Evidence-based dentistry: A new dimension in oral health

H. N. Santosh1, Tejavathi Nagaraj1, Aditi Bose2, Pooja Sinha1, I. P. Mahalaksmi1

1Department of Oral Medicine and Radiology, Sri Rajiv Gandhi College of Dental Sciences, Cholanagar, Bengaluru, Karnataka, India, 2Department of Periodontology, Sri Rajiv Gandhi College of Dental Sciences, Cholanagar, Bengaluru, Karnataka, India

Abstract

The success of evidence-based medicine depends on the integration of the best research evidence. It is a blend of our patient’s unique values and circumstances with our clinical expertise. Evidence-based dentistry is a new paradigm in medicine, meaning that a therapy should be based on evidence gathered from scientific studies, preferentially based on randomized clinical trials involving a substantial number of patients. There are three main inter-related aspects to the practice of oral medicine. They are clinical care, research, learning, and teaching. Most of the oral diseases are complex, chronic problems that do not have definitive etiology. Many diagnostic tests are costly and need to be critically evaluated for their sensitivity, specificity and cost-benefit analysis. Most treatment protocols are opinion-based, and prognosis of many oral diseases is difficult to predict. Hence, practice of evidence-based health care in oral medicine will definitely be helpful when clinical decisions are made.

Keywords
Evidence based dentistry, meta-analysis, oral medicine, randomized control trial

Introduction

Evidence-based dentistry (EBD) is a new paradigm in medicine, meaning that a therapy should be based on evidence gathered from scientific studies, preferentially based on randomized clinical trials involving a substantial number of patients.

As good as this sounds in theory, it is not always easy to apply in daily practice.

The foundation for evidence-based practice was laid by David Sackett who has defined it as “integrating individual clinical expertise with the best available external clinical evidence from systematic research.”

- How to use EBD?[1]
  1. Create an answerable question
  2. Track down the best evidence to answer the question
  3. Critically appraise the information
  4. Apply the results to one’s patients
  5. Evaluate one’s performance.

Several points have to be addressed in order to apply EBD in dental practice:

- Dentists have to learn to manage the available amount of scientific literature in an efficient way
- Literature has to be available also for those who cannot easily read and understand articles written in a foreign language and full of specific jargon (for instance statistical terms)
- Scientific evidence is very fragmented, and synopsis articles are not available for all aspects of dental practice.

Not all aspects of dental practice can be easily examined by a randomized clinical trial for ethical or logistic reasons. In many dental offices, quality management to measure the outcome of the own therapy is not available.

However, all efforts should be undertaken to orient dental practice from a mechanistic tradecraft-oriented activity to one based on scientific reasoning and critical self-reflection.

The success of evidence-based medicine (EBM) depends on the integration of the best research evidence. It is a blend of our patient’s unique values and circumstances with our clinical expertise.

The American Dental Association (ADA) defines the term “EBD” as follows: EBD is an approach to oral health care needs of the patients that requires the judicious integration of systematic assessments of clinically relevant scientific evidence, relating to the patient’s oral and medical condition and history, with the dentist’s clinical expertise.

Evidence-based practice has been defined as the practice of dentistry that assists in clinical decision making by integrating the best available evidences with clinical experience and what a patient prefers (Figure 1).
Evidence Based Practice

It is a way of providing health care that is guided by a thoughtful integration of the best available scientific knowledge with clinical expertise.

In this approach, the practitioner critically assesses the research data, clinical guidelines, and other information resources. This is done in order to correctly identify the clinical problem, apply the most high-quality intervention and re-evaluate the outcome for future improvement.

What to expect from EBD?

The use of EBD may help in decreasing the variations of patient care and outcomes that appears to be related with four factors:

1. The value of science underlying clinical care
2. The quality in making clinical decisions
3. The deviations of the level of clinical skill
4. The large and increasing volume of literature.

Goals of EBD

The two main goals of EBD are the best evidence/research and the transfer of this in practical use.

