernous sinuses are a paired structure, 2 cm long and 1 cm wide, within the sphenoid bone in the anterior portion of the middle cranial fossa. Located on either side of the sella turcica and the pituitary gland, these sinuses extend anteriorly from the superior orbital fissure to the petrous portion of the temporal bone posteriorly. The cavernous sinus contains some important vascular and neural struc-

tures including a portion of cranial nerves III, IV and V, and the sympathetic plexus as well as a segment of the internal carotid artery (ICA) and its intracavernous branches⁽¹⁾. Direct carotid-cavernous fistulas (CCFs) are high-flow shunts with a direct connection between the intracavernous ICA and the cavernous sinus, usually arising from trauma or a ruptured aneurysm⁽²⁾. The goal of treatment is to eliminate the fistula with concurrent preservation of the ICA.

With continuous and, recently, rapid evolution of endovascular technology, numerous direct CCFs have been successfully treated through the endovascular approach⁽³⁾. Endovascular therapies with various embolization agents have been used to occlude the CCFs including detachable balloons, microcoils, liquid adhesives and covered stents or stent grafts. Although detachable balloons represent an important therapeutic option due to their efficacy, safety and procedure simplicity, they also have some pitfalls including premature deflation leading to CCF recurrence, pseudoaneurysm formation and low patency of the parent artery ICA (71%-88%)⁽⁴⁻⁷⁾.

The use of a covered stent may provide immediate occlusion of the CCF and concurrent preservation of the parent artery, greatly simplifying the endovascular procedure. Thus, an increasing number of patients are being treated with covered stent reconstruction of the parent artery⁽⁸⁻¹³⁾.

This study was to investigate the effect and safety of endovascular treatment of CCFs from detachable balloons to covered stent reconstruction of the parent artery in one single center with long term follow-up results.

Materials and methods

From August 2005 to January 2012, thirty-two consecutive patients with traumatic direct CCFs were treated at our institution. There were 21 males and 11 females with an age range of 5 to 71 years (mean 42 years). Clinical findings included exophthalmos and chemosis (in all 32 patients), diplopia and increased ocular pressure (in 25), decreased visual acuity and orbital bruit (in 25), orbital pain (in 18) and ptosis (in 14). Oculomotor and trigeminal nerve deficits occurred in 8 and 4 patients respectively. The CCF was on the right side in 18 cases, on the left in 12 and on bilateral sides in 2 (Table 1).

Transarterial embolization was usually performed with detachable balloons after the diagnostic angiography in the same session. Before the embolization procedure, all patients were tested with temporary balloon occlusion, and if they tolerated the test well, embolization would ensue. Following systemic heparinization (5000 U loading dose and then 1000 U/h), an 8 F guiding catheter was placed in the ICA of the diseased side for passing the coaxial balloon assembly. Thereafter, a latex balloon (Ingenor Medical System, Paris, France) mounted on the tip of a 3 F microcatheter was then

slowly navigated through the guiding catheter into the ICA. By gentle inflation and deflation of the balloon and carefully manipulation of the microcatheter, the balloon was negotiated across the fistula into the cavernous sinus by the blood flow. The balloon was then progressively inflated with diluted nonionic iodine contrast material (Omnipaque 300, Sanofi Winthrop, New York, USA), and ICA angiography was performed after each inflation to determine the extent of closure of the CCF and the patency of the ICA. If the control angiography showed complete closure of the CCF without parent artery occlusion, the balloon would be detached subsequently by gently pulling the microcatheter under fluoroscopic monitoring.

Several detachable balloons may be needed to occlude a large fistula. In the case of ICA sacrifice, a detachable balloon would usually be navigated through the guiding catheter to the place of the fistula or a little farther with the detachable balloon remaining within the ICA. Then, the balloon was progressively inflated until the ICA was totally occluded. Afterwards, a second detachable balloon would be sent to the proximal place of the first balloon and inflated so as to enforce the effect of ICA occlusion. After embolization, low-molecular-weight heparin was administered for every patient for 48 hours, and head restriction was forbidden for the patient who had to lie in bed for 48 hours. For covered stent (Willis, MicroPort, Shanghai, China) deployment, the patient would have premedication with oral aspirin (100 mg/day) and clopidogrel (75 mg /day) for at least three days. For emergency, a loading dose of 300 mg aspirin and 300 mg clopidogrel would be prescribed before the procedure. Following the deployment of the covered stent, low-molecular-weight heparin was used subcutaneously every 12 hours for three days, and aspirin and clopidogrel would be administered for 12 weeks. Then, aspirin was continued indefinitely.

