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Long-term functional independence after minimally invasive endoscopic intracerebral hemorrhage evacuation

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OBJECTIVE Intracerebral hemorrhage (ICH) is a devastating form of stroke with no proven treatment. However, minimally invasive endoscopic evacuation is a promising potential therapeutic option for ICH. Herein, the authors examine factors associated with long-term functional independence (modified Rankin Scale [mRS] score ≤ 2) in patients with spontaneous ICH who underwent minimally invasive endoscopic evacuation.

METHODS Patients with spontaneous supratentorial ICH who had presented to a large urban healthcare system from December 2015 to October 2018 were triaged to a central hospital for minimally invasive endoscopic evacuation. Inclusion criteria for this study included age ≥ 18 years, hematoma volume ≥ 15 ml, National Institutes of Health Stroke Scale (NIHSS) score ≥ 6, premorbid mRS score ≤ 3, and time from ictus ≤ 72 hours. Demographic, clinical, and radiographic factors previously shown to impact functional outcome in ICH were included in a retrospective univariate analysis with patients dichotomized into independent (mRS score ≤ 2) and dependent (mRS score ≥ 3) outcome groups, according to 6-month mRS scores. Factors that reached a threshold of $p < 0.05$ in a univariate analysis were included in a multivariate logistic regression.

RESULTS A total of 90 patients met the study inclusion criteria. The median preoperative hematoma volume was 41 (IQR 27–65) ml and the median postoperative volume was 1.2 (0.3–7.5) ml, resulting in a median evacuation percentage of 97% (85%–99%). The median hospital length of stay was 17 (IQR 9–25) days, and 8 (9%) patients died within 30 days of surgery. Twenty-four (27%) patients had attained functional independence by 6 months. Factors independently associated with long-term functional independence included lower NIHSS score at presentation (OR per point 0.78, 95% CI 0.67–0.91, $p = 0.002$), lack of intraventricular hemorrhage (IVH; OR 0.20, 95% CI 0.05–0.77, $p = 0.02$), and shorter time to evacuation (OR per hour 0.95, 95% CI 0.91–0.99, $p = 0.007$). Specifically, patients who had undergone evacuation within 24 hours of ictus demonstrated an mRS score ≤ 2 rate of 36% and were associated with an increased likelihood of long-term independence (OR 17.7, 95% CI 1.90–164, $p = 0.01$) as compared to those who had undergone evacuation after 48 hours.

CONCLUSIONS In a single-center minimally invasive endoscopic ICH evacuation cohort, NIHSS score on presentation, lack of IVH, and shorter time to evacuation were independently associated with functional independence at 6 months. Factors associated with functional independence may help to better predict populations suitable for minimally invasive endoscopic evacuation and guide protocols for future clinical trials.

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KEYWORDS intracerebral hemorrhage; minimally invasive; endoscopic evacuation; vascular disorders

Spontaneous intracerebral hemorrhage (ICH) is a devastating form of stroke, with a 6-month functional independence rate of only 25%.[1] Craniotomy for evacuation of ICH has not resulted in improved functional outcomes in major trials.[2,3] Studies evaluating minimally invasive evacuation, however, have produced mixed results.[4–7] A meta-analysis of multiple randomized controlled trials (RCTs) has suggested that patients with ICH benefit more from minimally invasive evacuation than from conventional treatment.[7] Specifically, minimally invasive endoscopic evacuation has been associated with the greatest improvement in outcomes. Ongoing clinical

ABBREVIATIONS GCS = Glasgow Coma Scale; ICH = intracerebral hemorrhage; IVH = intraventricular hemorrhage; mGS = modified Graeb Scale; mRS = modified Rankin Scale; NIHSS = National Institutes of Health Stroke Scale; RCT = randomized controlled trial; SCUBA = Stereotactic Intracerebral Hemorrhage Underwater Blood Aspiration.

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trials such as the INVEST Feasibility Study (Minimally Invasive Endoscopic Surgery With Apollo in Patients With Brain Hemorrhage, NCT02654015), MIND trial (Artemis in the Removal of Intracerebral Hemorrhage, NCT03342664), DIST (Dutch Intracerebral Hemorrhage Surgery Trial Pilot Study, NCT03608423), and ENRICH study (Early Minimally Invasive Removal of Intracerebral Hemorrhage, NCT02880878) are evaluating endoscopic and endoport-based techniques for ICH evacuation. These newer, more promising minimally invasive techniques may improve intracavity visualization during evacuation, allowing for high evacuation percentages with low rebleed rates and earlier evacuation times.[8–10]

To better predict suitable populations and guide protocols for surgical evacuation of ICH, past studies have investigated factors associated with functional outcome after open craniotomy evacuation and certain minimally invasive techniques, including stereotactic catheter drainage with thrombolysis, but factors associated with long-term functional independence following minimally invasive endoscopic evacuation have yet to be explored. Evaluation of patient quality of life using the modified Rankin Scale (mRS) has suggested that a score of 2 or less most consistently correlates with maximal patient satisfaction.[11–13] Herein, we examined associations between long-term functional independence (mRS score ≤ 2) after minimally invasive endoscopic evacuation and key demographic, clinical, and radiographic variables. Factors associated with functional independence may help to better predict populations suitable for minimally invasive endoscopic evacuation and guide protocols for future clinical trials.

Methods

This study followed STROBE guidelines[14] and was approved by the Icahn School of Medicine at Mount Sinai Institutional Review Board, which deemed patient consent unnecessary.

