ORIGINAL RESEARCH

Safety and Efficacy of Adjunctive Balloon Remodeling during Endovascular Treatment of Intracranial Aneurysms: A Literature Review

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BACKGROUND AND PURPOSE: Concurrent temporary inflation of a nondetachable balloon in the parent artery has been reported to be useful during endovascular coiling of complex, wide-neck aneurysms, facilitating truer coil reconstruction of the native vessel. Nevertheless, there exists concern that adjunctive use of balloon assistance may lead to increased adverse events during aneurysm coiling.

MATERIALS AND METHODS: A literature search of all of the unassisted and balloon-remodeling studies published between 1997 and 2006 was conducted with application of strict selection criteria based on the reporting of complication incidence and outcome. The final cohort was analyzed to determine rates and clinical outcomes of iatrogenic aneurysm rupture and thromboembolism. Additional data were collected on the degree of initial and follow-up aneurysm occlusion rates.

RESULTS: A total of 83 potential studies (4973 patients) were identified, from which 23 articles reporting results for 867 traditional-unassisted and 273 balloon-assisted coiled aneurysms met inclusion criteria for the analysis of thromboembolic complications, and 21 articles with 993 routinely coiled and 170 balloon-remodeled aneurysms were eligible for iatrogenic perforation analysis. No statistically significant difference was found in the rates of thromboembolism. Iatrogenic perforation rates were also comparable, though the overall numbers were too few for meaningful statistical analysis. Both initial and follow-up aneurysm occlusion rates were higher in balloon-assisted cases.

CONCLUSION: This largest-to-date literature review and meta-analysis did not demonstrate a higher incidence of thromboembolic events or iatrogenic rupture with the use of adjunctive balloon remodeling compared with unassisted coiling. Balloon remodeling appears to result in higher initial and follow-up aneurysm occlusion rates.

Since introduction of the Guglielmi detachable coil in 1991, coil-supported endosaccular therapy has become an accepted alternative to conventional neurosurgical treatment of cerebral aneurysms. Although many aneurysms are amenable to coiling without the use of adjunctive techniques, certain aneurysms, particularly larger, wide-neck aneurysms, have proven technically challenging and problematic in terms of achieving uniformly complete coil packing of the aneurysm by unsupported primary methods. Several refinements, including complex shaped coils, and the use of stent-supported coiling or balloon remodeling techniques, have been incorporated into the treatment paradigm to address these technical difficulties and presumably provide an anatomically sounder treatment of this cohort. Recently published results from the Cerebral Aneurysm Rerupture after Treatment Study[1] suggest that an inverse relationship exits between the degree of endovascular occlusion and risk of subsequent aneurysm rerupture, strongly supporting efforts to achieve as complete an aneurysm exclusion as possible.

Temporary inflation of a nondetachable balloon across the aneurysm neck to facilitate optimal coil placement, known as balloon remodeling or balloon-assisted coiling, has reportedly been useful in securing placement of the initial coils within wide-necked aneurysms, as a "rescue" method in cases of coil prolapse and to allow for more optimal "packing" of the aneurysm fundus and neck region.[2] Some concern, however, has been expressed that the adjunctive use of balloons for this purpose may lead to an increased incidence of thromboembolism, even under optimized anticoagulation.[3] Three articles from 1 institution, by Sluzewski et al[4,5] and van Rooij et al,[6] reported either a trend toward[4] or a statistically significant increase[5,6] in the incidence of death or dependency in cases of balloon remodeling compared with those of unassisted coiling. Similarly, Derdeyn et al[7] noted a trend toward an increase in the incidence of thromboembolism with balloon remodeling at $P = .18$. Other authors have not demonstrated this association.[2,8,9]

Regardless of coil technique, thromboembolism remains the primary cause of clinically significant periprocedural morbidity.[8] Another major risk of endovascular treatment, intraprocedural aneurysm perforation, is less prevalent but carries a higher likelihood of permanent sequelae.

We have conducted a literature review to determine the incidence and outcome of intraprocedural thromboembolism and aneurysm perforation in the setting of balloon remodeling and "traditional" unassisted primary coiling. In addition, we have extracted data describing the degree of initial and follow-up aneurysm occlusion in these 2 groups.