This includes four basic phases:

- Enquiring evidence-based questions (framing an answerable question from a clinical problem)
- Probing for the best evidence
- Reviewing and critically evaluating the evidence
- Applying this information in a way to assist in clinical practice.

What is evidence?

Evidence has to be found in a well-defined manner, according to established procedures. The “keystone” of experimental technique in clinical sciences is the so-called prospective randomized controlled clinical trial.

The process starts with the formulation of a hypothesis (working hypothesis: Procedure A is better than procedure B) and a mutually exclusive null hypothesis (procedure A is equivalent to procedure B).

The experimental design is then chosen to test this hypothesis. In this experimental design, care must be taken to exclude as much as possible sources of error or “bias”. Before the start of the experiment, it has to be established WHAT shall be measured and to define the expected results (“outcome”).

A sufficient number of repetitions, samples or participating volunteers must be found as well as a technique to measure as precisely as possible the outcome.

Both groups must be equal in size and composition and volunteers (or samples) are allotted to one of the groups by chance (randomization).

Randomization is done preferably in a way that the observers (and in the case of human patients, the volunteers themselves) are not aware to which group they belong (blind or even double blind).

On the other hand, legal aspects largely preclude clinical studies to be performed in children. It is clear that not all clinical situations can be evaluated with sufficient precision due to the lack of funds, the lack of appropriate patients, sources of bias unsuspected at the start of the experiment or the ill-formulation of the working hypothesis.

Levels of Evidence (LOE)

The U.S. preventive services task force has developed a classification used for grading evidence about the effectiveness of treatments or screening:

Level I: Evidence found from at least one properly designed randomized controlled trial (RCT).

Level II-1: Evidence obtained from well-planned controlled trials without randomization. In these studies, samples of control and experimental group are not distributed randomly, either because of ethical or practical considerations.

Level II-2: Evidence attained from multiple time series with or without the intervention.

Levels III: Views of respected authorities, based on clinical experience, descriptive studies or reports of expert committees are included.

Oxford-based Center for EBM advocates LOE according to the study designs and critical appraisal of prevention, diagnosis, prognosis and therapy.

Level A: Consistent randomized controlled clinical trial, cohort study, clinical decision. Rule validated in different populations.
Level B: Consistent retrospective cohort, exploratory cohort, ecological study, outcomes research, case-control study or excerpts from level A studies.

Level C: Case-series study or extrapolations from level B studies.

Level D: Expert opinion without obvious critical appraisal, or based on physiology, bench research or first principles.

Steps in evidence-based research:
1. Asking answerable questions
2. Finding the best evidence
3. Critically appraising the evidence
4. Applying a decision
5. Evaluation.

Step 1:
- Asking answerable questions-focused, searchable, clinical
  - PICO\(^6\)
  - Patient, problem, population (subjects)
  - Intervention or therapy-may include coalition-building and/or collaborative programs (study groups)
  - Comparison, control, context (study groups)
  - Outcome (results).

Step 2:
- Finding the best evidence with which to answer the question through structured searches and to understand the literature
  - Primary studies
  - Clinical trials
  - RCT
  - Multicenter studies
- Secondary (synthesized, summarized) studies
  - Reviews
  - Meta-analyses.

Step 3:
- Critically appraising the evidence for its validity (closeness to the truth), impact (size of the effect) and applicability (usefulness in clinical practice)
  - Is it valid?
  - Is it important?
  - Can it help?

Step 4:
- Applying a decision-combining findings to make a recommendation, placing the evidence into context, incorporating recommendation into a specific patient situation, clinical setting or organization
  - How much will it help the patient or population?
  - Does it meet their values and goals?
  - Is it cost-effective?

Step 5:
- Evaluation-determining and measuring the effectiveness of the practice change over time
  - How could it be done better next time?
  - What is the outcome of using (or not using) particular information and its impact on clinical practice?

