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ORIGINAL RESEARCH

Mid-Term Anatomic Results after Endovascular Treatment of Ruptured Intracranial Aneurysms with Guglielmi Detachable Coils and Matrix Coils: Analysis of the CLARITY Series

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BACKGROUND AND PURPOSE: Matrix coils have been developed to prevent aneurysm recanalization. Midterm anatomic results in a prospective multicenter consecutive series including patients treated with GDC or Matrix coils for ruptured aneurysms are presented.

MATERIALS AND METHODS: Five hundred seventeen patients harboring ruptured aneurysms were treated with GDC (276 patients) or Matrix coils (241 patients). Postoperative and midterm anatomic results were evaluated anonymously and independently using the Modified Montreal Scale (complete occlusion, neck remnant, and aneurysm remnant).

RESULTS: In the midterm follow-up (mean, 16.7 months in the GDC group and 15.4 months in the Matrix group), complete occlusion was reported in 95/276 aneurysms (34.4%) in the GDC group and 80/241 (33.2%) in the Matrix group, neck remnant in 127/276 (46.0%) in the GDC group and 118/241 (49.0%) in the Matrix group, and aneurysm remnant in 54/276 (19.6%) in the GDC group and 43/241 (17.8%) in the Matrix group. Evolution of aneurysm occlusion was improvement in 35/272 aneurysms (12.9%) in the GDC group and 27/239 (11.3%) in the Matrix group, stable situation in 98/272 (36.0%) in the GDC group and 97/239 (40.6%) in the Matrix group, and worsening in 139/272 (51.1%) in the GDC group and 115/239 (48.1%) in the Matrix group. A total of 32/517 patients were retreated during the follow-up period: 9/276 (3.3%) in the GDC group and 23/241 (9.5%) in the Matrix group ($P = .003$).

CONCLUSIONS: In this study, midterm anatomic results and evolution of aneurysm occlusion were not different in patients with ruptured aneurysms treated with GDC or Matrix coils.

ABBREVIATIONS: ACA = anterior cerebral artery; AcomA = anterior communicating artery; CI = confidence interval; CLARITY = CLinical and Anatomical Results In the Treatment of ruptured intracranial aneurysms; GDC = Guglielmi detachable coil; PGLA = polyglycolic/polylactic acid; VB = vertebrobasilar system; WFNS = World Federation of Neurosurgical Societies

CLARITY is a prospective, multicenter series conducted in France from October 2006 to July 2007 to evaluate the clinical and anatomic results after endovascular treatment of ruptured intracranial aneurysms by using GDC (Boston Scientific, Natick, Massachusetts) or Matrix detachable coils (Boston Scientific) (2 groups).[1,2]

Endovascular treatment of ruptured aneurysms has been widely used since the results of the International Subarachnoid Aneurysm Trial study were published in 2002, but some controversy remains regarding the efficacy of this treatment to obtain stable anatomic results.[3-5] For this reason, the precise analysis of immediate and midterm anatomic results is mandatory. The present article is focused on midterm anatomic results.

Materials and Methods

Protocol

CLARITY is a prospective multicenter consecutive series that was conducted in 20 centers in France.[1] Institutional review board approval and informed consent were obtained. Inclusion criteria were consecutive patients, 18–80 years of age with an aneurysm <15 mm in maximum diameter, with a diagnosed rupture having occurred <7 days before treatment. Exclusion criteria were dissecting or fusiform aneurysms, aneurysms associated with a brain arteriovenous malformation, aneurysms already treated by a clip or coils, and patients previously treated for another aneurysm.

The initial CLARITY series (conducted between November 3, 2006, and June 29, 2007) involved patients treated with GDCs (CLARITY-GDC). In the second CLARITY series (conducted between April 23, 2007, and September 5, 2008), patients were treated with Matrix detachable coils (CLARITY-Matrix). In both series,[1,2] patients were consecutively included. During the first period, all patients were treated with GDCs. During the second period, all patients were treated with Matrix detachable coils. In all centers, the second series (CLARITY-Matrix) was started after the end of the inclusions in the first series (CLARITY-GDC). Consequently, the technique of treatment was selected only by the time during which the treatment was performed, and no blinding was done.

Immediate Postoperative and Midterm Imaging

Immediate postoperative anatomic evaluation was obtained at the end of the endovascular treatment by using DSA. Midterm anatomic evaluation was performed by using DSA or MRA. On DSA, anatomic evaluation was performed with nonsubtracted and subtracted images in frontal, lateral, and working views. 3D images were not required.

