

health status. Commendably, the European Union has supported its use. How health-care policy decisions are made and how health-care resources are invested will require more detailed data, but HLYs at age 50 years will be an appropriate measure to determine return on investment.

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## The GALA trial: answers it gives, answers it does not

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The best anaesthetic technique for an open carotid endarterectomy is debateable. To remove atheromatous plaque, surgeons must clamp the carotid artery. During this period, the ipsilateral brain hemisphere will receive its blood supply through the Willis arterial

circle. Because patients undergoing open carotid endarterectomy often have atherosclerosis on other vessels, the blood supply through the circle may be insufficient and brain ischaemia could occur during the clamping. A shunt can be inserted to avoid brain ischaemia during clamping, but the shunt itself might dislodge a part of the plaque or become occluded (thrombosis or kink) or damage the residual intima of the vessel, possibly favouring postoperative restenosis.

Thus many surgeons prefer to limit shunt insertions to patients with insufficient blood supply, as shown by an altered state of consciousness or contralateral motor weakness or seizure during a clamping test under regional anaesthesia. There is no other effective monitoring that will detect 100% of patients who would require a shunt. Sensitivity or capability to identify patients who require a shunt (as shown by a change in neurological status) under regional anaesthesia is 59–91%, and the specificity or capability to identify patients who do not is 57–99%.<sup>1</sup> Therefore, if the procedure is done under general anaesthesia, the choice is between risking a thrombus dislodgement from an unnecessary shunt (if all patients are systematically shunted) and failure to detect brain ischaemia or insertion of an unnecessary shunt (if a selective shunt insertion technique is used).

In *The Lancet* today, we are finally given the study we have been waiting for on this topic: the GALA trial of



Coloured angiogram of left carotid artery  
Narrowing at lower centre is severe stenosis.

general anaesthesia versus local anaesthesia for carotid surgery.<sup>2</sup> GALA was a large multicentre trial (95 centres from 24 countries) with data from 3526 patients collected over 8 years. The expected reduction in stroke or mortality at 30 days was not statistically significant; worse, a non-significant increased rate of myocardial infarction (local vs general anaesthetic: 0.5% vs 0.2%; effect difference 0.3% [95% CI -0.2% to 0.8%]) was reported. Despite this major effort by the researchers, the study is underpowered to exclude an absence of stroke or death reduction. To exclude a reduction of mortality from 1.5% to 1.1% (an incidence similar to that seen in non-randomised studies), the study would have needed about 25 000 patients ( $\alpha=0.05$  two-tailed,  $\beta=0.2$ ).<sup>3,4</sup>

The regional anaesthetic technique used in GALA was not optimal for all centres. We now know that a deep cervical plexus block does not add to the patient's comfort during the procedure compared with a simple superficial block, but increases the occurrence of complications arising from block placement (0.25% vs 0%).<sup>5-8</sup> Blood concentrations of norepinephrine (possibly indicating high anxiety or insufficient analgesia) and systolic arterial blood pressure are higher in patients operated under regional anaesthetics than under general anaesthetics.<sup>9</sup> Patients under regional anaesthetics are kept under very light sedation to allow early detection of brain ischaemia, which can be difficult to distinguish from oversedation and can happen at any moment during carotid clamping, specifically during an episode of hypotension.<sup>1</sup> Furthermore, the local anaesthetic solution used in GALA was not standardised. If the concentration of epinephrine added to the local anaesthetic is high (1:200 000 or higher), a 15% increase in heart rate will occur.<sup>10</sup> Thus the non-significantly increased incidence of myocardial infarction in GALA could, unfortunately, be real.

The good news: local anaesthesia reduced the need for shunt insertion (14% vs 43%,  $p<0.001$ ). Unfortunately, we do not know if the reduced shunt insertion rate had any effect on the rate of restenosis at 1 year. Restenosis at 1 year is said to be higher with stenting than with the open procedure, which is one of the arguments to keep the open procedure as the gold standard treatment in patients with low perioperative and anatomical risk.<sup>11,12</sup>

So what is next? Do we need another megatrial powered enough to demonstrate or refute the small

decrease in mortality while limiting the regional anaesthetic technique to a superficial cervical plexus block, with a low epinephrine concentration in the local anaesthetic solution and tight control of the perioperative haemodynamic variables? Should we say that the difference in stroke (30 per 10 000 procedures) or mortality (40 per 10 000 procedures) would probably be small anyway, and leave the choice of the anaesthetic technique to the patient, the anaesthesiologist, and surgeon? Should we favour a regional anaesthetic technique in patients with a contralateral occlusion because a trend, albeit not statistically significant, towards a reduction in the incidence of stroke (including retinal infarct) was recorded in this subpopulation in GALA (7/160 vs 13/150,  $p=0.098$ )? I leave the difficult task of drawing the final conclusion to *The Lancet's* readers.

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