Patient Selection

From December 2015 to October 2018, 571 patients with spontaneous supratentorial ICH presenting to a large New York City healthcare system were evaluated for minimally invasive endoscopic ICH evacuation at the central hospital (Supplementary Fig. 1). Inclusion and exclusion criteria for the current study were decided by a multidisciplinary team of physicians and were based on recent and ongoing clinical trials, including INVEST, MIND, and DIST. Inclusion criteria included age ≥ 18 years, hematoma volume (ABC/2) ≥ 15 ml, no evidence of vascular malformation on CT angiography, a National Institutes of Health Stroke Scale (NIHSS) score ≥ 6, and premorbid mRS score ≤ 3. Exclusion criteria included hemorrhage location in the cerebellum or brainstem; evidence of aneurysm, tumor, or vascular malformation on preoperative imaging; irreversible coagulopathy; or clear premorbid wishes against surgery and subsequent care. ICH expansion indicated by longitudinal CT or a spot sign did not disqualify a patient from the procedure. Differential treatment options for ICH included craniotomy and craniectomy for evacuation. During the study period, 10 patients underwent these emergent procedures. Six patients did not have enough time to be transferred to the main hospital for minimally invasive evacuation and underwent urgent decompression. Before acquiring consent for minimally invasive endoscopic evacuation, the clinical scenario was discussed with the patients or their healthcare proxies, including the risks, benefits, and alternatives to minimally invasive evacuation. The controversial history and risks surrounding ICH evacuation were described, including the outcomes of the STICH I and II trials (Surgical Treatment for Ischemic Heart Failure),[2,3] a meta-analysis of minimally invasive surgical trials,[7] and institutional experience with endoscopic evacuation.

Imaging Protocol and Surgical Technique

All patients underwent head CT and head and neck CT angiography on admission. A stability scan (a second CT performed at least 6 hours after the first) was not required to proceed with minimally invasive ICH evacuation in this cohort. If hematoma expansion was seen on repeat CT, the patient remained eligible for the procedure. All minimally invasive endoscopic evacuations were performed in the angiography suite using the Stereotactic Intracerebral Hemorrhage Underwater Blood Aspiration (SCUBA) technique.[9,15–20] The procedure involves stereotactic endoscopic evacuation of an ICH in a wet field with an adjunctive aspiration device introduced through the working channel of the endoscope. One of two aspiration devices were used throughout the study: the Apollo device (December 2015 to December 2017) or the Artemis device (October 2017 to October 2018; both Penumbra). For a 3-month period (October 2017 to December 2017) either one of the two devices was used, as the Apollo device was phased out and replaced by the Artemis. The SCUBA procedure is divided into two phases. Phase I is a debulking phase with high suction and low irrigation (Video 1), whereas phase II is a low-suction and high-irrigation phase to establish clear visualization of residual clot burden and permit reliable visualization and cauterization of active arterial bleeding (Video 2).

VIDEO 1. Clip showing surgical preparation, entry, and phase I of SCUBA procedure: entry and endoscopic evacuation of the clot. © Muhammad Ali, published with permission. Click here to view.

VIDEO 2. Clip showing phase II of SCUBA procedure: clear visualization of the cavity with identification and cauterization of actively bleeding vessels. © Muhammad Ali, published with permission. Click here to view.

Further details on the surgical technique are provided in Supplementary Materials.

Postoperative head CT is performed 12–24 hours after surgery to evaluate for rebleeding. MRI of the brain is also performed during the hospital course for diagnostic reasons. Additional CT scans are acquired on a case-by-case basis for evaluation for external ventricular drain removal, ventriculoperitoneal shunt placement, or neurological worsening.

Variables and Data Analysis

Demographic, clinical, and imaging variables previously found or suspected to modulate outcome in ICH

patients who have undergone surgical management were collected. Data included age, gender, race, hypertension status, presenting systolic blood pressure, anticoagulation and antiplatelet medication use, premorbid mRS score, presenting Glasgow Coma Scale (GCS) score,[38] presenting NIHSS score,[39] ICH score, intraventricular hemorrhage (IVH) co-presentation, modified Graeb Scale (mGS) score,[40] spot sign on any preoperative CT, hemorrhage origin and location, evacuation device used (Apollo vs Artemis), pre- and postoperative hematoma volume, evacuation percentage, meeting surgical goal of < 15 ml residual hematoma, intraoperative bleeding, bleed time to evacuation, total operative time, postoperative rebleeding, hospital length of stay, ICU length of stay, discharge destination, 30-day mortality, and 6-month mRS score.

Hematoma location was defined as deep (basal ganglia or thalamic) or lobar (frontal, parietal, occipital). If the hemorrhage appeared in both a lobar and a deep location, as in 1 case, the bleed was assigned to the category from which it originated.[21] Time to evacuation was defined as the time the patient was last known to be well to the end of the SCUBA procedure. Time to evacuation was influenced by multiple factors, including the time it took to arrive at the main hospital from ictus or from another hospital within the system, availability of operating rooms and teams, and surgeon preference. Patients undergoing evacuations after 72 hours were excluded from the study because meta-analyses of multiple randomized clinical trials have demonstrated the beneficial effects of minimally invasive surgery up to 72 hours from ictus.[6] Postoperative rebleeding was defined as a ≥ 5-ml increase in hematoma volume between any two CT scans up to 30 days after the procedure. Symptomatic rebleeding was defined as being associated with an increase in the NIHSS score of ≥ 4. Follow-up functional outcomes were collected in the form of the mRS score assessed using a standard and validated interview, the 9-question mRS (mRS-9Q) survey.[22] The interviews were collected by an advanced practice provider (APP) not involved in the surgery, by an outcomes researcher, or, on the occasions when no APP or researcher was available, by the operating surgeon. A total of 31 (34%) patients were assessed by an operating surgeon. All analyses were performed retrospectively. The outcome groups were divided as independent (mRS score ≤ 2) or dependent (mRS score ≥ 3) at 6 months.[11–13] For 11 patients in whom the 6-month outcome was not available, the last known mRS score was carried forward, as was done in the MISTIE (Minimally Invasive Surgery and rtPA for Intracerebral Hemorrhage Evacuation) trials.[4,5] Ten of these 11 patients were confirmed to be alive at the 6-month time point.

