

General versus local anesthesia for carotid endarterectomy: the West Australian experience

S. D. THOMAS^{1,2}, P. E. NORMAN², S. E. L. TEMPLE³, V. VIJAYAN¹, B. P. MWIPATAYI^{1,2}

¹Department of Vascular Surgery
Royal Perth Hospital, Perth, Australia

²School of Surgery
University of Western Australia, Perth, Western Australia

³School of Medicine and Pharmacology
University of Western Australia, Perth, Western Australia

Aim. The results of the GALA (general anaesthesia [GA] versus local anaesthesia [LA] in Carotid Surgery) trial demonstrated no significant differences between the two methods of anaesthesia. Variation in surgical and anaesthetic practices amongst the trial centers was not accounted for and differences may have influenced outcomes. The aim of this study was to report the West Australian experience of GA versus LA for carotid artery endarterectomy (CEA) with particular attention to an analysis of sonographic follow-up to determine disease progression.

Methods. The methods followed the GALA trial protocol as published previously. We analyzed the results for all patients entered into the trial from Western Australia. Duplex ultrasound of the ipsilateral and contralateral carotid arteries was performed at one month and one-year post procedure to determine if there was progression of the disease.

Results. All eighty patients undergoing CEA were analyzed in this study, of which 47 had been randomized to the GA group and 33 to the LA group. Six patients from the GA group and one patient from the LA group crossed over to the other group. There were no significant differences in patient baseline characteristics, use of patch angioplasty or shunts. There were no statistically significant differences in the primary outcomes (stroke of any type, myocardial infarction or death) at discharge or at one month follow up between the two groups. On sonographic follow-up, there was a trend towards more severe ipsilateral restenosis in the LA group compared to the GA group but this did not achieve statistical significance.

Conclusion. The Western Australian experience of GA versus LA in CEA suggests no significant difference in outcome between the two groups. This finding demonstrates that the GALA trial results are replicable in individual centers despite variations in practices. Sonographic follow-up suggests that the restenosis rate was similar for both groups with similar disease progression in contralateral carotids. Restenosis and contralateral disease progression occur and should be monitored via duplex scan.

KEYWORDS: Carotid arteries - Surgical procedures, operative - Stroke - Anesthesia.

Previous trials have established the role of carotid endarterectomy (CEA) in the prevention of ischemic stroke.¹⁻³ Benefit from CEA has been demonstrated in both the asymptomatic and symptomatic patient.^{4,5} The compli-

cation rate for an individual center or surgeon determines the efficacy of preventing stroke, particularly in asymptomatic patients.⁶

The GALA (general anaesthesia [GA] versus local anaesthesia [LA] in carotid surgery) trial aimed to determine if local anaesthesia in carotid surgery would have a beneficial effect on outcomes of carotid endarterectomy.⁷ Studies prior to GALA suggested that LA may be beneficial in terms of cerebral metabolism during CEA when compared to GA.⁸⁻¹⁰ However, the GALA trial demonstrated no significant differences in primary outcomes between LA and GA.⁶ Analysis of pre-specified subgroups similarly did not reveal any significant differences. Whilst there was a suggestion that patients with significant contralateral disease may have benefited from LA, the difference was not statistically significant. In terms of local applicability of the study results, an analysis of United Kingdom versus non-United Kingdom outcomes did not demonstrate any significant differences in outcomes, however significant differences in the CEA procedure were reported.¹¹

Ipsilateral carotid restenosis and contralateral disease progression after CEA requiring intervention has been previously reported (REF). The Asymptomatic Carotid Atherosclerotic Study (ACAS) follow up demonstrated an early (3-18 months) restenosis rate of 7.6%, where restenosis was defined as a Doppler determined diameter reduction of 60%.¹² Other studies similarly demonstrated that 6-14% of patients developed restenosis when defined as a Doppler reduction of 50% - accompanied by neurological events in 1-5% of cases.¹³ Using life table methods De-Groote *et al.*, reported that the probability of developing carotid restenosis in the long term (defined as 7 years, with stenosis >50%) was as high as 32%.¹⁴ Carotid restenosis and contralateral disease progression in the GALA trial have not been reported.

