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A COMPARISON OF MEASURES USED TO ASSESS EFFECTIVENESS OF THE TRANSDERMAL NICOTINE PATCH AT 1 YEAR

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Abstract— This study examines outcome measures of abstinence among studies reporting 12-month outcomes of the nicotine transdermal patch using different measures of effectiveness. This was achieved by reviewing published randomized controlled studies reporting 1-year abstinence rates of the nicotine transdermal patch. Comparisons are made across studies of three outcome measures used to report abstinence: point prevalence, continuous, and prolonged abstinence. Studies that measured outcome in terms of continuous and prolonged abstinence at 1 year showed double the effect for the active patch compared to placebo; however, this difference was not always apparent in those studies using point prevalence as the outcome measure. © 1997 Elsevier Science Ltd.

Nicotine transdermal patches were developed as an aid to smoking cessation and are designed to offer an efficient method of delivering nicotine in a controlled and continuous way (Palmer, Buckley, & Faulds, 1992) so that withdrawal symptoms are alleviated. Compared to other nicotine replacement therapies (gum and nasal spray), transdermal patches appear to offer the best risk-to-benefit ratio: they combine good smoking cessation efficacy and withdrawal suppression with a modest adverse effect profile and low abuse liability (Gross & Stitzer, 1989). Further, there is a high compliance and patient acceptance of the patches compared to the gum (Mendelsohn & Richmond, 1994).

Criteria for reporting abstinence in smoking cessation trials use one of three alternative outcome measures to evaluate efficacy. They are (a) point prevalence, the percentage of people not smoking at a particular point in time, including long-term and short-term quitters; (b) continuous abstinence, the most conservative measure of outcome, which is the percentage of people who have not smoked at all since commencement of the intervention to the 12-month follow-up point; and (c) prolonged abstinence, the percentage who have been continuously abstinent for a prolonged period since the previous assessment (Velicer, Prochaska, Rossi, & Snow, 1992). The outcome measure of prolonged abstinence reflects the natural process of stopping smoking, as some smokers succeed in quitting only after experiencing a series of delayed quit attempts, lapses, and relapses following an intervention (Prochaska & DiClemente, 1986). Although continuous abstinence may not account for this frequent occurrence in the dynamic process of quitting, it is regarded as the most rigorous measure, as abstinence is considered to be a direct result of intervention. Therefore, the gold standards for presenting efficacy are 12-month validated continuous or prolonged smoking abstinence rates, as these measures demonstrate stable abstinence over time.

A meta-analysis of 17 clinical trials of the nicotine transdermal patch using abstinence at 6 months found 22% for active treatment and 9% for placebo (odds ratio was

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