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Respective roles of clipping and coiling in the management of ruptured aneurysms: Results of Clarity GDCTM Study

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Abstract

INTRODUCTION: Since the International Subarachnoid Aneurysm Trial (ISAT), management of ruptured aneurysms has changed and endovascular coiling is now considered as treatment choice in most patients. This study aims to analyse, in a consecutive series of patients, the roles and indications for surgical clipping. METHODS: The Clarity GDC study included 381 consecutive patients from 15 French centres during the period from November 2006 to July 2007. RESULTS: 307 patients were treated by coiling (80.6 %) and 74 by clipping (19.4 %). Reasons for clipping were parenchymal haematoma in 12/381 aneurysms (3.1 %) and unfavourable aneurysmal morphology in 62/381 aneurysms (16.3 %). The majority of clipped aneurysms were located in the middle cerebral artery (MCA) (62/74, 83.6 %). Of 103 MCA aneurysms, 41 (39.8 %) were coiled and 62 (61.2 %) were clipped (12 due to haematoma, 50 resulting from aneurysm morphology). In centres that typically consider most MCA aneurysms for surgery, 29.2 % of all and 79.4 % of MCA aneurysms were clipped. In all other centres, 7.6 % of all and 30 % of MCA aneurysms were clipped. Risk of procedural complications and long-term clinical results were similar in both centre groups. Conclusion: In this consecutive series of patients with ruptured aneurysms, most were located in the MCA and 19.4 % of aneurysms were treated by clipping.

Keywords: intracranial aneurysms, embolisation, intracranial haemorrhage, coils, clipping.

Introduction

In 2002, the International Subarachnoid Aneurysm Trial (ISAT) showed that coiling should be considered the initial treatment of choice for ruptured aneurysms [1]. The ISAT trial showed that 23.7 % of patients allocated to coiling were dependent or dead at 1 year, compared with 30.6 % allocated to clipping. However, there have been several criticisms of the study [2-6]: 1) only aneurysms considered treatable by both techniques were randomised (resulting in only 22 % of patients presenting with a ruptured aneurysm included in the study), 2) a high proportion of the coiling cases were carried out by very experienced radiologists and, therefore, results of coiling may be less successful if performed by non-selected operators and 3) patients in good clinical condition were primarily recruited with anterior circulation aneurysms. Despite these criticisms, the ISAT has had a major impact on routine practice and choice of treatment, which has rapidly shifted from clipping to coiling in most countries [7-14]. The Barrow Ruptured Aneurysm Trial (BRAT) also favoured coil embolisation, with fewer poor outcomes compared to clip occlusion [15]. The decision to perform coiling as the first choice treatment in ruptured aneurysms has been evaluated in the Clarity study, a multicentre, prospective registry aiming to evaluate the use of coiling as the first choice treatment in a consecutive population of patients with ruptured aneurysms

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treated by non-selected operators [16]. The Clarity study showed that when non-selected operators performed coiling as treatment of choice in a consecutive series of ruptured aneurysms, clinical results were similar to the ISAT. The tremendous impact of the ISAT on clinical practice and the indication to use coiling as treatment of choice in most ruptured aneurysms seems justified. Following this change in therapeutic strategy, the respective role of coiling and clipping in ruptured aneurysms needs to be addressed. This paper aims to analyse the current roles of clipping in the non-selected population of the Clarity study in patients with ruptured aneurysms.

Materials and Methods

In the Clarity study, interventional neuroradiologists from 19 French centres were asked to enrol 30 consecutive patients treated with coil embolisation. A total of 431 patients were coiled between 30 November 2006 and 30 July 2007. In 15 centres, surgical data during the study period were strictly recorded and every patient consecutively clipped was also registered. For all clipped patients, the reasons to perform clipping instead of coiling were pre-defined and included the following: parenchymal haematoma requiring surgery, aneurysmal characteristics (location and morphology) and impossible endovascular access. Inclusion criteria were patients between 18 and 80 years of age with an aneurysm measuring less than 15 mm in maximum diameter, with a diagnosed rupture having occurred no more than 7 days previously. Exclusion criteria included dissecting or fusiform aneurysms, aneurysms associated with brain arteriovenous malformations (AVM), aneurysms previously treated by clips or coils and patients with a secondary previously treated aneurysm.

