**Background:**

Nicotine replacement therapy (NRT) assists smokers to quit, primarily, by relieving tobacco withdrawal symptoms. Products that deliver nicotine faster may provide greater withdrawal relief and increase abstinence rates.

Three novel NRTs — Zonnic 4 mg, gum, and Zonic 1 mg/dose mouth spray and Zonic 2.5 mg lozenge have been designed for rapid delivery of nicotine.

**Objectives:**

To compare the effects of the novel pouch, mouthspray and lozenge on withdrawal discomfort and craving after overnight abstinence from smoking with Nicorette® 4 mg nicotine chewing gum and placebo.

**Method:**

Design: Randomised, placebo controlled, single blind, repeated measures, cross over study.

Participants and procedure: A total of 77 dependent smokers aged 18–70 years were recruited (see Table 1 for participant characteristics).

The study was undertaken in two parts:

1. Part 1 (n=30) compared the pouch with gum and placebo pouch
2. Part 2 (n=47) compared lozenges, mouthspray and placebo lozenges

Participants reported to the study site at 0730 on each study day, after overnight abstinence from smoking with Nicorette® (carbon monoxide verified), provided baseline ratings, were randomly assigned to each NRT, then completed regular withdrawal ratings over 60 minutes on a 100mm visual analogue scale (VAS). Afterwards, they were asked to continue to abstain, use the product ad lib, leave the study centre, until returning at 1730 to report adverse effects and product satisfaction using a 5-item questionnaire adapted from Hajek et al. 1989.

**Primary outcome:** Mean change in craving score over 60 minutes (area under the curve/60 mins)

**Other outcomes:** Comparisons of VAS change from baseline at each time point; Satisfaction and helpfulness of the products — assessed using a 5-item questionnaire adapted from Hajek et al. 1989.

**Statistical Methods and Outcome measures:** Analysis of covariance (ANOVA) with individual participants included as random effects. The Tukey-Kramer method was used for multiple comparison adjustment.

**Results:**

Reduction in craving scores over time is shown in figures 1 and 2.

**Part 1:**

- Overall there was a 23, 15, and 9 unit reduction in craving over 60 minutes in the pouch, gum and placebo groups respectively.
- The pouch produced significantly greater reduction in craving compared to placebo (see table 2).

**Part 2:**

- Over 60 minutes the mouth spray showed the greatest reduction in craving (29 units) followed by the gum (26 units), lozenge (25 units) and placebo lozenge (9 units) (table 2).
- Compared to placebo, active NRTs had significantly greater craving relief (see table 2).
- Area under the curve comparisons between active products (lozenge, mouthspray and gum) showed no statistical differences at 60 minutes, but mouthspray showed superior craving relief than the gum throughout the first 20 minutes (see figure 2).

**Conclusions and recommendations:**

- Three novel nicotine treatments have shown equivalent efficacy in reducing craving after overnight abstinence, compared to gum and are likely to show similar efficacy in assisting smokers to quit.
- The pouch and mouthspray groups showed a trend for faster and greater craving relief than gum, which may result in increased efficacy as a quitting aid, although not significant.
- The pouch and the mouthspray hold promise of superior user compliance, and may be acceptable to a broader range of smokers attempting to quit, indicated by ratings of user efficacy.

**References:**


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