Using the Nicotine Patch to Stop Smoking

To the Editor.—The evidence from meta-analysis that the nicotine patch is indeed an effective aid to smoking cessation is encouraging.[1] It must have occurred to many cigarette smokers, however, that the steady delivery of nicotine by the patch is entirely different than that gratifying first deep drag on a freshly lit cigarette. Cigarettes would seem likely to deliver a sharp rise in blood nicotine that might even reach the toxic range transiently. If this is true, the cigarette industry has furnished smokers with an inhaler that delivers safe levels of nicotine. In my personal experience, cigars, with their long-wave delivery of nicotine, do not satisfy cigarette addiction.

The addictive component of cigarettes is nicotine, and carcinogens and pulmonary irritants are something else. Perhaps the manufacturers of patches or the manufacturers of cigarettes should develop another safe nicotine inhaler that would satisfy cigarette addicts without exposing them to the risk of pulmonary disease or cancer.

George S. Richardson, MD
Massachusetts General Hospital
Boston

1. Fiore MC, Smith SS, Jorenby DE, Baker TB. The effectiveness of the nicotine patch for smoking cessation: a meta-analysis. *JAMA.* 1994;271:1940-1947.

To the Editor.—In their meta-analysis of transdermal nicotine patch clinical trials, Dr Fiore and colleagues[1] reviewed the efficacy of this therapy compared with placebo patches, with a major emphasis on the relationship of counseling with patch use. Studies were categorized by intensity levels of counseling, and quit rates between "low counseling" and "high counseling" studies were compared. The authors report, "[t]here was no indication that low-intensity or high-intensity counseling resulted in greater efficacy of the nicotine patch in relation to placebo patch," and subsequently advocate a minimal counseling approach with initial transdermal nicotine patch use. There are several problems inherent in using this meta-analysis to arrive at such a conclusion, including two potential sources of bias.

First, performing a subgroup analysis for counseling intensity requires comparisons between studies, not across studies. Subjects in this meta-analysis were not randomly exposed to counseling of varying intensity. Given the likelihood that there was considerable heterogeneity between study populations, the pooling of outcomes among the counseling subgroups introduced selection bias.

Second and most important, no studies were representative of a truly minimal counseling model. All studies in the meta-analysis involved some degree of counseling, including initial assessment, patch instruction, follow-up assessment, withdrawal and side-effect monitoring, and validation of smoking. Even those studies that explicitly reported minimal counseling provided a substantially higher level of patient education than is likely occurring in general practice. As such, the classification of counseling into two tiers may have been forced, introducing a source of information bias.

Finally, while this study does show that patches consistently improve cessation rates over placebo, it provides no convincing evidence that using patches with little or no counseling in a general medical setting would be an effective intervention or provide significant cost savings. As health system reform develops on state and national levels, studies showing improved outcome either with less intervention or with lower costs are surely welcome. At this time, there remains a significant need to investigate the appropriate role of counseling intensity with nicotine patch use in the general medical community.

Susan H. Swartz, MD
Seattle Veterans Administration Medical Center
Seattle, Wash

1. Fiore MC, Smith SS, Jorenby DE, Baker TB. The effectiveness of the nicotine patch for smoking cessation: a meta-analysis. *JAMA.* 1994;271:1940-1947.
2. Orleans CT, Resch N, Noll E, et al. Use of transdermal nicotine in a state-level prescription plan for the elderly: a first look at 'real-world' patch users. *JAMA.* 1994;271:601-607.

To the Editor.—We read with interest the meta-analysis of nicotine patch studies by Dr Fiore and colleagues.[1] Their article is a major contribution to the literature and provides important information about several issues regarding the use of nicotine patches. However, we are concerned with their suggestion that "the nicotine patch might be offered first with minimal assistance" and, if this failed, move on to using the patch with an "intermediate-intensity adjuvant," such as support and follow-up provided via telephone or using the approach detailed in the National Cancer Institute's manual for physicians.[2] Many readers may conclude that the patch is effective when used alone. We believe that such a conclusion is premature and is not adequately supported by available research.

At a minimum, all of the studies analyzed by the authors provided instructions on use of the patch, some brief advice, and at least several follow-up contacts. Furthermore, of the three studies included in their analysis with "no significant counseling," only two had data beyond the end of treatment, and these data were contained in one manufacturer's unpublished Food and Drug Administration application. Interestingly, the package insert for this same manufacturer presents data suggesting their patch has questionable effectiveness when used without concomitant support.[3]

In addition, the way the authors defined high-intensity and low-intensity counseling for the purpose of the analysis does not correlate with the stepped-care approach suggested. For example, most studies in the low-intensity group are much more intensive than the intermediate-intensity approach mentioned herein and would be highly intensive compared with what occurs in medical practice, where many patients prescribed the patch apparently do not receive any follow-up[4] or advice on proper use of the patch or how to quit.[5]

Clearly, the authors present compelling evidence that supports the conclusion that formal behavioral counseling is not necessary for the patch to be effective, yet we believe more research is needed to define the minimum level of adjuvant

Requirements for Letters

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treatment that is effective with the nicotine patch. Until more is known, the use of adjuvant interventions outlined in the National Cancer Institute approach,[2] including brief advice and counseling, education on proper patch use, self-help materials, setting a quit date, and follow-up to monitor progress with quitting, should be encouraged. These interventions can be readily provided in most practice settings and have been used successfully in studies of the nicotine patch.[6]

Dean Haxby, PharmD
Oregon State University
William L. Toffler, MD
Oregon Health Sciences University
Portland

