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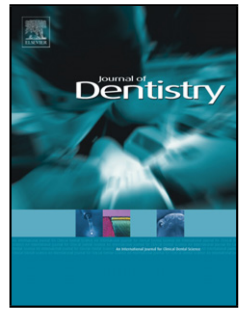

Title: Publication of statistically significant research findings in prosthodontics and implant dentistry in the context of other dental specialties

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Title Page

Publication of statistically significant research findings in prosthodontics & implant dentistry compared to in the context of other dental specialties

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Publication of statistically significant research findings in prosthodontics & implant dentistry compared to in the context of other dental specialties

Abstract

Objectives: To assess the hypothesis that there is excessive reporting of statistically significant studies published in prosthodontic and implantology journals, which could indicate selective publication.

Methods: The last 30 issues of 9 journals in prosthodontics and implant dentistry were hand-searched for articles with statistical analyses. The percentages of significant and non-significant results were tabulated by parameter of interest. Univariable/multivariable logistic regression analyses were applied to identify possible predictors of reporting statistically significance findings. The results of this study were compared with similar studies in dentistry with random-effects meta-analyses.

Results: From the 2323 included studies 71% of them reported statistically significant results, with the significant results ranging from 47% to 86%. Multivariable modeling identified that geographical area and involvement of statistician were predictors of statistically significant results. Compared to interventional studies, the odds that in-vitro and observational studies would report statistically significant results was increased by 1.20 times (OR: 2.20, 95% CI: 1.66-2.92) and 1.35 times (OR: 1.35, 95% CI: 1.05-1.73), respectively. The probability of statistically significant results from randomized controlled trials was significantly lower compared to various study designs (difference: 30%, 95% CI: 11%-49%). Likewise the probability of statistically significant results in prosthodontics and implant dentistry was lower compared to other dental specialties, but this result did not reach statistical significant (P>0.05).

Conclusions: The majority of studies identified in the fields of prosthodontics and implant dentistry presented statistically significant results. The same trend existed in publications of other specialties in dentistry.

Publication of statistically significant research findings in prosthodontics & implant dentistry compared to in the context of other dental specialties

1. Introduction

Statistical significance seems to influence the attractiveness and consequent publication of research.[1] Albeit the commonality of this approach, it is accepted that interpretation based solely on P-values can be misleading[2] and is usually made at the expense of other more meaningful measures, such as the effect size and the associated confidence intervals.[3-5] The authors' perception of the 'attractiveness' of the results can lead to selective reporting of study findings (reporting bias). The wider family of reporting bias includes, but is not limited, to time lag bias, multiple (duplicate) publication bias, location bias, citation bias, outcome reporting bias and publication bias.[6]

Publication bias is defined as the selective publication of studies based on the nature and direction of their results.[7] There is empirical evidence that studies with statistically non-significant results are more likely to be published with delay or not at all compared to studies with significant results. The discrepancy in the probability of publication between studies with significant vs. non-significant results has been associated with the unwillingness of researchers to submit "non-appealing" studies[8] to journals and/or the predilection of reviewers and journal editors to accept for publication studies with positive or significant results.[6] It has also been shown that trials with significant results, especially those with external financial support, are published sooner than non-supported studies.[9] Selective publication of studies may jeopardize the validity of systematic review estimates and consequently healthcare recommendations, as they are based on only a subsample of existing studies.

No evidence of association between reporting bias in the dental literature and journal impact factor has been identified,[10,11] whereas conflicting evidence exists between industry sponsorship and significant findings.[12,13] Less than half of the abstracts presented at leading dental conferences proceeded to full publication.[14] Disproportionate publication of significant research findings has been previously reported across[10-12] or within dental specialties,[15,16] but no such report exists exclusively for the field of prosthodontics or implant dentistry. It is difficult to directly assess the presence of publication bias, as this would require identifying all studies submitted to journals including those that were eventually not accepted for publication. However, the discordance in publications between studies with significant results and studies with non-significant results can be used as a possible proxy for publication bias.

Therefore, the objective of this study was to record the prevalence of reporting statistically significant results in prosthodontic and implant dentistry journals and to examine possible associations between significant/non-significant results and report characteristics. A secondary aim was, where applicable, to pool the results of this study with those of similar studies in dentistry.

