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Selected Problems in the Use of Transcutaneous Electrical Nerve Stimulation for Pain Control—An Appraisal with Proposed Solutions

A Special Communication

MICHAEL F. NOLAN

The purposes of this communication are 1) to call attention to several problematic issues related to the use of transcutaneous electrical nerve stimulation for pain control and 2) to consider strategies for correcting existing problems and averting additional problems in the future. Specific problems within two general areas of difficulty are identified, and proposed solutions to these problems are presented. It is hoped that discussion of these issues will encourage comment and debate, bring about further objective and critical evaluation of the effectiveness and value of TENS for pain control, and lead to a clearer understanding of the responsibilities of manufacturers and users of this therapeutic modality.

Key Words: Delivery of health care; Health services misuse; Physical therapy profession; patient services, professional issues; Transcutaneous electrical nerve stimulation.

The treatment of disease or dysfunction by the application of electrical stimulation to the skin has been known for hundreds of years.\textsuperscript{1,2} The commercial development of this technique, however, into the various products we are currently familiar with is a relatively recent event. Within the last two decades, great strides have been made toward achieving technical reliability and enhancing therapeutic efficacy.

Specifically, the use of transcutaneous electrical nerve stimulation in the management of pain has evolved from a simple evaluative technique to a sophisticated therapeutic modality in its own right. During the last 20 years, TENS has become a frequently used treatment technique complete with manuals and guidelines for application, a cadre of proponents and critics, and a sizable literature characterized by theories, opinions, and claims concerning its mechanism of action and clinical effectiveness.

The purposes of this communication are 1) to identify situations and problems regarding TENS that have compromised or have the potential to compromise either the effectiveness of the modality or the image of the professionals who manufacture, market, and use it and 2) to offer several suggestions aimed at overcoming these problems. The successful resolution of these issues will facilitate progress toward the further development of this useful treatment modality.

GENERAL PROBLEM—INAPPROPRIATE AND POORLY CONTROLLED ACCESS TO TENS DEVICES

Patients currently are better informed about matters of health care and health care delivery than at any time in the past. Their familiarity with these issues is derived from various sources of varying reliability. Patients with pain as a major component of their disease frequently inquire about pain-relieving methods, and many are aware of the potential benefits of TENS. Many of these patients, particularly those suffering from chronic pain, may be very well informed and may report previous experiences with this modality. Upon further questioning, individuals may volunteer that they obtained a TENS unit from a sympathetic family member or friend who purchased the device for a condition that no longer exists or for which TENS is no longer helpful. Other patients may indicate that they purchased a TENS unit at a local pawnshop, garage sale, or flea market.

More troublesome is the fact that most patients who acquire TENS devices by inappropriate means have little knowledge of how to use them properly. Collectively, these observations are indicative of a situation in which TENS devices can be acquired with relative ease by unauthorized individuals and subsequently misused. By the term "misuse," I am suggesting the use of TENS devices for conditions for which they were not prescribed and by individuals other than those for whom they were prescribed.

SPECIFIC PROBLEMS—RISK OF PHYSICAL INJURY AND EROSION OF PATIENT ATTITUDES REGARDING TENS EFFECTIVENESS

The accessibility of TENS units through nonprescription or other inappropriate means may contribute directly to specific problems worthy of attention. These problems include an increased potential to cause harm as a result of self-initiated treatment and the development of refractory or skeptical attitudes toward the modality or the health care practitioners who use it.

The improper use of TENS characteristic of self-initiated and unsupervised experimentation with the modality can cause physical harm. Reports in the literature suggest that...
complications or injuries associated with TENS are uncommon and relatively minor in most cases.\(^4\) This conclusion, however, should be interpreted with caution, because it might simply reflect the fact that the vast majority of clinicians who use TENS do not contribute to the published literature. Alternatively, the low number of reported adverse effects might indicate that TENS is being used primarily for appropriate conditions by adequately trained and experienced personnel. Another explanation might be that to date an insufficient amount of work has been done in this important area. Clinicians, therefore, should not hastily draw conclusions about the safety of TENS based on the dearth of evidence of adverse effects in published reports.

