EDITORIAL

Preferred Reporting Items for Diagnostic Accuracy Studies in Endodontics (PRIDASE): Guidance to improve manuscripts assessing the diagnostic accuracy of procedures, techniques and devices.

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Editorial

For centuries, diagnosis in Medicine and Dentistry has been considered more of an art than a science, an intuitive skill that could only be mastered by experienced clinicians. Indeed, it was considered impossible to develop standardized, practical, operationalized criteria. Understanding of the cognitive processes underlying diagnostic procedures have improved recently, and it is now recognized that rather than being mysterious, diagnostic proficiency is dependent largely on non-analytic pattern recognition (Loveday *et al.* 2013). This recognition is a product of practice and reflection, often largely subconscious, relating to feedback from earlier clinical trials. Not surprisingly, experience brings increased confidence and efficiency, but reliable scheme-based analytic strategies can also be learned by beginners (Coderre e*t al.* 2003), which is helpful when teaching students how to approach the complex task of diagnostics. Diagnostic algorithms based on commonly agreed disease definitions and operationalized diagnostic criteria are highly successful to correctly identify disease. In medicine, this is a major step forward as agreement on standardized diagnostic procedures has the potential to vastly improve research possibilities, similar to the way experimental interventions to treat disease follow strict methodological protocols in randomized clinical trials. That said, this approach is not without controversy, as differences in opinion remain on the exact characteristics of a certain condition, and also on the best approach to identify it.

Endodontics is struggling with the same issues. The endodontic diagnostic nomenclature, debated for many years, is ambiguous and lacks global consensus on specific criteria for common endodontic disorders. For example, the term *irreversible pulpitis* should mean that the level of pulp inflammation is such that pulp necrosis is inevitable and complete removal by pulpectomy or extraction is the only prescribed

therapy. Currently, the term is generally used simply as a clinical description of a set of specific signs and symptoms assumed to represent a severe state of inflammation in the entire pulp, which in reality does not necessarily reflect the differing levels of inflammation that may exist between the superficial (pulp horn) and deep (radicular) portions of the pulp. A comprehensive systematic review concluded that the scientific evidence is insufficient to determine if symptoms and signs (such as the presence, character and persistence of toothache) and response to stimuli (such as a heightened response to pulp testing or thermal provocation) can provide valid information about the true (histopathological) pulp status (Mejare *et al.* 2012). This would suggest that many pulps diagnosed as irreversibly inflamed could be managed conservatively and *vice versa*. On a clinical level, this may lead to systematic overtreatment (unnecessary root canal treatment [RCT]) and although the prognosis of RCT is good, unnecessary RCTs should be avoided, with data on a population basis indicating that about one tooth in ten is extracted within 5-6 years after RCT (Fransson *et al.* 2016). In addition, indiscriminate labeling of pulpitis as irreversible may lead to a lack of research focused on the development of innovative therapies for pulp preservation or on improved pulp diagnostics. These are compelling reasons why diagnostics need to be as accurate and precise as possible and in order to achieve this, studies investigating diagnostic accuracy need to be methodologically robust and meticulously reported.

It is likely that the lack of consensus between experts, clinicians and researchers is caused by a lack of evidence. To address this, endodontic researchers must start by systematically collecting the necessary data. One potential way forward is to identify a reliable diagnostic algorithm, similar to those in other medical areas. An example from dentistry is the Diagnostic Criteria for Temporomandibular Disorders (DC-