Results

Of the 32 patients, 3 patients were initially treated with ICA sacrifice to complete occlusion, 19 with detachable balloon embolization of the fistula (Fig.1), and the remaining 10 with covered stent reconstruction of the parent artery (Table 1 and Fig. 2). Among the 10 patients with covered stent reconstruction of the ICA, four patients (21.1%, 4/19) initially failed the balloon embolization because of a small-sized fistula in two patients and ICA steno-

sis in another two preventing the passage of the balloon. Two patients had endoleak immediately following deployment of the covered stent and balloon post-dilatation resulted in complete occlusion.

At angiographic follow-up (2 - 24 months), of the 19 CCFs treated initially with detachable balloons, four (21.1%) recurred and were retreated,

with ICA sacrifice in three patients and coil embolization in one.

Four patients (21.1%) had no recurrence of the CCF but formation of a pseudoaneurysm which was treated with a covered stent in one patient, stent-assisted coil embolization in another, and detachable balloons in the remaining two.

No./age/sex	Site	Therapy	No. of treatment	Pseudoane-urysm	Clinical follow-up	Results
1/41/m	Right	Balloon	1	no	6 years	Occlusion
2/55/m	Left	ICA sacrifice	1	no	6 years	Occlusion
3/42/m	Right	Balloon/	2	no	5 years	Occlusion
		ICA sacrifice				
4/42/m	Right	Balloon/	2	no	5 years	Occlusion
		ICA sacrifice				
5/49/f	Left	Balloon	2	yes	4 years	Occlusion
6/5/f	Right	Balloon/	2	no	4 years	Occlusion
		ICA sacrifice				
7/24/m	Left	ICA sacrifice	1	no	4 years	Occlusion
8/71/m	Right	ICA sacrifice	1	no	3 years	Occlusion
9/29/f	Right	Balloon	1	no	3 years	Occlusion
10/46/m	Right	Balloon	1	no	3 years	Occlusion
11/48/m	Bilateral	Balloon/coil/covered stent	3	yes	3 years	Occlusion
12/28/m	Right	Balloon	1	no	4 years	Occlusion
13/32/m	Right	Balloon	1	no	4 years	Occlusion
14/21/m	Left	Balloon	1	no	2 years	Occlusion
15/37/m	Right	Balloon	1	no	2.5 years	Occlusion
16/49/f	Right	Balloon	1	no	3 years	Occlusion
17/41/m	Left	Balloon	1	no	1 year	Occlusion
18/45/f	Bilateral	Balloon	1	no	2 years	Occlusion
19/47/f	Left	Balloon	2	no	1 year	Occlusion
20/33/m	Right	Balloon/coils	2	yes	2 years	Occlusion
21/34/m	Right	Balloon/covered stent	2	yes	3 years	Occlusion
22/51/m	Right	Balloon	2	no	2 years	Occlusion
23/59/f	Left	Covered stent	1	no	3 years	Occlusion
24/63/m	Left	Covered stent	1	no	2 years	Occlusion
25/50/f	Left	Covered stent	1	no	1.5 years	Occlusion
26/37/m	Right	Covered stent	1	no	2 years	Occlusion
27/42/f	Right	Covered stent	1	no	2 year	Occlusion
28/46/f	Left	Covered stent	1	no	2 year	Occlusion
29/57/f	Left	Covered stent	1	no	2 year	Occlusion
30/64/m	Right	Covered stent	1	no	2 year	Occlusion
31/42/m	Right	Covered stent	1	no	2 year	Occlusion
32/59/m	Left	Covered stent	1	no	2 year	Occlusion

Tab. 1: Clinical and follow-up data of the patients.

