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Varenicline alone or in combination with nicotine lozenges for smoking cessation

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INTRODUCTION

Smoking cessation support offered within hospitals remains limited and interventions are *ad hoc*.

Newer strategies are essential to facilitate long-term abstinence.

The effectiveness of the combination of varenicline and acute release forms of nicotine replacement therapy (NRT) is unknown.

OBJECTIVES

To determine if hopitalised smokers treated with varenicline and NRT lozenges achieve a higher prolonged smoking abstinence rate compared with those treated with varenicline alone.

METHOD

Design: Double-blind, placebo controlled, randomised controlled trial.

Inclusion criteria: Adult medical/surgical hospital in-patients self-reporting smoking ≥10 cigarettes per day, who were interested in quitting and available for follow-up for.

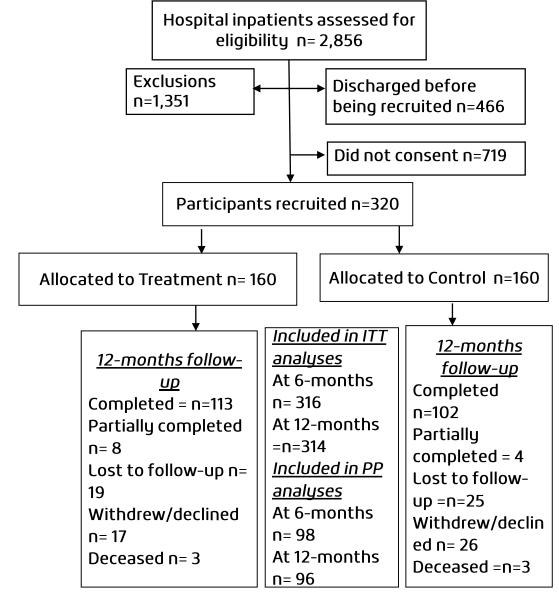
Exclusion criteria: Patients already receiving NRT/varenicline (or with contraindications) e.g. terminal disease, unstable cardiovascular condition or a major psychiatric illness.

Intervention: 12-week varenicline was initiated during hospitalization. 320 participants were randomised to use varenicline with NRT (2-mg) lozenges or placebo lozenges should there be an urge to smoke. Behavioural support (Quitline) was offered to all participants.

Outcome measures:

Primary endpoint: Biochemically verified abstinence at 12 months.

Secondary endpoints: Self-reported prolonged abstinence; 7-day point prevalence abstinence (6 and 12-months) and medicine-related adverse events.



RESULTS

Outcome	Intervention (n=160) n (%)	Control (n=160) n (%)	P-value	Odds ratio (95% CI)
Smoking abstinence at 3-months				
Self-reported prolonged abstinence	70 (44.3)	52 (32.7)	0.018	1.87 (1.11 – 3.14)
Self-reported 7-day point prevalence abstinence	57 (36.1)	40 (25.2)	0.022	1.88 (1.09 – 3.24)
Smoking abstinence at 6-months				
Biochemically verified prolonged abstinence	3 (1.9)	10 (6.3)	0.078	0.21 (0.036 – 1.19)
Self-reported prolonged abstinence	61 (38.6)	47 (29.7)	0.032	1.78 (1.05 – 3.02)
Self-reported 7-day point prevalence abstinence	54 (34.2)	37 (23.4)	0.011	2.06 (1.18 – 3.60)
Smoking abstinence at 12-months				
Biochemically verified prolonged abstinence	13 (8.3)	6 (3.8)	0.035	3.49 (1.09 – 11.16)
Self-reported prolonged abstinence	47 (29.9)	30 (19.1)	0.016	2.07 (1.15 – 3.73)
Self-reported 7-day point prevalence abstinence	48 (30.6)	31 (19.7)	0.008	2.21 (1.23 – 3.94)

DISCUSSION

Strengths:

Blinded outcome assessment, losses to follow up analysed as smokers.
Pragmatic trial conducted in public hospitals during pandemic.

Limitations:

Nicotine lozenges might have been recognised by some participants. Biochemical validation was affected by COVID-19 pandemic restrictions.

CONCLUSION

- The combination of varenicline and NRT lozenge was well tolerated and improved self-reported abstinence rates.
- Varenicline may be used in combination with an acute release oral dose form of NRT for better cessation outcomes, without compromising its safety.

REFERENCES & ACKNOWLEDGEMENTS

Gobarani RK, Abramson MJ, Bonevski B, et al., The efficacy and safety of varenicline alone versus in combination with nicotine lozenges for smoking cessation among hospitalised smokers (VANISH): study protocol for a randomised, placebo-controlled trial. BMJ Open 2020. **10**(10): e038184