Method of coiling

Because the GDC system (GDC®, Stryker Neurovascular, Fremont, CA, USA) has been utilised by all French interventional neuroradiologists for longer than any other existing coil system, and because our goal was to validate the results of the ISAT, we decided for consistency to treat all patients with GDC. Centres not using GDC coils as the standard coil in practice did not participate. The method of treatment (technique of coiling, anticoagulation and antiplatelet regimen, etc.) was not pre-specified in the protocol. All techniques (coiling alone, the use of the balloon remodeling technique and intracranial stenting) were allowed.

Clinical evaluation protocol

We evaluated World Federation of Neurological Surgeons (WFNS) scale at admission and the modified Rankin scale (mRs) at hospital discharge, at 3 to 6 months and at 12 - 18 months post-treatment. All patient were asked to answer the Reintegration to Normal Living Index questionnaire at 12 months post-treatment [17] to assess patient ability to return to normal life.

Procedural adverse events

Procedural adverse events were classified as follows: thromboembolic events (TEE) - any case with evidence of thrombus, irrespective of size, anywhere in the brain arteries with or without flow reduction or intraoperative rupture (IOR) - any case with coil protrusion outside the angiographic limits of the aneurysm with or without contrast medium leakage identified via control angiogram or CT-scan.

The protocol was approved by the Ethics Committee and the "CNIL" (French National Commission on Informatics and Liberty). The study aimed to analyse routine practice and the protocol did not pre-specify any modifications to an operator's habits and individual protocol. The sole technical criterion was the use of the GDC system. Only centres using the GDC system on a routine basis were asked to participate in the trial. Because no comparative study has ever shown any benefit of using one coil type over another and because the study did not alter the patient's routine treatment course, the Ethics Committee asked only for patient approved consent to use anonymous imaging and register clinical data on an electronic clinical report form. Informed consent was obtained from all patients. The study was designed and organised by the two principal investigators (CC, LP) who received funds through an educational grant provided by Stryker Neurovascular (Fremont, CA, USA). The protocol design, data collection and assessment of results were entirely independently controlled by the two principal investigators. Clinical data of every patient were collected and entered via an electronic website (Kika-Medical, Nancy, France). All data were controlled by an independent clinical monitoring company (Clinact, Paris, France). In cases where submitted data were insufficient or inexact, medical records were reviewed and evaluated by the two principal investigators (CC, LP). Statistical analysis was independently conducted by Ariana Pharmaceuticals (Paris, France). The Chi2 test was used to evaluate differences between the hospital groups. All statistical analyses were performed using the SPSS program.

Results

Among 381 patients recruited from the 15 centres, 307 patients were coiled (80.6 %) and 74 were clipped (19.4 %) (Table I). The reasons for clipping were parenchymal haematoma in 12 patients and aneurysmal characteristics (location and morphology) in 62 patients.

Among the clipped patients, 46/74 were female (62 %) and the mean age was 50 years (±11.2). Aneurysm locations included the internal carotid artery (ICA) in 7/74 patients (9.5 %), the anterior cerebral artery/anterior communicating artery ACA/AcomA in 4/74 (5.4 %), the MCA in 62/74 (83.8 %), and the vertebro-basilar (VB) in 1/74 (1.4 %). WFNS grade at admission was I in 27/74 patients (36.5 %), II in 11/74 (14.9 %), III in 14/74 (18.9 %), IV in 17/74 (23 %) and V in 5/74 (6.8 %). One patient underwent surgery due to unfavourable aneurysm morphology; however, surgery failed and coiling was subsequently performed.

