Decompressive craniectomy plus best medical treatment versus best medical treatment alone for spontaneous severe deep supratentorial intracerebral haemorrhage: a randomised controlled clinical trial

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Summary

Background It is unknown whether decompressive craniectomy improves clinical outcome for people with spontaneous severe deep intracerebral haemorrhage. The SWITCH trial aimed to assess whether decompressive craniectomy plus best medical treatment in these patients improves outcome at 6 months compared to best medical treatment alone.

Methods In this multicentre, randomised, open-label, assessor-blinded trial conducted in 42 stroke centres in Austria, Belgium, Finland, France, Germany, the Netherlands, Spain, Sweden, and Switzerland, adults (18–75 years) with a severe intracerebral haemorrhage involving the basal ganglia or thalamus were randomly assigned to receive either decompressive craniectomy plus best medical treatment or best medical treatment alone. The primary outcome was a score of 5–6 on the modified Rankin Scale (mRS) at 180 days, analysed in the intention-to-treat population. This trial is registered with ClincalTrials.gov, NCT02258919, and is completed.

Findings SWITCH had to be stopped early due to lack of funding. Between Oct 6, 2014, and April 4, 2023, 201 individuals were randomly assigned and 197 gave delayed informed consent (96 decompressive craniectomy plus best medical treatment, 101 best medical treatment). 63 (32%) were women and 134 (68%) men, the median age was 61 years (IQR 51–68), and the median haematoma volume 57 mL (IQR 44–74). 42 (44%) of 95 participants assigned to decompressive craniectomy plus best medical treatment and 55 (58%) assigned to best medical treatment alone had an mRS of 5–6 at 180 days (adjusted risk ratio [aRR] 0·77, 95% CI 0·59 to 1·01, adjusted risk difference [aRD] –13%, 95% CI –26 to 0, p=0·057). In the per-protocol analysis, 36 (47%) of 77 participants in the decompressive craniectomy plus best medical treatment group and 44 (60%) of 73 in the best medical treatment alone group had an mRS of 5–6 (aRR 0·76, 95% CI 0·58 to 1·00, aRD –15%, 95% CI –28 to 0). Severe adverse events occurred in 42 (41%) of 103 participants receiving decompressive craniectomy plus best medical treatment and 41 (44%) of 94 receiving best medical treatment.

Interpretation SWITCH provides weak evidence that decompressive craniectomy plus best medical treatment might be superior to best medical treatment alone in people with severe deep intracerebral haemorrhage. The results do not apply to intracerebral haemorrhage in other locations, and survival is associated with severe disability in both groups.

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Introduction

Spontaneous intracerebral haemorrhage accounts for 3·4 million of about 12·2 million strokes worldwide each year.[1] Treatment of people with severe deep supratentorial intracerebral haemorrhage is a major unresolved issue in stroke management. Apart from a care bundle protocol, all pharmacological and surgical treatment approaches have failed to reduce morbidity and mortality.[2–4] Neither the STICH I and II trials nor the MISTIE trial showed superiority of haematoma evacuation compared with best medical treatment in people with intracerebral haemorrhage.[5–7] The ENRICH-ICH trial, testing early minimally invasive surgery, showed an effect for lobar rather than deep intracerebral haemorrhage.[8]

Decompressive craniectomy in people with malignant middle cerebral artery infarction reduces mortality and improves functional outcome.[9,10] It is unknown whether decompressive craniectomy is beneficial in people with

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Research in context

Evidence before this study

We searched PubMed for randomised controlled trials published in English from database inception to Feb 8, 2024, which compared decompressive craniectomy without haematoma evacuation plus best medical treatment with best medical treatment alone in people with acute spontaneous severe deep intracerebral haemorrhage. The following search terms were used: "intracerebral haemorrhage" AND "decompressive surgery", OR "decompressive hemicraniectomy", OR "decompressive craniotomy". No randomised controlled trial met the criteria. Treatment of people with severe deep supratentorial intracerebral haemorrhage is a major unresolved issue in acute stroke management. No single specific evidence-based intervention is available. Decompressive craniectomy within 48 h of onset in people with malignant middle cerebral artery infarction reduces mortality and improves functional outcome, with a number needed to treat to save one patient's life and to reduce severe disability of two. It is unknown whether decompressive craniectomy improves outcome in people with spontaneous severe deep intracerebral haemorrhage.

Added value of this study

SWITCH was stopped early due to lack of funding. In the intention-to-treat analysis SWITCH showed that, in people with severe deep supratentorial intracerebral haemorrhage, decompressive craniectomy plus best medical treatment might be superior to best medical treatment alone. The confidence that the risk ratio is lower than 1 (ie, that there is a benefit of the intervention) was 97%. Secondary ordinal analysis showed lower modified Rankin Scale (mRS) score following decompressive craniectomy plus best medical treatment compared with best medical treatment alone. A similar proportion of participants with an mRS of 4–6 was observed in both groups. Several sensitivity analyses were consistent with the primary results. There were no differences in safety concerns.

