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Media Contacts:
Rachel Seroka, rseroka@aan.com, (651) 695-2738
Angela Babb, ababb@aan.com, (651) 695-2789

Guideline: Widely Used Device for Pain Therapy Not Recommended for Chronic Low-Back Pain

ST. PAUL, Minn. – A new guideline issued by the American Academy of Neurology finds that transcutaneous electric nerve stimulation (TENS), a widely used pain therapy involving a portable device, is not recommended to treat chronic low-back pain—pain that has persisted for three months or longer—because research shows it is not effective. The guideline is published in the December 30, 2009, online issue of *Neurology®*, the medical journal of the American Academy of Neurology.

The guideline determined that TENS can be effective in treating diabetic nerve pain, also called diabetic neuropathy, but more and better research is needed to compare TENS to other treatments for this type of pain.

Research on TENS for chronic low-back pain has produced conflicting results. For the guideline, the authors reviewed all of the evidence for low-back pain lasting three months or longer. Acute low-back pain was not studied. The studies to date show that TENS does not help with chronic low-back pain.

All but one of the studies excluded people with known causes of low-back pain, such as a pinched nerve, severe scoliosis (curving of the spine), severe spondylolisthesis (displacement of a backbone or vertebra) or obesity. In the one study that looked at low-back pain associated with known conditions, TENS was not shown to be effective. The only specific neurologic cause of chronic low-back pain where TENS was studied was multiple sclerosis, and TENS was not shown to help.

"The strongest evidence showed that there is no benefit for people using TENS for chronic low-back pain," said guideline author Richard M. Dubinsky, MD, MPH, of Kansas University Medical Center in Kansas City and a Fellow of the American Academy of Neurology. "Doctors should use clinical judgment regarding TENS use for chronic low-back pain. People who are currently using TENS for their low-back pain should discuss these findings with their doctors."

Dubinsky stated further that good evidence showed that TENS can be effective in treating diabetic nerve pain.

With TENS, a portable, pocket-sized unit applies a mild electrical current to the nerves through electrodes. TENS has been used for pain relief in various disorders for years. Researchers do not know how TENS may provide relief for pain. One theory is that nerves can only carry one signal at a time. The TENS stimulation may confuse the brain and block the real pain signal from getting through.

Back pain—both acute and chronic—is the second most common neurologic ailment in the United States, according to the National Institute of Neurological Disorders and Stroke, and is the most common cause of job-related disability. About 60 percent of people with diabetes will develop neuropathy.

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SPECIAL ARTICLE

Assessment: Efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review)

Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology

Richard M. Dubinsky, MD, MPH, FAAN
Janis Miyasaki, MD, MEd, FAAN

Address correspondence and reprint requests to American Academy of Neurology, 1080 Montreal Avenue, St. Paul, MN 55116
guidelines@aan.com

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ABSTRACT

Objective: To determine if transcutaneous electric nerve stimulation (TENS) is efficacious in the treatment of pain in neurologic disorders.

Methods: We performed a systematic literature search of Medline and the Cochrane Library from inception to April 2009.

Results: There are conflicting reports of TENS compared to sham TENS in the treatment of chronic low back pain, with 2 Class II studies showing benefit, but 2 Class I studies and another Class II study not showing benefit. Because the Class I studies are stronger evidence, TENS is established as ineffective for the treatment of chronic low back pain (2 Class I studies). TENS is probably effective in treating painful diabetic neuropathy (2 Class II studies).

Recommendations: Transcutaneous electric nerve stimulation (TENS) is not recommended for the treatment of chronic low back pain (Level A). TENS should be considered in the treatment of painful diabetic neuropathy (Level B). Further research into the mechanism of action of TENS is needed, as well as more rigorous studies for determination of efficacy. *Neurology*® 2010;74:1–1

GLOSSARY

CI = confidence interval; **TENS** = transcutaneous electric nerve stimulation; **TENS-burst** = burst-pattern TENS; **TENS-FM** = frequency-modulated TENS; **VAS** = visual analog scale.