Among the coiled patients, 168/307 were female (55 %), and the mean age was 50.4 years (+/- 12.9). Aneurysm location included the ICA in 71/307 patients (23.1 %), the ACA/AcomA in 169/307 (55 %), the MCA in 41/307 (13.4 %) and the VB in 26/307 (8.5 %). WFNS grade at admission was I in 144/307 patients (46.9 %), II in 63/307 (25 %), III in 12/307 (3.9 %), IV in 45/307 (14.7 %) and V in 43/307 (14 %). Coiling failed in 2 cases and patients were subsequently clipped.

The two populations had similar age and sex but clinical condition was significantly less severe in the coiling group with 207/307 patients (67.4 %) WFNS I or II compared to 38/74 (51.4 %) in the clipping group (p=0.01).

Indications for clipping was mainly dependent on aneurysm location. Surgery was performed in 4/173 (2.3 %) ACA/AcomA aneurysms, 1/27 (3.7 %) VB aneurysms, 7/78 (9.0 %) ICA aneurysms and in 62/103 (60.2 %) MCA aneurysms.

Discussion

The Clarity study is a French multicentre prospective series which aimed to evaluate the results of coiling when performed as the initial treatment in consecutive patients with ruptured aneurysms. This study had multiple objectives: 1) to analyse clinical results of coiling when used as the initial treatment in a consecutive population of patients with ruptured aneurysms treated by non-selected operators and to compare results with those of the ISAT study, 2) to analyse the respective roles of coiling and clipping in a consecutive series of patients with ruptured aneurysms and 3) to compare immediate and long term clinical and angiographic results in patients treated with "bioactive" Matrix™ (Stryker Neurovascular, Fremont, CA, USA) coils versus GDC™.

In this study we have presented the results of the analysis with respect to the aneurysmal location of clipping and coiling in the management of a non-selected, consecutive series of patients treated for ruptured aneurysms.

Among 381 patients, 307 were coiled (80.6 %) and 74 clipped (19.4 %). In previous papers describing the role of coil embolisation versus surgery in ruptured aneurysms, coiling was performed in 63 % to 97.5 % of the cases [18-21]. In a report spanning a decade of treatment data of ruptured aneurysms, Renowden et al. observed the percentage of coiled ruptured aneurysms progressively increasing from 33 % in 1996 to 97.5 % in 2005 [20]. Clarity is a more recent series (patients included from November 2006 to July 2007) but performed by 43 operators in 15 university hospitals. Indeed, the percentage of coiling was very wide (from 60 % to 100 %) depending on the respective neurosurgeons' and neuroradiologists' experience in each centre.

Reasons for clipping were parenchymal haematoma in 12/381 aneurysms (3.1 %) and unfavourable aneurysmal characteristics in 62/381 aneurysms (16.3 %). As a result of the parenchymal haematomas which required surgery, overall clinical status was significantly more severe in the clipping group where 38/74 (51.4 %) patients with WFNS I and II, compared to 207/307 (67.4 %) in the coiling group. Management of ruptured aneurysms with parenchymal haematoma can be performed by combined aneurysm and haematoma surgery, by coiling and haematoma surgery or by coiling alone if the haematoma is not considered life threatening. The Clarity methodology does not allow assessment of the strategy used in cases with parenchymal haematomas, but surgery was performed for this reason in only 3.1 % of the patients (12/381 cases).

The major reason for clipping was unfavourable aneurysm morphology with large neck/no neck aneurysm, branches arising from aneurysm neck or sac and/or aneurysm morphology difficult to understand during coiling. Coiling assisted techniques with balloons have significantly increased the number of aneurysms treatable by embolisation [22]. In addition, new technological advances in imaging with 3D biplane angiography have also facilitated treatment of aneurysms with difficult morphology. Nevertheless, there are some aneurysms in which morphology renders coiling too difficult and hazardous and clipping more appropriate.