Implications of all the available evidence

SWITCH provides some evidence that decompressive craniectomy plus best medical treatment might be superior to decompressive craniectomy alone. The evidence is weak, but the point estimate of the treatment effect is higher than that of any other specific intervention tested in people with intracerebral haemorrhage. Based on the 95% CI a null effect is plausible, but harm is unlikely. The results of SWITCH only apply to a subgroup of people with severe deep intracerebral haemorrhage and cannot be generalised to intracerebral haemorrhage in other locations. Irrespective of treatment, survival was associated with severe disability in both treatment groups. SWITCH informs physicians and caregivers about the treatment effect of decompressive craniectomy in people with severe deep intracerebral haemorrhage.

severe deep intracerebral haemorrhage, defined as a National Institutes of Health Stroke Scale (NIHSS) score of 10 or greater, intracerebral haemorrhage volume of 30 mL or greater, and Glasgow Coma Scale (GCS) score of less than 14. Two studies of animals with experimental intracerebral haemorrhage have shown that decompressive craniectomy reduces mortality and improves outcome compared with non-surgical treatment.[11,12] In humans, small retrospective series and a systematic review of observational studies evaluating decompressive craniectomy without clot evacuation showed a reduced mortality and an association with better outcome as compared with best medical treatment alone.[13] However, decompressive craniectomy is a major surgical intervention carrying considerable risk for haemorrhagic, infectious, and cerebrospinal fluid (CSF) disturbance-related complications.[14]

SWITCH aimed to assess whether decompressive craniectomy plus best medical treatment in people with spontaneous severe deep supratentorial intracerebral haemorrhage improves outcome at 6 months compared with best medical treatment alone.

Methods

Study design

SWITCH was a multicentre, randomised (1:1), controlled, parallel group, two-arm trial comparing decompressive craniectomy plus best medical treatment with best medical treatment alone, following spontaneous, supratentorial severe deep intracerebral haemorrhage. The trial was conducted in 42 stroke centres in Switzerland, Austria, Belgium, Finland, France, Germany, the Netherlands, Spain, and Sweden. The first participant was enrolled on Oct 6, 2014. Planned interim analyses were done after 100 and 150 participants were enrolled and resulted in the continuation of the trial (appendix p 8). Recruitment to the trial was officially stopped on April 30, 2023, before reaching the planned sample size of 300 participants, because of the lack of further funding.

Background and details of the trial design have been published previously[15] and the protocol and statistical analysis plan are available in the appendix (pp 47–138, including a revision history). The protocol was approved by all relevant local ethics committees and research boards. This trial is registered with ClinicalTrials.gov (NCT02258919).

Participants

The trial population consisted of adults (18–75 years) presenting with a supratentorial, severe deep intracerebral haemorrhage (ie, involving the basal ganglia and thalamus, and possibly extending into cerebral lobes, ventricles, or subarachnoid space). Inclusion and exclusion criteria are listed in the appendix (p 6). Enrolled

participants or their next of kin provided written informed consent, or, in some countries, a delayed informed consent was used in emergency circumstances in accordance with national law.

Randomisation and masking

Randomisation was performed within 66 h after symptom onset, and decompressive craniectomy no later than 6 h after randomisation. Participants were randomly assigned to one of the two treatment groups using probabilistic minimisation implemented in the web-based data capture system by NIHSS (≤20 *vs* >20), age (≤65 *vs* >65 years), expected time to decompressive craniectomy after intracerebral haemorrhage onset (≤36 *vs* >36 hours), and centre. The allocation was shown to the physicians after randomisation. If a person refused to participate in the SWITCH trial, that person or next of kin was asked for consent to participate in the observational group. Data of people in the observational group were not included in this analysis. The principal investigators and sponsor-investigators of the trial were masked to allocation, clinical data, and outcomes until the trial was stopped. The only information available to the sponsor-investigators was the open interim analysis report, which only included pooled data. The core laboratory staff were masked to group allocation, clinical information, and outcomes at all times.

Procedures

After clinical evaluation, all potential participants underwent either CT or MRI to diagnose the intracerebral haemorrhage and confirm stable haematoma volume (defined in the appendix p 7). All enrolled participants received best medical treatment.[16,17] Participants assigned to the experimental group received decompressive craniectomy (diameter ≥12 cm) without haematoma evacuation.[18,19] The bone flap was reinserted within 1–5 months after decompressive craniectomy, followed by a postoperative CT scan.

All visit timepoints were defined relative to the randomisation—ie, as the time since randomisation. Clinical and radiological examination with CT or MRI was performed at 48 h (±24 h). Clinical follow-up examination was at 7 days or at discharge. At 30 days (±7 days), the modified Rankin Scale (mRS) score was assessed during a clinical examination or telephone interview. At 150–180 days a CT or MRI was performed. At 180 days (±14 days) and at 12 months (±30 days), the mRS was assessed by an independent, blinded certified rater during a structured telephone interview. The EuroQol was assessed at 180 days and at 12 months.

Outcomes

The primary outcome was a score of 5–6 on the mRS at 180 days. The mRS is a 7-point scale of global disability ranging from 0 (no symptoms) to 6 (death). The secondary clinical efficacy outcomes were (1) mRS 5–6 at 30 days and 12 months; (2) mortality at 7, 30, and 180 days, and 12 months; (3) mRS 0–3 versus 4–6 at 30 days, 180 days, and 12 months; (4) categorical shift in mRS score at 180 days and 12 months; (5) quality of life, measured with the EuroQol at 180 days and 12 months; (6) NIHSS score at 7 days and 180 days; (7) GCS at 7 days and 180 days; (8) length of hospital stay; and (9) requirement for permanent residential care at 180 days and 12 months. The secondary efficacy outcomes evaluated on imaging were: (1) extent of infarction or post-haemorrhagic brain defect on CT or MRI at 180 days; (2) midline shift at 48 h and 180 days; (3) intracerebral haemorrhage volume at 48 h; (4) haematoma enlargement at 48 h; (5) number of participants with an extracranial ventricular drain at 7 days and 180 days; (6) number of participants with a CSF shunt at 180 days; (7) extension of intraventricular bleeding using the Graeb score at 48 h and 180 days (appendix p 7);[20] (8) surgical removal of haematoma at 7 days and 180 days; and (9) requirement for a minimally invasive procedure (clot lysis and endoscopic procedure) at 7 days and 180 days. Safety outcomes were all serious adverse events up to the study end and solicited adverse events at 7 days and 180 days.