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On MRA, anatomic evaluation was performed by using 3D time-of-flight images (native images and maximum-intensity-projection reconstructions).

Anonymous images were collected through a Web-based data base that was also used for clinical data collection (KIKA Medical, Nancy, France).

Image Analysis

Anatomic results were anonymously and independently reviewed by 2 experienced neuroradiologists (F.R. and R.A.) who were blinded to all clinical information. Discrepancies were resolved by consensus.

Postoperative and midterm aneurysm occlusion was evaluated by using the Modified Montreal Scale, which classifies the degree of aneurysm occlusion into 3 groups, which include complete occlusion, neck remnant, and aneurysm remnant.[3] We also used a 2-grade scale derived from the Modified Montreal Scale: adequate occlusion (complete occlusion or neck remnant) and aneurysm remnant.

Evolution of aneurysm occlusion was evaluated by directly comparing postoperative and midterm imaging. Evolution was classified in 3 groups: improvement, no change, or worsening.

Statistical Analysis

Data management and statistical analyses were independently conducted by Ariana Pharma (Paris, France) to determine patient demographics and aneurysm characteristics and to analyze anatomic results, aneurysm occlusion evolution, and retreatment rates in relation to the type of coils used (GDC or Matrix). Mean and frequency comparisons were performed with the Student t test and χ^2 test or the Fisher exact test, respectively. Differences were considered significant at $P = .05$. Statistical analysis was performed with the Statistical Package for the Social Sciences, Version 15.0 (SPSS, Chicago, Illinois).

Results

Patient Population, Aneurysm Characteristics, and Modalities of Treatment

The initial population in the CLARITY series was 782 patients (405 patients in the GDC group and 377 patients in the Matrix group). Endovascular treatment failed in 5 patients (3 patients in the GDC group and 2 patients in the Matrix group), and they were subsequently excluded from the analysis. In 4 patients, immediate postoperative DSA control was not available or readable (1 patient in the GDC group and 3 patients in the Matrix group).

During the follow-up period, 110 patients died (63 in the GDC group and 47 in the Matrix group). Eleven patients refused follow-up imaging (6 in the GDC group and 5 in the Matrix group), and 3 patients could not complete follow-up imaging for other reasons, including vegetative state (1 in the GDC group and 2 in the Matrix group).

Finally, 649 patients were theoretically able to undergo midterm follow-up imaging (331 in the GDC group and 318 in the Matrix group).

Ninety patients were lost to midterm follow-up (38 in the GDC group and 52 in the Matrix group). Thirty-five follow-up imaging cases were not transmitted to the core lab at the time of publication (12 in the GDC group and 23 in the Matrix group). Finally, 7 follow-up examinations were judged insufficient for accurate evaluation by the core lab (5 in the GDC group and 2 in the Matrix group). Finally midterm anatomic results were evaluated in a total of 517/649 patients (79.7%): 276/331 (83.4%) in the GDC group and 241/318 (75.8%) in the Matrix group.

Table 1: Patients characteristics in GDC and Matrix groups

	GDC		Matrix		
	No.	%	No.	%	*P*
Sex					.231
Female	161	58.3	153	63.5	
Male	115	41.7	88	36.5	
Age (yr)					.320
Younger than 65	243	88.0	205	85.1	
≥65	33	12.0	36	14.9	
WFNS score					.880
1–2	208	75.4	183	75.9	
3–5	68	24.6	58	24.1	
Total	276	100.0	241	100.0	

Table 2: Aneurysm characteristics in GDC and Matrix groups

	GDC		Matrix		
	No.	%	No.	%	*P*
Location					.077
ICA	64	23.2	79	32.8	
ACA/AcomA	152	55.1	110	45.6	
MCA	35	12.7	33	13.7	
VB	25	9.1	19	7.9	
Size					.180
≤5	106	38.4	106	44.0	
5–10	148	53.6	110	45.6	
>10	22	8.0	25	10.4	
Dome-to-neck ratio					.510
≤1.5	119	43.1	97	40.2	
>1.5	157	56.9	144	59.8	
Total	276	100.0	241	100.0	

Analysis of midterm anatomic results was conducted in a population of 517 patients (276 treated with GDCs and 241 treated with Matrix coils), 19–80 years of age (mean, 49.8 ± 13.0 years). The population included 314 women and 203 men. Age was younger than 65 years in 448 patients (86.7%) and older than or equal to 65 years in 69 patients (13.3%). The WFNS grade at admission was 1 in 271 patients (52.4%), 2 in 120 patients (23.2%), 3 in 21 patients (4.1%), 4 in 66 patients (12.8%), and 5 in 39 patients (7.5%). There was no significant difference between the GDC and Matrix groups in demographic characteristics (Table 1).