A potentially more serious problem resulting from the self-initiated, unsupervised use of TENS concerns the effect this practice might have on the desired therapeutic results when the patient enters the health care system for treatment of the pain problem. In these cases, individuals may come to a physician or therapist with a preestablished belief that TENS does not work or at least does not work for them. This belief can easily exert a negative influence on patient compliance, not only with further TENS trials but also with other aspects of a multidimensional pain control program that might be considered appropriate. Important factors to bear in mind in this regard are the subjective nature of the pain experience, the potentially valuable placebo effect associated with the use of TENS, the effectiveness of the relationship between the patient and the therapist, and the motivation and willingness of the patient to actively participate in the overall treatment program.

Many patients optimistically view TENS like they view medications: as a modality that is fully expected to be successful in doing what it is purported to do. The numerous reports in the clinical literature, some reliable and some less so, clearly indicate that the effectiveness of TENS for pain control, even in carefully selected patients, is still open to question.\(^5\)–\(^10\) Many clinical studies contain insufficient information or methodological weaknesses that warrant a cautious interpretation of the results. Thus, the risk of obtaining unsatisfactory treatment outcomes is increased by using a pain control technique that has had a previous unsuccessful experience with. Contributing to this problem are the observations of behaviorally-oriented clinicians, some of whom argue that the long-term use of any modality, including TENS, might actually reinforce certain pain behaviors, thereby prolonging pain-related complaints and disability.\(^11\)

Most clinicians occasionally obtain unsatisfactory results in the treatment of difficult pain-related conditions. Staff members in multidisciplinary pain clinics are particularly cognizant of the problems associated with the treatment of patients with pain, some of whom have long and extensive histories characterized by multiple physician visits, polypharmacy, and repeated medical or surgical interventions, most or all of which were unsuccessful. It is difficult to determine the reasons for therapeutic failure in many of these cases, in addition to the variety of factors that motivate pain behavior and the efforts of the patient to seek or to avoid help. Patients with pain, and in particular chronic pain, however, represent a formidable challenge to the health care delivery system, a challenge that from a financial perspective the health care delivery system appears reasonably unsuccessful at dealing with.\(^12\) Because of the complex nature of pain and the well-known difficulties associated with its evaluation and treatment, and because of the uncertainty that currently exists regarding both the efficacy and mode of action of TENS, it is appropriate, and indeed wise, to carefully consider the potential negative impact that TENS misuse can have on treatment outcomes.

**PROPOSED SOLUTION**

The proposed solution is predicated on the belief that an unacceptable number of TENS units exist in the public domain that are not being used by the individuals for whom they were prescribed or that are being used in an inappropriate way. The objective of this proposal is to reduce the number of TENS devices available for misuse. To achieve this objective, it is suggested that policies be adopted and procedures be developed whereby TENS devices are no longer made available for sale to patients. Rather, given the nature of pain, our still incomplete understanding of it, and the potential for misuse, it is recommended that TENS devices be made available to patients on a lease or rental basis only and that TENS treatment be offered only as long as the modality provides effective therapeutic results that can be documented reliably. When TENS is determined by a qualified health care practitioner to no longer be effective for a particular patient or when it is considered to contribute to further behavioral disability, the modality should be discontinued immediately.

A restriction against the sale of TENS units to patients would eventually reduce the number of units available for misuse. Such a prohibition would also reduce or eliminate the profit-motivated practice of some health care professionals and corporations of indiscriminately selling TENS devices without adequate attention to the important issue of therapeutic efficacy.

Regulations governing the leasing or rental of TENS units should include provisions for mandatory, periodic reevaluation of patients to ascertain whether the TENS unit is providing pain relief, and thus may be continued, or whether it no longer is therapeutically effective and should be recalled. Because the effective working lifetime of a rental TENS unit would be longer than that of a unit that is used for a period of time and then put away, rental costs could be reduced to a level more in line with actual production costs. Health care expenditures within a more closely regulated system would be less than the current costs for TENS therapy, which include both rental and purchase. A major benefit of this approach would be a reduction in the potential for harm associated with misuse of TENS devices.

