DEPARTMENT OF HEALTH & HUMAN SERVICES
Center for Practice and Technology Assessment

Public Health Service

Agency for Health Care Policy
and Research
2101 East Jefferson Street
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To: Director, Coverage and Analysis Group
Health Care Financing Administration

From: Director, Center for Practice and Technology Assessment

Subject: Request for review and opinion of the ECRI evaluation of the US District Court decision regarding electrical stimulation of chronic wounds

Background

In April, 1996 ECRI prepared a technology assessment for HCFA entitled "Electrical Stimulation for the Treatment of Chronic Wounds." In March 1997, ECRI prepared an update of the assessment that identified two additional studies which, after review, did not lead to any change in the previous assessment conclusions. The conclusions, summarized as "general findings," were:

1. "ES devices are safe when used appropriately."

2. "Most types of ES are more effective than minimal treatment (e.g., saline-soaked gauze)."

3. "ES is not markedly superior to or inferior to conventional or alternative therapies (defined in Sections 7.1.1 and 7.2.2). There is insufficient evidence to determine if clinically significant differences exist."

On the basis of the ECRI assessment, HCFA issued a national coverage decision denying Medicare reimbursement for the use of electrical stimulation for the treatment of wounds. The American Physical Therapy Association (APTA) and five named individuals filed a civil action against the Secretary of HHS and the HCFA Administrator, and were successful in obtaining an injunction against giving any effect to this HCFA national coverage decision (Nov. 1997).

In January, 1998 ECRI wrote a letter to HCFA addressing two specific technical issues in the court's decision and, on August 8, 1998, HCFA requested CPTA's opinion on ECRI evaluation of the court's decision.

On September 1, 1998 CPTA received a letter and Position Paper from the American Physical Therapy Association (APTA). APTA asked that CPTA review the position paper and include our review in our response to HCFA. CPTA opinion of the ECRI evaluation of the courts memorandum and order, and CPTA opinion of the APTA position paper are set out below.

ECRI Evaluation of the U.S. District Court Memorandum and Order

The ECRI evaluation (January, 1998 letter to HCFA) addresses two specific technical issues. The first issue relates to charges of apparent definitional inconsistencies – footnote 7 pages 14 and 15 of the M&O. ECRI (p.2) admitted using the terms "passive therapy", "concomitant standard therapy" and "personal therapy" to all mean the same. They further admit to "imprecision" and "unfortunate wording". These admissions alone would weaken the defensibility of their assessment conclusions. However, the overall conclusions appear to be accurate as reflected in the Background section above.

The second issue relates to the ECRI statement that "there were no comparative studies of ES vs conventional therapy". This statement is indeed true. However, its weight is diminished by ECRI's evaluation of noncomparative clinical studies of ES and conventional studies leading to their conclusion "that there seemed to be to no significant difference in effectiveness between ES and conventional therapies."

The remainder of the ECRI response concerns their thoughts on how technology assessments can be used more effectively by HCFA in making national coverage decisions.

APTA Position Paper

The APTA Position Paper consists of four sections. The first three will be addressed in this response. The fourth summarized the APTA proposed coverage policy presented to HCFA and requires no comment in this context.

Section I: The ECRI Report Supports Coverage of Electrical Stimulation for Certain Types of Wounds.

This title is misleading in suggesting that the report itself supports coverage when in fact the report is not concerned with the issue of coverage, which is an exclusive HCFA matter. However, it is indeed true that some of the findings in the report could be used in an argument made to support coverage of ES for certain types of wounds. Specifically, the ECRI report concluded with three general findings:

1. ES devices are safe.
2. Most types of ES are more effective than minimal therapy (e.g.; saline-scored dressings).
3. There is insufficient evidence to determine if clinically significant differences exist between ES and conventional or other alternative therapies.

Section II: ECRI Misinterpreted Some of the Underlying Electrical Stimulation Studies.

Attributing misinterpretation to someone else is an exercise in conjecture and subject to debate on whether this complaint can be upheld or rejected. The APTA suggestion that AHCPR review the underlying studies will be addressed below.

Section III: The AHCPR Guidelines Support Coverage of Electrical Stimulation For Certain Types of Wounds.