Statistical analysis

For the sample size calculation, we assumed a risk of mRS 5–6 of 0·53 in the control group.[1] A total sample size of 300 participants would then provide power of over 85% to detect a relative risk reduction of 33% using a χ^2 test at a two-sided α level of 0·05.

The primary endpoint and binary secondary endpoints were analysed using a Cochran–Mantel–Haenszel χ^2 test and treatment effects are reported as Mantel–Haenszel risk ratio and risk difference. For binary outcomes with rare (<5%) or frequent (>95%) events, we used Firth logistic regression (to reduce small sample bias[21]) and we report marginal risk ratios and differences. The categorical shift in mRS was analysed using proportional odds logistic regression and the Wilcoxon–Mann–Whitney test. Time to death is presented using a Kaplan–Meier curve and analysed using a stratified log-rank test. The difference in mortality at different time points was calculated from flexible parametric survival models.[22] Continuous endpoints were analysed using linear regression with robust standard errors adjusted for baseline values (if applicable). Length of hospital stay was analysed using a flexible parametric accelerated failure time model and the effect is presented as a time ratio.[23] All analyses were stratified or adjusted for the minimisation factors used at randomisation except for centre (due to few participants in some centres). The primary efficacy analysis was performed according to the intention-to-treat principle. Since missingness for the primary outcome was low (<5%), an analysis based on complete cases was considered the primary analysis, and an analysis using multiple imputations was included as a sensitivity analysis (as specified in the statistical

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See **Online** for appendix

analysis plan). As a prespecified sensitivity analysis, we applied a best-case and worst-case scenario. As post-hoc sensitivity analyses, we applied logistic regression, an unadjusted analysis, and an as-treated analysis (appendix p 9). Missing secondary outcomes were multiply imputed (binary, ordinal, and continuous variables; appendix p 10) or censored (time-to-event variables). For secondary outcomes not defined in case of death (ie, all outcomes except mortality and the mRS-based outcomes), we calculated separate estimands for living participants or all participants. For the score variables, we calculated an alternative variant of the latter, assuming the worst score for deaths (ie, GCS of 3 and NIHSS of 42).

In a per-protocol analysis for all efficacy outcomes, we excluded people who violated eligibility criteria, did not receive treatment as assigned, were assessed outside the visit windows, or had missing data for the respective outcome.

All effect measures are presented with 95% CIs and p value as measures of precision. The results for secondary outcomes are exploratory and are reported without any formal hypothesis test or any adjustment for multiple testing. To support interpretation, we constructed a confidence distribution for the primary outcome in a post-hoc analysis using a normal approximation on the estimated log risk ratio.[24]

The primary outcome was analysed for subgroups using logistic regression models (appendix p 11). Solicited adverse effects were summarised by treatment group and compared using risk differences with score-based 95% CIs and Fisher's exact test. The number of participants with at least one serious adverse event and the incidence of serious adverse events are shown by treatment group according to the Medical Dictionary for Regulatory Activities (MedDRA) system organ class. They were compared between groups using a risk difference and Fisher's exact test, and an incidence rate ratio and an exact Poisson test, respectively. Safety endpoints were analysed in all randomised participants according to the treatment they actually received.

All analyses were performed by a trial statistician using Stata version 18.0; plots were drawn in R version 4.3.1. A second statistician reproduced the main analysis of the primary outcome using R version 4.3.1. The CONSORT checklist was used when writing the report (appendix p 46).[25]

