Reporting quality of randomized trials on vital pulp treatments using the Preferred Reporting Items for RAndomized Trials in Endodontics

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Running Head: Reporting quality of clinical trials on vital pulp treatments

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ABSTRACT

The aim was to critically evaluate the reporting quality of randomized clinical trials (RCTs) on vital pulp treatments (VPT) published before the introduction of the Preferred Reporting Items for Randomized Trials in Endodontics (PRIRATE) 2020 guidelines. Forty-seven RCTs were identified, scored for 58 items and presented on a percentage scale. A score of '1' was given when the item was fully reported, a score of '0' when it was not reported; and '0.5' in case of inadequately reported item. Fifteen and 32 trials were given a "High" or "Moderate" score respectively, corresponding to >75% and between 25%- 75% scores respectively. Large number of authors, manuscripts by authors from Europe and endorsement of registration practices were associated with high scores. RCTs on VPT published before the introduction of the PRIRATE 2020 guidelines had suboptimal reporting quality. Future studies should adhere more strictly guidelines to ensure high reporting quality and credibility.

Keywords: PRIRATE 2020, reporting guidelines, vital pulp treatment, critical appraisal

INTRODUCTION

Randomized clinical trials (RCTs) are considered as the most valued and informative research design for evaluating the effectiveness and safety of clinical interventions and therapies [1,2]. Upon dissemination of their findings, RCTs should be characterized by optimal reporting quality to allow replication of their methods and precise evaluation of their results [3]. To facilitate the clear and transparent reporting of RCTs, all trials should be registered *a priori* in a public registry before the initiation of patient recruitment [4] (Tzanetakis & Koletsi 2021), which normally comprises the description of study background and methodology as recommended by the CONSORT statement (CONsolidated Standards of Reporting Trials) [5-7].

The assessment of the implementation of the CONSORT Statement in a previous evaluation of RCTs in various fields of dentistry revealed an improvement in the reporting quality of RCTs over time [8-11]. However, suboptimal reporting of key aspects of RCTs have been identified even after CONSORT endorsement including random sequence generation, allocation concealment and blinding with incomplete reporting of attrition bias and selective outcome reporting also being described [12-14].

The Preferred Reporting Items for RAndomized Trials in Endodontics (PRIRATE) 2020 guidelines concern exclusively the field of endodontics and related clinical research [15]. The PRIRATE 2020 checklist consists of 58 individual items under 11 sections including Title, Keywords, Abstract, Introduction, Methods, Results, Discussion, Conclusions, Funding details, Conflict of interest and the Quality of images [16]. The introduction of the PRIRATE guidelines has provided all stakeholders with the opportunity to evaluate in a quantitative way whether clinical trials published in the specialty of endodontics are in accordance with the state-of-the-art perspectives of reporting quality standards in scientific research [16]. The present assessment is intended to support authors, reviewers and editors to assess submissions to journals for their transparency and reporting quality. Evaluating how closely published RCTs adhere to the PRIRATE checklist and

analyzing the association between their publication characteristics and recently established reporting guidelines are both important components of improving the overall quality of RCTs in endodontics. Recently, VPT clinical trials have been widely reported and constitute a significant proportion of randomized trials in endodontics, particularly with an increasing interest in minimally-invasive biologically based therapies and maintenance of pulp vitality using several bioactive materials [17-20].

Therefore, the aim of the present study was two-fold: firstly, to critically appraise the reporting quality of VPT clinical trials published in endodontics based on the PRIRATE 2020 checklist and secondly, to investigate the association between the quality of reporting of these trials and specific publication characteristics such as authorship, continent, year and journal of publication along with the impact factor, registration practices and reported adherence to CONSORT guidelines.

METHODS

Search Strategy and Study Selection

A meta-research design was utilized in the present study. RCTs focusing on VPT for the management of deep or extremely deep caries published prior to the PRIRATE 2020 guidelines for reporting randomized trials in endodontics [15,16], were identified, screened, and appraised based on specific eligibility criteria. An electronic search was conducted in Scopus, PubMed (MEDLINE), Web of Science (WoS) Core Collection, Korean Citation Index (KCI), Russian Science Citation Index (RSCI), and SciELO Citation Index (SCIELO) databases on April 2, 2023, using a predefined search strategy detailed in **Table S1**. Deep caries was defined as the lesion reaching the inner quarter of dentine, but with a zone of hard or firm dentin between the caries and the pulp, radiographically detectable when located on an interproximal or occlusal surface and extremely deep caries the carious lesion penetrating the entire thickness of the dentine, radiographically detectable when located on an interproximal or occlusal surface [21].

The records retrieved from these databases were imported into the Rayyan environment [22] for the removal of duplicates. After deduplication, two independent reviewers (GNT, XP) conducted the screening process in two stages: first, by evaluating titles and abstracts, followed by a full-text assessment for the remaining studies. The authors of all studies that were not accessible in full text were contacted to request their articles. Studies were selected for appraisal based on the reporting items outlined in the PRIRATE 2020 checklist [15,16], if they met the specified inclusion and exclusion criteria:

Inclusion Criteria:

- RCTs on VPT for carious teeth with exposed pulps resulting from non-selective caries removal (direct pulp capping, partial pulpotomy, full pulpotomy), or with non-exposed pulps resulting from selective caries removal treated in either a one-visit setting as indirect pulp capping or a two-visit setting with stepwise excavation.
- RCTs submitted for publication after December 31, 1996, to ensure that the RCT was (theoretically) conducted in accordance with the first CONSORT guidelines [5].
- RCTs submitted for publication by December 31, 2019, to ensure that the RCT was conducted prior to the publication of the PRIRATE 2020 guidelines for reporting randomized trials in endodontics [15,16].

Exclusion Criteria:

- Non-randomized controlled clinical trials, single-arm prospective trials, observational clinical studies (prospective or retrospective), case series, case reports, animal studies, laboratory-based studies, and reviews.
- RCTs on vital pulp treatment of human teeth with exposed or non-exposed pulps as a result of traumatic dental injuries.
- RCTs that were considered to not meet basic methodological standards, such as the lack of randomization and a sample size (N) ≤10.
- Duplicate publications not detected during deduplication due to different journal publication and/or title changes.
- Studies published in languages other than English.

Any discrepancies between the two reviewers during the selection process were resolved by a third reviewer (DK).

Data Extraction

Data from the RCTs selected for appraisal were extracted systematically and synthesized using a structured data extraction form. The collected information included the first author's name, the corresponding author's country, publication year, number of authors, journal name, the journal's Impact Factor ('IF') at the time of the RCT's publication, the 'IF' according to the 2023 Journal Citation Reports (JCRs), the current 5-year 'IF', and details on quartile ranking and JCR category. Additionally, it was noted whether the study adhered to CONSORT guidelines (yes/no) and if the study protocol was preregistered in a clinical trial registry database. Two reviewers (GNT, XP) independently conducted the data extraction, and any discrepancies were resolved through discussion with a third reviewer (DK), until agreement was reached.

Quality assessment process using the PRIRATE 2020 checklist

To evaluate the quality of clinical trial reports, two reviewers independently (GNT, XP) appraised manuscript adherence to the 58 items outlined in the PRIRATE 2020 checklist [16]. Each item was scored on a scale of '1' for adequate reporting, '0.5' for inadequate reporting, and '0' for non-reporting. Reviewers were required to explicitly state when certain items did not apply, such as for example Item 5b (Methods - Trial Design), where deviations from the methodology post-trial commencement required detailed explanations. If no reporting of deviation was mentioned, a score of '0' was given. Similarly, irrelevant items were marked as 'Not Applicable (NA)'. After the independent evaluation, the reviewers discussed all items with disagreement and reached a consensus. Inter-rater agreement was calculated to assess the level of consistency between the reviewers.

The final score for each trial was computed by summing the assigned scores, excluding 'NA' items, with a maximum possible score of 58. Trials were then categorized based on their scores

into three groups: low quality (up to the 25th percentile), moderate quality (the interquartile range, 25^{th}- 75^{th} percentile), and high quality (the 75th percentile and above).

Descriptive analysis and visualization

A bibliometric analysis was conducted to characterize the included RCTs in terms of authorship patterns, geographical distribution, research topics, journal sources, and their respective impact factors (IFs). Metadata for each study was extracted in plain text format from the WoS database and imported into the R environment for statistical computing and graphics [23]. The accuracy of the metadata was ensured by manually verifying and refining the names of authors, institutions, and countries, addressing any transcription or indexing errors. Institutional affiliations were standardized at the university or research centre level, excluding specific departments or research units.

Descriptive analysis and network extraction were performed using R version 4.4.1 (2024-06-14) [22], and the R package *bibliometrix* version 4.3.0 [24]. The total number of authors and co-authors was recorded, along with the frequency of their appearance across the studies. To assess individual author contributions, both full counting and fractionalized counting methods were employed [25].

Co-authorship analysis was conducted to explore collaborative relationships, mapping networks among authors, institutions, and countries. Citation data, sourced from the WoS Core Collection (Times Cited Count), served as a measure of the impact and significance of each RCT. To analyze research themes, a keyword analysis was performed based on the frequency distribution of MeSH or EMTREE indexing terms and Keywords Plus, as provided by Clarivate Analytics databases.

Bibliometric networks and geographical data were visualized using the *bibliometrix* package version 4.0.0 [24] for network plots and the *wordcloud* package version 2.6 [26] for generating word clouds. These visualizations helped identify key research trends and collaboration patterns across the included studies.

