ORIGINAL RESEARCH

Safety and quality of endovascular therapy under general anesthesia and conscious sedation are comparable: results from the GOLIATH trial

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ABSTRACT

Background The "General or Local Anesthesia in Intra-Arterial Therapy" (GOLIATH) trial compared infarct growth and outcome in patients undergoing endovascular therapy (EVT) under either general anesthesia (GA) or conscious sedation (CS). The results were the same for the primary outcome (infarct growth) but successful reperfusion was higher in the GA arm.

Objective To further examine differences in the quality and safety of EVT with the two anesthetic regimens in a post hoc analysis of GOLIATH.

Methods In GOLIATH, 128 subjects with anterior circulation large vessel occlusion stroke within 6 hours of onset were randomized to either GA or CS (1:1 allocation). We compared the quality of reperfusion, treatment delay, use of catheters, and contrast and radiation dosage between the trial arms.

Results Sixty-five subjects were randomized to GA. Baseline demographic and clinical variables were similar between the treatment arms. We found no difference in procedure time, contrast dose, or radiation dose between the two arms. Tandem occlusions were associated with a longer procedure time, but there was no difference between the two arms. There was no difference in reperfusion rates between the direct aspiration technique and a stent retriever (86% vs 79%, respectively, p=0.54), but aspiration was associated with a shorter procedure time (28 min vs 42 min for a stent retriever), p=0.03.

Conclusion Safety and quality of EVT under either GA and CS are comparable.

Trial registration Unique identifier: NCT02317237;Post-results.

INTRODUCTION

Endovascular therapy (EVT) is the mainstay for treating ischemic stroke caused by large vessel occlusion (LVO).[1] Until recently, most neurointerventionalists would not perform thrombectomy unless their patients were under general anesthesia (GA), for fear of greater harm related to patient movement. Subsequently, patients were preferably treated under conscious sedation (CS) as retrospective studies began to report better outcomes with this approach.[2 3] However, three recent randomized trials showed no difference in outcome between patients randomized to either anesthetic modality,[4–6] suggesting that previous results might have been subject to confounding by indication.

We undertook this study to investigate the efficacy and safety of EVT under the two anesthetic regimens.

METHODS

The trial and the primary results have been described earlier.[6 7] In this secondary study, we compared the quality of EVT between the two anesthetic regimens, GA and CS. EVT performance was measured using procedure time, rate of successful reperfusion (modified Thrombolysis in Cerebral Infarction Score 2b and 3), contrast and radiation dose, and complications (perforation, vasospasm, dissection, emboli to non-affected territory, rate of aspiration pneumonia, and days spent at the stroke unit). Some of this information has not been reported in similar trials.[8] Results were also examined by the type of treatment approach used for EVT.

Trial

Criteria for inclusion in GOLIATH were an independently living patient with an occlusion in the anterior circulation and a National Institute of Health Stoke Scale Score ≥10 and where groin puncture could be achieved within 6 hours from symptom onset or last seen well. Patients received an MRI scan and infarct volume had to be ≤70 mL.

Randomization of patients between GA and CS was carried out when MR angiography demonstrated an LVO and the other trial inclusion criteria were fulfilled. Intravenous tissue plasminogen activator (tPA) was started if indicated and the patient was taken to the angio suite as quickly as possible. Initial consent was waived by the local ethics committee because eligible patients were not able to give consent and speed of treatment was critical. Consent to remain in the trial was later obtained from the patient or next of kin. Anesthesia was available 24/7 in-house and patients randomized to GA were intubated in the angio suite. Time from arrival at the angio suite to groin puncture was 9 min longer for the patients undergoing GA (to allow for intubation), but otherwise there were no differences in other time measures between GA and CS.[6] A follow-up scan was performed 48–72 hours after symptom onset to avoid false DWI reversal and to minimize early edema.

Quality measures

Procedure time was the time from groin puncture to reperfusion and thus could only be recorded for the patients who received reperfusion.

