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Advances in endovascular aneurysm treatment: are we making a difference?

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Abstract Recent advancements in endovascular aneurysm repair, including bioactive and expansile coils and intracranial stents, hold promise for improved aneurysm occlusion rates. We report the immediate and midterm clinical and angiographic outcomes of a consecutive series of patients treated since the advent of these technologies. Clinical and radiological records of 134 patients with 142 aneurysms treated between 2001 and 2004 were retrospectively evaluated by an independent neurologist. Endovascular procedures were analyzed by an independent neuroradiologist blinded to all clinical information. Seventy-two ruptured and 60 unruptured saccular aneurysms, nine fusiform and one post-traumatic aneurysm were treated. Matrix coils were used in 53% of saccular aneurysms and HydroCoils in 13% of all aneurysms. Neuroform stents were deployed in 19% of aneurysms. Angiographic total or subtotal occlusion was achieved in 76% of cases and in 96% at last follow-up. Aneurysm recanalization was observed in 14% over a mean follow-up of 12 months, and 18% of aneurysms were retreated. Clinically relevant complications occurred in 6.0%, resulting in procedure-related morbidity of 0.6% and 0.6% mortality at 6 months. No aneurysm bled over a cumulative 1,347 months of observation. Newer embolization technologies can be exploited successfully even in more complex aneurysms with very low morbidity and mortality.

Keywords Aneurysm · Coils · Endovascular treatment · Interventional neuroradiology · Intracranial aneurysm · Stents

Introduction

Endovascular coil embolization of intracranial aneurysms has gained broader acceptance and substantially increased utilization since the introduction of the Guglielmi detachable coil (GDC) in 1991. The recent large ISAT trial [1] and ISUIA series [2] indicate that endovascular therapy may be more appealing than classic neurosurgical treatment for many patients with ruptured and un-ruptured aneurysms. Detractors from the endovascular management of aneurysms are quick to point out that while surgically clipped aneurysms have a known long-term durability, there is a lack of extended follow-up of patients managed by coil embolization. Several newer reports have indicated excellent midterm occlusion rates following GDC treatment with recanalization rates ranging from 0 to 37% [3–9].

While surgical strategies have changed little, there continue to be significant advances in embolization

technology, with improved microcatheter design, coiling techniques (such as balloon remodeling), new coil design including bioactive and expansile hydrogel coils and the introduction of intracranial stents. These additions to the endovascular armamentarium are aimed at improving immediate occlusion rates and enhancing long-term durability without increasing procedure-related complications and morbidity. This study is intended to address whether this promise is being achieved.

Methods

We performed a retrospective review of clinical and radiological records of all patients treated endovascularly for a cerebral aneurysm at our tertiary referral center between October 2001 and July 2004. The study was approved by the local institutional review board. Records were reviewed by an independent neurologist. Aneurysm type was defined as saccular, fusiform, mycotic or traumatic. Aneurysm size was defined as the greatest diameter of the dome (small ≤ 7 mm; large > 7 mm), and neck size was rated as large [neck to dome ratio (n:d) > 0.5] or small (n:d < 0.5) Aneurysm presentation was dichotomized as either ruptured or un-ruptured. Subarachnoid hemorrhage (SAH) clinical grade was assessed by the Hunt and Hess (HH) score upon admission or just following emergent ventriculostomy placement. Fisher grade (FG) documenting SAH extent was modified to FG 1–3 with or without intraventricular hemorrhage (IVH). Patients had clinical assessments using the modified Rankin Scale (mRS). A change in mRS from baseline to mRS 2–5 at follow-up classified morbidity.

Materials used for embolization included: GDC and Matrix coils (Boston Scientific, Fremont, Calif.), HydroCoils (Microvention, Aliso Viejo, Calif.) and stents (Neuroform Stent, Boston Scientific, Fremont, Calif.). The use of balloon remodeling technique was also recorded. General anesthesia was used in 127 (94.8%) patients, and sedation in seven.

Complications were categorized by type and rated as technical (events during the procedure with no clinical consequence); transient (brief clinical symptoms resolving in less than 1 day, or a groin hematoma not requiring transfusion); minor (post-procedure clinical deficits without new disability or a groin hematoma requiring transfusion); or major (clinical changes resulting in disability or complications requiring surgical intervention). Immediate and follow-up angiographic results were graded by an independent blinded neuroradiologist on a three-point scale (complete occlusion, neck remnant, or residual aneurysm) as previously defined [5], or as treatment failure. Assessments were compared with angiographic results recorded in operative reports. When discrepancy existed, a consensus was obtained by simultaneous blinded angiogram review by two study authors.

