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A Randomized Trial of Nicotine Nasal Spray in Adolescent Smokers

Mark L. Rubinstein, M.D.,

Division of Adolescent Medicine, University of California, San Francisco, San Francisco, CA.

Neal L. Benowitz, M.D.,

Division of Clinical Pharmacology and Experimental Therapeutics, Departments of Medicine, Psychiatry and Biopharmaceutical Sciences, University of California, San Francisco, San Francisco, CA.

Glenna M. Auerback, M.P.H., and

Division of Adolescent Medicine, University of California, San Francisco, San Francisco, CA.

Anna-Barbara Moscicki, M.D.

Division of Adolescent Medicine, University of California, San Francisco, San Francisco, CA.

Abstract

OBJECTIVES—Nicotine nasal spray has been one of the most successful forms of nicotine replacement therapy in adult populations. The nasal sprayer has not been studied in adolescent smokers. The objective of this pilot study is to determine the feasibility and utility of using nicotine nasal spray (NNS) in adolescent smokers who want to quit smoking.

PARTICIPANTS—Forty adolescent smokers between 15 and 18 years-old, who smoked 5 or more cigarettes daily for at least 6 months were recruited from several San Francisco Bay area schools from 2005–2007.

METHODS—Using a randomized, open-label, 12-week trial, adolescent smokers were assigned to receive either weekly counseling alone (control) for 8 weeks or 8 weeks of counseling along with 6 weeks of NNS.

OUTCOME MEASURES—Self-reported smoking abstinence verified by both expired-air carbon monoxide and salivary cotinine.

RESULTS—There was no difference in cessation rates, the numbers of cigarettes smoked per day or cotinine levels at 12 weeks ($p=.16$, $p=.22$, and $p=.16$ respectively). Fifty seven percent of participants stopped using their spray after only one week. The most commonly reported side effect was nasal irritation and burning (34.8%) followed by complaints about the taste and smell (13%).

CONCLUSIONS—The unpleasant side effects, poor adherence, and consequent lack of efficacy observed in our pilot study do not support the use of nicotine nasal spray as an adjunct to counseling for adolescent smokers wishing to quit.

Keywords

Smoking cessation; adolescent; nicotine nasal spray

Address correspondence to: Mark L. Rubinstein, M.D. University of California, San Francisco, Division of Adolescent Medicine, 3333 California Street, Suite 245, San Francisco, CA 94118 USA, Email: Rubinsteinm@peds.ucsf.edu Tel: 415-476-9618, Fax: 415-476-6106.

The work was performed at the University of California, San Francisco, San Francisco, CA.

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INTRODUCTION

Most adolescent smokers who are daily smokers are addicted to nicotine and want to quit but find it difficult to do so (1,2). Rates of quitting smoking among adolescents not participating in structured cessation programs range from 0–11% (3,4). The role of nicotine replacement as an effective means of augmenting success rates among smokers wishing to quit has already been well established among adults (5). Quit rates nearly double when nicotine replacement therapy (NRT) is used in adults (6). To date, only a few studies have examined the efficacy of NRT for adolescent smoking cessation (7–10). Moreover, the only forms of NRT that have been evaluated in adolescents are the transdermal patch and the nicotine gum and those trials have demonstrated limited success (11).

Although not studied previously in adolescent populations, nicotine nasal spray (NNS) might be more useful than other types of NRT for adolescents for a number of reasons. First, the nasal spray employs a relatively fast system for delivering nicotine which is expected to speed relief of withdrawal and craving which adolescents are likely to value. Second, compared with the transdermal delivery of the patch, self-administration of the nasal spray allows for greater self-control of relief from withdrawal symptoms and self-control may play a large role in strategies for adolescents seeking to quit. In addition, among the different types of NRT, NNS appears to be one of the most efficacious in adults (6,12–14). The aim of this pilot study was to explore the feasibility and utility of using nicotine nasal spray in adolescent smokers wishing to quit.

