

Anesthesiology
74:387, 1991

In Reply:—The letter from Dr. Severinghaus states that benzocaine absorbed from the skin, mucous, or pulmonary membranes commonly causes methemoglobinemia. We have studied the Federal Register as well as the many references contained therein and find the Federal Register, Volume 44, Number 234 dated Tuesday, December 4, 1979 states, "The panel concludes that the occurrence of methemoglobinemia following the use of benzocaine is rare; the panel concludes it can be classified as an uncommon idiosyncratic response that is in no way injurious or life-threatening. The panel further states that benzocaine is one of the most widely used and safest topical anesthetics found in over-the-counter (OTC) preparations."

In a 1985 letter to us, Dr. John Adriani wrote, "The lethal dose of benzocaine has never been determined because there has never been a reported case of a fatality in a human being from the ingestion of the drug."

The panel further concluded that the available epidemiologic data on allergy, irritancy, and other reactions are inconclusive and in no way support the contention that benzocaine is a potent sensitizer.

There have been over 1 billion applications of Hurracaine® and only

one known report of methemoglobinemia. In addition, there are at least 24 other benzocaine-containing products used in dentistry daily throughout the United States. In addition, obstetricians, surgeons, otolaryngologists, gastroenterologists, and others use benzocaine daily. Many hospitals and clinics use benzocaine prior to or during various scoping procedures. Further, many people who spend time in the sun use benzocaine products to treat sunburn quite effectively and safely.

Based on the wide, safe, and effective use of Hurracaine® and the many other benzocaine-containing products, all should be applauded, commended, and recommended for a superlative record of safety and effectiveness.

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In Reply:—The relationship between methemoglobinemia and benzocaine is well-known, documented, and researched, as evidenced by the extensive list of references. The authors have, however, neglected to include the extensive evidence that the government and scientific experts have placed only minimum importance on the incidence of methemoglobinemia *vis-a-vis* the enormous quantity of the drug used daily both in over-the-counter and prescription products.

Speaking only for Cetylite Industries and its product, Cetacaine Spray, the following facts should provide a proper perspective. For the year 1989 only, based on the total number of bottles multiplied by the number of doses contained in each bottle, approximately 26,000,000 doses were administered. Even if the two-dose is used as the consumption rate, 13,000,000 professionally dispensed patient applications represent quite a significant figure.

Cetylite Industries has been producing and marketing Cetacaine for 35 y. Even the four cases of methemoglobinemia reported to the Food and Drug Administration (FDA) were multiplied by 100, there still would not be sufficient statistically valid evidence to condemn benzocaine by suggesting its removal from products that contain it. Even the authors' reference to "50 reports" does not support their findings, which admit to only one questionable reported case of mortality from benzocaine-associated methemoglobinemia.

A specific package warning to address the rare incidence of methemoglobinemia would contradict the findings of the blue-ribbon panel that investigated the subject and the conclusions of the FDA.

Among the expert panel findings were the following: 1) "the panel concludes that benzocaine when properly formulated is a safe and effective analgesic, anesthetic, and anti-pruritic on the intact or damaged skin" (44 Fed. Reg. 69799); and 2) "the Panel concludes that the occurrence of methemoglobinemia following the use of benzocaine is rare. Normal infants and children are no more prone to its development than adults. Why this simple, non-oxidizing chemical compound should cause this response on rare occasions is not known, but the Panel concludes it can be classified as an idiosyncratic response that is in no way injurious or life threatening. (44 Fed. Reg. 69797, December 4, 1979).

To include in the package insert every possible adverse reaction, however rare, creates a cumbersome document. The result is a further reduction of the all too few interested professionals and consumers that even take the time to read the literature. I believe that a package insert of such large proportions that it reduces its readership serves primarily to protect the manufacturer from liability rather than protect the consumer, physician or his patient from possible harm.

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A Double-lumen Endobronchial Tube for Tracheostomies

To the Editor:—Double-lumen endobronchial tubes (DLTs) are routinely used during thoracic operations. Prior to the introduction of DLTs constructed of polyvinyl chloride (PVC), all DLTs were made of red rubber. Rubber DLTs were seldom used for patients with tra-

cheostomies since tubes small enough to fit through a stoma have too small an internal lumen for safe one-lung ventilation.¹⁻⁵ Conventional DLTs made of PVC can be used with tracheostomies, but because of the shortened length of the upper airway, special attention is required