Statistical analysis was performed using VassarStats (available at http://faculty.vassar.edu/lowry/VassarStats.html). The χ^2 and Fisher-exact tests were used for categorical variables and Student's *t*-test was used to compare normally distributed data. Statistical significance was defined as $P < 0.05$.

Results

A total of 142 aneurysms were treated in 134 patients. The mean age was 56.2 years (range 11–88 years) and 100 (74.6%) patients were women. Hypertension was the most common risk factor ($n = 62$), followed by current/past tobacco use ($n = 26$). Aneurysm type included 132 saccular, nine fusiform (including one mycotic) and one traumatic aneurysm treated simultaneously with an un-ruptured saccular aneurysm. Demographic data, aneurysm characteristics and location, and baseline clinical status of ruptured and un-ruptured saccular aneurysm patients are reported in Tables 1, 2, 3 and 4.

Of 132 saccular aneurysms (125 patients), 129 were treated de novo and three aneurysms had prior incomplete repair (two coiling and one clipping) at outside institutions. The majority of ruptured aneurysms (68.1%) measured ≤ 7 mm whereas small aneurysms

Table 1 Demographics and aneurysm characteristics

	Ruptured	Un-ruptured
Patients (*n*)	71	54
Aneurysms (*n*)	72	60
Age (years), range (mean ± SD)	28–87 (56.9 ± 15.0)	11–88 (56.6 ± 13.5)
Gender (% female)	76.1	76.7
Time to therapy (days), range (mean ± SD)	0–14 (2.7 ± 3.2)	Not applicable
Anterior circulation (%)	83.3	93.3
Aneurysm number, range (mean ± SD)	1–4 (1.28 ± 0.61)	1–7 (1.65 ± 1.11)
Aneurysm size (mm), range (mean ± SD)	2.3–60.0 (7.7 ± 7.9)	2.0–25.0 (8.5 ± 5.0)
Large aneurysm (%)	31.9	52.6
Large neck (%)	51.4	60.7

Table 2 Aneurysm location (*ACA/A-comm* anterior cerebral/anterior communicating artery, *ICA* internal carotid artery, *P-Comm/ach* posterior communicating/anterior choroidal artery, *PICA* posterior inferior cerebellar artery)

Location	Saccular Ruptured/ un-ruptured (*n*)	Fusiform (*n*)
ACA/A-comm	21/7	0
Middle cerebral artery	3/3	1[a]
ICA bifurcation	3/9	0
ICA cavernous	0/3	0
ICA supraclinoid	3/5	0
Ophthalmic	4/8	0
P-Comm/ach	21/14	0
Superior hypophyseal	5/7	0
Posterior cerebral artery	0/0	3
Basilar tip	4/3	0
Basilar trunk	3/0	1
PICA	3/1	2
Vertebral–basilar junction	1/0	2
Superior cerebellar artery	1/0	0

[a]Treated following extracranial–intracranial bypass

constituted 47.4% of un-ruptured aneurysms ($P=0.02$). There was no significant difference between mean aneurysm size ($P=0.25$) or the proportion of large neck vs small neck aneurysms ($P=0.44$) by treatment cohort. In 132 aneurysms, GDC coils were placed in 56 cases, Matrix in 44 and Matrix/GDC combination in 16. HydroCoils were used in combination with GDC in three cases, Matrix in seven and both in three. Treatment failed in three cases. Balloon remodeling technique was used in 29 patients. Neuroform stents were deployed in 19 cases (four ruptured and 15 un-ruptured) during aneurysm embolization and in two cases in sessions prior to coil placement. Fourteen patients required retreatment. Only one patient was treated by surgery and the other 13 patients were treated endovascularly using GDC coils in one case, Matrix coils in three, Matrix coils/stent in four, Matrix/GDC/HydroCoils combination in two and Neuroform stents without additional coils in three (one patient had a stent placed within a previously deployed stent).

Nine fusiform aneurysms in nine patients were treated with parent vessel occlusion. Mean age was 48.1 years (range 23–75 years) and four of nine were women. Four patients presented with SAH. Pre-embolization, one patient had selective WADA testing and three patients had balloon test occlusion. Embolization was performed using GDCs coils in six cases, HydroCoils in two and GDC/HydroCoil combination in one.