Materials and Methods

A Medline search was conducted to identify relevant articles on the subject of traditional-unassisted and balloon-assisted coiling. For analysis of thromboembolism, articles were required to meet the qualifications described below.

Articles were to be published between 1997 and 2006. The first

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series of balloon remodeling experience appeared in 1997, by which time coiling protocols had more or less matured. Comparison of complication rates with those from earlier articles describing the developmental phase of unassisted coiling was felt potentially to be biased against the traditional coiling cohort, considering the significant manufacturing improvements in coil design and evolution in the use of adjunctive anticoagulation taking place throughout the early coiling experience.

They were to contain more than 10 subjects.

They were to provide information on the total number of cases, the number of balloon remodeling cases (if any), and the prevalence of thromboembolic events in the traditional-unassisted and balloon remodeling groups. Stent cases were excluded.

The articles were to clearly specify the clinical outcome of all of the thromboembolic events in a manner enabling the grouping of clinical outcomes into the following: 1) dead: immediate or delayed death, clearly attributed at least in part to the thromboembolic event; 2) symptomatic: transiently and permanently symptomatic patients were of necessity combined into one group, and variations in outcome reporting did not allow for confident subdivision into more specific categories; or 3) asymptomatic: for the higher-grade ruptured aneurysms, this category implies an unchanged clinical status after emergence from anesthesia.

A similar set of inclusion criteria was applied in the selection of articles for analysis of periprocedural aneurysm perforation. In addition, these articles were required to provide information on the baseline fraction of ruptured and unruptured aneurysms treated and of the aneurysms that sustained intraprocedural perforation. Separate perforation rates were calculated for aneurysms treated in the setting of a subarachnoid hemorrhage (SAH) and for unruptured cases. Although many studies were published over the past decade, due to wide variation in the reporting of complications and outcome, most articles did not meet the above inclusion criteria.

Coiling efficacy was estimated from the articles selected for either thromboembolism or perforation analysis. There was considerable variation in reporting, with many authors using numeric occlusion estimates (visually and according to predefined algorithms), as well as qualitative descriptions. Every attempt was made to preserve consistency in assignment of the occlusion category. The degree of occlusion was subdivided into categories of "complete occlusion," "near-complete occlusion," and "subtotal occlusion." "Complete occlusion" was reserved for aneurysms reported to be 100% or fully occluded. Numeric reports of 90%–99%, and verbal estimates of "near occlusion," "residual neck," "small remnant," and so forth were assigned the "near-complete occlusion" label. All of the other descriptions, such as "residual filling," "large remnant," and so forth, or <90%, were placed in the "subtotal occlusion" group.

We have attempted to compare both initial and follow-up occlusion rates of balloon remodeling and unassisted groups. Several articles provided data for the determination of initial or final occlusion rates but not both. In addition, because of large variation in follow-up reporting, calculation of the average length of follow-up was not possible.

No institutional review board clearance is required for literature reviews at our institution.

A meta-analysis for binary outcome data was conducted to compare procedures with and without balloon assistance in terms of the percentage of procedures with thromboembolic complications. This meta-analytic comparison, which seeks to minimize the impact of intergroup variability, could be applied validly only to publications containing both balloon-assisted and unassisted coiling patient groups within the same study. The comparisons were based on the Mantel-Haenszel method for calculating a weighted summary odds ratio. Because these calculations assumed a random-effects model, the estimates and confidence intervals for the summary odds ratio can be considered valid even in the presence of interstudy heterogeneity. For all of the comparisons, the odds ratio was defined as the odds of a complication among balloon remodeling procedures divided by the corresponding odds among routine procedures. Thus, an odds ratio >1 implies that complications are relatively more likely to occur among balloon remodeling procedures. In the analysis for each outcome measure, only studies providing relevant data for both groups being compared were included in the meta-analysis to avoid confounding of the differences between procedures with differences between studies. Comparisons of perforation rates between balloon-assisted and conventional coiling and of coiling outcome in terms of degree of occlusion could not be included in the meta-analysis because of an insufficient number of studies with valid data for both comparison groups. A comparison was declared statistically significant only when a 95% confidence interval for the relevant summary odds ratio failed to contain unity. All of the statistical computations were carried out by using MedCalc version 9.2 software (MedCalc, Mariakerke, Belgium).

