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Publication bias in oral and maxillofacial surgery journals: An observation on published controlled trials

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SUMMARY. Background: **Publication bias (PB) diminishes the full distribution of research, distorts and discredits the scientific record, and thus compromises evidence-based practice. The objective of this study was to analyse published controlled trials with regard to PB in leading oral and maxillofacial surgery (OMS) journals.** Methods: **All controlled trials published in the *International Journal of Oral and Maxillofacial Surgery*, *Journal of Cranio-Maxillofacial Surgery*, *Journal of Oral and Maxillofacial Surgery*, and *British Journal of Oral and Maxillofacial Surgery* in 2008 were analysed for a primary outcome, country of authors, sample size, gender of the first author, funding source and location of the study.** Results: **Of 952 published articles, 53 controlled trials (5.7%) were identified. The OMS journals preferentially published controlled trials with a positive outcome (77.4%) and from high-income countries (73.6%). Single-centred trials (86.8%) with low sample size ($n < 100$; 69.8%) were published more frequently. The majority of the first authors were male (75.5%). Funding source disclosure in most studies (73.6%).** Conclusions: **Our results suggest the possible existence of PB in the OMS literature. Hence, it should be borne in mind that the published articles may not be representative of all scientific works, especially when systematic reviews and meta-analyses are conducted or read. In the meantime, journals should establish measures to eliminate PB to uphold scientific integrity. However, this study was an observation based on the published articles. An analysis of all submitted manuscripts would provide more accurate estimates of PB. Ethical considerations on PB are also discussed. © 2009 European Association for Cranio-Maxillofacial Surgery**

Keywords: **publication bias, controlled trial, oral and maxillofacial surgery, scientific integrity, evidence-based practice, medical ethics**

INTRODUCTION

> 'The human intellect … is more moved and excited by affirmatives than by negatives.'
>
> Sir Francis Bacon, 1st Viscount St Alban KC (1561–1626)

Case reports and case series provide descriptions of general characteristics and the distribution of disease, complications attributable to an intervention, rare diseases, and sometimes, generate hypotheses. However, their retrospective nature is an obvious weakness. Bias in study methodology may also overestimate or underestimate the results. Controlled trials are designed to overcome the weakness of observational studies. They yield more accurate estimates of fact and are thus higher in the hierarchy of scientific evidence (*Petrisor* et al., 2006). However, as Sir Francis Bacon reminds us, human interest and decision are generated towards positives. Not all controlled trials are published due to bias in submitting, reviewing, accepting and publishing results.

Publication bias (PB), a form of selection, is the influence of study results on the chances of publication and the tendency of investigators, reviewers, and editors to submit or accept manuscripts for publication based on the direction or strength of the findings of quantitative

[*] Share equally in the credit and work for this paper.

studies (*U.S. National Library of Medicine*, 2009). A common form of PB is '*positive outcome bias*' or '*pipeline bias*' which is defined as the decreased tendency of studies being published when their results are near the null, not statistically significant, or otherwise 'less interesting' (*Møller* and *Jennions*, 2001; *Phillips*, 2004). In other words, journals (or editors or peer reviewers) are not beguiled by studies that demonstrate 'nothing'.

A recent Cochrane review revealed that controlled trials with positive findings were given priority in publication (*Hopewell* et al., 2009). Moreover, they are more likely to be published in journals with a higher impact factor, or in multiple forms (and some are redundant publications), and probably be cited by other authors, than studies showing non-significant results (*Thornton* and *Lee*, 2000; *Mahid* et al., 2008). Other factors increasing the tendency to be published include large sample size, previous presentation at a scientific meeting, providing results that favour a new therapy, and being a part of doctoral dissertation. Moreover, study quality, English language, industrial sponsorship, authors' gender, country of origin and location of studies also influence the chances of publication (*Thornton* and *Lee*, 2000; *Olson* et al., 2002; *Harris* et al., 2006). *Magos* et al. (2000) found bias against publication of surgical papers in prestigious medical journals: the *Lancet*, *British Medical Journal* (*BMJ*), *New England Journal of Medicine* and *Journal of the American Medical Association* (*JAMA*). PB not only lessens readers' chance to achieve the full distribution of research, but also probably distorts and discredits the scientific record, such as a systematic review with or without a meta-analysis (*Thornton* and *Lee*, 2000; *Harris* et al., 2006; *Mahid* et al., 2008). It is therefore unethical if journals let PB emerge without adequate recognition and control.