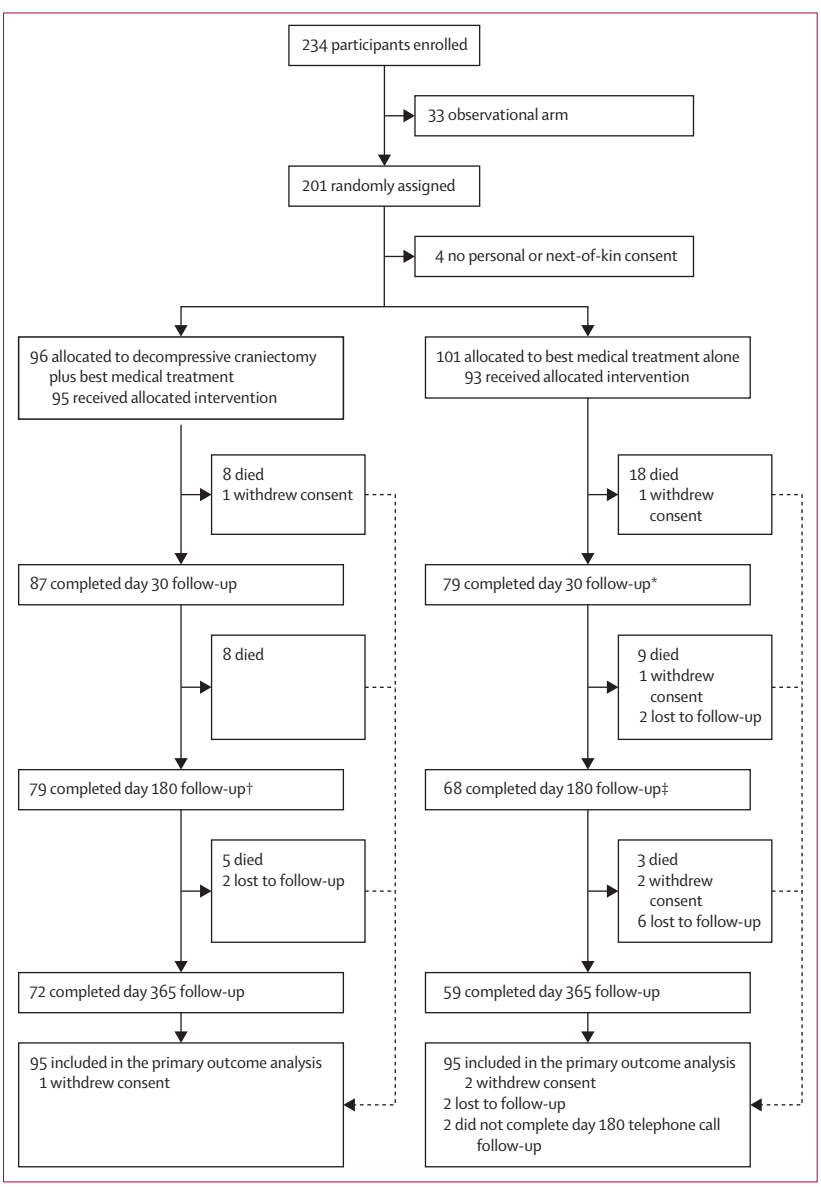

Figure 1: **Study flow chart**
The number of screened participants is not shown as no screening logs were kept. Visits were not necessarily done on exactly the days indicated. Two participants (one in each group) died on days 32 and 31, respectively and did not complete day 30 visit. *Three participants did not complete day 30 follow-up visit. †79 participants completed telephone call follow-up; 77 completed clinical visit follow-up, two did not complete clinical visit follow-up. ‡68 participants completed telephone call follow-up, two did not complete telephone call follow-up; 63 completed clinical visit follow-up, seven did not complete clinical visit follow-up.

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Oct 6, 2014, and April 30, 2023, 201 participants at 42 centres were randomly assigned (appendix pp 14, 34). Four participants were excluded after randomisation because delayed informed consent was refused. A total of 96 participants were assigned to decompressive craniectomy plus best medical treatment and 101 participants to best medical treatment alone (figure 1). Of the 197 participants, 188 received the allocated intervention. There were eight crossovers in the best medical treatment alone group and one in the decompressive craniectomy plus best medical treatment group (up to day 7), and other major prespecified protocol violations were documented in 45 participants

(appendix p 16). Haematoma was removed surgically in nine participants in the decompressive craniectomy plus best medical treatment group and in eight in the best medical treatment alone group, and two participants underwent a minimally invasive procedure (up to day 7). The characteristics of the participants at baseline are presented in table 1 and in the appendix (pp 17–18). The median time from symptom onset to imaging was 7·2 h (IQR 2·8–19·0) and to randomisation 24 h (IQR 13–39). The median time from symptom onset to surgery was 26 h (IQR 15–43), the median diameter of the decompressive craniectomy was 13 cm (IQR 12–14). The bone flap was reimplanted in 74 (85%) of 87 participants.

42 (44%) of 95 participants assigned to decompressive craniectomy plus best medical treatment and 55 (58%) of 95 assigned to best medical treatment alone had an mRS of 5–6 at 180 days (table 2, adjusted risk ratio [aRR] 0·77, 95% CI 0·59 to 1·01, adjusted risk difference [aRD] –13%, 95% CI –26 to 0, p=0·057, number needed to treat 7·6, 95% CI number needed to harm 217·8 to ∞ to number needed to treat 3·8; figure 2). The primary outcome data were multiply imputed for one participant in the decompressive craniectomy plus best medical treatment group and six participants in the best medical treatment alone group and reported as sensitivity results (table 2). The confidence that the risk ratio is lower than 1 (ie, that there is a benefit of the intervention) was 97·2%; the confidence that there is no harm larger than 10% was 99·5% (appendix p 35). In the per-protocol analysis, an mRS of 5–6 was observed in 36 (47%) of 77 participants in the decompressive craniectomy plus best medical treatment group and 44 (60%) of 73 participants in the best medical treatment alone group (aRR 0·76, 95% CI 0·58 to 1·00, aRD –15%, 95% CI –28 to 0; p=0·052). Sensitivity analyses using multiple imputations, best and worst cases, logistic regression, or no adjustment were consistent with the primary analysis (appendix p 36).

Prespecified secondary clinical efficacy outcomes and technical efficacy outcomes are shown in table 2 and in the appendix (pp 19–21). At 180 days, 16 (17%) of 96 participants assigned to decompressive craniectomy plus best medical treatment, and 27 (27%) of 101 assigned to best medical treatment alone had died (aRR 0·61, 95% CI 0·36 to 1·01, aRD –11%, 95% CI –21 to 0; for a Kaplan–Meier plot see appendix p 37). Secondary ordinal analysis showed lower mRS following decompressive craniectomy plus best medical treatment compared with best medical treatment alone (common odds ratio for a worse outcome 0·57, 95% CI 0·34 to 0·97; figure 2). The proportion of participants with an mRS of 4–6 was similar in both groups (83 [86%] of 96 in the decompressive craniectomy plus best medical treatment group and 87 [86%] of 101 in the best medical treatment group, aRR 0·99, 95% CI 0·89 to 1·11, aRD –1%, 95% CI –10 to 9). At 365 days, an mRS of 5–6 was observed in

