NicoBloc
Summary of research data

Alex R. Milne, Freelance neuroscience copy editor; occasional consultant with special interest in smoking. Author of 'Smoking, the inside story', 1998. *Woodside, High Onn, Stafford ST20 0AX, UK*

Competing interests: Dr Alex Milne, is an independent consultant who was engaged by NicoBloc to summarise published scientific data.

Abstract

The research data shows that NicoBloc reduces the delivery of tar (smoking machine tests, visible presence of tar in filter) and nicotine (smoking machine tests, physiological measurements). Plasma nicotine boost from smoking is also reduced by use of the fluid. Smokers reported no change in satisfaction or taste and no increased craving or withdrawal was experienced, although they reported increased resistance when drawing on the cigarette, and a slight decrease in strength. Both independent studies involving human smokers supported the potential utility of this alternative treatment approach; the Rosen Programme achieved a 42% quit rate in 680 enrolees and the Gariti study 53% of 19.

Available data

There are two categories of data: independent reports/publications, and company records from the Rosen Programme (forerunner to NicoBloc).

Note: NicoBloc fluid ('the fluid') has previously been available under the names Accu Drop, Take-out and The Rosen Fluid; all are the same formula.

Independent reports

1. **Stillwell & Gladding, New York (1st series - February 1989)**: smoking machine tests according to Federal Trade Commission-approved methods on two brands of cigarette, Marlboro and Winston. Percentages given are the reduction in nicotine and tars from the fluid-treated cigarettes vs. the untreated cigarettes.

- Winston: nicotine reduced by 98%, tars by 99%
- Marlboro: nicotine reduced by 88.5%, tars by 90%

2. **Stillwell & Gladding, New York (2nd series - April 1993)**: smoking machine tests using three drops of Accu Drop. One 35-mL puff, 2-s duration, once every minute.

- Winston King Size: nicotine reduced by 97.3% and tars by 99.2%
- Marlboro King Size, nicotine reduced by 98.1%, tars by 98.6%.

3. **University of Pennsylvania School of Medicine Treatment Research Centre**: Gariti, P. & Alterman, A. (1997) Accu Drop: testing a smoking cessation aid. College on Problems of Drug Dependence, 59th annual meeting, Nashville, TN, USA, June 1997. In: NIDA research monograph # 178. Problems of Drug Dependence. L. S. Harris (ed.), p 158. This publication reports results of a preliminary open trial using a 6-week 'brief motivational counselling protocol' plus Accu Drop and a decrease (optional) in the number of cigarettes smoked to assist smoking cessation.

- Nineteen participants (five male), ages 22–64 years, mean 42 years
- Thirteen (68%) completed treatment
- Ten (53%) were smoke-free at the end of treatment, confirmed by exhaled CO ≤ 9 ppm
- Seven (37%) were smoke-free at 1-month follow-up (CO ≤ 9 ppm)

- Subjective responses (excluding three early 'drop-outs'): all reported
- satisfaction
- adherence to using the drops
- decrease in strength but not taste of cigarettes
- progressive increase in difficulty of inhaling as number of drops increased
- no increased craving or withdrawal
- Subjective responses: some reported a tendency to take more puffs than usual
- The seven who were smoke-free at 1-month follow-up reported only mild to moderate withdrawal symptoms during the first week post-treatment
  The conclusion was that 'These findings support the potential utility of this alternative treatment approach'.
  4. National Institute of Drug Abuse, Addiction Research Center, Baltimore, MD, USA: Pickworth, W. B., Fant, R. V., Nelson, R. A. & Henningfield, J. E. (1998) Effects of cigarette smoking through a partially occluded filter. *Pharmacol. Biochem. Behav.*, **60**, 817–821. This study assessed the physiological effects of smoking a single cigarette with or without 'Take-out' fluid: exhaled CO, plasma nicotine, EEG, heart rate, blood pressure and subjective reports were recorded. It also reported on smoking-machine tests performed in a Canadian Laboratory. It did not address the question of quitting.
- Nineteen volunteers (10 men), mean age ~35 years, each smoked single cigarettes on five separate occasions, after ≥3 h self-reported abstinence. Two cigarettes were untreated, one smoked outside the experimental chamber and one inside. The other three, smoked inside the chamber, were treated with 1, 2 or 3 drops of Take-out fluid. Filters were coloured pink to disguise the number of drops applied (the fluid itself is pink). Smokers were instructed to smoke to a line 3 mm from the filter.
- Plasma nicotine, EEG and exhaled CO were measured, as were heart rate and systolic and diastolic blood pressure, and the number of puffs. Subjects scored, subjectively, satisfaction, taste, strength, draw, hotness, like and harshness.
- Machine smoking tests ('FTC conditions') measured nicotine, CO and tar yields with 0, 1, 2 or 3 drops of fluid. The cigarettes were from the same batch and lot as those used in the human smoking trials, and the tests were done by Labstat, Canada.
- Plasma nicotine and CO boosts were both significantly reduced by the drops; three drops reduced nicotine to 45% and CO to 59% (i.e reductions of 55 and 41% respectively) of the 0-drop condition (but see below re. CO data).
- Heart rate and blood pressures were all increased by smoking, with 'orderly but not significant' reductions in these values with increasing drop number.
- EEG did not change significantly as a result of any of the cigarettes/drops.
- Number of puffs taken to smoke the required length of cigarette was only significantly different between the two untreated cigarettes, with fewer puffs being taken in the 'natural' than smoking chamber location. Number of drops had no effect on number of puffs. (As smokers were required to smoke a particular length of cigarette, it would be hard to reach conclusions about 'compensatory' smoking behaviour.)
- Subjectively, 'draw' was significantly harder with increasing number of drops, and 'strength' showed the same tendency, though failed to make significance. Satisfaction, taste, hotness, like and harshness were all unaffected by the fluid.
- In the machine-smoking tests, nicotine and tar were both significantly reduced by the fluid, with CO not significantly affected. In the 3-drop condition, nicotine was reduced by 27% and tar by 23%.

