

Contents lists available at ScienceDirect

Journal of the American Pharmacists Association



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RESEARCH NOTES

What are pharmacists recommending for infant teething treatment?

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ARTICLE INFO

Article history: Received 24 July 2017 Accepted 15 October 2017

ABSTRACT

Objectives: In 2011, the Food and Drug Administration issued a warning to avoid the use of any benzocaine-containing products for infant teething treatment owing to a risk of methemoglobinemia. Several benzocaine-containing products targeted for infant teething are currently available over the counter. Pharmacists are commonly asked for medical advice in the community, and there is no current literature evaluating what pharmacists are recommending for infant teething. The objectives of this study were to evaluate what pharmacists are currently recommending for infant teething treatment and assess what percentage would inappropriately recommend a benzocaine-containing product.

Methods: From March to June 2016, a 16-item in-person paper-and-pen questionnaire was administered to 200 pharmacists in the San Francisco Bay area at 115 outpatient over-the-counter pharmacies. Questions included demographic information, work and educational background, infant teething recommendations, and preferred educational resources.

Results: The overall response rate was 94.3%. One-half (50.5%) of the pharmacists' approaches to infant teething treatment was to recommend a nondrug option first and then, if needed, an over-the-counter medication. A majority (63.0%) of the pharmacists surveyed would inappropriately select a benzocaine-containing product.

Conclusion: Despite warnings, the majority of pharmacists would still inappropriately recommend a benzocaine-containing product for treatment of infant teething. Further education is warranted to ensure that all pharmacists, health care providers, and consumers are aware of the potential harm of benzocaine use in infants.

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On average, infants begin teething at 6 months. Because many parents are unsure which over-the-counter (OTC) products are the safest and most appropriate to relieve their infants' discomfort, community pharmacists are often called on to provide recommendations. There are several benzocaine-containing OTC topical anesthetic products on the market targeted for treatment of infant teething. The ease of accessibility to these products paired with the limited awareness of their potential risks in the infant population

has led to inappropriate use and resulted in numerous cases of methemoglobinemia, a serious condition characterized by impaired oxygen transport within the hemoglobin molecule. Consequently, adverse effects may include cyanosis, shortness of breath, confusion, and, in severe cases, death.^{3,4}

Initially, in 2002, the Institute for Safe Medication Practices (ISMP) recommended against the use of high-dose topical benzocaine because of methemoglobinemia related to its use, based on the Food and Drug Administration (FDA) MedWatch database that consisted of about 100 case reports. A.5 Next, in 2009, the American Association of Poison Control Centers reported approximately 100 cases of methemoglobinemia (based on hospital-reported cases of methylene blue treatment), and in March 2011, FDA's Adverse Event Reporting System identified 21 cases associated with the use of OTC benzocaine gel or liquid products with the majority of cases involving the pediatric population less than 2 years of age. As a result, FDA released a Drug Safety Communication in April 2011 recommending against the use of any benzocaine-containing products for infant

Disclosure: The authors declare no conflicts of interest or financial interests in any product or service mentioned in the article. This includes grants (pending or received), employment, gifts, stock holdings or options, honoraria, consultancies, expert testimony, patents, and royalties for all authors and members of their immediate families.

Previous presentation: California Society of Health-System Pharmacists Seminar Meeting, Anaheim, CA, October 28, 2016.

* Correspondence: Eric J. Ip, PharmD, BCPS, CSCS, CDE, FCSHP, Touro University California College of Pharmacy, 1310 Club Drive, Vallejo, CA 94592. E-mail address: eric.ip@tu.edu (E.J. Ip). teething treatment, except when under the advice and supervision of a health professional. The actual number of benzocaine-induced methemoglobinemia cases is expected to be much higher because of unreported cases to Poison Control Centers in the United States and the difficulty in diagnosing the condition. An addition, FDA recommends avoiding the use of viscous lidocaine and herbal or homeopathic products for infant teething due to adverse effects.

It is important to identify whether community care pharmacists, who are commonly asked for medical advice, ^{10,11} are recommending appropriate options for teething because infants are at a risk of developing methemoglobinemia.

