

# **The Methodological Quality of Randomised Controlled Trials in Plastic Surgery: 2009-2011**

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## **Abstract**

### **Background**

Randomized controlled trials (RCTs) represent the criterion standard in evaluating healthcare interventions. However, RCTs can yield biased results if they lack methodological rigour, especially where surgical techniques are involved. Surgical RCTs have a number of unique challenges and can be performed poorly. Our objective was to assess the methodological quality of RCTs in Plastic Surgery.

### **Methods**

Medline was searched by an information specialist from 1 January 2009 to 30 June 2011 for the MESH heading "Surgery, Plastic" with limitations for English language,

human studies and randomized controlled trials. Results were then manually searched for relevant RCTs involving surgical techniques. The papers were then scored out of seven using the authors own extended version of the Linde Internal Validity Scale (ELIVS). Secondary scoring was then performed and discrepancies resolved by consensus.

## **Results**

57 papers involving 3,878 patients across 16 countries met the inclusion criteria from a manual search of 254 papers retrieved from Medline. The median ELIVS score was 3.0 with a mean of 3.2 (range 1.0-6.5). Compliance was poorest with items related to: use of intention to treat analysis (4%), blinding of patients (23%) and the handling and reporting of patient withdrawals (25%). There was no link between journal ELIVS score and 2010 impact factor or number of authors (Spearman rho correlations 0.14 and 0.27 respectively). Multicentre trials had a higher average ELIVS score than single centre ones (3.6 vs 2.7) although this did not reach significance. There was no correlation between the volume of RCTs performed in a particular country and methodological quality.

## **Conclusion**

The methodological quality of RCTs in Plastic Surgery is poor, as in other surgical specialties. Further education on trial methodology is advocated, especially the value of intention to treat analysis.