Continuous demographic variables were presented as a mean and standard deviation if they were normally distributed according to the Kolmogorov-Smirnov test. If not, they were presented as a median and interquartile range. A preliminary univariate analysis was performed to test for associations between the aforementioned demographic, clinical, and radiographic variables and functional independence at 6 months. Chi-square tests were used for binary variables, and t-tests were used for continuous variables. Factors with a $p < 0.05$ were included in a multivariate logistic regression. The role of the 6-month outcome assessor, either involved in the surgery or not, was also accounted for in the multivariate analysis. Univariate and multivariate ordinal shift analyses were performed to continue exploring the relationship between IVH severity as measured by the mGS and 6-month mRS scores. With this analysis, mRS scores were not dichotomized into independent and dependent cohorts but rather analyzed as a linear function from 0 to 6. Lastly, a propensity score adjustment analysis was run with time to evacuation ≤ 48 hours as the treatment group and time to evacuation > 48 hours as the control group. A propensity score–adjusted logistic regression analysis with an inverse propensity score as a weight, which was the normalized sample size, was performed for variables originally associated with functional independence (mRS score ≤ 2) to confirm previous analyses. The Prism 8.3 (GraphPad Software Inc.) and RStudio 3.6 (R Foundation for Statistical Computing) statistical software packages were used for analysis. During analysis, researchers were blinded to the identity of the operating surgeon.

Results

Cohort Demographics

Ninety patients underwent minimally invasive endoscopic evacuation within 72 hours of symptom onset. Patient characteristics are presented in Table 1. The mean age was 63 ± 14 years. Sixty-two (69%) patients were male. The patient population consisted of 32 (36%) African American patients, 26 (29%) White patients, 18 (20%) Asian patients, and 14 (16%) nonwhite Hispanic patients. Seventy-two (80%) patients had hypertension, 10 (11%) were taking anticoagulants, and 23 (26%) were on antiplatelets. The mean systolic blood pressure of the group was 172 ± 37 mm Hg. Twenty (22%) patients had a premorbid mRS score greater than 0.

On presentation to the hospital, the median NIHSS and ICH scores were 17 (IQR 12–22) and 2 (1–3), respectively. IVH was concurrently present with ICH in 40 (44%) patients, whose median mGS score was 6 (IQR 2–14). IVH was co-evacuated in 23 (58%) of those patients. Pre- and postoperative mGS scores and shunt dependency of the patients co-presenting with IVH dichotomized by IVH evacuation status are presented in Supplementary Table 1. A spot sign was present in 15 patients. In 10 of those cases, a bleeding vessel was intraoperatively identified and treated with cauterization (Video 2). The majority of ICHs were classified as deep (66%), whereas the remainder (34%) were classified as lobar (Table 1). Fifty-two (58%) patients presented with a right-sided hemorrhage.

The median preoperative hematoma volume was 41 (IQR 27–65) ml and the median postoperative volume was 1.2 (0.3–7.5) ml, resulting in a median evacuation percentage of 97% (85%–99%). A total of 77 (86%) patients had a postoperative hematoma volume < 15 ml. The mean time to evacuation was 32 ± 20 hours, and the mean operative time was 2.5 ± 1.1 hours. The median ICU length of stay was 8 (IQR 4–14) days, and the median hospital length of stay was 17 (9–25) days. Eight (9%) patients died within 30 days of surgery. Twenty-four (27%) patients had

TABLE 1. Summary of patient demographics and clinical characteristics

Variable	Value
Age in yrs	63 ± 14
Gender	
Male	62 (69%)
Female	28 (31%)
Race	
African American	32 (36%)
White	26 (29%)
Asian	18 (20%)
Hispanic	14 (16%)
Hypertension	72 (80%)
Systolic blood pressure in mm Hg	172 ± 37
Anticoagulant therapy	10 (11%)
Antiplatelet therapy	23 (26%)
Premorbid mRS score	
0	70 (78%)
1–3	20 (22%)
Presentation NIHSS score, 0–42	17 (12–22)
Presentation ICH score, 0–6	2 (1–3)
IVH	40 (44%)
mGS score	6 (2–14)
Presentation GCS score, 3–15	
13–15	29 (32%)
9–12	26 (29%)
3–8	35 (39%)
Spot sign	15 (17%)
Lobar origin	31 (34%)
Frontal	14 (16%)
Frontal only	8 (9%)
Frontal-parietal	4 (4%)
Frontal-parietal-temporal	2 (2%)
Parietal	12 (13%)
Parietal only	6 (7%)
Parietal-temporal	3 (3%)
Parietal-occipital	2 (2%)
Parietal-temporal-occipital	1 (1%)
Temporal	3 (3%)
Temporal only	1 (1%)
Temporal-parietal	2 (2%)
Occipital only	2 (2%)
Deep origin	59 (66%)
Basal ganglia	45 (50%)
Basal ganglia only	39 (43%)
Basal ganglia–thalamus	5 (6%)
Basal ganglia–frontal	1 (1%)
Thalamus only	14 (16%)
Rt-sided hemorrhage	52 (58%)
Device	
Artemis	27 (30%)
Apollo	63 (70%)

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TABLE 1. Summary of patient demographics and clinical characteristics

Variable	Value
Preop hematoma vol in ml	41 (27–65)
Postop hematoma vol in ml	1.2 (0.3–7.5)
Evacuation percentage	97% (85%–99%)
Residual hematoma <15 ml	77 (86%)
Time to evacuation in hrs	32 ± 20
Op time in hrs	2.5 ± 1.1
Length of stay in days	
Hospital	17 (9–25)
ICU	8 (4–14)
Discharge location	
Home	5 (6%)
Acute rehabilitation	53 (59%)
Subacute rehabilitation	23 (26%)
Skilled nursing facility	3 (3%)
Hospice	4 (4%)
Rebleeding w/in 30 days	
Asymptomatic	4 (4%)
Symptomatic	0 (0%)
Mortality at 30 days	8 (9%)
6-mo mRS score	
0–2	24 (27%)
3–6	66 (73%)

Values are expressed as the mean ± standard deviation, median (interquartile range), or number (%).

attained functional independence (mRS score 0–2) by the 6-month follow-up.

Factors Associated With Functional Independence at 6 Months

Univariate analysis of the independent versus dependent cohorts yielded 4 variables with $p < 0.05$ (Table 2). Patients with functional independence at 6 months had lower NIHSS scores on initial presentation than those who depended on assistance (13 [IQR 10–15] vs 20 [15–24], $p < 0.0001$). They were also more likely to have a lobar hemorrhage than the dependent patients (54% vs 27%, $p = 0.02$). Dependent patients had a greater incidence of concurrent IVH (55% vs 17%, $p = 0.002$). Finally, dependent patients also had a greater time from ictus to evacuation (35 ± 21 vs 22 ± 14 hours, $p = 0.005$).