Certainly, this proposal will require attitudinal as well as behavioral changes on the part of both the health care community and the manufacturers and retailers of TENS devices. Moreover, these recommendations might not be warmly embraced in all quarters of the health care delivery system, particularly in those where profit loss might be a result of greater control over TENS usage. A persistent belief prevails, however, that considerable and needless abuse currently exists in the system and that changes, perhaps in line with those presented in this proposal, might be in the long-term best interest of the patients, the economy, and the health care delivery system.

If, as a counterargument, proponents of the status quo suggest that the modality is essentially innocuous and therefore does not warrant further regulation, then perhaps a proposal that TENS devices be sold without a prescription...
should be advanced. Such a proposal would permit the marketplace to determine the retail price of TENS devices and would allow patients themselves to determine whether they wish to use the modality. Although it is beyond the scope of this communication, it might be worthwhile to speculate as to the impact legal deregulation might have on the clinical efficacy of the modality and on the organization and operation of the TENS industry.

GENERAL PROBLEM—HIGH COST AND LIMITED EFFICACY OF TENS IN PAIN MANAGEMENT

The use of TENS in the treatment of pain has increased during the past two decades as evidenced by the growing number of manufacturers and retailers of TENS devices. During this time period, thousands or perhaps tens of thousands of TENS devices have been sold to patients at a cost of several hundred dollars each. Although industry-wide figures are not available, it is generally accepted that several million dollars have been spent on the purchase or rental of TENS devices and associated supplies. These costs have primarily been absorbed by insurance carriers; however, numerous TENS devices have been purchased by patients out of pocket. Justification for these expenditures is based on the belief that the devices, when properly and appropriately used, produce the results they are designed to produce. In addition to being valid and reliable, evidence supporting claims of efficacy must be available to those vested with the responsibility to authorize payments and reimbursements for the purchase of TENS devices. Thus, the issues of cost and clinical efficacy are closely related.

In this regard, numerous questions can be raised about the data used to support claims concerning the validity and reliability of TENS for pain control. Concern may also be expressed regarding the way in which these reports are used to justify expenditures for this mode of therapy.

SPECIFIC PROBLEM—VALIDITY AND RELIABILITY OF TENS

The scholarly literature concerning the use of TENS for pain control documents the collective efforts of many individuals who have attempted to develop protocols for its use, establish proof of its clinical efficacy, and understand its mechanisms of action. To be of value, the literature must be based on studies of sound design, using reliable methods and valid techniques. Currently, over 400 articles have been published that deal with the subject of TENS. The majority of these articles are clinical studies on case reports. Most of these articles argue that TENS is an effective modality in the treatment of pain, although some suggest that TENS is without effect.13–16

Two major methodological weaknesses, which threaten the validity and reliability of the reported results, appear repeatedly in the TENS literature. These weaknesses are the use of inappropriate or unproven techniques and methods and the failure to provide sufficient information in the written report to permit the reader to either replicate the original work or place confidence in the conclusions drawn from the results. Concerning proposed mechanisms of action, the TENS literature, particularly that provided by manufacturers, is characterized by an apparent misuse or careless interpretation of the basic neuroscience literature. Information provided by TENS manufacturers, which is used in marketing, frequently blurs the distinction between theory or hypothesis and fact.

Moreover, contemporary authors generally appear to be unaware of or unfamiliar with the large number of published works dealing with TENS.17 A growing number of authors present the results of their experiences with TENS as if they were new when a thorough review of the literature would have revealed that similar or identical results had been reported previously. The net effect of a lack of rigor in the review, conduct, and reporting of research on TENS is the development of a literature that contributes little to the establishment of its validity and worth. A weak or misleading literature can effectively inhibit or prevent a useful modality from being properly accepted or wrongly encourage the use of an ineffective modality.

