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Abstract

Introduction: Approximately 10 million past 30-day e-vapor users are in the US but limited data exist on the quality of life in smokers switching to e-vapor products (EVPs). This study was designed to assess biomarkers and questionnaire responses in a cross-section of current regular users of EVPs relative to conventional cigarette (CC) smokers.

Method: 144 subjects with 6+ months of exclusive EVP use after 10+ years of CC use and 73 CC smokers with 10+ years of CC use history were recruited to participate in a cross-sectional study between January and March 2017. Subjects were telephone screened then provided a log-in to an online portal where they were rescreened, provided informed consent, and completed quality of life (QGEN® and TQOLIT™v1) and subjective measure (mCEQ) questionnaires. The QGEN® was used to estimate generic health profiles; the TQOLIT™ supplements the QGEN and includes smoking/vaping specific domains. An ANOVA model was used to assess the difference between the groups in summary scores for the questionnaires.

Results: Overall, subjects in the EVP group reported statistically significant and clinically meaningful differences in quality of life as measured by the QGEN® and TQOLIT™ instruments, as compared to the CC group: higher Physical Health General Score (50 vs. 45.8), Emotional Health General Score (51.7 vs. 48), ePhysical Component Summary (51.9 vs. 47.5), Physical Function – extended (52.2 vs. 48.5), and General Health – confidence scores (56.1 vs. 49.9); and lower Smoking Symptom (47.8 vs. 60.4) and Smoking/Vaping Impact scores (47.2 vs. 57.4). Subjects in the EVP group reported a significantly lower frequency of cough in the past 30 days (28%) relative to smokers (47%). Subjects in the EVP group had higher Smoking/Vaping Satisfaction factor scores than subjects in the CC group (5.3 vs. 4.5).

Conclusions: The study demonstrated differences in assessments of quality of life, frequency of cough, and satisfaction between self-reported exclusive users of EVP and CC smokers with smoking history of 10+ years. To confirm that the observed differences are due to switching to exclusive use of EVP, a prospective study of EVP users is warranted.

Objectives

The objectives of this observational study are to measure and compare biomarkers of exposure (BOEs), biomarkers of potential harm (BOPHs), and responses to questionnaires in exclusive EVP users and CC smokers.

- BOEs included total 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol (NNAL), urinary nicotine equivalents (nicotine and 5 of its metabolites), 3-hydroxypropyl mercapturic acid (3-HPMA), carboxyhemoglobin (COHb)
- BOPHs included white blood cells, high-density lipoprotein cholesterol (HDL-C), 11-dehydrothromboxane B2, 8-epi-prostaglandin F2 α , soluble intercellular adhesion molecule-1 (sICAM-1)
- Questionnaire evaluations* included General Quality of Life (QGEN®), Tobacco Quality of Life Impact Tool (TQOLIT™v1), Cough-related symptoms, Reasons for Vaping *focus of this poster

Study Design



Comparison of Quality of Life and Subjective Measures Between Adult E-vapor Users and Adult Conventional Cigarette Smokers Douglas Oliveri, Qiwei Liang, Yuxi Zhao, George Karles, Mohamadi Sarkar

Altria Client Services LLC, Center for Research and Technology, 601 East Jackson Street, Richmond, VA 23219, USA SRNT 24th Annual Meeting, February 21 - 24, 2018, Baltimore, MD, USA

Methods



Subjects: Male and Female Adults (30–65 years of age)

Group A: approximately 150 exclusive everyday EVP users • Whave switched to EVP exclusive use (no other tobacco or nicotine containing products) for at least 6 months and be former smokers of at least 10 cigarettes per day for at least 10 years

- Users of cartridge-based products will be oversampled such that they represent at least 50% of Group A
- Users of tanks, mods, etc., will comprise the remainder of Group A
- **Group B:** approximately 75 exclusive CC smokers

• Will be current CC smokers and have smoked at least 10 cigarettes per day for at least the last 10 years and have not used any other tobacco or nicotine containing products for the past month before bio-sample collection

