Report 2012: Intracranial aneurysms: clips or coils

How to choose clipping versus coiling in treating intracranial aneurysms

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A B S T R A C T
Background. – After the decision is made to treat an intracranial aneurysm, clinicians must choose between two competing treatment options: open surgery or endovascular therapy. The rationale underlying the choice of treatment modality is usually unclear, as there is little good quality evidence available.

Methods. – We discuss the patient and aneurysm-related factors cited in the neurovascular literature that are considered to influence aneurysm treatment choices.

Results. – The relevance and direction of influence of rupture status, age, type of presentation, and general medical condition, as well as aneurysm size, location, morphology, and multiplicity are discussed. The validity of these factors in influencing treatment decisions remains unclear, with frequently opposing views on the same factor by clinicians practicing opposing techniques. Perceived differences in efficacy and safety of the two different treatment approaches are commonly used in an attempt to justify treatment choices. Difficulties with treatment selection and case-by-case reasoning are reviewed.

Conclusion. – Properly designed and conducted randomized trials are necessary in order to settle the controversy and to determine the optimal treatment modality for intracranial aneurysms. In the absence of reliable knowledge on which to base treatment decisions, the ethically appropriate choice for any clinician, from surgical or endovascular backgrounds, is to participate in randomized trials.

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1. Introduction

Human decision-making in the presence of uncertainty is a complex, poorly understood process (Platt and Huettel, 2008). Yet, “humans are condemned to choice and action” (Korsgaard, 2009). The liberty of freedom of action, or agency, comes with tremendous responsibility for those who make decisions that impact the lives of others. Few decisions have the immediate, personal, and potentially life-long consequences on an individual as those decisions made inside a doctor–patient relationship. This is perhaps particularly true in the management of intracranial aneurysms. Unfortunately, there is little evidence to guide clinicians in this difficult process. By nature, surgeons confronted with a patient harbouring an aneurysm are inclined to favour clipping, and interventionists coiling. The choice can be even more ambiguous for cross-trained endovascular neurosurgeons.

In the present manuscript, we will review some factors commonly evoked by neurovascular specialists when making decisions. Lines of reasoning used by each type of specialist will be found to center on the perceived trade-off between two themes: to optimize patient safety and maximize treatment efficacy. Conflicting data on patient and aneurysm-related factors used by clinicians with opposing viewpoints when attempting to justify treatment recommendations will be reviewed. We will then discuss the logical problems and potential pitfalls of case-by-case reasoning. Finally, we will address the best and only means to properly address this controversial question.

2. Factors considered to influence treatment decisions

Table 1 is a summary of some decisional factors considered by clinicians, gathered from articles collected during a recent systematic review of surgical clipping of unruptured aneurysms (Naggara et al., 2010). The factors listed here are non-systematic, non-exhaustive review, with references to be used as examples only:

3. Patient-related factors

Factors considered in this portion of the discussion will include rupture status, age, and presentation with mass effect or cranial nerve palsy. The general medical condition of the patient is certainly an important factor in clinical decisions, but little reported...
data supports this claim, as physiological wellness can be difficult to quantify reliably (Solomon et al., 1994; Yoshimoto and Mizoi, 1997; Gerlach et al., 2007; Nussbaum et al., 2007; Darsaut et al., 2011a).

3.1. Rupture status

For surgery, rupture status of an aneurysm is an important technical aspect to consider. Compared to their unruptured counterparts, ruptured aneurysms have more fragile domes, anatomy can be obscured by subarachnoid blood, and surgical working corridors constrained due to brain edema or intraparenchymal hematoma. A strategy of delayed clipping had been adopted by some, but a large cooperative study could not show this approach beneficial, supposedly because the better conditions of late surgery were outdone by the increased re-bleeding rate while awaiting operation (Kassell et al., 1990). With endovascular treatment, the mechanics of coiling a ruptured aneurysm are remarkably similar to coiling unruptured aneurysms, except perhaps for the common practice of intentionally undersizing coils in ruptured cases. Coiling of ruptured aneurysms is associated with more frequent hemorrhagic complications, however, as compared to unruptured aneurysms (Roy et al., 2001; Cloft and Kallmes, 2002).