Association between characteristics and quality of randomized clinical trials

The study examined the relationship between various characteristics and the reporting quality of the included randomized clinical trials. The following characteristics were assessed:

- **Number of authors**: Categorized into four groups (1-2, 3-4, 5-6, >6 authors).
- **Geographic origin of reports**: Based on the continent of the corresponding author (North America and Canada, South America, Europe, Asia, Oceania, Middle East).
- **Journal type**: Whether published in endodontic specialty journals or non-endodontic specialty journals.
- **Publication in a journal with an Impact Factor ('IF')**: Classified as either yes or no.
- **Year of publication**: Ranging from 1998 to 2019. The variable "*year*" was further dichotomized to latest 5 years and prior than that to explore any meaningful association between reporting quality and publication recentness.
- **Endorsement or not of CONSORT guidelines**: this relates to whether the published RCT included a statement of whether the reporting of the trial followed CONSORT or not).
- **Registration or not of the trial protocol in a public access clinical registry base**: this relates to whether the RCT protocol was registered or not.

Statistical analysis

The compiled data were analyzed using Stata (version 15.1, Stata Corporation). Descriptive statistics, including frequency and percentage analyses, were used to summarize the data. To assess associations between the reporting quality categories and the publication characteristics mentioned above, Pearson chi-square or Fisher's exact tests were employed as appropriate. A p-value of .05 was considered the threshold for statistical significance.

RESULTS

Characteristics of included studies

The search strategy yielded a total of 4,223 records. After deduplication, which resulted in the removal of 2,204 duplicates, 2,019 articles remained for further screening. A review of titles and

abstracts led to the exclusion of 1,960 records. Following a meticulous screening process, 59 studies were identified for full-text evaluation. However, two of these studies could not be obtained in full text, and ten were subsequently excluded for reasons detailed in **Table S2**. Ultimately, 47 RCTs were deemed suitable for appraisal, as illustrated in the flowchart in **Figure 1**. **Table 1** outlines the main characteristics of the studies analyzed, including details such as the first author, the country of the corresponding author's primary affiliation, the year of publication, the number of authors involved, the journal name, the Impact Factor ('IF') for the year of publication, and the overall PRIRATE score. A full list of the 47 included studies is available in **Table S3**. This study considers not only RCTs published in journals with an 'IF' but also those indexed in the Clarivate Analytics' Emerging Sources Citation Index (ESCI) (n=4), SCOPUS, MEDLINE or Korean Citation Index (KCI) (n=4).

The greatest number of analyzed RCTs were published in 2017, with 10 articles, followed by 7 articles in both 2013 and 2018, 6 articles in 2019, and four articles in 2014. There were two articles published each in 2010 and 2012, and one article in 1998.

Among the analyzed studies, 39 were published in 15 of the most relevant journals, referenced in the JCR (**Table 1**). The highest number of RCTs originated from the *Journal of Endodontics* (12 articles), followed by *Clinical Oral Investigations* (5 articles) and *International Endodontic Journal* (4 articles) (**Figure 2**).

Reporting quality of included RCTs assessed using the PRIRATE 2020 checklist

The inter-rater agreement between the reviewers was calculated and showed a mean percentage of 83% ± 9% (SD), indicating a high level of consistency in the assessment process. According to the interquartile range (IQR) of the overall scores, 15 out of 47 randomized clinical trials (32%) were classified as "High" reporting quality, while 32 studies (68%) fell into the "Moderate" category. No trials were rated as "Low" quality. Within the 'High' quality group, Labib et al. [27], published in *BMJ Open*, achieved the highest score of 93% followed by the studies of Ali et al. [28], published in the *Journal of Dental Research*, with a score of 86%, and Kundzina et al. [29], published in the *International Endodontic Journal*, with a score of 83%.

Table 2 presents the scores for individual PRIRATE items according to the PRIRATE 2020 checklist. Items 5m—describing any interim analyses and stopping guidelines when applicable—and 11e—ensuring that patient identifiers (names, patient numbers) have been removed to maintain anonymity—were consistently well-documented across all analyzed clinical trials. In contrast, Item 5b, which requires detailed explanations for any changes to the methodology after the initiation of the trial (such as eligibility criteria), received a score of 0, as it was entirely omitted from the reports. Additionally, Item 5k, which calls for a rationale and empirical support for considering primary or secondary outcomes as surrogate outcomes, was marked as 'NA' in all trials, indicating it was not applicable. **Figure 3** illustrates overall results related to the individual PRIRATE items.

Relationship between study characteristics and reporting quality

The following is a brief summary of each characteristic related to the reporting quality of the analyzed RCTs (**Table 3**):

1. **Number of Authors**: Studies with more than six authors were more likely to be classified as high quality (47%) compared with those with fewer authors. The majority of studies in the moderate quality group had three to four authors (44%). Overall, there was a significant difference in the distribution of author category according to the reporting quality category ($p=0.01$).
2. **Continents**: Trials from Asia and the Middle East were more commonly positioned in the moderate quality group (44% each), while high-quality studies were distributed across Europe (33%), Asia (33%), and South America (20%). There was a significant difference in the distribution of originating continents of authorship of the RCTs across the reporting quality categories ($p=0.004$).
3. **Journal Specialty**: Most RCTs in the high-quality category were published in non-endodontic specialty journals (73%), while a similar pattern was noted for the moderate quality category, with 56% of the examined RCTs published in non-specialty journals.
4. **Impact Factor**: The majority of trials were published in journals with IFs, and this was also reflected in the distribution of both reporting quality categories.

5. **Year of Publication**: Studies published between 2015 and 2019 were more likely to achieve high-quality reporting (67 %) compared to older studies (33%). A similar pattern was noted for the moderated reporting quality category as well, with 56% of the RCTs of this category being published more recently.
6. **Adherence to CONSORT guidelines:** The majority of studies did not report the use of the CONSORT guidelines for the reporting of the RCT across both moderate (63%) and high (53%) reporting quality categories.
7. **Protocol Registration**: The majority of studies in the moderate reporting quality category group had not registered a study protocol (75%), while in the high-quality group, most RCTs presented with a protocol registration (67%) (p=0.01).

Authorship and collaboration

The 47 RCTs examined in this study were authored or co-authored by 174 individuals, yielding 228 author appearances; no single-authored manuscripts were identified. On average, each document had approximately five co-authors, indicating strong collaboration, with 23% involving international partnerships. These RCTs accrued an average of 52 citations each (approximately five per year). **Table S4** ranks the most productive authors using both full and fractional counts (TRCTs and TRCTsF). Notably, ASGARY S and EGHBAL MJ (Shahid Beheshti University of Medical Sciences, Iran) were the most prolific, reflecting both a high volume of RCTs and considerable collaborative efforts.

The authors represented 56 institutions across 20 countries, spanning Europe, Asia, the Middle East, South America, North America, and Oceania**. Figures 4a** and **4b** depict collaboration networks: 63% (30/47) of the RCTs were products of international teams, while 37% (17/47) involved single-country efforts. India led single-country publications with nine RCTs, followed by Turkey (five) and Brazil (four). Iran produced seven single-country RCTs plus one multi-country RCT, reflecting a blend of national and international collaboration. Thailand contributed two single-country RCTs and one multi-country paper, whereas Denmark published two multi-country trials without any single-country studies. These observations underscore the diverse degrees of

cooperation worldwide, emphasizing the importance of both independent and international initiatives in advancing VPT research.

Keyword analysis

The research was further characterized by 153 Indexed Keywords (MeSH or EMTREE indexing terms or Keywords Plus, words or phrases generated from cited titles and associated with articles by Clarivate Analytics databases) and 115 author-specific keywords, providing a comprehensive framework for understanding the topics and themes present in the analyzed studies.

The analysis of both indexed (MeSH or EMTREE indexing terms and Keywords Plus) and author-provided keywords from RCTs focusing on VPT for managing deep or extremely deep caries showed that the most indexed keywords were "mineral trioxide aggregate", "calcium hydroxide", and "MTA". These materials are central to vital pulp therapy, underscoring their importance in clinical trials for managing deep caries. Similarly, the most displayed author-provided keywords, emphasized procedural terms such as "pulpotomy" and "direct pulp capping", alongside materials like "mineral trioxide aggregate" and "calcium hydroxide". These terms highlight important therapeutic techniques, such as pulpotomy and direct pulp capping, as well as the consistent reliance on specific materials such as MTA in treatment protocols.

DISCUSSION

The present critical appraisal is the first study to assess the quality of reporting of randomized clinical trials on VPT using the PRIRATE 2020 checklist [16]. A total of 47 trials published before the introduction of PRIRATE guidelines were included and evaluated in this assessment. Approximately one third of the studies were categorized as high quality of reporting and the remaining two thirds were classified as medium reporting quality whereas no study was evaluated as low quality. These findings, although promising, confirm the results of a previous similar report which emphasized the suboptimal reporting of RCTs in endodontics [30], and

pointed out a large number of deficiencies observed in the reporting of such type of clinical studies.

A substantial amount of information is disseminated in the present study related to the 58 items of the PRIRATE 2020 checklist. Overall, the items that were poorly or adequately reported are discussed below.

Title

While Item 1a was adequately reported in approximately two-thirds of the included RCTs, many titles did not explicitly convey the study's nature or design, potentially hindering immediate comprehension for readers. By contrast, Item 2b was generally well-addressed, suggesting that most authors recognized the importance of clearly stating the interventions under evaluation. These findings highlight a need for clearer and more descriptive titles, as they serve as a primary entry point for understanding the study's focus.

Keywords

Most included RCTs complied with Item 2a by providing relevant keywords. However, journal-imposed limitations on keyword number can hamper precision in indexing. Employing appropriate Medical Subject Headings (MeSH) terms remains essential for accurately reflecting the study's scope and enhancing discoverability.

Abstract

Six PRIRATE items were assessed for abstract reporting. Only 23% of the studies fully described the rationale (item 3a), a shortfall potentially tied to journal-imposed word limits, yet a single sentence often proves insufficient to convey the rationale for vital pulp treatments. Approximately one-third of the studies did not adequately specify their objectives (item 3b). Items 3c and 3d also received low scores, indicating insufficient detail on methodology (e.g., exclusion criteria, blinding, confidence intervals) and results. Moreover, few studies adequately

reported registration or funding (item 3f), a newly recommended PRIRATE requirement. Encouragingly, most abstracts did provide a clear conclusion (item 3). These findings align with earlier appraisals [30,31], and underscore the need for authors, reviewers, and editors to enhance abstract reporting in endodontic RCTs.