Comparisons

It is hard to reconcile the smoking-machine tests in the Patents and from Stillwell & Gladding, which report tar and nicotine reductions of 88–99%, with those of Pickworth/Labstat which found 23–27% reductions. Labstat data are presented as histograms with error bars, but without stating whether these are SD or SEM, and without the number of cigarettes. Error bars are noticeably larger in the 2- and 3-drop conditions than 0- and 1-drop, hinting at a methodological problem. The patents emphasize the need to (i) totally cover the end of the filter with fluid, and (ii) not allow the fluid to dry before smoking (NicoBloc recommends applying the fluid not more than 15 mins before smoking).

The Pickworth paper demonstrates a reduction in plasma nicotine boost when the fluid was used on the filter (no practical method exists for measuring the tar consumed by the smoker).

- The nicotine results look robust, with six measurements over 1 h after smoking plotted as plasma nicotine vs. time, telling a coherent story (though results in the 1- and 2-drop conditions are very close, lying roughly midway between the 0- and 3-drop conditions)
- The picture with CO boost is less clear:
- the abstract of a poster presentation based on results from all 19 participants claims ‘exhaled CO increased after smoking but did not change as a function of treatment’
- the abstract of the full paper states ‘In the 3-drop condition, there was a significant reduction in exhaled CO levels’ (presumably a reduction in CO boost)
- in the body of the paper, they claim significant reductions in CO boost between 0 and all other drops, and between 2 and 3 drops. However, the CO results (a histogram with one bar per drop condition) also show very little difference between 1 and 3 drops, i.e. the 2-drop condition gave more CO boost than either 1 or 3. It is not stated whether the error bars on the histogram are SD or SEM, so it is difficult to assess significance.
- A drop in CO boost would suggest that less of the cigarette was smoked; given the lack of change in number of puffs with treatment, this would indicate smaller puffs.
- In the Discussion, the authors state that 3 drops ‘reduced the plasma nicotine and CO boosts by 45 and 59%, respectively’. It is clear from Fig. 2 and values quoted in the text that the reductions were *to* the quoted percentages, i.e. by 55 and 41%, respectively.
- There is an unanswered question concerning the pink colour used to disguise the presence of the fluid and whether this affected either the untreated cigarette or the action of the fluid. No information is given concerning this colour; the action of the Take-out fluid could be modified by any of a number of things added to the filter, including a drop of aqueous food colouring or some dry colouring pigment.

The Gariti paper demonstrates the efficacy of the programme followed in helping quitters succeed. It does not attempt to assess the separate contributions made by the fluid and other aspects of the programme.

The subjective responses of the subjects in the Gariti and Pickworth papers are similar where common categories exist. All reported an increase in difficulty of draw with more drops, and a slight decrease in strength but not in satisfaction or taste of the cigarettes.

Rosen Programme company records

Over the past 8 years, approaching 3,000 smokers in Ireland and the UK enrolled on Rosen Stop Smoking courses. Analysis of the totality of data is being undertaken. However, a subset has already been looked at: in 2000, data on all enrolees since the first UK courses (January 1998) were collected and examined. In this period, a total of 680 smokers enrolled on 88 Rosen Stop Smoking courses. The mean number of enrolees was 7.7/course, range 1–26. All participants smoked their own preferred brand(s) during the course.