Indication for clipping was mainly dependent on aneurysm location. Surgery was performed in 2.3 % of ACA/Acom aneurysms, in 3.7 % of VB aneurysms, in 9 % of ICA aneurysms and in 60.2 % MCA. Indeed, in some centres, MCA aneurysms, despite morphology characteristics, were initially and primarily considered for surgery, while in other centres aneurysm morphology was the primary criteria in deciding the best

therapeutic option and most MCA aneurysms were coiled. In our series, MCA aneurysms represent 13.4 % (41/307 cases) of coiled and 83.8 % of clipped cases (62/74). Among 103 patients with MCA aneurysms, 41 (39.8 %) were coiled and 62 (61.2 %) were clipped (12 because of a haematoma, 50 because of aneurysm morphology). In fact, some operators considered the MCA location by itself as an indication for surgical clipping. Higher complexity of coil embolisation due to aneurysm shape, involvement of MCA bifurcation branches and presumed easier surgical clipping are the reasons proposed for choosing surgery as the treatment of first choice [23-26]. In contrast, other operators considered MCA as any other location and have coiled up to 100 % of all ruptured aneurysms in their respective centres (in the 30 consecutively treated cases from their centre).

In our study, some centres considered all aneurysms for coiling as initial treatment despite location. In these centres, only 7.6 % of all aneurysms were clipped. MCA represented 30 % of clipped aneurysms (12/40) and 17.6 % of all coiled aneurysms. In other centres where surgery was considered the initial treatment, 29.2 % of all aneurysms were clipped, of which 79.4 % were MCA. In this group, MCA represented 8.8 % of all coiled aneurysms (Table 2). The risk of peri-procedural complications (TEE, aneurysm IOR, mRs at 3 months, patient able to return to normal life as assessed by QOL questionnaire) was similar in both groups (Table 3). This confirmed that there is no rationale for using surgery instead of coiling in MCA aneurysms when morphology is suitable for coiling.

The ratio of MCA aneurysm in the ISAT was 14 % (13.9 % in our study), which is lower than in the general population of subarachnoid haemmorhage (SAH) (approximately 25 %). However, in the ISAT, the large number of patients (313) with MCA aneurysms may allow generalisation of these results to a global population [14]. It is also important to note that in recent literature no published paper has shown an increased risk in coiling of MCA aneurysms compared to other locations [27-33].

In a recent publication of the global cohort of the Clarity study (782 patients), Pierot et al. analysed the risk of complications associated with MCA aneurysms as compared to other locations [34]. The univariate analysis showed that the frequency of TEE was higher in the MCA group, although not significantly (17.0 % versus 11.8 %; p=0.139), but the morbidity and mortality of TEE was higher in the MCA group (7.5 % versus 3.3 %; p=0.038) due to the eloquence of the brain territory fed by the MCA. However, in the multivariate analysis of morbidity and mortality related to TEE, the MCA location was a risk factor. On the contrary, the frequency of IOR was higher in the MCA group (8.5 % versus 3.7 %; p=0.029) and the morbidity and mortality of IOR was higher but not significantly (1.9 % versus 0.4 %; p=0.112). In the multivariate analysis, the MCA group was significantly associated with IOR (p=0.037). A similar association was previously reported by Renowden et al., in which MCA aneurysms accounted for 24 % of all procedural re-ruptures in their large series of 711 patients with ruptured aneurysms and 13 % MCA aneurysms [20]. In the ATENA study, a similar trend was also observed [35]. IOR was encountered in 4.1 % of MCA aneurysms, 2.2 % of ACA/Acom aneurysms, 1.9 % of ICA aneurysms and 0.0 % of VB aneurysms (3). This increased risk of IOR in MCA aneurysms could be explained by increased treatment difficulty due to complex anatomy or by the peri-aneurysmal environment [36].

This study has some limitations. The main weakness of our study is the absence of an independent neurological evaluation. In Clarity, patients were evaluated during a consultation by the neurologist, neurosurgeon or interventional neuroradiologist at 3-6 months and 12-18 months. To avoid bias of self-reported evaluation by the operators, patients were asked to complete the Reintegration to Normal Living

Index questionnaire 1-year post-treatment [23]. This series has been funded by the industry and a single predefined treatment device was used. Consequently, industry funded series may be considered less reliable than publicly funded. However, study design and data analysis were performed by the two principal investigators independently. Moreover, independent clinical monitoring was performed for clinical data control and an independent core lab was used for angiographic result analysis.