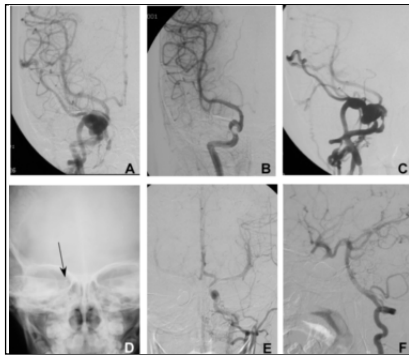


Fig. 1: A 5-year-old girl (patient 6) had a traumatic CCF on the right side. Injection through the right ICA revealed a direct CCF with venous drainage primarily through the ophthalmic vein. **B.** The detachment of a detachable balloon within the right cavernous sinus led to the complete obliteration of the fistula with concurrent compromise of the ICA. The right anterior cerebral artery was primarily supplied by the contralateral collateral circulation through the anterior communicating artery. **C.** Half a month later, the CCF was recurrent due to the premature rupture of the balloon within the cavernous sinus. **D.** Plain cranial x-ray film demonstrated the small mark on the deflated balloon (arrow). **E&F.** The right ICA was successfully sacrificed using two balloons with one detached within the right cavernous sinus and the other in the right ICA proximal to the fistula. Injection through the left ICA showed that the right anterior cerebral artery was supplied by the left ICA (**E**). Injection through the right vertebral artery demonstrated that the right middle cerebral artery was supplied by the right vertebral artery through the posterior communicating artery (**F**).

Another patient was intentionally treated in two different sessions of endovascular procedure, resulting in complete occlusion. One patient with coil embolization at the second time had formation of a pseudoaneurysm which was treated with a covered stent to reconstruct the parent artery. In total, 23 patients were treated once, 8 twice, and 1 thrice. Ten patients had covered stent reconstruction of the parent artery once only, and three patients had the initial treatment of ICA sacrifice, with one procedure for each patient. In the remaining 19 patients with the deployment of balloons, coils or covered stents, 29 embolization procedures were performed and ICA sacrifice was performed in another three patients (15.8%), with 9 patients each having more than one treatment procedures (the retreatment rate of 47.4%) and 10 patients only one procedure each.

A total number of 6 patients had ICA sacrifice, accounting for 27.3% of patients before the application of a covered stent. A statistically significant difference ($P < 0.05$) existed between patients with covered stent reconstruction of the parent artery and

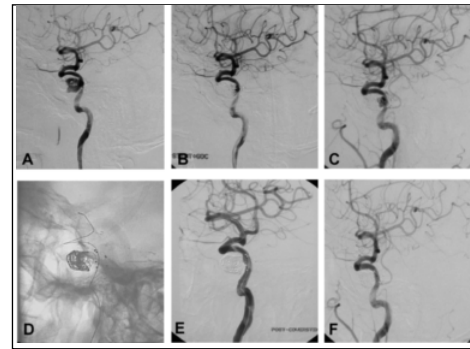


Fig. 2: A 48-year-old man (patient 11) had a traumatic bilateral CCFs that had been successfully treated with detachable balloon embolization. **A.** One and a half month after the embolization, a pseudoaneurysm was formed on the intracavernous portion of right ICA. **B.** Embolization with stent-assisted technique resulted in the total obliteration of the pseudoaneurysm. **C.** Follow-up cerebral angiography five months after the stent-assisted embolization demonstrated recurrence of the pseudoaneurysm due to coil compression. **D.** A microguidewire was navigated into the right middle cerebral artery for implantation of a covered stent. **E.** Post-stenting angiography showed occlusion of the pseudoaneurysm. **F.** Follow-up cerebral angiography three months after the covered-stenting procedure demonstrated total obliteration of the pseudoaneurysm.

those treated with balloons and ICA sacrifice, with covered stent reconstruction significantly better (Table 2). Clinical follow-up was performed for all patients 2-6 years after the endovascular procedure, all the CCFs and the pseudoaneurysms were completely occluded (Table 1).