2. Materials and Methods

Four dental journals with emphasis on prosthodontics (*The International Journal of Prosthodontics, Journal of Oral Rehabilitation, The Journal of Prosthetic Dentistry, The International Journal of Periodontics & Restorative Dentistry*), 4 dental implantology journals (*Clinical Implant Dentistry & Related Research, Clinical Oral Implants Research, Implant Dentistry, The International Journal of Oral & Maxillofacial Implants*) and 1 general dental journal *(Journal of Dentistry*) were included in the study. The contents of the last 30 issues of these nine journals, were hand-searched from March 2012 backwards by 2 authors (S.N.P. and D.K.).[5] Case reports, review articles, editorials, letters, and any reports without statistical analyses were excluded. When an article contained both statistically significant and statistically non-significant results, the decision was based on the primary outcome comparison or the first reported result, if no distinction between primary and secondary outcomes was provided.

From the included articles two authors (S.N.P., D.K.) extracted information on year of publication, continent of origin (based on the corresponding author), ethical approval, methodologist involvement, number of involved study centers, study type (*in vitro*, interventional, or observational), and trial type whether the study was an RCT. Custom data collection forms were prepared and the two authors were calibrated before the start of the study. The calibration exercise comprised of 80 randomly selected reports. Inter-rater reliability was assessed using the kappa statistic on sixty eighty randomly chosen reports.

In the first part of the study factors associated with reporting of statistically significant results from the included studies were investigated. After confirming that the data were normally distributed, descriptive Descriptive statistics (frequency and sample size) were calculated and univariable logistic regression analyses were implemented in order to examine possible associations between statistical significance or absence of statistical significance presence or absence of statistical significance (independent variable) and the following report characteristics: journal, publication year, geographical area, ethical approval, study design, trial type, methodologist involvement and number of centers. A The multivariable logistic regression was conducted to control for confounding and included only significant predictors at $\alpha = 0.20$ from the univariable analyses to avoid multiplicity issues. Model fit was examined using the Hosmer-Lemeshow test. Statistical significance was set at a two-sided $P < 0.05$. The results of the logistic regression are reported as Odds Ratio (OR) with associated 95% Confidence Interval (CI).

In the second part of the study, the results of the present study were compared with similar bibliographic studies published in dentistry.[10,12,17-23] through meta-analysis of the The proportions of statistically significant results. were pooled across studies with A random-effects model meta-analysis according to the DerSimonian and Laird[25 24] method was chosen, as several factors have been shown to affect the reporting of statistically significant results. Forest plots were constructed to present the resulting probabilities with their 95% CIs. Heterogeneity across studies was identified through inspection of the forest plots and calculating the I^2 statistic, defined as the proportion of total variability in the results explained by heterogeneity and not by chance.[25] The 95% uncertainty intervals (95% UIs) (similar to CIs) around the I^2 were calculated using the non-central approximation of Q. Differences according to the design of the assessed studies or among the various dental specialties were investigated with mixed-effects subgroup analysis with the Knapp-Hartung adjustment.[26] When considerable heterogeneity was identified (I^2 between 75% and 100%), data were not pooled to avoid producing misleading results[25]. All statistical analyses were conducted with the statistical software Stata 13.1 (Statacorp, College Station, TX, USA) and the macros *logit, metaprop*, *heterogi*, and *metareg*.

3. Results

In total, 3667 articles were examined initially; 1344 were excluded for not adhering to the predetermined inclusion criteria, leaving 2323 for assessment (Fig. 1). Inter-rater agreement was found to be excellent (kappa 0.88, 95% CI: 0.87-0.89). The included articles reported on a wide selection of topics ranging from surgical implant procedures and techniques, survival of implants and prostheses, biological responses, clinician's perspective of esthetics and patient satisfaction. Table 1 shows the distribution of statistically significant and non-significant findings for the 2323 articles by journal, publication year, continent, ethical approval, involvement of a methodologist, number of centers, study type (*in vitro*, observational or interventional) and trial type [randomized controlled trial (RCT) or non-RCT]. Seventy one percent of the selected articles reported statistically significant results with a range from 47% 57%-86% depending on the examined parameter (Table 1). The % of studies with statistically significant results by journal are shown in Fig. 2.

