An Assessment of the Risk of Bias in Randomized Controlled Trial Reports Published in Prosthodontic and Implant Dentistry Journals

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Purpose: The objective of this study was to assess the risk of bias of randomized controlled trials (RCTs) published in prosthodontic and implant dentistry journals. **Materials and Methods:** The last 30 issues of 9 journals in the field of prosthodontic and implant dentistry (*Clinical Implant Dentistry and Related Research*, *Clinical Oral Implants Research*, *Implant Dentistry*, *International Journal of Oral & Maxillofacial Implants*, *International Journal of Periodontics and Restorative Dentistry*, *International Journal of Prosthodontics*, *Journal of Dentistry*, *Journal of Oral Rehabilitation*, and *Journal of Prosthetic Dentistry*) were hand-searched for RCTs. Risk of bias was assessed using the Cochrane Collaboration's risk of bias tool and analyzed descriptively. **Results:** From the 3,667 articles screened, a total of 147 RCTs were identified and included. The number of published RCTs increased with time. The overall distribution of a high risk of bias assessment varied across the domains of the Cochrane risk of bias tool: 8% for random sequence generation, 18% for allocation concealment, 41% for masking, 47% for blinding of outcome assessment, 7% for incomplete outcome data, 12% for selective reporting, and 41% for other biases. **Conclusion:** The distribution of high risk of bias for RCTs published in the selected prosthodontic and implant dentistry journals varied among journals and ranged from 8% to 47%, which can be considered as substantial. *Int J Prosthodont 2015;28:586–593. doi: 10.11607/ijp.4357*

Randomized controlled trials (RCTs) are considered the gold standard to study the effectiveness of medical interventions,[1] but despite their status RCTs are still susceptible to bias.[2] Bias is defined as the systematic deviation from the actual treatment effect and can have serious implications for clinical practice. A common classification of the types of bias that can be encountered in RCTs is the one proposed by the Cochrane Collaboration.[3] This classification scheme includes selection, performance, detection, attrition, and reporting biases, which are applicable to different trial stages. The extent to which these biases operate in a given trial may yield inaccuracies of varying magnitude and direction in the estimates of a treatment effect.

The Cochrane Collaboration has developed a tool to assess potential bias in RCTs by examining seven relevant domains (sequence generation, allocation concealment, masking, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other sources of bias).[3] This tool is used in all Cochrane reviews and is supported by empirical evidence.[2,4–7]

In recent years the number of published RCTs in the biomedical field has increased exponentially; however, there is evidence that the quality in terms of methods and reporting is often suboptimal.[8–17] Although several reports have assessed the reporting quality of RCTs

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in various dental fields,[8–11,13,14,16] reporting quality is not directly associated with risk of bias. To the best of the present authors' knowledge, the risk of bias as a proxy to internal validity of RCTs has not been assessed previously in any field of dentistry, including prosthodontics and implant dentistry. Therefore, the objective of this study was to assess the risk of bias in RCTs published in prosthodontic and implant dentistry journals and to explore possible associations between risk of bias and report characteristics.

Materials and Methods

The contents of the last 30 issues of the following 9 prosthodontic and implant dentistry journals were hand-searched from March 2012 backward by two authors (S.N.P. and D.K.): *Clinical Implant Dentistry and Related Research* (CIDRR), *Clinical Oral Implants Research* (COIR), *Implant Dentistry* (ID), *International Journal of Oral & Maxillofacial Implants* (IJOMI), *International Journal of Periodontics and Restorative Dentistry* (IJPRD), *International Journal of Prosthodontics* (IJP), *Journal of Dentistry* (JD), *Journal of Oral Rehabilitation* (JOR), and *Journal of Prosthetic Dentistry* (JPD). A study was included if it was stated in the title, abstract, or text that it was an RCT. Nonrandomized and nonclinical studies were excluded.

From the included articles, two authors (S.N.P. and D.K.) extracted information on journal, year of publication, continent of origin (based on the corresponding author), ethical approval, statistical significance of the main outcome, number of authors, statistician/methodologist involvement (from affiliations or explicit statement), and number of involved centers.