Results

Incidence

A total of 83 potential studies (4973 patients harboring 5157 aneurysms) were initially identified. Most of these articles did not contain specific information on the numbers of balloon cases and associated complications and were therefore rejected.

Twenty-three articles,[2,7,8,10-29] with 867 traditionally coiled and 273 balloon-assisted procedures met inclusion criteria for thromboembolism analysis, and 21 articles[10,12-31] with 993 traditionally coiled and 170 balloon-assisted procedure aneurysms were eligible based on inclusion criteria for perforation analysis. For the thromboembolism analysis, 12 articles contained cases exclusively treated by traditional-unassisted coiling, 6 articles described results for cases exclusively using balloon remodeling, and 5 reports provided relevant information for both unassisted and balloon remodeling cases, henceforth referred to as "mixed" reports. For the perforation analysis, the breakdown of exclusively unassisted, exclusively balloon remodeled, and mixed articles was 13, 5, and 3, respectively.

The incidences of thromboembolism and perforation for each group are given in Table 1. Because aneurysms treated in the setting of SAH have been reported to have a higher incidence of periprocedural perforation than unruptured ones,[4,8,32] the rates of iatrogenic perforation were calculated separately for previously ruptured and unruptured aneurysms. Among the traditional-unassisted group, 51% of aneurysms were treated in the setting of acute SAH compared with 35% in the balloon remodeling cohort.

There was an insufficient number of "mixed" studies (single-center articles reporting outcome for both traditional-unassisted and balloon-assisted cases) for a similar meta-analytic analysis of perforation incidence. Nevertheless, although not assessable by our statistical methods, for unassisted cases, the rate of perforation in the setting of SAH (3.4%) was higher

Table 1: Summary of data describing the number and incidence of thromboembolic and perforation events during unassisted and balloon-assisted coiling of cerebral aneurysms						
Variable	% Incidence ± SD	No. of Events	No. of Aneurysms	No. of Articles	Odds Ratio	Confidence Interval
Thromboembolic incidence, all articles, balloon	8.1 ± 5.7	22	273	11	NA	NA
Thromboembolic incidence, all articles, no balloon	8.0 ± 5.7	69	867	17		
Thromboembolic incidence, "mixed articles," balloon	7.9 ± 6.1	7	89	5	0.7	0.3-1.7
Thromboembolic incidence, "mixed articles," no balloon	10.5 ± 8.4	36	344	5		
Perforation incidence, balloon SAH cases	1.7 ± 9.4	1	59	7	NA	NA
Perforation incidence, nonballoon SAH cases	3.4 ± 6.3	17	507	13		
Perforation incidence, balloon non-SAH cases	1.8 ± 2.1	2	111	8	NA	NA
Perforation incidence, non-balloon non-SAH cases	1.4 ± -2.3	7	486	12		

Note:—"Mixed articles" indicates studies reporting results for both balloon-assisted and unassisted coiling cases and were the ones subject to meta-analysis. The incidence of thromboembolism for the larger cohort of "all articles," which includes a wider range of studies reporting exclusive experience with either unassisted or balloon-assisted cases, does not lend itself to strict meta-analysis, however, is included in the chart for comparison with the analyzed results for the "mixed article" groups. SAH indicates subarachnoid hemorrhage; NA, no analysis.

Table 2: Clinical outcomes of thromboembolic and iatrogenic perforation events following unassisted and balloon-assisted coiling of cerebral aneurysms						
	Balloon Remodeling			No Balloon Remodeling		
Variable	Death	Symptomatic	Asymptomatic	Death	Symptomatic	Asymptomatic
Periprocedural aneurysm perforation: number of cases (% incidence) in setting of recent SAH	1 (1.7)	0 (0)	0 (0)	2 (0.7)	6 (2.0)	5 (1.7)
Periprocedural aneurysm perforation: Number of cases (% incidence) in unruptured aneurysms	1 (0.9)	0 (0)	1 (0.9)	0 (0)	2 (0.6)	1 (0.3)
Thromboembolic events	1 (0.4)	12 (4.4)	9 (3.3)	10 (1.2)	39 (4.6)	23 (2.7)

Note:—SAH indicates subarachnoid hemorrhage.