Variables	ICA sacrifice	Balloons (%)	Covered stent (%)	Total
Once	3 (100%)	10 (52.6%)	10 (100%)	23
Twice	0	8 (42.1%)	0	8
Thrice	0	1 (5.3%)	0	1
Recurrence	0	4 (21.1%)	0	4
Pseudoaneurysm	0	4 (21.1%)	0	4
Treatment failure	0	4 (21.1%)	0	4

Tab. 2: No. of treatment, treatment failure, pseudoaneurysm formation and recurrence for patients with different initial treatment modalities.

Note: ICA, internal carotid artery. Significant difference ($P < 0.05$) existed in the patients treated with balloons compared with those treated with covered stent reconstruction.

Discussion

Endovascular embolization has been increasingly used for treating CCF, an infrequent complication of head trauma, despite improved techniques in cranial base surgery^(1, 6, 14-16), and in recent decades,

the endovascular approach has been considered the optimal treatment for direct CCF and has achieved a great success.

Although a number of different endovascular techniques are available, the most commonly used device worldwide is the detachable balloon first introduced by Serbinenko⁽¹⁷⁾. However, the balloon is not easy to use, and problems such as spontaneous detachment, premature deflation leading to CCF recurrence and parent artery perforation have been reported. Moreover, the greatest disadvantage for using detachable balloon is the rate of ICA sacrifice. Lewis et al⁽⁶⁾ reported a rate of ICA patency of 71% to 81% in treating 100 patients with CCFs using detachable balloons made by different companies. The size of the fistula may also greatly affect the likelihood of successful occlusion of the fistula with balloons. If the fistula is too small, it may affect the passage of the deflated balloon into the cavernous sinus, and if the fistula is too large, it may take many balloons to completely occlude the cavernous sinus and the balloon may also protrude into the ICA causing stenosis or distal embolization. Furthermore, a balloon already within the cavernous sinus may be an obstacle for the insertion of another balloon. Due to these pitfalls of detachable balloons, the treatment with this technique for direct CCF has even been withdrawn from the market in Brazil in 2009⁽¹⁸⁾.

Because of their good manageability, coils are now used more often either transarterially or transvenously for the treatment of direct CCF especially for small fistulas with a diameter of 2-3 mm^(12, 18-20). However, many coils may be needed for larger direct CCFs, which may increase the procedure cost and the probability of cranial nerve compression symptoms. Coil herniation into the parent artery is another risk, leading to possible distal misembolization, parent artery stenosis or occlusion^(7, 14, 21). Because direct CCFs are high flow fistulas, the use of solid (polyvinyl alcohol particles) or liquid agents (cyanoacrylate monomers, ethylene vinyl alcohol, absolute ethanol) as embolization materials have a great risk for distal migration, possibly leading to mis-embolization of the brain⁽²²⁾.

Covered stents or stent grafts are a recent promising technique for the treatment of direct CCFs, especially for recurrent, residual and multiple fistulas and those combined with pseudoaneurysms and parent artery dissections^(8, 9, 12, 13, 23).

This technique is quite simple and can achieve a rapid effect without the disadvantages of other

techniques with detachable balloons, coils or liquid agents.

However, the limitations for current covered stents include the stiffness, difficulty of navigation and the absence of unified preprocedural medications. The stiffness of the current covered stents may cause dissection of the parent artery. Endoleaks after deployment of the covered stent may also happen and have to be managed with postdilation with a balloon of larger diameter⁽²⁴⁻²⁶⁾. Thus, the refinement of the current covered stents is necessary for intracranial use. The Willis covered stent used in this study was made specifically for intracranial vasculature and could be navigated relatively easily^(27, 28). Long-term follow-up in our study revealed good patency of the covered stent. With the use of the covered stent, the parent artery may be spared from being occluded in techniques using detachable balloons, coils, and liquid materials. Since the use of covered stents in our center, the treatment goal of occlusion of the CCFs and concurrent preservation of the parent artery in treating direct CCFs was really achieved.