Objectives

The objectives of this study were to evaluate what community care pharmacists are currently recommending for infant teething treatment and to assess what percentage would inappropriately recommend a benzocaine-containing product.

Methods

Study population and data collection

Male and female registered pharmacists in California practicing at retail, health-system outpatient, hospital discharge, and independent pharmacy settings were recruited by study investigators. One hundred fifteen pharmacies were chosen from 40 cities spanning more than 80 miles. To ensure a well-proportioned representation, the study area was split into 4 zones, including the North Bay area, East Bay area, South Bay area, and San Francisco peninsula. We aimed to have onefourth of the study population fall under each preset zone. All pharmacists present at each pharmacy were solicited in person during normal business hours to complete the survey. Non-English speaking individuals and individuals who began the survey but did not complete it were excluded. Participants were provided consent forms providing additional information regarding the study and assured confidentiality and anonymity. No individually identifiable data were collected. The study received institutional review board approval from Touro University California.

Study design

This was a cross-sectional study among a convenience sample of community care pharmacists in the San Francisco Bay area from March to June 2016. A 16-item paper-and-pen questionnaire that contained multiple-choice, shortanswer, and "select all that apply" questions was administered to the pharmacists (Appendix 1). The questionnaire was separated into 4 sections: demographics, education and work experience, infant teething recommendations, and preferred educational resources. Independent variables that were assessed included gender, age, graduation year, postgraduate training, educational level, and outpatient pharmacy setting (e.g., community retail, independent pharmacy, health-system outpatient, or hospital discharge). To assess infant teething recommendations, the pharmacists were asked, "What is your general approach in counseling parents on treatment of infant teething?" as well as presenting a hypothetical scenario. The scenario was: "A mother comes into your pharmacy and asks for a medication recommendation on infant teething. Please select the most likely medication regimen that you would recommend for her infant at this visit. Assume the infant is otherwise healthy, on no medications, and has no allergies. (Select all that apply.)" Appropriate potential medication regimens included acetaminophen, ibuprofen, or a combination of acetaminophen with ibuprofen.

The investigators waited for each participant on site to complete their survey and then provided a short educational consultation (verbal instruction with handout) regarding FDA recommendation to avoid benzocaine-containing products in infants as well as providing appropriate treatment options. Participants were aware that they would receive a \$5 gift card if they completed the survey.

Table 1Demographics of pharmacists

Demographics	Number (%)
Age, y	
18-29	41 (20.5)
30–39	53 (26.5)
40-49	61 (30.5)
50-59	31 (15.5)
≥ 60	14 (7.0)
Gender	
Male	64 (32.0)
Female	136 (68.0)
Ethnicity	
White	45 (22.5)
African American/Black	4 (2.0)
Hispanic/Latino	7 (3.5)
Asian/Pacific Islander	133 (66.5)
American Indian/Alaskan Native	0 (0)
Other ^a	11 (5.5)
Highest pharmacy degree	
BS	25 (12.5)
MS	3 (1.5)
PharmD	169 (84.5)
PhD	3 (1.5)
Postgraduate training	, ,
Yes	13 (6.5)
No	187 (93.5)
Years of practice	13.2 ± 11.1
Board of Pharmacy Specialties Certification	_
Yes	9 (4.5)
No	191 (95.5)
Pharmacy practice setting	, ,
Community retail	132 (66.0)
Health-system outpatient	44 (22.0)
Hospital discharge outpatient	16 (8.0)
Independent	8 (4.0)
Other ^a	0 (0)
Role in pharmacy	- (-)
Staff pharmacist	96 (48.0)
Floater pharmacist	33 (16.5)
Pharmacy manager	42 (21.0)
Pharmacist-in-charge	25 (12.5)
Other ^a	4 (2.0)
Working hours per week	1(2.0)
0–9	1 (0.5)
10–19	6 (3.0)
20–29	20 (10.0)
30–39	41 (20.5)
> 40	132 (66.0)
<u> </u>	132 (00.0)

^a Other includes any ethnicity, pharmacy setting, or role not represented by any of the aforementioned categories.

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