

The authors in their methodology described to be using the Fagerström Test for Nicotine Dependence (FTND), and it would be of interest also to know whether estimates with FTND as dependency parameter gave a similar result. Also, it would be of interest to know the actual duration of nicotine-free inhalator use in each of the two groups (median and range), and whether the concordance with the smoking cessation intervention (bupropion and high-dose nicotine patch) differed in the two groups, if these data are available.

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- 1 Caponetto P, Cibella F, Mancuso S, *et al.* Effect of a nicotine-free inhalator as part of a smoking-cessation programme. *Eur Respir J* 2011; 38: 1005–1011.

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From the authors:

We are pleased that our recent work published in the *European Respiratory Journal* regarding the positive role of a nicotine-free inhalator (Paipo; Echos Srl, Milan, Italy) used in the context of smoking cessation interventions [1] has attracted so much interest. In particular, we are grateful to K. Fagerström and C.N. Meyer for raising a number of stimulating and relevant points. A pronounced effect on quit rates was observed with Paipo in smokers with a supposedly high degree of behaviour dependence to smoking (*i.e.* in those for whom handling and manipulation of their cigarettes played an important part in the ritual of smoking). This was measured by the Glover–Nilsson Smoking Behavioral Questionnaire (GN-SBQ), which determines the importance of the behaviour component in smoking dependence [2].

Based on the current knowledge of predictors of smoking cessation [3], the pronounced effect on quit rates observed with Paipo in the participants with high behaviour dependence to smoking was surprising. There may be several explanations for this. Using a different cut-off point on the GN-SBQ scale might have affected results, but we have followed the recommendations of the GN-SBQ developers and used the canonical cut-off point of 22 for the analyses [2]. Alternatively, our findings reflect the fact that aspects of tobacco dependence that are behavioural in nature are very little studied and that characterisation of behavioural sub-phenotypes in smokers may be a far stronger and more relevant determinant of smoking cessation outcomes [4]. We agree with K. Fagerström that future research has to address in

depth the behavioural component of tobacco dependence in smoking cessation studies.

A second area of concern was the possibility of unbalanced distribution of pharmacological treatment between the two study groups. By study design, all participants in both groups were prescribed high-dose nicotine patch plus bupropion 300 mg per day. However, it cannot be established with confidence whether the level of adherence to medical treatment was similar between groups.

It was incorrectly pointed out that "...the effect of the inhalator was stronger at week 24 than at week 4". Overall in the Paipo study group, quit rates decreased from 38.3% at week 4 to 33.3% at week 24. The use pattern of Paipo varied widely, particularly in relation to their level of behaviour dependence to smoking. In most cases with high GN-SBQ, use of Paipo was perceived as extremely helpful and maintained constant throughout the study with a median usage of 6 weeks. Quite a few of these patients continued using Paipo *ad libitum* even after termination of the study. However, the majority of cases with low GN-SBQ lost confidence in the utility of Paipo very quickly and discontinued its use.

The notion that participants with low behaviour dependence levels quickly lost confidence in the utility of Paipo may also explain why the product negatively influenced quit rates in this specific sub-group. The Paipo might not have helped with coping with some of the psychological/behavioural aspects of tobacco dependence in the low GN-SBQ group, thus failing to meet the expectations of these smokers undergoing the smoking cessation programme. This failure experience by itself would constitute an additional stressor, and its associated decrease in self-efficacy should produce increased negative affect [5]. This is likely to be the cause of an additional sense of failure and more stress. Smokers in these stressful situations react by adopting the best coping strategy known to them, *i.e.* lighting up a cigarette. Therefore, in smokers with low GN-SBQ scores, the Paipo could cause a paradoxical effect, the product triggering relapse in order to compensate for the additional frustration/stress. Besides, the purpose of the study may convey to participants the message that there is an easy remedy for tobacco addiction (*i.e.* "the nicotine free inhalator may help you stay quit during your attempt"), thus generating false expectations in the smokers' mind. This, unintentionally, would produce a boomerang effect that undermines motivation to continue to abstain from smoking in some participants (particularly those with low GN-SBQ scores), who would then quickly relapse. This interpretation is speculative and warrants specifically designed study, but, if confirmed, smokers with low GN-SBQ scores should not be given the device. In addition, we have shown that success rates in smokers with low GN-SBQ scores appear to be markedly dependent on their initial level of motivation (OR 12.7). Although motivation levels (assessed at baseline by Mondor test) were evenly distributed between the Paipo and reference study groups, as well as between low GN-SBQ and high GN-SBQ subgroups, and considering that smoking cessation is not an event but a process, the predictor variable "level of motivation" recorded at baseline may not be very representative of the dynamic psychological and physical changes occurring in the smokers struggling to quit. Dynamic changes in motivation levels may occur in both

