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The methodological quality of randomized controlled trials in plastic surgery needs improvement: A systematic review

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Bias

Summary *Background:* Our objective was to assess the methodological quality of randomized controlled trials (RCTs) in Plastic Surgery.
Methods: An information specialist searched MEDLINE for the period of 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 manually searched for RCTs involving surgical techniques. The papers were then scored with the authors' seven point extended version of the Linde Internal Validity Scale (ELIVS). Secondary scoring was then performed and discrepancies resolved by consensus.
Results: 57 papers met the inclusion criteria. The median ELIVS score was 3.0 with a range of 1.0 —6.5. Compliance was poorest with use of intention to treat analysis (4%), blinding of patients (23%) and the handling and reporting of patient withdrawals (25%). There was no statistically significant correlation between journal ELIVS score and 2010 impact factor or number of authors (Spearman rho 0.10 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 needs improvement.

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Background

Randomized controlled trials (RCTs) are the best way of determining the cause and effect relationship between interventions and outcomes. However, poor quality RCTs contain irremediable bias.[1,2] The purpose of the current study is to systematically review the methodological quality of recent surgical RCTs in Plastic Surgery.

Methods

Search methods

An information specialist based at a plastic surgery unit (Queen Victoria Hospital) searched MEDLINE from 1 January 2009 to 30 June 2011 for the Medical Subject Headings (MESH is the NLM controlled vocabulary thesaurus used for indexing articles for PubMed) heading "Surgery, Plastic" with the 'explode' function activated and limitations set for English language, human studies and randomized controlled trials. Results were then manually searched by two of us (EE and CFC) for relevant RCTs involving surgical techniques. Papers involving purely pharmacological therapies in all arms, cost analyses, study protocols, interim or non-randomized studies, short communications and RCTs involving virtual or simulated procedures were excluded.

Scoring

Primary scoring of the RCTs was done by EE. These scores were then validated and checked by CFC and any disagreements were resolved by consensus. An extended version of the Linde Internal Validity Scale[3] (see Table 1) was used to score the RCT's methodological quality:

The LIVS builds on the Jadad score,[4] is simple, easy to remember and has been used on numerous occasions[5,6] for the assessment of methodological quality. Our extension is to supplement the standard LIVS with allocation concealment to form an extended version (ELIVS).

Potential correlations between ELIVS score and 2010 impact factor, number of authors, single vs multicentre study, year of publication and country of corresponding author were assessed. Spearman rho was calculated using SPSS version 20.

Results

From an initial set of 254 papers retrieved from MEDLINE, 63 were selected following a manual search and assessment of the abstract. Subsequent to complete download of all 63 papers, six were excluded for being a study protocol, purely pharmacological or theoretical, retrospective or an interim study. This resulted in 57 RCTs which met the inclusion criteria (seven were multicentre), published across 28 journals. All RCTs compared treatment interventions and none related to diagnosis (Figure 1).

During the scoring process, out of 399 items, there were 31 initial disagreements (kappa = 0.86) between primary and secondary scorers and these were resolved through discussion. The median ELIVS score was 3.0 (range 1.0—6.5, interquartile range 2.5). There was no significant trend in improvement of median ELIVS scores (see Table 2) (Table 3):

ELIVS score and impact factor

There was no correlation between ELIVS score and impact factor (Spearman rho correlation = 0.10, $p = 0.295$), see Figure 2 below:

Table 1 Extended Linde Internal Validity Scale items (items 7i and 7ii were worth 0.5 points each).

Item	Description	Further detail
1	Treatment allocation	Was it randomized?
2	Randomization method	The method of randomization was described in the paper, and that method was appropriate
3	Allocation concealment	Steps taken to conceal the allocation sequence was detailed and this was sufficient
4	Post-randomization baseline comparison	Usually in a table. Showing both groups are similar postrandomization for all known prognostically important factors
5	Patients blinded	The method of blinding was described, and it was appropriate
6	Evaluators blinded	The method of blinding was described, and it was appropriate
7i	Handling and reporting of withdrawals	Full accounting for all patients who entered the trial
7ii	Intention to intention treat analysis	A per-protocol analysis could be provided in addition as part of a sensitivity analysis