METHODS

Study Population

The research design and procedures were reviewed and approved by the Institutional Review Board at the University of California San Francisco. In 2005–2006, adolescent smokers were recruited from five San Francisco Bay area high schools using fliers and posters. Study staff also recruited directly from smoking cessation classes situated in each of the schools. Participants were required to be between 15 and 18 years-old, smoke 5 or more cigarettes per day (cpd) for at least 6 months and want to quit smoking. The cutoff of 5 cigarettes per day was chosen based on estimates that the daily intake of 5mg nicotine or less (roughly corresponding to 5 cigarettes per day) is the threshold level that can readily establish and maintain addiction in adults (15). Adolescents who were using or had used nicotine replacement in the prior week were excluded. Those who used bupropion (Zyban®) within the past 30 days were also excluded.

Informed written consent was obtained from the adolescent subject and from one parent or legal guardian prior to data collection. Participants were randomly assigned in a 1:1.5 ratio to receive either weekly counseling alone for 8 weeks or 8 weeks of counseling in conjunction with 6 weeks of NNS using a computer generated randomization list. The randomization sequence was generated by Dr. Rubinstein and concealed until interventions were assigned. Participants were provided with remuneration for their participation in this open label trial.

Nicotine Nasal Spray group

Participants assigned to use the nasal spray were given training on proper usage and were instructed to begin using the sprayer following the second week of counseling. Nicotrol® Nasal spray (Pfizer) delivers a metered dose spray of approximately 0.5 mg of nicotine. One dose (2 sprays, one in each nostril) is considered to deliver a dose of 1 mg of nicotine. Participants were advised to use their sprayer whenever they had strong cravings for a cigarette, but not to exceed 40 doses per day. Participants were instructed to stop using the spray by their last visit

(at 8 weeks) if possible. To achieve this, participants were instructed to begin using the spray less frequently during the weeks prior to the final visit. Empty sprayers were collected prior to new ones being distributed, and participants were instructed not to share their sprayer with anyone.

Counseling and Follow-up

Group counseling was based on the American Lung Association's Not On Tobacco curriculum (16), a smoking cessation program designed specifically for teen smokers. Each group counseling session was run by a trained facilitator from the American Lung Association, was comprised of between 6 and 12 participants, and lasted approximately 45–60 minutes. Participants returned weekly for a total of 8 counseling sessions. Quit dates were arranged to follow the second counseling session at which time the first weeks' supply of nasal sprayers was distributed to participants randomized to the NNS group. Post-counseling follow-up visits were conducted after the last counseling session and four weeks later (e.g., at 8 and 12 weeks).

Measures

Baseline characteristics—At baseline, participants completed a self-administered questionnaire which included demographics, and baseline smoking characteristics (e.g., frequency and quantity of cigarette smoking, depth of inhalation, and amount of each cigarette smoked). Number of cigarettes smoked each day was calculated by averaging the number of cigarettes smoked that they reported for each day of the last week during which they smoked. Participants were asked how much of each cigarette they smoked (e.g., 100%= down to the filter to 0%= none) and how deeply they inhaled (e.g., “very deeply” to “no smoke at all”). Nicotine dependence was assessed using the Fagerström Tolerance Questionnaire modified for use in adolescents (mFTQ; (17)). Participants were also asked to describe the degree to which they felt addicted to tobacco by using a scale from 0= “not at all addicted” to 100= “totally addicted.” The participants' motivations for quitting were assessed using the Reason for Quitting (RFQ) scale (18) which includes sub-scales which measure self-concept issues, health concerns, and social influence.

Craving and Withdrawal—Nicotine craving and withdrawal were assessed at all visits. Craving was assessed using the following question. “How soon after you wake up do you crave your first cigarette?” Possible responses ranged from 1= “less than 15 minutes,” to 7= “I don't crave cigarettes.” This question was chosen to best measure craving based on recent literature suggesting that responses were highly correlated with addiction among smokers (19). Nicotine withdrawal symptoms were measured using the Minnesota Withdrawal Scale (20).