Table 3 Baseline status of ruptured cohort

HH score	Patients (*n*)	Fisher grade	No IVH (*n*)	IVH (*n*)
I	16	1	8	2
II	19	2	16	2
III	23	3	26	16
IV	13	Isolated IVH		1
V	0			

Angiographic results

Immediate angiographic results showed complete occlusion in 80/142 (56.3%) aneurysms, including nine fusiform aneurysms treated by parent artery occlusion, neck remnant in 28/142 (19.7%), residual aneurysm in 31/142 (21.8%) and failure in three. Complete occlusion was significantly more frequent in saccular aneurysms with small necks (69.6 vs 41.4%, $P=0.003$), in small domes (66.7 vs 34.0%, $P=0.0005$) and in saccular aneurysms presenting with SAH (62.5 vs 43.3%, $P=0.04$).

Complications

Technical complications included two thromboembolic complications treated with intraarterial abciximab, three coil migrations, two intraoperative ruptures controlled with coils, two groin hematomas and one dissection. Transient complications included one hemorrhage with brief post-operative hemiparesis and one thromboembolic with transient Wallenberg syndrome. Minor complications included one groin hematoma requiring blood transfusion, one oculomotor nerve palsy and two thromboembolic events (one embolic infarct with symptomatic quadrantinopia and one mild hemiparesis more likely related to concurrent SAH induced vasospasm than the procedure). Major complications included one thromboembolism resulting in persistent hemianopia, one coil migration requiring surgical extraction and one case of bilateral subdural hematomas requiring surgical evacuation. This latter patient's 1-month mRS was four, but significantly improved by 6 months to a mRS of one. In another patient with a giant aneurysm, vessel perforation of the ACA by the microwire was responsible for SAH/IVH, culminating in death. The latter two patients were both under high-dose antithrombotic therapy (aspirin, clopidogrel and abciximab) for planned Neuroform stent assisted coil embolization.

Overall, clinically significant procedural complications including mortality occurred in eight of 134 patients (6.0%) with 142 treated aneurysms (5.6%) by 156 procedures (5.1%), including 14 aneurysm retreatments with no complications. Complications were not associated with patient age (≤ 50 years vs >50 years, $P=0.92$), aneurysm neck size (large vs small, $P=0.28$), aneurysm dome size (≤ 7 mm vs >7 mm, $P=0.62$) or clinical cohort (ruptured vs un-ruptured, $P=0.23$).

Table 4 Clinical characteristics of un-ruptured cohort

Aneurysm symptoms	*n*	Baseline mRS	*n*
Incidental	27	0	43
Headache	12	1	9
Diplopia	6	2	0
Tinnitus	3	3	2[a]
Seizure	1	4–5	0
Focal deficit	1		
Past SAH	4		

There were no complications during pre- or post-treatment angiographic studies.

Angiographic outcome

Angiographic follow-up of at least 6 months duration was available for 77/142 aneurysms (54.2%), with mean follow-up of 12 months (ranging from 6 to 31 months). Among these 77 aneurysms, 43 (55.8%) were initially occluded (including four fusiform aneurysms treated with parent artery occlusion), 18 (23.4%) had neck remnants and 16 (20.8%) were residual aneurysms.

Of 43 initially complete aneurysms, 33 (76.7%) remained occluded, nine (21.0%) developed neck remnants (one aneurysm was subsequently clipped and four aneurysms were retreated endovascularly) and one (2.3%) became a residual aneurysm. Of 18 aneurysms with initial neck remnants, 15 (83.3%) were unchanged (five were retreated), two (11.1%) progressed to complete occlusion and one (5.6%) recanalized to a residual aneurysm. Of 16 initial residual aneurysms, eight (50%) progressed to complete occlusion, four (25%) evolved to neck remnants (one was retreated) and four (25%) persisted as residual aneurysms (three were retreated). Overall, 52 (67.5%) aneurysms were unchanged in classification of angiographic occlusion (33 occlusion, 15 neck remnants and four residual aneurysm). Initial occlusion rates were not statistically different between patients with vs without midterm follow-up ($P = 0.78$). Eleven (14.3%) aneurysms recanalized (including the appearance of nine small neck remnants). Recanalization was independent of rupture status ($P = 0.51$), neck size ($P = 0.38$) or dome size ($P = 0.44$).