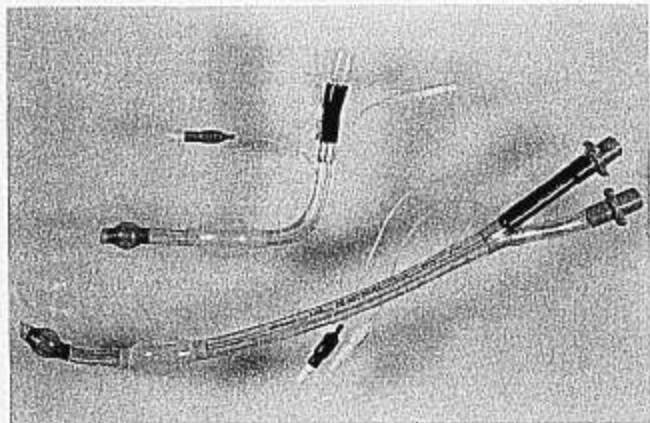


FIG. 1. Modified left-sided polyvinyl chloride (PVC) tracheostomy double-lumen endobronchial tube (DLT) next to a standard left-sided PVC DLT (Broncho-Trach, Sheridan, Argyle, NY).

to prevent kinking and subsequent luminal obstruction.⁴ Fixation of the tube to prevent movement and displacement may also be a problem with the standard DLT. These problems are greatly magnified if the tube is required for extended periods, as may occur when selective split-lung ventilation in the intensive care unit is indicated.⁵

Therefore, we designed and the manufacturer modified to our specifications a left-sided 41F Broncho-Trach DLT (Sheridan, Argyle, NY), which we have used successfully in patients with tracheostomies (Figure 1).

The distance between the distal tip of the endobronchial lumen and the bifurcation of the tracheal and endobronchial lumens is shortened to 18.5 cm from 32.0 cm to reflect the markedly reduced length of the upper airway. The proximal length of both lumens after they bifurcate are also shortened, to 3.0 cm from 7.5 cm, to reduce the chance of kinking. A 90° bend is placed approximately 2.5 cm proximal to the proximal edge of the tracheal cuff to allow the tube to exit from the neck at a less awkward angle. The tubings to the pilot balloons are shortened to 11.0 cm from 23.0 cm for convenience. In all other aspects the tube is identical to a standard 41F Sheridan PVC DLT.

A plastic DLT intended for tracheostomies has been described previously.⁶ It consists of two conventional endotracheal tubes (6-mm ID,

8-mm OD) solvent-welded together side by side. In contrast to modern DLTs, this tube has low-volume/high-pressure cuffs. Our tube offers all the advantages of a standard PVC DLT and in addition has been shortened and its body further modified with a bend to more closely conform to the altered anatomy of the upper airway and neck in patients with tracheostomies. A 41F DLT (13.7-mm OD) is just slightly larger than a #10 Shiley (Shiley Inc., Irvine, CA.) single-lumen tracheostomy (39F, 13.0-mm OD) tube and can be used in most adult patients with tracheostomies. If necessary, other (37F and 39F) PVC DLTs may be similarly modified for smaller patients.

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Fentanyl and Sufentanil Anesthesia Revisited: Establish an Effective Plasma Concentration and Achieve It at the Right Time

To the Editor:—In our opinion, the study entitled "Fentanyl and Sufentanil Anesthesia Revisited: How Much Is Enough?"¹ and the accompanying editorial² miss the mark on certain issues. The study attempts to address the question of whether there is dose-related suppression of hemodynamic and hormonal responses to surgical stimulation and uses two protocols. However, only in protocol II were plasma opioid (sufentanil) concentrations measured.

The technique used in this protocol resulted in the highest plasma sufentanil concentrations (means ranging from 23 to 54 ng/ml) at the time of the least painful stimulation (during induction) and the lowest plasma sufentanil concentrations at possibly the times of greatest stimulation (after sternotomy and cannulation). The magnitude of the decreases in plasma sufentanil between the end of the loading dose and

intubation (ranging between 57 and 69%) indicates that the authors must have delayed tracheal intubation for some time after induction of anesthesia.

If the object of a study is to demonstrate the effectiveness of sufentanil at blocking hemodynamic and hormonal stress responses, laryngoscopy and intubation would best be accomplished at the time that plasma sufentanil concentrations are at or closest to their highest value (*i.e.*, immediately after the loading dose was administered). Furthermore, subsequent infusion rates of sufentanil should be calculated so that plasma concentrations do not decrease by 80% or more by sternotomy, and additional boluses of sufentanil should be administered just prior to sternotomy or cannulation, in anticipation of these more stressful events. The study design of Philbin and co-workers did none of the