Studies: Research Design–Descriptive
- Investigator studies people and exposures in nature, observational
- No control or comparison group
- Studies.
  - Correlational-statistical association between variables
  - Case studies-new diseases and treatments, etc.
  - Case report-documenting research’s experience
  - Case series-following a group over time
  - Cross-sectional study—survey
  - Qualitative study—interview w/ open-ended question
  - Migrant studies.

Studies: Research Design-Observational Analytic
- Investigator collects data without making changes to patient’s life or introducing treatments
- Control/comparison group, not randomized
- Studies.
  - Case control-etiologic; examine associations between disease/disorder/health issue and one or more risk factors
  - Cohort study—measurement of one characteristic, outcome, or issues across two groups.
    - Prospective cohort
    - Retrospective cohort
    - Time series study.
  - Cross-sectional-to determine prevalence.

Studies: Research Design-Experimental\(^7\)
- Investigator chooses and tests an intervention, treatment or exposure:
  - The decision as to group distribution can be by either random or non-random methods
  - Control and/or comparison group are used
  - Note: Random allocation of subjects is used to reduce selection bias by investigator and to evenly allocate subjects on the basis of known and unknown characteristics.

Research Design-Experimental
- Studies
  - Clinical trials
    - Non-randomized trials (quasi-experiment)
      - Interrupted time series.
    - RCT
      - Double-blind randomized trial
      - Single-blind randomized trial
      - Non-blind trial
      - Crossover trial (may also be observational).
  - Community trials – conducted directly through doctors and clinics
  - Laboratory trials.
Studies: RCT

- Gold standard—especially for therapy studies
- Participants are randomly allocated into intervention (treatment) and control (placebo).
  - Phase I—Healthy subjects
  - Phase II—Small group
  - Phase III—Large group prior to marketing
  - Phases IV—post-marketing study.
- Rigorous evaluation of a single variable
- Seeks to falsify (rather than confirm) its own hypotheses
- PubMed MeSH: RCT (PT).

Meta-analysis\(^8\)

- Meta-analysis uses works consisting of studies using a quantitative method of combining the results of independent studies (usually drawn from the published literature) and synthesizing summaries and conclusions which may be used to evaluate therapeutic effectiveness, plan new studies, etc.
- A statistical analysis combining or integrating the results of several independent clinical trials is considered by the analyst to be “combines” when it is to the level of re-analyzing the original data, pooling and quantitative synthesis
- The ADA defines the process of EBD as follows:
  - Question—developing a clear question based on the patient’s clinical problem.
  - Find-finding the latest evidence through efficient searching for information.
  - Appraise—critically appraising the evidence to assess its value.
  - Act—acting on the evidence you find if appropriate and relevant to the clinical situation to provide treatment for the patients.
  - Evaluation—each aspect of the performance in this process can and should be evaluated as this is increasingly relevant with the development of continuing professional development.

Evidence-based learning and teaching: Learning theories\(^9\)

There are several theories on learning:
1. Behavioral—student is a passive recipient of knowledge, (i.e., “empty vessel” to be filled with the knowledge); transmission of known facts by the “dominant” teacher; this is how children learn (pedagogy)
2. Cognitive—the mind has cognitive faculties that can be developed over time
3. Experiential—based on one’s experiences; learning by doing.
   a. Lewinian model—concrete experiences lead to observation and reflection, forming abstract concepts, then testing these concepts in new settings
   b. Dewey’s model—a more explicit transformation of impulses and feelings of experiences into action.

EBP has generally embraced experiential learning, which is most like adult learning (andragogy), because:
- Adult learning typically encompasses internal motivation, learning what is not known (as opposed to facts)
- Learning by doing.
- However, EBP requires learning of research design and definition of terms, which encompasses behavioral and cognitive skills as well.

Teaching methodologies\(^10\)

Method 1:
- Self-directed online learning of foundation concepts
- Small group active learning exercises
- Large group discussion.

Method 2:
- Self-directed formation of PICO question, computer-based search, critical appraisal of the evidence
- Small group discussion of hypothetical patient cases.