Only one embolization session was performed in 63 aneurysms, while 14 aneurysms required retreatment. Only one aneurysm of 14 was retreated by surgery after a 6-month follow-up angiogram showed the development of a neck remnant. The other 13 aneurysms (ten neck remnants and three residual aneurysms) were retreated endovascularly from 3 to 15 months (mean 7 months) after the first endovascular treatment. Immediately after the second treatment, there were four complete occlusions and nine small neck remnants.

At last follow-up there were 49 (63.6%) completely occluded aneurysms (six after second treatment), 25 (32.5%) neck remnants (seven despite second treatment) and three (3.9%) residual aneurysms. Angiographic outcome is summarized in Table 5.

Clinical outcome

Table 6 summarizes functional outcome by clinical presentation. Among 134 patients, 12 died (one from the endovascular procedure and 11 due to SAH related complications), 16 patients were lost at 1-month follow-up and 14 at 6-month follow-up. Thus, there were 106 patients at 1-month follow-up and 92 patients at 6-month follow-up. In the latter 92 patients, follow-up was available for a mean of 13 months (ranging from 6 to 33 months). All patients with procedure-related complications had at least 1 month mRS.

The median 1-month and 6-month mRS was 0 for both ruptured and un-ruptured cohorts (mean mRS: ruptured 1-month = 1.25; 6-month = 0.61; un-ruptured 1-month = 0.16; 6-month = 0.05). In the fusiform cohort, one patient had procedural morbidity at 1 month and 6 months, while the other patients showed good tolerance to parent artery occlusion.

For 156 total procedures (including 14 retreatments), 1-month and 6-month procedural morbidity rates were 1.3 and 0.6%, respectively, with a procedural mortality rate of 0.6%. No patient experienced aneurysm rupture over a mean of 9.5 months (range 0–32.6 months, totaling 1,347 cumulative months) follow-up.

Table 5 Angiographic results

Outcome	Immediate		Last follow-up
	All cases *n* (%)	Cases with follow-up *n* (%)	*n* (%) [with retreatment, *n*]
Complete	80 (56.3)	43 (55.8)	49 (63.6) [6]
Neck remnant	28 (19.7)	18 (23.4)	25 (32.5) [7]
Residual aneurysm	31 (21.8)	16 (20.8)	3 (3.9)
Total	139 (97.9)	77 (100)	77 (100)

Table 6 Six month functional status by clinical presentation

Ruptured	Six-month mRS		
	0–2 (*n*)	3–5 (*n*)	6 (*n*)
HH I–II (*n* = 29)	26	1	2
HH III (*n* = 17)	12	1	4
HH IV–V (*n* = 12)	4	3	5
Un-ruptured	Six-month mRS		
	0–2 (*n*)	3–5 (*n*)	6 (*n*)
n = 43	42	0	1

Discussion

Advances in endovascular devices and embolic materials have broadened the indications for endovascular aneurysm repair. Many aneurysms in this series were treated with new devices and techniques, including bioactive (49%) and expansile coils (13%), stents (19%) and balloon remodeling (22%). To our knowledge, this is the largest series of aneurysm embolization to date that incorporates these newer techniques, allowing for an assessment of their benefit on clinical and angiographic outcome compared with other large recently published cohorts.

Our initial complete and subtotal occlusion rates of 56.3 and 76.0%, respectively, compare well with series using bare platinum coils (mostly GDC) where occlusion rates varied between 33 and 73% [2–8, 10–12]. Immediate complete occlusion was significantly more common in patients with small aneurysm domes and necks and in those treated in the acute setting of SAH. These findings have been associated with improved angiographic outcome across many series. In our series, the association between complete occlusion and ruptured aneurysms is likely a consequence of significantly greater numbers of small aneurysms in the ruptured vs un-ruptured cohorts, even though mean aneurysm size did not significantly differ between groups. This association was also reported in one large series [10] but not confirmed in another [6].

Our classifications enabled a simplified determination of which complications had clinical implications. Our complication rate was 6.0% (5.1% per procedure), while other authors using similar definitions [6, 10] report rates of 6.1–14.4%. In other series [8, 9, 11], major complications were reported in 2.4–5.2%. In accordance with another series [5], we did not find an association between complication rate and patient age, aneurysm neck or dome size or rupture status. One study [11] found increased complications during coiling of posterior circulation aneurysms. Although endovascularly treated aneurysms may require retreatment, no complications were observed in our retreated patients. Our two major hemorrhagic complications occurred in patients planned for stent deployment and were consequently aggravated and/or related to the antithrombotic therapy needed for this procedure.