Introduction

Nearly all evaluated RCTs adequately addressed item 4a, which requires stating the scientific background and rationale for the trial, highlighting the need to justify VPT as an alternative to conventional root canal treatment. However, about one-third did not clearly formulate the main clinical research question (item 4b). Employing a PICO framework [32] could assist authors in clearly defining their population, interventions, comparisons, and outcomes, thereby improving the clarity of VPT research objectives.

Methodology

Overall, 18 items were assessed under the domain of Materials and Methods section. Important items such as interventions in experimental groups or in control groups (item 5g, h) or primary and secondary outcomes (item 5i) were adequately described in most of the evaluated studies showing the capacity of authors to describe sufficiently crucial parts of their work on VPT. In addition, the description rate for inclusion and exclusion criteria (item 5e) was satisfactory, which is crucial for the credibility of the study and its reproducibility in future research. However, several other items were inadequately described or not described at all. Details about the nature or the design of the trials (item 5a) were adequately described only in approx. 21% of the studies. Terms such as superiority, non-inferiority or parallel design were missing on several occasions, as most of the authors failed to use the appropriate terminology when describing their study. This may have an impact on other items as well, such as item 5l, as appropriate sample size calculation is directly related to the design of a trial. Regarding other items, it is worth noting that 1 out of 3 studies did not provide proof of ethical approval for their study nor information regarding the

process of obtaining informed consent from participants. This finding is critical and extremely sensitive, as the practice of conducting clinical research on humans without explicit official approval by an institutional ethics board cannot be acceptable. This is beyond research and scientific standards and should be a unanimous and *defacto* reported item in all published clinical evidence [33]. The official registration of the trial in a clinical base registry before the commencement of the study could further aid in that direction, minimizing or eliminating the cases of trials lacking ethical approval. However, the results of the present study revealed that only 38% of the VPT trials provided adequately their registration number and the name of the registry where the authors registered the protocol of their work. This lack of registration of clinical trials in endodontics has been previously pointed out by Alamri & Alharbi [9]. This finding shows clearly that all peer reviewed journals need to adopt the policy of official pre-registration of any trial as prerequisite for study submission. Randomization, allocation concealment and blinding (items 5n, 5o, 5p respectively) were adequately described in approximately half of the studies. This is a major drawback of VPT trials bringing into question their credibility and findings. Even worse were the findings about the adequacy and suitability of statistical methods used for the analysis of the results of the trials as well as the management of any clustering effects. Overall, only 40% of the studies described sufficiently their statistical methods, whereas 53% reported them inadequately. This is a significant and continued shortcoming of many trials on VPT as shown in the present study, reflected mainly by the failure of authors to incorporate the effect of time on treatment outcome, which in several cases relates to survival of the treated teeth. This subsequently leads to lack of acknowledgement of how the amount of time a tooth is under evaluation impacts on the outcome, and failure to present the instantaneous amount of risk for failure of a treatment, as is accurately reflected by the reporting of effect measures such as Hazard Rations or Kaplan-Meier survival curves [34]. On the contrary, authors of RCTs in the field frequently report *rates* or *survival rates*, while their analysis in reality failed to incorporate any effect of time and was confined only to reporting frequencies and Odds Ratios for the treatment effect. Consequently, further problems that may arise are related to the inability of similar future studies to directly compare their findings. The above findings are in contrast with the results of a similar appraisal on randomized trials in endodontics [30] in general, in which the authors found that

almost 3 out of 4 studies described sufficiently the statistical analysis of their results. Also, failure to address the presence of any clustering effects due to involvement of more than one operator or due to inclusion of more than one tooth per patient may lead to incorrect and spurious findings [35]. In the present study, only 13% of the evaluated trials succeeded in adequately describing how any cluster effects (item 5r) were managed during their statistical analysis. This finding which is in agreement with the results of similar studies in orthodontic research [36] and leading dental specialty journals [37] is quite disappointing because it is considered a vital step of the analysis to avoid misleading results, thus also misleading interpretation of trial findings, risking flawed inferences. The above findings regarding the methodology and analysis presented in VPT trials demonstrate overall that the future submissions to journals related to this topic should incorporate major changes in their Materials and Methods section to be considered eligible for publication, useful and informative for the research and clinical community of endodontics.

Results

Items 6a, 6b, and 6e were generally reported more fully than other items in the Results. However, many trials lacked a flowchart, and without official registration, study durations or recruitment dates were often unclear. Suboptimal reporting was also noted for items 6f and 6g, particularly regarding absolute and relative effect sizes [38], which were adequately described in only 10–15% of the studies. Additional analyses (item 6h), such as subgroup or adjusted analyses, were similarly underreported. Furthermore, only half of the trials provided details on adverse events (item 6i). PRIRATE guidelines specify that any adverse events should be reported or explicitly stated as absent if none occurred.

Discussion

Although 31–68% of RCTs met the Discussion-related PRIRATE items (7a–7g), the clinical relevance of outcomes (item 7c) was comparatively well-addressed. However, nearly half of the trials offered insufficient interpretation of their findings (item 7d), underscoring the need for

clear contextualization of results within existing literature. Moreover, fewer than 36% of studies adequately reported strengths (7e), limitations (7f), or future implications (7g)—all of which are essential for evaluating the robustness and applicability of VPT research. Recognizing both methodological rigor and potential weaknesses is particularly important in this rapidly evolving field, where identifying gaps can guide future investigations and improve clinical practice.

Conclusions

In most trials, conclusions were clearly stated in a separate section, whereas others integrated them into the Discussion—likely reflecting varying journal policies. Establishing a dedicated Conclusions section can help ensure that key findings and clinical implications are clearly delineated, thereby enhancing the clarity and impact of VPT research.

Funding and support

A high proportion of RCTs (approximately 80%) disclosed their funding sources, reflecting both a growing emphasis on transparency and the burgeoning interest in bioactive materials for pulp tissue repair. Nevertheless, universal reporting remains a critical benchmark for maintaining ethical standards and credibility in VPT research [39].

Conflict of interest

Approximately 70% of the RCTs disclosed potential conflicts of interest, while the remainder omitted such statements despite commercial involvement in novel bioactive materials [40]. Given that RCTs with declared COIs are more likely to report positive outcomes [41], consistent COI declarations are crucial for ensuring transparency and credibility in endodontic research.

Quality of images

Although PRIRATE guidelines emphasize high-quality radiographic and clinical imaging, fewer

than half of the trials evaluated provided sufficient images, and some omitted them entirely. Limited use of operating microscopes and inadequate reporting of imaging equipment hinder both accurate documentation and reliable outcome assessment, reflecting on credibility issues. Future VPT studies should therefore prioritize comprehensive imaging protocols to enhance methodological rigor and clarity.

Relationship between characteristics of vital pulp treatment trials and their reporting quality

Three factors emerged as significantly linked to higher reporting quality. First, trials with more than six authors tended to have stronger reporting [12], highlighting the benefits of collaborative, often multicenter efforts in VPT research [30]. Second, continent of authorship played a role, with European-based trials exhibiting higher quality than those from Asia or the Middle East, despite the latter regions producing more RCTs overall. Quantity alone may not suffice if methodological standards remain suboptimal. Third, registration practices were strongly associated with improved reporting quality, corroborating earlier findings [30] and reinforcing calls for mandatory trial registration to minimize selective reporting [4].

By contrast, no significant associations were identified for journal specialty, impact factor, or publication year. Although three-quarters of these VPT RCTs appeared in non-endodontic journals, this does not necessarily reflect lower standards; high-impact endodontic journals may have stricter submission criteria. Likewise, endorsing CONSORT guidelines did not guarantee high-quality reporting, suggesting that experience, methodological rigor, and thorough application of guidelines may matter more than mere adherence statements. PRIRATE was introduced to address such shortcomings by offering an endodontics-focused framework that can benefit both seasoned researchers and those new to clinical trial methodology. Notably, Mineral Trioxide Aggregate and pulpotomy were the most frequently investigated topics, reflecting the field's growing emphasis on bioactive materials. Finally, India, Iran, Turkey, and Brazil emerged as the most productive countries in VPT research, a finding consistent with the results of another study that underscored a similar pattern on clinical research [42].

Strengths and limitations

The present study included all RCTs comprising comparisons between different VPT treatment modalities or between different capping materials involving the same VPT treatment modality. A total of 47 RCTs were finally included which had been published in both endodontic specialty and non-specialty journals, thus following a plan to minimize selection bias upon the initial evaluation of the trials. In addition, several databases were used to identify potential eligible trials. This was a challenging and rigorous process, and all relevant trials were finally identified and included.

The current appraisal is not free of limitations. The subjectivity of the evaluators, although experienced, is a possible limitation in such studies, so a third reviewer was involved to discuss and resolve any disagreements between the two principal evaluators. In addition, it is acknowledged that the trichotomous scoring system employed in this study ("1", "0.5" and "0") may involve some degree of subjectivity, especially in comparison to a binary scoring system ("1" and "0"). Nonetheless, it must be taken into consideration that each PRIRATE item encompasses several distinct elements. Accordingly, a score of "1" was assigned if all elements were fully reported, a score of "0.5" if at least one element (but not all) was missing, and a score of "0" if all elements associated with the item were missing, which resulted in the avoidance of subjective appraisals of adequacy. For example, many "0.5" scores were assigned to Abstract-related items when at least one (but not all) of the required (sub)-elements were absent. Ultimately, this clear-cut approach ensured consistency and transparency by focusing on the presence or absence of essential reporting components rather than subjective judgments. Finally, all the included trials had been published before the introduction of the PRIRATE 2020 guidelines. While a direct comparison of pre- and post- PRIRATE studies would be ideal, the limited number of RCTs published adopting the PRIRATE guidelines currently precludes a meaningful evaluation of its impact. Instead, this study establishes a baseline of reporting practices prior to PRIRATE introduction and highlights the existing methodological gaps in the literature. These findings should inform authors and guide improvements in future trials, particularly as more studies adopting PRIRATE are published and become available for comparison. On this note, a future similar study is planned to evaluate whether VPT trials published after the introduction of the PRIRATE guidelines have endorsed them in their manuscripts and whether the overall quality of

reporting has been improved. It is accepted that in the future changes in terminology within the VPT area may reflect reporting, as the terms deep and extremely deep caries were only introduced in 2019 [21].

