**SOFIA Aspiration System as first-line Technique (SOFAST) – a prospective, multi-center study to assess the efficacy and safety of the SOFIA™ 6F aspiration catheter for endovascular stroke thrombectomy**

Supplementary Materials

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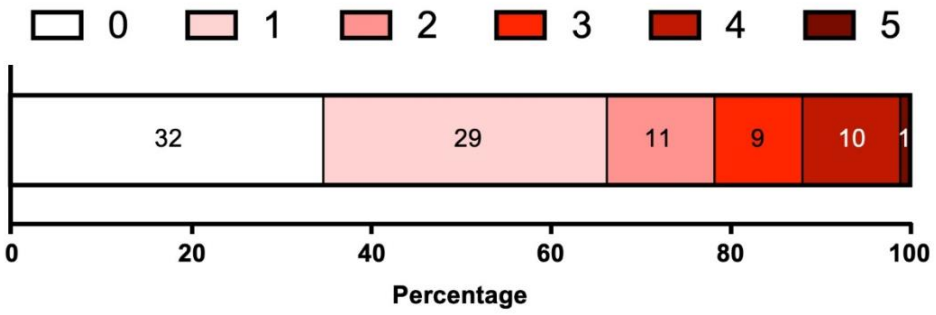
|---|---|
| 0 | **No perfusion** or anterograde flow beyond site of occlusion |
| 1 | **Penetration but no perfusion**: Contrast penetration exists past the initial obstruction but with minimal filling of the normal territory |
| 2 | **Incomplete perfusion** wherein the contrast passes the occlusion and opacifies the distal arterial bed but rate of entry or clearance from the bed is slower or incomplete when compared to non-involved territories |
| 2a | **Some perfusion** with distal branch filling of <50% of territory visualized |
| 2b | **Substantial perfusion** with distal branch filling of ≥50% of territory visualized |
| 2c | **Near complete perfusion** except for slow flow/occlusion in 1 of 2 branches of few distal cortical vessels, or presence of small distal cortical emboli |
| 3 | **Complete perfusion** with normal filling of all distal branches |

Supplemental Table I: mTICI with 2c scale

| Criteria | Number of patients not enrolled |
|---|---|
| IC#5 (Symptom onset is within 6/8 hours of when groin puncture can be achieved) OR EC#4 (More than 8 hours have passed since symptom onset) | 160 |
| IC#3 (Neuroimaging (CT/CTA and/or MR/MRA collected at no more than 60/90 minutes pre-treatment) demonstrates large vessel proximal occlusion (distal ICA through MCA bifurcation)) | 68 |
| IC#7 (Patient is considered by the treating physician to be treatable using the direct aspiration as first line treatment technique (and the decision to use this technique and the study device has been made by the treating physician outside the context of the SOFAST study and prior to study enrollment)) | 60 |
| IC#1 (Patient is ≥ 21 and ≤ 80/85 years of age) OR EC#2 (Patient is < 21 or > 80/85 years of age) | 38 |
| EC#5 (Severe unilateral or bilateral carotid artery stenosis or dissection requiring stent treatment) | 34 |
| EC#16 (Imaging exclusion criteria; core lesion >50cc/ASPECTS<6/mass effect/ischemic changes in post circ/ICH in initial imaging) | 27 |
| IC#4 (Patient has an NIHSS score ≥ 5 at time of intervention) | 21 |
| EC#1 (Inability to obtain written informed consent) OR IC#8 (Patient or patient's legally authorized representative (LAR) has provided written informed consent) | 14 |
| EC#13 (Patient has a severe or life-threatening comorbidity that could confound study results, or that will render the procedure unlikely to benefit the patient) | 13 |
| IC#2 (Patient has a pre-morbid mRS ≤ 1) OR EC#3 (Patient has a pre-morbid mRS ≥ 2) | 8 |
| EC#15 (Patient is enrolled in another device or drug study in which participation could confound study results) | 8 |
| EC#8 (Patient has vascular anatomy/tortuosity or other vascular disease preventing access to the target occlusion or that will likely result in unstable access) | 6 |
| EC#6 (Presence of a pre-existing large territory infarction) | 4 |
| IC#6 (Patient will undergo treatment via femoral access and the decision to use femoral access has been made by the treating physician outside the context of the SOFAST study and prior to study enrollment) | 3 |
| EC#9 (Patient is pregnant) | 2 |
| EC#10 (Known or suspected pre-existing/chronic large vessel occlusion in the symptomatic territory) | 1 |
| IC#9 (Patient is considered by the treating physician to be available for and able to complete all follow-up visits with a trained site investigator) | 1 |

Supplemental Table II: Reasons for screen failure




Supplemental Figure I: Day-90 mRS outcome distribution among patients who completed the study (n=92). A total of 16 subjects could not complete day-90 follow up due to various reasons, including death in 8 subjects, lost to follow up for 5 subjects, protocol deviations for 2 subjects and vessel tortuosity (SOFIA™ 6F could not reach the clot) in 1 subject.