

Hydrocephalus after subarachnoid hemorrhage: A meta-analytic comparison of aneurysm treatments

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RESULTS: Because indications for the two treatments are different, there is little clinical equipoise for treating most cases. The single randomized, controlled trial dealt with a small subset of ruptured aneurysms. Neither this nor pooled values from other studies which compared the two treatments had the power to demonstrate significant differences between the two treatments. Nor was there an apparent difference when observational data were meta-analytically pooled. However, when meta-regression was used to correct for predictive variables known to differ between the two treatment groups, a highly-significant difference appeared. Coiling is used more commonly in older, sicker patients with aneurysms in certain locations. These cases are more likely to develop hydrocephalus. When corrected for these covariates, the risk of hydrocephalus was found to be significantly lower in coiled vs clipped cases ($P = 0.014$).

CONCLUSION: Pooled observational data were necessary to demonstrate that coiling ruptured cerebral aneurysms is associated with a lower risk of developing hydrocephalus than is clipping.

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Key words: Subarachnoid hemorrhage; Cerebral aneurysm; Hydrocephalus; Meta-analysis; Meta-regression; Observational data

Core tip: Several treatment comparisons in clinical medicine are not amenable to randomized controlled trials. The conditions may be too rare for trials to obtain adequate statistical power. There may be a lack of clinical equipoise on the part of patients or clinicians. Comparisons of different treatments are nevertheless still important and can only be addressed by pooling observational data.

Abstract

AIM: To compare two treatments for ruptured cerebral aneurysm with reference to the relative risk of developing hydrocephalus.

METHODS: We reviewed the English language literature on the risk of developing hydrocephalus after aneurysm treatment. Data were divided by type of study (randomized controlled trial, cohort trial, nonrandomized comparison, prospectively- and retrospectively-collected observational study). They were also divided by type of aneurysm treatment (microvascular - clipping, or endovascular - coiling). Additional predictive variables collected for each publication were average age, gender distribution, measures of hemorrhage volume and subarachnoid hemorrhage severity, aneurysm locations, time to treatment, duration of follow-up and date of publication. We employed meta-analysis to calculate pooled risk ratios of developing hydrocephalus in cases receiving aneurysm clipping vs those receiving coiling. Meta-regression was used to correct pooled results for covariates.

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INTRODUCTION

Cerebral aneurysms are small spherical outpouchings of the arteries that run along the surface of the brain. Affecting approximately 3.2% of adults^[1], they are usually clinically silent and cause no symptoms. However, as its weakened wall stretches, the aneurysm is prone to rupture, bleeding into the subarachnoid space that surrounds the brain^[2]. This subarachnoid hemorrhage occurs annually in about 9 per 100000 population worldwide, many countries experiencing much higher rates^[3]. The most common cause of nontraumatic subarachnoid hemorrhage (SAH), ruptured cerebral aneurysm, is associated with high mortality and morbidity, and is considered an important cause of disabling stroke. One common complication of SAH is hydrocephalus, enlarging of the brain's fluid spaces^[4]. This is thought to be caused by the blood and the inflammation it incites clogging the pathways and preventing circulation and absorption of cerebrospinal fluid (CSF). Hydrocephalus is extremely common in the first days after SAH; as many as 30% of hydrocephalus cases are permanent and require long-term treatment.

Ruptured aneurysms are commonly treated acutely, in order to prevent repeat hemorrhage. One standard treatment is craniotomy with application of a spring-loaded clip across the neck of the aneurysm. Usually this procedure is performed with the aid of an operative microscope and is termed "microvascular" or "clipping". The other technique involves threading a catheter within the artery from the groin to the aneurysm and filling the aneurysm sac with tiny platinum coils. Termed "endovascular" or "coiling", this approach induces the blood within the aneurysm to clot. Both approaches are usually successful in preventing aneurysms from bleeding again. The choice of which procedure is most appropriate often varies according to the characteristics of the aneurysm and the patient^[5,6]. Recent guidelines have been published to establish the relative strengths and weaknesses of both approaches^[7].