Of the 4 variables accounted for in a multivariate analysis of independent functional outcome at 6 months, NIHSS score on presentation, IVH presence, and time to evacuation remained significant (Table 3). Patients attaining functional independence were more likely to present with a lower NIHSS score (OR per point 0.78, 95% CI 0.67–0.91, $p = 0.002$) and were five-fold less likely to present with IVH (OR 0.20, 95% CI 0.05–0.77, $p = 0.02$). Every hour saved between ictus and evacuation was associated with a 5% greater likelihood of functional in-

TABLE 2. Univariate analysis of functional independence versus dependence at 6 months

Variable	Independent at 6 Mos	Dependent at 6 Mos	p Value
No. of patients	24	66	
Age in yrs	59 ± 11	64 ± 15	0.08
Male gender	19 (79%)	43 (65%)	0.30
African American race	9 (38%)	23 (35%)	0.82
Hypertension	17 (71%)	55 (83%)	0.24
Anticoagulant therapy	3 (13%)	7 (11%)	0.72
Antiplatelet therapy	6 (25%)	17 (26%)	>0.99
Premorbid mRS score >0	2 (8%)	18 (27%)	0.08
Functional impairment on presentation, NIHSS score	13 (10–15)	20 (15–24)	**<0.0001***
IVH	4 (17%)	36 (55%)	**0.002***
Preop mGS score	7 (6–8)	6 (2–14)	0.63
Postop mGS score	4.5 (2–9)	4 (2–6)	0.28
Spot sign	4 (17%)	11 (17%)	>0.99
Lobar origin	13 (54%)	18 (27%)	**0.02†**
Rt-sided hemorrhage	13 (54%)	39 (59%)	0.68
Artemis device	10 (42%)	17 (26%)	0.15
Preop hematoma vol in ml	37 (21–58)	46 (29–74)	0.16
Postop hematoma vol in ml	1 (0–5)	2 (0–8)	0.41
Evacuation percentage	98% (82%–100%)	97% (87%–99%)	0.50
Residual hematoma <15 ml	21 (88%)	56 (85%)	>0.99
Time to evacuation in hrs	22 ± 14	35 ± 21	**0.005***
Op time in hrs	3 ± 1	2 ± 1	0.38

Values are expressed as mean ± standard deviation, number (%), or median (interquartile range), unless indicated otherwise. Boldface type indicates statistical significance.
* $p < 0.01$.
† $p < 0.05$.

TABLE 3. Multivariate analysis for functional independence at 6 months

Factor	OR	95% CI	p Value
Functional impairment on presentation, per NIHSS point	0.78	0.67–0.91	**0.002***
Presence of IVH	0.20	0.05–0.77	**0.02†**
Lobar origin	2.14	0.61–7.47	0.23
Time to evacuation, per hr	0.95	0.91–0.99	**0.007***

Boldface type indicates statistical significance.
* $p < 0.01$.
† $p < 0.05$.

dependence (OR per hour 0.95, 95% CI 0.91–0.99, p = 0.007).

IVH

Of the 40 patients who co-presented with IVH, only 4 (10%) attained long-term functional independence (mRS score ≤ 2) as compared with 20 (40%) of the 50 patients who did not co-present with IVH (p = 0.001; Fig. 1). There was no significant difference in preoperative or postoperative mGS scores between those who attained independence and those who were still dependent at 6 months (preoperative scores: 7 [IQR 6–8] vs 6 [2–14], respectively, p = 0.63; postoperative scores: 4.5 [2–9] vs 4 [2–6], p = 0.28; Table 2). Because of the small number of patients attaining functional independence, the relationship between IVH severity and functional outcomes was analyzed using an ordinal shift analysis with mRS scores not dichotomized into independent and dependent cohorts but analyzed as a linear function from 0 to 6. Although greater mGS scores tended to be associated with a worse outcome, neither preor postoperative mGS scores were statistically associated with long-term outcomes among patients co-presenting with IVH (preoperative OR per point 1.02, 95% CI 0.97–1.08, p = 0.43; postoperative OR per point 1.05, 95% CI 0.97–1.13, p = 0.21; Supplementary Figs. 2 and 3).

Time to Evacuation

When evacuation was conducted within 12 hours from ictus, the probability of 6-month functional independence was 40.9%; from 12 to 24 hours, 33.3% (from 0 to 24 hours, 35.9%); and from 24 to 48 hours, 31.0%. However, the probability of functional independence was only 4.5% when evacuation was conducted 48–72 hours after ictus (Fig. 2). On univariate analysis, evacuation within 24 hours was associated with an 11.8 times greater likelihood of achieving long-term independence (p = 0.006) and evacuation between 24 and 48 hours was associated with a 9.5 times greater likelihood of attaining long-term independence (p = 0.02), as compared to evacuation after 48 hours (Fig. 3). A multivariate analysis including significant univariate factors as well as the role of the 6-month functional evaluator as covariates revealed that evacuation within 24 hours was associated with a 17.7 times greater likelihood of long-term independence (OR 17.7, 95% CI 1.90–164, p = 0.01) and evacuation between 24 and 48 hours was associated with an 11.5 times greater likelihood of long-term independence (OR 11.5, 95% CI 1.26–105, p = 0.03), as compared to evacuation after 48 hours.