Method 3:
- Self-directed formation of PICO question, computer-based search, critical appraisal of the evidence
- Small group discussion of actual patient cases.

Sources of evidence\(^11,12\)

- Primary sources: They are original research publications that have not been synthesized or filtered.
- Secondary sources are synthesized publications of primary literature. These include meta-analyses, systematic reviews, evidence-based articles, etc.
- Both primary and secondary sources can be found by conducting a search in Medline, EMBASE, Health STAR and the cumulative index to nursing and allied health.

Meta analyses\(^13,14\)

The first meta-analysis was done by Karl Pearson in 1904, in order to overcome the problem of reduced statistical power in studies with small sample sizes. Analyzing the results from a group of studies can allow more accurate data analysis. The advantages of meta-analysis compared with classical literature reviews, simple overall means of effect sizes etc., are as follows:
- If the results are other than what is expected from the sample diversity
- Derivation and statistical testing of overall factors and its effect on other values in related studies
- Simplification to the population of studies
- Ability for control between-study variation.

Meta-analysis is a statistical procedure for combining the findings from independent studies.

Meta-analysis is used in order to evaluate the clinical effectiveness of healthcare interventions. This is done by means of combining data from two or more RCT.

Meta-analysis of trials provides an exact estimate of treatment effect, giving equal weight to the size of the different studies included.
The validity of the meta-analysis depends on the quality of the systematic review on which it is based upon. An ideal meta-analyses aims for complete coverage of all the relevant studies look for the presence of heterogeneity and explore the robustness of the main findings using sensitivity analysis.

Clinical situation to understand EBD

E.g., Dental caries[16]
Asking answerable questions:
- PICO
  - Patient, problem, population (subjects)
  - Intervention or therapy-may include coalition-building and/or collaborative programs (study groups)
  - Comparison, control, context (study groups)
  - Outcome (results).
- Applying the best evidence
- Guidelines/consensus statements
- ADA-professionally-applied topical fluoride
- National institute for clinical excellence-recall interval between routine dental examinations
- Scottish intercollegiate guidelines network (SIGN) 83-intervention for prevention and management of dental caries in pre-school children
- SIGN 47-prevention of Dental Caries in Children at High Caries Risk -Targeted intervention for the prevention of dental caries in the permanent teeth in the age group of 6-16 years old presenting for dental care.
- Consensus Statement overview-diagnosis and management of dental caries throughout life.

Critically appraising the evidence[16]
- Cochrane review abstracts:
  - Antibiotic use for irreversible pulpitis
  - Combinations of topical fluoride (In the form of mouth rinses, toothpastes, gels and varnishes) versus single topical fluoride for preventing dental caries in children and adolescents
  - Complete or ultraconservative removal of decayed tissue in unfilled teeth
  - Fluoridated milk for preventing dental decay
  - Fluoride gels for preventing dental decay in children and adolescents
  - Fluoride mouth rinses as a preventive strategy for dental caries in children and adolescents
  - Fluoride toothpastes for preventing dental decay in children and adolescents
  - Fluoride varnishes to prevent dental caries in children and adolescents
  - Use of fluorides for the prevention of white spots on teeth during fixed brace treatment
  - Comparison of manual and powered tooth brushing for oral health
  - Use of one topical fluoride (in the form of toothpastes, mouth rinses, gels or varnishes) versus the other for preventing dental caries in children and adolescents
  - Ozone therapy for the treatment of dental decay
  - Pre formed metal crowns for carious primary molar teeth
  - Pulp therapy for extensive decay in primary teeth
  - Recall intervals for review of oral health in primary care patients
  - Incremental release of fluoride by slow-release fluoride devices for the control of dental decay.
- Applying a decision
  - How much will the decision help a patient or population?
  - Does it meet their required values and goals?
  - Is it a cost-effective measure?
- Evaluation
  - Ways in which it could it be done better next time?
  - What is the outcome of using (or not using) particular information and its impact on clinical practice?