CONCLUSION

Overall, the reporting of clinical trials on VPT prior to the introduction of the PRIRATE 2020 guidelines was substandard. Although adherence to the CONSORT statement was not found to improve the reporting quality to high standards overall, the bespoke nature of PRIRATE may further aid in this direction. Several domains and specific items of each domain could benefit from the endorsement and close adherence to the PRIRATE 2020 guidelines by editors, reviewers and authors of future similar trials in endodontics.

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Table and Figure legends

Table S1. Electronic Databases and Search Strategy

Table S2. List of Excluded Studies and Reasons for Exclusion

Figure 1. Study selection flowchart

Table 1. Characteristics of included RCTs

Table S3. List of RCTs included in the current study

Table S4. The Most Productive Authors from 47 RCTs

Figure 2. RCTs (n =47) published in various journals

Table 2. Percentages of adequately reported PRIRATE items

Table 3. Relationship between the reporting quality and publication characteristics of the included studies.

Figure 3. Graphical wheel illustrating overall results related to the individual PRIRATE items

Figure 4a. Most productive countries for VPT clinical trials showing also possible international collaborations among them.

Figure 4b. Country's co-authorship network. Each network node represents a country whose si ze is proportional to the frequency, that is the number of randomized clinical trials. A line is established when two nodes have a relationship of co-authorship. Different colours represent distinct clusters.

Table 1. Characteristics of included RCTs

Study ID	First author	Country (Corresponding author)	Year published	Number of authors	Journal	JCR® IF for the year in which the study is published	Overall score (%)
1	ASGARY S	IRAN	2013	2	AOS	1.309	65.96%
2	ASGARY S	IRAN	2013	4	COI	2.285	73.40%
3	ASGARY S	IRAN	2014	3	COI	2.352	69.09%
4	ASGARY S	IRAN	2015	5	COI	2.207	74.47%
5	ASGARY S	IRAN	2018	4	JOE	2.833	68.09%
6	AWAWDEH L	JORDAN	2018	4	JOE	2.833	69.15%
7	BJORNDAL L	DENMARK	2010	18	EJOS	1.9	80.91%
8	BJORNDAL L	DENMARK	2017	9	JDR	5.383	83.64%
9	BRIZUELA C	CHILE	2017	7	JOE	2.886	69.15%
10	CENGIZ E	TURKEY	2016	2	JOE	2.807	54.26%
11	CHAILERTVANITKUL P	AUSTRALIA	2014	7	IEJ	2.971	56.25%

12	EL MELIGY OAS	EGYPT	2006	2	PD	0.766	55.56%
13	EPPA HR	INDIA	2018	6	CCD	-[a]	42.59%
14	GALANI M	INDIA	2017	6	JOE	2.886	74.55%
15	GHODDUSI J	IRAN	2012	5	NYSDJ	-[b]	37.04%
16	HILTON TJ	USA	2013	3	JDR	4.144	81.91%
17	JANG Y	SOUTH KOREA	2015	6	JOE	2.904	74.47%
18	KANG CM	SOUTH KOREA	2017	7	JD	3.770	71.82%
19	KATGE FA	INDIA	2017	2	JOE	2.886	60.91%
20	KESWANI D	INDIA	2014	4	JOE	3.375	65.45%
21	KUMAR V	INDIA	2016	5	CCD	-[a]	77.78%
22	KUNDZINA R	NORWAY	2017	4	IEJ	3.015	82.98%
23	LABIB ME	GERMANY	2019	5	BMJO	2.496	92.71%
24	MALTZ M	BRAZIL	2013	7	CR	2.500	79.79%
25	MALTZ M	BRAZIL	2012	10	JDR	3.826	80.85%
26	MALTZ M	BRAZIL	2018	9	COI	2.453	79.79%
27	NOSRAT A	IRAN	2013	3	IJPD	1.540	75.47%

28	ÖZGÜR B	TURKEY	2017	3	PD	-[c]	66.36%
29	PARINYAPROM N	THAILAND	2018	14	JOE	2.833	79.46%
30	QUDEIMAT MA	KUWAIT	2007	3	EAPD	-[b]	60.91%
31	SINGH S	INDIA	2019	3	CR	2.186	81.25%
32	SONG M	SOUTH KOREA	2015	4	JOE	2.904	71.82%
33	SUHAG K	INDIA	2019	4	JOE	3.118	77.17%
34	TAHA NA	JORDAN	2017	2	JOE	2.886	71.70%
35	UESRICHAI N	THAILAND	2019	6	IEJ	3.801	77.27%
36	VURAL UK	TURKEY	2017	3	NJCP	0.717	51.04%
37	WHITWORTH JM	UK	2005	5	IEJ	1.606	64.89%
38	MORITZ A	AUSTRIA	1998	4	LSM	1.649	35.11%
39	VURAL UK	TURKEY	2017	3	OD	2.13	55.36%
40	ALI AH	UK	2018	7	JDR	5.125	86.36%
41	CORRALO DJ	BRAZIL	2013	2	CR	2.500	72.73%
42	ASGARY S	IRAN	2010	2	Odont	1.071	73.40%
43	KHOKHAR M	INDIA	2018	2	CCD	-[a]	64.29%

44	BANOMYONG D	THAILAND	2013	2	JICD	-[b]	52.13%
45	SHARMA SIDHARTHA	INDIA	2014	3	RDE	-[d]	57.14%
46	DURMUS N	TURKEY	2019	4	COI	2.812	70.91%
47	ARAFA A	EGYPT	2019	3	EDT	-[a]	53.57%

AOS, Acta Odontologica Scandinavica; **COI**, Clinical Oral Investigations; **JOE**, Journal of Endodontics; **EJOS**, European Journal of Oral Sciences; **JDR**, Journal of Dental Research; **IEJ**, International Endodontic Journal; **PD**, Pediatric Dentistry; **CCD**, Contemporary Clinical Dentistry; **NYSDJ**, New York State Dental Journal; **JD**, Journal of Dentistry; **BMJO**, BMJ Open; **CR**, Caries Research; **IJPD**, International Journal of Paediatric Dentistry; **EAPD**, European Archives of Paediatric Dentistry; **NJCP**, Nigerian Journal of Clinical Practice; **LSM**, Laser Surgery and Medicine; **OD**, Operative Dentistry; **Odont**, Odontology; **JICD**, Journal of Investigative and Clinical Dentistry; **RDE**, Restorative Dentistry & Endodontics; **EDT**, Endodontics & Dental Traumatology.

[a] The journal indexed in the Clarivate Analytics' Emerging Sources Citation Index.

[b] The journal indexed in SCOPUS and MEDLINE.

[c] Pediatric Dentistry was suppressed from 2017 JCR Data due to anomalous citation patterns found in the 2017 citation data.

[d] The journal indexed in KCI- Korean Journal Database and MEDLINE.

Table 2. Percentages of adequately reported PRIRATE items

PRIRATE Checklist Items	Overall score (%)	Overall score (%) - partially adequately reported items
1a. The phrase 'Randomized clinical trial' or 'Randomized controlled trial' must be included in the title	65.96%	2.13%
1b. Details of the specific area(s) of interest using words and phrases that identify the clinical problem and the intervention(s) must be provided	91.49%	8.51%
2a. Keywords indicating the specific area(s) of interest using MeSH terms must be included	87.23%	6.38%
3a. The Introduction of the Abstract must explain briefly the rationale for the trial	23.40%	76.60%
3b. Abstract – The aim/objective(s) of the trial must be provided at the end of the introduction section within the Abstract	68.09%	31.91%
3c. The Methodology section within the Abstract must provide essential information on the nature of the trial (e.g. superiority, noninferiority, equivalence), its design (e.g. parallel, split mouth, crossover), the inclusion/ exclusion criteria, randomization process, blinding process and statistical analysis	0.00%	85.11%
3d. The Results section within the Abstract must describe the number of participants that were randomized and analysed, the size and direction (group favoured) of the difference(s) between the intervention(s) and control groups with statistical analysis (P values and 95% CI). Adverse events or side effects (if any) must also be reported or if none occurred, that must be mentioned explicitly	6.38%	89.36%
3e. The Conclusion section within the Abstract must summarize the findings and emphasize the clinical implication(s) of the results	72.34%	27.66%
3f. The prospective registration (number and name of the registry) and source(s) of funding must be provided	12.77%	2.13%
4a. The scientific background and rationale for the trial must be provided, including the gap(s) or inconsistencies in knowledge	95.74%	4.26%

4b. The specific aim/objective (s) of the trial must be provided and the main clinical research question formulated clearly, preferably use the PICO framework (Problem/ Population, Intervention, Control and Outcome)	65.96%	34.04%
5a. Details of the nature of the trial (superiority, noninferiority, equivalence of experimental intervention(s)), its design (parallel, split mouth, crossover, single/double-blinded) and test:control allocation ratio must be provided. If applicable, important information about the study design must also be provided, for example pragmatic or preference trial, phase (drug trials), patient or public involvement in planning, etc.	21.28%	76.60%
5b. Changes to the methodology after the trial commenced (such as eligibility criteria) must be provided along with detailed explanations	0.00%	0.00%
5c. Details of the ethical approval of the protocol and the process for obtaining informed consent must be provided	59.57%	38.30%
5d. Details of the trial protocol including registration number and name of registry/clinical database and where it can be accessed (open access webpage, if applicable) must be provided	38.30%	2.13%
5e. A list of inclusion and exclusion criteria at the individual/tooth/root level must be provided	82.98%	17.02%
5f. Details of the setting/ environment of the trial must be provided. Details on how many operators were involved in performing the intervention and control and their relevant experience/qualifications are essential. The setting where the data were collected must be described. If several operators are included and/or if it is a multi-centre set-up, details of how standardization/calibration between individuals or centres were achieved must be provided	59.57%	38.30%
5g. The treatments in the intervention (experimental) group(s) must be described with sufficient detail to allow replication, including how and when they were actually administered	89.36%	10.64%
5h. The interventions or absence of interventions in the control group must be described with sufficient details to allow replication, including how and when the interventions(s) was actually administered	89.36%	10.64%
5i. The primary and secondary (if any) outcome measures must be described, including how and when they were assessed and by whom	78.72%	21.28%
5j. Details of any changes made to the study outcomes after the commencement of the trial must be described	2.13%	0.00%