Further analysis of early (< 24 hours), interim (24–48 hours), and late (> 48 hours) evacuation suggested that patients with early evacuation had statistically significant lower rates of anticoagulation medication (3%) than both the interim (17%, p = 0.03) and late (18%, p = 0.03) evacuation groups (Table 4). Additionally, early evacuation was associated with a greater probability of encountering intraoperative bleeding (82%) than either interim (45%, p = 0.001) or late (45%, p = 0.001) evacuation. The early

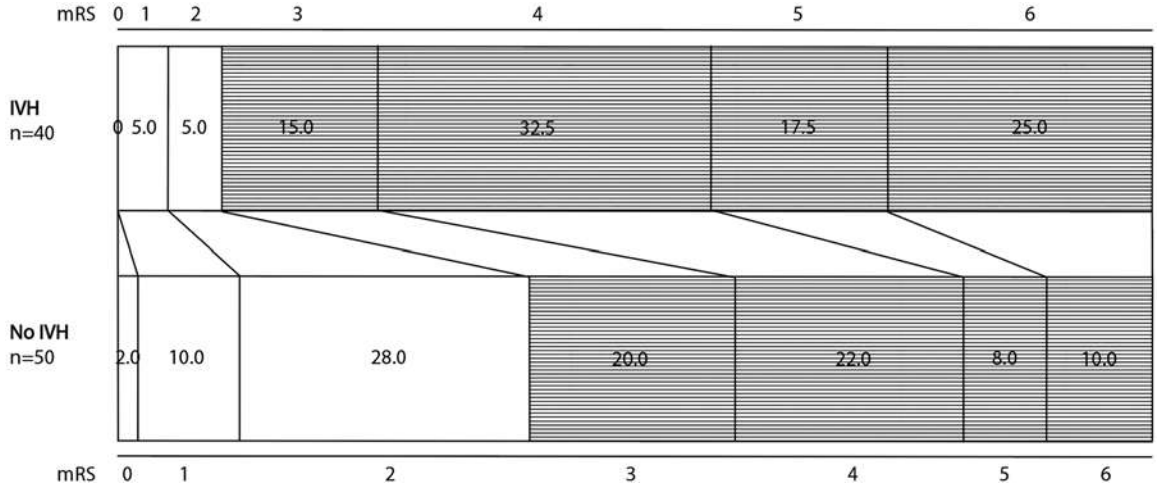

FIG. 1. Proportions of patients with mRS scores from 0 to 6 dichotomized into IVH or no-IVH groups. Six-month functional independence (mRS score 0–2) was independently associated with a lack of IVH (OR 0.17, 95% CI 0.04–0.65, p = 0.009).

evacuation group also had a longer SCUBA operative time (3 ± 1 hours) than the interim (2 ± 1 hours, p = 0.009) evacuation group, and the late evacuation group had a greater mortality rate (23%) than both the early (5%, p = 0.04) and interim (3%, p = 0.03) groups.

Discussion

Minimally invasive endoscopic evacuation is a promising treatment for ICH, a condition with acute mortality rates reaching 40%.[1] While minimally invasive techniques have achieved high rates of procedural success, it is still unclear if this will translate into improved functional outcomes. This is the first study to report factors associated with long-term functional independence following endoscopic evacuation of ICH. A lower extent of functional impairment at presentation (OR per NIHSS point 0.78, p = 0.002), lack of concurrent IVH (OR 0.20, p = 0.02), and shorter time to evacuation (OR per hour 0.95, p = 0.007) were all associated with functional independence at 6 months in this surgical cohort (Table 3). The multivariate results were confirmed by propensity score–matched ad-

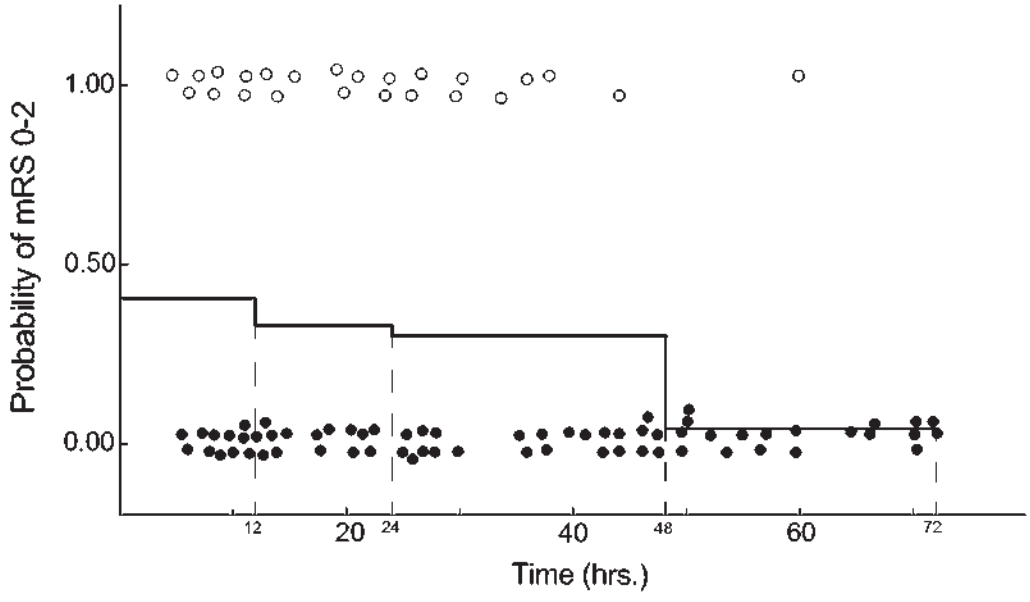

FIG. 2. Time to evacuation versus probability of functional independence at 6 months. *White dots* represent functional independence at 6 months, or an mRS score of 0–2. *Black dots* represent patients with a 6-month mRS score of 3–6. The *solid black line* represents the discrete probability of functional independence at 6 months as a function of time from ictus to evacuation. The discrete probability of long-term functional independence up to 12 hours after ictus is 40.9%; from 12 to 24 hours, 33.3%; from 24 to 48 hours, 31.0%; and from 48 to 72 hours, 4.5%.