	Decompressive craniectomy plus best medical treatment (n=96)	Best medical treatment alone (n=101)
Age at inclusion, years	60 (49–68)	61 (53–67)
Sex		
Male	64 (67%)	70 (69%)
Female	32 (33%)	31 (31%)
Glasgow Coma Scale	10 (9–12)	10 (9–12)
NIHSS score*	18 (16–22)	19 (15–21)
Pre-stroke score on the modified Rankin scale†		
0	80 (83%)	86 (85%)
1	16 (17%)	15 (15%)
Volume of haematoma, mL‡	55 (45–74)	59 (44–77)
Systolic blood pressure, mm Hg§	142 (130–154)	150 (130–170)
Blood glucose level, mmol/L¶	7·5 (6·4–9·2)	7·4 (6·3–8·9)
Risk factors		
Previous ischaemic stroke	7 (7%)	6 (6%)
Previous asymptomatic intracerebral haemorrhage	0	0
History of hypertension	51 (53%)	60 (59%)
History of diabetes	19 (20%)	15 (15%)
Known heart disease	18 (19%)	12 (12%)
Haematoma with intraventricular haemorrhage extension	27 (28%)	30 (30%)
Medication		
Warfarin or other anticoagulant	6 (6%)	9 (9%)
Acetylsalicylic acid or other antiplatelet agent	17 (18%)	17 (17%)
Baseline imaging‖		
CT	94 (98%)	100 (99%)
MRI	2 (2%)	1 (1%)
Side of intracerebral haemorrhage		
Left	43 (45%)	54 (53%)
Right	53 (55%)	47 (47%)
Graeb score**	2·0 (0·0–5·0)	3·0 (0·0–5·0)
Symptom onset to randomisation, hours	23 (13–37)	25 (12–41)
Symptom onset to imaging, hours	6·9 (2·5–18·6)	7·5 (3·0–19·5)

Data are median (IQR) or n (%). NIHSS=National Institutes of Health Stroke Scale. *Scores on the NIHSS range from 0 to 42, with 0 indicating no deficits and a higher score indicating more severe neurological symptoms. †Scores on the modified Rankin scale range from 0 (no symptoms) to 6 (death). Pre-stroke disability was assessed by the treating physician using information provided by the participant, health-care records, or family members. ‡Data from the imaging core laboratory were missing for one participant in the best medical treatment alone group. For this case, the values documented by the investigators were used. §Data were missing for one participant in the best medical treatment alone group. ¶Data were missing for one participant in the decompressive craniectomy plus best medical treatment group and two participants in the best medical treatment alone group. ‖Baseline imaging modality was chosen according to the standard of care of the enrolling centre. **Data were missing for one participant in the decompressive craniectomy plus best medical treatment group and one participant in the best medical treatment alone group.

Table 1: **Participants' baseline characteristics**

	Decompressive craniectomy plus best medical treatment (n=96)		Best medical treatment alone (n=101)		Adjusted effect (95% CI)*	p value †
	N‡ (imputed)	N (%) or median (IQR)	N‡ (imputed)	N (%) or median (IQR)		
Primary outcome (mRS 5–6 at 180 days)						
Complete cases (main analysis)	95	42 (44%)	95	55 (58%)	RR 0·77 (0·59 to 1·01); RD −13% (−26 to 0)	0·057
With multiple imputations	96 (1)	43 (45%)	101 (6)	59 (58%)	RR 0·76 (0·59 to 0·99); RD −14% (−27 to 0)	0·042
Secondary efficacy outcomes						
mRS 5–6 at 365 days	96 (3)	41 (43%)	101 (12)	52 (51%)	RR 0·81 (0·60 to 1·08); RD −10% (−23 to 4)	0·15
Mortality at 180 days	96	16 (17%)	101	27 (27%)	RR 0·61 (0·36 to 1·01); RD −11% (−21 to 0)	0·065
Mortality at 365 days	96	21 (22%)	101	30 (31%)	RR 0·70 (0·45 to 1·08); RD −9% (−21 to 2)	0·14
mRS 4–6 at 180 days	96 (1)	83 (86%)	101 (6)	87 (86%)	RR 0·99 (0·89 to 1·11); RD −1% (−10 to 9)	0·89
mRS at 180 days	96 (1)	4 (4–5)	101 (6)	5 (4 to 6)	Common OR 0·57 (0·34 to 0·97); Mann–Whitney statistic§ 0·43 (0·35 to 0·50)	0·039; 0·074 (0·046)¶
NIHSS at 180 days	80 (22)	12 (8–15)	74 (30)	11 (8–16)	MD −0·64 (−2·99 to 1·71)	0·59
GCS at 180 days	80 (17)	15 (13–15)	74 (23)	15 (13–15)	MD −0·03 (−0·83 to 0·78)	0·95
Length of hospital stay, days	81	19·5 (11·0–30·0)	74	23·5 (16·0–31·0)	TR 0·74 (0·57 to 0·95)	0·018
Quality-of-life dimensions at 180 days						
Problems with mobility	80 (3)	75 (94%)	74 (11)	69 (93%)	RR 1·00 (0·91 to 1·11); RD 0 (−9 to 9)	0·67
Problems with self-care	80 (3)	75 (94%)	74 (11)	68 (92%)	RR 1·02 (0·92 to 1·13); RD 2% (−7 to 11)	0·63
Problems with usual activities‖	80 (3)	80 (100%)	74 (11)	73 (99%)	RR 1·02 (0·97 to 1·09); RD 2% (−3 to 8)	0·42
Problems with pain or discomfort	80 (4)	38 (48%)	74 (13)	53 (72%)	RR 0·66 (0·50 to 0·87); RD −25% (−40 to −9)	0·0030
Problems with anxiety or depression	80 (10)	48 (60%)	74 (15)	53 (72%)	RR 0·83 (0·65 to 1·07); RD −12% (−28 to 4)	0·14
Visual analogue scale	80 (20)	32 (13–53)	74 (26)	31 (16 to 55)	MD −1·15 (−10·91 to 8·60)	0·82
Secondary efficacy outcomes evaluated on imaging						
Intracerebral haemorrhage volume at 48 h, mL	95 (1)	56 (43–77)	99 (10)	59 (43–76)	MD 0·68 (−2·92 to 4·28)	0·71
Size of infarction or post-haemorrhagic brain defect at 180 days, mL	82 (21)	20 (8–38)	74 (49)	24 (8–40)	MD −0·51 (−16·60 to 15·57)	0·95
Presence of CSF shunt at 180 days	80 (1)	15 (19%)	74 (11)	6 (8%)	RR 2·30 (0·85 to 6·26); RD 10% (−1 to 21)	0·083
Graeb score at 48 h**	95 (2)	3·0 (1·0–5·0)	99 (11)	3·0 (0·2–5·0)	MD 0·35 (0·03 to 0·67)	0·031