In addition, recurrences after coiling are more frequent in ruptured than in unruptured aneurysms (Raymond et al., 2003). For ruptured aneurysms we have a direct comparison between clipping and coiling that is available: The publication of the landmark International Subarachnoid Aneurysm Trial (ISAT) study in 2002, which showed better 1 year clinical outcomes for coiled patients, lent further justification to choosing coils over clips, at least for small, anterior circulation ruptured aneurysms (Molyneux et al., 2002). The opposing argument for continued clipping of ruptured aneurysms centers on the efficacy argument, with surgeons downplaying the absolute risk reduction of 6.9%, citing instead the higher recurrence rate (20 to 40%) for coiled aneurysms (Raymond et al., 2003), although the clinical significance of aneurysm recurrences post-coiling remains unclear (Campi et al., 2007; Johnston et al., 2008; Raymond and Darsaut, 2011a).

3.2. Age

The age of the patient presenting with an aneurysm often influences treatment decisions, again with opposing viewpoints from clippers and coilers, who would both prefer to treat younger

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**Table 1**

Factors considered to influence treatment decisions.

<table>
<thead>
<tr>
<th>A. To treat or not to treat unruptured aneurysms</th>
<th>B. Against clipping</th>
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<tr>
<td><strong>Age</strong></td>
<td><strong>Age</strong></td>
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<tr>
<td>Inagawa et al., 1992; Solomon et al., 1994; Yamashita et al., 1997; Wiebers, 1998; Bederson et al., 2000; Kashiwagi et al., 2000; Orz et al., 2000; Raabe et al., 2002; Krieh et al., 2006; Ogilvy et al., 2006; Gerlach et al., 2007; Nussbaum et al., 2007; Hauck et al., 2008; Komotor et al., 2008; Seifert et al., 2008</td>
<td>Lot et al., 1999; Gerlach et al., 2007, &gt; 4 mm (Regli et al., 1999; Aghakhani et al., 2008)</td>
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<td><strong>Size</strong></td>
<td><strong>Ratio neck/dome</strong></td>
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<td>&gt; 10 mm (Lot et al., 1999)</td>
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<td><strong>Ratio dome/neck</strong></td>
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<td>&lt; 1.5 (Regli et al., 1999, 2002), ≤ 2.5 (Aghakhani et al., 2008)</td>
<td>≤ 1.5 (Regli et al., 1999, 2002), ≤ 2.5 (Aghakhani et al., 2008)</td>
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<td><strong>Inadequate endovascular access</strong></td>
<td><strong>Inadequate endovascular access</strong></td>
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<td><strong>Intraluminal thrombus</strong></td>
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<td>Raftopoulos et al., 2003; Raftopoulos et al., 2003; Raftopoulos et al., 2003</td>
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<td><strong>Arterial branch occlusion</strong></td>
<td><strong>Arterial branch occlusion</strong></td>
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<td>Regli et al., 1999, 2002; Raftopoulos et al., 2003</td>
<td>Raftopoulos et al., 2003; Gerlach et al., 2007; Seifert et al., 2008</td>
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<td><strong>Complete occlusion unlikely</strong></td>
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<td><strong>Stent implantation or balloon remodeling</strong></td>
<td><strong>Stent implantation or balloon remodeling</strong></td>
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<td>Age &lt; 50 years (Hauck et al., 2008), &lt; 70 years (Solomon et al., 1994), young patient with small anterior circulation aneurysm (Komotor et al., 2008)</td>
<td>Age &lt; 50 years (Hauck et al., 2008), &lt; 70 years (Solomon et al., 1994), young patient with small anterior circulation aneurysm (Komotor et al., 2008)</td>
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<td><strong>Difficult access</strong></td>
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<td>Ogilvy et al., 2002; Gerlach et al., 2007; Seifert et al., 2008</td>
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<td><strong>No efferent branches</strong></td>
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<td>Gerlach et al., 2007; Seifert et al., 2008</td>
<td>Gerlach et al., 2007; Seifert et al., 2008</td>
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<td><strong>High-grade SAH</strong></td>
<td><strong>High-grade SAH</strong></td>
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<td><strong>Extended cranial base access</strong></td>
<td><strong>Extended cranial base access</strong></td>
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<td>Gerlach et al., 2007; Seifert et al., 2008</td>
<td>Gerlach et al., 2007; Seifert et al., 2008</td>
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<td><strong>Vasospasm</strong></td>
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<td>Gerlach et al., 2007; Seifert et al., 2008</td>
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<td><strong>Poor medical condition</strong></td>
<td><strong>Poor medical condition</strong></td>
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<td>Solomon et al., 1994; Yoshimoto and Mizoi, 1997</td>
<td>Solomon et al., 1994; Yoshimoto and Mizoi, 1997</td>
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patients. For younger patients, in the event of a complication, the potential years of contributory life lost are greater, and endovascular therapists will cite the better outcomes of ISAT (perhaps lesser for very young patients, and appropriate for RIA s, but not UIAs), while surgeons will claim that the long-term benefits due to the better durability (efficacy) of clipping maintains primacy of their modality. This latter argument was supported by a controversial publication on Markov-modeling using specific age-related sub-group projections (Mitchell et al., 2008; Raymond et al., 2009).

