

Evidence-based Dental Practice: Part III. Critical Appraisal of the Literature, Relevance and Application of the Evidence

W. L. Adeyemo,¹ J. A. Akinwande,¹ B. O. Bamgbose²

¹Department of Oral & Maxillofacial Surgery,
College of medicine, University of Lagos.

²Department of Oral Pathology, Radiology and Medicinè,
College of Dentistry, University of Iowa, USA.

Correspondence: Dr. W. L. Adeyemo

ABSTRACT

Evidence-based dentistry involves defining a question focused on a patient-related problem and searching for reliable evidence to provide an answer. Once potential evidence has been found, it is necessary to determine whether the information is credible and whether it is useful in one's practice by using the technique of critical appraisal.

This article discusses the guidelines that have been developed to guide clinicians in assessing the validity and the relevance of published studies (randomized control trials, systematic reviews, cohort studies and case-control studies). The concept and tools of "critical appraisal" of published research works were developed by the evidence-based medicine group at McMaster University, Canada.

INTRODUCTION

The ability to make a sound clinical decision is based in large part on the quality of evidence that supports an accepted clinical practice and practitioner's ability to evaluate this evidence with regards to benefit, risks and appropriateness of the treatment options. Other factors that influence clinical decision making (for example, experience with similar therapeutic situations and the practitioner's level of clinical training) are important, but they rest heavily on the cumulative knowledge base that is integrated by the clinician in arriving at a decision.¹

Evidence-based dentistry involves defining a question focused on a patient-related problem and searching for reliable evidence to provide an answer. Once potential evidence has been found, it is necessary to determine whether the information is credible and whether it is useful in one's practice by using the technique of critical appraisal.² Once a research finding has been published, especially in respected peer-reviewed journals, it achieves a certain level of respectability and credibility. However, methodological research has shown that acceptance of the findings of many published studies is not always deserved.^{3,4} Hence, the need for critical appraisal of published evidence. The concept and tool of "critical appraisal" of published research works were developed by the evidence-based medicine group at McMaster University, Canada,^{2,5,6} and these are also applicable to evidence-based dental practice. Critical appraisal of the literature assists the reader in assessing the validity (closeness to the truth) and the relevance (applicability and usefulness in everyday practice) of research findings.

This article (part III in the series) discusses the concept of critical appraisal of the literature, the relevance and validity of research findings and tools for selecting the most appropriate therapy for clinical dental practice.

Critical Appraisal of the Literature

Once clinical evidence has been found in the literature, the clinician needs to decide if the results are believable and whether the findings can be applied to his/her patient. Assessing the *validity* (closeness to the truth) and the *relevance* (importance and usefulness of the findings, can I apply the findings in my practice?) of research findings is as important as searching for answers to clinical questions. As part of critical appraisal of the evidence, there is also a need to continually re-evaluate generally accepted clinical practices in light of emerging evidence and to base therapeutic decisions on the best available evidence, not to rely solely on expert opinion or the longevity of a clinical practice.¹ Persistence of a therapeutic approach that has been documented to be ineffective or unsafe is an irrational clinical practice.¹ For example, proneness of the mandibular angle to fracture in the presence of impacted lower third molars (ILTM) has long been a strong point for prophylactic removal of lower wisdom teeth, especially in adolescents and young adults who frequently play contact sports. In fact, there is incontrovertible evidence in the literature regarding the proneness of mandibular angle to being fractured in the presence of impacted lower third molars.⁷⁻¹⁰ One mechanism by which third molars have been hypothesized to increase the risk of angle fractures is by occupying osseous space and, thereby, weakening the angle region by decreasing the cross-sectional area of bone.⁷ However, recent emerging evidence suggests that the presence of incompletely erupted mandibular third molars diminished the incidence of condyle fractures.^{11,12} These recent findings^{11,12} suggest that when the mandible is traumatically injured in the absence of ILTM, more force is transmitted to the condylar region; and there is increased incidence of associated condylar fractures. What are the implications of the recent findings regarding the proneness of mandibular condyles being fractured in the absence of ILTMs to us as surgeons and health care providers? In terms of patients' care, mandibular angle fractures are easily accessible, and excellent reduction and stable fixation are easily performed with minimal postoperative complications.¹³ On the other hand, most surgeons would agree that condylar fracture is one of the most difficult to treat in the maxillofacial