Corresponding author: B. P. Mwipatayi, Department of Vascular Surgery, Royal Perth Hospital, Wellington Street, 6001 Perth, Australia. E-mail: bibombe@iinet.net.au

The design of the GALA trial was pragmatic and variation in surgical technique such as the use of patch closure or intraoperative shunts was permitted. The aim of this study was therefore to report the West Australian experience of patients recruited into the GALA trial with particular attention to sonographic follow-up of disease progression and to determine if differences in surgical and anaesthetic technique influenced cerebral accident events in our population group.

Materials and methods

Study design

Patients undergoing CEA at Royal Perth and Fremantle Hospitals, Perth, Western Australia (WA) were enrolled into the GALA trial between June 1999 and October 2007. The institutional review board and ethics committees at each hospital approved the study protocol and written informed consent was obtained from all patients before enrolment. Both asymptomatic and symptomatic patients were enrolled and consented for randomization. The inclusion/exclusion criteria, protocols and methods for this trial have been published previously.^{7, 15} Baseline demographic data, operative and anaesthetic details as well as outcomes at discharge were recorded. All patients were reviewed by an independent neurologist at one month where outcomes were reviewed. Outcome at 12 months was recorded by way of a questionnaire sent to the patient's general practitioner. A duplex ultrasound scan of the carotid arteries was performed at one and 12 months postsurgery.

The primary outcome as per GALA trial was the proportion of patients with stroke (including retinal infarction), myocardial infarction or death between randomization and 30 days postsurgery. Secondary outcomes included survival free of stroke, myocardial infarction or death up to 1 year after surgery, length of stay in high dependency unit and overall in-hospital length of stay. Given the small sample size and high crossover rate, the data was analyzed on the basis of actual treatment not intention to treat.

In our institution, we selectively shunt during CEA if patient become neurologically symptomatic if the surgery is performed under LA or if the contralateral carotid has severe stenosis or is occluded, associated with a poor back-flow or a carotid stump pressure of less than 40mmHg if the surgery was performed under GA. One of our surgeons performed routine shunting for GA carotid surgery and did not rely on any of the described methods for testing post-clamp brain perfusion.

Stenosis identified subsequently was categorized as mild, moderate, severe or occluded based on criteria used in the CAVATAS Trial.¹¹ We reviewed the files of patients noted to have moderate to severe stenosis to determine if patients were symptomatic or required re-intervention.

Statistical analysis

Patients were analyzed by an 'on-treatment' or 'efficacy' analysis. Data were analyzed with the use of the statistical software SPSS (version 16.0). Student's independent t-test and chi-square were used in univariate analysis to compare

continuous data and categorical data, respectively. Continuous data were expressed as means \pm SD. A P-value below 0.05 was considered to be statistically significant.

Results

Patient characteristics

A total of 80 patients were enrolled, two from Fremantle Hospital and 78 from Royal Perth Hospital, with 47 randomized to GA and 33 to LA. Six patients from the GA group received LA as a result of patient preference or anaesthetic preference. One patient from the LA group had to be converted to GA during the procedure and thus for purposes of analysis crossed over to the GA group.

There were no significant differences in baseline characteristics (Table I), indication for surgery or method of imaging (Table II) between the GA and LA groups of the WA cohort. There was a higher grade of stenosis in the index carotid in the GA group compared to the LA group (85.5% versus 72.7%, respectively, p value=0.051. Contralateral carotid occlusion was noted in 7% of patients in GA group and 6.1% in LA group.

Pre-randomization antithrombotic/antiplatelet drugs were commonly used in both the GA group and LA group with approximately 82% of patients in both groups on aspirin preoperatively (Table II). Clopidogrel use was higher in the LA group compared to the GA group (21.9% versus 4.5%, respectively; $P=0.021$).

Surgical and anaesthetic procedure

There were no significant differences in operative and anaesthetic details between the GA and LA groups (Table III). There was a trend to higher shunt use in the GA group compared to the LA group (11.1% versus 6.1%, respec-

TABLE I.—Baseline patient characteristics for patients randomized for carotid endarterectomy in the West Australian cohort of the GALA trial.

