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#### **ORIGINAL** RESEARCH

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### **Comparison of the Risk of Oculomotor Nerve Deficits between Detachable Balloons and Coils** in the Treatment of Direct Carotid Cavernous **Fistulas**

BACKGROUND AND PURPOSE: Transarterial balloon embolization used to be the preferred method for treating DCCFs; however, a strayed, overinflated, or migrated balloon may lead to oculomotor palsy. This investigation compared the use of detachable balloons and GDCs, which were previously used only in cases of balloon-technique failure and are now increasingly used as a first-line treatment for DCCFs, in terms of the risk of oculomotor nerve deficit, mortality/morbidity, and initial angiographic results.

MATERIALS AND METHODS: Among 48 patients with DCCFs treated with endovascular embolization at our institution between March 2004 and May 2009, 38 patients were included in this review. Patients who underwent trapping procedures, a second intervention within 2 weeks, or any procedure that included n-BCA infusion were excluded. Twenty of the enrolled patients were treated with transarterial balloons and the other 18, with GDCs.

RESULTS: Five patients (25%) in the balloon group and none in the coil group had oculomotor nerve deficits within 2 weeks. The rate of procedure-related oculomotor nerve deficit was significantly higher in the balloon group than in the coil group (P = .048). There were no significant differences in terms of procedure-related mortality/morbidity or initial angiographic results between the 2 groups.

CONCLUSIONS: The risk of procedure-related oculomotor nerve deficit in the treatment of DCCFs was significantly lower when using a GDC than with a detachable balloon. GDCs may, therefore, be considered as feasible, effective, and safe for DCCFs as detachable balloons.

ABBREVIATIONS: CS = cavernous sinus; DCCF = direct carotid cavernous sinus fistula; GDC = Guglielmi detachable coil; ICA = internal carotid artery; n-BCA = n-butyl cyanoacrylate

CCFs are high-flow shunts between the cavernous portion of the ICA and the CS. They are usually caused by traumatic laceration of the ICA or rupture of a pre-existing aneurysm in the cavernous segment of the ICA. The most serious complications of DCCFs are those associated with venous hypertension transmitted to either the eye or the brain, depending on the available route of venous drainage. Transarterial balloon embolization has historically been the preferred method of treatment for DCCFs, the aim of which is to occlude the fistula while preserving flow in the parent ICA. However, this can be risky or even impossible to achieve in some situations. Higashida et al<sup>1</sup> reported preservation of the parent ICA in 88% of patients with DCCFs treated by using detachable balloons, while other authors have described a need for parent artery occlusion in as many as 20% of cases.<sup>2,3</sup> In addition, straying, overinflation, or migration of a detached balloon may lead to deterioration of ocular palsy.4 GDCs were

previously used in cases in which the balloon technique failed. However, in the past few years, there has been a lack of availability of detachable balloons worldwide; therefore, the use of GDCs for the treatment of DCCFs has increased.

Detachable balloons have been used to treat DCCFs in our institution for the past 13 years, and detachable coils were previously used only when balloon embolization failed, partially because the cost was not always covered by the national health insurance, and if it was, it still usually took approximately 2 weeks to obtain approval. In the past 2 years, patients have been treated with GDCs as the initial treatment choice because the detachable balloon is no longer readily available. In this study, we compared the risk of oculomotor deficit in patients with DCCFs treated with detachable balloons and those treated with GDCs. In addition, the procedure-related mortality/morbidity and initial angiographic results were also compared.

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#### Materials and Methods

#### **Patients**

From March 2004 to May 2009, 48 patients with traumatic DCCFs were treated in our institution. Patients who underwent trapping procedures (n = 4), a second intervention within 2 weeks (n = 3), or any procedure that included n-BCA infusion (n = 3) were excluded from this study. Among the 38 patients enrolled, 20 were treated with transarterial balloon (GVB; Minvasys, Gennevilliers, France) detachment and the other 18, with GDC (Target Therapeutics/Boston Sci-

Patient demographics, fistula location, periprocedural complications, and outcomes			
	Balloon ( $n=20$ )	Coil (n = 18)	P Value
Mean age (yr)	38.5 ± 14.3	38.7 ± 14.7	.874
Sex (male)	13 (65.0%)	11 (61.0%)	.804
Mean time between trauma and treatment (days)	$67.3 \pm 73.2$	$151.1 \pm 230.5$	.077
Location of fistula <sup>a</sup>			.903
C2	1 (5.0%)	1 (5.6%)	
C3	6 (30.0%)	6 (33.3%)	
C4	11 (55.0%)	8 (44.4%)	
C5	2 (10.0%)	3 (16.7%)	
Procedure-related oculomotor nerve deficit	5 (25.0%)	0 (0.0%)	.048
Cranial nerve III	1		
Cranial nerve IV	0		
Cranial nerve VI	5		
Procedure-related mortality/morbidity	5 (25.0%)	1 (5.6%)	.184
Initial angiographic result			.880
Partial sealing	6 (30.0%)	5 (27.8%)	
Complete sealing	14 (70.0%)	13 (72.2%)	

