Pharmacokinetics and Subjective Effects of the JL Electronic Nicotine Delivery System (ENDS) Compared to Five ENDS, a Heated Tobacco Product, and a Combustible Cigarette

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Introduction

- Electronic nicotine delivery system (ENDS) comprise a heterogeneous and continually evolving group of products; there are numerous technologies available on the marketplace.
- Recent studies have assessed the nicotine delivery of the JL ENDS, a closed-system ENDS with a nicotine-salt formulation, however there are limited data systematically comparing the nicotine pharmacokinetic (PK) profile and subjective effects of the JL ENDS to other tobacco products including ENDS and heated tobacco products.
- The primary objective of this study was to characterize the nicotine PK profiles and subjective effects of the JL ENDS 5.0%, five comparator ENDS products (blu, MarkTen 4.0%, VUSE Solo 4.8%, PHIX 5.0% and NJOY Daily EXTRA 6.0%), a heated tobacco product (IQOS), and a combustible cigarette (Marlboro Red) across controlled and ad libitum puffing conditions among adult smokers.

Methods

- Adult smokers (N=25; 72.0% male; mean age (SD) = 30.44 [7.75] years) completed a randomized, open-label, 16-arm within-subjects cross-over product-administration study over the course of three days.
- There was a total of eight study test products: 1) JL ENDS Virginia Tobacco 5.0%; 2) mybl Original 2.4%; 3) MarkTen Bold Classic 4.0%; 4) VUSE Solo Original 4.8%; 5) PHIX Original Tobacco 5.0%; 6) NJOY Daily EXTRA Virginia Tobacco 6.0%; 7) IQOS HeatStick Regular; and 8) Marlboro Red.
- Each product was administered under controlled (1 puff; 3 seconds in duration, taken at 30 second intervals) and ad libium (45 minutes) puffing conditions (16 total conditions).
- Each administration period was separated by a wash-out period of at least 120 minutes.
- Blood samples were collected 5 minutes prior (-5) to and 1.5-, 3-, 5-, 10-, 15-, 20-, and 30-minutes post-product administration. The time course of plasma nicotine concentration (PK curve) was evaluated and the following PK parameters were assessed:
  - Baseline-adjusted maximum plasma level (Cmax,ad)
  - Rate of plasma nicotine rise (speed of absorption; Cmax,ad / Tmax)
  - Total nicotine exposure (baseline-adjusted area under the curve [AUC0-60-BL])
  - Time to maximum plasma nicotine level (Tmax)

Results

- Across both puffing conditions, the cigarette had the highest mean Cmax,ad, rate of plasma nicotine rise, and AUC0-60-BL.
- Mean Cmax,ad, rate of plasma nicotine rise, and AUC0-60-BL for the JL ENDS generally did not differ significantly from the IQOS tobacco HeatStick (except rate of plasma nicotine rise, ad lib condition) and the PHIX (except Cmax,ad, controlled condition) and NJOY Daily EXTRA (except rate of plasma nicotine rise) ENDS products.
- Mean Cmax,ad and rate of plasma nicotine rise, and AUC0-60-BL for the JL ENDS were significantly greater than the VUSE Solo, mybl, and MarkTen ENDS products.
- Cmax,ad in the IQOS HeatStick and the VUSE Solo, NJOY Daily EXTRA ENDS products, but not significantly different from the VUSE SOLO and PHIX ENDS products.

Subjective Effects (Table 2)

- Across both puffing conditions, the cigarette had the highest mean nPES “Satisfaction” and “Psychological Reward” composite subscale scores.
- For the nPES “Psychological Reward” composite subscale:
  - In the controlled puffing condition, the mean score for the JL ENDS was significantly higher than the VUSE Solo and MarkTen ENDS products, but not significantly different from the IQOS tobacco HeatStick and the mybl, PHIX, and NJOY Daily EXTRA ENDS products.
  - In the ad libitum puffing condition, the mean score for the JL ENDS was significantly greater than the IQOS tobacco HeatStick and the MarkTen, NJOY and NJOY Daily EXTRA ENDS products, but not significantly different from the VUSE SOLO and PHIX ENDS products.

Conclusions

- Out of all the tobacco products assessed, the combustible cigarette had the highest peak nicotine levels, speed of nicotine absorption and total nicotine exposure and was rated highest on subjective measures of satisfaction and psychological reward.
- The PK and subjective effects profiles of the JL ENDS were within the range of other marketed ENDS products and similar to that of the IQOS tobacco HeatStick.

References