Table 3: Initial and follow-up angiographic outcome in traditional unassisted and balloon-assisted coiling of cerebral aneurysms						
	Balloon			Nonballoon		
Variable	% Occlusion	No. of Total Patients	No. of Studies	% Occlusion	No. of Total Patients	No. of Studies
Initial total occlusion	73	141	4	49	283	8
Initial subtotal occlusion	22			39		
Initial incomplete occlusion	5			13		
Follow-up total occlusion	72	138	5	54	193	8
Follow-up subtotal occlusion	17			34		
Follow-up incomplete occlusion	10			11		

than in the unruptured cohort (1.4%). This appears to validate our study population given the higher reported incidence of iatrogenic perforation in acutely ruptured aneurysms.

Outcome

The clinical outcomes from perforation and thromboembolic events are given in Table 2. Both incidence and actual number of cases in each group are provided to allow for a more complete understanding of group size and frequency of complications.

Occlusion Analysis

Ten articles[2,13,14,16-18,22,23,26,28] provided sufficient information on the degree of initial occlusion. Follow-up information was available in 11 articles.[2,14-17,21-24,26,28] Results of the occlusion analysis are given in Table 3. The average length of follow-up could not be calculated due to variation in reporting. Most follow-up angiograms were obtained at least 6 months after treatment. Note that follow-up occlusion rates contain an element of unspecified crossover because the degree of occlusion for a particular aneurysm may change for better or worse on subsequent angiograms.

Discussion

Because of the great heterogeneity in reporting of neurointerventional data, we chose prospectively to apply rather strict inclusion criteria to filter the initial cohort of 83 articles to a smaller but more rigorous dataset. Although looser inclusion criteria would have increased the number of cases, the probable compromise in quality of the data pool was felt to be deleterious to meaningful interpretation.

The results of our analysis suggest that aneurysm coiling supported by balloon remodeling is not associated with a statistically significantly increased risk of thromboembolism compared with traditional-unassisted coiling methods. Among studies eligible for the meta-analysis (Table 1), the composite incidence of thromboembolism accompanying balloon remodeling procedures was not statistically different from that attending unassisted coiling procedures (7.9% versus 10.5%). This observation was further supported by the findings within the more heterogeneous "all articles" cohort, in which the incidence of thromboembolism was 8.1% and 8.0% for balloon remodeling and unassisted procedures, respectively.

There were not enough occurrences of intraprocedural rupture to carry out a comparable meta-analysis of the perforation incidence in balloon remodeling and unassisted coiling cohorts. Ross and Dhillon[33] did report a nonstatistically significant increase in perforation incidence in cases requiring balloon remodeling. In our cohort, only 1 instance of perforation in the "balloon-SAH" cohort and 2 instances in the "balloon-no SAH" subgroup were identified, which render statistical inference extremely unreliable. Overall, the incidence of perforation is markedly less than that of thromboembolism, especially among unruptured aneurysms.

Both thromboembolism and perforation data may suffer from potential limitations. Among the studies analyzed, the methodology of determining thrombotic events varies considerably, probably leading to underreporting bias of this complication. Determination of the true incidence of thromboembolism is more difficult than that of perforation. The latter is probably radiologically and/or clinically obvious in most cases. For thromboembolic events, evidence suggests that a significant number of minor embolic events[34,35] may remain clinically silent and, unless detected by rigorous angiographic analysis or by follow-up MR imaging diffusion, are probably underreported. This may be particularly true in the setting of high-grade SAH, with the attendant decrease in sensitivity of the patient's clinical examination and baseline depression of mental status.

It should be noted that prospective application of our inclusion criteria resulted in exclusion of several noteworthy publications addressing complications experienced with balloon remodeling,[3-6] particularly those by Sluzewski et al[4,5] and van Rooij et al,[6] 2 of which[5,6] reported a statistically higher incidence of clinically significant complications in the setting of balloon remodeling compared with unassisted coiling. These latter articles, unfortunately, did not provide data on asymptomatic or temporarily disabling events and, furthermore, did not distinguish among untoward outcomes with regard to etiology (thromboembolism versus intraprocedural rupture).