<sup>&</sup>lt;sup>a</sup> According to the segmental division of the ICA classification by Debrun et al. <sup>10</sup>

entific, Natick, Massachusetts) placement. Double-balloon techniques were used in 3 patients in the balloon-treated group. In the GDC group, 9 patients were treated with stent-assisted coil placement and 2, with balloon-assisted coil placement. GDCs were the initial form of treatment for 5 patients, and a total of 13 patients were treated with GDCs after transarterial balloon embolization failed.

#### **Procedure**

All embolizations were performed via the percutaneous transarterial approach. Balloon embolization was performed with the patient under local anesthesia, and coil embolization, with the patient under general anesthesia. Neurologic status, including cranial nerve function, was checked immediately after the procedure in patients treated under local anesthesia and after waking in those treated under general anesthesia. All patients were admitted to the intensive care unit for at least 2 days after embolization with limited activities to prevent early balloon/coil migration and to monitor neurologic function. Patients were then transferred to the neurosurgical ward for at least another 2 days. Any event that occurred within 2 weeks of embolization was defined as procedure-related.

#### Statistical Analysis

Continuous variables were expressed as means  $\pm$  SDs and were compared by performing the Student t test. The Mann-Whitney rank sum test was used when the normality assumption of continuous data was not met. Categoric variables were compared by using the  $\chi^2$  test or the Fisher exact test. All statistical analyses were performed by using Stata statistical software (Release 10.1; StataCorp, College Station, Texas). A P value  $\leq$  .05 indicated a significant statistical difference.

#### **Results**

#### Patient Population and Lesion Location

The patient demographic and fistula location data are presented in the top half of the Table. There were no significant differences between the groups in mean age, sex, or fistula location. The average time between trauma and the embolization procedure was  $67.3 \pm 73.2$  days in the balloon group and  $151.1 \pm 230.5$  days in the coil group. Two reasons contributed to the greater time interval in the coil group: first, it took, on average, approximately 2 weeks to receive national health in-

surance approval for the insertion of GDCs. Second, in more than half of the patients treated with coils, initial treatment with balloons had been attempted but failed. However, this difference in time interval between trauma and procedure was statistically insignificant.

## Procedure-Related Complications and Initial Angiographic Results

The procedure-related oculomotor nerve deficit, mortality/ morbidity, and initial angiographic results are summarized in the bottom half of the Table. Five patients (25%) in the balloon group had oculomotor nerve deficit after embolization; 4 had sixth cranial nerve palsy, and 1 had simultaneous third and sixth cranial nerve palsy. Oculomotor nerve deficit was noted immediately after the procedure in 3 patients and on the 2nd day after embolization in 2 patients. No patient in the coil group experienced procedure-related oculomotor palsy, and the proportion of patients with procedure-related oculomotor nerve deficit was significantly higher in the balloon group than in the coil group (P = .048). One patient experienced ICA dissection during coil placement, which led to ipsilateral ischemic stroke and contralateral limb weakness. No mortality or morbidity other than oculomotor nerve deficit was identified in patients treated with balloon embolization, and there were no significant differences between the groups in terms of procedure-related mortality/morbidity. Complete sealing of the fistula was achieved in 70% of patients who underwent balloon embolization and 72.2% who underwent coil placement.

#### Discussion

Ever since the use of balloons for the treatment of DCCFs was described by Debrun et al<sup>5</sup> and Serbinenko, <sup>6</sup> transarterial balloon embolization has been the criterion standard treatment for most patients with DCCF. Higashida et al<sup>1</sup> reported preservation of the parent artery in 88% of patients with DCCFs treated by using detachable balloons; other authors have described a need for parent artery occlusion in as many as 20% of cases. <sup>2,3</sup> Technical difficulties are not uncommon and are related to the size of the fistula and the cavernous sinus. The fistula should be smaller than an inflated balloon but large

enough to allow passage of a deflated or partially inflated balloon, and the CS should be large enough to accommodate an inflated balloon or balloons. Failure often occurs when the fistula orifice is too small to allow entry or when a large fistula is combined with a small CS, allowing retraction of the inflated balloon into the ICA.<sup>7</sup> We previously developed a double-balloon technique for use in such difficult cases.<sup>8</sup> In addition to these technical difficulties, complications related to detachable balloon embolization of DCCFs are not uncommon and include venous stasis, orbital congestion, cerebral ischemia (3%), cerebral infarction (4%), and permanent neurologic damage (3%).<sup>9</sup> Third and sixth nerve palsy after balloon embolization has also been observed. Debrun et al<sup>10</sup> reported a 20% incidence of transient oculomotor nerve palsy, which is usually attributable to sixth cranial nerve dysfunction.<sup>11</sup>