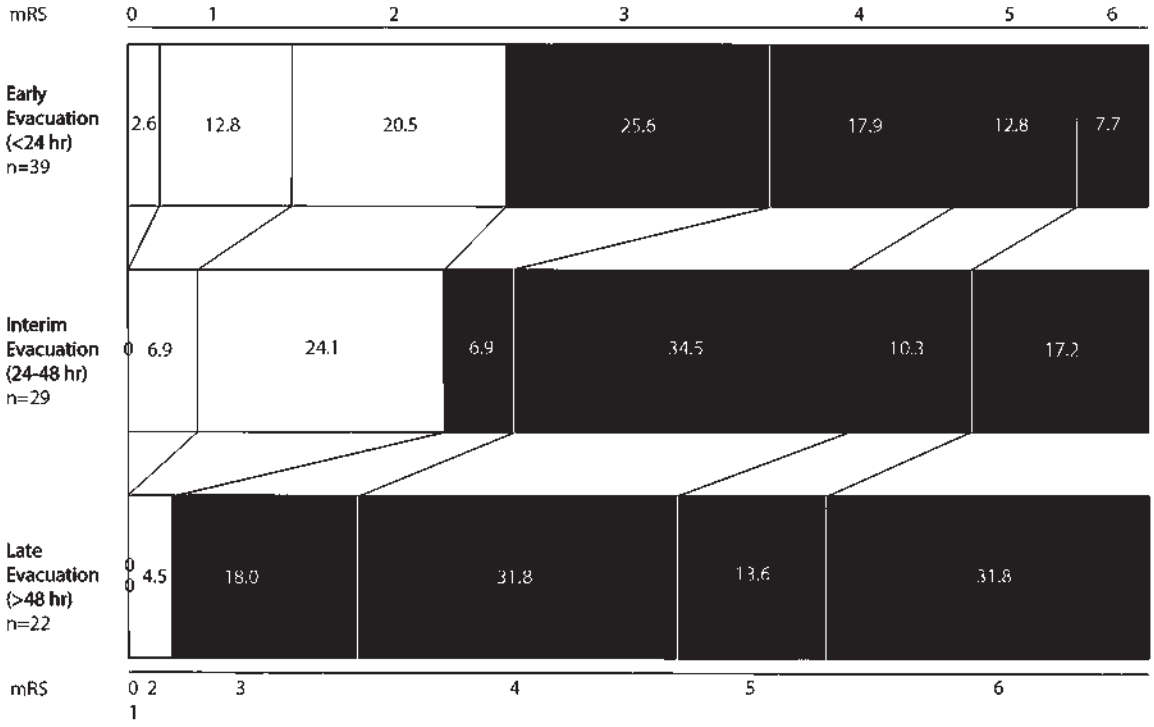

FIG. 3. Proportion of patients with mRS scores from 0 to 6 divided into those with time from ictus to evacuation < 24 hours, from 24 to 48 hours, and > 48 hours. Six-month functional independence (mRS score 0–2) was independently associated with evacuation within 48 hours (OR 6.31, 95% CI 1.79–22.20, p = 0.004).

justed logistic regression analysis for long-term functional independence with an evacuation time ≤ 48 hours as the treatment group and evacuation time > 48 hours as the control group (Supplementary Table 2). The 3 aforementioned factors may help to better predict suitable treatment populations and guide protocols for future clinical trials of endoscopic ICH evacuation.

Functional Impairment on Presentation

The degree of functional impairment at presentation was independently associated with long-term outcome after endoscopic ICH evacuation, with each additional NIHSS point decreasing the odds of independence at 6 months by a factor of 0.78 (OR 0.78, 95% CI 0.67–0.91, p = 0.002). The extent of functional impairment at presentation has previously been associated with outcome following ICH. In a 1987 study, Portenoy et al. found that 95% of patients with favorable outcomes had a presentation GCS score between 9 and 15 but that only 30% of patients with a poor outcome presented with a GCS score of 9–15 (OR 2.57, p < 0.001).[23] Though our study did not find an effect of similar magnitude, preliminary evidence suggests that surgical evacuation normalizes some of the impact of presentational functional impairment on long-term outcomes. In a meta-analysis of 859 patients with a presenting GCS score between 9 and 12 and undergoing surgery versus medical management, surgical intervention, as compared to medical management, reduced the odds of a poor outcome by a factor of 0.54 (OR 0.54, 95% CI 0.37–0.77, p < 0.001).[24] A post hoc analysis of the STICH I trial suggested that patients with a GCS score ≥ 9 may have responded favorably to surgery.[2] Therefore, these patients were evaluated in the STICH II trial, but the results of that study were neutral.[3] Auer et al. (endoscopic study) and Pantazis et al. (early evacuation study) also found that surgical intervention was associated with better outcomes, with a greater effect of surgery on patients with greater GCS scores on presentation.[25,26] The NIHSS is frequently used in place of the GCS to evaluate patients with acute stroke, including those presenting with ICH, both in clinical practice and in research. Analysis of the cohort in the present study revealed that a presenting NIHSS score correlated with functional independence by a factor of 0.78 per additional point. Currently, patients presenting with significant neurological impairment are not excluded from minimally invasive evacuation studies. More analysis is required to formally evaluate the correlation between presenting NIHSS score and surgical effect.

IVH

More than 40% of the patients in this study had concurrent IVH, which, in addition to the ICH, was endoscopically evacuated if the intraventricular bleed was accessible from the access point used to reach the ICH. A total of 23 patients, 58% of those presenting with IVH, had co-evacuation of the IVH. Overall, concurrent IVH evacuation was successful in decreasing the IVH burden in the target ventricle. The postoperative mGS score was 2 points lower on average than the preoperative scores for patients who had undergone IVH evacuation (Supplementary Table 1).