Determination of Smoking Status—A salivette® (Sarstedt Ltd) was used to collect saliva for measurement of cotinine levels at baseline and 12 week follow-up. The salivette is a cotton swab within a plastic container, designed for collection of saliva samples for drug analysis. Adolescents were asked to open the salivette® tube, place the cotton swab into their cheek for two minutes, remove the swab, place it immediately into the salivette® container, and secure the cap tightly on the tube. Cotinine was measured using liquid chromatography-tandem mass spectrometry with a lower limit of detection of 0.1 ng/ml (21). Adequate saliva samples for cotinine measurement were obtained from 31 (78%) of the 40 smokers. Participants also had expired-air carbon monoxide (CO) measured using the Vitalograph Breath CO monitor (Vitalograph, Inc.) at baseline and each follow-up visit. All procedures were performed under the supervision of research staff. The principle criterion used for determination of abstinence was self-reported continuous abstinence for at least 7 days, validated by a CO concentration of < 4 ppm (22).

Attitudes about the nasal spray—At the 8 week follow-up, participants who were assigned to use the nasal spray were asked to rate their experiences with regards to ease of use, efficacy, and side effects using a 5-point Likert type scale (1= “strongly agree” to 5= “strongly disagree”). We also collected spontaneous qualitative data by asking participants to list three things they liked and three things they disliked about the spray.

Spray use—Use of the spray was determined by self-report of the number of sprays administered each day. In addition, open ended questions were asked regarding potential side effects of the sprayer at each visit.

Data Analysis

The original power calculation for the NNS trial was based on standard assumptions (e.g., $\alpha = .05$, $\beta = .80$) for an efficacy study and would have required a sample size of 144. These estimates proved to be unrealistic given difficulties in recruitment (e.g., negative word of mouth regarding the burning associated with the spray) and thus we truncated the study for a feasibility study. Power levels in the final sample size ($n = 40$) were sufficient for exploratory analysis of effects. Descriptive univariate analyses of all the variables were performed and means and standard deviations were calculated. Chi square tests were used to compare abstinence rates. Independent t-tests were used to compare the change in cigarettes smoked per day, withdrawal symptoms and craving between groups, and from baseline to follow-up. In all cases P values of $< .05$ were considered to be significant. An intention to treat analysis was used to determine abstinence such that participants who did not complete the study were considered to still be smoking. Correlation coefficients were calculated to assess the relationship between sprays per day and cigarettes smoked per day. In addition, associations between cotinine and self-reported smoking were assessed using bivariate correlation.

RESULTS

Demographic and smoking characteristics

Forty adolescents aged 15–18 (mean=16.7, $SD = .99$) were recruited (see Figure 1). As the main group of interest, the NNS plus counseling group was over-represented such that 23 participants were randomized to receive the NNS plus counseling and 17 were randomized to receive counseling alone (see Table 1). The sample was racially diverse with less than half being white: 54% were female. Mean baseline smoking rate was 9.9 cpd ($SD = 6.4$) and mean baseline cotinine was 123 ng/ml ($SD = 79$). Baseline cotinine was correlated with the reported number of cigarettes smoked per day at baseline ($r = .40$, $p = .02$). Forty percent reported that their father or male guardian smoked, 43% reported a mother or female guardian smoked, and 90% reported that their best friend smoked. Seventy seven percent of participants reported having tried to quit in the past. When asked how confident they were that they could “quit smoking for good” this time, 77% reported that they were “fairly or very confident.” Eleven (28%) participants reported having used a nicotine patch, and 9 (23%) reported using nicotine gum during a prior unsuccessful quit attempt. None had used the nasal spray.

The proportions of randomized participants who completed the 8-week study were similar between both groups (e.g., 83% and 76% for the NNS plus counseling and counseling-only groups respectively, $p = .62$). At the 12 week follow-up 65% of participants in the NNS plus counseling and 70% of participants in the counseling-only group completed questionnaires ($p = .39$). Participants who withdrew from the study prior to completion had higher levels of salivary cotinine at baseline compared with participants who completed the study (169 ng/ml versus 104 ng/ml, $p = .04$). There were no differences at baseline for age, cigarettes smoked per day, score on the mFTQ, self-described level of addiction, score on the RFQ or number of prior

quit attempts between those who withdrew prior to completion of the study and those who completed the study (p values ranged from .29–.74).