The AHCPR guidelines do not address the issues of coverage. The guidelines simply state that ES could be considered as treatment for certain pressure ulcers unresponsive to conventional therapy.

In addition, the guideline panel recommendation to consider ES treatment in these cases was made on the basis of level B evidence (observational studies) derived from five clinical trials involving only 147 patients (not all receiving the treatment). These were not adequately powered studies or persuasive because of other methodological faults. In fact, a recent survey stated that over 95% of published articles in medical journals failed to reach minimum standards of quality and clinical relevance. (Haynes RB. Where's the meat in clinical journals? ACP Journal Club 1993:119:A22-23).

<u>The APTA submitted four published articles to AHCPR suggesting we review them independently of the ECRI report</u>

The first article (Wood et al) described the use of ES in the treatment of 43 ulcers in 41 patients with a chronic ulcer refractory to standard nursing care (unspecified) compared with sham treatment of 31 ulcers in 30 patients. The study was performed in 4 separate centers using a common protocol.

<u>Comment</u>

In essence this study demonstrated 58% of the ES treatment ulcers healed in 8 weeks vs only one (3%) healed in the untreated group. The study demonstrated that ES promoted healing (which concurs with the ECRI report) but says nothing about what further treatment may have accomplished in the untreated control patients.

The second article (Stefenovska et al) described the use of ES in addition to conventional treatment (unspecified) in 100 treated patients and 50 non ES patients as controls. The data strongly supported the hypothesis that ES contributed to the faster healing of decubitus ulcers.

Comment

The authors took great pains to emphasize that the initial pretreatment lesions had great variability and that it was impossible to vary only one parameter.

The following text is taken from the conclusion of the article:

"In the work presented, we have paid particular attention to the role of only one parameter: electric currents yes or no? We have been compiling data for six years and we are now able to say that the AC current we have applied has a stronger influence on healing than all the other parameters. Furthermore, an arbitrarily chosen wound has a chance of healing twice as fast when treated with AC treatment. In practice, however this means that it is possible that some wounds will not benefit at all, while others will heal at even more than twice the normal rate. Can we then say that we have proved the efficiency of AC treatment in pressure sore healing? The answer is no because it does not hold true for every sore: the truth is simple only for simple systems, and not for systems as complex as biological ones. In these systems, what is true is true only under certain circumstances. Therefore, we have to acquire data for all particular cases."

"A further reason for acquiring new data is that we may wish to optimize the treatment, for example to find the optimal stimulation current, primal electrode placement, or to determine whether it is optimal to stimulate only two hours a day or whether it is better to apply EC overnight. It is clear that the quantity of experimental data we need is vastly increasing."

I agree with the authors that the efficiency of AC treatment for pressure ulcers is not proven and more data are needed.

The third article (Stiller, et al) was a RCT involving 31 patients each having a recalcitrant ulcer. Eighteen patients were randomized to active ES treatment and 13 to the placebo group. Eight treatment centers participated in the trial and the different centers applied varying ancillary treatments in addition to the daily treatment with the active or placebo ES device, (which were indistinguishable to patients and investigators). Results demonstrated statistically significant improvement in healing in patients treated with the active device. 50% of the ES treated ulcers healed or markedly improved compared with none in the placebo group.

Comment

These positive results await confirmation in trials with larger numbers of patients. The treatment of 18 patients in 8 different centers is inherently problematic.

The fourth article (Kath and Feedar) described a clinical trial involving treatment of patients and untreated controls all of whom were unresponsive to unspecified prior treatments. Necrotic tissue in both groups were debrided manually and with enzymes. Three patients in the control group were given sham treatments. Results of the study supported the hypothesis that ES enhances the rate and extent of wound healing although additional studies are required to determine the optimal number and duration of treatments.

Comment

This study (of only 9 treated patients) also supports the claim that ES promotes healing of skin ulcers. This concept is not contested by anyone. The issue for HCFA that has been highlighted by the ECRI report is the lack of persuasive evidence that ES is better than conventional or other alternative treatments.

Summary

In summary, we believe that the conclusions of the ECRI technology assessment remain valid, as listed in the Background section above.

Douglas B. Kamerow, M.D., M.P.H.
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