The Cochrane Collaboration's risk of bias tool was used to assess the internal validity of the included RCTs.[18] The risk of bias tool examines the following seven domains:

1. Random sequence generation: adequate if the method is stated and is considered truly random (eg, computer-generated sequence, random number table, or coin toss). This domain is associated with selection bias.
2. Allocation concealment: adequate if an appropriate method to prevent knowing or predicting the allocation sequence in advance is stated to have been used (eg, central randomization or sequentially numbered opaque envelopes). This domain is associated with selection bias.
3. Masking (blinding of participants and personnel): adequate if the use of any form of blinding of participants, investigators, or caregivers is reported. This domain is associated with performance bias.
4. Blinding outcome assessment: adequate if outcome assessment is blinded or it is judged that the outcome and the outcome measurement are not likely to be influenced by lack of blinding. This domain is associated with detection bias.
5. Incomplete outcome data: adequate if any one of the following is true: no missing outcome data; reasons for missing outcome data unlikely to be related to true outcome; missing outcome data balanced in numbers across groups; or similar reasons for missing data across groups. This domain is associated with attrition bias.
6. Reporting bias: adequate if the study protocol is available and all of the study's prespecified outcomes have been reported or if the study protocol is not available but it is clear that the published reports included all prespecified outcomes. This domain is associated with reporting bias.
7. Other bias: adequate if the study appears to be free of other sources of bias (eg, stopped early due to some data-dependent process; extreme baseline imbalance; or claimed to have been fraudulent).

Custom data collection forms were prepared and the two authors were calibrated before the start of the study. Interrater reliability was assessed using Cohen's kappa on 80 randomly chosen reports from the overall sample.

The characteristics of the included trials and the distribution of the risk of bias assessments (low, unclear, high) overall and per trial characteristic were tabulated. Due to the relatively small number of RCTs and the large number of variables, only descriptive statistics were carried out using the Stata 13 statistical software package (StataCorp).

Results

In total, 3,667 articles were examined; 3,520 were excluded for not adhering to the predetermined inclusion criteria, leaving 147 RCTs for detailed assessment (Fig 1). Interrater agreement was found to be excellent (Cohen's kappa 0.88, 95% CI: 0.87 to 0.89). The included articles reported on a wide selection of topics including surgical implant procedures and techniques, survival of implants and prostheses, biological responses, clinicians' perspective of esthetics, and patient satisfaction. The characteristics of the included trials are shown in Table 1. The journals that had published the greatest number of RCTs in descending order were: COIR (n = 46), IJOMI (n = 24), JD (n = 21), and IJP (n = 20). The number of published RCTs increased as a function of the publication year and the geographic region. Contributing the most was Europe (59%), followed by Asia/other regions (21%), and

Table 1 Characteristics of the 147 Included Randomized Controlled Trials

	n (%)
Journal	
CIDRR	13 (9)
COIR	46 (31)
ID	4 (3)
IJOMI	24 (16)
IJPRD	15 (10)
IJP	20 (14)
JD	21 (14)
JOR	2 (1)
JPD	2 (1)
Publication year	
2007	4 (3)
2008	12 (8)
2009	13 (9)
2010	41 (28)
2011	42 (29)
2012	35 (24)
Continent	
Europe	86 (59)
Americas	30 (20)
Asia/other	31 (21)
Ethics	
No	41 (28)
Yes	106 (72)
Significant results	
No	60 (41)
Yes	87 (59)
Number of authors	
1–3	35 (24)
4–5	60 (41)
≥6	52 (35)
Statistician/methodologist involvement	
No	92 (63)
Yes	55 (37)
Number of centers	
Single-center	42 (29)
Multicenter	105 (71)

CIDRR = *Clinical Implant Dentistry and Related Research*; COIR = *Clinical Oral Implants Research; ID = Implant Dentistry*; IJOMI = *International Journal of Oral & Maxillofacial Implants*; IJPRD = *International Journal of Periodontics and Restorative Dentistry*; IJP = *International Journal of Prosthodontics*; JD = *Journal of Dentistry*; JOR = *Journal of Oral Rehabilitation*; JPD = *Journal of Prosthetic Dentistry*.