However, before the application of the covered stents, the rate of parent artery occlusion was 27.3%; for 19 patients with detachable balloons, the recurrence rate was 21.1%, and the incidence of pseudoaneurysm formation 21.1%. The appearance of endoleaks after the covered stent reconstruction of the parent artery is nothing compared with the recurrence, retreatment, formation of pseudoaneurysm, balloon or coil protrusion and distal migration leading to cerebral misembolization, and frequent parent artery sacrifice when using detachable balloons or coils. The endoleaks can be treated with postdilation using a slightly larger balloon or deployment of a second covered stent. The advent of the covered stent represents a great step forward.

When occluding the CCFs especially larger ones including those involving bilateral ICAs, one important issue we should take into consideration is to avoid hyperperfusion syndrome caused by abrupt occlusion of the blood shunt through larger fistulas. If a large fistula was abruptly completely obliterated, the cerebral perfusion pressure might increase suddenly due to closure of large shunts of blood flow and serious complications like intracranial hemorrhage might take place. In patient 11 with bilateral fistulas, we attempted in the first place to completely occlude bilateral fistulas in one session of procedure. However, the patient suddenly felt uncomfortable with vomiting and after total

embolization of the left smaller fistula and placement of a detachable balloon within the right cavernous sinus. So, the procedure was emergently stopped and another procedure was arranged for complete obliteration of the right larger fistula. The patient had a one-week interval for adaptation before the second procedure and no severe complications occurred except slight to mild headache caused by hyperperfusion resulted from complete occlusion of the right large blood shunt.

Since then, we adopted a strategy to embolize in two or more sessions a large fistula to avoid severe complications possibly caused by abrupt occlusion of large shunts of blood blow through the bigger fistula. Case 20 had a large fistula and we decided to occlude it in two different sessions. We first delivered 6 detachable coils within the cavernous sinus and then, three detachable balloons were detached within the same cavernous sinus, which did not result in total occlusion of the large fistula. The 6 coils together with three detached balloons had reduced the fistula to a smaller one. When the patient had adapted to the hemodynamic change brought about by partial embolization of the fistula, a second embolization procedure was carried out to totally obliterate the fistula without possible severe sequela. In this patient, the second procedure with detachable balloons allowed the patient two months for adaptation before the large fistula was completely occluded safely.

There is a certain incidence of pseudoaneurysm which usually develop a few weeks after embolization either because of deflation or migration of the detached balloons^(7,29). They are generally asymptomatic and may decrease in size and spontaneously seal off. However, large pseudoaneurysms may induce trigeminal pain or oculomotor palsy, necessitating occlusion with a second detached balloon or permanent sacrifice of the ICA. Pseudoaneurysms occurred in 14 of 74 (18%) patients in the series by Tsai et al⁽³⁰⁾, and Higashida et al⁽⁵⁾ reported an incidence of pseudoaneurysm of 2.8% (5/181). In our series, the incidence of pseudoaneurysm was 21.1% (4/19).

All these pseudoaneurysms happened secondary to deflation of the balloon and at a time when the fistula had disappeared. Because of the fragile wall and numerous lobulations of some pseudoaneurysms, endovascular management with covered stents would be a better choice than with detachable coils which might perforate the pseudoaneurysm. Utility of covered stents has been

reported with good results in treating extracranial and intracranial aneurysms and arteriovenous fistulas including CCFs^(8, 9, 11, 12, 23-25, 31-32). But the current generation of covered stents designed for coronary use is rather stiff and difficult to navigate in tortuous vessels particularly in the intracranial vasculature. More efforts should be directed towards the development of covered stents with sufficient longitudinal flexibility exclusively employed in the intracranial vasculature.

There were some limitations in this study, including retrospective nature, a small case series, non-control and non-randomization. Future studies may be directed towards prospective nature, randomization and control with a large cohort and multiple centers involved.

In conclusion, the endovascular technique for the management of direct CCFs is increasingly becoming refined from balloon detachment to covered stent reconstruction of the parent artery, with safer, greater efficiency, less recurrence and less retreatment.

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