Transcutaneous electric nerve stimulation (TENS) has been used in the treatment of neurologic and other disorders for the last several decades. The biologic basis of the analgesic effect of TENS is not known, but the rationale for the use of TENS is based on the gate theory of pain.[1] TENS is used extensively for pain relief in various disorders.

TENS is the application of a mild electrical current to the cutaneous nerve fibers using surface electrodes. The stimulation is characterized by current, pulse width, and changes in frequency, though in some paradigms a stochastic or quasi-random stimulation frequency is used. The amplitude of the current is usually adjusted to just above or just below the sensory threshold. Duration of application varies from short time periods (e.g., 30 minutes) once to continuous stimulation. Duration of treatment can be days to months.

A fundamental question in any therapeutic trial is whether adequate blinding can be maintained for the intervention. In a study of TENS-naïve participants with chronic low back pain, TENS was compared to sham TENS (TENS-sham; in this case a nonfunctioning unit identical to the TENS unit with a light flashing at the stimulus frequency indicating that the unit was "on"). The blinding was mostly successful, with 100% of the TENS group and 84% of the TENS-sham group identifying their unit as working, though with a lesser degree of conviction in the TENS-sham group.[2]

This assessment summarizes evidence on the efficacy of TENS in the treatment of pain, specifically the pain associated with neurologic disorders.

DESCRIPTION OF THE ANALYTIC PROCESS

We performed a Medline search from inception to April 2009, using the terms "transcutaneous electric

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From the Department of Neurology (R.M.D.), University of Kansas Medical Center, Kansas City, KS; and Toronto Western Hospital (J.M.), Toronto, Ontario, Canada.

Appendices e-1 through e-4 and table e-1 are available on the *Neurology*® Web site at www.neurology.org.

Approved by the Therapeutics and Technology Assessment Subcommittee on April 28, 2009; by the Practice Committee on July 10, 2009; and by the AAN Board of Directors on October 19, 2009.

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nerve stimulation" (MeSH) and "nervous system diseases" (MeSH) or "peripheral nervous system diseases" (MeSH) or "central nervous system diseases" (MeSH), which was limited to "clinical trial, meta-analysis, practice guideline, randomized controlled trial, human." The Cochrane Library was searched using the terms "transcutaneous electric nerve stimulation" or "TENS." Inclusion criteria were clinical trials of TENS compared to placebo or to another therapy for well-defined painful neurologic disorders with more than 10 subjects. The titles and abstracts were reviewed, and articles meeting criteria were reviewed in full and assigned a class of evidence (appendix e-3). Recommendations were based on the level of evidence (appendix e-4). Disagreement about the assigned level of evidence was resolved through discussion. Additional articles were obtained from the bibliographies of these articles and of review articles.

We adopted the definitions used in each paper for meaningful reduction in pain, realizing that this varies between treatments for acute and for chronic pain. In 2 studies of patients presenting to emergency departments with acute onset or worsening of pain, the patient self-determined minimum significant change in pain (i.e., a little bit worse, a little bit better) correlated with a mean change in visual analog scale (VAS) of ±13 mm (95% confidence interval [CI] 10–16) in trauma patients and ±9 mm (95% CI 6–13) in a mixed population of trauma and nontrauma patients.[3,4] Although the World Health Organization classifies significant pain reduction in the treatment of patients with cancer as >50% using a 100 mm VAS or a decrease to a level of 3 or less using a verbal rating scale of pain intensity from 0 to 10, the definition of meaningful pain reduction is controversial. Thus, many of the articles used a decrease of 20 mm or a 25% decrease with a baseline VAS of 50 mm or less as clinically significant.

ANALYSIS OF THE EVIDENCE The primary and secondary searches yielded 263 articles. Eleven studies met the inclusion criteria (table e-1). Two studies of chronic pain were excluded because etiologies of pain were diverse and meaningful data on any one type of pain could not be extracted from presented data.