For older patients, age is increasingly recognized to influence health care decisions (Robb et al., 2002), but without a basis in reliable evidence. Both clipping and coiling are associated with worse outcomes in old patients as compared to young patients, in both ruptured and unruptured aneurysms (Wiebers et al., 2003; Molyneux et al., 2005; Raymond, 2009). The common sense practice of sending older patients for “minimally-invasive” clipping, remains unfounded. From an endovascular perspective, older patients have more tortuous vascular anatomy, a higher relative burden of atheroma, and there is ample material to suggest that the elderly tolerate coiling, as well as clipping, poorly as compared to younger patients (Kashiwagi et al., 2000; Molyneux et al., 2005).

Epidemiological studies seem to favour clipping, but they are fraught with insurmountable bias. A proper randomized comparison of clipping for coiling for the elderly is ongoing in France (Protocol 2007/042/HP) (Proust et al., 2010).

3.3. Presentation with Mass Effect or cranial nerve palsy

Aneurysms present in a variety of ways, but there are few plausible rationales for considering one treatment over another with those discovered in the context of seizure, headache (non-SAHI), or ischemic symptoms (SUlIA 2003); these will not be discussed. Patients who present with signs of mass effect, such as a cranial nerve deficit or brainstem compression have been widely discussed in the literature (Chen et al., 2006; Pickett et al., 2007; Hanse et al., 2008; Hui et al., 2011; Schuss et al., 2011). Decisions can be swayed towards surgical therapy, with surgeons claiming that aneurysm deflation following clipping leads to more consistent, more rapid resolution of mass effect (Chen et al., 2006; Guresir et al., 2011; Park et al., 2011; Schuss et al., 2011). This line of reasoning also contends that endovascular filling of the aneurysm sac with non-resorbable platinum coils can only maintain the symptomatic local pressure. On the other hand, coilers claim that the volume occupied by coils is only a small fraction of the total aneurysmal volume (typically 20 to 30% in most cases); the clinical course of a coiled aneurysm is of a non-significant or transient increase in size with swelling due to fresh thrombus, followed by volume reduction and aneurysm constriction as the thrombus matures and retracts (Hanse et al., 2008). Furthermore, they point out that significant neurological deficits due to continued mass effect with coiling, or from inflammation, are rare. In most cases mass effect symptoms disappear after treatment or with time alone (Raymond and Theron, 1986; Stiebel-Kalish et al., 2003; Mansour et al., 2007; van Rooij and Sluzewski, 2008; Panagiotopoulos et al., 2011). Finally, they argue that the surgical dissection of cranial nerves necessary to properly clip a symptomatic aneurysm can render an otherwise transient neurological deficit permanent (Day, 1990; Roy et al., 1997; Birchall et al., 1999; Turner et al., 2008).

4. Aneurysm-related factors

Here, we will consider arguments to choose clipping or coiling on the basis of aneurysm size, location, and multiplicity. Morphology considerations, including neck size, dome-to-neck ratios, and presence of intra-aneurysmal thrombus and calcification will also be discussed.

4.1. Aneurysm size: small aneurysms

Small, unruptured aneurysms (for the sake of this discussion, taken to be less than 3 mm) are usually fairly simple to treat surgically, so long as there is sufficient tissue to hold a clip. With unruptured aneurysms, the more important consideration is whether they should be treated at all, which this paper does not address (Wiebers, 1998). For their ruptured counterparts, dissection remains relatively simple once complete vascular control is established, but difficulties can arise from premature or intraoperative rupture, which may be more common with small lesions (Houkin et al., 1999). Small aneurysms, compared to larger ones, are also more difficult to embolize, as there is a smaller margin for error with microcatheter placement, and the forces applied by the coil exiting into the aneurysm are distributed across a smaller surface area, increasing the risk of perforation, particularly in recently ruptured lesions (Sluzewski and Van Rooij, 2003). While many series boast that this can still be achieved safely, there are also reports supporting the claim that clipping very small ruptured aneurysms is more risky than larger lesions (Nguyen et al., 2008; Gupta et al., 2009; Brinjikji et al., 2010; Sluzewski and Van Rooij, 2003; van Rooij and Sluzewski, 2006).

