CNS 2018 ANNUAL MEETING
HOUSTON, TEXAS
OCTOBER 6-10, 2018

Assessment of spontaneous intracranial hemorrhage load on Interventional Neuroradiology team for possible enrolment into SAH treatment clinical study

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Introduction

While participating in EDGE-Newton-II study for aneurysmal-SAH therapy it was required to report all SAH admissions in order to assure efficient candidate screening. The inclusion and exclusion protocol parameters led to small group of candidates that should be analyzed also with the general load estimate on Interventional Neuroradiology team (INR) and Neurosurgery during participation.

Methods

From December 2016 to March 2018, we reviewed daily reports of all admissions with primary diagnosis of any non-traumatic sub-arachnoid hemorrhage (NT-SAH) in our institute which is an academic tertiary center with full service neurosurgery and INR team. The clinical parameters, as well as procedures and outcome (mainly 30-day) served as an estimate of the load on interventional neuroradiology team during the participation in trial.

SAH due to vascular lesion acute bleeding

No DSA			At least 1 DSA										TOTAL	16 MONTHS 12/16-3/18
1M MORTALITY	1M DEATH	No	NUMBER OF ANGIO PR	NUMBER OF F-U PR	NEED ANGIO F-U	NEED ADDITIONAL COILING	NUMBER OF ANGIOPLASTY	NEED ANGIOPLASTY	1M MORTALITY	1M DEATH	ATTEMPT/ NO NEED TO COIL	COILED		
100%	3	3	48	11	9	3	12	3	9.1%	2	6	16	25	ALL SAH WITH EVD
100%	2	2	°	°	°	°	°	°	11.8%	2	1	16	19	ANEURYSMS WITH EVD
100%	2	2	°	°	°	°	°	°	0.0%	0	1	10	13	ANTERIOR CIRCULATION ANEURYSM WITH EVD
°	0	6	82	26	23	5	3	1	2.1%	1	25	23	54	SAH W/O EVD
°	0	0	°	°	°	°	°	°	4.3%	1	3	20	23	ANEURYSMS W/O EVD
33%	3	9	130	34	29	11	15	4	4.3%	3	31	39	79	ALL SPONTANEOUS VASCULAR LESION BLEEDING

SAH due to acute bleeding from vascular lesion

Conclusions

Screening patients for clinical trials enables the creation of registry and farther evaluation of workloads and institutional achievements. The ratio of 3 dosing per 10 potentials in the EDGE trial was not lower then we predicted.

Learning Objectives

Systematic recording of patients and procedures load can be useful for assessment of potential for clinical study participation.

Results

Three-hundred patients with NT-SAH were admitted. All underwent diagnostic radiology for evaluation, and 221 out of them were negative. Thirteen of these bleedings underwent craniotomy for evacuation and their mortality was significant lower compared with the non-operative group (8% vs. 37%, P=0.03). Vascular lesion was found in 79 patients (or still suspected after negative angiography). Ruptured aneurysm was the bleeding cause in 42 patients of whom 37 were acutely coiled (within mean 10 hours of presentation). One and 3-month mortality was 8.1% and 10.8% respectively. Of ten patients with EVD and anterior circulation lesion, 6 were screened for the study, and 3 randomized. Study patients underwent 21% of the 130 angio-suite visits until now. Referrals and early analysis led to increase in lost to follow-up rate from 10% in 1-month to 29% in 3-month in 42 patients with aneurysms (p=0.029).

References

The impact of enrollment in clinical trials on survival of patients with glioblastoma. Shahar T, Nossek E, Steinberg DM et al. J Clin Neurosci 2012; 19:1530-4.

SAH due to spontaneous bleeding from other cause