For DCCFs that are not successfully treated with ICA preservation by using a detachable balloon, transarterial GDC embolization is an alternative treatment. In 1992, Guglielmi et al<sup>12</sup> successfully treated DCCFs by transvenous GDC embolization, and there have been several subsequent reports of transarterial GDC embolization of DCCFs with favorable results. 13-15 The advantages of using GDCs are the ability to control their placement and easy retrieval and repositioning or exchange if necessary. It is also technically easier to guide a microcatheter and microguidewire combination through a small fistula than a balloon. However, in some cases, the anatomy of the involved compartment of the CS may prohibit efficient and correct packing of coils, leaving a partially patent DCCF. Repeat embolization is, therefore, common in patients undergoing GDC embolization of DCCFs. Bavinzski et al<sup>14</sup> reported a case of a DCCF treated with GDC embolization in which the patient developed a massive exophthalmos and had abducens palsy and a decrease in visual acuity 6 days after embolization, owing to thrombosis of the superior ophthalmic vein. Another disadvantage of the GDC is its cost. As noted above, in the past few years, there has been a lack of availability of detachable balloons worldwide; thus, the use of GDCs as the primary choice for the treatment of DCCFs has increased.

In this investigation, we found that the risk of oculomotor nerve deficit was significantly higher when using a detachable balloon than a GDC for the treatment of DCCF. A possible reason for the occurrence of oculomotor palsy may be overinflation or migration of the balloon, leading to direct compression of the cranial nerves. The structures within the CS are contained within a membranous structure, and the inferior and medial portions of the membranes are composed of periosteum and are continuous with the periosteal layer of dura covering the middle fossa and sella turcica. The superior and lateral portion of the membranes are continuous with the connective tissue sheaths of cranial nerves III, IV, and V and may indirectly affect the course of cranial nerve VI, which runs across the ICA and enters the superior orbital fissure beneath the ophthalmic division of the trigeminal nerve. Consequently, a space-occupying lesion or increased pressure within the CS, which can be caused by a tumor, a DCCF, a dural fistula, thrombosis, or a balloon, may compress or affect some of these structures. In contrast, a GDC is very pliable and adapts to the shape of the CS without exerting a significant mass effect on the cranial nerves.<sup>12</sup>

The average time between trauma and embolization for the 5 patients who developed oculomotor deficits after embolization was 94.0  $\pm$  108.4 days, which was in between the averages for the balloon and coil groups. Oculomotor nerve deficit was noted immediately after the procedure in 3 patients and on the second day after embolization in 2 patients. Three patients recovered from oculomotor nerve deficit (60%), but the condition was still observed at 2 weeks after embolization in 2 patients and at 1 month after embolization in 1 patient. One patient had not recovered from the oculomotor deficit 3 months after embolization and was subsequently lost to follow-up; the other patient had not regained oculomotor nerve function by the 1-month clinical follow-up. This patient was angiographically cured after the first embolization with a detachable balloon but developed cranial nerve III and VI palsy. Recurrent symptoms of exophthalmos and conjunctival injection were noted 1 month after embolization, and recurrent DCCF was diagnosed and cured by endovascular trapping.

Transarterial *n*-BCA embolization of DCCFs has been reported to be an efficient treatment for DCCFs when a transarterial detachable balloon or GDC fails to seal the fistula; this procedure has the advantage of being relatively easy to deliver through a microcatheter, producing rapid induction of thrombosis and permanent occlusion after polymerization. Luo et al<sup>16</sup> reported that 16.7% of patients who underwent *n*-BCA embolization experienced temporary impairment of cranial nerve function, which resolved completely in each case within 6 months. We did not include patients treated with *n*-BCA in this study because we were concerned that complications associated with *n*-BCA might confuse our conclusions. However, it is important to investigate the complications associated with *n*-BCA, especially if this procedure is routinely used for the embolization of DCCFs.

Finding no obvious differences in terms of patient characteristics, fistula location, procedure-related mortality/morbidity, or initial angiographic results between the 2 groups suggests that GDCs may be as feasible, effective, and safe for DCCFs as detachable balloons. However, we did not include long-term follow-up results in the statistical analysis because almost one-fifth of the patients included in this retrospective study were lost to follow-up after 3 months. This is a limitation of this study and further investigation is necessary.

#### **Conclusions**

The risk of procedure-related oculomotor nerve deficits for the treatment of DCCFs was significantly lower using GDCs than using detachable balloons. GDCs may, therefore, be considered a feasible, effective, and safe method for the treatment of DCCFs, but there is a need for investigation of long-term results.

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