Until now, PB in oral and maxillofacial surgery (OMS) literature has not been evaluated and reported. The aim of this study was to analyse published controlled trials with regard to PB in leading OMS journals.

MATERIALS AND METHODS

An electronic search was conducted to identify controlled trials, involving a therapy to living humans or parts of their bodies, published in the top 4 highly ranked OMS journals in 2008. The chosen journals were the *International Journal of Oral and Maxillofacial Surgery* (*IJOMS*), *Journal of Cranio-Maxillofacial Surgery* (*JCMS*), *Journal of Oral and Maxillofacial Surgery* (*JOMS*), and *British Journal of Oral and Maxillofacial Surgery* (*BJOMS*). They were chosen for their high impact factor and journal quality, as well as being the core OMS journals for most world regions (*Lau* and *Samman*, 2007; *Brennan*, 2009). We analysed only the published controlled trials because observational studies may yield bias, even though PB is absent, and because it remains difficult to evaluate the quality of observation studies (*Thornton* and *Lee*, 2000). According to *Olson* et al. (2002)'s criteria, this cohort included articles that 1) reported results of a prospective study, 2) assigned participants to an intervention, 3) had at least 1 comparison group, and 4) used a statistical test to compare differences in outcomes between groups. Such studies were either randomised or non-randomised.

Each eligible article was carefully screened by 2 independent assessors for information on characteristics examined previously by others (*Olson* et al., 2002; *Harris* et al., 2006; *Yousefi-Nooraie* et al., 2006): a primary outcome (positive vs negative), country of authors, sample size, gender of the first author, funding source and location of the study (multicentre vs single centre). As described by *Olson* et al. (2002) and *Harris* et al. (2006), we considered a primary outcome '*positive*' in case of 1) improved outcome with the tested intervention, 2) similar outcome with new treatment compared to standard treatments, 3) one that supported the study objective, 4) one with statistical significance ($P < 0.05$; 95% confidence interval [CI] for difference excluding 0 or 95% CI for ratio excluding 1), or 5) combinations of these, and '*negative*' when it did not meet the aforementioned criteria.

Countries of authors were classified according to the World Bank income criteria (*World Bank Group*, 2007) into low, lower-middle, upper-middle and high-income groups. If the first-author gender was unclear, we did an internet search for the author by name and institution, and other strategies as described by *Kurichi* et al. (2005). Industrial support for only drugs or devices was not recognised as a funding source. When the authors declared no financial conflicts and did not mention a funding source, we speculated that the fund for that study came from their own department. If multiple countries were involved, we classified them according to the country of the supervising or principal institution.

If agreement between the 2 assessors could not be reached, advice was sought from a third party and the determination was made by consensus. To confirm the accuracy of categorisation and data entry between the reviewers, the results were analysed by the percentage of agreement and Kappa statistics (κ). We assumed that manuscripts with each parameter category, such as positive and negative outcomes, would be accepted for publication in equal proportion. The hypothesis was tested by chi-square test. Variables with P-value of less than 0.05 were considered statistically significant.

The recommendations of the 'Helsinki declaration' were thoroughly maintained during this study. Since this study did not involve human subjects or records, ethical approval by an ethics committee and consent from the authors of the articles studied were not required.

RESULTS

During the study period, 952 articles were published in the 4 OMS journals. Of these, 53 controlled trials (5.7%) met all inclusion criteria (*IJOMS*: 16/208 [7.7%]; *JCMS*: 3/65 [4.6%]; *JOMS*: 26/444 [5.9%]; *BJOMS*: 8/235 [3.4%]). There was an excellent agreement (100% inter-examiner percentage agreement, $\kappa = 1.0$) for inter-observer reliability in data extraction.

A substantial number of the controlled trials presented positive outcomes (77.4%), were based on low sample