Aneurysm location included the ICA in 143 patients (27.7%), ACA/AcomA in 262 patients (50.7%), the MCA in 68 patients (13.2%), and the VB in 44 patients (8.5%). Aneurysm size was ≤5 mm in 212 patients (41.0%), between 5 and 10 mm in 258 patients (49.9%), and >10 mm in 47 patients (9.1%). Dome-to-neck ratio was ≤1.5 in 216 aneurysms (41.8%) and >1.5 in 301 cases (58.2%). There was no significant difference in the anatomic characteristics between the GDC and Matrix groups (Table 2).

Endovascular coiling without the use of an adjunctive device was performed in 402/517 aneurysms (77.8%): 220/276 in the GDC group (79.7%) and 182/241 in the Matrix group (75.5%). The balloon-remodeling technique was used in 105/517 aneurysms (20.3%): 55/276 in the GDC group (19.9%) and 50/241 in the Matrix group (20.7%). Intracranial stent

placement was performed in 10/517 aneurysms (1.9%): 1/276 in the GDC group (0.4%) and 9/241 in the Matrix group (3.7%).

Postoperative Aneurysm Occlusion

Interobserver agreement was good between both readers (κ = 0.803).

Postoperatively, complete occlusion was reported in 139/276 aneurysms (50.4%; 95% CI, 44.3%–56.4%) in the GDC group and 111/241 aneurysms (46.1%; 95% CI, 39.6%–52.6%) in the Matrix group, neck remnant in 105/276 aneurysms (38.0%; 95% CI, 32.3%–44.1%) in the GDC group and 108/241 aneurysms (44.8%; 95% CI, 38.4%–51.3%) in the Matrix group, and aneurysm remnant in 32/276 aneurysms (11.6%; 95% CI, 8.1%–16.0%) in the GDC group and 22/241 aneurysms (9.1%; 95% CI, 5.8%–13.5%) in the Matrix group (P = .263).

Adequate occlusion was observed in 244/276 aneurysms (88.4%; 95% CI, 84.0%–91.9%) in the GDC group and 219/241 aneurysms (90.9%; 95% CI, 86.5%–94.2%) in the Matrix group (P = .361).

Midterm Aneurysm Occlusion

Midterm follow-up imaging was obtained between 3.8 and 38.6 months after the initial treatment (16.1 ± 4.8 months) in the entire population, between 4.1 and 35.9 months (16.7 ± 5.1 months) in the GDC group, and between 3.8 and 38.6 months (15.4 ± 4.3 months) in the Matrix group (P = .003).

Midterm follow-up was evaluated by MRA in 146/517 patients (28.2%) in the whole group (GDC group: 78/276 patients, 28.3%; Matrix group: 68/241 patients, 28.2%) and by DSA in 371/517 patients (71.8%) in the whole group (GDC group: 198/276 patients, 28.3%; Matrix group: 173/241 patients, 28.2%).

Interobserver agreement was good between both readers (κ = 0.938).

At midterm follow-up, complete occlusion was reported in 95/276 aneurysms (34.4%; 95% CI, 26.8%–40.4%) in the GDC group and 80/241 aneurysms (33.2%; 95% CI, 27.3%–39.5%) in the Matrix group, neck remnant in 127/276 aneurysms (46.0%; 95% CI, 40.0%–52.1%) in the GDC group and 118/241 aneurysms (49.0%; 95% CI, 42.5%–55.5%) in the Matrix group, and aneurysm remnant in 54/276 aneurysms (19.6%; 95% CI, 15.1%–24.8%) in the GDC group and 43/241 aneurysms (17.8%; 95% CI, 13.2%–23.3%) in the Matrix group (P = .780).

Adequate occlusion was observed in 222/276 aneurysms (80.4%; 95% CI, 75.3%–85.0%) in the GDC group and 198/241 aneurysms (82.2%; 95% CI, 76.7%–86.8%) in the Matrix group (P = .617).

Evolution of Aneurysm Occlusion (Midterm Versus Postoperative)

Direct comparison of midterm versus postoperative aneurysm occlusion was not feasible for technical reasons in 6 cases (4 in the GDC group and 2 in the Matrix group).