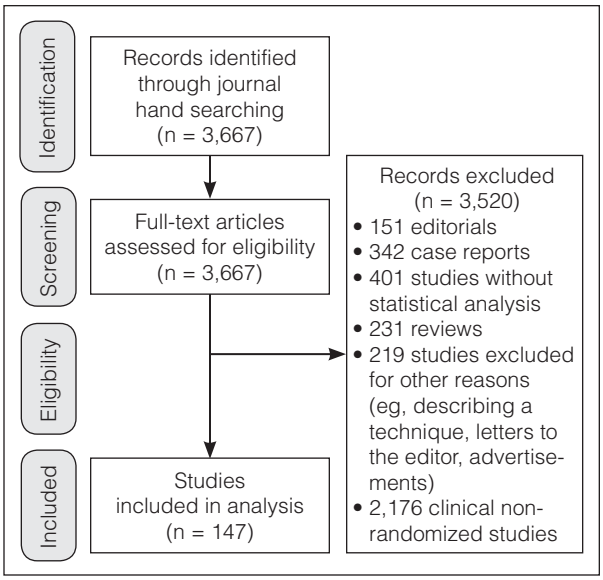

Fig 1 Flow diagram of study selection.

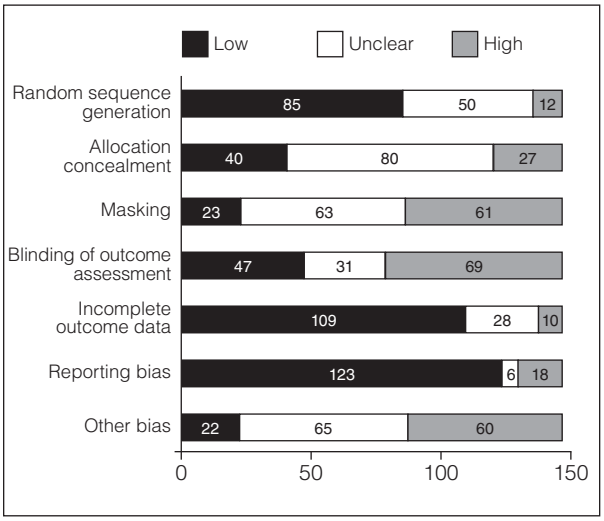

Fig 2 Distribution of risk of bias across domains.

Table 2 Overall Risk of Bias Assessment of the 147 Included Randomized Controlled Trials

Risk of bias	Low (%)	Unclear (%)	High (%)
Random sequence generation	85 (58)	50 (34)	12 (8)
Allocation concealment	40 (27)	80 (54)	27 (18)
Masking	23 (16)	63 (43)	61 (41)
Blinding of outcome assessment	47 (32)	31 (21)	69 (47)
Incomplete outcome data	109 (74)	28 (19)	10 (7)
Reporting bias	123 (84)	6 (4)	18 (12)
Other bias	22 (15)	65 (44)	60 (41)

North/South America (20%). Statistically significant results were reported by 59% of the identified RCTs, while 71% of the identified RCTs were multicenter.

The overall risk of bias assessment of the included RCTs per domain is given in Table 2 and Fig 2. High risk of bias for the included trials was found in 8% for random sequence generation, in 18% for allocation concealment, in 41% for masking, in 47% for blinding of outcome assessment, in 7% for incomplete outcome data, in 12% for selective reporting, and in 41% for other biases.

The risk of bias assessment of the included trials per domain and trial characteristics is shown in Table 3.

