

Core Laboratory versus Self-reported Evaluations of Angiographic Images of Coiled Cerebral Aneurysms: A Meta-analysis

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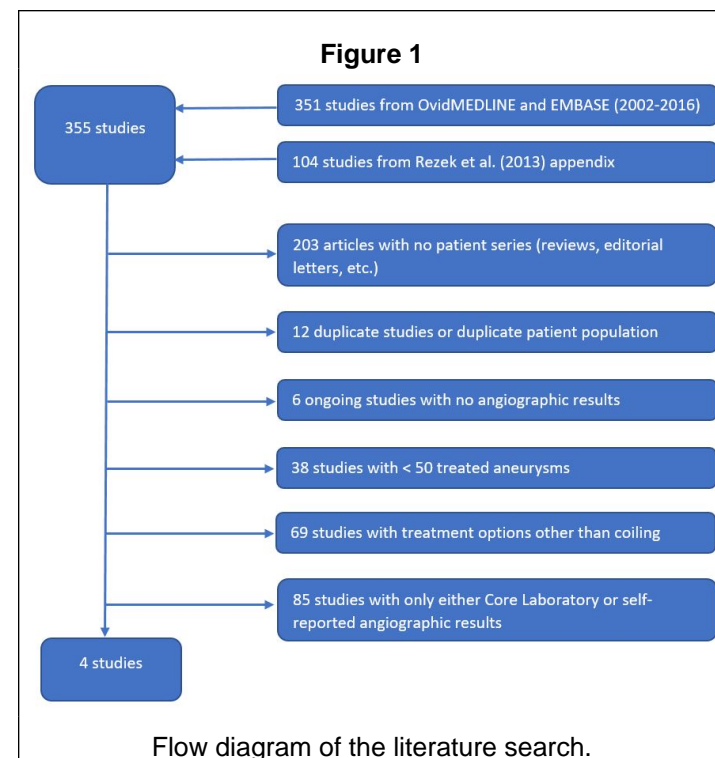
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Learning Objectives

Trials of intracranial aneurysm coiling commonly only report operator evaluations. Self-reported results tend to have more favorable outcomes when compared with Core Laboratory evaluations. This bias should be kept in mind when interpreting results from these trials.

Introduction

Intracranial aneurysm coiling trials commonly report only operator interpretations of angiographic outcomes. Individual studies have shown that self assessments tend to report more favorable outcomes when compared with assessments made by independent evaluators. In the current study, we aim to compare the difference between self-report and Core Laboratory assessments of angiographic outcomes within the same trials.



Methods

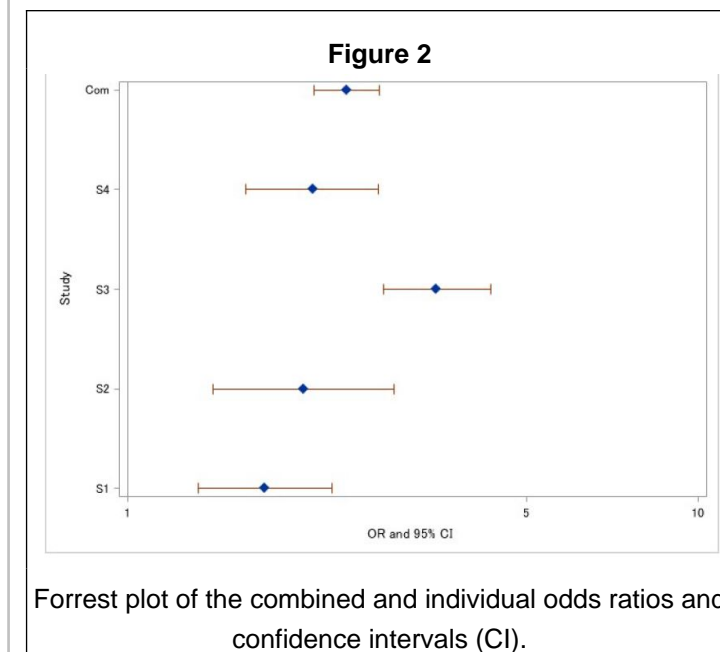
We conducted a thorough search of the literature in Ovid MEDLINE and EMBASE, using the search terms "subarachnoid hemorrhage", "intracranial aneurysms", "endovascular treatment", "coiling", and "trials". The search covered from 2002-2016. Inclusion criteria were clinical trial, >50 aneurysms treated, and reporting of both independent core imaging facility and operator interpretations of angiographic results. Differences between and the Core Laboratory and the operator assessments were analyzed for statistical significance.

Table 1

Study	GREAT (Taschner 2016) S4	Cerebryte (Rezek 2014) S1	Clarity (Pierot 2010) S3	French Matrix (Pierot 2006) S2
Study type	RCT (Hydrogel vs. bare)	RCT (Cerebryte vs. bare)	Prospective series (GDC vs. Matrix)	Prospective series (Matrix and combination)
Total IAs treated	513	465	773	261 patients
Reported IAs	484	434	773	244 self-report 232 CoreLab
Time of angiographic result	Immediate post-procedure	Immediate post-procedure, 5-7 mo. follow up	Immediate post-procedure	Immediate post-procedure
IA size	6.8mm (243) 7.1mm (241)	Not reported	<6mm (448) >6mm (325)	1-5mm (90) 6-10mm (115) 11-15mm (29) 16-25mm (10)
Rupture	208 ruptured	227 ruptured*	773 ruptured	98 unruptured*
# of CoreLab readers	2	1	2	2
Scale used	3-point Raymond scale	4-point scale	Modified Montreal scale	3-point Raymond scale
# favorable outcome by self-report	340	226	586	150
# favorable outcome by CoreLab	254	167	366	102

Results

The search yielded 356 studies, out of which four fulfilled our inclusion criteria: GREAT, Cerebryte, CLARITY series, and the Endovascular Treatment of Intracranial Aneurysms with Matrix Detachable Coils registry. These four studies included data on a total of 1,935 aneurysms for analysis. Angiographic outcomes were all graded by using the Raymond Grading Scale (complete occlusion, residual neck, residual aneurysms). All four studies reported more favorable results by operator self-assessment compared with Core Laboratory assessments, with odd ratios of 1.74 (CI 1.33-2.28), 1.99 (CI 1.38-2.87), 3.49 (CI 2.81-4.33), and 2.14 (CI 1.64-2.78). The combined odds ratio of favorable outcomes by self-report is 2.42 (CI 2.12-2.76).



Conclusions

Self-reported interpretations tend to report higher rates of favorable outcomes compared with Core Laboratory assessments. Interpretations of self-report only trials should be aware of this bias, and decision making for device approvals should take into account our findings.