Subjects Demographics

	Demographics		Conventional					
	3	Cigarette Smokers		Exclusive EVP Users				
				All EVP	Tank-based	Cartridge-based		
Assessment		Statistic	(N=62)	(N=132)	(N=70)	(N=62)		
Age (years)		Mean	47.1	4 <mark>4.</mark> 4	44.0	44.9		
		SD	8.48	8.31	8.64	7.95		
		Median	46.5	44.0	44.0	45.5		
		Min	32	30	31	30		
		Max	64	65	65	63		
		Ν	62	132	70	62		
Age Group	30 to <45 years	<u>n</u> (%)	28 (45.2)	67 (50.8)	37 (52.9)	30 (48.4)		
	45 to <=65 years	<u>n</u> (%)	34 (54.8)	65 (49.2)	33 (47.1)	32 (51.6)		
	45 to <55 years	<u>n</u> (%)	23 (37.1)	49 (37.1)	23 (32.9)	26 (41.9)		
	55 to <=65 years	<u>n</u> (%)	11 (17.7)	16 (12.1)	10 (14.3)	6 (9.7)		
BMI (kg/m2)	Screening	Mean	26.50	27.54	27.71	27.36		
		SD	4.807	5.047	5.400	4.654		
		Median	25.99	26.59	26.60	26.36		
		Min	18.8	18.1	18.1	18.6		
		Max	36.9	39.5	39.5	38.4		
		N	62	132	70	62		
BMI (kg/m2)	PSC	Mean	27.40	29.25	29.74	28.70		
		SD	5.909	6.375	6.851	5.797		
		Median	26.60	27.95	27.70	28.15		
		Min	18.4	17.0	17.7	17.0		
		Max	40.9	49.0	49.0	40.9		
		N	62	132	70	62		

Analysis

- Subjects were telephone screened then provided a log-in to an online portal where they were rescreened, provided informed consent, and completed quality of life (QGEN® and TQOLIT™v1) and subjective measure (mCEQ) questionnaire
- QGEN® was used to estimate generic health profiles and comprises 10 content domains (1 item/domain): physical functioning, role limitations attributed to general health, role limitations due to physical health, role limitations due to emotional problems, pain, general health, vitality, social functioning, mental health, and health distress. Scores for the domains were used to estimate generic health profiles as well as the following summary measures: Physical health general score, Emotional health general score, Estimated physical component summary, Estimated mental component summary. All scoring were done using the John Ware Research Group (JWRG) scoring service. QGEN® is standardized and normed to have a mean of 50 (SD=10) in the general US population in 2011.
- **TQOLIT™v1** was used to assess a total of 4 summary scores: 2 Supplemental Generic Measures (Physical function extended score which consists of 4 items that cover a range of activities from typical daily activities to strenuous physical tasks, General health-confidence score which consists of 3 items that assess an individual's self-evaluation of their current and future health) and 2 Smoking Specific Measures (Smoking symptoms score which measures the presence and frequency of 8 smoking-related symptoms, such as bad breath or smoker's cough; Smoking/vaping impact score which measures the impact of smoking or vaping on health-related quality of life).
- mCEQ assesses the subjective effects of EVP use or CC smoking as appropriate. It consists of 12 items, each with self-reported responses ranging from 1 (not at all) to 7 (extremely). The following 5 summary scores were evaluated as the mean item score for the included items: Aversion (items 9, 10), Craving reduction (item 11), Enjoyment of respiratory tract sensation (item 3), Psychological reward (items 4 to 8), Smoking/vaping satisfaction (items 1, 2, 12).
- A similar ANOVA model as for biomarkers, excluding the study group × age group, study group × BMI group interaction terms, was used to assess the difference between the 2 groups in continuous summary scores for the questionnaires.

Results

General Quality of Life

- General Quality of Life (QGEN[®][^] Overall, how would you rate your health? How easy or hard is it for you to do your usual physical activities (such as walking or climbing stairs In the past 4 weeks, how much did pain limit your everyday activities or quality of life? In the past 4 weeks, did your physical health make it easy or hard for you to make the effort you needed to do your daily activities (at work or home)? How often during the past 4 weeks were you discouraged by your health problems? In the past 4 weeks, has your health made it easy or hard for you to have a social life?
- In the past 4 weeks, on average, did you feel tired or energetic most of the time? How happy and satisfied have you been with your life during the past 4 weeks?
- In the past 4 weeks, was it easy or hard to do your usual work, school or other daily activities because of how you felt emotionally?). In the past 4 weeks, did your health make it easy or hard for you to do your daily work or
- activities, both at home and away from home? ^ the QGEN instrument was used through a license from John Ware Research Group

Factor	Cigarette	EVP	Tank	Cartridge
Physical Health General Score	45.8	50.0	48.9	51.2
Emotional Health General Score	48.0	51.7	51.0	52.4
e Physical Component Summary	47.5	51.9	51.2	52.7
e Emotional Component Summary	48.6	51.3	50.6*	52.1

Scores normed such that 50 = US population average and 10 = 1 standard deviation *Not statistically significant; all other differences between the Cigarette and EVP groups are statistically significant (p<0.5)

Cough-Related Symptoms

Cough Questionnaire

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1.	Did you have a cough in the past 30 days?
2.	How long have you had the cough?
3.	When does the cough occur?
4.	Do you have a cough that comes mainly from your chest and NOT from your throat?

