RESEARCH LETTER

Smoking Termination Opportunity for inPatients (STOP): superiority of a course of varenicline tartrate plus counselling over counselling alone for smoking cessation: a 12-month randomised controlled trial for inpatients

Rationale Smoking cessation interventions in outpatient settings have been demonstrated to be cost effective. Given this evidence, we aimed to evaluate the effectiveness of varenicline tartrate plus Quitline-counselling compared with Quitline-counselling alone when initiated in the *inpatient* setting.

Methods Adult patients (18–75 years) admitted with a smoking-related illness to three hospitals, were randomised to receive either 12-weeks of varenicline tartrate plus Quitline-counselling, (n=196) or Quitline-counselling alone, (n=196), with 12-months follow-up.

Results For the primary analysis population (intention-to-treat), the proportion of subjects who remained continuously abstinent were significantly greater in the varenicline plus counselling arm (31.1%, n=61) compared with counselling alone (21.4%, n=42; RR 1.45, 95% CI 1.03 to 2.03, p=0.03).

Conclusions The combined use of varenicline plus counselling when initiated in the inpatient setting has produced a sustained smoking cessation benefit at 12-months follow-up, indicating a successful opportunistic treatment for smokers admitted with smoking related illnesses.

Trial registration http://www.clinicaltrials.gov/ ClinicalTrials.gov identification number: NCT01141855.

Smoking accounts for 15% of all deaths, 80% of all lung cancer deaths and is responsible for the greatest disease burden in Australia.[1] In the outpatient setting, varenicline tartrate has been shown to raise the odds of quitting smoking by 2.5–3-times compared with placebo, 12-months after quitting.[2 3] Of the available primary prevention initiatives, general practioners (GPs) significantly under-use Quitline services or medications, and only 6% of patients who are encouraged to use Quitline by their GP do so.[4] Abstinence from smoking, following a hospital admission, has been associated with reduced readmissions, with patients who stop smoking by the time of discharge, after 5 year follow up, having up to 31% less hospital admission bed days, 13% less outpatient visits and 50% less bed days used compared with those that continue smoking,[5] yet to our knowledge initiation of varenicline has not been evaluated in an inpatient-initiated setting, where the opportunity for a targeted secondary prevention programme combined with counselling could be used. Inpatient stays may provide (i) an opportunity to use a patient's reflection upon their illness (ii) bedside phone to ensure initial contact with Quitline counselling service, and (iii) observation period for any medication related adverse effects. We therefore conducted a randomised, multicentre controlled clinical trial, with a 12-week treatment phase and 12-months follow-up.

Participants were recruited following admission to hospital due to a serious smoking related illness, within the disciplines of respiratory, cardiology, neurology and vascular medicine. They were aged 18–75 years, smoked at least 10 cigarettes per day over the past 12 months with a plan of discharge to go home. Screening 1959 patients provided 392 subjects who were randomised to either varenicline tartrate (titrated from 0.5mg daily to 1mg twice daily) plus Quitline counselling (n=196) or Quitline counselling alone (n=196).

For the primary outcome of continuous abstinence at 12-months, the proportion of successful subjects in the varenicline plus counselling arm was significantly greater with 31.1% (n=61) compared with 21.4% (n=42) in the counselling alone arm (RR 1.45, 95% CI 1.03 to 2.04, p=0.03; table 1). The secondary outcome of continuous abstinence for weeks two through 26 was superior for varenicline plus counselling compared with counselling alone (39.8% vs 27.6% respectively, p=0.02), as were weeks two through 12, (48.4% vs 36.2% respectively, p=0.02). Following adjustment for baseline discipline differences, each of these results became more significant. The differential gap in smoking between groups was maintained, with both arms showing reuptake of smoking; however, this gap remains significant despite the plateau (figure 1).

At the end of the 12-week treatment period, the abstinence for varenicline plus counselling over counselling alone and adverse event profile were similar to results reported in outpatient studies.[2] Targeting inpatients during the period of hospital confinement where admissions result from smoking-related diseases, utilises an opportunity for initiation of best practice treatment. The STOP trial has provided a real world assessment of varenicline in the inpatient setting, demonstrating effectiveness for patients following an acute smoking-related admission.

Table 1 Continuous smoking abstinence at each follow-up period

Levels of continuous abstinence								
Defined as a total of <5 cigarettes during the defined period of follow-up								
	Varenicline		Control					
Continuous	n	%	n	%	RR	95% CI	p Value	Adj. p value
2–52-weeks	61	31.1	42	21.4	1.45	1.03 to 2.04	0.03	0.01
2–26-weeks	78	39.8	54	27.6	1.43	1.07 to 1.90	0.02	0.006
2–12-weeks (EOT)	95	48.5	71	36.2	1.32	1.04 to 1.67	0.02	0.01

Based on intention-to-treat analysis; sample size in each arm n=196.
Adj, Adjusted for baseline discipline differences (cardiology, respiratory, neurology, Vascular); EOT, End of treatment.

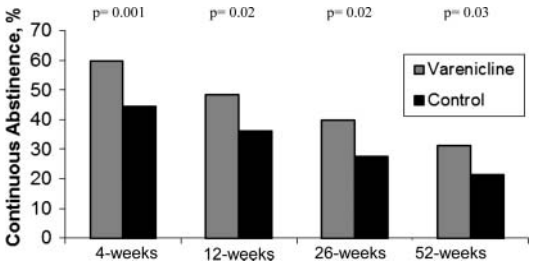

Figure 1 Differential gap over the 52-week study period in continuous smoking abstinence between groups.

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► An additional data is published online only. To view this file please visit the journal online (http://dx.doi.org/10.1136/thoraxjnl-2012-202484).

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