TABLE 4. Univariate analysis of early, interim, and late evacuation

Variable	Early (<24 hrs)	Interim (24–48 hrs)	Late (>48 hrs)	p Value		
				Early vs Interim	Early vs Late	Interim vs Late
No. of patients	39	29	22			
Age in yrs	60 ± 13	65 ± 14	66 ± 15	0.21	0.12	0.76
Male gender	24 (62%)	23 (79%)	15 (68%)	0.12	0.60	0.37
African American race	12 (31%)	10 (34%)	10 (45%)	0.75	0.25	0.63
Hypertension	32 (82%)	25 (86%)	15 (68%)	0.65	0.22	0.12
Anticoagulation therapy	1 (3%)	5 (17%)	4 (18%)	**0.03†**	**0.03†**	0.93
Antiplatelet therapy	7 (18%)	11 (38%)	5 (23%)	0.06	0.65	0.25
Premorbid mRS score >0	8 (21%)	5 (17%)	7 (32%)	0.73	0.32	0.22
Functional impairment on presentation, NIHSS score	18 (13–22)	16 (13–22)	16 (12–22)	0.75	0.84	0.94
IVH	17 (44%)	14 (48%)	9 (41%)	0.70	0.92	0.82
Preop mGS	8 (2–15)	7 (3–9)	4 (2–13)	0.37	0.20	0.38
Postop mGS	7 (2–13)	5 (3–8)	2 (2–7)	0.51	0.45	0.51
Spot sign	8 (21%)	3 (10%)	4 (18%)	0.26	0.83	0.42
Lobar origin	13 (33%)	12 (41%)	6 (27%)	0.46	0.62	0.30
Artemis device	16 (41%)	8 (28%)	3 (14%)	0.25	**0.03†**	0.23
Preop hematoma vol in ml	46 (23–70)	45 (29–69)	40 (29–57)	0.92	0.42	0.46
Postop hematoma vol in ml	1 (0–6)	3 (0–14)	1 (0–4)	0.83	0.49	0.33
Evacuation percentage	98% (82%–100%)	95 (76%–99%)	97 (91%–99%)	0.39	0.64	0.27
Residual hematoma <15 ml	34 (87%)	23 (79%)	20 (91%)	0.38	0.66	0.26
Op time in hrs	3 ± 1	2 ± 1	2 ± 1	**0.009***	0.07	0.54
Intraop bleeding encountered	32 (82%)	13 (45%)	10 (45%)	**0.001***	**0.001***	0.96
Asymptomatic rebleeding at 30 days	0 (0%)	3 (10%)	1 (5%)	—	—	0.45
Length of stay in days						
Hospital	14 (7–24)	19 (10–27)	19 (11–27)	0.19	0.26	0.78
ICU	6 (3–14)	8 (5–14)	11 (7–16)	0.81	0.57	0.73
Mortality at 30 days	2 (5%)	1 (3%)	5 (23%)	0.74	**0.04†**	**0.03†**
6-mo mRS score 0–2	14 (36%)	9 (31%)	1 (5%)	0.68	**0.006***	**0.02***

Values are expressed as mean ± standard deviation, number (%), or median (interquartile range), unless indicated otherwise. Boldface type indicates statistical significance.
* $p < 0.01$.
† $p < 0.05$.

We found that the presence of IVH was independently associated with long-term functional outcome among patients undergoing endoscopic ICH evacuation, with the presence of IVH on admission decreasing the odds for functional independence at 6 months by a factor of 5 (OR 0.20, 95% CI 0.05–0.77, p = 0.02). However, the severity of IVH as measured by the mGS score was not associated with 6-month mRS scores (Supplementary Fig. 2). Concurrent IVH has been shown to be an independent predictor of hematoma expansion, mortality, and poor outcome.[27,28] INTERACT2 (The Second Intensive Blood Pressure Reduction in Acute Cerebral Haemorrhage Trial, NCT00716079) showed a significantly higher rate of mortality and poor outcome at 90 days in patients with IVH and a near-continuous relationship between IVH volume and outcome, with IVH reducing the odds of a favorable outcome by almost 3 times (OR 2.7, 95% CI 1.37–5.33, p = 0.004).[29] While analyzing from 8 studies the association of IVH co-presentation on outcome in 2186 patients undergoing surgery versus medical management, Gregson et al. found that the absence of IVH reduced the odds of a poor outcome by 0.77 (OR 0.77, 95% CI 0.61–0.98, p = 0.03).[24] Despite a well-established correlation between the presence of IVH and a poor outcome in both medically and surgically managed patients, the patients with IVH are, by and large, included in ongoing minimally invasive evacuation studies. Further work is necessary to better understand the effect of minimally invasive ICH evacuation in this population as well as the effect of concurrent IVH evacuation.

Time to Evacuation

Across a 72-hour range from bleed to evacuation, an earlier time to evacuation was independently associated with functional independence at 6 months. The odds ratio for time to evacuation suggested that each additional hour lost before evacuation was associated with a 5% reduction in the odds of obtaining functional independence (OR

0.95, 95% CI 0.91–0.99, p = 0.007). Interestingly, the discrete probability of functional independence at 6 months decreased from 31% if the evacuation took place 24–48 hours after ictus to 5% if the evacuation took place 48–72 hours after ictus (Fig. 2). Evacuation within 24 hours was associated with an 18 times increased likelihood of long-term independence (OR 17.7, 95% CI 1.90–164, p = 0.01) as compared to evacuation after 48 hours.

The benefit of early evacuation has been shown in preclinical studies, a patient-level meta-analysis, and two study-level meta-analyses. A patient-level meta-analysis of multiple RCTs has suggested that randomization within 8 hours of symptom onset followed by surgery may be superior to medical management (OR 0.59, 95% CI 0.42–0.84, p = 0.003), whereas surgery at later time points did not appear to be superior to medical management.[24] A study-level meta-analysis of minimally invasive surgical trials revealed that intervention within 24 and 72 hours was associated with 0.36 (OR 0.36, 95% CI 0.22–0.59, p < 0.0001) and 0.49 (OR 0.49, 95% CI 0.38–0.63, p < 0.0001) times, respectively, the likelihood of death or severe functional debility as compared to intervention thereafter.[7] Another study-level meta-analysis demonstrated that a shorter mean time to evacuation among all surgical ICH evacuation trials was associated with greater treatment effect (β = –0.0063, p = 0.04).[30] These meta-analyses suggest that an RCT focusing on early minimally invasive evacuation, if performed safely without intraoperative or postoperative rebleeding, may be able to capitalize on the potential benefit of early evacuation. Studies with a long average time to evacuation, such as MISTIE III (average time to initiation of the treatment protocol at 58.3 hours and earliest initiation of the treatment protocol at 18 hours after ictus), would be unlikely to demonstrate a time-based benefit over medical management at such late time points. Unlike the surgical protocol of MISTIE III, the SCUBA technique does not require a stability scan and therefore permits urgent evacuation, which may mitigate the deleterious effect of hematoma expansion and thereby further improve outcome relative to that with medical management in which expansion would occur unabated.