EBD and Oral Medicine[17]

There are three main inter-related aspects to the practice of oral medicine.
- Clinical care
- Research
- Learning and teaching.
  - Most of the oral diseases are complex, chronic problems that do not have definitive etiology
  - Many diagnostic tests are costly and need to be critically evaluated for their sensitivity, specificity and cost benefit analysis
  - Most treatment protocols are opinion based, and prognosis of many oral diseases is difficult to predict. Hence, practice of evidence-based health care in oral medicine will definitely be helpful when clinical decisions are made
  - Most of the published evidence-based databases in oral medicine are available through;
    - Cochrane Organization
    - Clinical evidence
    - 4th World Workshop on oral medicine.
    - Cochrane collaboration has developed in response to late Archie Cochrane’s call for systematic up-to-date reviews of all relevant RCT of healthcare.

The Cochrane library consists of regularly updated collections of EBM databases. The following entries are of relevance to practice of oral medicine:
1. Methods of preventing oral candidiasis for patients receiving treatment for cancer
2. Interventions for treating oral lichen planus
3. Interventions for the treatment of burning mouth syndrome
4. Treatment strategies for oral leukoplakia
5. Avenues for treating oral mucositis in patients receiving treatment for cancer
6. Interventions for mucous membrane pemphigoid and epidermolysis bullosa acquista
7. Screening programs for prompt detection and prevention of oral cancer.

Clinical evidence is a monthly updated directory of evidence on the effects of common clinical interventions. It is published in
paper form every 6 months or is available electronically through “National Library for Health.”

From this NLeH site, we go to “search clinical evidence.” Here on the menu on the left side of the page are entries for the following conditions.
1. Ear, nose and throat disorders-acute sinusitis
2. Infectious diseases-post herpetic neuralgia
3. Neurological disorders-bells palsy, trigeminal neuralgia
4. Oral health-Aphthous ulcers-recurrent
5. Burning mouth syndrome, candidiasis.

Fourth World Workshop on oral medicine held in Puerto Rico in 2006 led to review of current understanding of ten topics.
a. Use of prophylactic antifungal in the immunocompromised host
b. Management of recurrent oral herpes simplex infections
c. Management of oral epithelial dysplasia: A review
d. Oral lichen planus and oral lichenoid reactions; diagnostic and therapeutic considerations
e. Management of neuropathic orofacial pain
f. Management of burning mouth syndrome; systematic review
g. Management of dental patients taking common hemostasis-altering medications
h. Management of oral lesions in HIV patients
i. Salivary dysfunction associated with systemic diseases: Systematic review and clinical management
j. Management of salivary hypofunction during and after radiotherapy.

Limitations[18]

As evidence from controlled randomized trials is regarded as the keystone of medical science, the concept bears some limitations. In order to achieve a maximal control, it can be either impossible to find a perfect match or the perfectly matched control group presents such a small difference with regards to the experimental group which on its turn makes it difficult to prove a hypothesis. Other limitations may be of organizational or ethical considerations.

Very rare conditions also preclude the application of EBM principles just because a sufficient number of cases cannot be found.

Then there are other, more down-to-earth reasons based on the functioning of research in the framework of institution and financing of research.

• Not all questions that deserve answering find somebody dedicated to do so by the lack of funding or the lack of somebody who defends the project in funding committees
• In dental science, evidence can be found in a general way (how long do posterior composite resin restorations last?), but not always for one specific product
• Product turn-over generally is faster that the process of setting up a clinical study, performing it, interpretation of the results, writing of the report and having it published.

The End of the Beginning: Conclusion

As of today, EBM remains a relatively young discipline whose positive impacts are just beginning to be proved. As several undergraduates, postgraduates and continuing medical education programs adopt and adapt it, there will be a continuous evolution of this knowledge process providing further information and understanding about what EBM is and is not. All of this will help in formulating definitive treatment plans to several oral diseases.

References