- 5. Do you cough up phlegm? 6. Do you cough more than the average person?
- '. Have you taken medications for your cough?
- 8. Have you sought the help of a health care provider to treat your cough?
- 9. In the last 24-hours, has your cough disturbed your sleep? 10. In the last 24-hours, how many times have you had coughing bouts?

Question	Response	Cigarette	EVP	Tank	Cartridge
1. Did you have a cough in the past 30 days?	No	53%	72%	67%	77%
6. Do you cough more than the average person?	Yes	69%	35%	30%	43%

No difference between groups for other 8 questions (characteristics of cough)

Summary

- QEN® (estimated generic health profile): higher scores (better health) for all summary measures were apparent among exclusive EVP users compared to CC smokers (scores are normed to have a mean of 50 in the general US population)
- TQOLIT[™]v1 (tobacco-related QOL): higher scores for physical functioning and general health-confidence (better functioning and health outlook, respectively) and lower scores for smoking symptoms and smoking/vaping impact (fewer smoking symptoms and less impact of smoking/vaping on QOL, respectively) were evident among exclusive EVP users compared to CC smokers (scores are normed to have a mean of 50 in the general US population)
- Cough questionnaire: cough-related symptoms were less common in exclusive EVP users compared to CC smokers • Subjective effects of CC and EVPs varied by domain/item of interest: lower scores (lower effect) for aversion*, craving reduction, and psychological reward* and higher scores (higher effect) for enjoyment of respiratory tract sensation and smoking satisfaction were observed among exclusive EVP users compared to CC smokers (*differences not statistically significant)



This poster may be accessed at www.altria.com/ALCS-Science

Smoking/Vaping Quality of Life

- Tobacco Quality of Life Impact Tool (TQOLIT[™]v1[^])
- How easy or hard is for you to: Walk more than a mile?
- Run errands and shop?
- Do your usual physical activities (such as walking or climbing stairs)?
- Do strenuous activities (such as backpacking, skiing, playing tennis, bicycling or jogging? How TRUE or FALSE is <u>each</u> of the following for you:
- I am very confident in my health?
- I am confident in having good health in the future? I have doubts about having good health in the future?
- . How often do you have:
- Bad breath?
- Yellowing of teeth Cold hands or feet?
- Loss of taste and sme . How often do you have:
- Nicotine-stained fingers and teeth?
- Smoker's cough (loose cough that often produces phlegm)? A hoarse voice?
- Smell of smoke in clothes and hair? In the past 4 weeks, how much did smoking/vaping limit your everyday activities or quality
- . In the past 4 weeks, how often Did smoking/vaping limit your usual physical activities?
- Did you have difficulty doing work or other daily activities because of smoking/vaping?
- Did smoking/vaping make you worn out or too tired to work or do daily activities? In the past 4 weeks, how often:
- Did smoking/vaping limit your usual social activities with family, friends, or others close to
- Did you feel frustrated or fed up because of smoking/vaping?
- Did smoking/vaping make you worry about your health or future health problems? ^ the TQOLITv1 instrument was used through a license from John Ware Research Group

Factor	Cigarette	EVP	Tank	Cartridge
Physical Function – extended	48.5	52.2	50.7*	53.6
General Health – confidence	49.9	56.1	54.5	57.7
Smoking Symptoms	60.4	47.8	48.8	46.8
Smoking/Vaping Impact	57.4	47.2	47.4	46.9

Scores normed such that 50 = US population average and 10 = 1 standard deviation

*Not statistically significant; all other differences between the Cigarette and EVP groups are statistically significant (p<0.5)

mCEQ

Questionnaire
1. Was Smoking Cigarettes/Using the e-Vapor Product Satisfying?
2. Did the Cigarettes/e-Vapor Product Taste Good?
Did You Enjoy the Sensations in Your Throat and Chest?
4. Did Smoking Cigarettes/Using the e-Vapor Product Calm You Down?
5. Did Smoking Cigarettes/Using the e-Vapor Product Make You Feel More Awake?
6. Did Smoking Cigarettes/Using the e-Vapor Product Make You Feel Less Irritable?
7. Did Smoking Cigarettes/Using the e-Vapor Product Help You Concentrate?
8. Did Smoking Cigarettes/Using the e-Vapor Product Reduce Your Hunger for Food?
9. Did Smoking Cigarettes/Using the e-Vapor Product Make You Dizzy?
10. Did Smoking Cigarettes/Using the e-Vapor Product Make You Nauseous?
11. Did Smoking Cigarettes/Using the e-Vapor Product Immediately Relieve Your Craving for a Cigarette?
12. Did You Enjoy Smoking Cigarettes/Using the e-Vapor Product?



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