Direct comparison of midterm versus postoperative aneurysm occlusion showed improvement in 35/272 aneurysms (12.9%; 95% CI, 9.1%–17.4%) in the GDC group and 27/239 aneurysms (11.3%; 95% CI, 7.6%–16.0%) in the Matrix group, stable situation in 98/272 aneurysms (36.0%; 95% CI, 30.3%–42.1%) in the GDC group and 97/239 aneurysms (40.6%; 95% CI, 34.3%–47.1%) in the Matrix group, and worsening in 139/272 aneurysms (51.1%; 95% CI, 45.0%–57.2%) in the GDC group, and 115/239 aneurysms (48.1%; 95% CI, 41.6%–54.7%) in the Matrix group (P = .555).

The midterm evolution was not significantly affected by the initial angiographic results. In the GDC group, midterm aneurysm occlusion was stable or improved in 68/138 aneurysms, completely occluded postoperatively (49.3%; 95% CI, 40.7%–57.9%) in 50/103 aneurysms with a postoperative neck remnant (48.5%; 95% CI, 38.6%–58.6%) and in 15/31 aneurysms with a postoperative aneurysm remnant (48.4%; 95% CI, 30.2%–66.9%). In the GDC group, midterm aneurysm occlusion was worsened in 70/138 aneurysms completely occluded postoperatively (50.7%; 95% CI, 42.1%–59.3%), in 53/103 aneurysms with a postoperative neck remnant (51.5%; 95% CI, 41.4%–61.4%), and in 16/31 aneurysms with a postoperative aneurysm remnant (51.6%; 95% CI, 33.1%–69.9%).

In the Matrix group, midterm aneurysm occlusion was stable or improved in 56/111 aneurysms completely occluded postoperatively (50.5%; 95% CI, 40.8%–60.1%), in 59/108 aneurysms with a postoperative neck remnant (54.6%; 95% CI, 44.8%–64.2%), and in 9/20 aneurysms with a postoperative aneurysm remnant (45.0%; 95% CI, 23.1%–68.5%). In the Matrix group, midterm aneurysm occlusion was worsened in 55/111 aneurysms completely occluded postoperatively (49.5%; 95% CI, 39.9%–59.2%), in 49/108 aneurysms with a postoperative neck remnant (45.4%; 95% CI, 35.8%–55.2%), and in 11/20 aneurysms with a postoperative aneurysm remnant (55.0%; 95% CI, 31.5%–76.9%).

Retreatment

During the follow-up period, we retreated 32/517 patients: 9/276 (3.3%; 95% CI, 1.5%–6.1%) in the GDC group and 23/241 (9.5%; 95% CI, 6.1%–14.0%) in the Matrix group (P = .003).

The interval between initial treatment and retreatment was 4.2–15.3 months (9.6 ± 3.8 months) in the GDC group and 0.5 to 25.1 months (8.8 ± 6.9 months) in the Matrix group (P = .731).

Discussion

In the European practice, endovascular treatment with coils is now the first treatment technique of choice for both unruptured and ruptured aneurysms.[5,6] One of the shortcomings of aneurysm coiling, however, is the immediate and midterm anatomic results. Some aneurysms are not completely occluded at first treatment and have a risk of rebleeding in cases of recently ruptured aneurysms.[7] Moreover, aneurysm occlusion is not always stable with time: Aneurysm reopening can occur in cases with initial complete occlusion; growth of a neck or aneurysm remnant can be observed.[3,4,8] Several approaches have been proposed to overcome these limitations, including increase of aneurysm coil packing, the use of surface-modified coils, and intracranial stent placement.[9-13]

Two types of surface-modified coils have been proposed to improve midterm aneurysm occlusion: hydrogel-coated coils and PGLA-coated coils, including Matrix coils.[10-12] Several

series have evaluated PGLA-coated coils showing a similar safety compared with bare platinum coils.[10-12,14] However, no direct comparison between patients harboring aneurysms treated with bare platinum and PGLA-coated coils has been made regarding midterm anatomic results, to our knowledge.

CLARITY is a nonrandomized study designed to compare clinical and anatomic results in patients harboring aneurysms treated with bare platinum coils (GDC coils) and PGLA-coated coils (Matrix).[1] Clinical results will be published separately. Immediate anatomic results have been published showing similar postoperative occlusion in patients treated with GDC and Matrix coils.[1] However PGLA-coated coils have been designed to improve the durability of aneurysm occlusion in the midterm. The present article is dedicated to the analysis of midterm anatomic results.