Nasal spray use

During the first week of spray use, only 6 (26%) participants assigned to the NNS plus counseling group used their spray every day. Median use was reported at 1.14 sprays per day (range= .14–3). Ten (43%) participants assigned to the NNS plus counseling group were still using their spray by end of treatment (e.g., week 6 of nicotine replacement/week 8 of counseling) with a median of .64 sprays per day (range= .29–2). The other 13 (57%) participants stopped using their spray after only one week.

Abstinence

All participants who withdrew from the study prior to completion were considered to still be smoking. There was no difference in cessation rates between groups: 2 (11.8%) participants from the counseling only group quit smoking at 8-weeks and none of the participants in the NNS plus counseling group quit ($p=.16$). At 8 weeks, both groups had decreased their smoking rates from baseline with participants in the NNS plus counseling group reporting a 50% drop versus 28% among participants in the counseling only group ($p=.10$). The self-reported drop in cpd among the NSS users was highly correlated with the number of sprays administered in the preceding week such that the greater number of sprays used was associated with a greater reduction in the number of cigarettes smoked ($r=.55$, $p=.03$). At 12 week follow-up, participants in the NNS plus counseling group reported a 42% reduction in cigarettes smoked per day versus 32% for the counseling only group ($p=.61$). Teens also reported inhaling less deeply ($p=.02$) and smoking less of the cigarette ($p=.03$) at 12 weeks compared with baseline. Although the number of cigarettes smoked per day was correlated with cotinine at baseline, self-reported cigarettes per day was not correlated with cotinine level at 12 week follow-up in either group ($r=-.06$, $p=.84$).

Tobacco withdrawal symptoms and craving

Scores on the withdrawal scale were not different between the NNS plus counseling group and the counseling only group at 8-week follow-up (8.84 versus 9.58, $p=.26$; see Table 2). Similarly, after controlling for current cigarettes smoked per day, there were no significant differences in craving between participants in the NNS plus counseling and counseling only groups at the 8 week follow-up (3.47 versus 2.75, $p=.20$).

Side effects

Of the participants assigned to use the spray, 38.9% agreed or strongly agreed that the spray had “lots of side effects” (see Table 3). The most commonly reported side effect was nasal irritation and burning (34.8%) followed by complaints about the taste and smell (13%).

Attitudes about the spray

Seventy one percent of participants either “agreed or strongly agreed” that the spray “is good for preventing smoking” (see Table 3). Eighty three percent of participants assigned to use the spray “agreed or strongly agreed” that the spray made their “urge to smoke less” and 69% “agreed or strongly agreed” that the spray “controls my cravings.” Only, 39% of participants “agreed or strongly agreed” that they would recommend the spray to friends.

DISCUSSION

This study evaluated the utility and feasibility of using nicotine nasal spray in adolescent smokers attempting to quit smoking. Although our total sample was small, this is the first study

to evaluate the use of this mode of nicotine replacement in adolescent smokers. Despite 8 weeks of formal smoking cessation counseling and the addition of nicotine replacement in some participants, only 2 participants were able to quit smoking by the end of the trial. One of the reasons that might explain the low rate of overall quit rates was the infrequent use of the nasal spray. Although those participants assigned to use NNS were advised to use their spray whenever they had cravings, mean daily use was minimal (e.g., 1.5–.5 sprays per day). This low rate may have been due to the nasal irritation frequently reported by the participants. We did observe that the number of sprays used each day was highly correlated with the subsequent reduction in cigarettes smoked per day reported among participants assigned to the NNS plus counseling group. This might suggest that NNS may have been alleviating craving even with far fewer sprays than reported in adults. Unfortunately, we suspect that the reduction in cigarettes smoked per day may have been a result of underreporting since the reduction in cigarettes smoked per day was not associated with the expected decrease in saliva cotinine levels. Alternatively, teens may offset the drop in cigarettes smoked per day by a compensatory increase in smoking vigor (e.g., greater depth of inhalation etc.), thereby taking in more nicotine per cigarette. However, at follow-up participants reported a decrease in the amount of each cigarette smoked ($p=.02$) as well as lower volumes of inhalation ($p=.03$). Although, the self-reporting of depth of inhalation may not be reliable in adolescents.

