Actual Use Study of Nicotine Pouches Among US Adult Smokers

Tiffany A. Parms[1], Patrudu Makena[1], Mandara Shetty[2], Rachel Hart[2], Peter Chen[1], Kristen Prevette[1], Krishna Prasad[2], Sarah Baxter[1], Kristen Jordan[1]

[1] RAI Services Company, 950 Reynolds Blvd, Winston-Salem, 27105 USA; [2]British American Tobacco, Research and Development, Regents Park Road, Southampton, SO15 8TL, United Kingdom

Introduction

- Premarket and modified risk tobacco product applications require information on how market availability of the new tobacco product(s) will affect tobacco and nicotine product selection and use behavior of current tobacco consumers.
- Multiple lines of evidence indicate that it is the combustion of tobacco during smoking rather than the nicotine that exposes tobacco consumers to the most risk. If the tobacco product is not burned during use, risks associated with exposure to toxic chemicals generated during combustion are potentially decreased.
- This study was designed to evaluate how US adult tobacco consumers (21-60 years old) used Velo Pouches (Study IP), a novel oral tobacco leaf-free nicotine pouch, over a 6-week actual use period (AUP) in their real-life naturalistic environment and in the context of typical consumer marketing materials.
- In total, 1,105 regular smokers of cigarettes (had smoked ≥100 cigarettes in their lifetime, smoked an average of ≥5 cigarettes per day [CPD] on days smoked, and smoked on ≥20 days of the past 30 days) were enrolled in this study. Enrolled subjects met all the inclusion, and none of the exclusion criteria and signed 2 informed consent forms.
- Subjects could choose up to five (out of 12 available) IP variants to use at a time and were allowed to use other commercially available tobacco and nicotine products (TNPs).
- Daily TNP use was recorded in a smartphone-based eDiary during a 1-week baseline period and throughout the AUP.
- Site visits were scheduled periodically to review eDiary compliance, complete interviewer-led questionnaires, and dispense additional Study IP/return used Study IP containers.

Objectives and Endpoints

Primary Objective:

- Describe the acceptance of Study IP and the pattern of cigarette consumption in the context of Study IP availability among current regular cigarette smokers.

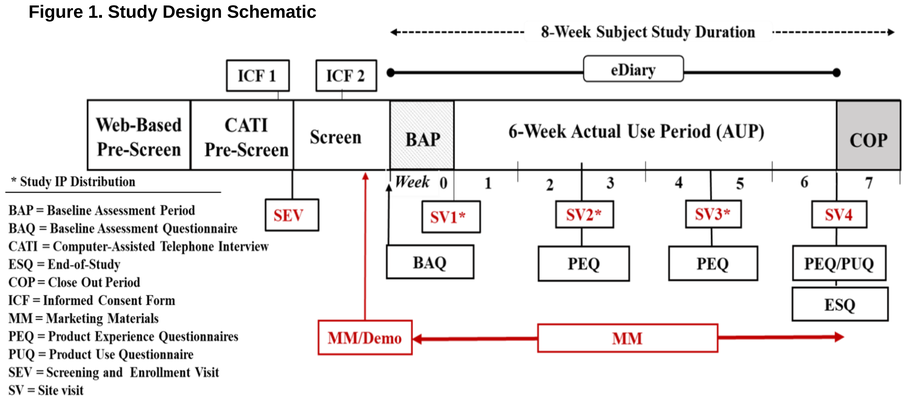
Primary Endpoints:

1. Number and proportion of subjects who meet the definition of "established users" of the Study IP (defined as using ≥100 pouches) over the 6 weeks of the AUP.
2. Number and proportion of subjects among "established users" who reduce their CPD consumption by at least 50% at the end of the AUP.
3. Descriptive weekly average CPD consumption per subject among all subjects who complete the study, including both established and non-established users of Study IP.

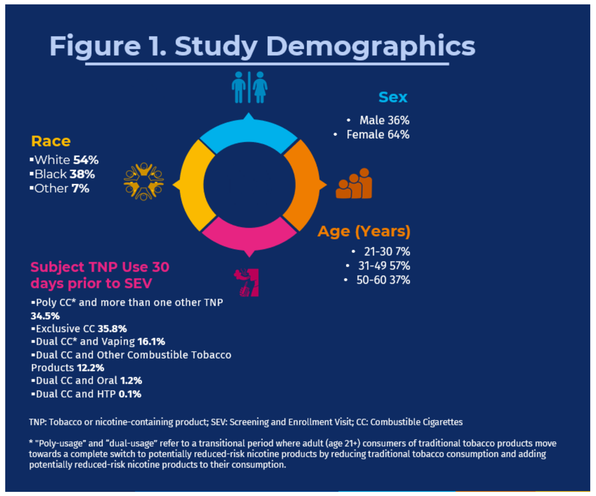
Secondary objectives and endpoints, as well as exploratory endpoints were also assessed in this study (data not shown).