All time points are relative to the randomisation—ie, indicate the time since randomisation. CSF=cerebrospinal fluid. GCS=Glasgow Coma Scale. NIHSS=National Institutes of Health Stroke Scale. MD=mean difference. mRS=modified Rankin Scale. OR=odds ratio. RD=risk difference. RR=risk ratio. TR=time ratio. ‡Number of non-missing data. *The analyses were stratified or adjusted for the minimisation factors used at randomisation. †No adjustment for multiple testing was made for any of the secondary outcomes. §The probability that a random participant from the decompressive craniectomy plus best medical treatment group has a worse outcome (higher mRS) than a random participant from the best medical treatment alone group. ¶Crude p value from Mann–Whitney–Wilcoxon test (stratified p value from a van Elteren test). ||Analysed with Firth logistic regression due to rare or frequent events. **The Graeb score at 180 days was 0 for all but one participant and not included in the analysis.

Table 2: **Primary and secondary efficacy outcomes**

41 (43%) of 96 participants in the decompressive craniectomy plus best medical treatment group and 52 (51%) of 101 in the best medical treatment alone group (aRR 0·81, 95% CI 0·60 to 1·08, aRD −10%, 95% CI −23 to 4); 21 (22%) of 96 and 30 (31%) of 101 participants had died (aRR 0·70, 95% CI 0·45 to 1·08, aRD −9%, 95% CI −21 to 2).

The intracerebral haemorrhage volume at 48 h and the extent of post-haemorrhagic brain defects at 180 days were similar in both groups (median 56 mL, IQR 43–77 and 20 mL, IQR 8–38 in the decompressive craniectomy plus best medical treatment group and 59 mL, IQR 43–75 and 24 mL, IQR 8–40 in the best medical treatment alone group, mean difference 0·68 mL, 95% CI −2·92 to 4·28 and −0·51 mL, 95% CI −16·60 to 15·57). 15 (19%) of 80 participants in the decompressive craniectomy plus best medical treatment group and six (8%) of 74 in the best medical treatment alone group had a CSF shunt at 180 days (aRR 2·30, 95% CI 0·85 to 6·26, aRD 10%, 95% CI −1 to 21).

Participants in the decompressive craniectomy plus best medical treatment group stayed in hospital for a median of 19·5 days (IQR 11·0–30·0) and those in the best medical treatment alone group for 23·5 days (IQR 16·0–31·0, time ratio 0·74, 95% CI 0·57 to 0·95).

Per-protocol analysis, an analysis including participants who died (for outcomes not defined in case of death), and a complete case analysis of the secondary outcomes were consistent with the primary results (appendix pp 22–32).

At the end of the study, participants in the decompressive craniectomy plus best medical treatment group were asked whether they would have undergone surgery again and 48 (77%) of 62 answered yes.

42 (41%) of 103 participants receiving decompressive craniectomy plus best medical treatment had a total of

60 serious adverse events and 41 (44%) of 94 participants receiving best medical treatment alone had a total of 54 serious adverse events (risk difference –3%, 95% CI –16 to 11, incidence rate ratio 0·87, 95% CI 0·59 to 1·28; table 3, appendix p 33). We did not find any evidence for a difference in the solicited adverse events at days 7 and 180 (appendix pp 38–39), or any unexpected complications related to decompressive craniectomy (appendix p 40).

We did not find evidence for a treatment effect modification (appendix pp 41–43).

