The Anecdotal Tradition and the Need for Evidence-Based Care for Temporomandibular Disorders

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Every effort should be made to treat according to scientific principles by avoiding anecdotal reports of therapeutic efficacy in favor of reliance on clinical research data obtained from randomized controlled trials of therapeutic approaches.[1p34]

Temporomandibular disorders (TMD) and other orofacial pain conditions include a broad range of unresolved problems for the dental profession and for the general public. Collectively, they are a significant health problem, with a prevalence comparable to other major dental diseases. Temporomandibular disorders themselves encompass a group of clinical problems that involve the masticatory musculature, the temporomandibular joints (TMJs), or both. Such conditions are considered to be a subclassification of musculoskeletal disorders and have been identified as a major cause of non-dental pain in the orofacial region. The most common presenting symptom is pain, which is frequently aggravated by chewing or other jaw function. The pain may also be accompanied by limited jaw movement, palpable muscle tenderness, joint soreness, or joint sounds. Furthermore, pain in the orofacial region can seriously interfere with an individual's quality of life.

Signs and symptoms of TMD may be associated with such TMJ conditions as osteoarthrosis, arthritis, or derangements of the articular disc, or with such masticatory muscle conditions as myofascial pain or myositis. Oral habits, such as bruxism, and their possible sequelae, such as excessive tooth wear or tooth mobility, may be related problems. In addition, behavioral and psychosocial factors have been associated with many of these disorders and must be given serious consideration when caring for such patients. This is especially important when the pain is chronic. Pain in the orofacial or craniofacial regions may also originate from dental, neurologic, otolaryngologic, vascular, metaplastic, or infectious diseases; that is, from non-TMD or musculoskeletal conditions.[2] All of these factors must be considered during the process of differential diagnosis. Thus, the care of patients with signs and symptoms of TMD or other types of orofacial pain requires an understanding and application of important aspects of medicine and clinical psychology, as well as of dentistry.

Key words: temporomandibular disorders, evidence-based, anecdotal

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The Issue

Although it is axiomatic that "optimal patient care depends on keen diagnostic acumen and thoughtful analysis of the trade-offs between the benefits and risks of tests and treatments,"[1p2] its fulfillment can be difficult in a multidisciplinary field, where many clinicians find themselves trying to contend with their patients' problems in the presence of controversial and conflicting ideas concerning etiology, diagnosis, and management.[3] The reasons for these controversies and conflicts are complex and are undoubtedly the result of many factors, including the history of the field itself. There can be little doubt that an overdependence on anecdotal reports of clinical success, coupled with a need for and application of scientific evidence, are very important factors. This situation was recognized by the 1997 U.S. National Institutes of Health Technology Assessment Conference on Management of Temporomandibular Disorders, which concluded that "there are no data to support some commonly held beliefs."[4p6]

This long-standing anecdotal tradition is certainly not unique to the field of TMD. However, other areas of dentistry and medicine have been making serious attempts to escape from, or at least reduce the influence of, this tradition. In the past, physicians did "what was best," whether or not scientifically credible evidence supported the diagnostic testing or therapeutic choices.[5] Now, physician decisions are expected to be based on credible scientific evidence. In other words, medicine has been evolving from "doing what seems best" to "knowing what is best."[5] In the field of TMD, however, the anecdotal tradition has persisted and has continued to influence many dentists' approaches to treatment.[6] This might imply that many clinicians who care for such patients do not adequately understand, appreciate, or apply the concept of evidence-based care. The question is, why?

Anecdotally based views, which range from outright "cultist" to what appear to be reasonable explanations based on observable results, are commonplace. Many made perfect sense in the context of the times, given the primacy of structurally related observations, the surgical/restorative nature of most dental treatment, and the absence of objectively derived clinical evidence. Furthermore, anecdotally based ideas are reinforced by clinical success which, in the case of TMD, is commonly observed and reported. However, although high success rates exist for many therapeutic modalities for TMD, their scientific bases are generally not well understood. It is also highly significant that, despite the fact that the literature is replete with claims of therapeutic successes,[6] diametrically opposed theoretical concepts with regard to their modes of action are frequently invoked. Such contradictions should make one very suspicious of the scientific foundation of any claim made in the absence of objective research data.[7]

It should also be remembered that clinical success, however noteworthy, is *not* scientific proof of cause and effect.[3] Before such claims can be made, there must be clear evidence that the treatment regimen has a specific therapeutic effect, in contrast to other possible mechanisms, such as placebo effects or cyclical remission of the signs and symptoms. This is especially true with regard to musculoskeletal disorders such as TMD. The issue of cyclical remission is particularly relevant in view of the number of publications that have reported that most patients' TMD signs and symptoms improve with time, with or without treatment.[8] This phenomenon, which is actually a form of "regression to the mean,"[6] has led many clinicians to believe that their particular mode of treatment was effective when, in actuality, the patient's signs and symptoms would have improved anyway.