One unresolved issue is whether one approach is more successful in preventing chronic hydrocephalus. Each has its strong points. Microvascular surgery promotes dissipation of the blood surrounding the aneurysm. On the other hand, the brain exposure and manipulation involved in microvascular surgery may itself predispose to hydrocephalus, a problem the endovascular approach avoids.

Clinical trials reporting incidence of hydrocephalus after each aneurysm treatment have reported wide variations in the incidence of chronic hydrocephalus. Studies reporting outcomes from both approaches have measured conflicting relative risks. Since there are few controlled clinical trials, it is apparent that meta-analytic

pooling of results is necessary to predict the relative risks associated with the two aneurysm treatments. Point estimates of the actual probability of hydrocephalus are often required for decision analyses and cost-effectiveness determinations. Since these values may be difficult to determine from meta-analytically pooled risk ratios, Einarson proposed meta-analysis of observational data^[8]. However, this and similar approaches to meta-analysis have been criticized as precise but not necessarily valid^[9,10]. Our study compares analysis of trials, in which both treatments are compared, with observational data to predict relation between treatment and risk of chronic hydrocephalus

MATERIALS AND METHODS

We performed a structured search in Medline, EMBASE and the Cochrane database of articles published in English before March 2013 containing a combination of the terms "subarachnoid", "hemorrhage/haemorrhage", "intracranial aneurysm", "treatment" and "hydrocephalus," either as keywords or in the text or title. We supplemented our search using the "Related Citations" feature of PubMed and manual reviews of the bibliographies of selected articles. Abstracts of returned articles were examined for a likelihood of yielding useful data. Unlikely abstracts were excluded; the others were reviewed by at least two authors. We excluded series reporting fewer than 10 treated cases. We also excluded publications that reviewed or duplicated data from other reports or dealt only with special cases, such as giant or pediatric aneurysms. For purposes of this study, we defined "hydrocephalus" as the placement of a permanent ventricular shunt at any time in the acute or follow-up period. The articles were divided into two groups, those treated by microvascular clip occlusion and those with endovascular coil occlusion. If an article reported on both approaches, it was included in the analysis only if results of the two treatment groups were reported separately. We included only cases in which a permanent CSF shunt was placed; acute but transient hydrocephalus was not included.

In addition to treatment and hydrocephalus incidence, the following categories of data were also extracted: (1) number of cases surviving acute care; (2) median Fisher grade (FG) a measure of hemorrhage volume, median Hunt-Hess grade (HHG) a measure of the hemorrhage's clinical severity; (3) mean age; (4) gender distribution; (5) ruptured aneurysm location and diameter; (6) proportion of microvascular cases with attempted clot removal; (7) mean time to treatment; (8) duration of follow-up; and (9) date of publication.

We used meta-analytic technique to calculate pooled risk ratios from randomized controlled trials (RCTs), non-randomized cohort studies, and retrospective reviews of case series that reported results from both treatment approaches. In addition we pooled observational data meta-analytically, creating pooled means and distributions for each variable {Einarson, 1997 #36}, calculating risk ratios from the pooled results.