5k. If primary or secondary outcomes are to be regarded as surrogate outcomes, the rationale and empirical support for the connection between surrogate(s) and the outcome(s) of clinical relevance must be provided	NA	NA
5l. How the sample size was determined must be described with reference to the published literature, or a pilot study. The sample size may be modified after an internal feasibility study. Sample size calculations should generally refer to the primary outcome measure. If secondary outcome measures constitute the base for sample size calculation, an explanation must be provided	63.83%	6.38%
5m. Any interim analyses and stopping guidelines must be described, when applicable	100.00%	0.00%
5n. The method used to generate the random allocation sequence along with any details of the type of restriction (e.g. blocking) if applicable must be described. The persons responsible for randomization and recruitment must be provided. For multi-centre trials, a central randomization procedure is preferred and must be described. The unit of randomization should be specified and justified. Any stratification variables must be detailed	57.45%	31.91%
5o. Methods for allocation concealment up to the assignment of the participants into the intervention groups must be described	51.06%	23.40%
5p. Information on who was/were blinded after assignment to the interventions (e.g. participants, caregivers, evaluators) must be described in detail. Blinding through masking of interventions (e.g. similar looking drugs/instruments) should be described. Detailed reasons for lack of blinding (if applicable) must be described	51.06%	38.30%
5q. The statistical methods used for analysis of the primary and secondary (if any) outcomes, additional subgroup analyses and adjusted analyses (if applicable) must be described in detail. Consideration of dropouts should be included in the calculations	40.43%	53.19%
5r. How any cluster effects were managed during the analysis must be described	12.50%	0.00%
6a. The number of participants who were randomly assigned, received the intended treatment and were analysed for the primary and secondary (if any) outcome(s) for each group must be described. A flowchart must be provided	65.96%	31.91%
6b. Reasons for losses/dropouts and exclusions after randomization must be described for each group and included in the flowchart. If intention-to-treat analyses are used, details of the process must be provided	72.34%	17.02%

6c. The dates of recruitment, follow-up and study duration must be described	38.30%	61.70%
6d. Reason(s) for any early termination of the trial must be described	97.87%	0.00%
6e. The baseline demographic and clinical characteristics of each group must be provided	63.83%	21.28%
6f. The results for each group for each primary and secondary (if any) outcome(s), along with the estimated effect size and its precision, must be provided	14.89%	80.85%
6g. Both absolute and relative effect sizes for binary outcomes must be provided	10.64%	34.04%
6h. The results from any other analyses performed must be described, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	21.28%	34.04%
6i. The incidence and management of any adverse effects or unintended effects in each group must be described	48.94%	42.55%
7a. An estimate of the overall internal validity must be provided as well as the generalizability (external validity, applicability, real-world relevance) of the trial findings	31.91%	65.96%
7b. The rationale for inclusion, exclusion criteria and study duration must be provided	44.68%	55.32%
7c. An explanation of the clinical relevance of the primary and secondary outcomes must be provided	68.09%	31.91%
7d. A detailed interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence must be provided	53.19%	46.81%
7e. The strength(s) of the trial must be provided	36.17%	63.83%
7f. The limitations of the study must be provided, addressing the sources of potential bias, imprecision and, if applicable, multiplicity of analyses	36.17%	57.45%
7g. Implication for future research and clinical practice must be described	34.04%	61.70%
8a. A rationale for the conclusion(s) must be provided, and the clinical significance highlighted	78.72%	21.28%

8b. Explicit conclusion(s) from the trial must be provided	76.60%	23.40%
9a. Sources of funding and other support (such as supply of drugs, equipment) as well as the role of funders must be acknowledged and described	80.85%	0.00%
10a. An explicit statement on conflicts of interest must be provided	70.21%	8.51%
11a. Details of the equipment, software and settings used to acquire the image(s) must be described in the text or legend	42.86%	39.29%
11b. The reason why the image(s) was acquired and the rationale for its inclusion in the manuscript must be provided in the text. A justification for all images which involve radiation must be included	85.19%	14.81%
11c. The circumstances (conditions) under which the image(s) were viewed and evaluated by the authors must be provided in the text	44.44%	40.74%
11d. The resolution and any magnification of the image(s) or any modifications/enhancements (e.g. adjustments for brightness, colour balance, or magnification, image smoothing, staining) that were carried out must be described in the text or legend	8.33%	8.33%
11e. Patient(s) identifiers (names, patient numbers) must be removed to ensure they are anonymized	100.00%	0.00%
11f. An interpretation of the findings (meaning and implications) from the image (s) must be provided in the text	74.07%	25.93%
11g. The legend associated with each image must describe clearly what the subject is and what specific feature(s) it illustrates. Images of patients must describe the age, gender and ethnicity of the person, if relevant	40.74%	59.26%
11h. Markers/labels must be used to identify the key information in the image(s) and defined in the legend	38.10%	28.57%
11i. The legend of each image must include an explanation whether it is pre-treatment, intra-treatment or post-treatment and, if relevant, how images were standardized over time	81.48%	14.81%

Table 3. Relationship between the reporting quality and publication characteristics of the included studies.

Characteristics	Groups	Reporting Quality categories						*P* values*
		Low		Moderate		High		
		Number	Percentage (%)	N	Percentage (%)	N	Percentage (%)	
Authors	1-2	0	0.00	9	28.13	0	0.00	0.01
	3-4	0	0.00	14	43.75	5	33.33	
	5-6	0	0.00	6	18.75	3	20.00	
	>6	0	0.00	3	9.38	7	46.67	
Continents	Asia	0	0.00	14	43.75	5	33.33	0.004
	Europe	0	0.00	2	6.25	5	33.33	
	Middle East	0	0.00	14	43.75	1	6.67	
	North America	0	0.00	0	0.00	1	6.67	
	South America	0	0.00	2	6.25	3	20.00	
Journal	Non-Endodontic	0	0.00	18	56.25	11	73.33	0.34

	Specialty							
	Endodontic Speciality	0	0.00	14	43.75	4	26.67	
Impact Factor	No	0	0.00	7	21.88	1	6.67	0.41
	Yes	0	0.00	25	78.13	14	93.33	
Year	1998	0	0.00	1	3.13	0	0.00	
	2005	0	0.00	1	3.13	0	0.00	
	2006	0	0.00	1	3.13	0	0.00	
	2007	0	0.00	1	3.13	0	0.00	
	2010	0	0.00	1	3.13	1	6.67	
	2012	0	0.00	1	3.13	1	6.67	
	2013	0	0.00	4	12.5	3	20.00	
	2014	0	0.00	4	12.5	0	0.00	
	2015	0	0.00	3	9.38	0	0.00	
	2016	0	0.00	1	3.13	1	6.67	

	2017	0	0.00	8	25.00	2	13.33	
	2018	0	0.00	4	12.50	3	20.00	
	2019	0	0.00	2	6.25	4	26.67	
Year [dichotomized]	1998- 2014	0	0.00	14	43.75	5	33.33	0.54
	2015- 2019	0	0.00	18	56.25	10	66.67	
Adherence to CONSORT guidelines	No	0	0.00	20	62.50	8	53.33	0.55¥
	Yes	0	0.00	12	37.50	7	46.67	
Protocol Registration	No	0	0.00	24	75.00	5	33.33	0.01*
	Yes	0	0.00	8	25.00	10	66.67	
Total				32	100.00	15	100.00	

* fisher's exact test; ¥ pearson chi-square

Table S1. Electronic Databases and Search Strategy [April 2, 2023]

Database (n)	Search strategy #1 AND #2 AND #3
Total (n=1,351) WoS (n=1,321) SciELO (n=53) KCI (n=8) https://www.webofscience.com	#1 TS=((permanent OR secondary OR adult OR carious) AND (dentition OR t??th OR molar OR premolar)) (n=95,672) #2 TS=(pulpotom* OR pulp capping OR ((vital pulp OR atraumatic restorative) AND (therapy OR treatment)) OR excavation OR ((selective OR non-selective OR stepwise OR complete) AND caries removal)) (n=69,258) #3 TS=(((Clinical OR randomised OR controlled OR pilot) AND (trial OR study)) OR phase 3 OR phase III OR P3 OR PIII) (n=12,833,397)
Scopus (n=1,360) https://www.scopus.com	#1 TITLE-ABS-KEY ((permanent OR secondary OR adult OR carious) AND (dentition OR teeth OR molar OR premolar)) (n=166,842) #2 TITLE-ABS-KEY (pulpotom* OR (pulp W/1 capping) OR ((vital W/1 pulp) OR (atraumatic W/1 restorative) AND (therapy OR treatment)) OR excavation OR ((selective OR non-selective OR stepwise OR complete) AND (caries W/1 removal))) (n=95,848) #3 TITLE-ABS-KEY (((clinical OR randomised OR controlled OR pilot) AND (trial OR study)) OR "phase 3" OR "phase III" OR p3 OR PIII) (n=13,371,991)
PubMed (n=1,512) https://pubmed.ncbi.nlm.nih.gov/	#1 "Dentition, Permanent"[Mesh] OR ("permanent"[Title/Abstract] OR "secondary"[MeSH Subheading] OR "secondary"[Title/Abstract] OR "adult"[MeSH Terms] OR "adult"[Title/Abstract] OR "carious"[Title/Abstract]) AND ("dentition"[MeSH Terms] OR "dentition"[Title/Abstract] OR "dentitions"[Title/Abstract] OR "tooth"[MeSH Terms] OR "tooth"[Title/Abstract] OR "teeth"[Title/Abstract] OR "molar*"[Title/Abstract] OR "premolar*"[Title/Abstract]) (n=108,470)