Discussion

This cross-sectional study assessed the risk of bias of RCTs recently published in prosthodontic and implant dentistry journals using the Cochrane risk of bias tool. The percentage of RCTs with low risk of bias varied considerably (15% to 84%) among the seven domains of the Cochrane tool. Considerable differences were also found in the present study in the percentage of RCTs with low risk of bias for each of the seven domains compared to similar studies in medicine:[12,19–21] random sequence generation, 58% in the present study (32% to 59% in medicine); allocation concealment, 27% in the present study (25% to 50% in medicine); masking, 16% in the present study (31% to 89% in medicine); blinding of outcome assessment, 32% in the present study (20% to 60% in medicine); incomplete outcome data, 74% in the present study (33% to 89% in medicine); reporting bias, 84% in the present study (79% to 98% in medicine); and other bias, 15% in the present study (39% to 98% in medicine). However, different types of interventions might be prone to different kinds of bias,[2,22,23] and therefore, comparisons across fields should be exercised with caution.

Studies in the biomedical literature have reported that the terms "randomization" and "randomly assigned to groups" are often used incorrectly or are not completely reported.[13,16,24–29] Empirical evidence has shown that inadequate or unclear randomization is associated with effect exaggeration by 11%, which is accentuated in RCTs with subjective outcomes.[2]

Masking (blinding of participants or personnel) or blinding of outcome assessors was also assessed to be inadequate in the included RCTs. Although masking might not be always feasible in RCTs of oral implantology or prosthodontics, blinding of the outcome assessors or data analysts is almost always feasible. Similar inadequacies have been reported in other fields of dentistry[16] and are indicative of the low emphasis given to blinding. Empirical evidence indicates that inadequate blinding is associated with a 13% exaggeration of intervention effects[2] in RCTs with subjective outcomes. The effect of lack of blinding appeared to be greater than the effect of inadequate or unclear random sequence generation or allocation concealment.[2]

Attrition and selective outcome reporting are also a source of bias for RCTs.[4–7] Among the RCTs included in the present study neither type of bias was overly present, with low risk of bias found in 74% and 82% of the trials, respectively.

A number of characteristics were collected from each RCT (Table 1) and used to tabulate the risk of bias (Table 3). However, due to the limited number of RCTs and the high data dispersion, no inferential statistics were performed to formally test significant associations, and the characteristics were analyzed descriptively.

Considerable variability was found in all domains of the Cochrane tool among the nine selected journals. This may be related to the fact that journals with higher visibility and impact may attract trials of better quality. The assessment of the included trials was based only on their published reports, and it is possible that incomplete reporting of trials might have influenced their risk of bias assessment.

The assessed risk of bias of the RCTs did not seem to be associated with publication year in this study. However, the varying number of issues per year for each journal and the inclusion of the last 30 issues meant that different years were covered for each journal. Therefore, a direct comparison among publication years cannot be made.

The risk of bias in this study was not consistently influenced by the trial's country of origin in this study. According to empirical evidence,[30] RCTs from developing countries tend to show more favorable treatment effects than RCTs originating from developed countries. This could arise from biases in study conduct or reporting or could mirror genuine differences in baseline risks or differences in treatment modalities. This can be supported in part from this study by the lower prevalence of low risk for RCTs from Asia/other continents in the masking and blind outcome assessment compared to RCTs from Europe or America.

The importance of a statistician/methodologist in improved study quality has been previously documented.[31] Research without methodological assistance has been reported to be more susceptible to rejection without review and/or publication.[32] In this study, RCTs with involvement of a methodologist were more likely to have low risk of bias in the random sequence allocation and the allocation concealment domains, which could be attributed to their methodological input in the design of the trial.

The number of trial centers influenced almost all assessed domains, as multicenter RCTs were more likely to have low risk of bias in the random sequence, allocation concealment, masking and blinding, reporting bias, and other bias domains than single-center RCTs, which is consistent with the medical literature.[33] In a recent cross-sectional study in oral implantology, the reporting quality of multicenter RCTs' abstracts was higher than that of single-center RCTs.[14] The same was observed for the full reports of RCTs in orthodontics.[34]

The limitations of this study included the absence of duplicate data extraction on the entire sample of articles. The interrater agreement of the Cochrane tool has been reported to be problematic in some cases.[18] In this study, the interrater agreement was fairly

