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## **Is the Risk of Balloon Assistance Underinflated?**

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## Is the Risk of Balloon Assistance Underinflated?

In this issue of the *American Journal of Neuroradiology*, Nelson et al<sup>1</sup> make an effort to compare the incidence of complications of coiling with and without balloon assistance in a review and meta-analysis. They conclude that in the published literature to date, the use of a supportive balloon is not associated with a higher complication rate. In general, a meta-analysis should start with an unbiased systematic review that incorporates articles chosen by using predetermined inclusion criteria. If the data extracted from these studies are, to some level, homogeneous, these data can be combined by using meta-analysis.<sup>2</sup>

In a meta-analysis, the choice of inclusion criteria may determine results. What is put in is what will come out. How about the inclusion criteria in the article by Nelson et al?<sup>1</sup> Some of their inclusion criteria can be disputed. For the most part, studies dealing exclusively with either conventional coiling only or balloon-assisted coiling only are included. A minority of included studies contain data on both techniques. However, in these “mixed articles” alone can direct comparison of complication rates be made. Most articles dealing exclusively with balloon-assisted coiling come from expert centers and may have publication bias: bad results are not likely to be published. Moreover, in most of these articles, a random study period is chosen (with possible bias) and patients are not necessarily consecutive.

Curiously, the authors use a strict inclusion criterion on reporting the frequency and outcome of thromboembolic complications and procedural ruptures as separate entities. Also, both transient and permanent complications need to be reported. As a consequence of these peculiar inclusion criteria, important articles specifically dealing with the subject with the largest patient groups<sup>3,4</sup> are excluded because “thrombo-embolic complications and procedural ruptures and transient and permanent complications were not separately reported.”<sup>1</sup> Surprisingly (or not?), these excluded articles happen to report the opposite of what is found by Nelson et al<sup>1</sup>: a higher complication rate with balloon assistance. Apparently, in the opinion of the authors, procedural death or disability is only of importance (and thus worth reviewing!) if the distinction between procedural rupture and thromboembolism as the cause of the complication can be made. Is there a difference between being bitten by the dog or the cat? Of course not; the only issue that matters is outcome.

The criteria used by the authors introduce an inclusion bias toward articles with just over 10 patients dealing with either assisted or unassisted coiling only and to articles either without complications or with either thrombo-embolic complications or procedural ruptures only. What would be the reason to choose the inclusion criteria in such a way that essential articles with opposite results are excluded? The publication of our study in 2006<sup>3</sup> about an increased complication rate with balloon assistance generated a number of commentaries<sup>5,6</sup> and was subject to debate at several meetings. The neurointerventional community indicated that our complication rate exceeded reported data by far and raised questions about the methodology, aneurysm selection, and the types of balloons that were used.<sup>7</sup> In the mean time,

more recent publications have reported complication rates of balloon-assisted coiling to be in the same range as those for conventional coiling.<sup>8-11</sup> We acknowledge that differences in complication rates with balloon assistance may exist between centers. To some extent, this can be explained by different study time frames, differences in aneurysm selection, anticoagulation regime, and more liberal or restricted use of balloon assistance. In addition, recent advancements, such as the availability of easy-to-place stents, dedicated balloons, and powerful thrombolytic drugs are likely to improve the clinical results of the treatment of difficult aneurysms.

Although we find it hard to conceive that insertion of an adjunctive balloon catheter that needs to be passed across the aneurysm neck and repeatedly occludes the parent vessel does not increase the complication rate, we encourage publication of results that are better than ours. This will stimulate meaningful and sincere discussion on the use of balloon assistance and, in time, will contribute to some form of consensus. The article of Nelson et al<sup>1</sup> does not promote this discussion. The approach of selectively including studies that reinforce a preconceived notion should not be considered a meta-analysis.

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Harry Cloft

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