Discussion

SWITCH is the first trial studying whether decompressing the brain via a large craniectomy without haematoma evacuation in people with a severe deep supratentorial intracerebral haemorrhage might prevent secondary post-haemorrhagic brain defects. SWITCH showed weak evidence that decompressive craniectomy plus best medical treatment might be superior to best medical treatment alone.[26] The point estimate reflects a substantial treatment effect with an absolute risk reduction of 13% (95% CI 0 to 26) and a relative risk reduction of 23% (95% CI 41 to –1) for a population without any therapeutic alternative of proven benefit. There is uncertainty about the treatment effect and, based on the 95% CIs, an absolute risk reduction from 0 to 26% is plausible. Accordingly, the confidence that the risk ratio is lower than one was high (97·2%). Several sensitivity analyses were consistent with the primary analysis and confirmed the robustness of the primary results. The point estimate of the treatment effect is clinically meaningful and is considerably higher than that of any other treatment intervention in people with intracerebral haemorrhage (appendix p 45), even though such a comparison is hampered by differences in eligibility criteria, interventions, and definitions of outcome. In the STICH I and II trials, surgical haematoma evacuation was associated with an absolute risk reduction of 2% (p=0·41) and 4% (p=0·37), respectively.[5,6,27] The INTERACT 2 and ATACH-2 trials, both investigating blood pressure reduction, estimated an absolute risk reduction of unfavourable outcome of 4% (p=0·06) and 1% (p=0·83), respectively.[28,29] The MISTIE trial using minimally invasive surgery techniques showed an absolute risk reduction of 4% (adjusted, 3% unadjusted, p=0·33) in a severely affected group of people with large intracerebral haemorrhage (41·8 mL), of which two-thirds were in the basal ganglia.

Compared with these other trials, SWITCH had very narrow eligibility criteria, focusing on people with severe intracerebral haemorrhage with a large haematoma in the basal ganglia and thalamus. In all the mentioned intracerebral haemorrhage trials, both haematoma volume and the proportion of people with severe deep intracerebral haemorrhage was lower than in the SWITCH trial. When designing the SWITCH trial, we therefore dichotomised favourable versus poor outcome between mRS 0–4 and 5–6, as opposed to between 0–3 and 4–6 as in most other intracerebral haemorrhage trials. Our definition of favourable outcome is also in line with the pooled analysis of the three pivotal trials assessing decompressive craniectomy in people with malignant middle cerebral artery infarction.[8] We believe that an mRS of 0–4 is a more realistic outcome for very severely affected people fulfilling our eligibility criteria. SWITCH showed that the benefit of decompression did not come at the cost of an increased number of participants with an mRS of 5, and most survivors were switched into the mRS 4 group. However, there was no difference in the number of participants with mRS 0–3 between the two treatment groups. Ultimately, it remains a highly individual decision whether an mRS of 4 can be considered as a better outcome than being dead. In this context, we asked survivors from the surgery group whether they would have undergone surgery again and 48 (77%) of 62 answered yes. We deliberately excluded people with a GCS of 4–7, since the aim of the trial was to reduce disability and to avoid, if possible, an outcome of mRS 5, rather than to reduce mortality at any cost.

Decompressive craniectomy did not increase the incidence or proportion of solicited adverse events or serious adverse events. Length of hospital stay was shorter in participants receiving decompressive craniectomy. However, decompressive craniectomy might be associated with a higher risk of CSF circulation disorder, given the higher rate of permanent shunting in survivors (15 [19%] of 80 *vs* six [8%] of 74). The complications associated with bone flap replacement were low (four [6%] of 72), but long-term results are awaited, especially regarding aseptic necrosis and resorption of reimplanted autologous bone

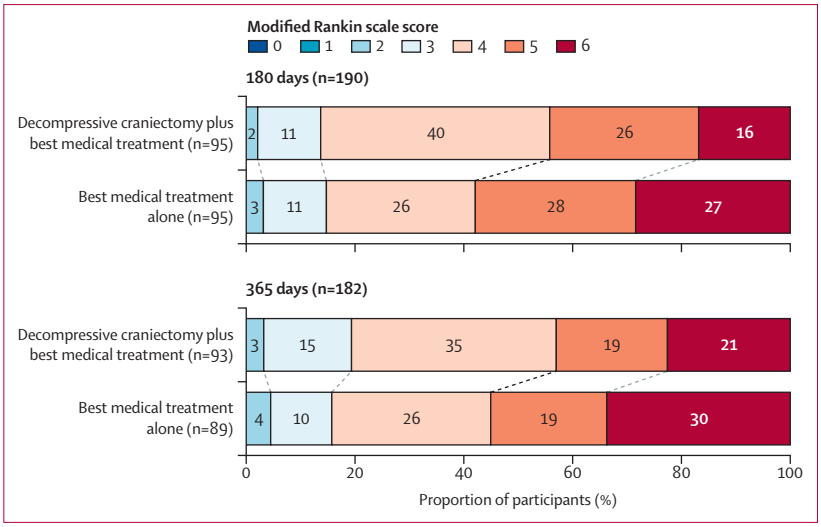

Figure 2: **mRS score at day 180 and day 365**
mRS scores are shown for participants for whom data were available. Scores range from 0 (no symptoms) to 6 (death). The thick dashed line between the stacked bar charts shows the cutoff for primary outcome (mRS 5–6). Numbers in the bars refer to the number of participants. mRS=Modified Rankin Scale.

