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Inadequacy of current pediatric epinephrine autoinjector needle length for use in infants and toddlers

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ABSTRACT

Background: Epinephrine injection represents the standard of care for anaphylaxis treatment. It is most effective if delivered intramuscularly, whereas inadvertent intraosseous injection may be harmful. The needle length in current pediatric epinephrine autoinjectors (EAIs) is 12.7 mm; however, the ideal needle length for infants and toddlers weighing less than 15 kg is unknown.

Objective: To determine the skin-to-bone distance (STBD) and skin-to-muscle distance (STMD) at baseline and after simulated EAI application in infants and toddlers (weighing 7.5–15 kg).

Methods: Study participants recruited from 2 North American allergy clinics underwent baseline and compression (10-lb pressure) ultrasonography of the anterolateral thigh with a modified ultrasound transducer mimicking the footprint and maximum pressure application of an EAI device. Ultrasound images, with clinical data masked, were analyzed offline for STBD and STMD in short-axis approach.

Results: Of 53 infants (mean age, 18.9 months; 54.7% male; 81.1% white; mean weight, 11.0 kg), 51 had adequate images for short-axis STBD measurements. In these infants, the mean (SD) baseline STBD was 22.4 (3.8 mm), and the mean (SD) STMD was 7.9 (1.7) mm. With 10-lb compression, the mean (SD) STBD was 13.3 (2.1) mm, and the mean (SD) STMD was 6.3 (1.2) mm. An EAI with a needle length of 12.7 mm applying 10-lb pressure could strike the bone in 43.1% of infants and toddlers in this cohort.

Conclusion: Our data suggest that the optimal EAI needle length for infants and toddlers weighing 7.5 to 15 kg should be shorter than the needle length in currently available pediatric EAIs to avoid accidental intraosseous injections.

Introduction

Anaphylaxis is a potentially life-threatening allergic reaction that can be caused by a number of different triggers, most commonly from ingested foods, insect stings, and medications.[1] The incidence of anaphylaxis is highest in young children up to 4 years of age, with a concomitant increase in the incidence of hospital admissions for anaphylaxis.[2–4] Prompt administration of epinephrine is the treatment of choice for anaphylaxis. Current recommendations for self-treatment of food allergy causing anaphylaxis include strict avoidance of the food trigger and consistent availability of an epinephrine autoinjector (EIA) to treat reactions occurring at home or in community settings.[1]

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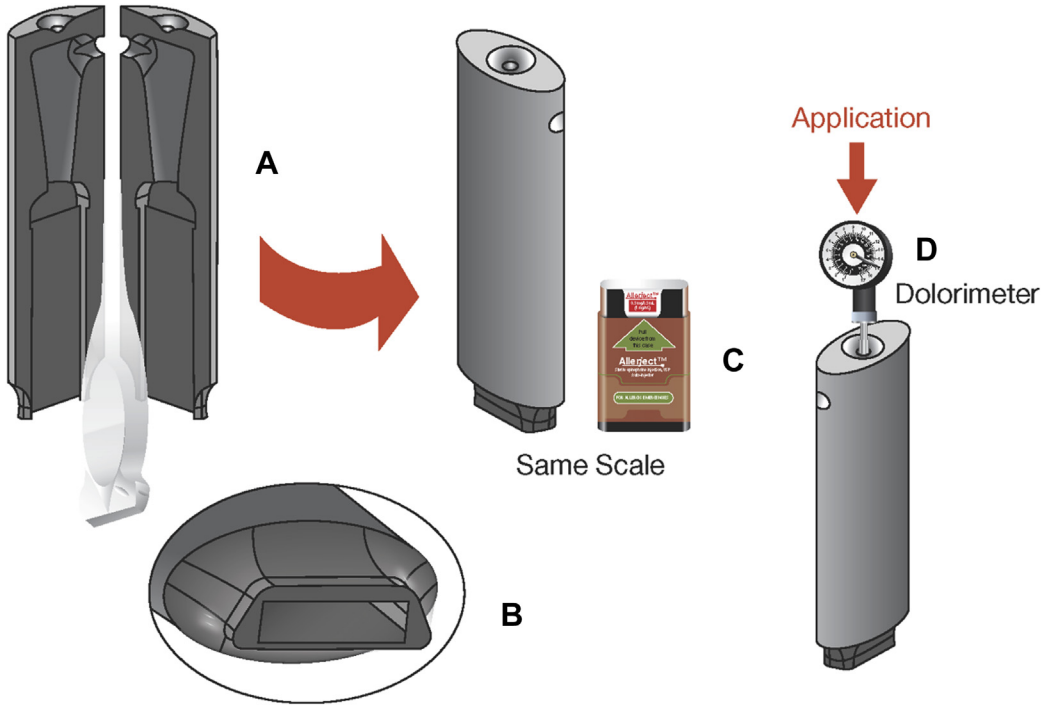