region, and may be associated with malocclusion and facial nerve injury. Condylar fractures are usually more severe, are more difficult to treat, and have greater risk of long lasting complications than angle fractures.^{14,15} Is it appropriate to strengthen the mandibular angle region and to make the mandible more vulnerable to condylar fractures by means of removing an asymptomatic ILTM? Therefore, in the light of the emerging evidence, prophylactic removal of asymptomatic ILTM may not be beneficial as a means for reducing the chances of angle fracture in those patients at risk of maxillofacial trauma.

The first step in critical appraisal of the research findings is to critically assess the origin/source of the information:

- If it is a journal, is it a peer-reviewed journal? Does the journal belong to a reputable academic or association, postgraduate medical college, or university? What is the Impact Factor (IF) of the journal? Most of the reputable dental journals belong to one of the above mentioned institutions. For example, Journal of Oral and Maxillofacial Surgery is the official journal of the American Association of Oral and Maxillofacial Surgeons (AAOMS), while International Journal of Paediatric Dentistry is the official journal of the British Society of Paediatric Dentistry (BSPD) and the International Association of Paediatric Dentistry (IAPD). Implant Dentistry is the official journal of the International Congress of Oral Implantologists. Impact factor (IF), a tool created by the *Institute for Scientific Information* (ISI) is a mainstay tool in scientific publication to determine the impact of journals among scientific and medical communities. However, it has been shown that the IF is not well correlated with the quality scores published studies.¹⁶
- If it is a web-based source, is it a well recognized reputable source? Is the source regularly updated? Several academic centre sites generally feature many useful resources. These include not only ways to find valid, up-to-date clinical information, but also tools to help clinicians to learn to practice evidence-based care and to teach it to others. A good example of a well respected regularly updated web-based evidence-based source in medicine and dentistry is Cochrane Collaboration (www.cochrane.org).

In essence, the source (s) of information for evidence-based care must be sound and unquestionable.

The Concept and Tools of Critical Appraisal: The concept and tool of "critical appraisal" of published research works were developed by the evidence-based medicine group at McMaster University, Canada.^{2,5,6} For all intents and purposes these are also applicable to evidence-based dental practice. There are different techniques to evaluate and critically appraise research studies based on whether they are related to questions of therapy/preventive interventions, diagnosis, aetiology or prognosis.

Questions related to therapy and preventive interventions are best answered with randomized control trials or better still a systematic review/meta-analysis of randomized control trials.

Randomized controlled trials (RCTs): The following guidelines (questions) have been developed to assess the validity and the importance of a study about treatment or preventive interventions:^{2,17,18}

- *Was the allocation of patients to study group randomized?* Randomization ensures that treatment and control groups are similar at the outset and that differences at the end of the trial are due to the intervention and not to some "selection" factor.²

- *Were all the patients who entered the trial accounted for and analyzed at the end of the study?* Generally, follow-up of less than 80% of the patients enrolled at the beginning of the trial is considered unacceptable.⁵

- *Were patients, clinicians and study personnel "blinded"?* The greater the extent of blinding of all personnel, the more rigorous the trial.²

- *Were the groups similar at the outset and treated equally throughout the study?* The investigators should present baseline data on all patients in each group and if there are significant differences, assure the reader that these differences were adjusted for in the statistical analysis.