Table 3 Risk of Bias of Included Randomized Controlled Trials Tabulated by Trial Characteristics

	Random sequence generation, N (%)			Allocation concealment, N (%)			Masking, N (%)		
	Low	Unclear	High	Low	Unclear	High	Low	Unclear	High
Journal									
CIDRR	6 (46)	7 (54)	0 (0)	0 (0)	10 (77)	3 (23)	1 (8)	7 (54)	5 (38)
COIR	33 (72)	12 (26)	1 (2)	12 (37)	29 (63)	0 (0)	5 (11)	27 (59)	14 (30)
ID	3 (75)	1 (25)	0 (0)	2 (50)	1 (25)	1 (25)	0 (0)	1 (25)	3 (75)
IJOMI	13 (54)	11 (46)	0 (0)	7 (29)	17 (71)	0 (0)	3 (13)	12 (50)	9 (38)
IJPRD	10 (67)	2 (13)	3 (20)	3 (20)	3 (20)	9 (60)	5 (33)	0 (0)	10 (67)
IJP	10 (50)	3 (15)	7 (35)	3 (15)	5 (25)	12 (60)	3 (15)	4 (20)	13 (65)
JD	9 (43)	12 (57)	0 (0)	8 (38)	13 (62)	0 (0)	6 (29)	10 (48)	5 (24)
JOR	1 (50)	1 (50)	0 (0)	0 (0)	1 (50)	1 (50)	0 (0)	1 (50)	1 (50)
JPD	0 (0)	1 (50)	1 (50)	0 (0)	1 (50)	1 (50)	0 (0)	1 (50)	1 (50)
Year									
2007	1 (25)	2 (50)	1 (25)	1 (25)	1 (25)	2 (50)	0 (0)	2 (50)	2 (50)
2008	7 (58)	4 (33)	1 (8)	2 (17)	7 (58)	3 (25)	1 (8)	4 (33)	7 (58)
2009	8 (62)	4 (31)	1 (8)	4 (31)	5 (38)	4 (31)	3 (23)	2 (15)	8 (62)
2010	24 (59)	13 (32)	4 (10)	14 (34)	21 (51)	6 (15)	5 (12)	19 (46)	17 (41)
2011	23 (55)	19 (45)	0 (0)	12 (29)	25 (60)	5 (12)	7 (17)	19 (45)	16 (38)
2012	22 (63)	8 (23)	5 (14)	7 (20)	21 (60)	7 (20)	7 (20)	17 (49)	11 (31)
Continent									
Europe	50 (58)	28 (33)	8 (9)	24 (28)	46 (53)	16 (19)	12 (14)	40 (47)	34 (40)
Americas	20 (67)	8 (27)	2 (7)	8 (27)	20 (67)	2 (7)	8 (27)	11 (37)	11 (37)
Asia/other	15 (48)	14 (45)	2 (6)	8 (26)	14 (45)	9 (29)	3 (10)	12 (39)	16 (52)
Ethics									
No	26 (63)	11 (27)	4 (10)	12 (29)	16 (39)	13 (32)	8 (20)	14 (34)	19 (46)
Yes	59 (56)	39 (37)	8 (8)	28 (26)	64 (60)	14 (13)	15 (14)	49 (46)	42 (40)
Significant results									
No	39 (65)	14 (23)	7 (12)	15 (25)	31 (52)	14 (23)	6 (10)	27 (45)	27 (45)
Yes	46 (53)	36 (41)	5 (6)	25 (29)	49 (56)	13 (15)	17 (20)	36 (41)	34 (39)
Authors (no.)									
1–3	24 (69)	9 (26)	2 (6)	11 (31)	17 (49)	7 (20)	8 (23)	16 (46)	11 (31)
4–5	31 (52)	23 (38)	6 (10)	15 (25)	32 (53)	13 (22)	5 (8)	22 (37)	33 (55)
≥ 6	30 (58)	18 (35)	4 (8)	14 (27)	31 (60)	7 (13)	10 (19)	25 (48)	17 (37)
Statistician/methodologist involvement									
No	47 (51)	38 (41)	7 (8)	20 (22)	56 (61)	16 (17)	15 (16)	43 (47)	34 (37)
Yes	38 (69)	12 (22)	5 (9)	20 (36)	24 (44)	11 (20)	8 (15)	20 (36)	27 (49)
Number of centers									
Single-center	21 (50)	16 (38)	5 (12)	10 (24)	25 (60)	7 (17)	5 (12)	19 (45)	18 (43)
Multicenter	64 (61)	34 (32)	7 (7)	30 (29)	55 (52)	20 (19)	18 (17)	44 (42)	43 (41)
Total	85 (58)	50 (34)	12 (8)	40 (27)	80 (54)	27 (18)	23 (16)	63 (43)	61 (41)