Questions concerning the efficacy of TENS for pain control are difficult to answer. Adding to this difficulty is the almost indiscriminate application of TENS to heterogeneous populations of patients with pain. The list of pain conditions that have been treated with TENS is impressive in its length and continues to grow. The literature contains reports that TENS has been used in the management of numerous musculoskeletal, visceral, arthritic, and head pains.18–22 Unfortunately, many of these pain conditions are poorly defined, and important details concerning the patients and their specific complaints are not included in many published reports. In addition, clinical reports describing the results of trials with TENS frequently fail to provide sufficient information concerning the therapeutic intervention, methods of pain assessment, and criteria for success to allow the reader to assess the validity and reliability of the results. In many early clinical studies, for example, TENS was administered to patients only after various other therapeutic modalities had been tried unsuccessfully, a situation that could have had a significant impact on therapeutic effectiveness. Clinicians must question why some of these more performance-proven and “reliable” methods were ineffective and why in light of their ineffectiveness a modality such as TENS might be considered helpful. Proponents of TENS argue that the modality should be used early in the treatment program.23 Presumably, this procedure would permit a more reliable assessment of effectiveness before conditions worsen or before the development of psychological sets and behavioral strategies that might preclude or severely limit expected therapeutic results. Where are the studies that might support the belief that TENS used early in the treatment of patients with pain is more beneficial than TENS used as a last resort? Where are the studies that address the problem of inconsistent clinical results even when TENS is used in a relatively homogeneous population of pain patients? Where are the studies whose results might help the clinician to use TENS in a more effective manner? Where are the studies that will bring clarity to a TENS literature that is characterized by inconsistency, contradictory findings, and insufficient information to allow interested persons to replicate or evaluate the research of others with confidence?

Contributing to this problem has been the rapid development of new stimulation modes. When TENS was first introduced as a means of pain control, individual units were relatively simple in construction and operation. With most commercially available units, the therapist or patient was able...
to individually control one or more of three stimulation characteristics (amplitude, rate, and pulse width) in an attempt to maximize the pain-relieving effects of stimulation. The selection process was largely by trial and error. Most TENS units available at that time delivered stimulation in a mode that currently is commonly referred to as “conventional” TENS. Subsequently, new modes of stimulation (ie, “burst,” “modulated,” “brief-intense,” “acupuncture-like,” and “strength-duration”) were introduced and proclaimed as being better, by some set of criteria, than the other available modes. Interestingly, however, TENS in the eighties seems to be no more effective than was TENS in the seventies. Stimulation characteristics are still selected largely by trial and error. Clinical reports and case studies continue to be published, and the list of pain conditions for which TENS is considered helpful continues to grow. Nevertheless, the efficacy of the modality has remained essentially unchanged. Noteworthy is the fact that none of the newer modes of TENS delivery have convincingly been shown to be significantly more effective in relieving clinical pain than any of the older modes, including the original (conventional) mode.

Manufacturers have had an important part in the development of TENS as an accepted therapeutic modality, and their role will continue to be important in the future. Concerns, however, may be raised as to the nature and intent of their contributions. For example, it should not be unreasonable to believe that new TENS delivery modes were developed as a result of a recognized need to increase therapeutic effectiveness. Similarly, it might reasonably be assumed, as many manufacturers claim, that each newly developed mode of stimulation offers advantages over those previously available. In this regard, one would expect to find accurate and reliable evidence in either the basic or clinical literature supporting these various claims. A careful and critical examination of the TENS literature, however, will reveal deficiencies in this area. Evidence of the clinical superiority of one mode of stimulation over another is largely anecdotal. The thorough and rigorous scientific work that normally precedes the introduction and marketing of a new or improved therapeutic modality is, in the case of TENS, notable by its paucity. Nonetheless, the TENS industry continues to disseminate information, in the form of printed advertisements and other promotional materials, proclaiming the unique value of a particular device or method of stimulation.