Low back pain. There were 2 Class I studies and 3 Class II studies evaluating the efficacy of TENS in the treatment of low back pain of various etiologies (some diagnoses were readily accepted as neurologic illness, while others may be controversial; however, all patients experienced low back pain for at least 3 months). The Class I studies compared TENS to TENS-sham in the treatment of chronic low back pain with the duration of treatment either 4 or 6 weeks.[5,6] In one study, a 2 × 2 factorial design was used to compare TENS, TENS-sham, exercise, and no exercise. No benefit was found for TENS compared to TENS-sham using a VAS and other outcome measures, but benefit was found comparing exercise to no exercise.[5] In the other Class I study, TENS vs TENS-sham was studied in patients with multiple sclerosis (MS) and chronic low back pain. After correction for multiple comparisons, there were no significant differences in the VAS or the secondary measures.[6] Both studies were adequately powered to find at least a 20% difference in pain reduction by VAS between TENS and TENS-sham.

A Class II study compared different TENS modalities in a randomized 3-session trial. Although various diagnoses were included (including non–low back pain), sufficient data were presented to allow review of the low back pain data. Conventional TENS, frequency-modulated TENS (TENS-FM), and burst-pattern TENS (TENS-burst) were assessed with a VAS compared to baseline after a single 30-minute session. Benefit was reported in 8/11 patients who had TENS-FM, 4/11 who had TENS-burst, and 1/11 who had conventional TENS. One subject did not have benefit with any modality.[7] In a study comparing TENS and TENS-sham to a control group, a modest benefit in pain reduction (15 mm or greater decrease on a VAS compared to baseline) was seen after 1 and after 10 weeks of therapy, but not for the unpleasantness of pain.[8] This study excluded patients with scoliosis greater than 15 degrees, spondylolisthesis, surgical lesions, vertebral compression fractures, and obesity. The benefit continued to 3 and 6 months after completion of TENS or TENS-sham with no difference between the 2 treatments. The last Class II study examined the benefit of TENS compared to TENS-sham for patients with MS and low back pain. After correction for multiple comparisons, no significant differences were found.[9]

Conclusions. There was conflicting evidence for the use of TENS for chronic low back pain. In 2 Class I studies adequately powered to detect a 20% difference in the proportion of patients with benefit, no benefit was found. Two Class II studies demonstrated a modest benefit, while a third Class II study did not demonstrate benefit. Because the Class I studies are stronger evidence, TENS is established as ineffective for the treatment of chronic low back pain.

Painful diabetic distal symmetric polyneuropathy. Two Class II studies compared TENS to TENS-sham, and 1 Class III study compared high-frequency muscle stimulation to TENS in the relief of pain associated

with mild diabetic peripheral neuropathy (distal symmetric neuropathy, excluding patients with mononeuropathies and plexopathies).[10–12] A modest reduction in VAS was found for TENS compared to TENS-sham, and a larger proportion felt benefit with the high-frequency muscle stimulation compared to TENS.

Conclusion. On the basis of 2 Class II studies, TENS is probably effective in reducing pain from diabetic peripheral neuropathy.

Clinical context. Many treatment options are commonly used for diabetic neuropathy, but there are presently no comparative studies of TENS to other treatment options.

RECOMMENDATIONS

1. TENS is not recommended for the treatment of chronic low back pain due to lack of proven efficacy (Level A, 2 Class I studies).
2. TENS should be considered for the treatment of painful diabetic neuropathy (Level B, 2 Class II studies).

RECOMMENDATIONS FOR FUTURE RESEARCH

For such a widely used therapeutic modality, the evidence for the efficacy of TENS in treating pain associated with neurologic disorders is meager.

1. Studies should be performed on TENS-naïve subjects, when possible.
2. The optimal paradigm of TENS for alleviation of induced pain needs to be determined and then applied to painful disorders.
3. Once the optimal paradigm is established, future studies of the efficacy of TENS should be randomized controlled clinical trials of TENS compared to TENS-sham, rather than comparison of different TENS paradigms or untreated controls. These studies should utilize TENS for chronic therapy, rather than single sessions; have an adequate number of subjects with well-defined painful conditions; and be directed toward common painful neurologic conditions.
4. Other pain syndromes, such as posttraumatic nerve injuries, should have the same rigorous methodologies applied to determine the efficacy of TENS.