Overall cessation rates obtained in our study were below those reported previously in samples of adolescent smokers (7,9,10,23–25). One possible explanation for this discrepancy is that our participants were less motivated to quit and more interested in the monetary compensation. There are several limitations of our study in addition to the small sample size. First of all, we utilized a school-based sample, which may not be generalizable to the office practice. Second, the lack of a placebo spray arm along with the interval lack of association between self-reported smoking and cotinine levels at follow-up may point to a possible measurement bias. Participants assigned to the NNS plus counseling group may have been more inclined to report what they feel to be a more socially desirable response (e.g., having cut down their smoking).

Nasal burning, especially during the first week of treatment was the most common complaint offered by participants in the NNS plus counseling group and was the reason most often given for poor adherence. Ironically, most participants viewed the spray positively. However, only a third would recommend it to friends to help with smoking cessation, suggesting the side effects are clearly an obstacle to its use. What is more, participants with severe nasal burning were so vocal in their complaints that many potential participants were reluctant to try the spray, a factor that clearly interfered with recruitment efforts (data not shown).

Based on our small, open label trial, use of nicotine nasal spray was not well tolerated resulting in poor adherence and a failure to promote quitting. Although a larger, blinded study of nicotine nasal spray is needed to definitively determine its efficacy for use in adolescent smokers, our pilot study does not support the use of nicotine nasal spray as an adjunct to counseling for adolescent smokers wishing to quit.

Abbreviations

NNS, nicotine nasal spray; NRT, nicotine replacement therapy; mFTQ, modified Fagerström Tolerance Questionnaire; RFQ, Reason for Quitting scale; CO, expired-air carbon monoxide.

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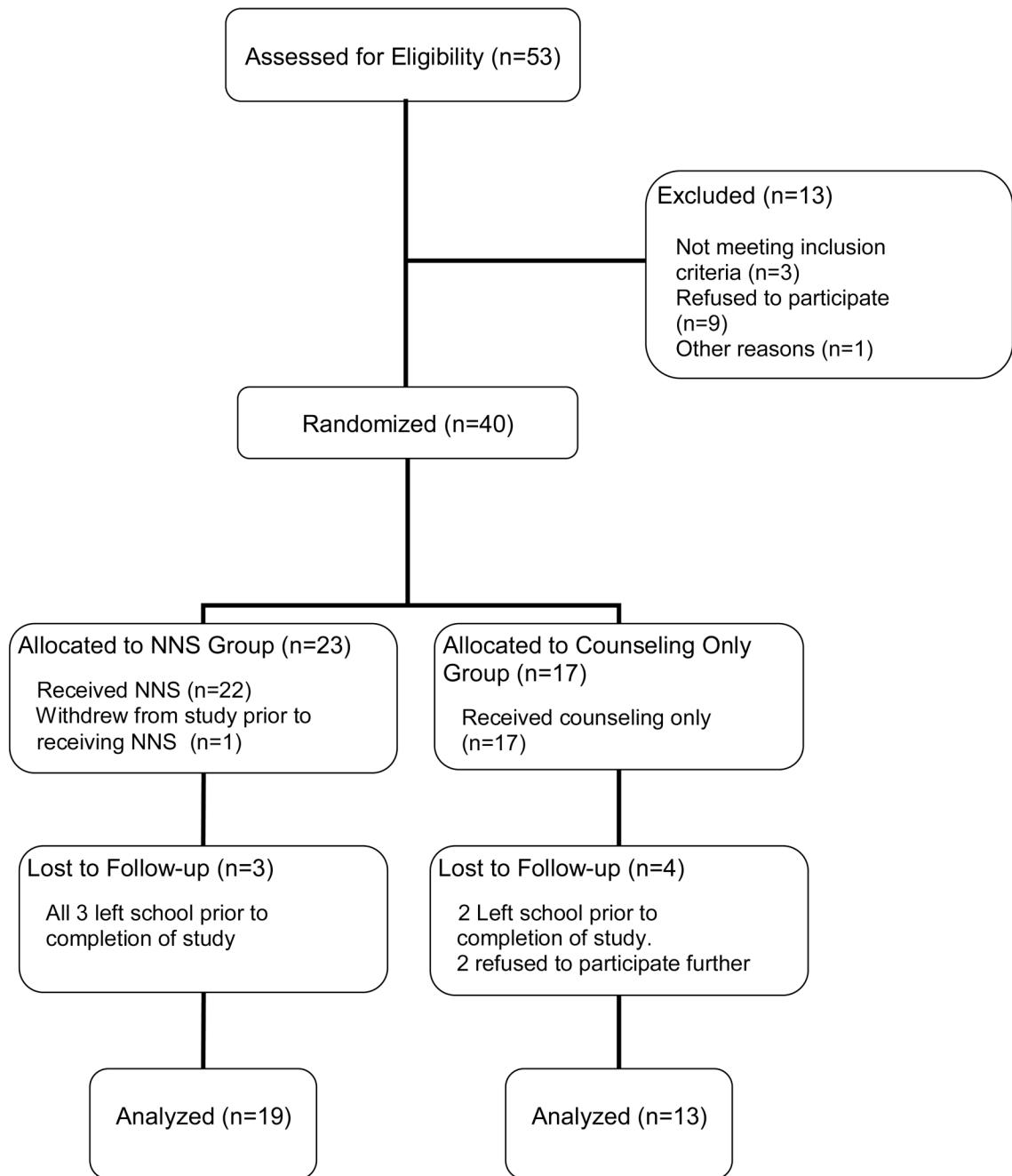


