REPORTING ADVERSE EVENTS IN PLASTIC SURGERY: A SYSTEMATIC REVIEW OF RANDOMIZED CONTROLLED TRIALS

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PLASTIC SURGERY

BACKGROUND: Accurate knowledge of adverse events is critical for evaluation of the safety and efficacy of interventions. Historically, adverse events in surgical trials have been poorly reported. The objective of this study was to systematically evaluate the reporting of adverse events in randomized controlled trials (RCTs) in the plastic surgery literature.

METHODS: Two independent reviewers conducted a systematic search using MEDLINE, EMBASE, and SCOPUS of the top seven plastic surgery journals with the highest impact factors. RCTs describing a potentially invasive treatment, published between January 2012 and December 2016, were included.

RESULTS: One hundred and forty-five RCTs involving 10,266 patients were included, of which 30% were registered. Anticipated adverse events were clearly defined in 15% of trials, and in 70% it was not clear who would be documenting adverse events. Furthermore, 72% of RCTs reported the occurrence of adverse events, of which 61% failed to report events occurring in the intra-interventional period. Of the trials not documenting any adverse event, two-thirds included a statement declaring that no adverse events had occurred. Binary logistic regression revealed that funded RCTs were 4.04 times more likely to report adverse events compared to non-funded RCTs (95% CI 1.41-10.83, p=0.009).

CONCLUSIONS: Our findings suggest the need for reporting standards for adverse events in the plastic surgery literature, as such reporting remains heterogeneous and is lacking rigor. Improved quality and transparency is needed to strengthen evidenced-based practice and permit a balanced intervention assessment. This study provides a set of recommendations aimed at improving adverse event reporting.