In Table 2, the ORs and 95% CIs derived from the univariable and multivariable logistic regression analyses are presented. In the univariable analysis, journal, ethical approval, continent, study type and RCT vs Non-RCT were identified as significant predictors. In the multivariable analysis great variability in the odds of reporting significant findings was seen among the various journals, with ORs ranging from 1.07 to 3.94 compared to baseline. Most multivariable ORs were slightly altered compared to the univariable ORs, with the exception of *Journal of Dentistry* and *Journal of Prosthetic Dentistry*, where the ORs were almost halved. Significant findings were more frequently reported from studies originating from Europe, Asia, or other continents (apart from Americas) compared to Europe Americas. The odds of reporting a significant result were increased by 1.35 and 1.20 times for observational and *in vitro* studies, respectively, compared to interventional studies. Also, there was some evidence that non-randomized studies were more likely to report significant results compared to randomized studies (OR: 1.47; 95% CI: 1.00 to 2.17). Finally, there was evidence that involvement of a statistician (OR: 1.30, CI 95%: 1.01, 1.68) and ethics approval (OR: 1.31, 95% CI: 1.06, 1.62) were associated with reporting of statistically significant results.

The reported probabilities of significant results of the present study together with the results of other similar studies are shown in Table 3, divided in reports including various study designs and reports including only RCTs. No meta-analysis within each subgroup was conducted, due to extreme heterogeneity (I^2>75%). The probability of statistically significant results in studies including all designs ranged between 71% to 88%, while the corresponding probability in RCTs ranged between 31% to 84% (Fig. 3). Mixed-effect subgroup analysis indicated that reports including various study designs were associated with increased probability of reporting statistically significant results compared to RCTs (difference: 30%, 95% CI: 11%-49%, P=0.001). The probability of statistically significant results stratified according to dental specialty, are reported in

Fig. 4-5. Considerable variation in the probability of significant results was found among specialties across all study designs (range: 68% 76%-90%; Fig. 4) and solely within RCTs (range: 38%-68%; Fig. 5), though this variation among specialties was not statistically significant (P>0.05 in both cases for mixed-effect subgroup analysis according to dental specialty).

4. Discussion

This cross-sectional study investigated the prevalence of statistically significant results in the prosthodontic and implant dentistry literature and explored possible associations between study results and report characteristics. Evidence for the preponderance of statistically significant results was found in the prosthodontic and implant dentistry literature. The multivariable analysis indicated that journal, ethical approval, continent, statistician involvement and study design were significant predictors associated with reporting of statistically significant results. However, the prevalence of publications with statistically significant research findings was relatively low compared to the published prevalence in dentistry among various study designs (low end of the spectrum in Fig 3), but relatively high compared to the published prevalence in dentistry among RCTs (high end of the spectrum in Fig 3).

Considerable variability in the reporting of significant results was found among the 9 investigated journals. However, this could be due to differences in the study types published in each journal, as some of the included journals published considerably more *in vitro* or observational studies and a smaller percentage of clinical trials compared to others.

Reporting of significant results was not associated with study publication year, although this was difficult to assess, as the varying number of issues/year for each journal and the inclusion of the last 30 issues meant that different years were covered for each journal.

According to the results of the multivariable analysis, there was a significant association between ethical approval obtained for the study and reporting of significant results. It has been previously been reported, that even studies with ethical approval are associated with excessive reporting of statistically significant findings.[27] Ethical approval is usually sought for clinical studies that include patients or patient tissues, while the rate of ethical approval varies among RCTs, cohort, and cross-sectional studies.[28] It might be hypothesized that researchers conducting clinical studies are under pressure to find statistically significant results originating from the corresponding funding agencies. However, interpretation should be done with caution.

The results of this study showed that papers originating from Asia had increased odds of reporting significant results compared to papers originating from Europe. This is in accordance with previous studies[12] and reflects recent empirical evidence[26 29] indicating that trials from developing countries tend to show more favorable treatment effects than trials originating from developed countries. This could arise from biases in study conduct / reporting or could mirror genuine differences in baseline risks or treatment modalities.

The importance of the participation of a statistician in improved study quality has been documented.[27 30] Research without methodological assistance has been reported to be more susceptible to rejection without review and/or publication.[28 31] This finding could be attributed to the moderate statistical skills of clinical medical[29 32] and dental researchers[30,31 33,34] or dental postgraduate students,[32 35] which could lead to misuse of statistics. In this study, involvement of a statistician was associated with higher odds of reporting of significant findings.