No one can deny that the elimination or continued reduction of a patient's pain may be considered a success. However, it does not automatically follow from such success that the cause of the problem has been determined or that the answer to the treatment rendered is the answer to all patients with similar conditions. The sense of security that is derived from such experiences, which is actually anecdotal, is very gratifying. As Robbins stated, "Our enthusiasm for anecdotal information is narcotic in nature. It makes us feel good."[9] This tendency is compounded when so-called "expert opinion" is used as the sole basis for the development of concepts or points of view by individual clinicians. And when "expert opinion" is given by those with the most passion or with the largest platform, audience, or loyal following, the tendency is to further reinforce the predefined sense of certainty about the etiology, treatment, and biologic mechanisms underlying a disorder. However, if the field of TMD and orofacial pain is to be considered part of a true "learned profession," it is obligated to move from an anecdotal tradition to evidence-based care, or as Feussner defined it, "substituting credible evidence for what would previously be classified as expert opinion."[5]

Standards and Criteria of Scientific Evidence

There should be a scientific basis for establishing a treatment modality and testing its efficacy.[10p183]

Scientific evidence emanates from application of the scientific method, which is a mode of research in which a problem is identified, a hypothesis is formulated, relevant data are gathered through observation and experimentation, and the hypothesis is tested. According to Feussner,[5] 2 issues should be considered regarding the credibility of scientific evidence: The first is the level of evidence, and the second is the quality of evidence establishing treatment effectiveness. The level of evidence, as defined by the U.S. Preventive Services Task Force,[11] refers to its strength and is classified according to how the evidence was derived. For example, level III denotes "opinions of respected authorities, descriptive studies, or reports of expert committees" and is considered the weakest of the levels. Level I, on the other hand, is "evidence from at least one properly designed randomized controlled study." Rules of evidence necessary to establish therapeutic effectiveness determine the quality of scientific evidence and are derived from a traditional research paradigm.[5]

The 2 most important criteria for evaluating the merit of scientific evidence are *reliability* and *validity*.[12,13] *Reliability* refers to the ability to be repeated, which means that the measures being used to define and describe the phenomenon being studied, as well as the phenomenon itself, can be replicated. Evidence of reliability serves to minimize investigators' preconceived ideas and conscious or unconscious bias. Case reports and case series, although they may have value as research hypotheses, do not meet these requirements. Thus, although they can provide valuable insights into what is observed or "what works" under a particular set of circumstances, case reports cannot be taken as scientific evidence.

Validity means that the phenomenon is correct or real and has not occurred by chance. Testing for validity requires a testable hypothesis, objective measures, and appropriate controls. Controls are needed to show that any differences or changes in the phenomenon being studied are not the result of confounding variables. If, therefore, the phenomenon occurs equally in both groups, the research hypothesis or clinical premise is not valid.[12] A distinction should also be made between *technical* or *measurement validity*—which means that a procedure, technique, or measure accurately records some physical or biologic phenomenon—and *diagnostic validity*, which means that the recordings can actually be used to identify a particular condition and help to differentiate it from other conditions with similar characteristics. Evidence for diagnostic validity requires that the resultant clinical data yields acceptable levels of sensitivity and specificity, as well as positive and negative predictive values, as determined by decision matrix analysis.[2,14]

The first requirement of a clinical research study that is intended to evaluate treatment effectiveness is an explicitly stated hypothesis.[15] In other words, the research question or clinical premise must be clearly stated so that it can be answered after collection, analysis, and interpretation of the resulting data. To achieve objective data for subsequent analysis and interpretation, certain design features and criteria are required to determine whether or not the hypothesis or clinical premise is valid. The research protocol must allow for an outcome that is not confounded by uncontrolled variables and is not the result of chance. Thus, studies of the efficacy of a treatment or treatment regimen for TMD should meet contemporary scientific standards.

Among the factors that must be considered in planning a clinical research study or in evaluating the credibility of such a study are:

1. Use of predefined criteria or "gold standard" to allow for identification of individuals who have and do not have the disorder
2. An acceptable classification system based upon recognized inclusion and exclusion diagnostic criteria, such as the Research Diagnostic Criteria that have been developed for TMD[16]
3. Use of clinical trials or blind comparisons to control groups
4. Appropriate sample size determined by statistical power analysis
5. Evidence of acceptable intra-examiner and interexaminer reliability
6. A well-defined test population that is appropriate to the question and similar to "typical" patients, including a clinically relevant spectrum of mild and severe cases[5,15]
7. Random assignment of patients' treatments[5,15]
8. Data collection by "blinded" examiners to control for unintended bias
9. Control for potential confounding variables during design or analytic phases
10. Data analysis that accounts for all patients and subjects in the study[5,15]

11. Treatment interventions that are explicit enough to replicate and feasible in practice[5,15]
12. Validation of therapeutic effects by the use of well-accepted and quantifiable outcome measures that are clearly related to the patient's condition
13. Evidence that the modality has a specific therapeutic effect, in contrast to other possible mechanisms, such as cyclical remission of the signs and symptoms or placebo effects.[13]