The use of disability (mRS≥2) and not dependency (mRS≥3) as the cut-off point for morbidity is stricter than other endovascular and most surgical series, including ISAT and ISUIA. Our 1-month and 6-month procedural morbidity (1.3 and 0.6%, respectively, with a 0.6% procedural mortality rate) is much lower than that of ISUIA, reporting 5.8% morbidity and 3.1% mortality [2]. In other recent cohorts [2, 5–12], morbidity ranged from 0.8 to 8.3% and mortality varied from 0 to 3.1%, where the lowest morbidity and mortality rates reported in ruptured aneurysm series. Our series demonstrates that recent advancements in embolization techniques and materials have not led to an increased rate of complications, morbidity or mortality.

At follow-up, we report a midterm complete occlusion rate of 63.6% compared with 35–88% reported in the literature [3–9, 11]. However, what constitutes technical success is debated. Neurosurgical series [13] consider neck remnants ≤ 2 mm a technical success because of their low risk of rupture. Several endovascular series show progressive thrombosis of small remnants, the rate of which seems greatest in the first 6 months, but still occurs through 2 years of follow-up [6]. In addition, in the acute setting of a SAH, a subtotal aneurysm occlusion may suffice to prevent early rebleeding [14]. Using these criteria, our technical success rate was 96.1%.

More significant angiographic outcome is derived from midterm angiography because up to 30% of completely occluded aneurysms recur at follow-up, and 5–85% of initial neck remnants and residual aneurysms go on to complete occlusion [3]. Our aneurysm recurrence rate was 14%, with rates up to 37% reported in the literature [3–9]. One series quoted no further recanalization after 6 months, while others [8] reported significant 8–14% recurrence rates between 6 and 38 months [4, 6]. Aneurysm recanalization, due to coil compaction and aneurysm regrowth, has been associated with large aneurysm dome and neck, ruptured aneurysms, incomplete initial occlusion and follow-up duration [4, 5, 15]. In our study, aneurysm recanalization was not significantly associated with aneurysm dome, neck size or rupture status.

In our cohort, 18% of aneurysms were retreated, similar to other series reporting 8–34% re-treatment [1, 6–11]. Our rate may be an underestimation because only 54% of aneurysms had midterm angiography. However, this may not be significant because results after endovascular treatment did not differ significantly between patients with or without follow-up angiography. Perhaps the most important technical outcome is the rate of

aneurysm bleeding after repair, which was 0% in our series over a cumulative clinical follow-up of 1,347 months. This rate is consistent with the low rates of 0–3.3% found in other endovascular series [1, 5–9, 11, 16, 17], similar to rates from surgical series [6, 18, 19].

Our angiographic results were consistent with previous reports. However, comparisons of angiographic outcomes across series are difficult to interpret. First, a standard definition of what constitutes complete occlusion is lacking, and quantifying residual aneurysm filling is subjective, especially because of the potential for progressive thrombosis. Authors who report lower occlusion rates generally have higher percentages of progressive occlusion, and those with higher occlusion rates have higher recanalization rates. Second, investigators who grade their own aneurysm occlusion potentially bias most large series. Angiogram review by an independent blinded neuroradiologist is paramount to the attainment of accurate occlusion rates and is one of the strengths of this study. In addition, an independent investigator should perform review and analysis of clinical data, as in this study, so that valid complication rates and clinical outcomes can be ascertained.

Limits of our study could be the lack of a control group and a selection bias because patients were not randomized to new devices vs standard endovascular treatment. In addition, endovascular treatment of aneurysms referred to a tertiary center such as ours may be more challenging than in a random sample of intracranial aneurysms. However, these biases are common to most aneurysm series and should not significantly affect our findings.

Conclusion

In conclusion, given recent advances in neuro-interventional device design, most intracranial aneurysms, including challenging lesions can be efficiently and safely treated by an endovascular approach. Morbidity and mortality remain low despite more sophisticated and complex procedures. Our success in achieving complete occlusion and minimizing recanalization was high, even with very complex lesions. Nonetheless, further progress will be needed to achieve higher complete and persistent aneurysm occlusion rates.

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