Table 1 Series used for analysis

Series	Trial type	Treatment	No. of cases	Hydrocephalus incidence
Akyuz <i>et al</i> ^[21]	Ret	Clip	145	6.9%
Andaluz <i>et al</i> ^[22]	Pro	Clip	106	6.6%
Auer <i>et al</i> ^[23]	Ret	Clip	138	6.5%
Bailes <i>et al</i> ^[24]	Ret	Clip	27	96.3%
Chan <i>et al</i> ^[25]	Ret	Clip	89	57.3%
de Oliveira <i>et al</i> ^[26]	Ret	Clip	212	17.5%
Dehdashti <i>et al</i> ^[12]	Cohort	Both	245	13.9%
Diaz <i>et al</i> ^[27]	Ret	Coil	31	15.5%
Dorai <i>et al</i> ^[28]	Ret	Clip	651	23.3%
Fanning <i>et al</i> ^[29]	Ret	Coil	178	1.7%
Ferch <i>et al</i> ^[30]	Ret	Clip	73	53.4%
Fujimura <i>et al</i> ^[31]	Ret	Clip	39	17.9%
Fukuhara <i>et al</i> ^[32]	Pro	Clip	62	9.7%
Gao <i>et al</i> ^[33]	Ret	Coil	221	4.1%
Giltsbach <i>et al</i> ^[34]	Ret	Clip	138	23.2%
Graff-Radford <i>et al</i> ^[35]	Ret	Clip	3521	8.9%
Gruber <i>et al</i> ^[36]	Ret	Both	187	21.4%
Harrigan <i>et al</i> ^[37]	Ret	Both	349	41.2%
Hernesniemi <i>et al</i> ^[38]	Ret	Clip	57	31.6%
Hirashima <i>et al</i> ^[39]	Ret	Clip	114	34.2%
Hoh <i>et al</i> ^[40]	Ret	Both	20585	5.4%
Hornyak <i>et al</i> ^[41]	Ret	Clip	92	20.7%
Jartti <i>et al</i> ^[42]	Ret	Both	209	30.1%
Joakimsen <i>et al</i> ^[43]	Pro	Clip	47	10.6%
Kaku <i>et al</i> ^[44]	Ret	Both	100	18.0%
Kang <i>et al</i> ^[45]	Pro	Coil	76	5.3%
Kasuya <i>et al</i> ^[46]	Ret	Clip	108	29.6%
Kolluri <i>et al</i> ^[47]	Ret	Clip	500	4.2%
Komotar <i>et al</i> ^[48]	Ret	Clip	582	10.3%
Krayenbühl <i>et al</i> ^[49]	Ret	Clip	218	10.1%
Kung <i>et al</i> ^[50]	Ret	Coil	102	30.4%
Kwon <i>et al</i> ^[51]	Ret	Coil	107	12.1%
Liew <i>et al</i> ^[52]	Ret	Clip	13	69.2%
Lin <i>et al</i> ^[53]	Ret	Clip	147	15.6%
Milhorat <i>et al</i> ^[54]	Ret	Clip	29	20.7%
Moriyama <i>et al</i> ^[55]	Ret	Clip	58	32.8%
Nam <i>et al</i> ^[56]	Ret	Both	736	19.7%
Natarajan <i>et al</i> ^[57]	Ret	Both	192	14.3%
Ohwaki <i>et al</i> ^[58]	Ret	Clip	74	33.8%
O'Kelly <i>et al</i> ^[59]	Ret	Both	3120	18.7%
Park <i>et al</i> ^[60]	Ret	Clip	94	13.8%
Park <i>et al</i> ^[61]	Ret	Coil	118	5.9%
Pinsker <i>et al</i> ^[62]	Ret	Clip	31	48.4%
Raimondi <i>et al</i> ^[63]	Ret	Clip	30	13.3%
Säveland <i>et al</i> ^[64]	Pro	Clip	247	1.2%
Schmieder <i>et al</i> ^[65]	Ret	Clip	138	10.9%
Sethi <i>et al</i> ^[66]	Ret	Both	100	6.0%
Sindou <i>et al</i> ^[67]	Ret	Clip	197	12.7%
Spallone <i>et al</i> ^[68]	Ret	Clip	125	7.2%
Stenhouse <i>et al</i> ^[69]	Ret	Clip	27	11.1%
Sundt <i>et al</i> ^[70]	Ret	Clip	616	9.4%
Taha <i>et al</i> ^[71]	Ret	Both	133	22.5%
Tapaninaho <i>et al</i> ^[72]	Ret	Clip	835	9.7%
Theander <i>et al</i> ^[73]	Ret	Clip	16	6.3%
Tomasello <i>et al</i> ^[74]	Pro	Clip	47	4.3%
Tsimentzis <i>et al</i> ^[75]	Pro	Clip	61	6.6%
Vale <i>et al</i> ^[76]	Ret	Clip	90	20.0%
Vanninen <i>et al</i> ^[11]	RCT	Both	106	13.2%
Varelas <i>et al</i> ^[77]	Ret	Both	163	7.3%
Vassilouthis <i>et al</i> ^[78]	Ret	Clip	181	6.1%
Widenka <i>et al</i> ^[79]	Ret	Clip	283	18.4%
Williams <i>et al</i> ^[80]	Ret	Clip	19	42.1%
Yang <i>et al</i> ^[81]	Ret	Both	88	25.0%