The programme centred around the use of the 'Rosen Fluid' (NicoBloc) and did not contain any elements of counselling (beyond what was incidental to the programme) or any other 'therapy'. Each participant was given an adequate supply of the fluid (and shown how to use it), a record card to note their daily cigarette consumption and a smoking reduction plan for the ensuing week. The sessions in Ireland worked in the same way.

During the weekly group session, a suitable health promotion video was shown (a different one each week) which kept the rest of the group beneficially occupied while each person had a brief one-to-one session with the 'group leader' who checked their smoking record for the previous week and gave independent feedback to the smoker via an exhaled CO monitor which would show a corresponding reduction if their consumption had reduced. Then the amount of Rosen fluid used would be checked against their consumption and this would reveal whether they were using it properly or not (e.g. a 20-a-day smoker using 1 drop on each cigarette for a week would use roughly a quarter of a bottle). Based on their previous week's smoking record, the number of drops they were using and how long they had been using it, an individual reduction plan for the following week would be agreed.

Overall, 491 (72%) completed their course and 285 (42% of enrolees, 58% of completers) quit.

Twelve of the 88 courses had 100% of enrolees quitting and a further five had 100% of completers quitting. Eight courses had no quitters.

Subjectively, those on the course typically reported little drop in strength of the cigarettes and no change in taste. However, many of those who inadvertently smoked an untreated cigarette after at least a few days using the fluid were surprised that it tasted 'much stronger', and this in itself became an additional motivator to stay on course. Adherence to the regime was not generally perceived as a problem and troublesome cravings and withdrawal symptoms were not reported and, indeed, specifically denied on many post-course feedback forms.

Cigarette consumption and exhaled CO were recorded weekly. Even in the courses with no quitters, both these had reduced appreciably between weeks 1 and 6.

Long-term follow-up

These data are very incomplete at present as they were not systematically collected as part of the Rosen Programme. Results of 1–3-yr follow-up have so far been obtained from three courses (38 enrolees, 30 quitters), and they indicate that 26 (87%) of the quitters were still smoke-free 1–3 years later. With the 80% quit rate on these three courses, this is an outlying subset.

Collecting this kind of follow-up information is (i) hampered by people moving or changing jobs, (ii) very open to bias; of those who can be traced, the 'still smoke-free' will be eager to report the fact, the 'smoking again' will be less so. A much larger sample will be needed to draw any meaningful conclusion.

Overall Conclusions

- The fluid reduces the delivery of tar (smoking machine tests, visible presence of tar in filter) and nicotine (smoking machine tests, physiological measurements).
- Plasma nicotine boost from smoking is also reduced by use of the fluid.
- Smokers reported increased resistance when drawing on the cigarette, and a slight decrease in strength. They reported no change in satisfaction or taste.
- Both independent studies involving human smokers concluded that the fluid could be a useful adjunct to a quitting programme; the Rosen Programme achieved a 42% quit rate in 680 enrolees and the Gariti study 53% of 19.
- Long-term follow-up data is sparse: the Gariti study showed that 37% of the 19 smokers (70% of the 10 quitters) were still smoke-free 1 month after the end of the study. Data so far collected from the Rosen Programme is from a small and outlying (atypically successful) subset but shows that 26 of 30 quitters (87%) were smoke-free 1–3 years later.

Comment from Rosen Programme/NicoBloc personnel

The published evidence clearly shows that use of the NicoBloc fluid reduces the delivery of tars and nicotine. However, there are other important elements of the NicoBloc programme which also contribute to the quitting attempt. These include behavioural modification (applying the fluid to the cigarettes, breaking the pack-to-mouth routine), goal-setting (record keeping and planned reductions), psychological shift (making decisions to smoke rather than trying not to smoke) and feedback (sight of the accumulated tars on the filter end, unpleasant taste if the accumulated tar comes into contact with the tongue, increased sense of wellbeing as cigarette consumption decreases and, finally, use of the nicotine test kit to confirm the absence of nicotine).

Experience with the Rosen Programme suggests that attempting to reduce smoking more quickly, to quit in less than 6 weeks, makes the quit attempt more difficult. We believe that, for many would-be quitters, the combination of NicoBloc fluid and slow reduction in the number of cigarettes smoked result in decreasing the consumption of nicotine sufficiently slowly that cravings and other withdrawal symptoms either do not occur or are mild enough to be tolerated. In conjunction with the positive psychological and behavioural aspects of the programme, NicoBloc is an effective quitting aid.