#2	("pulpotomy"[MeSH Terms] OR "pulpotomy"[Title/Abstract] OR "pulpotomies"[Title/Abstract]) OR ("dental pulp capping"[MeSH Terms] OR ("dental"[Title/Abstract] AND "pulp"[Title/Abstract] AND "capping"[Title/Abstract]) OR "dental pulp capping"[Title/Abstract] OR ("pulp"[Title/Abstract] AND "capping"[Title/Abstract]) OR "pulp capping"[Title/Abstract]) OR ("vital pulp"[Title/Abstract] AND ("therapy"[Title/Abstract] OR "treatment"[Title/Abstract])) (n=4,715) 4,754 ("pulpotomy"[MeSH Terms] OR "pulpotomy"[Title/Abstract] OR "pulpotomies"[Title/Abstract]) OR ("dental pulp capping"[MeSH Terms] OR ("dental"[Title/Abstract] AND "pulp"[Title/Abstract] AND "capping"[Title/Abstract]) OR "dental pulp capping"[Title/Abstract] OR ("pulp"[Title/Abstract] AND "capping"[Title/Abstract]) OR "pulp capping"[Title/Abstract]) OR ("vital pulp"[Title/Abstract] AND ("therapy"[Title/Abstract] OR "treatment"[Title/Abstract]) OR "Dental Atraumatic Restorative Treatment"[Mesh] OR "excavation"[Title/Abstract]) OR (("selective"[Title/Abstract] OR "non-selective"[Title/Abstract] OR "stepwise"[Title/Abstract] OR "complete"[Title/Abstract]) AND "caries removal"[Title/Abstract]) (n=8,054)
#3	"Clinical Trial, Phase III" [Publication Type] OR Clinical Trial[Publication Type] OR Randomized Controlled Trial[Publication Type] OR ((randomized OR randomised OR controlled OR clinical OR pilot) AND (trial* OR study)) OR ("phase 3"[Title/Abstract] OR "phase3"[Title/Abstract] OR "phase-3"[Title/Abstract] OR "phase III"[Title/Abstract] OR P3[Title/Abstract] OR "PIII"[Title/Abstract]) (n=5,441,108)

n - number of hits, WoS - Web of Science Core Collection, SciELO - SciELO Citation Index, KCI - Korean Citation Index, TS - Topic (article title, abstract and keywords)

Table S2. List of Excluded Studies and Reasons for Exclusion

ELIGIBILITY CRITERIA

Inclusion criteria

Vital pulp therapy randomized clinical trials (including studies with no pulp exposure but deep caries treatment, such as selective caries removal and indirect pulp capping) published until 31-12-2019 (before publication of PRIRATE guidelines).

Exclusion criteria

1. Studies published after 31/12/2019: these studies have been excluded during the screening stage (Title/Abstract screening) based on our joint agreement to exclude the possibility of any influence of the PRIRATE guidelines that were published in 2020 on the reporting quality of the studies.

2. Studies published before the first CONSORT guidelines published in 1996: these studies have been excluded during the screening stage (Title/Abstract screening). Elaboration: since no consolidated reporting guidelines for RCTs were available before 1996, it is not justified to appraise studies using the PRIRATE items when published before 1996.

3. Studies that, after full text assessment, did not fulfill the criteria to be considered as randomized clinical trials.

4. Studies that after full text assessment were considered to not meet the basic methodological standards of RCTs (e.g., critical methodological flaws, such as, no randomization reported, extremely low sample size N≤10).

5. Duplicate publication (not detected during deduplication process due to publication in different journal and/or with slightly altered title).

6. Non-English written manuscripts: these studies have been excluded during the screening stage (Title/Abstract screening).

List of excluded articles during eligibility assessment of full text manuscripts **(with reason)**

1. Mente J, Hufnagel S, Leo M, Michel A, Gehrig H, Panagidis D, Saure D, Pfefferle T. Treatment outcome of mineral trioxide aggregate or calcium hydroxide direct

pulp capping: long-term results. J Endod. 2014 Nov;40(11):1746-51. doi: 10.1016/j.joen.2014.07.019. Epub 2014 Sep 13. PMID: 25227216. (**reason for exclusion: 3**).

2. Mente J, Geletneky B, Ohle M, Koch MJ, Friedrich Ding PG, Wolff D, Dreyhaupt J, Martin N, Staehle HJ, Pfefferle T. Mineral trioxide aggregate or calcium hydroxide direct pulp capping: an analysis of the clinical treatment outcome. J Endod. 2010 May;36(5):806-13. doi: 10.1016/j.joen.2010.02.024. PMID: 20416424. (**reason for exclusion: 3**).

3. Hegde S, Sowmya B, Mathew S, Bhandi SH, Nagaraja S, Dinesh K. Clinical evaluation of mineral trioxide aggregate and biodentine as direct pulp capping agents in carious teeth. J Conserv Dent. 2017 Mar-Apr;20(2):91-95. doi: 10.4103/0972-0707.212243. PMID: 28855754; PMCID: PMC5564251. (**reason for exclusion: 4**).

4. Aminov L, Salceanu M, Hamburda T, Giuroiu C, Vataman M. Comparative study on vitality preservation of young permanent teeth using bioactive materials. Romanian J Oral Rehab 2014. (**reason for exclusion: 4**).

5. Eftimoska et al. Clinical and histological analyzes of the response of the pulp after its direct capping with Calxyl, MTA and Biodentine. Research Journal of Pharmaceutical, Biological and Chemical Sciences 2015 (**reason for exclusion: 4**).

6. Moritz A, Schoop U, Goharkhay K, Sperr W. The CO2 laser as an aid in direct pulp capping. J Endod. 1998 Apr;24(4):248-51. doi: 10.1016/S0099-2399(98)80106-4. PMID: 9641128. (**reason for exclusion: 5**).

7. Safwat O, Elkateb M, Dowidar K, Salam HA, El Meligy O. Microbiological Evaluation of Ozone on Dentinal Lesions in Young Permanent Molars using the Stepwise Excavation. J Clin Pediatr Dent. 2018;42(1):11-20. doi: 10.17796/1053-4628-42.1.3. Epub 2017 Sep 22. PMID: 28937899. (**reason for exclusion: 4**).

8. Yazdanfar I, Gutknecht N, Franzen R. Effects of diode laser on direct pulp capping treatment: a pilot study. Lasers Med Sci. 2015 May;30(4):1237-43. doi: 10.1007/s10103-014-1574-8. Epub 2014 Apr 23. PMID: 24756324. (**reason for exclusion: 4**).

9. Maltz M, Henz SL, de Oliveira EF, Jardim JJ. Conventional caries removal and sealed caries in permanent teeth: a microbiological evaluation. J Dent. 2012

Sep;40(9):776-82. doi: 10.1016/j.jdent.2012.05.011. Epub 2012 Jun 2. PMID: 22664566.(**reason for exclusion: 3**).

10. Leksell E, Ridell K, Cvek M, Mejàre I. Pulp exposure after stepwise versus direct complete excavation of deep carious lesions in young posterior permanent teeth. Endod Dent Traumatol. 1996 Aug;12(4):192-6. doi: 10.1111/j.1600-9657.1996.tb00513.x. PMID: 9028183. (**reason for exclusion: 2; it was a borderline case as it had been accepted for publication in 1995-confirmed after full text retrieval, hence excluded**).

Table S3. List of RCTs included in the current study

1. Ali AH, Koller G, Foschi F, Andiappan M, Bruce KD, Banerjee A, et al. Self-Limiting versus Conventional Caries Removal: A Randomized Clinical Trial. J Dent Res. 2018 Oct;97(11):1207–13.

2. Arafa A, Kenawi LMM, Issa N. Assessment of reparative hard tissue formation after direct pulp capping with Biodentine versus mineral trioxide aggregate. Endod Pract Today. 2019 Fall;13(3):227–36.

3. Asgary S, Eghbal MJ. The effect of pulpotomy using a Calcium-Enriched Mixture cement versus one-visit root canal therapy on postoperative pain relief in irreversible pulpitis: a randomized clinical trial. Odontology. 2010 Jul;98(2):126–33.

4. Asgary S, Eghbal MJ. Treatment outcomes of pulpotomy in permanent molars with irreversible pulpitis using biomaterials: A multi-center randomized controlled trial. Acta Odontol Scand. 2013 Feb;71(1):130–6.

5. Asgary S, Eghbal MJ, Fazlyab M, Baghban AA, Ghoddusi J. Five-year results of vital pulp therapy in permanent molars with irreversible pulpitis: a non-inferiority multicenter randomized clinical trial. Clin Oral Investig. 2015 Mar;19(2):335–41.

6. Asgary S, Eghbal MJ, Ghoddusi J, Yazdani S. One-year results of vital pulp therapy in permanent molars with irreversible pulpitis: an ongoing multicenter, randomized, non-inferiority clinical trial. Clin Oral Investig. 2013 Mar;17(2):431–9.

7. Asgary S, Eghbal MJ, Ghoddusi J. Two-year results of vital pulp therapy in permanent molars with irreversible pulpitis: an ongoing multicenter randomized clinical trial. Clin Oral Investig. 2014 Mar;18(2):635–41.

8. Asgary S, Hassanizadeh R, Torabzadeh H, Eghbal MJ. Treatment Outcomes of 4 Vital Pulp Therapies in Mature Molars. J Endod. 2018 Apr;44(4):529–35.