CIDRR = *Clinical Implant Dentistry and Related Research*; COIR = *Clinical Oral Implants Research*; ID = *Implant Dentistry*; IJOMI = *International Journal of Oral & Maxillofacial Implants*; IJPRD = *International Journal of Periodontics and Restorative Dentistry*; IJP = *International Journal of Prosthodontics*; JD = *Journal of Dentistry*; JOR = *Journal of Oral Rehabilitation*; JPD = *Journal of Prosthetic Dentistry*.

good due to the calibration of the two authors, but discussion was still needed in some instances until a consensus was reached. Also, classification of RCTs was based on reporting only; however, lack of information on the published article does not necessarily mean that correct procedures were not implemented.[35,36] Such domains without adequate description are judged as unclear in the Cochrane tool and differ from domains with low risk. One must also bear in mind that some trials labeled by their authors as RCTs probably are not RCTs.[27,28] Finally, the sample of journals assessed in this study was limited to prosthetic or implant dentistry, and the findings may not be generalizable to other fields.

The CONSORT reporting guidelines were formally adopted by only five (CIDRR, COIR, JD, JOR, and JPD) of the nine included journals. Although the adoption of the CONSORT criteria by many journals seems to

Blind outcome assessment, N (%)			Attrition bias, N (%)			Reporting bias, N (%)			Other bias, N (%)			Total, N (%)
Low	Unclear	High	Low	Unclear	High	Low	Unclear	High	Low	Unclear	High	
2 (15)	6 (46)	5 (38)	6 (46)	3 (23)	4 (31)	12 (92)	0 (0)	1 (8)	0 (0)	4 (31)	9 (69)	13 (9)
20 (43)	11 (24)	15 (33)	41 (89)	4 (9)	1 (2)	40 (87)	0 (0)	6 (13)	9 (20)	21 (46)	16 (35)	46 (31)
0 (0)	2 (50)	2 (50)	4 (100)	0 (0)	0 (0)	4 (100)	0 (0)	0 (0)	0 (0)	3 (75)	1 (25)	4 (3)
11 (46)	3 (13)	10 (42)	16 (67)	8 (33)	0 (0)	20 (83)	1 (4)	3 (13)	3 (13)	13 (54)	8 (33)	24 (16)
3 (20)	1 (7)	11 (73)	7 (47)	7 (47)	1 (7)	9 (60)	4 (27)	2 (13)	4 (27)	1 (7)	10 (67)	15 (10)
2 (10)	2 (10)	16 (80)	16 (80)	2 (10)	2 (10)	20 (100)	0 (0)	0 (0)	5 (25)	5 (25)	10 (50)	20 (14)
9 (43)	4 (19)	8 (38)	16 (76)	4 (19)	1 (5)	15 (71)	1 (5)	5 (24)	0 (0)	18 (86)	3 (14)	21 (14)
