REVIEW

Evolution of reports of randomised clinical trials in plastic surgery

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Summary   Well-designed, well-conducted and well-reported randomised clinical trials (RCTs) can significantly impact medical care, by contributing to a strong evidence base from which clinical guidelines can be derived. In a previous study, we assessed the quality of reports of RCTs in plastic surgery published from 1966 to 2003. The aim of the present study was to verify what have changed over the last years. RCTs in plastic surgery published from 2004 to 2008 were identified through electronic searches, and classified according to their allocation concealment. Trials with allocation concealment appropriately described were evaluated as to their quality. Two independent reviewers performed the evaluations, using two tools: the Delphi List and the Jadad's quality scale. From 3840 identified studies, 96 were selected for classification according to allocation concealment; 28 (29%) of them appropriately described allocation concealment. From 1966 to 2003, 34 (17%) RCTs appropriately described allocation concealment ($\chi^2 = 22.98$, $p < 0.000$). In the evaluation of the 28 RCTs by the Delphi List, the agreement coefficient between raters (kw) was 0.46 ($z = 7.24$, $p < 0.000$). Groups were similar at baseline in 96.4% of these trials, and this was the only item of the Delphi List, which significantly improved when compared with the period from 1966 to 2003 ($\chi^2 = 18.53$, $p < 0.000$). When evaluated by Jadad's criteria, 14% of the RCTs were scored two points or less and thus considered of low quality ($kw = 0.72$, $z = 8.57$, $p < 0.001$). From 1966 to 2003, 59% of RCTs were scored two points or less ($\chi^2 = 17.07$,

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$p < 0.004$). We concluded that the quality of reports of RCTs in plastic surgery (as measured by the Jadad's criteria and only one component of the nine components of the Delphi List) significantly increased over the last years.

Research in plastic surgery will have a greater impact on clinicians' practice if higher-impact-level studies are published.[1] Considering the growing demands for state-of-the-art treatment, and the limited health-care resources, increasing interest is being focussed on the practice of evidence-based medicine.[2–4]

The randomised controlled trial (RCT) is defined as a study design in which patients are allocated at random to an intervention group or to a control group.[2,5,6] Well-designed RCTs provide the highest level of evidence in health-care interventions, and their outcomes can significantly impact medical care, by contributing to a strong evidence base from which clinical guidelines can be derived.[7,8]

The essence of evidence-based medicine is the integration of clinical expertise with the best available evidence from systematic research.[2,9] By systematically identifying and assessing the reporting and methodologic quality of RCTs and their impact in our speciality, we can improve evidence-based practice in plastic surgery, thus directly benefiting our patients.[2,8]

However, the application of evidence-based medicine, and specifically the RCT, to surgical research has been slower than in medical specialities.[3,4,10,11] The execution of a plastic surgery RCT is challenging. Challenges include surgical equipoise, surgical learning curve, differential care, randomisation, concealment, blinding and loss to follow-up, among others.[3,4] Despite of the difficulties in conducting RCTs in plastic surgery, if the field of plastic surgery is to advance, it must adopt well-established methodologic principles.[4]

A previous study identified RCTs in plastic surgery published from 1966 to 2003, and assessed the quality of reports of the RCTs, which have appropriately described allocation concealment.[12] The aim of the present study was to evaluate the quality of reports of RCTs in plastic surgery published from January 2004 to December 2008, using the same tools, to verify what have changed over the last years.

Methods

An electronic search was conducted to identify the maximum number of studies published as RCTs in plastic surgery, in the English language, from January 2004 to December 2008. Strategies of electronic search were elaborated for each database consulted: Cochrane Controlled Trials Register (CCTR), Excerpta Medica Database (EMBASE), Latin-American and Caribbean Literature in Sciences of Health (LILACS) and MEDLARS — Medical Literature Retrieval System — online (MEDLINE). These strategies are presented in Table 1.

Possible RCTs in plastic surgery were identified and selected. Trials that have not been carried out by plastic surgeons or with the participation of at least one plastic surgeon were excluded. One author conducted the searches and another author performed the selection of trials, by reading all the abstracts. After selection, the full texts of the trials were assessed.

Two reviewers independently classified the trials according to allocation concealment;[13] disagreements were resolved at a consensus meeting. RCTs in plastic surgery with allocation concealment appropriately described were then selected, and they constituted the sample of this study. For each of these RCTs, basic data were gathered, such as journal and year of publication and country of association.

The selected RCTs were then evaluated as to their quality. The assessment was independently made by two raters and cross-checked. Two validated tools were used to assess the quality of RCTs: the Delphi List[14] and the Jadad's quality scale[15] (Table 2).

The Delphi List is a generic criteria list for quality assessment in RCTs, which should be used alongside other instruments.[14] The Jadad's quality scale is scored thus: a score of one point is given for each "yes" and zero points for each "no". Point awards for the first two items (randomisation and double blinding) depend not only on whether the trial is described as randomised or double blind, but also on the appropriateness of the methods used to randomise and blind the trial: if these methods are described and are appropriate, one additional point is given for each item. Conversely, if the methods used to generate a randomisation sequence or create blinded conditions are described, but are inappropriate, the relevant item is given zero points. Thus, the scale produces scores from 0 to 5. A trial could be judged as having poor quality, if it is awarded two points or less.[15]

The results were compared with data from the previous study, which has assessed quality of reports of RCTs in plastic surgery from 1966 to December 2003.[12]

Statistical method

The chi-square test for two independent variables was applied to compare the time periods 1966–2003 and 2004–2008 with regard to percentile distribution of trials among the four searched databases. The same test was used to compare time periods (1966–2003 and 2004–2008) with regard to distribution of the RCTs with allocation concealment appropriately described, according to journal where they were published, continent (country) of origin and items of Delphi List.

The chi-square test for one variable was used to compare 5-year periods, from 1984 to 2008, with regard to distribution of RCTs with allocation concealment appropriately described.

Kappa statistic was used to study agreement between the two reviewers in the assessment of trials' allocation concealment, in data collection for the Delphi List and in data collection for Jadad's quality scale. The agreement coefficients (kw) were calculated, and significance was