	GA	LA
Number patients	47	33
Age (mean \pm SEM)	73.3 \pm 1.2	73.7 \pm 1.4
Gender (% male)	68.1	75.8
Weight (kg) (mean \pm SEM)	77.8 \pm 2.5	83.4 \pm 2.9
Risk factors (%)		
Hypertension	79.5	68.8
Systolic blood pressure (mmHg)	146.4 \pm 2.7	146.3 \pm 3.5
Diastolic blood pressure (mmHg)	77.4 \pm 1.4	75.4 \pm 1.9
Peripheral arterial disease	27.3	18.2
Cardiac failure	2.3	0
Aortic aneurysm	6.8	6.1
Previous myocardial infarction	15.9	24.2
History of angina	34.1	42.4
Atrial fibrillation	11.4	9.1
Previous coronary surgery/ angioplasty	18.2	18.2
Chronic lung disease	15.9	15.2
Smoking	43.2	48.2
Diabetes	34.1	25
ASA grade (%)		
1	2.3	3
2	59.1	51.5
3	31.8	39.4
4	6.8	6.1

TABLE II.—Indications for carotid endarterectomy, degree of artery stenosis, and anti-coagulant use in patients randomized to the West Australian cohort of the GALA trial.

	GA	LA	P value
Number patients	47	33	
Indication for surgery (%)			
Asymptomatic carotid stenosis	51.1	51.5	NS
Hemispheric stroke	11.1	12.1	NS
Hemispheric TIA	24.4	27.3	NS
Vertebrobasilar Stroke	2.2	0	NS
Vertebrobasilar TIA	4.4	9.1	NS
Retinal infarct	6.7	0	NS
Amaurosis fugax	15.6	24.2	NS
Stenosis assessed by (%)			
Ultrasound	97.7	100	NS
MR angiography	2.3	3	NS
CT angiography	2.3	3	NS
Catheter angiography	2.3	3	NS
Stenosis of artery to be operated on			
Left (%)	85.5 ± 2.1 (n=28)	72.7 ± 5.8 (n=22)	P=0.051
Right (%)	78.9 ± 4.5 (n=26)	69.9 ± 6.4 (n=21)	NS
Complete occlusion (%)	2.3	3	NS
Contralateral carotid occlusion (%)	7	6.1	NS
Pre-Op anti-coagulant Agent use (%)			
Aspirin	86.7	87.5	NS
Clopidigrel	84.1	81.2	NS
Dipyridamole	4.5	21.9	P=0.021
Warfarin	2.3	0	NS
Others	0	0	NS

TABLE III.—Procedural and anesthetic details.

	GA	LA	P Value
Number patients	47	33	
Grade of surgeon (%)			
Trainee	22.2	42.4	NS
Consultant	77.8	57.6	
Grade of anesthetist (%)			
Trainee	13.3	12.1	NS
Consultant	86.7	87.9	
Patch Used (%)	95.6	100	NS
Shunt Used (%)	11.1	6.1	NS
Reason for shunt (%)			
Surgeon preference	4.44	0	NS
Operation under GA	2.22	0	
Unable to tolerate cross clamp	2.22	0	
Patient confused/ restless	0	3.03	
Contralateral neurology on clamping	0	3.03	
Duration of surgery (mean ±SEM)	119.1±4.03	112.8±4.0	NS
Intra-operative heparin used	100	97	NS

tively; Table III). This higher shunt use in the GA group may be explained by the routine use of shunts with GA by one of our surgeons. As per the GALA protocol, selective shunting was applied in the LA group with two patients requiring use of a shunt due to a change in neurological status after clamp application. One patient did not respond favorably and therefore was converted to GA.

All patients randomized to the LA group received local anaesthetic as per protocol for the trial. One patient was converted to GA as aforementioned due to significant change in neurological status. In the LA group 36% and 39% of patients required intra-operative sedation and intra-operative analgesia, respectively (data not shown).

The WA-GALA data demonstrated a trend towards

higher shunt usage in the GA group compared to the LA group (Figure 1). Two patients in the LA group required shunt insertion due to neurologic deterioration. In one of these patients, their neurological symptoms consisted of agitation and confusion, requiring the addition of a general anaesthetic. This octogenarian did not suffer any long-term neurologic sequelae of this episode.