0 (0)	1 (50)	1 (50)	1 (50)	0 (0)	1 (50)	2 (100)	0 (0)	0 (0)	1 (50)	0 (0)	1 (50)	2 (1)
0 (0)	1 (50)	1 (50)	2 (100)	0 (0)	0 (0)	1 (50)	0 (0)	1 (50)	0 (0)	0 (0)	2 (100)	2 (1)
0 (0)	2 (50)	2 (50)	1 (25)	2 (50)	1 (25)	4 (100)	0 (0)	0 (0)	0 (0)	2 (50)	2 (50)	4 (3)
3 (25)	2 (17)	7 (58)	7 (58)	5 (42)	0 (0)	9 (75)	1 (8)	2 (17)	1 (8)	4 (33)	7 (58)	12 (8)
2 (15)	1 (8)	10 (77)	11 (85)	2 (15)	0 (0)	9 (69)	3 (23)	1 (8)	2 (15)	6 (46)	5 (38)	13 (9)
16 (39)	6 (15)	19 (46)	32 (78)	6 (15)	3 (7)	37 (90)	0 (0)	4 (10)	6 (15)	15 (37)	20 (49)	41 (28)
13 (31)	9 (21)	20 (48)	34 (81)	6 (14)	2 (5)	32 (76)	2 (5)	8 (19)	8 (19)	19 (45)	15 (36)	42 (29)
13 (37)	11 (31)	11 (31)	24 (69)	7 (20)	4 (11)	32 (91)	0 (0)	3 (9)	5 (14)	19 (54)	11 (31)	35 (24)
31 (36)	15 (17)	40 (47)	65 (76)	16 (19)	5 (6)	70 (81)	4 (5)	5 (12)	12 (14)	39 (45)	35 (41)	86 (59)
11 (37)	6 (20)	13 (43)	20 (67)	7 (23)	3 (10)	25 (83)	1 (3)	3 (4)	4 (13)	15 (50)	11 (37)	30 (20)
5 (16)	10 (32)	16 (52)	24 (77)	5 (16)	2 (6)	28 (90)	1 (3)	3 (2)	6 (19)	11 (35)	14 (45)	31 (21)
11 (27)	8 (20)	22 (54)	28 (68)	9 (22)	4 (10)	34 (83)	3 (7)	4 (10)	4 (10)	17 (41)	20 (49)	41 (28)
36 (34)	23 (22)	47 (44)	81 (76)	19 (18)	6 (6)	89 (84)	3 (3)	14 (13)	18 (17)	48 (45)	40 (38)	106 (72)
18 (30)	15 (25)	27 (45)	39 (65)	12 (20)	9 (15)	51 (85)	0 (0)	9 (15)	11 (18)	20 (33)	29 (48)	60 (41)
29 (33)	16 (18)	42 (48)	70 (80)	16 (18)	1 (1)	72 (83)	6 (7)	9 (10)	11 (13)	45 (52)	31 (36)	87 (59)
13 (37)	11 (31)	11 (31)	24 (69)	7 (20)	4 (11)	29 (83)	1 (3)	5 (14)	5 (14)	13 (37)	17 (49)	35 (24)
12 (20)	11 (18)	37 (62)	46 (77)	11 (18)	3 (5)	50 (83)	4 (7)	6 (10)	9 (15)	23 (38)	28 (47)	60 (41)
22 (42)	9 (17)	21 (40)	39 (75)	10 (19)	3 (6)	44 (85)	1 (2)	7 (13)	8 (15)	29 (56)	15 (29)	52 (35)
33 (36)	20 (22)	39 (42)	66 (72)	18 (20)	8 (9)	78 (85)	2 (2)	12 (13)	9 (10)	46 (50)	37 (40)	92 (63)
14 (25)	11 (20)	30 (55)	43 (78)	10 (18)	2 (4)	45 (82)	4 (7)	6 (11)	13 (24)	19 (35)	23 (42)	55 (37)
12 (29)	12 (29)	18 (43)	33 (79)	6 (14)	3 (7)	33 (79)	1 (2)	8 (19)	3 (7)	20 (48)	19 (45)	42 (29)
35 (33)	19 (18)	51 (49)	76 (72)	22 (21)	7 (7)	90 (86)	5 (5)	10 (10)	19 (18)	45 (43)	41 (39)	105 (71)
47 (32)	31 (21)	69 (47)	109 (74)	28 (19)	10 (7)	123 (84)	6 (4)	18 (12)	22 (15)	65 (44)	60 (41)	147 (100)