- *Were clinically important outcomes assessed?* Evidence-based practice is about making clinical decisions, so a clinically important outcome is one that is important to the patient. For example, a carious tooth that requires treatment is important to a patient; a cariogenic bacteria count generally is not.²

- *Can the results of the study be applied to my patients?* If the results can be generalized to your patients, it is important to consider if the benefit is greater than any potential harm, added cost or inconvenience. For example, open reduction and internal fixation (ORIF) is the gold standard for the treatment of maxillofacial fractures,¹⁹ but titanium plates and screws are not readily available in Nigeria due to technical and financial constraints.^{19,20} Previous Nigerian reports have, however attested to the satisfactory results obtained using simple conservative methods (arch bars and eyelet wires) of closed reduction and maxillo-mandibular fixation.^{20,21}

Systematic reviews/meta-analysis of RCTs: The following questions (guidelines) have been developed to judge the validity and usefulness of a systematic review/meta-analysis of RCTs:^{2,22,23}

- *Was a clearly stated questions asked?* A well focused question is the key element in systematic review.

- *Were the inclusion criteria appropriate?* Specific inclusion and exclusion criteria related to the population, intervention, outcome and acceptable study design must be well defined and clearly stated.²

- *Was a comprehensive literature search done and search strategy clearly stated?* It is important that all pertinent studies are included and that important ones have not been missed to make the findings as representative and comprehensive as possible.

- *Was the validity (quality) of the primary studies assessed?* This is important because, if many of the studies were weak, their combined results will not be believable.²

- *Was the assessment of the studies reproducible and free of bias?* To overcome bias, 2 or more authors of the review should perform each of review steps (inclusion criteria, validity and meaning of primary studies etc) independently, blind to each other's decisions, and then come to agreement by consensus.²

- *Were the results similar from study to study?* Similarity and variability (if any) of the studies should be stated.

- *Were the findings of the studies combined appropriately?* A systematic review can still be done if the studies can not be combined mathematically. However, if the study results are similar enough to combine mathematically, a meta-analysis is possible. One of the major advantages of meta-analysis is that the results of a number of small but similar studies can be combined to achieve a large enough sample to detect an effect.²

- *Were the authors' conclusions supported by the data?* Are the conclusions justified, given the methodological quality of the studies? Do the results and conclusion answer the original questions asked?

- *Most importantly, will the results help in caring for patients?*

Assessment of publications related to diagnosis, aetiology and prognosis

Assessing Diagnostic Tests: The most useful tests help to establish an accurate diagnosis, which supports the most appropriate treatment leading to the best outcome for the patient. The best tests are the ones that have high sensitivity and high specificity.²⁴ The guidelines below have been developed to judge the validity and usefulness of a diagnostic test.^{25,26}

- *Was the test compared blindly and independently with a "gold" standard?* A gold standard test is a well-established test that shows that a condition does or does not exist. For example, computerized tomography (CT) has replaced conventional radiography as "gold" standard in diagnosis of maxillofacial fractures because of higher sensitivity and specificity.

- *Was the test evaluated in a range of patient representative of a clinical practice setting?*

- *Did everyone who received the new test get the gold standard?*

- *Can the test be replicated in my practice?*

- *Do the results of the test apply to my patient?* Will the test have the same accuracy for my patients as for the study patients? Will the results change my treatment approach?

Assessing publications about aetiology: Understanding cause and effect relationship, particularly how they relate to harmful exposures, is important in the daily practice of dentistry.²⁴ It would be unethical to design a randomized trial to study a harmful exposure, so most often researchers have to rely on the next powerful design-the cohort study in which exposed and non-exposed patients are assembled, followed forward in time, and monitored for the outcome of interest.²⁴ The following guides help clinicians to critically appraise an article on aetiology or harm:

- *Were the comparison groups similar?* Besides exposure to the suspected causal agent, a number of other "confounding factors" can influence the outcome of a study. It is important that these factors be similar in the comparison groups.

- *Were the exposures and the outcomes measured in the same way in both groups?* Bias during measurement of either the exposure or the outcomes in cohort and case-control studies are minimized by blinding.

