

STITCH

see [Simple interrupted stitch](#)

Surgical Trial In Traumatic intraCerebral Haemorrhage (STITCH)

This international multi-center, patient-randomized, parallel-group trial compared early surgery (hematoma evacuation within 12 h of randomization) with initial conservative treatment (subsequent evacuation allowed if deemed necessary). Patients were randomized using an independent randomization service within 48 h of TBI. Patients were eligible if they had no more than two intraparenchymal hemorrhages of 10 mL or more and did not have an extradural or subdural hematoma that required surgery. The primary outcome measure was the traditional dichotomous split of the [Glasgow Outcome Scale](#) obtained by postal [questionnaires](#) sent directly to patients at 6 months. The trial was halted early by the UK funding agency (NIHR HTA) for failure to recruit sufficient patients from the UK (trial registration: ISRCTN19321911). A total of 170 patients were randomized from 31 of 59 registered centers worldwide. Of 82 patients randomized to early surgery with complete follow-up, 30 (37%) had an unfavorable outcome. Of 85 patients randomized to initial conservative treatment with complete follow-up, 40 (47%) had an unfavorable outcome (odds ratio, 0.65; 95% confidence interval, CI 0.35, 1.21; $p=0.17$), with an absolute benefit of 10.5% (CI, -4.4-25.3%). There were significantly more deaths in the first 6 months in the initial conservative treatment group (33% vs. 15%; $p=0.006$). The 10.5% absolute benefit with early surgery was consistent with the initial power calculation. However, with the low sample size resulting from the premature termination, we cannot exclude the possibility that this could be a chance finding. A further trial is required urgently to assess whether this encouraging signal can be confirmed ¹⁾.

The [STICH](#) (Surgical Trial in Lobar Intracerebral Haemorrhage) I and II trials randomized patients with [spontaneous intracerebral hemorrhage](#) (ICH) to early surgery or initial conservative treatment. Both were nonsignificant; possibly because surgery has minimal effect on recovery, or because surgery benefits some and harms others.

Gregson et al., introduced a new nonparametric method of analysis. The method is then applied to data from a third trial, [STITCH](#)(Trauma) (Surgical Trial in Traumatic Intracerebral Haemorrhage), which addressed a similar surgical question in head-injured patients.

Data from 1541 patients from the STICH trials were analyzed using (1) standard meta-analysis of prognosis-based dichotomized outcome and prespecified standard subgroups of Glasgow Coma Scale (GCS): 3-8, 9-12, and 13-15; (2) new nonparametric regression of ranked Extended Glasgow Outcome Scale against ranked GCS and ranked volume; and (3) analysis (1) repeated using categories identified by analysis (2). Results- Standard meta-analysis showed more favorable outcomes, although nonsignificant, with surgery if presenting GCS was 9-12 (spontaneous ICH odds ratio, 0.70 [95% CI, 0.48-1.03; $P=0.07$]; traumatic odds ratio, 0.48 [95% CI, 0.18-1.26; $P=0.14$]). Ranked analysis showed a similar pattern of results for both spontaneous and traumatic ICH. Surgery was harmful for small lesions with increasing benefit for larger volumes. With GCS, surgery had little effect at either ends of the spectrum but suggested a beneficial effect in the range 10 to 13 (identified graphically). Repeating the meta-analysis with this categorization showed significant benefit for surgery (spontaneous odds ratio, 0.71 [95% CI, 0.51-1.00; $P=0.05$]; traumatic odds ratio, 0.16 [95% CI, 0.05-0.51; $P=0.002$]). Conclusions- The nonsignificant results observed in the STICH trials are because of mixing patients who benefit from surgery with those who are harmed. Patients with a GCS 10-13 or

a large ICH are likely to benefit from surgery. Our analysis showed a similar effect on traumatic ICH/contusion data and promises to be a valuable tool. Clinical Trial Registration- URL: <http://www.isrctn.com/> . Unique identifiers: ISRCTN19976990 (STITCH), ISRCTN22153967 (STICH II), and [ISRCTN19321911](#) (STITCH[Trauma])²⁾.

While it is accepted practice to remove extradural (EDH) and subdural haematomas (SDH) following traumatic brain injury, the role of surgery in parenchymal traumatic intracerebral haemorrhage (TICH) is controversial. There is no evidence to support Early Surgery in this condition.