Thirty patients, or a third of our cohort, underwent evacuation within 18 hours, and the earliest surgery in our cohort was 5 hours after ictus. Performing "ultra early" evacuation within 4 hours has been controversial given an increased risk of rebleeding and mortality observed in a pilot study of early versus ultra early craniotomy for ICH evacuation published in 2001 by Morgenstern et al.[31] Indeed, repeat acute imaging demonstrating hematoma stability was required in some minimally invasive ICH evacuation trials, although this requirement was recently waived in the MIND trial.[32,33] However, minimally invasive endoscopic evacuation may confer an advantage over open craniotomy by improving visualization in the cavity, allowing for identification and cauterization of active bleeding. In our study, only 4 patients experienced postoperative rebleeding, and all had undergone surgery at least 24 hours after ictus. In a single-center cohort of 68 patients undergoing minimally invasive endoscope-assisted evacuation, including 57 patients undergoing ultra early evacuation within 4 hours, rebleeding was encountered in only 1 patient.[34] Ongoing trials evaluating early minimally invasive ICH evacuation include DIST (endoscopic evacuation within 8 hours), ENRICH (endoport-mediated evacuation within 24 hours), and EVACUATE (Ultra-Early, Minimally Invasive Intracerebral Haemorrhage Evacuation Versus Standard Treatment, NCT04434807, surgiscope-mediated evacuation within 12 hours). These ongoing studies will be critical to evaluating the safety and efficacy of early evacuation utilizing a variety of minimally invasive evacuation techniques.

Further analysis of early (< 24 hours), interim (24–48 hours), and late (> 48 hours) evacuation suggested that patients in the early cohort had a greater probability of intraoperative bleeding (82%) than the interim (45%, p = 0.001) or late (45%, p = 0.001) evacuation patients. The early evacuation group also had longer operative times (3 ± 1 hours) than the interim evacuation group (2 ± 1 hours, p = 0.009). With the endoscopic technique, however, this bleeding was managed in all cases and the evacuation percentage in the early group was similar to that in the late group (98% vs 97%, p = 0.64). In addition, rebleeding occurred at similar rates in the two groups (0% vs 5%). Finally, the late evacuation group had a greater mortality rate (23%) than both the early (5%, p = 0.04) and interim groups (3%, p = 0.03), further suggesting that an earlier time to evacuation may be associated with improved outcomes.

Generalizability

While the endoscope has been a critical component of the neurosurgeon's armamentarium in endonasal and intraventricular procedures, its use in ICH evacuation is less common. Numerous techniques are currently employed in the United States and globally to perform minimally invasive ICH evacuation.[35,36] These techniques range in the size of the access port (4.8 mm in the MISTIE technique to 15.8 mm in endoport-mediated techniques), trading smaller size for less access to the cavity to address clot aspiration or accomplish hemostasis. The SCUBA technique utilizes a 6.9-mm sheath, making it the smallest technique with which to perform "active" evacuation early while still addressing ongoing bleeding. "Active" refers to the entire evacuation being performed in one procedure without the use of thrombolytics. Good intracavitary visualization, continuous irrigation for washing and intracavitary tamponade, and direct cauterization of bleeding vessels may confer a procedural advantage with this technique.

The use of the endoscope in ICH evacuation requires a novel skill set and technical approach, which we have attempted to describe as the SCUBA technique. We also report outcomes utilizing this technique. As with the use of any new tool or technique, there is a learning curve involved in reaching a steady state of optimal outcomes, limiting the immediate generalizability of this novel approach. A multicenter feasibility study is ongoing, evaluating the safety and feasibility of endoscopic ICH evacuation with the Apollo or Artemis adjunctive aspiration device, which will provide important information on the generalizability of this technique (INVEST). Given the findings presented here, including the suggested benefit of early evacuation and minimal to no increased risk of post-

operative rebleeding in the early cohort, we have evolved our technique to treat patients urgently, building on the systems of care already in place for the triage and urgent surgical management of the acute stroke patient.

Study Limitations and Future Directions

This study has several limitations. It is a retrospective analysis of a surgical cohort performed at a single institution, limiting its broad applicability. However, the patient population is racially diverse, with 36% African American, 29% White, 20% Asian, and 16% nonwhite Hispanic subjects, increasing the study's applicability for underserved, at-risk ICH populations.[37] The study does not include a nonoperative control arm and thus can only demonstrate correlation. Because time to evacuation is not randomized, factors such as time to arrival at the main hospital from ictus or from another hospital within the system, availability of operating rooms and teams, and surgeon preference may introduce confounding bias that is not accounted for in the multivariate analysis. Outcome assessors were not blinded and may have been subject to observer bias. However, the role of the 6-month outcome assessor—whether they were involved in the surgery or not—was accounted for in the multivariate analysis. The use of the mRS as an outcome measure provided its own limitations, as it can be imprecise in detailing patients' cognitive recovery. However, the utility of the mRS in ICH, especially in the surgical evacuation of ICH, has been validated in previous and ongoing trials and therefore was selected as this study's primary outcome measure.[4,5] Six-month mRS scores were not available for 11 patients, and the most recent scores were carried forward, as has been done in recent large clinical trials.[4,5] Given these limitations, we encourage further investigation into factors that may be associated with long-term functional independence in minimally invasive endoscopic ICH evacuation via prospective feasibility and randomized controlled studies.

Conclusions

Multivariate analysis of a 90-patient cohort revealed that a lower NIHSS score at presentation (OR per point 0.78, $p = 0.002$), the lack of IVH (OR 0.20, $p = 0.02$), and a shorter time to evacuation (OR per hour 0.95, $p = 0.007$) were associated with long-term functional independence in patients undergoing minimally invasive endoscopic ICH evacuation. Factors associated with functional independence may help to better predict populations suitable for minimally invasive endoscopic evacuation and guide protocols for future clinical trials.

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Conception and design: Ali, Mocco, Kellner. Acquisition of data: Mocco, Kellner. Analysis and interpretation of data: Ali, Kellner. Drafting the article: Ali, Kellner. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Ali. Statistical analysis: Ali, Zhang. Administrative/technical/material support: Kellner. Study supervision: Mocco, Kellner.

Supplemental Information

Videos

Video 1. https://vimeo.com/695643893.
Video 2. https://vimeo.com/695645763.

Online-Only Content

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