Outcomes

There was no statistical difference in the length of stay in hospital (mean of 2.5 days) between both groups. On analysis of the combined primary end points of stroke, myocardial infarction and death at 30 days, there was no

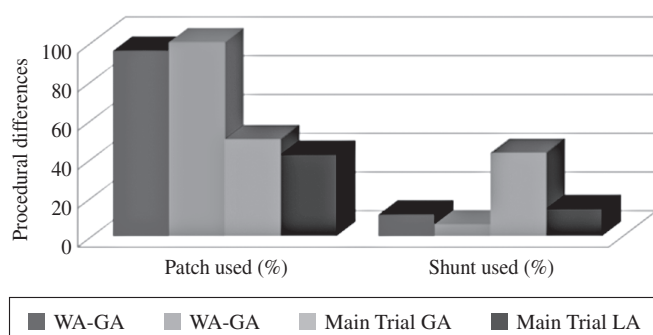


Figure 1.—Procedural differences. There was a tendency toward more patching and shunting in our population group compared to the GALA trial population.

statistically significant difference between the two groups (Table IV). No deaths occurred in either group in the 30-day postoperative period. One patient in the GA group, who suffered a post-operative stroke, had a fall whilst in hospital and died two months after surgery. The other patients who had a stroke were followed up at 6 months and were noted to have a Rankin score of zero.

One-year follow up was available for 29 of 40 patients in the GA group and 30 of 38 patients in the LA group. In the GA group, one patient had died at two months (see above) and one patient died at 6 months post operatively of myo-

cardial infarction. The other 21 patients were noted to still be alive; however 8 patients had been readmitted during the first post-operative year with other complaints. In the LA group, 1 patient had an ipsilateral stroke and another myocardial infarction in the first postoperative year. On statistical analysis there was no difference in survival free of stroke, myocardial infarction or death to 1 year.

Duplex ultrasound follow-up

Patients had a duplex ultrasound examination at approximately one month and one year post surgery (Table V). Results were available for 29 patients in the GA group and 30 patients in the LA group (Table V). Two patients in the GA group developed ipsilateral moderate restenosis at 1 year. On review of their files, neither was found to be symptomatic of their lesions and was managed conservatively. Three patients in the LA group developed ipsilateral restenosis. One of these patients was noted to have severe restenosis. This patient's hospital notes indicated he was symptomatic of his lesion and therefore underwent carotid angioplasty and stenting. The other two patients were asymptomatic and managed conservatively. Whilst there was a trend in the data to develop more severe restenosis in the LA group, statistically there was no significant effect of the type of anesthesia received on the development of restenosis on 1 year follow up (Table V). There were a significant number of patients with contral-

TABLE IV.—Summary of perioperative complications as reported at 30-day review with independent neurologist.

	GA	LA	P value
Number patients	40	38	
Primary outcomes			
Stroke of any type (>24hrs)	2 (5.0%)	1 (2.6%)	NS
Myocardial infarction	1 (2.5%)	1 (2.6%)	NS
Death	0	0	NS
Other complications			
New or worsening angina	1 (2.5%)	0	NS
New arrhythmia requiring treatment	0	0	NS
New/ worsening heart failure	1 (2.5%)	1 (2.6%)	NS
Deep vein thrombosis	0	0	NS
Wound haematoma	3 (7.5%)	3 (7.8%)	NS
Wound infection	2 (5.0%)	1 (2.6%)	NS
Chest infection	1 (2.5%)	2 (5.2%)	NS
Retention of urine	3 (7.5%)	0	NS
Pulmonary embolism	0	0	NS
Ipsilateral headache	2 (5.0%)	4 (10.4%)	NS
Lower cranial nerve injury	6 (15.0%)	7 (18.4%)	NS

TABLE V.—Duplex surveillance at 1 year.