- *Did the exposure precede the outcome?*

- *Is there a dose-response relationship?* Increased quantity or duration of exposure should lead to an increased risk for or severity of outcome.

- *Does the association make sense?* Does the association make biological sense and is it in keeping with current understanding of the basic sciences?

- *Can I apply the results to my practice?*

Assessing publications about prognosis: The best research design for studying prognosis is the cohort study. In the event of rare outcomes or a lengthy duration from the first evidence of a prognostic factor to the development of the condition, a case-control design can be used, but the inferences that can be made from its findings are much weaker.²⁴ The following questions can help clinicians to decide if the results of a study of prognosis are valid and suitable:²⁸

- *Were the patients well described, representative and at a similar point in the development of their disease?*

- *Was follow-up sufficiently long and complete?* Loss to follow-up in clinical studies is an extremely important validity issue. One rule of thumb is to have serious reservations about the results of the study if more than 20% of the patients did not complete the study.²⁴ If the proportion of patients lost to follow-up is large and the proportion of remaining patients developing the adverse event is small, then the validity of the study is questionable.

- *Were the outcome criteria explicit and applied objectively?*

- *Were extraneous prognostic factors adjusted for?* Factors such as age and socioeconomic status can interfere with the assessment of prognosis. Therefore, the authors should state that these other variables have been adjusted for in the analysis.

- *Were the study patients similar to my own?* Will the results help to select or avoid therapy or provide advice for patients? Knowing the expected clinical course of a condition can help to decide if and when to intervene and what to tell the patient.

Relevance and Application of the Evidence

Assessment of the relevance of a published study relating to a given clinical question is a fundamental step in evidence-based practice. For example, after assessing the validity of a published study relating to therapy, the clinician (the end user) can make a reasonable judgement as to whether or not the results of the study are useful in the management of the patient problem at hand and may want to ask the following questions:

- Is the treatment option easily accessible?
- Is the treatment option affordable by the patient?
- Is the result generalizable to my patients?
- Is the result applicable and practicable in the light of resources available?

McMaster Online Rating of Evidence (MORE): A New Concept in Evidence-based Practice: A new concept in the assessment of relevance and application of published

studies to clinical practice is presently being pioneered by McMaster University, Canada. It is a Clinical Relevance Online Rating System called "McMaster Online Rating of Evidence" (MORE). As the name connotes, it is purely an online (web-based) rating of clinical evidence.²⁹ This concept was borne out of the fact that most articles in clinical journals are not appropriate for direct application by individual clinicians.³⁰ It is a second-order peer review of published literature by experts selected across various specialties to rate clinical articles (RCTs, cohort studies, case-control studies and systematic reviews) in their area of specialty. This is based on a 7-point relevance scale (highest point, 7) and 7-point newsworthiness (defined as useful new information for physicians) scale (<http://hiru.mcmaster.ca/More/RatingFormSample.htm>).²⁹ Although, no specialty of dentistry is presently included in "MORE" concept, it is hoped that as the concept expands, published articles related to dental therapy shall be included. However, there is a similar work on systematic reviews from the dental literature currently in progress by the American Dental Association (<http://www.ada.org/prof/resources/ebd/index.asp>). It is anticipated that these critical reviews will be online within the next year.

CONCLUSIONS:

Before a piece of evidence is admissible or accepted in evidence-based dental practice, it must go through a process of "critical appraisal" which has been developed by the evidence-based medicine group at McMaster University, Canada. However, in clinical practice it must be understood that sometimes one may not find any evidence supporting a given clinical question in the literature or there may be conflicting evidence. In fact, results of systematic reviews may be equivocal. In that case, common sense dictates that one should adhere to the existing methods/techniques in one's practice that is not injurious to the patient. The principles and philosophy of evidence-based practice rapidly are becoming established in all areas of health care. Therefore, this concept must be embraced by Nigerian medical and dental practitioners, health institutions and governmental agencies.

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