Table 1 Successful reperfusion and procedure time evaluated for the device used. A direct aspiration first pass technique (ADAPT) was used for 49 patients, a stent retriever for 29, and both for 20 patients. For the remaining 30 a mixture of spontaneous reperfusers (9), intra-arterial tissue plasminogen activator used alone (3), and a carotid stent was used alone (2) or EVT was not possible owing to anatomy or stenosis (15). One patient had reperfusion by manipulation of the catheter alone.

	Successful reperfusion	P value	Procedure time (min)	P value	Treated under GA
ADAPT (n=49)	42/49 (86%)		28 (19-41)		25/49 (51%)
Stent retriever (n=29)	23/29 (79%)	0.54, ADAPT compared with stent retriever	41 (30–50.75)	0.03, ADAPT compared with stent retriever	17/29 (59%)
Both (n=20)	11/20 (55%)	0.01 compared with ADAPT 0.11 compared with stent retriever	61 (52.25–66.5)	0.0002 compared with ADAPT 0.007 compared with stent retriever	10/20 (50%)

EVT, endovascular therapy; GA, general anesthesia.

The primary reperfusion technique was chosen by the interventionalist. Generally, either a direct aspiration first pass technique (ADAPT) or a stent retriever (eg, TREVO, Preset etc) was used. When considered necessary, carotid angioplasty with stenting was performed and, in some cases, intra-arterial tPA was given.

The level of occlusion was registered as: internal carotid artery (ICA) occlusion in the neck alone, intracranial ICA, first division of the middle cerebral artery (M1), second division of the middle cerebral artery (M2) and a tandem occlusion which signifies ICA in the neck and any intracranial occlusion.

Ventilator aspiration pneumonia was defined as occurring when antibiotics were started for an assumed pneumonia while the patient was still in the stroke unit.

Statistical analysis

For normally distributed data, mean and SD are shown. For data not distributed normally, median and interquartile ranges (IQR) are reported. The X^2 test was used to compare categorical data. The Mann-Whitney test and Kruskal-Wallis test were used to compare non-normally distributed data within the trial.

RESULTS

GOLIATH enrolled 128 patients. Sixty-five were randomized to GA and 63 to CS. As previously reported, the procedure time in patients who were reperfused (n=88) did not differ between patients receiving GA and CS (34 min vs 28.5 min respectively, p=0.27), but more patients underwent successful reperfusion in the GA group (76.9%) than in the CS group (60.3%, p=0.04). For the time between groin puncture and the end of the procedure (catheter exiting the groin) (n=128), there was no difference between the GA group (median 55 min, IQR 37.75–79.5) and the CS group (median 56 min, IQR 35.25–77.25; p=0.92).

The amount of contrast used did not differ between the GA patients (median 75 mL [IQR 58.75–110]) and the CS patients (median 85 mL [IQR 55–110], p=0.79). Radiation dose, which was available for 117 patients (59 of the 65 GA patients and 58 of the 63 CS patients), did not differ between treatment arms. In the GA arm a median of 98 Gy/cm^2 (IQR 60–172) was administered compared with a median of 101 Gy/cm^2 (IQR 64–143) in the CS patients (p=0.92).

In the GA group, 12 (18%) 65 patients had an aspiration pneumonia, compared with 17 (27%) of 63 in the CS group (p=0.25). Patients in both the GA and CS groups were admitted for a median of 4 days to the stroke unit (IQR 3–5) (p=0.71).

Additional analyses of EVT performance

There was no difference in the rate of successful reperfusion between ADAPT (86%) and a stent retriever (79%, p=0.54), but the procedure time was shorter using the ADAPT technique (28 min, IQR 19–41) than with a stent retriever (41 min, IQR 30–50.75; p=0.03). When both approaches were used in the same patient, this was always because a rescue operation was needed owing to failure of the first line of approach. In this case the procedure time was longer and the reperfusion rate was lower than with ADAPT alone. The choice of reperfusion technique did not depend on the anesthetic management (p=0.71) (table 1). When a stent retriever was used, a balloon guide catheter and distal aspiration were used in 18 cases and this choice was also not related to anesthetic management (p=0.73). In the remainder (11 cases), a distal access catheter was used.