The results of this study also highlighted the fact that study design seems to be associated with reporting of significant results, with interventional studies, and especially randomized clinical trials, being less likely to report significant results compared to observational or *in vitro* studies. Combining the results of the present study with other similar studies, significantly higher prevalence of statistically significant research findings was found among studies of various designs compared to RCTs (P=0.001). This is an important finding with implications on appropriate interpretation of weaker designs and is in agreement with previous reports.[12,18] Misleading interpretation of weaker studies can be further exacerbated by the predominance of exaggerated treatment effects often associated with those studies compared to RCTs.[33 36,37]

Publication in a journal is dependent on the three entities involved in the publication process, namely the authors, the reviewers and the editors. Authors can be influenced by their perception of the importance of their results, which can arise from the significant results of either pre-specified or data driven analyses. Bias from the authors' perspective accounts to some degree for the disproportional publication of positive results,[35 38] as these are thought to be more suitable for submission to a prestigious journal. Failure to publish a negative report of a well-conducted trial, especially when funded by federal/national agencies, is considered as scientific misconduct, as it can guide to inappropriate treatment decisions and waste of resources.[36 39]

Selective publication of research findings can also be precipitated from the editorial side of a scientific journal. Peters and Ceci[37 40] resubmitted 12 articles, already accepted and published, to psychology journals after slightly altering the title and the introduction, and substituting the authors' names and institution details with unknown authors and small institutions (the article dealt with open reviews). Of the 12 manuscripts, 9 (75%) were not identified as already published, and a striking 67% (8) were rejected for reasons related to the soundness and validity of their methods. Abbot and Ernst,[38 41] in contrast to the previous study, reported that reviewers were no more likely to recommend publication of a paper based on the statistical significance of its results. Moreover, when the authors were allowed to propose reviewers, manuscripts judged by the reviewers appointed by the editor received on average lower scores than when reviewed by the author preferred referees.[39 42] The accumulated evidence supporting editors' bias in favoring manuscripts includes a survey of 36 editors, which showed that articles were judged based on a vaguely defined criterion of ''significance and importance of work'' rather than the validity of the experimental and statistical methods.[40 43]

4.1. Limitations

The limitations of this study included the absence of duplicate data extraction on the whole sample of articles. However, misclassification between reviewers was expected to be limited given that the outcome was fairly easy to be correctly identified, as confirmed also by the high inter-rater agreement. Classification of clinical trials was based on reporting only; however, lack of information on the published article does not necessarily mean that correct trial procedures were not implemented. Additionally, in this study the significance of research findings were divided into significant and non-significant. Another approach, as pointed out in a recent article,[13] would be to classify the results as positive, mixed or negative on the basis of their statistical and their clinical implications, however this includes a certain degree of subjectivity. Furthermore, although we adopted a meta-analytical synthesis approach, this was not done in the framework of a proper systematic review. Finally, it is difficult to directly assess the presence of publication bias, as this would require identifying all studies submitted to journals including those that were eventually not accepted for publication. In this sense, the discordance in publications between studies with significant results and studies with non-significant results can be used as a proxy for publication bias.

4.2. Recommendations

Reporting bias is a multifaceted phenomenon and therefore must be dealt at various levels of the research procedure. Researchers undertaking clinical trials should register them prospectively, before their results become available, to minimize selective publication of studies and/or study results and authors should modify their preference to submit positive results or submit them more often to prestigious journals. Non-publishing is misconduct[36 39] and along these lines the AllTrials initiative (www.alltrials.gov) has been established to promote registration and publication of all trials. Finally, peer-reviewers and editors should refrain from seeking only "attractive" manuscripts in terms of statistical significance.[40 43]

5. Conclusions

The analysis of the selected prosthodontic and implant dental literature indicated that 71.3% of included study reports reported statistically significant results, which might indicate selective publication of research finding, favoring statistically significant results. The adjusted analysis showed evidence of association between reporting significant results and journal, geographical area, involvement of a methodologist, ethical approval, and study design.

Compared to similar studies in various dental specialties, the prevalence of significant research findings in prosthodontics and implant dentistry is lower, whereas reporting statistically significant findings in RCTs is on the higher end of the spectrum.

Conflicts of interest

The authors declare that they have no conflict of interest.

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Tables

Table 1 – Distribution of 2323 included articles by report characteristics and statistical significance status. CIDRR = Clin Implant Dent Relat Res; COIR = Clin Oral Implants Res; ID = Implant Dent; IJOMI = Int J Oral Maxillofac Implants; IJPRD = Int J Periodontics Restorative Dent; IJP = Int J Prosth; JD = J Dent; JOR = J Oral Rehab; JPD = J Prosthet Dent; RCT = randomized controlled trial.

* row percentage; † column percentage.