Yasui <i>et al</i> ^[82]	Ret	Clip	82	46.3%
Yoshioka <i>et al</i> ^[83]	Ret	Clip	576	37.3%

RCT: Randomized controlled trial; Pro: Prospective data collection; Ret: Retrospective; Clip: Microvascular approach; Coil: Endovascular approach; Both: Clipping and coiling procedures reported in series.

To assess the effects of follow-up length, date of publication and other covariates on results, we employed meta-regression {Thompson, 2002 #39}. Statistical associations between a predictor variable such as type of aneurysm treatment and hydrocephalus incidence assume that treatment was independent of other influences. If there were other predictor variables that might interact with treatment (covariates), their contributions were analyzed using multiple regression analysis. In the case of pooled data, this required meta-regression. Meta-analytic pooling, meta-regressions and statistical analyses were done using Stata 12 (StataCorp LP; College Station, Texas).

RESULTS

The search returned 857 abstracts of which 303 were relevant to our study. Some published series were excluded from our analysis since they reported only on elderly, pediatric or other specialized groups of patients. Figure 1 illustrates our search results, and Table 1 summarizes the publications used in our analysis, along with the study type, treatments used and incidence of hydrocephalus. In all, there were 65 publications reporting 38081 cases surviving acute care. Note that 14 papers (termed “comparative studies”) reported outcomes for both clipped and coiled patients separately. There was only one RCT^[11] and one prospectively collected cohort study^[12]. The other 12 papers involved retrospective data review of cases having one procedure or the other. This suggests that the bulk of the evidence was Level 4^[13]. The incidence of hydrocephalus varied from 1 to 96% in individual series.

We compared the risk ratios (endovascular/microvascular) reported by the single RCT, the cohort study, the pooled values of the 14 comparative studies and pooled value of all 65 publications treated as observational studies. The results are shown in Table 2. The pooled mean incidence of chronic hydrocephalus, calculated from all sources, is 0.191 (\pm 0.023). The probability of hydrocephalus was lower after coiling than clipping (0.161 ± 0.199 and 0.209 ± 0.115 , respectively). This corresponds to a risk ratio of 0.770 (relative risk = 0.726, absolute difference 0.048), the difference being non-significant ($P = 0.289$) on the Student's *t* test.

For the observational analysis we also investigated the influence of variables other than treatment on hydrocephalus incidence. Table 3 reports the results of simple linear meta-regression for the associations between hydrocephalus incidence and the other measured variables, demonstrating several other significant differences between the two groups. These include HHG, time to treatment, and patient age, the last of which is

Table 2 Risk ratios by study type

Study type	Number of studies	Risk ratio (coil/clip)	95%CI
RCT	1	0.286	0.008-1.011
Cohort study	1	1.512	0.956-2.068
All comparative studies	14	1.150	0.982-1.318
Observational studies	65	0.770	0.539-1.005

RCT: Randomized controlled trial; Clip: Microvascular approach; Coil: Endovascular approach.