9. Awawdeh L, Al-Qudah A, Hamouri H, Chakra RJ. Outcomes of Vital Pulp Therapy Using Mineral Trioxide Aggregate or Biodentine: A Prospective Randomized Clinical Trial. J Endod. 2018 Nov;44(11):1603–9.

10. Banomyong D, Messer H. Two-year clinical study on postoperative pulpal complications arising from the absence of a glass-ionomer lining in deep occlusal resin-composite restorations. J Investig Clin Dent. 2013 Nov;4(4):265–70.

11. Bjørndal L, Fransson H, Bruun G, Markvart M, Kjældgaard M, Näsman P, et al. Randomized Clinical Trials on Deep Carious Lesions: 5-Year Follow-up. J Dent Res. 2017 Jul;96(7):747–53.

12. Bjørndal L, Reit C, Bruun G, Markvart M, Kjældgaard M, Näsman P, et al. Treatment of deep caries lesions in adults: randomized clinical trials comparing stepwise vs. direct complete excavation, and direct pulp capping vs. partial pulpotomy. Eur J Oral Sci. 2010 Jun;118(3):290–7.

13. Brizuela C, Ormeño A, Cabrera C, Cabezas R, Silva CI, Ramírez V, et al. Direct Pulp Capping with Calcium Hydroxide, Mineral Trioxide Aggregate, and Biodentine in Permanent Young Teeth with Caries: A Randomized Clinical Trial. J Endod. 2017 Nov;43(11):1776–80.

14. Cengiz E, Yilmaz HG. Efficacy of Erbium, Chromium-doped:Yttrium, Scandium, Gallium, and Garnet Laser Irradiation Combined with Resin-based Tricalcium Silicate and Calcium Hydroxide on Direct Pulp Capping: A Randomized Clinical Trial. J Endod. 2016 Mar;42(3):351–5.

15. Chailertvanitkul P, Paphangkorakit J, Sooksantisakoonchai N, Pumas N, Pairojamornyoot W, Leela-Apiradee N, et al. Randomized control trial comparing calcium hydroxide and mineral trioxide aggregate for partial pulpotomies in cariously exposed pulps of permanent molars. Int Endod J. 2014 Sep;47(9):835–42.

16. Corralo DJ, Maltz M. Clinical and Ultrastructural Effects of Different Liners/Restorative Materials on Deep Carious Dentin: A Randomized Clinical Trial. Caries Res. 2013;47(3):243–50.

17. Durmus N, Tok YT, Kaya S, Akcay M. Effectiveness of the ozone application in two-visit indirect pulp therapy of permanent molars with deep carious lesion: a randomized clinical trial. Clin Oral Investig. 2019 Oct;23(10):3789–99.

18. El Meligy OAS, Avery DR. Comparison of mineral trioxide aggregate and calcium hydroxide as pulpotomy agents in young permanent teeth (apexogenesis). Pediatr Dent. 2006 Oct;28(5):399–404.

19. Eppa HR, Puppala R, Kethineni B, Banavath S, Kanumuri PK, Kishore GVS. Comparative Evaluation of Three Different Materials: Mineral Trioxide Aggregate, Triple Antibiotic Paste, and Abscess Remedy on Apical Development of Vital Young Permanent Teeth. Contemp Clin Dent. 2018 Jun;9(2):158–63.

20. Galani M, Tewari S, Sangwan P, Mittal S, Kumar V, Duhan J. Comparative Evaluation of Postoperative Pain and Success Rate after Pulpotomy and Root Canal Treatment in Cariously Exposed Mature Permanent Molars: A Randomized Controlled Trial. J Endod. 2017 Dec;43(12):1953–62.

21. Ghoddusi J, Shahrami F, Alizadeh M, Kianoush K, Forghani M. Clinical and radiographic evaluation of vital pulp therapy in open apex teeth with MTA and ZOE. N Y State Dent J. 2012;78(3):34–8.

22. Hilton TJ, Ferracane JL, Mancl L. Comparison of CaOH with MTA for Direct Pulp Capping: A PBRN Randomized Clinical Trial. J Dent Res. 2013 Jul;92(S7):S16–22.

23. Jang Y, Song M, Yoo IS, Song Y, Roh BD, Kim E. A Randomized Controlled Study of the Use of ProRoot Mineral Trioxide Aggregate and Endocem as Direct Pulp Capping Materials: 3-month versus 1-year Outcomes. J Endod. 2015 Aug;41(8):1201–6.

24. Kang CM, Sun Y, Song JS, Pang NS, Roh BD, Lee CY, et al. A randomized controlled trial of various MTA materials for partial pulpotomy in permanent teeth. J Dent. 2017 May;60:8–13.

25. Katge FA, Patil DP. Comparative Analysis of 2 Calcium Silicate-based Cements (Biodentine and Mineral Trioxide Aggregate) as Direct Pulp-capping Agent in Young Permanent Molars: A Split Mouth Study. J Endod. 2017 Apr;43(4):507–13.

26. Keswani D, Pandey RK, Ansari A, Gupta S. Comparative Evaluation of Platelet-rich Fibrin and Mineral Trioxide Aggregate as Pulpotomy Agents in Permanent Teeth with Incomplete Root Development: A Randomized Controlled Trial. J Endod. 2014 May;40(5):599–605.

27. Khokhar M, Tewari S. Outcomes of Partial and Complete Caries Excavation in Permanent Teeth: A 18 Month Clinical Study. Contemp Clin Dent. 2018 Sep;9(3):468–73.

28. Kumar V, Juneja R, Duhan J, Sangwan P, Tewari S. Comparative evaluation of platelet-rich fibrin, mineral trioxide aggregate, and calcium hydroxide as pulpotomy agents in permanent molars with irreversible pulpitis: A randomized controlled trial. Contemp Clin Dent. 2016 Dec;7(4):512–8.

29. Kundzina R, Stangvaltaite L, Eriksen HM, Kerosuo E. Capping carious exposures in adults: a randomized controlled trial investigating mineral trioxide aggregate versus calcium hydroxide. Int Endod J. 2017 Oct;50(10):924–32.

30. Labib ME, Hassanein OE, Moussa M, Yassen A, Schwendicke F. Selective versus stepwise removal of deep carious lesions in permanent teeth: a randomised controlled trial from Egypt-an interim analysis. BMJ Open. 2019 Sep;9(9):e030957.

31. Maltz M, Garcia R, Jardim JJ, de Paula LM, Yamaguti PM, Moura MS, et al. Randomized Trial of Partial *vs*. Stepwise Caries Removal: 3-year Follow-up. J Dent Res. 2012 Nov;91(11):1026–31.

32. Maltz M, Jardim JJ, Mestrinho HD, Yamaguti PM, Podesta K, Moura MS, et al. Partial Removal of Carious Dentine: A Multicenter Randomized Controlled Trial and 18-Month Follow-Up Results. Caries Res. 2013;47(2):103–9.

33. Maltz M, Koppe B, Jardim JJ, Alves LS, de Paula LM, Yamaguti PM, et al. Partial caries removal in deep caries lesions: a 5-year multicenter randomized controlled trial. Clin Oral Investig. 2018 Apr;22(3):1337–43.

34. Moritz A, Schoop U, Goharkhay K, Sperr W. Advantages of a pulsed CO_2 laser in direct pulp capping:: A long-term in vivo study. Lasers Surg Med. 1998;22(5):288–93.

35. Nosrat A, Seifi A, Asgary S. Pulpotomy in caries-exposed immature permanent molars using calcium-enriched mixture cement or mineral trioxide aggregate: a randomized clinical trial. Int J Paediatr Dent. 2013 Jan;23(1):56–63.

36. Özgür B, Uysal S, Güngör HC. Partial Pulpotomy in Immature Permanent Molars After Carious Exposures Using Different Hemorrhage Control and Capping Materials. Pediatr Dent. 2017 Oct;39(5):364–70.

37. Parinyaprom N, Nirunsittirat A, Chuveera P, Lampang SN, Srisuwan T, Sastraruji T, et al. Outcomes of Direct Pulp Capping by Using Either ProRoot Mineral Trioxide

Aggregate or Biodentine in Permanent Teeth with Carious Pulp Exposure in 6-to 18-Year-Old Patients: A Randomized Controlled Trial. J Endod. 2018 Mar;44(3):341–8.

38. Qudeimat MA, Barrieshi-Nusair KM, Owais AI. Calcium Hydroxide vs. Mineral Trioxide Aggregates for Partial Pulpotomy of Permanent Molars with Deep Caries. Eur Arch Paediatr Dent. 2007 Jun;8(2):99–104.

39. Sharma S, Logani A, Shah N. Comparative efficacy of photo-activated disinfection and calcium hydroxide for disinfection of remaining carious dentin in deep cavities: a clinical study. Restor Dent Endod. 2014;39(3):195–200.

40. Singh S, Mittal S, Tewari S. Effect of Different Liners on Pulpal Outcome after Partial Caries Removal: A Preliminary 12 Months Randomised Controlled Trial. Caries Res. 2019;53(5):547–54.

41. Song M, Kang M, Kim HC, Kim E. A Randomized Controlled Study of the Use of ProRoot Mineral Trioxide Aggregate and Endocem as Direct Pulp Capping Materials. J Endod. 2015 Jan;41(1):11–5.

42. Suhag K, Duhan J, Tewari S, Sangwan P. Success of Direct Pulp Capping Using Mineral Trioxide Aggregate and Calcium Hydroxide in Mature Permanent Molars with Pulps Exposed during Carious Tissue Removal: 1-year Follow-up. J Endod. 2019 Jul;45(7):840–7.

43. Taha NA, Khazali MA. Partial Pulpotomy in Mature Permanent Teeth with Clinical Signs Indicative of Irreversible Pulpitis: A Randomized Clinical Trial. J Endod. 2017 Sep;43(9):1417–21.