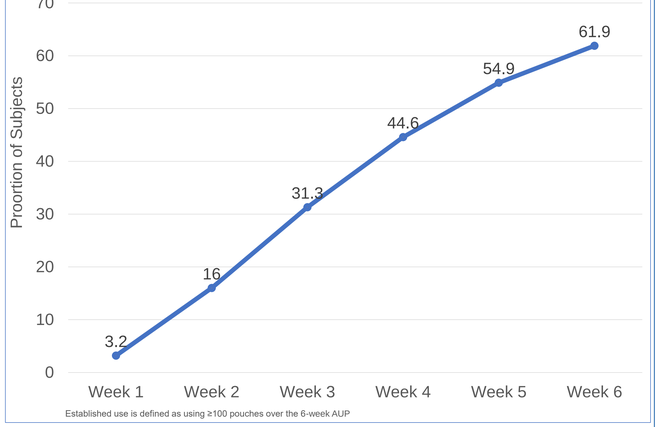
Study Design

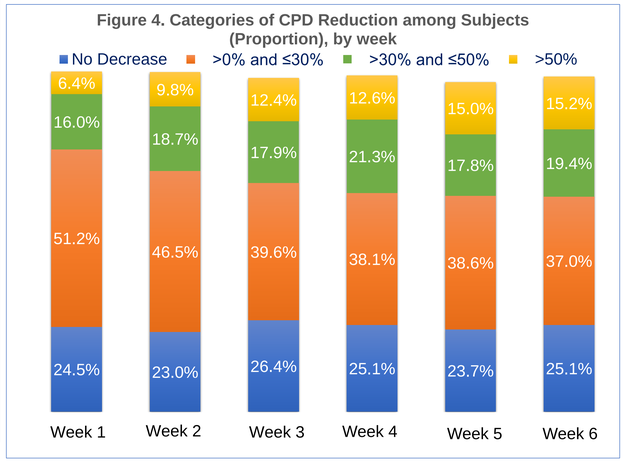
Figure 1. Study Design Schematic

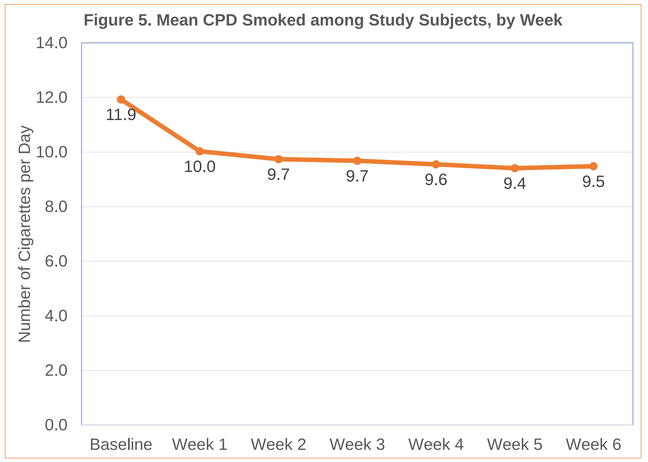


Results









Materials and Methods

This was a prospective observational study to assess Study IP use over time in a "real-life" setting. The design was an open-label, 8–week study, conducted at multiple sites geographically dispersed within the US. Subjects were provided the Study IP for ad libitum use over a six-week AUP in their real-life, naturalistic environments and in the context of typical consumer marketing materials. Subject-reported consumption of Study IP, cigarettes, and other TNPs (e.g., electronic nicotine delivery systems, smokeless tobacco, etc.) was assessed. Further details on study design can be found in **Figure 1.**
This study was not intended to confirm or reject any hypotheses; therefore, the statistical analyses were descriptive in nature. Summary statistics for categorical and continuous data were performed (i.e., means, frequencies, percentages, and other appropriate summary statistics of the data captured in this study).

Note: The Full Analysis Set (FAS) was the primary analysis set for analyses reported herein. These subjects met all inclusion criteria and no exclusion criteria, documented consumption of at least one cigarette during the 1-week baseline period, and documented consumption of Study IP during the six-week AUP.

Results (Continued)

- The FAS was largely comprised of female (63.7%), White (53.5%) subjects aged 31-49 years (57%), and predominantly CC smokers (35.8%) (**Figure 2**; percentages have been rounded).
- Approximately 61.9% of study subjects became "established users" of Velo pouches, defined as using ≥100 pouches over the 6-week AUP (**Figure 3**).
- Approximately 15.2% of subjects reduced their combustible cigarette consumption by ≥50% at week 6 of the AUP (compared to baseline week) (**Figure 4**). This percentage increased to 20% among established users (not shown).
- The mean CPD decreased from approximately 12 (during the baseline week) to 9.5 in week 6 (**Figure 5**).

Conclusions

- Among a significant proportion of adult tobacco users in this study, the use of Velo Pouches was well accepted.
- When used in real-life settings, Velo Pouches have the potential to positively impact public health by decreasing combustible cigarette consumption.

Acknowledgements

- The data presented herein was generated and analyzed in studies commissioned by RAI Services Company and conducted by Cerner Enviza.
- The authors thank Christine (Chris) Campbell for her valuable contributions to this work.

To see more of our scientific research visit ReynoldsScience.com

RAI SERVICES COMPANY