Another important limitation is that most of the included articles and all of the balloon remodeling studies subject to the meta-analysis constitute a retrospective series. The only prospective study by Roy et al[26] reported a 7.2% incidence of thromboembolism with aneurysm coiling but did not contain any balloon remodeling subjects and, therefore, could not contribute to our "mixed group" analysis. Although balloon remodeling and unassisted methods are presented as uniform cohorts, there is a wide variability in technique among operators, including anticoagulation regimens, which may influence outcome in a way not measured by this analysis.

The largest retrospective single institution series comparing thromboembolic events in balloon-assisted versus unassisted coiling was published by Layton et al.[9] In this cohort of 221 patients there was no statistically significant difference between balloon and control groups in terms of thrombus formation, though the rate in the balloon cohort was higher at 14% versus 9% in the controls. The authors noted that approximately 600 patients would have been needed to exclude the possibility of a type 2 error for this 5% difference, corresponding with a power of 20% for the 221 patients analyzed. If there is one conclusion to be reached with reasonable confidence, it is that, if an overall difference in complication rates should in fact exist between balloon-assisted and unassisted coiling, it will not be large, further underscoring the need for multicenter trials to answer this and many other questions regarding aneurysm treatment.

With regard to outcome analysis of both thromboembolism and perforation complications, no obvious differences were found. Unfortunately, the very small number of events in the balloon remodeling perforation cohort precludes meaningful statistical analysis, making it impossible to draw firm conclusions as to the likelihood that balloon assistance affects the risk of intraprocedural rupture. A predictably higher rate of perforation was seen in the traditionally coiled aneurysms treated in the setting of SAH compared with unruptured ones. This well-described phenomenon requires no additional confirmation but does corroborate the legitimacy of our patient population.

We have chosen to focus primarily on safety, rather than efficacy of balloon remodeling, compared with traditional-unassisted coiling. Balloon remodeling is frequently used in the treatment of broad-based aneurysms in which it is probably more difficult to achieve optimal packing of the aneurysm neck. Despite this possible negative bias, a higher rate of reported occlusion on initial and subsequent angiograms in the balloon remodeling cohort (Table 3) was observed.

This potentially important difference[1] is mitigated by the widely heterogeneous subjective methods used to report occlusion, which appear especially prone to operator bias. In contrast to the thromboembolism analysis, occlusion data come almost solely from exclusively balloon remodeling or exclusively unassisted coiling reports. A comparison of treatment efficacy in "mixed" articles was not possible because no distinction is usually made of angiographic outcome for balloon remodeling and unassisted coiled subjects within such studies. Moreover, the aneurysms treated by the 2 methods may differ morphologically to such an extent that bias would be introduced unless the analysis were controlled for relevant aneurysm characteristics, that is, size and neck features (often unavailable from the reports). In our analysis, the information derived from the selected studies was insufficient to provide for this kind of control, and we decided against a potentially misleading "overall" statistical comparison between occlusion rates. This latter point underscores what we feel is a significant shortcoming in the interventional neuroradiology literature.

Many of the potentially available patient data, in many of the articles reviewed, were either incomplete or not useful for secondary analysis. As the field of neurointerventional radiology matures, a more comprehensive body of analyzable information will be required. This could be facilitated further by the adoption of a standardized reporting format with universal metrics to increase transparency and render data useful for secondary evaluation.

Conclusions

Our findings suggest that balloon remodeling is not associated with higher rates of thrombotic complication compared with traditional-unassisted coiling. Additional data on rates of periprocedural aneurysm rupture, outcome, and coiling efficacy do not suggest higher complication rates in the balloon remodeling cohort, though rigorous statistical analysis of these parameters was not possible. This deficiency underscores a need for more uniform reporting of endovascular treatments. A prospective, multicenter data base would be immensely useful for clarification of many unanswered questions and is likely to lend further legitimacy to the endovascular coiling technique.

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