		Total n (%*)	Significant n (%†)	Non-significant n (%†)
Journal	CIDRR	196 (100 8)	139 (71)	57 (29)
	COIR	366 (100 16)	283 (77)	83 (23)
	ID	134 (100 6)	76 (57)	58 (43)
	IJOMI	431 (100 19)	297 (69)	134 (31)
	IJPRD	185 (100 8)	87 (47)	98 (53)
	IJP	348 (100 15)	227 (65)	121 (35)
	JD	288 (100 12)	248 (86)	40 (14)
	JOR	219 (100 9)	173 (79)	46 (21)
	JPD	156 (100 7)	126 (81)	30 (19)
Year	2005	10 (100 0)	7 (70)	3 (30)
	2006	12 (100 1)	9 (75)	3 (25)
	2007	102 (100 4)	68 (67)	34 (33)
	2008	209 (100 9)	137 (66)	72 (34)
	2009	282 (100 12)	183 (65)	99 (35)
	2010	612 (100 26)	456 (75)	156 (25)
	2011	689 (100 30)	536 (78)	153 (22)
	2012	407 (100 18)	260 (64)	147 (36)
Continent	Europe	1070 (100 46)	746 (70)	324 (30)
	Americas	559 (100 24)	363 (65)	196 (35)
	Asia/other	694 (100 30)	547 (79)	147 (21)
Ethics	Yes	1196 (100 51)	834 (70)	362 (30)
	No	1127 (100 49)	822 (73)	305 (27)
Statistician	Yes	413 (100 18)	306 (74)	107 (26)
	No	1910 (100 82)	1350 (71)	560 (29)
Multicenter	Yes	1631 (100 70)	1157 (71)	474 (29)
	No	692 (100 30)	499 (72)	193 (28)
Study type	*In vitro*	832 (100 36)	668 (80)	164 (20)
	Interventional	728 (100 31)	445 (61)	283 (39)
	Observational	763 (100 33)	543 (71)	220 (29)
RCT	Yes	148 (100 6)	87 (59)	61 (41)
	No	2175 (100 94)	1569 (72)	606 (28)
	Total	2323 (100)	1656 (71)	667 (29)

Table 2 - Univariable and multivariable logistic regression derived odds ratios and confidence intervals for a significant main article finding rather than a non-significant finding by publication characteristics (n=2323). OR = odds ratio; CI = confidence interval; IJPRD = Int J Periodontics Restorative Dent; CIDRR. Clin Implant Dent Relat Res; COIR = Clin Oral Implants Res; ID = Implant Dent; IJOMI = Int J Oral Maxillofac Implants; IJP = Int J Prosth; JD = J Dent; JOR = J Oral Rehab; JPD = J Prosthet Dent; RCT = randomized clinical trial.

		Univariable			Multivariable		
		OR	95% CI	P-value	OR	95% CI	P-value
Journal	IJPRD	*Baseline*			*Baseline*		
	CIDRR	2.75	1.80, 4.19	<0.001**	2.09	1.35, 3.25	0.001**

	COIR	3.84	2.63, 5.61	<0.001**	2.93	1.96, 4.38	<0.001**
	ID	1.48	0.94, 2.31	0.09	1.07	0.67, 1.70	0.78
	IJOMI	2.50	1.75, 3.56	<0.001**	1.73	1.18, 2.52	0.01*
	IJP	2.11	1.47, 3.04	<0.001**	1.48	1.01, 2.18	0.05*
	JD	6.98	4.49, 10.86	<0.001**	3.94	2.43, 6.38	<0.001**
	JOR	4.24	2.74, 6.54	<0.001**	2.65	1.66, 4.25	<0.001**
	JPD	4.73	2.89, 7.74	<0.001**	2.64	1.55, 4.50	<0.001**
Publication year	pro year (per unit)	1.04	0.98, 1.11	0.20			
Ethics	No	*Baseline*			*Baseline*		
	Yes	1.20	1.01, 1.44	0.04*	1.31	1.06, 1.62	0.01*
Continent	Europe Americas	*Baseline*			*Baseline*		
	Americas Europe	1.24	1.00, 1.54	0.05*	1.28	1.66, 2.92 1.01, 1.62	0.04*
	Asia / other	2.01	1.56, 2.58	<0.001**	1.93	1.05, 1.73 1.48, 2.51	<0.001**
Statistician involvement	No	*Baseline*			*Baseline*		
	Yes	1.19	0.93, 1.51	0.17	1.30	1.01, 1.68	0.05*
Number of centers	Single	*Baseline*					
	Multicenter	1.06	0.87, 1.29	0.57			
Study type	Interventional	*Baseline*			*Baseline*		
	In vitro	2.59	2.06, 3.25	<0.001**	2.20	1.66, 2.92	<0.001**
	Observational	1.57	1.26, 1.95	<0.001**	1.35	1.05, 1.73	0.02*
RCT vs. Non-RCT	RCT	*Baseline*			*Baseline*		
	Non-RCT	1.78	1.27, 2.51	<0.001**	1.46 1.47	1.00, 2.17	0.05*