	GA	LA	P value
Number Patients	29	30	
Ipsilateral disease (%)			
Mild restenosis	0	0	NS
Moderate restenosis	4.2	3.0	NS
Severe restenosis	0	3.0	NS
Occlusion	0	3.0	NS
Contralateral disease (%)			
Mild stenosis	3.0	0	NS
Moderate stenosis	15.2	24.0	NS
Severe stenosis	9.1	8.0	NS
Occlusion	3.0	12.0	NS

ateral disease. However on statistical analysis, there was no significant difference between the GA and LA groups (Table V).

Discussion

The GALA trial did aim to determine if the type of anesthesia given affected outcomes of carotid endarterectomy. Whilst the results of the GALA trial did not demonstrate any significant differences between the two anaesthetic practices, we sought here to clarify if similar outcomes were reported in our cohort of patients. In particular, we were interested in the rates of restenosis in the two groups as demonstrated on sonographic follow up.

In the WA-GALA patients, there was no significant difference in the combined primary end point at discharge, 1 month or 1 year. When analyzed independently, the type of anesthesia did not significantly affect death, stroke or myocardial infarction outcomes. The type of anesthesia did not significantly affect the number of patients with sonographic restenosis. Whilst there was a trend to more significant restenosis in the LA group, in this small cohort, this finding was not statistically significant. Secondary outcomes also did not vary significantly between the two groups.

The WA-GALA patients had an overall restenosis rate of 8.5% over the 1 year of follow up. Carotid restenosis rates have been reported to vary from 10% to 34% where re-intervention was considered in only 1-8% of these cases.¹⁶ One patient in the LA group who developed severe symptomatic restenosis went on to have carotid angioplasty and stenting. Whilst operative technical factors have been reported to affect the carotid restenosis (residual disease) rates¹⁷, we were unable to demonstrate any significant difference between LA and GA with regard to restenosis. A statistically significant difference may not be identified due to our small cohort of patients and incomplete follow-up of all patients.

Interestingly, our reported rate of myocardial infarction of 2.6% for both groups was approximately 10 fold higher than that reported in the GALA trial. Our patients would therefore account for 25% and 11% of the myocardial infarcts reported in the GA and LA groups respectively in the main trial. The WA-GALA patients did not demonstrate a higher proportion of risk factors for cardiovascular disease when compared to the main trial. In comparison to the GALA trial however, we reported patients with a documented clinical history and/or elevation in cardiac enzymes and/or electrocardiograph changes as having had a myocardial infarction. For inclusion into the main trial, the trial cardiologist for inclusion as a primary event outcome would have independently audited these adverse events. The definition of myocardial infarction can thus vary between trial and clinical contexts, particularly in the setting of carotid endarterectomy.

Variation in reported myocardial infarction rates post carotid endarterectomy is well demonstrated in the recent literature. Rates of myocardial infarction post carotid endarterectomy range from 0.6%¹⁸ and 2.3%¹⁹ up to 7.5%.²⁰ Importantly, the definition of myocardial infarction varies significantly between these trials,²¹ where electrocardio-

graphic and enzymatic criteria used to define a myocardial infarction are not constant.

Forty-seven patients in the WA-GALA cohort were randomized to GA whilst 33 were randomized to LA. The GALA trial used balanced randomization within each participating block of centers to optimize total end randomization. The allocation of patients in the WA-GALA cohort seems quite unbalanced. However this is likely the result of the WA patients being randomized en block with other Australian participating sites leading to unbalanced numbers in the WA cohort.

This imbalance in randomization therefore may account for the seemingly higher grade of index carotid stenosis in the GA group compared to the LA group (85.5% versus 72.7%, respectively, p value=0.051). Similarly, the rate of Clopidogrel usage is also unbalanced (4.5% versus 21.9%, respectively; $P=0.021$; Table II). There is no obvious covariant in the data to explain this significant difference between the two groups. All other baseline characteristics are well distributed between the two groups with no statistically significant differences.

Reported performance of the carotid procedure in our cohort was consistent with best practice. Most patients were on antiplatelet pre-operatively, received intravenous heparin intra-operatively and had patch angioplasty performed.