Table 3 Association between variables and incidence of hydrocephalus

Variable	B coefficient	95%CI	P value
Treatment ¹	-0.048	-0.131-0.034	0.249
Mean hunt-hess grade	0.146	0.064-0.228	0.001
Mean fisher grade	0.015	-0.106-0.136	0.805
Mean age (yr)	0.010	0.002-0.018	0.019
% Female patients	-0.047	-0.544-0.451	0.852
% Vertebrobasilar aneurysms	0.001	-0.002-0.004	0.434
Time to treatment	-0.011	-0.021-0.0004	0.042
Duration of follow-up	-0.000	-0.004-0.003	0.833
Year of publication	0.001	-0.002-0.005	0.455

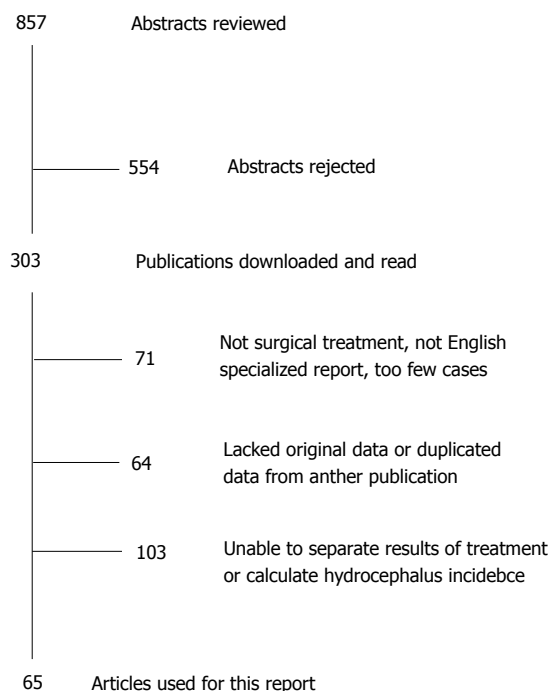
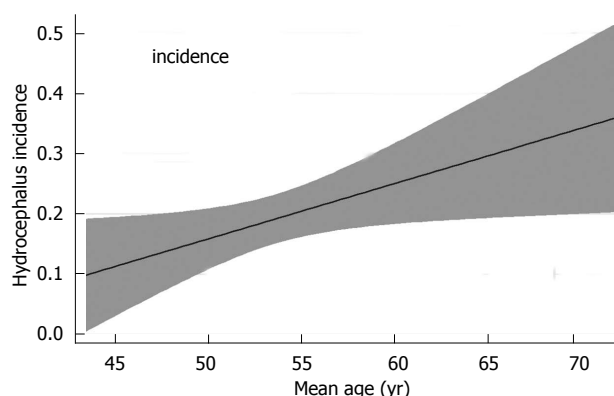
¹Clipping scored 1, coiling 2.

shown in Figure 2. Of note, there was no significant association between date of publication and hydrocephalus incidence, suggesting no progress has been made over time to lower its risk. In addition, neither sex distribution nor the mean FG appeared to influence hydrocephalus occurrence. Other variables, such as the presence of vasospasm, intraventricular hemorrhage (IVH), removing the subarachnoid clot surgically or with antifibrinolytics, acute hydrocephalus and aneurysm diameter lacked sufficient pooled data to permit meaningful analysis.

We cannot assume that all the predictor variables for hydrocephalus are independent. Since the treatment was not chosen randomly, we must consider whether characteristics of the patients or the hemorrhages influenced choice of treatment. Statistical comparisons revealed significant differences between clipped and coiled cases regarding patient age ($P = 0.045$), % females ($P = 0.038$), and % vertebrobasilar aneurysms ($P = 0.018$). In all cases, the higher values were in the coiled group. Although the lower risk of hydrocephalus in coiled patients was not significant in single regression, adjusting with multivariable meta-regression for these covariates (age, sex, aneurysm location) revealed that treatment became a highly significant independent predictor of hydrocephalus ($P = 0.014$). HHG ($P = 0.001$) and age ($P = 0.032$) remained the only other independent significant predicting variables. Correcting the comparative series for covariates did not alter the non-significant association between treatment type and hydrocephalus incidence.

