

SMOKING REDUCTION WITH A 4 MG NICOTINE GUM - FINAL RESULTS FROM A PLACEBO-CONTROLLED TRIAL OVER 13 M

Björn Landfeldt¹, Anil Batra², Hubertus Magnus Friederich², Karl Klingler³, Åke Westin¹

1. Pfizer Consumer Healthcare, Helsingborg, Sweden 2. Dep. of Psychiatry and Psychotherapy, University of Tübingen, Germany

3. Klinik Hirslanden, Dep. of Pulmonary, Sleep and Critical Care, Zürich, Switzerland

Background

Several studies have investigated the effect of nicotine replacement therapy (NRT) on smoking reduction, and concluded that NRT

- helps smokers to cut down their cigarette consumption in a safe way
- promotes smoking cessation

in smokers not ready to quit¹⁻⁵. Thus, offering smoking reduction as a new approach to cessation involves a broader population of smokers compared to traditional interventions. This study was performed to confirm these findings.

Methods

Regular smokers (n=364), not ready to quit but willing to reduce smoking, consuming at least 20 cigarettes per day, were randomized to ad libitum use of either nicotine 4 mg or placebo gum for up to 12 Months. Table 1.

Smoking reduction was defined as a reduction of cigarettes smoked by at least 50% compared to baseline from w 6, and verified by any decrease in carbon monoxide (CO) compared to baseline. A CO below 10 ppm verified self-reported abstinence.

Table 1. Demography

	Placebo n=180		Active n=184	
	Mean	Std	Mean	Std
Age (yrs)	43.5	10.3	42.6	9.9
Age when starting smoking	17.4	2.9	17.6	3.7
Cigarettes/day	29.6	9.5	27.9	9.1
CO (ppm)	28.2	10.2	29.1	10.9
FTND score	5.9	1.9	5.7	1.8

Results

Table 2. Efficacy

Definition	Time	Placebo n (%)	Active n (%)	Fischer's exact test
Sustained reduction from w 6	W 10	20 (11.1)	37 (20.1)	0.021
	M 4	12 (6.7)	29 (15.8)	0.008
	M 12	5 (2.8)	16 (8.7)	0.023
	M 13	5 (2.8)	15 (8.2)	0.036
Point prevalence abstinence	W 10	1 (0.6)	9 (4.9)	0.020
	M 4	4 (2.2)	12 (6.5)	0.071
	M 12	7 (3.9)	16 (8.7)	0.084
	M 13	8 (4.5)	22 (12.0)	0.012

Table 3. Daily gum dose and percentage reduction of cigarettes, CO, Thiocyanate (SCN) and cotinine in subjects with active treatment.

Time point	Gums/Day			Cigarette reduction (%)			CO Reduction (%)			SCN reduction (%)			Cotinine reduction (%)		
	N	Mean	Std	N	Mean	Std	N	Mean	Std	N	Mean	Std	N	Mean	Std
4 m	54	6.5	2.7	54	54.1	23.7	54	35.3	39.2	45	14.3	28.0	48	6.9	39.5
6 m	32	6.6	3.1	32	62.0	24.2	31	34.9	41.9
12 m	15	6.1	4.1	15	68.6	28.5	14	49.3	43.4	11	28.4	48.2	11	-6.3	70.9

Table 4. Intention to change smoking in the next month – all subjects

Time point	Placebo				Active			
	Stay quit	Quit	Reduce current level	Keep current level	Stay quit	Quit	Reduce current level	Keep current level
W 2	1	1	112	37	1	1	114	35
M 4	3	15	65	27	2	17	74	20
M 12	5	19	37	26	4	14	44	40
M 13	8	17	37	39	7	21	41	48

Table 5. Has your participation in this study changed your attitude towards quitting?

	Changed your attitude towards quitting?				More interested
	No	More interested in quitting	Less interested in quitting	I don't know	Yes
M 4	92	126	20	11	51%
M 13	92	150	5	4	60%

Conclusions

- Smoking reduction can be achieved by using 4 mg nicotine chewing gum
- Smoking reduction reduces toxin intake
- Smoking reduction increases intention to quit smoking
- Smoking reduction improves attitude towards quitting
- Smoking reduction promotes cessation among inveterate smokers

References

1. Fagerström KO, Tejdning R, Westin Å, Lunell E. Aiding reduction of smoking with nicotine replacement medications. Hope for the recalcitrant smoker? *Tob Control* 1997; 6(4): 311-316.
2. Bolliger CT, Zellweger JP, Danielsson T, van Biljon X, Robidou A, Westin Å, Perruchoud AP, Säwe U. Smoking reduction with oral nicotine inhalers: double blind, randomised clinical trial of efficacy and safety. *BMJ* 2000; 321(7257): 329-33.
3. Eliasson B, Hjalmarson A, Kruse E, Landfeldt B, Westin Å. Effect of smoking reduction and cessation on cardiovascular risk factors. *Nicotine & Tobacco Research* 2001; 3:249-255.
4. Bolliger CT, Zellweger JP, Danielsson T, van Biljon X, Robidou A, Westin Å, Perruchoud AP, Säwe U. Influence of long-term smoking reduction on health risk markers and quality of life. *Nicotine & Tobacco Research* 2002;4(4): 433-439.
5. Wennike P, Danielsson T, Landfeldt B, Westin Å, Tønnesen P. Smoking reduction promotes smoking cessation. Results from a double blind, randomised, placebo-controlled trial of nicotine gum with 2-year follow-up. *Addiction* 2003;98: 1395-1402.

Acknowledgement:

Thanks to Tobias Danielsson for his valuable input in designing and performing this study and for his help analyzing the results.