



Letter

Evaluation of breath alcohol levels after fluticasone nasal spray

Fluticasone propionate nasal spray is widely prescribed for allergic rhinitis. Fluticasone propionate nasal spray, 50 μg , is an aqueous suspension of microfine fluticasone propionate for topical administration to the nasal mucosa by means of a metering, atomizing spray pump. Fluticasone propionate nasal spray also contains microcrystalline cellulose and carboxymethylcellulose sodium, dextrose, 0.02% (wt/wt) benzalkonium chloride, polysorbate 80, and 0.25% (wt/wt) phenylethyl alcohol and has a pH between 5 and 7.

Fluticasone nasal spray is often used at a dosage of 1 to 2 puffs once daily. We tried to determine whether instillation of fluticasone nasal spray, 2 sprays on each side, causes any increase in the breath alcohol levels for a period of 30 minutes. The age group of 16 to 20 years was chosen because the legal limit for drunk driving is 0.02% blood alcohol concentration up to the age of 21 years (0.08% blood alcohol concentration for those older than 21 years).

The breath analyzer model used was Alco-Sensor FST. The Alco-Sensor FST is the model generally used by the law enforcement department to measure alcohol levels in suspected drunk driving cases.

A review of the literature does not reveal any specific study linking fluticasone nasal spray and its effect on blood alcohol concentration in humans.^{1–6} A study by Gomez et al⁷ examined 5 different kinds of nasal sprays, but this study did not involve humans.

After an extensive search, no data were available addressing the exact metabolism of phenylethyl alcohol after intranasal administration. The search was limited to review articles and pharmacokinetic studies in humans.

After intranasal administration, a medication can enter systemic circulation through direct local absorption in the mucosa or oral absorption of swallowed material.⁸ In vivo, systemic phenylethyl alcohol is first metabolized to phenylacetaldehyde by multiple NAD⁺ dependent alcohol and aldehyde dehydrogenases. Phenylacetaldehyde is further metabolized to phenylacetic acid by aldehyde dehydrogenase. Phenylacetic acid is further conjugated with glucuronic acid, glutamine, taurine, or glycine and/or eliminated as the free acid. However, the conjugation with glycine, to form phenaceturic acid, has only been evaluated in animal models.^{9,10} Ethyl alcohol is not a metabolite in the degradation pathway.

Healthy adolescents between the ages of 15 and 19 years (9 male and 5 female adolescents) took part in the study. Each adolescent had 2 sprays of fluticasone propionate nasal spray instilled in the nostril on each side. They were screened before the study. The criteria for inclusion into the study were as follows: age of 15 to 19 years; has not had alcohol intake in the past 48 hours in any form, direct or indirect, via any medication; and willing to stay for 60 minutes after the nasal spray is given.

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Individuals were excluded if they had demonstrated hypersensitivity to or experienced a serious adverse event in response to fluticasone propionate, had a fever (defined as a temperature $>38.0^{\circ}\text{C}$) during the past 24 hours, had upper respiratory tract infection symptoms (defined as clear or mucopurulent nasal discharge), had type 1 or type 2 diabetes mellitus, were younger than 15 years, were 20 years or older, had epistaxis (active or history of recurrent epistaxis), had history of nasal septal perforation, were legally and/or mentally incapacitated, were pregnant or nursing, or had alcohol consumption in the past 48 hours.

Before starting the study, their breath alcohol was measured using a breath analyzer. The nasal spray was instilled into the nose, and serial breath alcohol measurements were taken at 1-, 5-, 10-, 15-, 20-, and 30-minute intervals. Informed consent was obtained before the study from the parents and patients.

The breath alcohol level at 1, 5, 10, 15, 20, and 30 minutes using a breath analyzer was 0 at all intervals for every participant. There were zero complications noted during or after the study.

The use of fluticasone propionate nasal spray did not increase the blood alcohol level when measured by a breath analyzer at different times up to 30 minutes. The current legal limit for breath alcohol level is 0 for teens between 15 and 19 years old. The study was meant to determine whether there was any transient elevation of the breath alcohol levels in teenagers because of the zero tolerance policy or alcohol when driving. The levels were found to be 0 at 5 minutes and 0 at 30 minutes. This means that there is no immediate or delayed increase in blood alcohol levels after therapeutic use of fluticasone propionate nasal spray. It is safe for teenagers to use it and drive. In addition, a positive test result on a breath analyzer cannot be attributed to inhalation of fluticasone propionate nasal spray. This study will help clear the controversy regarding a positive breath alcohol test result and inhalation of fluticasone for law enforcement.

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