Claims of efficacy should also be supported by evidence of whether the modality itself solely provides the therapeutic effect, or whether it must be supplemented by other types of therapy. It should also be accompanied by evidence that the therapy is safe and, as far as possible, cost-effective. In summary, scientific rigor is required to enhance the reliability and validity of the resulting evidence.[13]

Investigators and clinicians should also be prepared to consider alternate hypotheses or alternate explanations for phenomena that appear to be reliable and valid.[3,13,17] This approach is best accomplished by making strong efforts at disproving a research hypothesis or clinical premise instead of trying to prove it. Such an approach gives the investigator and clinician more confidence in the outcome of the study and, in the case of differential diagnosis, more confidence in the outcome of the diagnostic process.[3,7] This is known as "strong inference"[18] and is based on the concept that every investigator or clinician should ask, when hearing any scientific explanation or clinical premise:

> *On hearing any scientific explanation or theory, one should ask: "What experiment could disprove the hypothesis?"*
>
> *On hearing a scientific experiment described, one should ask: "What hypothesis does the experiment disprove?"*[18]

To avoid "labeling bias" of potential TMD patients, the concept of "disproof" should also be used during the process of differential diagnosis. Failure to do so has been shown to lead to "diagnostic errors" that are the result of clinical "self-fulfilling prophecies."[19] Thus, application of the principles of clinical decision-making can help to reduce uncertainty and thereby provide more confidence in the working diagnosis and in subsequent therapeutic options.[3,7]

Role of Dental Education

> *Dental Education must be scientifically based and undertaken in an environment in which the creation and acquisition of new scientific and clinical knowledge are valued and actively pursued.*[20p3]

The practicing dentist should be able to evaluate the claims and the evidence of any diagnostic or therapeutic concept or technique that may affect patient care to be assured of their scientific merit and clinical value.[13] Unfortunately, the dearth of problem-solving opportunities, analytic experiences, and training in the interpretation of scientific evidence in dental education almost assures a complete reliance on the views and opinions of others on the part of many, if not most, dental school graduates.[13] After graduation, clinicians are constantly exposed to new ideas, concepts, and opinions—not to mention the reinforcement of old ones—from a wide range of sources. In many instances, such information is promulgated by individuals, organizations, or companies that have a vested interest in the information that is imparted. The busy but scientifically unprepared practitioner, upon hearing such information, often comes to believe it as "fact," even if it is based on opinion or on incomplete or unsound evidence. In this manner, unscientific information becomes "truth," particularly when the clinician's ability to critically assess the information that is being espoused has never been developed.[3] A consequence of this is the frequent comment, "It works in my hands. Why isn't that good enough?"[21,22] As stated by Neidle, "It is no wonder that practicing dentists will adopt a method of treatment based on the testimonials of a colleague or on unpublished anecdotes and truly believe that they have made an informed decision based on professional judgment."[23p565]

Our dental educational system has been remiss, at all levels, in not teaching its graduates to read, understand, and critically assess scientific evidence to reduce their dependency on the interpretations of others.[3] As noted by Robbins, "the impact of anecdotal information on future decision-making will be diminished to the degree that discriminating cognitive skills are developed in the dental student."[9] Thus, graduates of dental institutions, although they may know many didactic "facts" and may be technically competent, are generally scientifically naive, the consequences of which are likely to be unfavorable over time.[24] It is no wonder, therefore, that instruction in the principles of evidence-based medicine is being advocated in dental education.[25]

All faculty who are engaged in the teaching of dentistry, at whatever level, should encourage each of their students to understand and appreciate the standards and criteria used in clinical research. This is important if the student is to learn how to evaluate the scientific merit of research evidence; interpret new and existing information in the professional literature, as well as from meetings, conferences, and continuing education courses; and to assess the applicability of such information to clinical practice. As with all teaching, this goal is best attained when the individual teacher is seen to have an inherent interest in clinical research, in addition to their requisite clinical ability. Thus, the dental faculty should be personally and actively engaged in ongoing research activities, which should be seen as an essential component of the educational mission, and not, as is too often the case, a distraction from that mission. In fact, faculty research and scholarship is considered vital to the overall academic, including the educational, mission of the university. Finally, if any further justification for faculty research is still needed, the statement by Flexner,[26] in his now-famous report on medical education in 1910, is still applicable. He wrote:

> *Educationally, then, research is required of the medical faculty because only research will keep teachers in condition. A nonproductive school, conceivably up to date today, would be out of date tomorrow; its dead atmosphere would soon breed a careless and unenlightened dogmatism . . . The person for whom there is no place in the medical (or dental) school, the university, or the college, is precisely he who has hitherto generally usurped the medical field—the scientifically dead practitioner, whose knowledge has long since come to a standstill and whose lectures, composed when he first took his chair, like pebbles rolling in a brook, get smoother and smoother as the stream of time washes over them.*[26p56–57]

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