4.2. Large/Giant aneurysm

For ruptured aneurysms, size larger than 10 mm has been a poor prognostic factor, as compared to smaller lesions, both for clipping and coiling, with comparable results in ISAT (Molyneux et al., 2005). For unruptured aneurysms, size larger than 12 mm was also shown to be associated with poor outcomes, as compared to smaller lesions, for both clipping and coiling (Wiebers et al., 2003). From an endovascular perspective, large aneurysms are simple to catheterize, but difficult to completely and durably occlude. Larger aneurysms have a greater recurrence rate than smaller lesions (Gruber et al., 1999; Murayama et al., 2003).

The poor rates of durable occlusion of large and giant aneurysms may be changing with the advent of stents and flow-diverting technologies, but these devices pose different, additional risks related to the fact that they treat the parent vessel and not the aneurysm fundus (Lylyk et al., 2009; Pitiot et al., 2010; Fiorella et al., 2010; Szikora et al., 2010; Nelson et al., 2011). The long-term consequences of stent and flow diverter implantation, in terms of risk of acute vessel thrombosis, delayed in-stent stenosis, or hemorrhagic risk from dual antiplatelet therapy or rupture of unruptured lesions cannot be ignored (Naggara et al., 2010; Kulcsar et al., 2011).

That large and giant aneurysms pose greater surgical risk than their smaller counterparts is well known (Morley and Barr, 1969; Lawton and Spetzler, 1995; Rychnovsky et al., 1998; Darsaut et al., 2011a). Successful obliteration can require complex clip configurations, surgical bypasses, or aneurysmorrhaphy. Dysplastic arterial wall can be more difficult to understand, and more extensive dissection required in order to gain sufficient exposure. These lesions frequently contain thrombus, which poses an embolic risk, or can have calcified walls, factors which will be discussed in a separate section. Although the durability of clipping of larger aneurysms has never been properly demonstrated, the known high recurrence rates following coiling lead many to consider surgery as first option for these lesions, at least in the pre-flow diverter era. A proper comparison of clinical and angiographic outcomes for large and giant aneurysms treated by current endovascular or surgical management paradigms remains to be done, although
this question is addressed in an ongoing study on flow diversion (Raymond et al., 2011a).

4.3. Aneurysm location

Location can significantly influence the decision to clip or coil, as arguments are commonly made for endovascular treatment of any aneurysms requiring a surgical approach more difficult than a standard pterional craniotomy (i.e.: anterior clinoidectomy for ophthalmic artery or paraclinoidal aneurysms, or a far-lateral approach for a vertebrobasilar junction aneurysm). Basilar apex aneurysms are currently almost exclusively managed endovascularly, (Raymond et al., 1997) although some continue to clip even these potentially difficult lesions (Lawton, 2002; Sanai et al., 2008).

Interventionists claim increased exposure-related morbidity due to cranial nerve manipulation, more extensive soft tissue dissection, or risk of postoperative CSF leak. Surgeons commonly counter the endovascular claims of increased safety by minimizing the estimate of surgical risk and claiming increased efficacy with clipping.

From an endovascular perspective, more distal lesions, such as pericallosal artery aneurysms, are thought to present additional risk of perforation or incomplete occlusion, as compared to other locations (Keston et al., 2004; Nguyen et al., 2007). The opposing argument is that dissection of densely adherent cingulate gyri, without proximal vessel control, creates increased surgical risk, with higher intraoperative bleeding and poorer outcomes than in clipping aneurysms at other locations (de Sousa et al., 1999; Kawashima et al., 2003).

Once more, for locations readily accessible by both modalities, such as with most supracharoid carotid aneurysms, the interventionist claims an improved safety profile while the surgeon counters with better efficacy.

4.4. Multiple aneurysms

Multiple aneurysms, accessible through one craniotomy, can render surgical treatment appealing. The opposite is true when eradication of all lesions would require multiple craniotomies (Orz et al., 2000).