ACKNOWLEDGMENT

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DISCLOSURE

Dr. Dubinsky serves on a scientific advisory board and speakers' bureau for Allergan, Inc.; receives honoraria from BrioMed; receives research support from Allergan, Inc., Merz Pharmaceuticals GmbH, and the NIH [NHGRI/NINDS 1R01HG02449–01 (Site Investigator), NIAM/NINDS R01NS052592 (Site Investigator), NIAM/NINDS R01NS052619–01 (Site Investigator), NIAM/NINDS R01NS052592–01 (Site Investigator), NCCAM #2007P000827 (Site Investigator), NCCAM UO1AT000613 (Site Investigator)]; and his spouse owns stock in Abbott. Dr. Miyasaki has served on a scientific advisory board for Teva Pharmaceutical Industries Ltd.; has received honoraria for educational activities not funded by industry; serves on the editorial board of *Movement Disorders*; has received speaker honoraria from Biovail Corporation; serves/has served as a consultant to Janssen-Ortho, Inc., Merz Pharmaceuticals GmbH, Schering-Plough Corp., the NIH (Independent Medical Monitor), Ontario Drug Benefits, and Common Drug Review, Canada; and receives research support from Teva Pharmaceutical Industries Ltd., Boehringer Ingelheim, Solvay Pharmaceuticals, Inc., Solstice Neurosciences, Inc., Impax Laboratories, Neurogen, Medivation, Inc., the National Parkinson Foundation, the Parkinson Society Canada, the Michael J. Fox Foundation, and the Huntington Study Group.

DISCLAIMER

This statement is provided as an educational service of the American Academy of Neurology. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved. The clinical context section is made available in order to place the evidence-based guideline(s) into perspective with current practice habits and challenges. No formal practice recommendations should be inferred.

CONFLICT OF INTEREST

The American Academy of Neurology is committed to producing independent, critical, and truthful clinical practice guidelines (CPGs). Significant efforts are made to minimize the potential for conflicts of interest to influence the recommendations of this CPG. To the extent possible, the AAN keeps separate those who have a financial stake in the success or failure of the products appraised in the CPGs and the developers of the guidelines. Conflict of interest forms were obtained from all authors and reviewed by an oversight committee prior to project initiation. AAN limits the participation of authors with substantial conflicts of interest. The AAN forbids commercial participation in, or funding of, guideline projects. Drafts of the guideline have been reviewed by at least 3 AAN committees, a network of neurologists, *Neurology*® peer reviewers, and representatives from related fields. The AAN Guideline Author Conflict of Interest Policy can be viewed at www.aan.com.

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EDITORIAL

Utility of transcutaneous electrical nerve stimulation in neurologic pain disorders

Andreas Binder, MD
Ralf Baron, MD

Address correspondence and reprint requests to Dr. med. Andreas Binder, Division of Neurological Pain Research and Therapy, Department of Neurology, Christian-Albrechts-Universität Kiel, Arnold-Heller-Str. 3, Haus 41, 24105 Kiel, Germany
a.binder@neurologie.uni-kiel.de

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Transcutaneous electrical nerve stimulation (TENS) has now been used over 40 years in the treatment of pain. In 1967, Wall and Sweet successfully treated patients with "chronic cutaneous pain"; this proved to be the beginning for the increasing and widespread use of TENS in different nociceptive and neuropathic pain syndromes. The scientific basis for this treatment was presumed to be Wall and Melzack's gate control theory,[1] which stated that large nerve fiber activation, as applied by TENS, could modulate pain sensations conducted in small fiber nerves, by gating or blocking the transmission within central nociceptive pain pathways. Recent research and clinical observations in some patients, such as those with delayed analgesia or persisting anesthesia after stimulation, has made it clear that the gate control theory cannot explain all effects of TENS; nevertheless, the lack of a solid scientific rationale has not hindered the implementation of TENS in pain therapy.

In this issue of *Neurology*®, Dubinsky and Miyasaki,[2] representatives of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology, present the results of a concise meta-analytic evidence-based review of TENS' efficacy in painful neurologic disorders. There are 3 main results: first, probable efficacy could be substantiated in the treatment of painful diabetic neuropathy only (level B); second, TENS cannot be recommended in chronic low back pain (level A); and third, the number of controlled trials is low and the intertrial comparisons are weakened by heterogeneous trial designs, treatment paradigms, and efficacy parameters.