The present study included a sonographic assessment of the patients after carotid endarterectomy and whilst demonstrating a trend for more severe restenosis in the LA group, no statistically significant difference was detected. As it is routine in most practices to sonographically follow up post carotid endarterectomy patients, such an analysis in the GALA trial may shed further light on detectable differences between GA and LA groups.

Any difference between GA and LA in Carotid endarterectomy is unlikely to be borne out in a small cohort; particularly given that GALA itself failed to demonstrate any statistically significant difference in its large cohort. Our total reported event rate of stroke was 3.75% (3/80) for both groups which is consistent with outcomes of modern day endarterectomy.¹⁸ Too few events occurred in our cohort for any statistically significant difference to be detected between the two groups. Significantly, the unbalanced randomization in this cohort would have made any statistically significant result difficult to interpret.

This study is based on a subgroup analysis of the main GALA patient population. Subgroup analyses are limited by their diminished power to detect significant differences and as such, these findings are more indicative of a trend in the patient population being analyzed, generating hypotheses rather than firm conclusions.

With respect to the West Australian practice of carotid endarterectomy as demonstrated in the WA-GALA cohort, there is no obvious difference between GA and LA in terms of primary or secondary outcomes. Restenosis rates as demonstrated on sonographic follow are statistically similar for both groups.

We therefore see no reason to disagree with the findings of the GALA trial that point to patient selection and preference, surgeon and anesthetist preference when selecting GA or LA for carotid endarterectomy.

Riassunto

Anestesia generale versus anestesia locale per l'endoarteriectomia carotidea: l'esperienza in Australia Occidentale

Obiettivo. I risultati dello studio GALA (anestesia generale [GA] versus anestesia locale [LA] nella chirurgia della carotide) non hanno mostrato nessuna differenza significativa tra i due metodi anestetici. Le variazioni nelle pratiche chirurgiche e anestetiche tra i centri dello studio non sono state prese in considerazione; pertanto, le differenze avrebbero potuto influenzarne gli esiti. Obiettivo del presente studio è stato quello di riportare l'esperienza in Australia Occidentale con l'utilizzo della GA versus LA per l'endoarteriectomia carotidea, con particolare attenzione all'analisi del follow-up ecografico, al fine di determinare la progressione della malattia.

Metodi. I metodi hanno seguito il protocollo dello studio GALA come pubblicato in precedenza. Abbiamo analizzato i risultati per tutti i pazienti dello studio reclutati in Australia Occidentale. L'ecografia duplex delle arterie carotidi omolaterali e controlaterali è stata effettuata un mese e un anno dopo la procedura per determinare se si fosse verificata una progressione della malattia.

Risultati. Tutti gli ottanta pazienti sottoposti a endoarteriectomia carotidea sono stati analizzati nel presente studio: 47 randomizzati nel gruppo GA e 33 nel gruppo LA. Sei pazienti del gruppo GA e un paziente del gruppo LA hanno sono stati sottoposti a crossover nell'altro gruppo. Non vi erano differenze significative nelle caratteristiche basali dei pazienti, nell'utilizzo dell'angioplastica con patch o nell'utilizzo degli shunt. Non vi erano differenze statisticamente significative tra i due gruppi per quanto concerne gli esiti primari (ictus di qualsiasi tipo, infarto del miocardio o decesso) al momento delle dimissioni o a un mese di follow-up. Al follow-up ecografico, vi era una tendenza verso una maggiore restenosi omolaterale grave nel gruppo LA rispetto al gruppo GA ma ciò non ha raggiunto nessuna significatività statistica.

Conclusioni. L'esperienza in Australia Occidentale con l'anestesia generale versus anestesia locale nell'endoarteriectomia carotidea suggerisce che non vi siano differenze significative nell'esito tra i due gruppi. Tale riscontro dimostra che i risultati dello studio GALA sono replicabili nei singoli centri nonostante le differenze nelle pratiche. Il follow-up ecografico suggerisce che il tasso di restenosi era simile per entrambi i gruppi con un'analoga progressione della malattia nelle carotidi controlaterali. La restenosi e la progressione della malattia controlaterale devono essere monitorate mediante scansione duplex.

Parole chiave: Arterie carotidi - Trattamento chirurgico - Ictus - Anestesia.

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