TABLE 1 Cross tabulation (intent-to-treat analysis at week 24) comparing quit rates relative to physical (*i.e.* the Fagerström Test for Nicotine Dependence (FTND)) and behavioural dependence (*i.e.* the Glover–Nilsson Smoking Behavioral Questionnaire (GN-SBQ)) in the Paipo users

	Relapse	Quit
High FTND and high GN-SBQ	5/16 (31.3)	11/16 (68.7)
High FTND and low GN-SBQ	27/30 (90.0)	3/30 (10.0)
Low FTND and high GN-SBQ	3/8 (37.5)	5/8 (62.5)
Low FTND and low GN-SBQ	5/6 (83.3)	1/6 (16.7)
Total	40/60 (66.7)	20/60 (33.3)

Data are presented as n/N (%). High and low FTND classes are defined as FTND ≥ 6 and < 6 , respectively; high and low GN-SBQ classes are defined as GN-SBQ ≥ 23 and < 23 , respectively. n=60.

directions in a smoking cessation study, with smokers losing confidence in their ability to quit experiencing a reduction in their level of motivation, and smokers achieving success boosting them up. We could not establish with confidence whether motivation levels were still balanced between groups throughout the duration of the study.

Lastly, it was suggested to expand upon the correlation between behavioural (*i.e.* GN-SBQ) and physical (*i.e.* the Fagerström Test for Nicotine Dependence (FTND)) dependence to clarify if they are independent of each other or correlated, in the assumption that a smoker highly dependent on nicotine would also tend to be more behaviourally dependent. In our study, the results of the logistic model analyses indicate that only the use of Paipo is an important predictor of success in smokers with high GN-SBQ score (OR 8.45), whereas FTND has no impact in the model. We also carried out additional analyses in the Paipo users (table 1); cross tabulation of quit rates at week 24 (intent-to-treat analysis) showed that in smokers with low GN-SBQ, chance of success was much higher in low FTND (16.7% success rate) compared to high FTND group (only 10.0% success rate). However, the numbers in some of the cells is so small that no sound conclusion can be

reached about potentially important interactions between behavioural and physical dependence.

Perhaps, as sensibly pinpointed by K. Fagerström, the main strength of this study is that it has the potential to open up a new line of research, in which improved characterisation of behavioural sub-phenotypes in smokers undergoing smoking cessation programmes can be exploited to advance current understanding of tobacco dependence and its management.

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Upper age limit for bronchiolitis: 12 months or 6 months?

To the Editors:

MIDULLA *et al.* [1] published their interesting results on virus-specific 1-yr outcome of infants with bronchiolitis requiring hospital treatment. Originally, 313 bronchiolitis patients aged < 12 months with no previous wheezing histories were recruited during a 5-yr period, excluding summer times. On admission, 195 viruses were detected in 174 (55.6%) infants by PCR from

nasal wash samples. As the authors concluded, the virus detection rate was rather low [1]. When nasopharyngeal aspirates are studied and the available PCR panel covers all notable respiratory viruses, the rate can be nearly 100%, as was seen in our recent study in < 6 -month-old infants with bronchiolitis [2].

12 months later, 262 (83.7%) parents were contacted by telephone and interviewed using structured questionnaires,