44. Uesrichai N, Nirunsittirat A, Chuveera P, Srisuwan T, Sastraruji T, Chompu-Inwai P. Partial pulpotomy with two bioactive cements in permanent teeth of 6-to 18-year-old patients with signs and symptoms indicative of irreversible pulpitis: a noninferiority randomized controlled trial. Int Endod J. 2019 Jun;52(6):749–59.

45. Vural UK, Kiremitçi A, Gökalp S. Clinical assessment of mineral trioxide aggregate in the treatment of deep carious lesions. Niger J Clin Pract. 2017 May;20(5):600–4.

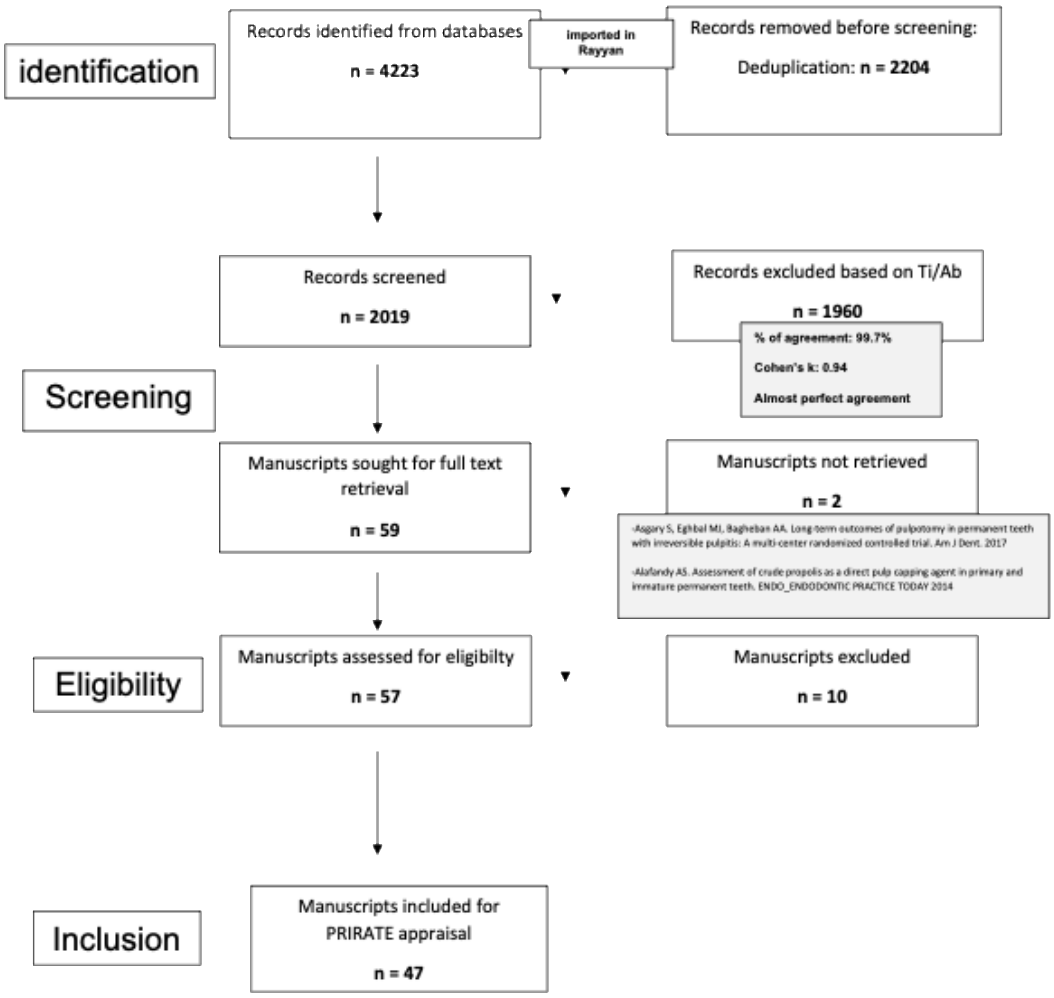
46. Vural UK, Kiremitçi A, Gökalp S. Randomized Clinical Trial to Evaluate MTA Indirect Pulp Capping in Deep Caries Lesions After 24-Months. Oper Dent. 2017 Oct;42(5):470–7.

47. Whitworth JM, Myers PM, Smith J, Walls AWG, McCabe JF. Endodontic complications after plastic restorations in general practice. Int Endod J. 2005 Jun;38(6):409–16.

Table S4. The most productive authors from 47 RCTs

Rank	Authors	Total number of RCTs (TRCTs)
1	ASGARY S	7
2	EGHBAL MJ	6
3	TEWARI S	5
4	GHODDUSI J	4
5	MALTZ M	4
6	DE PAULA LM	3
7	DUHAN J	3
8	JARDIM JJ	3
9	MESTRINHO HD	3
10	MOURA MS	3
11	SANGWAN P	3
12	YAMAGUTI PM	3

Figure 1. Study selection flowchart



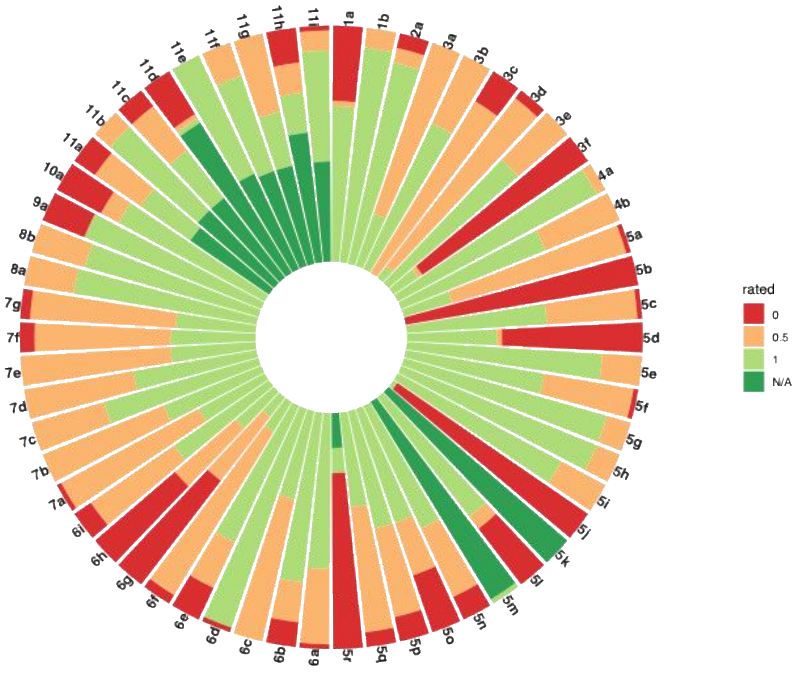


Figure 3

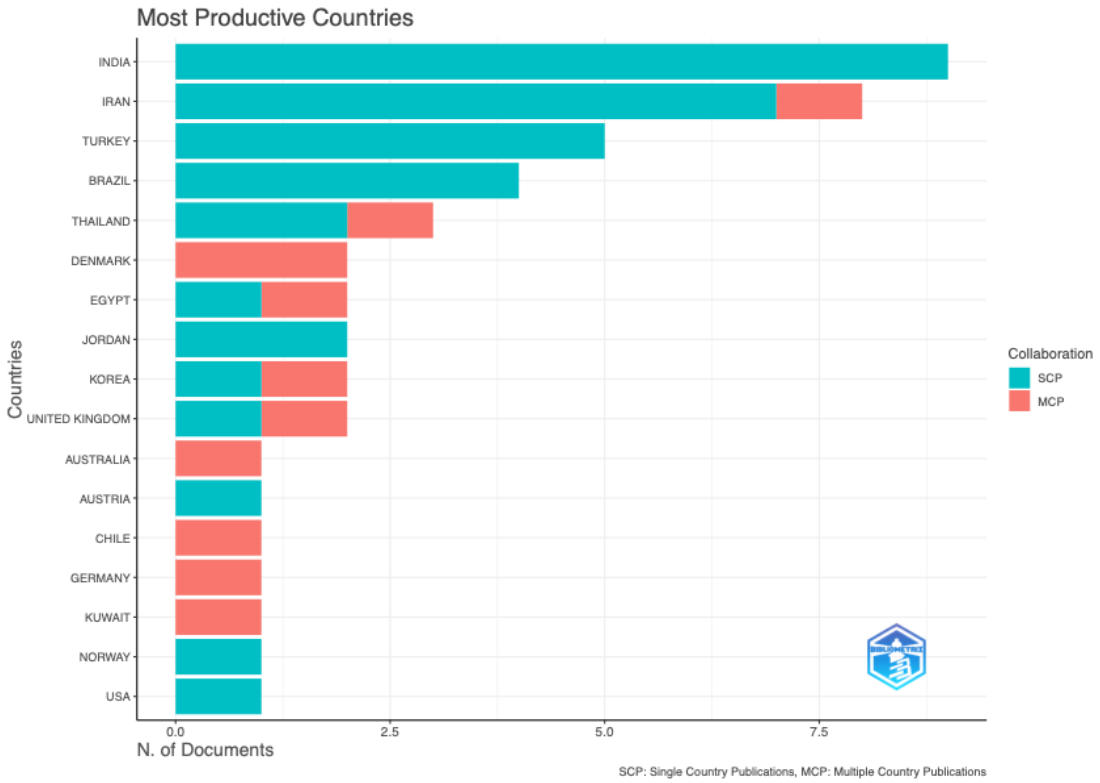

Most Productive Countries
INDIA
IRAN
TURKEY
BRAZIL
THAILAND
DENMARK
EGYPT
JORDAN
KOREA
UNITED KINGDOM
AUSTRALIA
AUSTRIA
CHILE
GERMANY
KUWAIT
NORWAY
USA
Countries
0.0
2.5
5.0
7.5
N. of Documents
Collaboration
SCP
MCP
SCP: Single Country Publications, MCP: Multiple Country Publications

Figure 4a


brazil
austria
thailand
iran
usa
india
turkey
chile
spain
norway

Figure 4b