Figure 1. Modified ultrasound transducer mimicking the surface of an epinephrine autoinjector (Auvi-Q) with attached Dolorimeter. (A) Plastic shell surrounding ultrasound transducer. (B) Surface of plastic shell mimicking surface of the epinephrine autoinjector. (C) Plastic shell and epinephrine autoinjector side by side. (D) Dolorimeter attached to the plastic shell and embedded ultrasound transducer.

The US Food and Drug Administration–approved EAIs in the United States and Canada (Auvi-Q/Allerject, EpiPen Jr) are indicated for use in children weighing 15 to 30 kg and administer 0.15 mg of epinephrine during intramuscular injections.[5–7] The exposed needle length of these pediatric EAIs is 11.43 to 13.97 mm (mean, 12.7 mm) for the Auvi-Q device (23-gauge needle) and 10.16 to 15.24 mm for the EpiPen Jr (22-gauge needle).[8] Additional devices include Adrenaclick and a generic autoinjector, which are both available with 0.15 mg of epinephrine. Although epinephrine is used in the treatment of anaphylaxis in approximately 30% of young children, there are limitations and challenges with current strategies for prescribing epinephrine for young children, particularly for infants and toddlers weighing less than 15 kg.[9,10] Because of the lack of a suitable alternative, the currently available 0.15-mg EAIs are used in these younger children, based on recommendations from the Canadian Society of Allergy and Immunology and the Joint Task Force (American Academy of Allergy, Asthma, and Immunology and American College of Allergy, Asthma, and Immunology) on Practice Parameters.[11,12] Given that the suggested dose of epinephrine is 0.01 mg/kg, using a 0.15-mg EAI for a child weighing 10 kg would deliver a 1.5-fold higher dose than recommended, and data on the effects of higher doses of epinephrine in very young children are lacking. On the basis of case reports, higher doses of epinephrine may cause ventricular dysrhythmias and cardiac ischemia.[13] In addition, there may be a risk of injection of epinephrine into the bone in children weighing less than 15 kg given their current needle length based on prior reports of pediatric patients presenting to emergency departments with EAI needles embedded in the lateral thigh.[14,15] Despite evidence from these studies suggesting that current EAIs are not optimized to the weight of every patient, EAIs are the preferred delivery method for non–health care professionals over using a vial and syringe to draw up and inject epinephrine in an emergency.[9,16] In this study, we sought to use ultrasonography to measure the soft-tissue distances of the anterolateral thighs in infants and toddlers weighing 7.5 to 15 kg with a modified ultrasound transducer mimicking the surface and injection pressure of an actual EAI device (Auvi-Q).

Methods

Study Design and Setting

This was a prospective, observational study in infants and toddlers weighing 7.5 to 15 kg. The primary objective of this study was to determine the skin-to-bone distance (STBD) at baseline and at the time of simulated needle activation, as previously described, but using a modified ultrasound transducer.[14] Secondary objectives were to determine the skin-to-muscle distance (STMD) at baseline and at the time of simulated needle activation, measuring thigh circumference and assessing safety of this approach. The modified device used in this study contained an ultrasound transducer that mimicked the footprint and maximum base activation force (10 lb) that an actual EAI device (Auvi-Q) would provide (Fig 1). This pressure was chosen based on the maximum activation force provided from the manufacturer. However, no needle was used and no medication was administered in this study; instead, only noninvasive ultrasound measurements were acquired with the modified transducer. This noninvasive approach was chosen to avoid discomfort to the study participants.

Selection of Participants

A total of 53 infants and toddlers were recruited from 2 allergy clinics in North America. The main inclusion criteria were male and female infants and toddlers weighing 7.5 to 15 kg regardless of a prior history of allergies. The main exclusion criteria were physical disabilities, specifically relating to leg function; evidence of thigh cellulitis, abscess, hematoma, lymphedema, or any skin disorder; prior thigh surgery; injection to the examined thigh (eg, vaccine) within 1 week of ultrasound assessment; withdrawal of consent during the screening process; and lack of cooperation or any