These observations raise potentially troublesome concerns regarding the perhaps difficult relationship between the profit-motivated behavior of the TENS industry and its commitment to the ideals of cost containment and the quality of health care delivery. Why, for example, does such a disparity exist between money spent on advertising and marketing as compared with that allocated for the support of sound clinical research that might lead to more effective and less expensive pain control strategies involving TENS? One answer appears evident: Marketing sells TENS units, research does not; advertising yields profits, science does not. As long as physicians continue to write prescriptions for TENS devices, and as long as individuals or third-party payers are willing to pay for them, the proliferation of TENS units will continue. Consequently, as has happened in the past, TENS units will eventually come to rest in closets, medicine cabinets, pawnshops, and flea markets where they remain until pressed into service again, typically for conditions or purposes other than those for which they were originally intended.

PROPOSED SOLUTION

The major goal to be achieved is the identification of reliable therapeutic methods that maximize the pain-relieving effects of TENS. An associated objective is to develop an understanding of pain-related conditions that can be treated successfully with TENS, as well as those for which TENS is likely to be ineffective. Success in this endeavor will be the result of a considerably enhanced research effort and will be reflected in the development of a valid and reliable TENS literature.

A mechanism for achieving these goals might include the formation of a “TENS Research Foundation.” Such an organization would be supported by regular donations from TENS manufacturers and retailers in addition to contributions from other interested individuals and corporations. The purpose of this foundation would be to support clinical and basic research aimed at establishing the clinical efficacy of TENS; elucidating its mode of action; and providing manufacturers, health care providers, and patients with valid and reliable information regarding its therapeutic uses and associated effects.

This proposal entails a substantial financial commitment on the part of the TENS industry to support research concerning the use of TENS in pain management. Studies directed to this end should not be solely clinical reports and case reviews, but rather carefully constructed clinical trials, adequately and appropriately controlled to allow the investigator to draw valid and useful conclusions from the data. A particularly important aspect of this work must be the utilization of research personnel in all phases of the project who are well trained and experienced in research design, conduct, and evaluation, that is, investigators who are familiar with the existing literature and who can ensure the accuracy and reliability of the published report. A commitment of this type would serve as an indication of the manufacturer’s interest in the delivery of health care and would help justify the manufacturer’s intent to profit through the manufacture and distribution of TENS devices.

Research efforts must also focus on questions concerning the basic mechanisms of electrical stimulation-induced effects on pain perception. The answers to fundamental questions regarding how TENS alters the experience of pain are the foundation upon which the therapeutic use of TENS must be based. Without a firm, scientific underpinning, little can be hoped for or achieved. The TENS industry is asked to become a more prominent and effective partner in scientific efforts aimed at developing a sharper and more complete understanding of pain and the disability it produces.

Physical therapists must also assume greater responsibility in the area of pain control with TENS. They must become critical readers of the TENS-related literature. Clinicians must honestly and intelligently question claims made by the manufacturers of the TENS devices they use. Therapists must compel the TENS industry to provide the evidence upon which they base their claims, and most importantly, must critically evaluate that evidence. Researchers and writers in the area of TENS, particularly those who rely on the use of theories and hypotheses (such as the gate theory) to explain their experimental results or clinical findings, must be held accountable for their work. Studies claiming clinical efficacy must be examined carefully for defects that might weaken or invalidate such claims.

The physical therapy community must itself become more
involved in the research process, particularly in efforts to validate the numerous techniques, methods, and modalities routinely used in the treatment of patients. Physical therapists must become proactive rather than reactive in establishing the value of the various therapeutic interventions that constitute our profession. They must not only be problem solvers but also skilled at anticipating and avoiding problems that can retard the continued growth of our profession.

CONCLUSION

I have presented what I perceive to be important and persistent problems related to the use of TENS for pain control together with their proposed solutions. Clinicians familiar with TENS may view these problems differently or may be aware of other, more troublesome problems not mentioned in this communication. Furthermore, the remedies offered might be considered reasonable and attractive to some clinicians but not to others. Therapists who use TENS in the management of pain bear a responsibility to be aware of not only the indications and contraindications for use but also the likely effects of unauthorized or inappropriate use.

The process of identifying and solving problems by means of open and honest discussion is essential to the growth and development of any therapeutic modality and the professionals who use it. It is hoped that the comments presented in this communication will facilitate that process and encourage further discussion and debate on these and other clinically pertinent topics.

REFERENCES

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