*P-value≤0.05; **P-value≤0.001

Table 3 – Forest plot for the pooled prevalence of statistically significant research findings from random-effects meta-analyses, tabulated according to the design of included studies. CI = confidence interval; P_{SG} = P for difference between subgroups; RCT = randomized controlled trial.

Subgroup: type of study	Reports	% Probability - Range[a]	Difference [a]	P_{SG} [b]
Any study	5	71% to 88%	30% (11%, 49%)	0.001
Only RCTs	7	31% to 84%		

[a] Pooled probabilities for each subgroup were not calculated, due to extreme heterogeneity.
[b] From mixed-effects subgroup analyses.

Figure Legends

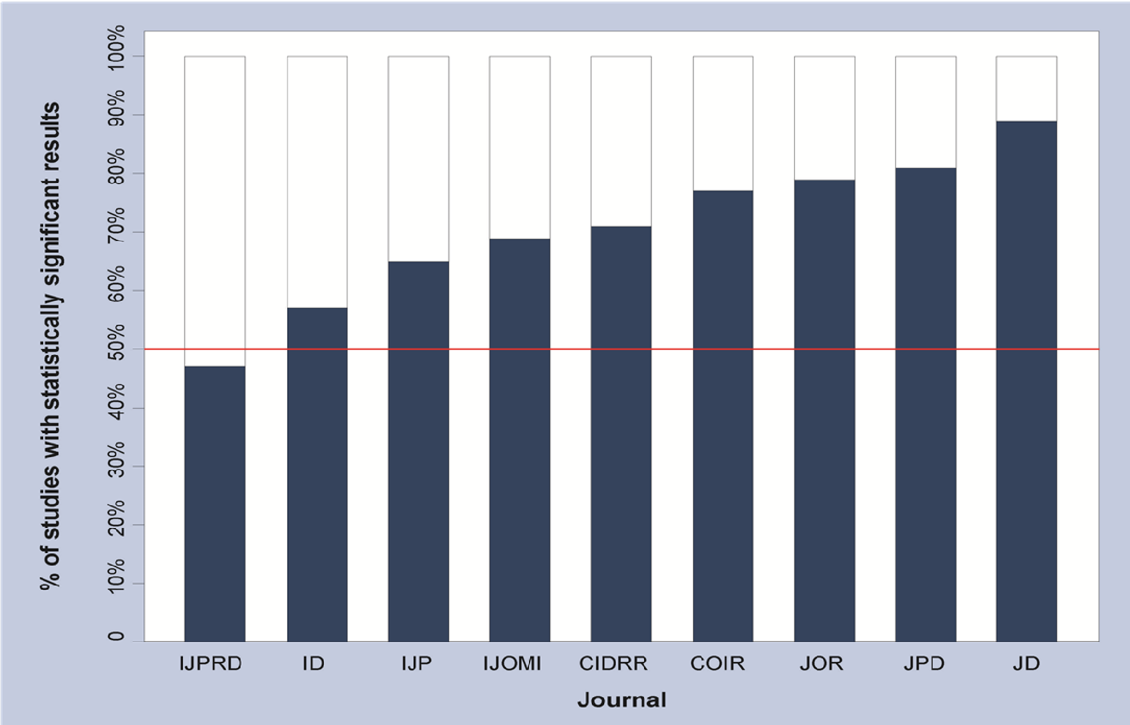
Fig. 1 – Flow diagram of study selection.

Fig. 2 – Probabilities of reporting statistically significant results in the included reports by journal.

Fig. 3 – Forest plot for the probability of statistically significant research findings according to the design of the included studies.

Fig. 4 – Forest plot for the probability of statistically significant research findings from studies of various designs according to the dental specialty.

Fig. 5 – Forest plot for the probability of statistically significant research findings from randomized controlled trials according to the dental specialty.



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