OBJECTIVES: There have been a number of trials investigating surgery for spontaneous intracerebral haemorrhage but none for TICH. This study aimed to establish whether or not a policy of Early Surgery for TICH improves outcome compared with a policy of Initial Conservative Treatment.

DESIGN: This was an international multicentre pragmatic parallel group trial. Patients were randomised via an independent telephone/web-based randomisation service.

SETTING: Neurosurgical units in 59 hospitals in 20 countries registered to take part in the study.

PARTICIPANTS: The study planned to recruit 840 adult patients. Patients had to be within 48 hours of head injury with no more than two intracerebral haematomas greater than 10 ml. They did not have a SDH or EDH that required evacuation or any severe comorbidity that would mean they could not achieve a favourable outcome if they made a complete recovery from their head injury.

INTERVENTIONS: Patients were randomised to Early Surgery within 12 hours or to Initial Conservative Treatment with delayed evacuation if it became clinically appropriate.

MAIN OUTCOME MEASURES: The Extended Glasgow Outcome Scale (GOSE) was measured at 6 months via a postal questionnaire. The primary outcome was the traditional dichotomised split into favourable outcome (good recovery or moderate disability) and unfavourable outcome (severe disability, vegetative, dead). Secondary outcomes included mortality and an ordinal assessment of Glasgow Outcome Scale and Rankin Scale.

RESULTS: Patient recruitment began in December 2009 but was halted by the funding body because of low UK recruitment in September 2012. In total, 170 patients were randomised from 31 centres in 13 countries: 83 to Early Surgery and 87 to Initial Conservative Treatment. Six-month outcomes were obtained for 99% of 168 eligible patients (82 Early Surgery and 85 Initial Conservative Treatment patients). Patients in the Early Surgery group were 10.5% more likely to have a favourable outcome (absolute benefit), but this difference did not quite reach statistical significance because of the reduced sample size. Fifty-two (63%) had a favourable outcome with Early Surgery, compared with 45 (53%) with Initial Conservative Treatment [odds ratio 0.65; 95% confidence interval (CI) 0.35 to 1.21; $p = 0.17$]. Mortality was significantly higher in the Initial Conservative Treatment group (33% vs. 15%; absolute difference 18.3%; 95% CI 5.7% to 30.9%; $p = 0.006$). The Rankin Scale and GOSE were significantly improved with Early Surgery using a trend analysis ($p = 0.047$ and $p = 0.043$ respectively).

CONCLUSIONS: This is the first ever trial of surgery for TICH and indicates that Early Surgery may be a valuable tool in the treatment of TICH, especially if the Glasgow Coma Score is between 9 and 12, as was also found in Surgical Trial In spontaneous intraCerebral Haemorrhage (STICH) and Surgical Trial In spontaneous lobar intraCerebral Haemorrhage (STICH II). Further research is clearly warranted.

TRIAL REGISTRATION: Current Controlled Trials ISRCTN 19321911.

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References

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Mendelow AD, Gregson BA, Rowan EN, Francis R, McColl E, McNamee P, Chambers IR, Unterberg A, Boyers D, Mitchell PM; STITCH(Trauma) Investigators. Early Surgery versus Initial Conservative Treatment in Patients with Traumatic Intracerebral Hemorrhage (STITCH[Trauma]): The First Randomized Trial. J Neurotrauma. 2015 Sep 1;32(17):1312-23. doi: 10.1089/neu.2014.3644. Epub 2015 May 21. PubMed PMID: 25738794; PubMed Central PMCID: PMC4545564.

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Gregson BA, Mitchell P, Mendelow AD. Surgical Decision Making in Brain Hemorrhage. Stroke. 2019 May;50(5):1108-1115. doi: 10.1161/STROKEAHA.118.022694. PubMed PMID: 30932784; PubMed Central PMCID: PMC6485298.

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Gregson BA, Rowan EN, Francis R, McNamee P, Boyers D, Mitchell P, McColl E, Chambers IR, Unterberg A, Mendelow AD; STITCH(TRAUMA) investigators. Surgical Trial In Traumatic intraCerebral Haemorrhage (STITCH): a randomised controlled trial of Early Surgery compared with Initial Conservative Treatment. Health Technol Assess. 2015 Sep;19(70):1-138. doi: 10.3310/hta19700. PubMed PMID: 26346805; PubMed Central PMCID: PMC4780887.

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