Our series shows that in France, 80.6 % of consecutive ruptured aneurysms are treated by coils. However, the strategy is very different from one centre to another. Some centres consider all aneurysms for coiling as the first intention treatment despite location and only 7.6 % of all aneurysms were clipped. Other centres consider most MCA aneurysms for surgery first and 29.2 % of all aneurysms in this group were clipped. However, the risk of coiling complications (TEE, aneurysm IOR) and clinical results (mRs at 3 months, patient able to return to normal life) were similar in both groups. Our series emphasises the fact that even if the ISAT has demonstrated that coiling should be the first line treatment for ruptured aneurysms, some operators still consider surgery the best option for MCA aneurysms. Our study is not designed to determine which treatment is the best therapeutic option for MCA aneurysms, but it does demonstrate similar long-term clinical results between both groups, irrespective of initial treatment choice. Finally, our series shows that parenchymal haematoma is a rare reason for surgery in patients arriving alive to the hospital.

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Conflict of interest

CC consults for Stryker, Covidien, Codman, Microvention and proctors for Sequent. LP consults for Sequent.

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Tables

Table 1 - Comparison of coiling versus clipping population

	Coiling (307 cases)	Clipping(74 cases)
Mean age (years)	50.4	50
Female	168 (55 %)	46 (62 %)
ICA	71 (23.1 %)	7 (9.5 %)
ACA/AcomA	169 (55 %)	4 (5.4 %)
MCA	41 (13.4 %)	62 (83.8 %)
VB	26 (8.5 %)	1 (1.4 %)
WFNS I to II	207 (67.4 %)	38 (51.4 %) P = 0.010
WFNS III and V	100 (32.6)	36 (48.6)

Table 2 - Comparison of clip to coil in all locations and MCA aneurysms in centres performing 0 to 20 % clipping and >20 % clipping

% of clipping	0-20 %	>20 %	Total	p value
Coiled / Treated A°	159/172	148/209	307/381 (80.6 %)	<0.001
Clipped / Treated A°	13/172 (7.6 %)	61/209 (29.2 %)	74/381 (19.4 %)	<0.001
MCA / Treated A°	40/172 (23.3 %)	63/209 (30.1 %)	103/381 (27.0 %)	0.132
MCA/ all coiled A	28/159 (17.6 %)	13/148 (8.8 %)	41/307 (13.4 %)	0.023
MCA / all clipped A°	12/13 (92.3 %)	50/61 (82.0 %)	62/74 (83.8 %)	P=0.679

Table 3 - Comparison of initial clinical grades (WFNS), 3 months follow up clinical grades (mRs), risk of thrombo-embolic complications (TEE) and intra-operative rupture (IOR) for coiled aneurysms in centres doing between 0 to 20% clipping and >20% clipping

% of clipping	0-20 %	>20 %	Total	p value
Coiled / Treated A°	159/172 (92.5 %)	148/209 (70.8 %)	307	<0.001
WFNS 1,2	107 (67.3 %)	100 (67.6 %)	207 (67. 4%)	0.959
mRS 1,2	123 (77.4 %)	114 (77 %)	237 (77.2 %)	0.945
Back to normal life	102 (81.0 %)	89 (80.9 %)	191 (80.9)	0.993
TEE	18 (11.3 %)	26 (17.6 %)	44 (14.3 %)	0.119
TEE/permanent deficit	3 (1.9 %)	7 (4.7 %)	10 (3.3 %)	0.205
TEE with death	1 (0.6 %)	3 (2.0 %)	4 (1.3 %)	0.355
IOR	7 (4.4 %)	3 (2.0 %)	10 (3.3 %)	0.339
IOR/ permanent deficit	1 (0.6 %)	0	1 (0.3 %)	1.000
IOR with death	0	0	0	NA