	Safety set (n=197)	Received decompressive craniectomy plus best medical treatment (n=103)	Received best medical treatment alone (n=94)	Risk difference (95% CI)	p value
Any serious adverse event	83 (42%)	42 (41%)	41 (44%)	−3% (−16 to 11)	0·77
Cardiac disorders	7 (4%)	2 (2%)	5 (5%)	−3% (−10 to 2)	0·26
Gastrointestinal disorders	2 (1%)	2 (2%)	0	2% (−2 to 7)	0·50
General disorders and administration site conditions	15 (8%)	6 (6%)	9 (10%)	−4% (−12 to 4)	0·42
Hepatobiliary disorders	1 (1%)	1 (1%)	0	1% (−3 to 5)	1·00
Immune system disorders	1 (1%)	1 (1%)	0	1% (−3 to 5)	1·00
Infections and infestations	23 (12%)	12 (12%)	11 (12%)	0 (−9 to 9)	1·00
Injury, poisoning, and procedural complications	15 (8%)	10 (10%)	5 (5%)	4% (−3 to 12)	0·29
Metabolism and nutrition disorders	2 (1%)	1 (1%)	1 (1%)	0 (−5 to 4)	1·00
Neoplasms benign, malignant, and unspecified (including cysts and polyps)	3 (2%)	2 (2%)	1 (1%)	1% (−4 to 6)	1·00
Nervous system disorders	34 (17%)	17 (17%)	17 (18%)	−2% (−12 to 9)	0·85
Psychiatric disorders	1 (1%)	0	1 (1%)	−1% (−6 to 3)	0·48
Renal and urinary disorders	3 (2%)	1 (1%)	2 (2%)	−1% (−7 to 3)	0·61
Respiratory, thoracic, and mediastinal disorders	9 (5%)	3 (3%)	6 (6%)	−3% (−11 to 3)	0·31
Surgical and medical procedures*	15 (8%)	8 (8%)	7 (7%)	0 (−8 to 8)	1·00
Vascular disorders	2 (1%)	1 (1%)	1 (1%)	0 (−5 to 4)	1·00

Data are numbers and percentages of participants with at least one serious adverse event involving the respective system organ class. Incidences are shown in the appendix (p 33). *Including two decompressive craniectomies at days 8 and 9.

Table 3: **Serious adverse events**

flaps, and the subsequent need for revision surgery reported in other trials.[30]

Several trials are currently evaluating minimally invasive surgery in people with intracerebral haemorrhage with the rationale that brain tissue damage could be minimised by microsurgical access. The MIND trial (NCT03342664) has been halted; the EVACUATE trial (NCT04434807), the DIST trial (NCT05460793), and the EMINENT-ICH trial (NCT05681988) are ongoing, but results are not expected before 2026–27. The ENRICH-ICH trial (NCT02880878) showed a beneficial effect for intracerebral haemorrhage, but only after adaptation of the inclusion criteria and the subsequent exclusion of people with severe deep intracerebral haemorrhage during the trial. People with severe deep intracerebral haemorrhage might not gain any benefit from minimally invasive surgery. The concept of decompressive craniectomy only, without removing the clot, has not been analysed in a randomised trial before, and based on the results of the SWITCH trial, decompressive craniectomy only might be a promising approach for this subgroup of people with severe deep intracerebral haemorrhage. However, the concept of a combination of decompressive craniectomy with (partial) removal of the clot needs to be further tested in randomised controlled trials.

This trial has several limitations. First, it stopped early after randomisation of 201 of the planned 300 participants, making it underpowered for the primary endpoint. Nevertheless, SWITCH is the largest ever trial on decompressive craniectomy in people with stroke (HAMLET had 64 participants, DESTINY I 32, DESTINY II 109, and DECIMAL 38). Running multinational academic clinical trials over a period of 9 years with a limited budget is a major challenge since most academic funders only provide grants for shorter periods. Second, with a relative risk reduction of 33%, we assumed a large effect for the sample size calculation. Even if the target sample size had been reached, a smaller but still worthwhile effect might have been missed. Third, SWITCH included more than 42 sites and their randomisation rates were uneven. Fourth, during the course of the trial standards of care might have changed and some sites started to adopt minimally invasive surgery techniques. Furthermore, the long recruitment period might have resulted in a potential selection bias. Fifth, in SWITCH the crossover rate was 1% from decompressive craniectomy plus best medical treatment to best medical treatment alone and 8% vice versa. This crossover rate can be considered low for a surgical trial in which the intervention potentially saves lives but where it is unclear whether the intervention will reduce disability. The rate of haematoma removal was low (10% and 8% at 7 days) as was the rate of minimally invasive procedures (0 and 2% at 7 days). Sixth, to avoid a major bias, the primary outcome was assessed during a structured telephone interview by certified assessors, unaware of the treatment allocation. However, participants were not blinded to the treatment group and participants could have accidentally disclosed the treatment group during the telephone interview. Seventh, only a third of participants were female. Eighth, information on

ethnicity of participants is absent. Lastly, imaging core laboratory information on the exact location of involvement of different structures (eg, anterior and posterior capsule, and thalamus) is absent.

Decompressive craniectomy plus best medical treatment might be superior to best medical treatment alone in people with severe deep supratentorial intracerebral haemorrhage, but the evidence is weak. The point estimate of the treatment effect was higher than that seen with any other specific intervention previously tested in people with intracerebral haemorrhage. Based on the 95% CI a null effect is plausible, but harm is unlikely. The results of SWITCH apply to a subgroup of people with severe deep intracerebral haemorrhage and cannot be generalised to people with intracerebral haemorrhage in other locations. Irrespective of treatment, survival was associated with severe disability in both treatment groups.

Contributors

UF and JBe were responsible for the overall principal leadership for the study. The manuscript was written by UF, JBe, and LB. Statistical analyses and drawing of figures were performed by LB. All authors contributed to data acquisition and made critical revisions to the manuscript text and all authors have seen and approved of the final text. LB and SB had full access to the data and verified the underlying raw data. JBe and UF were responsible for the decision to submit the manuscript for publication.

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Data sharing

Data from the SWITCH trial are currently not publicly available. The plan is to make them available in the future. A complete de-identified dataset will be made accessible, together with a data dictionary. Requests for access to the data can be made by sending an email together with a research plan to urs.fischer@insel.ch.

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