TMD) for pain-related diagnoses. Using a specific combination of anamnestic findings (the history) and clinical examinations, it is possible to correctly identify 80–86% of cases and 97–98% of non-cases with an inter-examiner reliability of ≥85% (Schiffman *et al*. 2014). However, this is not straightforward; a prerequisite for building a diagnostic algorithm with known predictive properties is that the diagnostic value of each item in the process must be known. Currently, there is a relative paucity of studies on diagnostic accuracy in Endodontics, with the majority of existing studies demonstrating a low quality of reporting compounded by methodological flaws. This may be due to many published studies having been undertaken at a time when there was little awareness of the effect of systematic errors on the reliability of the results. That said, it still means that for many of our current diagnostic methods there is a need to reassess their accuracy and reliability in various clinical populations, as well as developing new diagnostic tests. In addition, it is necessary to include the aspects of differential diagnostic value. A test designed to reveal a specific endodontic condition should ideally not only reliably distinguish between for example periapical disease and pulp disease, but also exclude all other conditions with overlapping clinical presentations, such as tooth pain due to TMD or post-traumatic trigeminal neuropathic pain, both known to mimic painful endodontic conditions (Wright 2000, Baad-Hansen 2008, Baad-Hansen *et al.* 2017).

The issue of the reporting quality of research manuscripts was brought into focus by the emergence of systematic reviews of the literature, with many journals now stipulating that authors follow and submit checklists. These may be generic or specific for the area of research such as, in Endodontics, the PRIRATE 2020 guidelines for randomized clinical trials (Nagendrababu *et al.* 2020a) based on the CONSORT 2010 guidelines (Schulz *et al.* 2010) and the Preferred Reporting items for OBservational studies in

Endodontics (PROBE) guidelines for observational studies in Endodontics (Nagendrababu *et al.* 2020b) based on STROBE *(*von Elm *et al.* 2007). As with all clinical studies, diagnostic accuracy studies are at risk of bias due to shortcomings in their design and conduct (Cohen *et al.* 2016). Some may be difficult to overcome; for example, in Endodontics the lack of a robust and clinically available non-invasive reference standard is particularly challenging. Another difficulty is the large variation in settings and patient groups. In this regard, patients present with a spectrum of signs and symptoms with few clear thresholds, and are affected by various levels of fatigue, systemic conditions and mental health states that affect their anamnestic descriptions (history) and responses to clinical testing. Indeed, great care must be taken to describe the population characteristics and prevalence of disease in order for readers to be able to determine if the results of the study can be extrapolated to their clinical practice, also with consideration of differential diagnostic aspects as described above.

A significant number of papers on diagnostic accuracy in Endodontics suffer from lack of transparency and completeness in reporting, meaning that the quality of the research itself is not possible to determine. Although guidelines for reporting mainly aim to improve the quality of manuscripts submitted for publication, they are also immensely helpful when designing a study in that systematic methodological errors can more easily be avoided. Being aware of flaws in the design of previous studies and taking care to minimize risk of bias can improve the quality of the research. To improve the completeness and transparency of diagnostic accuracy studies, the Standards for Reporting of Diagnostic Accuracy Studies (STARD) was developed in 2003 and updated in 2015, STARD 2015 (Bossuyt *et al*. 2015). Based on this, several specialized guidelines have been published, for example STARDdem (STARD for dementia; Cochrane Dementia

and Cognitive Improvement Group), STARD-BLCM (Standards for the Reporting of Diagnostic accuracy studies that use Bayesian Latent Class Models), and STRADAS-paraTB (Standards for Reporting of Animal Diagnostic Accuracy Studies for paratuberculosis) (Gardner *et al.* 2011, Noel-Storr *et al.* 2014, Kostoulas *et al.* 2017). In this issue of the *International Endodontic Journal*, the process being followed to develop *Preferred Reporting Items for Diagnostic Accuracy Studies in Endodontics* (PRIDASE) guidelines is presented, in which STARD 2015 is being modified and adapted to fit the nature of Endodontics whilst also incorporating the principles of *Clinical and Laboratory Images in Publication (CLIP)* (Lang e*t al*. 2012). The purpose of PRIDASE is to improve the accuracy, transparency, completeness and reproducibility of diagnostic accuracy study reporting in the specialty of Endodontology. We hope that studies on endodontic diagnostic accuracy in our field will benefit from clearer guidelines, and also that they will lead to future positive developments in the field of endodontic diagnostics. In general, the term "diagnostic accuracy" is often used interchangeably with "diagnostic efficacy" or "diagnostic efficiency". Hence, the term "diagnostic accuracy" will be used in all the documents related to the PRIDASE guidelines.

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