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# Cost-effectiveness analysis alongside a multicentre multinational randomised controlled trial: The GALA study

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## Objectivos (Objectives):

In economic evaluation of health care, increasing attention has been recently given to cost-effectiveness analysis (CEA) undertaken alongside randomised controlled trials (RCTs), motivated by the ascending availability of patient-level cost data, and the progressive use of trial-based economic evaluation in decision making. The choice of statistical methods for CEA that use individual patient data (IPD) from RCTs needs to consider specific statistical issues such as the correlation between costs and effects, skewed data, subgroup analysis and incomplete data, since they can challenge the analyses. The aim of this study is to analyse cost-effectiveness data from a multicentre multinational RCT, accounting for these issues.

## Metodologia (Methodology):

We conducted a CEA using IPD from the GALA trial, a multicentre multinational RCT that investigates local anaesthesia (LA) versus general anaesthesia (GA) for carotid endarterectomy. We analysed health outcomes and resource use data from 3522 individuals from 95 centres in 24 countries (including Portugal), from 1999 to 2007. The health outcome is the survival (in days) to stroke, myocardial infarction or death, between randomisation and 30 days after the surgery. Costs were calculated from resource use data collected alongside clinical outcomes, and were costed using the UK health system perspective. Cost-effectiveness results were presented in terms of incremental cost per event-free day gained, within a time horizon of 30 days.

The statistical analysis was carried out using a system of seemingly unrelated regression equations (SUR). This bivariate approach has strong potential for CEA that use IPD from RCTs. SUR allows for the correlation between costs and effects at patient level. It facilitates explicit modelling of costs and effects while allowing the inclusion of a different set of covariates in each equation as to adjust for subgroup effects. It can be used in either an incremental cost-effectiveness or incremental net-benefit approach.

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In addition, because we have censored data, estimating mean costs using only uncensored cases may bias the estimation toward the cost of those with shorter survival times, since they are less likely to be censored. Therefore, to ensure that we obtained an unbiased estimate, we applied inverse probability weighting to the SUR approach. Uncertainty around the point estimates was assessed and represented using confidence ellipses and cost-effectiveness acceptability curves.

**Resultados (Results):**

At 30 days, a patient undergoing a carotid endarterectomy under LA incurs, on average, in less costs [-£178 (56.6)] and is associated with a longer event-free survival [0.16 (0.13)] when compared to a patient undergoing carotid endarterectomy using GA. The unadjusted analysis (when censoring and correlation are not accounted for) led to a different and more imprecise mean incremental cost-effectiveness (the ICER almost tripled).

The analysis of uncertainty showed that LA is cost-effective in relation to GA over a wide range of willingness-to-pay values. Incremental cost-effectiveness differences of LA versus GA are relatively higher for UK patients than for non-UK patients. The results also showed that incremental costs and incremental effects of LA versus GA are relatively higher for patients aged over 75 years, those with a high baseline surgical risk, or symptomatic stenosis.

**Conclusões (Conclusions):**

This is the first economic evaluation assessing the cost-effectiveness of LA versus GA for carotid endarterectomy. Given the current evidence, carotid endarterectomy under LA is more cost-effective when compared with carotid endarterectomy using GA. Neglecting important issues in the statistical analysis may lead to significant variations in the cost-effectiveness estimates and their precision. Further evidence is required to investigate the long-term cost-effectiveness of LA versus carotid endarterectomy.