These conclusions may heat up the discussion on the usability of TENS and may be viewed as supporting the critics who questioned the value of TENS in pain therapy. However, absence of evidence is not evidence of absence. The clinical impact of meta-analyses is always limited by the quantity and quality of conducted trials. This becomes true in particular when talking about nonpharmacologic treatment options like TENS. Moreover, Nnoaham and Kumbang[3] already stated that there seem to be no attempts to improve our knowledge in the last years.

TENS is still in use and has a longstanding role as a treatment option that also has been implemented in treatment guidelines.[4] Thus, there seems to be considerable empirical evidence that, at least in some patients, TENS is useful. The advantages are obvious in these instances: it appears to be a safe treatment modality, with a fast onset of analgesia in responding patients, usually without notable adverse effects and lacking interactions with other treatments. Only a few contraindications exist. TENS is an easy to handle device with a favorable benefit to risk ratio that can be discontinued easily if it is not efficacious. All these are desired properties when treating pain.

Dubinsky and Miyasaki[2] also translate the results of their work into a call for further trials and present clearcut recommendations for their conduction. These include the determination of "optimum" pain-relieving stimulation paradigms. Further, they call for trials in TENS-naive patients in randomized sham-controlled trials and in well-defined neurologic pain syndromes. Moreover, for the pain community it will be necessary to search for predictors of response to improve TENS therapy. To accomplish this, it may be useful to stratify patients with regard to the possible mechanisms of different pain syndromes, as detectable by (for example) quantitative sensory testing and pain questionnaires.[5,6] Based on the presumed mode of action of TENS therapy, we could hypothesize that patients with extended nerve fiber degeneration and predominant deafferentation pain may show a poorer or lack of response than those with preserved nerve function and predominant sensitization pain processes.

This updated evidence-based review is valuable in providing the limits of our evidence base. Nevertheless, it is not unreasonable to take a practical

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From the Division of Neurological Pain Research and Therapy, Department of Neurology, Christian-Albrechts-Universität Kiel, Kiel, Germany.
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position that, in spite of the relatively weak scientific and clinical evidence, TENS still represents a valuable therapeutic alternative in neurologic pain disorders. Taking the favorable benefit-risk ratio when compared with other pain relieving methods into account, TENS remains a valuable part in the armamentarium of pain therapy.

DISCLOSURE

Dr. Binder has received travel expenses for lectures and educational activities not funded by industry and has received honoraria for speaking engagements and educational activities from Grünenthal, Allergan, Inc., and Pfizer Inc. Dr. Baron serves on scientific advisory boards, as a consultant, and on speakers' bureau for Pfizer Inc., Genzyme Corporation, Grünenthal, Mundipharma International, Allergan, Inc., Sanofi Pasteur, Medtronic, Inc., Eisai Inc., UCB, Eli Lilly and Company, and Astellas Pharma Inc.; has received travel expenses for lectures or educational activities not funded by industry; serves as an Associate Editor of *Pain* and on the editorial advisory boards of *Nature Reviews Neurology* and *European Journal of Pain*; and has received research support from Pfizer Inc., Genzyme Corporation, Grünenthal, the German Ministry of Research, and DFG, Deutsche Forschungsgemeinschaft.

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Richard M. Dubinsky Discusses New Guideline on the Efficacy of TENS for Treatment of Pain

The Technology and Therapeutics Assessment Subcommittee of the Practice Committee of the AAN has released its evidence-based review of the efficacy of TENS (transcutaneous electric stimulation) for treatment of pain. Daniel B. Hier, MD, MBA, interviewed the lead guideline author, Richard M. Dubinsky, MD, MPH, for AAN.com about the recently published assessment of TENS.

AAN.com: Briefly summarize your conclusions regarding the efficacy of TENS for pain in neurological conditions.

Dubinsky: TENS was found to be of no benefit for people with chronic low back pain. However, people with diabetic neuropathy received some benefit from therapy with TENS.