Figure 1.
Consort Diagram

Table 1

Baseline Characteristics of the study population.

Characteristics	Nicotine Nasal Spray Plus Counseling (SD)	Counseling Only (SD)	p
Female (%)	43.5%	68.8%	
Age (years)	16.9 (.9)	16.5 (1.1)	.26
Amount smoked per day (cpd)	10.6 (7.2)	8.8 (5.1)	.37
Saliva cotinine (ng/ml)	151.49 (70)	63.68 (62)	<.01
mFTQ*	4.2 (1.5)	4.0 (1.4)	.76
Self-rated addiction (1–100%)	67.4% (28.1)	75.9% (16.6)	.30
Duration of smoking (years)	5.2 (3.0)	5.0 (2.4)	.84
Times tried to quit before	3.5 (2.4)	2.9 (1.7)	.48

* Modified Fagerström Tolerance questionnaire (17).

TABLE 2
Adolescent characteristics at 8-week and 12-week follow-up.

Characteristics	NNS plus Counseling (SD) n=19	Counseling Only (SD) n=13	P	NNS plus Counseling (SD) n=15	Counseling Only (SD) n=12	P
Cigarettes per day	5.0 (4.2)	6.4 (5.1)	.44	4.8 (3.1)	7.8 (7.9)	.22
Cotinine				161.04 (83.8)	101.32 (55.6)	.16
mFTQ	3.8 (1.6)	4.00 (1.6)	.76	3.7 (2.1)	3.0 (1.6)	.55
Withdrawal	8.8 (6.2)	9.6 (5.4)	.26	9.3 (4.6)	9.0 (6.0)	.91
Craving	3.5 (1.7)	2.8 (1.1)	.20	3.8 (2.3)	4.6 (2.2)	.49
Self-rated addiction (1–100%)	64.6(25.8)	72.1 (17)	.39	52.1 (25.8)	48.7 (39.1)	.83

Table 3
Adolescents' Perceptions Of The Nicotine Nasal Spray At The 8 Week Follow-Up.

	strongly agree	agree	neither agree or disagree	disagree	strongly disagree
The spray is easy to use	11.8%	35.3%	35.3%	11.8%	5.9%
The spray is good for preventing smoking	11.8%	58.8%	29.4%	0	0
The spray controls my cravings	25%	43.8%	31.3%	0	0
The spray made my urge to smoke less than before I used it	16.7%	66.7%	16.7%	0	0
The spray had lots of side effects	27.8%	11.1%	27.8%	22.2%	11.1%
I would recommend the spray to friends	16.7%	22.2%	38.9%	11.1%	11.1%