DISCUSSION

Meta-analytic techniques to pool observational data and

**Figure 1 Articles reviewed for this study****Figure 2 Influence of age on hydrocephalus incidence.** In the meta-regression, the line represents the fitted mean and the gray are the 95%CI.

correct for covariates enabled us to demonstrate a lower risk of hydrocephalus following endovascular aneurysm repair compared to microvascular treatment. This knowledge may aid aneurysm surgeons in selecting the ideal approach to individual patients after subarachnoid hemorrhage.

The task is complicated by a strong bias in selecting patients for each surgical approach. For example, older and sicker patients and those harboring aneurysms in certain locations are more likely to be selected for endovascular over microvascular surgery. The single RCT^[11] was limited to the small subset of cases in which clinical equipoise was thought to exist. Not only is this report of limited generalizability to the ruptured aneurysm population, it is too small to demonstrate significance. Nor is a significant difference obtained by pooling results from non-randomized trials in which the two approaches are compared. Only the larger numbers obtained by treating

all studies as observational allowed the underlying pattern to emerge. Surgeons are more likely to employ coiling to treat aneurysms in older, sicker patients and those whose aneurysms are in the vertebrobasilar circulation, all of which have been shown to predispose to hydrocephalus. Correcting for these covariates allowed us to demonstrate that the risk of hydrocephalus was significantly lower after endovascular coiling than microvascular clipping. Among attempts to extend the utility of meta-analysis in clinical medicine^[14,15], employing observational data has been reported as a valuable addition^[8,16-18]. Not only can it be used to generate pooled probabilities, but, as here, to explore possible causal relationships in situations in which RCTs have not or cannot be done.

This study has several important limitations. It could be argued that possible selection bias creates two overlapping but distinct populations, for which any statistical comparison is invalid. The role of meta-analysis for observational data has been criticized as introducing possible confounding and heterogeneity^[9], and there are situations in which it creates misleading conclusions^[10]. Nevertheless, guidelines have been established in reporting observational meta-analyses^[19] along the lines of the QUOROM specifications^[20].

In a conclusion, we propose that analysis of observational data is necessary to display a significant association between treatment choice for subarachnoid hemorrhage and subsequent hydrocephalus. We used meta-analysis to create pooled estimates of frequency and meta-regression to correct for covariates.

COMMENTS

Background

Cerebral aneurysms are common causes of hemorrhagic stroke, and hydrocephalus is a common complication of a ruptured aneurysm. Aneurysm treatment usually consists of occlusion by intracranial clipping or intravascular coiling. There is lack of consensus about which treatment has the lower risk of hydrocephalus. However, because of the different indications for the two treatments, different patient ages and other discordances, a suitable trial has not been done.

Research frontiers

Authors' present an approach to the problem which employs observational meta-analysis and meta-regression to compare the two procedures in reference to the risk of hydrocephalus and to correct for covariates, such as subject age and aneurysm location.

Innovations and breakthroughs

Previous comparisons of relative risks and treatment effects were generally limited to randomized clinical trials.

Applications

This approach permits comparison of risks and effectiveness of treatment strategies from observational data in the absence of randomized clinical trials.

Terminology

Cerebral aneurysms: small spherical outpouchings of the arteries that run along the surface of the brain. Aneurysm rupture: tear in the thinned wall of the aneurysm. Subarachnoid hemorrhage: bleeding resulting from aneurysm rupture. Hydrocephalus: enlargement of the fluid spaces of the brain secondary to impairment of fluid flow or absorption.

Peer review

This paper presented a very well-written meta-analysis of published literature aiming to determine whether endovascular coiling or (open) surgical clipping of (cerebral) aneurysm affects incidence of chronic hydrocephalus.

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