4.5. Aneurysm shape and wall thickness

Wide-necked aneurysms, or lesions with a dome:neck ratio less than 1.5 (other ratios have been proposed) are thought be less favourable for coating, and thus inferred to be best managed by clipping (Fernandez Zubillaga et al., 1994; Debrun et al., 1998) wide neck (Lot et al., 1999; Gerlach et al., 2007) (> 4 mm [Regli et al., 1999,2002; Aghakhani et al., 2008]), size (> 10 mm [Lot et al., 1999]), ratio neck/dome (> 1.3 [Lot et al., 1999]), ratio dome/neck (< 1.5 [Regli et al., 1999,2002]) (≤ 2.5 [Aghakhani et al., 2008]). The introduction of stents can mitigate the risk of coil herniation into the parent vessel lumen, but increases potential thrombo-embolic risks due to the permanent foreign body implanted, and increases major hemorrhagic risks from antplatelet agents, estimated from cardiology studies to be approximately 1 to 2% per year (Bowry et al., 2008; Sorensen et al., 2009; Raymond and Darsaut, 2011b; Raymond et al., 2011b).

The presence of large or essential branches originating near the aneurysm neck can also factor into a decision to clip (Regli et al., 1999,2002; Raftopoulos et al., 2003; Gerlach et al., 2007; Aghakhani et al., 2008; Seifert et al., 2008). Morphological factors tending away from surgery include a calcified aneurysm wall, which could render clip application technically difficult or impossible, and the presence of intra-aneurysmal thrombus, which could embolize during aneurysm dissection. The countering argument is again related to treatment efficacy; because most calcified or partially thrombosed lesions are large or giant, endovascular strategies are likely to suffer a higher recurrence rate than clip-based therapies.

4.6. Proximal Access Vessel Morphology

Direct carotid or brachial artery puncture can be contemplated, but only a minority of interventionists remains comfortable with approaches other than standard femoral access. The confounder in this case is that most patients with such vessels are either older or have a greater burden of comorbid disease, rendering perceived surgical risks higher as well (Wiebers et al., 2003) (ISUIA 2003). Arguments can easily be constructed to favour clipping or coiling.

5. Experience, risk factors, clinical judgment and decision-making

Very few physicians treat all patients indiscriminately. Most claim to personally tailor treatment recommendations to individual needs and circumstances of each unique patient. Yet, the first thing to notice is that the end result of this complex, poorly defined decision-making process is a binary decision: to treat or not to treat. When the decision is abstention, the expert sometimes chooses to refer the patient to a practitioner of the alternate form of treatment; when the decision is to treat, it is usually with the modality the consulted expert was trained to do.

Hesitation can arise when a set of aneurysm or patient-related circumstances recall previous difficulties or a poor outcome, as compared to more standard cases. Here, experts may be more tempted to resort to alternatives. This phenomenon occurred in the early years of coiling, when endovascular case series comprised mainly patients ‘thought to be poor surgical candidates’, that is, older patients, those with poor grade subarachnoid hemorrhage, and large or giant aneurysms, with a disproportionately high number of basilar bifurcation or ophthalmic segment aneurysms (Roy et al., 1997; Raymond et al., 1997). As history will later show, these were not found to be the ‘best endovascular cases’ either, but at least in the beginning, they were considered ‘standard’ endovascular cases.

Nowadays, endovascular coils, confronted with perceived difficulties, such as the anatomy of an MCA bifurcation or pericallosal aneurysm, may be tempted to consider surgical clipping. Sometimes experts rely solely on intuition, but other times, the reasons they use to justify their choices are based on weak observational evidence, especially if the data tends to confirm their clinical experience. Authors can then construct maxims or general rules that are thought to be self-evident or to make common sense, as shown in the present review. Each specialty defines in this way its comfort zone, and indications for clipping and coiling become entrenched in practices and “confirmed” by analyzing “risk factors” for poor outcomes in case series or epidemiological studies.

The entire process relies on misleading estimates, invalid comparisons and unjustified inferences. Estimates such as the relative risk of treating a ruptured versus an unruptured aneurysm, or a large versus a small aneurysm can only mislead; the patient has a lesion with particular characteristics that he or she cannot change; comparing an endovascular series with a surgical series, both with carefully selected patients, is invalid. For example, inferring to an elderly patient that endovascular treatment is indicated because in most surgical series, clipping of old patients led to poor relative outcomes is not justified. Comparing difficult patients with standard patients within each respective treatment modality, when the direct comparison of the two treatments in the same patients is lacking, can never give proper guidance to the decision-maker. Clinicians that rely on “clinical judgment”, as well as on “experience”, to come up with decisions that purport to be individualized...
according to the unique character of each clinical case, are in fact reacting to an experience that was biased from the start. Results of case series and observational studies are comforting and ‘make sense’ because they correspond to their immediate experience. But the logic of clinical inferences becomes impossible: is the patient old enough (beware of clipping) to balance the fact that the lesion is large enough (beware of coiling) to justify tilting the decision in one direction or another?