There was no difference in the rate of successful reperfusion according to the level of occlusion. However, procedure time was longer for a tandem occlusion (51 min, IQR 34.25–56) than for M1 occlusion alone (25 min, IQR 16.5–36; p=0.0005) and for isolated carotid occlusion at the neck (median 20 min, IQR 13.75–34.25; p=0.04). (table 2)

No vessel perforation or severe vasospasm was observed. Three cases of dissection occurred, one in the CS group and two in the GA group. Sixteen cases of emboli to non-affected territory were seen: six in the CS group and 10 in the GA group (p=0.57).

Table 2 Procedure time for different levels of occlusion. Procedure time for tandem occlusion is significantly longer than that for internal carotid artery at the neck and M1 occlusions.

	Procedure time for reperfusion (n)	General anesthesia	Conscious sedation	P value, comparing GA and CS
Internal carotid artery at the neck alone	20 (13.75–34.25) (n=5)	24 (n=3)	12.5 (n=2)	0.08
Intracranial carotid artery occlusion	43 (17–69.75) (n=11)	43 (25–53.5) n=5	26 (19-43) n=6	0.30
First branch of the middle cerebral artery	25 (16.5–36) (n=40)	23 (16-34) n=18	26 (19-43) n=22	0.43
Second branch of the middle cerebral artery	35 (29–44.25) (n=13)	41 (33.75–46.25) n=9	28 (17-34) n=4	0.09
Tandem occlusion	51 (34.25–56) (n=19)	51 (33.25–56) n=15	46 (38-52) n=4	0.73

DISCUSSION

The GOLIATH trial[6] together with the SIESTA[4] and the ANSTROKE[5] trials showed that EVT under GA yields outcomes comparable to those with CS. The data reported here for the quality of EVT treatment further support the equivalence of endovascular treatment performed under GA and under CS. Procedural time, contrast use, and radiation dose did not differ between the two groups. Also, the rate of pneumonia was similar in the two groups, with no difference in the number of days the patients stayed in the stroke unit.

GOLIATH showed no significant difference in the primary outcome—that is, growth of the ischemic lesion. But the shift analysis for modified Rankin score showed a better outcome in the GA group.[6] This was primarily driven by a higher reperfusion rate in the GA group. Possibly, keeping the patient immobile provides more optimal working conditions for the interventionalist, although the rate of successful reperfusion has generally been the same in the GA and CS groups in other randomized trials and observational studies.[9 10]

The choice of primary reperfusion approach was not randomized. ADAPT was the preferred technique for the interventionalists in GOLIATH. This choice did not depend on anesthetic management. The rate of successful reperfusion was similar between the ADAPT and stent retriever groups. A faster procedure time was observed in the ADAPT group, but this might be related to the greater preference for, and experience with, the ADAPT technique among the trial interventionalists. However, a non-randomized trial comparing the two techniques in basilar occlusion also found a faster procedure time in the ADAPT group.[11] A randomized trial comparing first-line ADAPT and first-line stent retriever in patients with LVO in the anterior circulation showed no difference in reperfusion rate or procedure time between the arms, although there was a numerically lower procedure time in the stent retriever group.[12]

The postprocedure complication profile was comparable, and the rate of pneumonia was not statistically different between the GA and CS groups. This was also seen in the HERMES meta-analysis.[13] Prolonged ventilation after EVT increases the risk of pneumonia,[14] and all but three patients were extubated in the angio suite immediately after the procedure.

CONCLUSION

The safety and quality of EVT is similar between patients treated under GA and those treated under CS.

Contributors LS and MR: study concept andcollected data. LOS and SK: collected data. AJY: imaging analysis. KES: dataanalysis. CZS: study concept, drafting manuscript, statistics. Editingmanuscript: all.

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