have improved the reporting of RCTs,[37–39] poor reporting is still a common problem, especially in countries with a limited experience in conducting RCTs. A recent report indicated that reporting quality in public health dentistry has not significantly improved since the publication of the CONSORT statement.[40] Journal editors and peer reviewers have an important role in ensuring optimal reporting of RCTs. This has driven some to suggest the need to better regulate the peer-review process, including enforcement of good practice guidelines.[41] Others recommend that more journals should adopt the CONSORT criteria, and that those who endorse it should do more to ensure adherence of submitted trials.[42,43] In this direction, an active implementation strategy of CONSORT adherence adopted by an orthodontic journal[44] improved the reporting quality of RCTs and might be more effective than passive adoption of guidelines. More emphasis

on clinical trial methodology in education and better adherence to existing guidelines for randomized trials may facilitate improvements in the quality of RCTs in prosthodontics and implant dentistry.

Conclusions

The analysis of the selected prosthodontic and implant dental literature indicated that the risk of bias in RCTs of these fields might be considerable. The percentage of RCTs with high risk of bias ranged from 8% to 47% in the various domains of the Cochrane risk of bias tool. Adherence to existing guidelines can improve the internal validity of RCTs.

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Literature Abstract

Tooth Loss, Periodontal Disease, and Cognitive Decline in the Atherosclerosis Risk in Communities (ARIC) Study

Growing evidence has linked tooth loss and periodontal disease to a greater age-related cognitive decline and to neurodegenerative diseases, such as Alzheimer's disease. Thus, the objective of this study was to establish if tooth loss and current inflammatory state of periodontal disease predicted 8-year changes in cognitive function among community-dwelling, late-middle-aged adults in the Atherosclerosis Risk in Communities (ARIC) study. Prospective data was obtained from the ARIC study from a group of middle-aged adults aged 52 to 75 years from 1996 to 1998 at two study sites. Oral health measures, consisting of collection of intraoral data such as periodontal probing as per the BGI classification, GCF, dental plaque, and serum were examined in 558 of 785 dentate patients. Cognitive function was also evaluated by means of a delayed word recall (DWR), digit symbol substitution, and word fluency (WF). The generalized estimating equations method was used to analyze repeated measures of cognitive scores with adjustment for sociodemographic characteristics and cardiovascular risk factors, alongside directed acrylic graphs and change-in-estimate procedure. Overall, in a total of 911 study participants, 13.8% were found to be edentulous. Of the dentally examined participants, 13% had periodontal pockets (≥ 4 mm) with severe bleeding. During the subsequent visit, DWR and WF scores were lower in edentulous compared to dentate people, whereas other oral health measures were not associated with cognitive function. Mean values declined over time for all three cognitive measures, although poor oral health conditions were not associated with greater degree of decline in cognitive function. It is then concluded that complete tooth loss was significantly associated with lower cognitive performance. The author listed four possible mechanisms that have been proposed for the relation between poor oral health and lower cognitive function: *(i)* residual confounding by sociodemographic factors or other environmental factors, *(ii)* nutritional deficiency resulting from tooth loss (tooth loss is often a consequence of severe periodontal disease), *(iii)* increased systemic inflammatory response, and *(iv)* an adverse impact of cognitive decline on oral hygiene. However, neither edentulism, number of teeth, or periodontal disease predicted greater subsequent cognitive decline.

Naorungroj S, Schoenbach VJ, Wruck L, Mosley TH, Gottesman RF, Alonso A, Heiss G, Beck J, Slade GD. *Community Dent Oral Epidemiol* 2015;43:47–57. **References:** 35 **Reprints:** Gary D. Slade, Department of Dental Ecology, School of Dentistry, UNC, Koury Oral Health Sciences Building, Room 4501E, CB#7455, Chapel Hill, NC 27599-7455, USA. Fax: 919-966-5339. Email: gary_slade@unc.edu—*Sheralyn Quek, Singapore*