An immediately related problem with the literature born from treatments carried out with case-by-case reasoning is that the focus shifts to the best achievable results using each technique. This highly selective process leads to best case series, personally reassuring for doctors and specialties, but unfortunately bypassing the overall real patient outcomes. Case series are seemingly ever-improving, as patients are more highly selected, but only because the patients denied access to the series have been treated with the opposing modality. No one ever knows what the outcome would have been had the other treatment modality been used. While everyone believes they know the recipe for their best personal series, no one knows what the best treatment would be for patients facing the dilemma.

We have reviewed factors that are thought to be favorable or unfavorable for each treatment modality. It is time to study factors that are favorable to patients. The old man with a large aneurysm has no need to be told by his surgeon that surgery would lead to better outcomes if he was younger, and no need to be told by his interventionist that the treatment would be more durable if his aneurysm was smaller. He wants to know if he should be treated by clipping or coiling. As things stand, no one knows. Any independent observer, without a direct personal interest or stake in the decision-making process, recognizes that the commonly-provided justifications offered by surgeons to clip or by interventionists to coil an aneurysm usually conflict. The apparent reason this occurs is because the choice of how to treat an aneurysm is centered NOT on a direct comparison of how the patient would do if treated with one modality or another.

The only way to escape this situation is to admit from the start that two options exist, and that they should be offered to each individual patient eligible for these two options, by using randomized trials. Unfortunately, this notion of “eligibility” cannot escape our biased experiences, and only a small minority of patients are typically included in RCTs. One must constantly focus on the fact that the uncertainty is there, and will remain, until valid, randomized comparisons are made.

5.1. Resolution of the conflict

For ruptured aneurysms, the ISAT trial showed that clipping leads, in general, to better outcomes than clipping (Molyneux et al., 2002). There are plenty of clinical circumstances for which this conclusion remains doubtful, and those clinicians who believe certain patients should be treated by clipping should submit their beliefs to a new trial (Raymond, 2011).

For unruptured aneurysms, the uncertainty remains for the majority of patients. We cannot state with any certainty that the benefits of treating unruptured aneurysms outweigh the risks (Raymond et al., 2011c), but treatment is often performed nonetheless, both with surgical or endovascular means. Surgical clipping, for years the standard treatment, is gradually becoming supplanted by endovascular treatment (Lin et al., 2011), without randomized outcome data available to justify this trend. To address this gaping hole in the management of unruptured aneurysms, the Canadian UnRuptured Endovascular versus Surgery (CURES) trial has been launched (Darsaut et al., 2011b), a two-phase pragmatic study to compare angiographic and clinical outcomes following treatment of UIAs. The most important outcome for both patients and clinicians is long-term morbidity and mortality, a measure that we estimate (with simple power calculations using common estimates of morbidity and efficacy) will require more than 1000 patients. All patients enrolled in CURES will contribute to the final clinical outcome measure, but in addition, the study is powered to look at the data at one intermediate time-point, where treatment efficacy will be considered. At the completion of Phase I, which will require 260 patients (Darsaut et al., 2011b), we aim to have an answer to the question: Which treatment modality is associated with a greater incidence of treatment failure? Treatment failure is here defined as a composite primary end-point comprising the occurrence of either: failure to accomplish aneurysm obliteration with the initial treatment modality, a major saccular aneurysm remnant or recurrence, or intracranial hemorrhage following treatment at 1 year. After completion of Phase I, we will have reliable randomized morbidity and mortality data with which to formulate a precise hypothesis for the pivotal, international clinical outcome portion of the study, destined to manage in the most responsible way any patient with an unruptured aneurysm, wherever treatment is being considered.

6. Conclusion

We have reviewed the most common factors claimed to play a role in the choice of clipping vs. coiling for the treatment of intracranial aneurysms. As we have seen, for many patients arguments can be constructed as easily for one option as the other. These reasons conflict for a significant number of patients routinely encountered in clinical practice. The responsible way to care for patients, for whom uncertainty exists, is to recruit them into properly designed RCTs.

Disclosure of interest

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