1. Fiore MC, Smith SS, Jorenby DE, Baker TB. The effectiveness of the nicotine patch for smoking cessation: a meta-analysis. *JAMA.* 1994;271:1940-1947.
2. Glynn TJ, Manley MW. *How to Help Your Patients Stop Smoking: A National Cancer Institute Manual for Physicians.* Washington, DC: US Dept of Health and Human Services, Public Health Service; 1990. National Institutes of Health publication NIH 90-3064.
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5. Orleans CT, Resch N, Noll E, et al. Use of transdermal nicotine in a state-level prescription plan for the elderly: a first look at 'real-world' patch users. *JAMA.* 1994;271:601-607.
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In Reply.—We thank Dr Richardson, Dr Swartz, and Drs Haxby and Toffler for their comments concerning our article on the effectiveness of the nicotine patch for smoking cessation.

Richardson is correct in stating that the nicotine patch does not produce the same subjective effects as a cigarette and is undoubtedly less reinforcing. Therefore, the patch is unlikely to support long-term addictive use in the same manner as cigarette smoking. Of course, most clinicians do not expect or want the nicotine patch to become a permanent replacement for smoking. Rather, the hope is that the nicotine patch will make quitting smoking less unpleasant and more successful. Products such as nicotine inhalers and intranasal sprays have been developed that appear to mimic some of nicotine's reinforcing actions with high rates of long-term use.[1] The use of such devices may help smokers stop smoking, but questions remain about whether smokers will have difficulty stopping the use of nicotine inhalers or sprays.

Swartz and Haxby and Toffler expressed concerns about our statements concerning the role of behavioral counseling in the treatment of nicotine dependence. We agree with Swartz that there were potential sources of bias that compel cautious interpretation of the counseling intensity analyses. In our article, we pointed out how such biases could have influenced the outcome of the counseling analyses and warned readers to consider our data in light of these potential biases.

Swartz implies that we advocated the use of the nicotine patch with minimal counseling on the basis of analyses that compared high-intensity vs low-intensity counseling between different studies. This is not really true. The basis for our belief that the nicotine patch is effective, even when used with minimal counseling, is that in studies where minimal counseling was used the active patch produced higher abstinence rates than did the placebo patch. No cross-study comparisons are necessary to make this point.

Swartz and Haxby and Toffler also addressed the important issue that clinical trials, because of their methodologic rigor, require patient contact that might be viewed as more intensive than the minimal counseling that typically occurs in general practice. We agree and acknowledged this in our article. Since the finalization of our meta-analysis, two studies have been published on the "real world" use of the nicotine patch.[2,3] Neither was a placebo-controlled blinded study, and neither experimentally contrasted different counseling intensities. However, both studies suggest that the nicotine patch can boost the clinical effectiveness of modest counseling interventions.

We also agree with Haxby and Toffler that more research is needed to establish optimal combinations of nicotine patch therapy and counseling. Although we stated that a stepped-care approach may be appropriate for smoking, we recognize the need for smoking cessation clinical trials specifically designed to test this approach. We also recognize that smokers attempting to quit smoking are heterogeneous and that optimal treatment may require matching patient needs with treatment approaches of proven efficacy.

Michael C. Fiore, MD, MPH
Stevens S. Smith, PhD
Douglas E. Jorenby, PhD
Timothy B. Baker, PhD
University of Wisconsin Medical School
Madison

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World War II's Most Highly Decorated US Physician

To the Editor.—Recent commemoration of the Normandy invasion makes it timely to call attention to John Erbes, MD, who was the most highly decorated US physician in World War II. Dr Erbes, a 1939 graduate of the University of Nebraska College of Medicine, was a battalion surgeon in the Second Armored Division and saw front-line duty in French Morocco, Tunisia, Sicily, Normandy, northern France, Belgium, and Germany. His awards include the Distinguished Service Cross, the Silver Star with three Oak Leaf Clusters, and the Bronze Star, as well as two unit awards. The latter include the Presidential Unit Citation, given to his battalion for breaking the Siegfried line near Aachen on October 4, 1944, and the Belgian Fourragere, given for the division's decisive role in turning back the German spearhead at its deepest penetration in the Battle of the Bulge. This was the first time the latter award was given to a foreign unit.

Our recent contacts with official US Army and Navy historians have revealed no instances where a Distinguished Service Cross or Navy Cross recipient equaled or exceeded Dr Erbes' four Silver Stars (oral communication, R. F. Still, regimental historian, Army Medical Department, Ft Sam Houston, Tex, and J. K. Herman, editor, *Navy Medicine,* Washington, DC). No physician serving in World War II received the Congressional Medal of Honor.[1]

The courage that earned Dr Erbes the Silver Star and Oak Leaf Clusters is exemplified by action 2 days after the penetration of the Siegfried line. While attempting to rescue the crew of a tank damaged by an enemy shell, he was blown from the tank by another shell blast. However, he resumed his attempt to rescue the crew.

He earned his Distinguished Service Cross near Aachen on November 17, 1944, when German fire was repeatedly directed at corpsmen when they left cover, preventing them from aiding several soldiers lying wounded in an open field. Dr Erbes, waving the Red Cross flag from his jeep, emerged from behind the cover. The Germans held their fire, and Dr Erbes, carrying the flag, led corpsmen to the wounded. While they were attending them, an uninjured soldier suddenly decided to change foxholes, causing the Germans to resume fire. After diving for cover, Dr Erbes retrieved and waved the flag, and the firing stopped. Two of the wounded men