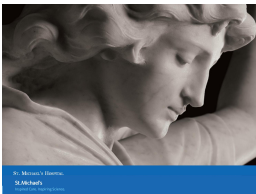




Center-effect in Patient Outcome After Enrollment into Randomized Clinical Trials in Aneurysmal Subarachnoid Hemorrhage

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Introduction

•Differences between centers in patient outcome after subarachnoid hemorrhage from ruptured intracranial aneurysms (SAH) could be of relevance for design of multicenter studies, particularly randomized clinical trials (RCT), and standardization of management practices for improved quality of care for all patients

•Aim: To investigate whether differences in outcome exist between centers enrolling patients into randomized clinical trials in SAH, and if so, quantifying such center-effect

Methods

•Study population: 6036 patients from three multicenter RCT (IHAST, MASH & Tirilazad)

•Random-effects logistic regression models used to estimate between-center differences in 3-month unfavorable outcome (GOS 1-2 versus 3-5)

•Compared centers at 97.5th versus 2.5th percentile of outcome distribution

Baseline characteristics of study population

	IHAST	IMASH	TIRILAZAD
Patients (N)	1000	1484	3552
Centers (N)	30	9	144
Countries (N)	5	3	21
Age years: Median(IQR)	43 (52 – 60)	48 (56 – 65)	42 (51 – 62)
Poor grade (WFNS 3-5)	51 (5.1%)	408 (27.5%)	1217 (34.3%)
Unfavorable outcome (GOS 3-5)	144 (14.4%)	398 (26.9%)	1061 (30.3%)

Results

• Overall, 3.8-fold difference in odds of unfavorable outcome between centers at the lower end compared with centers at the higher end of the outcome distribution, after adjusting for differences in patient characteristics

•Europe = 6.28-fold; Oceania = 3-fold; North America = no difference

Conclusions

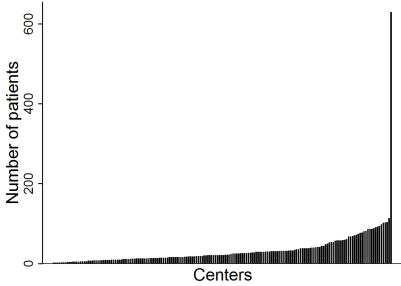
•The outcomes of patients who are enrolled into multicenter clinical trials in SAH differ considerably between centers and regions

•The reasons and implications of these findings should be studied, as such might lead to improvement in some aspects of trial design and management practices

Center effect measured as difference in the Odds of unfavorable outcome between centers at the 97.5th versus 2.5th Percentiles of the outcome distribution

	Unadjusted	Adjusted (Age and WFNS)
North America	5.29	1.00
Europe	4.95	6.28
Oceania	11.31	3.00
Combined	5.92	3.83

Histogram of number of patients per center



N=6036 patients in 176 centers.
Range: 1 - 628 patients (median: 20; IQR: 12-37)

Learning Objectives

1.Have a better understanding of between-center variability in outcome after aneurysmal subarachnoid hemorrhage

2. Discuss the likely reasons for the study findings

3.Discuss the implications of our findings for prospective multicenter studies in SAH, and patient care

Acknowledgement

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