Midterm anatomic results were evaluated in a high percentage of surviving patients (79.7%) with a very strict methodology (independent and anonymous analysis of postoperative and midterm aneurysm imaging by 2 experienced diagnostic and interventional neuroradiologists). The mean time interval between initial treatment and midterm follow-up was very close in the GDC and Matrix groups (16.7 months in the GDC group and 15.4 months in the Matrix group). Because definitions of reopening or recanalization are very heterogeneous in the literature, anatomic results were evaluated postoperatively and in the midterm follow-up by using the 3-grade Modified Montreal Scale. Because the clinical significance of complete occlusion and neck remnant is likely similar, a 2-grade scale was also used, grouping complete occlusion and neck remnant as an adequate occlusion in opposition to aneurysm remnant as incomplete. Evolution of aneurysm occlusion was evaluated by directly comparing postoperative and midterm imaging. Evolution of aneurysm occlusion was simply classified into 3 groups: improved, stable, and worsened.

In the CLARITY series, postoperative and midterm aneurysm occlusion and evolution of occlusion were not different in the GDC and Matrix groups. As reported from the whole series, postoperative aneurysm occlusion was not different in the GDC and Matrix groups: Adequate occlusion was observed in 88.4% in the GDC group and 90.9% in the Matrix group. Similar results were reported in the systematic review published by Ferns et al[4] showing adequate occlusion in 91.2%.

At follow-up, adequate occlusion was observed in a similar percentage of cases in the GDC and Matrix groups: 80.4% in the GDC group and 82.2% in the Matrix group. This result is again similar to that reported in the Ferns et al[4] review: adequate occlusion in 83.4% of cases.

Evolution of aneurysm occlusion between postoperative and follow-up imaging was also similar in both groups: Aneurysm occlusion was stable in 36.0% in the GDC group and 40.6% in the Matrix group, improved in 12.9% in the GDC group and 11.3% in the Matrix group, and worsened in 51.1% in the GDC group and 48.1% in the Matrix group.

Contrary to previous reports, evolution of aneurysm occlusion in the midterm was not linked to the quality of postoperative aneurysm occlusion in both the GDC and Matrix groups in our series.[15,16]

Retreatment rates are difficult to interpret because indications for retreatment are subjective and not similar from 1 center to another. In the Ferns et al[4] review, the retreatment rate was 10.3% for the whole population (ruptured and unruptured) and 7.2% in ruptured aneurysms alone. The retreatment rate was higher in patients treated with modified coils (11.7%) compared with patients treated with bare platinum coils (9.6%). A similar result was observed in our series, with a significant difference in the retreatment rate in the GDC and Matrix groups (3.3% and 9.5%, respectively; $P = .003$). This difference cannot be explained by differences in patient or aneurysm characteristics or in postoperative or midterm aneurysm occlusion results because they are similar in both groups. It is likely explained by the lack of clear indications for retreatment in cases of aneurysm remnant.

Our study has several limitations. First, it was not a randomized study. However, both GDC and Matrix groups were recruited on a multicentric and consecutive basis, and patient and aneurysm characteristics were not different in the 2 groups. A second limitation is that the recanalization rate was not concisely evaluated because its definition is quite heterogeneous in the literature. Our evaluation, however, was assessed on 4 points (postoperative and follow-up aneurysm occlusion, aneurysm occlusion evolution, and retreatment), leading to a precise comparison of both groups. A third limitation is that midterm evaluation was conducted by using 2 different modalities (DSA and MRA). However, previous articles have shown that MRA was highly sensitive for the detection of neck and aneurysm remnants.[17,18] A fourth limitation is that the Modified Montreal Scale is quite difficult to use because classification between complete occlusion and neck remnant or neck and aneurysm remnant is not always easy. To overcome this limitation, we used a strong methodology with independent and anonymous analysis of the results by 2 experienced readers. In most other published reports, anatomic results were evaluated by the treating physician, introducing a strong bias.

Conclusions

In our large nonrandomized series, postoperative and midterm aneurysm occlusion and evolution of aneurysm occlusion were not different in patients harboring ruptured aneurysms treated with bare coils (GDC) or PGLA coils (Matrix). On the basis of these results, the use of Matrix coils to improve the durability of aneurysm occlusion singularly in the midterm cannot be recommended.

Appendix

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Disclosures: Laurent Pierot—*Consultant*: Boston Scientific, eV3, Microvention. Christophe Cognard—*Consultant*: Boston Scientific.

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