AAN.com: What was the motivation of the Technology and Therapeutics Assessment (TTA) Subcommittee for assessing TENS?

Dubinsky: W**e** sought to address the lack of any evidence-based guidelines on the utility of TENS for neurologic conditions.

AAN.com: What procedure did your subcommittee utilize to assess TENS?

Dubinsky: Systematic literature review, using the AAN Quality Standards and Technology and Therapeutics Assessment methodology to find papers and to rank them based on their inherent levels of potential bias. From the articles, conclusions about efficacy were made, followed by recommendations.

AAN.com: How did you define a meaningful improvement in pain for this technology assessment?

Dubinsky: We adopted the definition for meaningful improvement used in each individual study. The amount of improvement considered clinically significant in these studies was less than the typical values used in studies of cancer-associated pain (verbal analog scale, or VAS).

AAN.com: How was TENS-sham used as blinded control for TENS in some of the studies?

Dubinsky: Inactive units with blinking lights similar to the active TENS devices were used in some studies, and in others different TENS modalities were compared without a placebo arm.

AAN.com: No Class I studies showed a benefit for TENS in lower back pain. What is the difference between a Class I and a Class II study?

Dubinsky: A Class I study is a well controlled, randomized clinical trial, which is double blinded. Cohort assignment is completely randomized and cannot be influenced by the study personnel. The populations are well defined, and there is a low drop-out rate.

AAN.com: What further studies are needed to better assess the utility of TENS for pain in neurological disorders?

Dubinsky: First, the optimum TENS paradigm needs to be determined. Then TENS needs to be compared to sham TENS in well defined populations, which are naïve to TENS, for long-term treatment of painful disorders.

Author Disclosures

Dr. Dubinsky holds financial interests in Abbott and Allergan.

Within the past 24 months, Dr. Hier received compensation for medical legal consulting. In the same period he gave expert testimony in medical malpractice cases.

AAN Summary of Evidence-based Guideline for CLINICIANS

EFFICACY OF TRANSCUTANEOUS ELECTRIC NERVE STIMULATION IN THE TREATMENT OF PAIN IN NEUROLOGIC DISORDERS

This is a summary of the American Academy of Neurology (AAN) guideline regarding efficacy of transcutaneous electric nerve stimulation (TENS) in the treatment of pain in neurologic disorders. Recommendations are presented for use of TENS in treating chronic low-back pain and painful diabetic neuropathy.

Please refer to the full guideline at www.aan.com for more information.

CHRONIC LOW-BACK PAIN

What is the efficacy of TENS in the treatment of chronic low-back pain?	
Strong evidence	TENS is not recommended for the treatment of chronic low-back pain due to lack of proven efficacy (**Level A**†, two Class I studies).

PAINFUL DIABETIC NEUROPATHY

What is the efficacy of TENS in the treatment of painful diabetic neuropathy?	
Good evidence	TENS should be considered for the treatment of painful diabetic neuropathy (**Level B**, two Class II studies).

CLINICAL CONTEXT*

Many treatment options are commonly used for diabetic neuropathy, but there are presently no comparative studies of TENS

†**Classification of Recommendations: A** = Established as effective, ineffective, or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)* **B** = Probably effective, ineffective, or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.) **C** = Possibly effective, ineffective, or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.) **U** = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is >2).

Classification of Evidence for Studies of Therapeutic Intervention: Class I = Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population. The following are required: a) Primary outcome(s) is/are clearly defined; b) Exclusion/inclusion criteria are clearly defined; c) Adequate accounting for dropouts and crossovers with numbers sufficiently low to have minimal potential for bias; d) Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences. **Class II** = Prospective matched group cohort study in a representative population, with masked outcome assessment that meets a–d above OR a randomized controlled trial in a representative population that lacks one criterion a–d. **Class III** = All other controlled trials including well-defined natural history controls or patients serving as own controls in a representative population, where outcome assessment is independently assessed or independently derived by objective outcome measurement.** **Class IV** = Evidence from uncontrolled studies, case series, case reports, or expert opinion.

**Objective outcome measurement: an outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data)

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