

## Clinical Communications

### Outcomes of 84 consecutive open food challenges to extensively heated (baked) milk in the allergy office

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#### Clinical Implications

- Many milk allergic children tolerate oral challenges to baked milk under supervision. Milk serum-IgE antibody levels can identify patients likely to tolerate baked milk during challenges and ultimately incorporate baked milk into their diet.

#### TO THE EDITOR:

Cow's milk (CM) is among the most common childhood food allergens. A recent Australian birth cohort study found a prevalence of IgE sensitization to CM of 5.6% among infants.<sup>1</sup> Although the majority outgrow cow's milk allergy (CMA) by school age, children with CM specific-IgE (sIgE) antibody levels exceeding 50 kU<sub>A</sub>/L may retain CMA into adolescence. Although standard of care has been strict avoidance of all CM products, a majority of CMA children tolerate extensively heated (baked) CM (BM).<sup>2,4</sup> Incorporating dietary BM expands and improves nutrition, and regular ingestion of BM may accelerate acquisition of tolerance to unbaked milk.<sup>4</sup> In the process of acquiring tolerance to unbaked milk, patients tolerate higher doses of progressively less well-baked CM proteins.<sup>3,4</sup>

Since 2008, as part of our clinical practice, we have offered BM-oral food challenges (BM-OFC) to select patients with CMA. To provide practitioners with a practical report of the feasibility and safety of BM-OFC conducted in the allergy office, here we retrospectively review outcomes of these BM-OFC, and compare clinical and serologic markers among those tolerating and reacting. The study was approved by the institutional review board of the Icahn School of Medicine at Mount Sinai and a waiver of informed consent was granted. Patients with CMA were offered BM-OFC to muffin based on allergists' interpretation of history and testing (with CM-sIgE generally <15 kU<sub>A</sub>/L), and family preference;<sup>2,5</sup> strict criteria for BM-OFC were not implemented in our clinical practice. BM-OFC were conducted at Mount Sinai Pediatric Allergy Practice by trained staff per standard protocol. Our analysis included all children who tolerated a full serving of BM and all who reacted to any amount of BM during OFC between January 2008 and December 2015. Serum CM-sIgE levels (ImmunoCAP; Thermo Fisher Scientific, Portage, Mich) and skin prick tests (SPT) using CM extract (Greer Laboratories, Lenoir, NC) were performed before OFC.<sup>3</sup>

The total BM-OFC dose was 1 muffin (1.3 g milk protein; Table E1, available in this article's Online Repository at [www.jaci-inpractice.org](http://www.jaci-inpractice.org))<sup>4,6</sup> given in 4 increasing doses every 15 minutes,

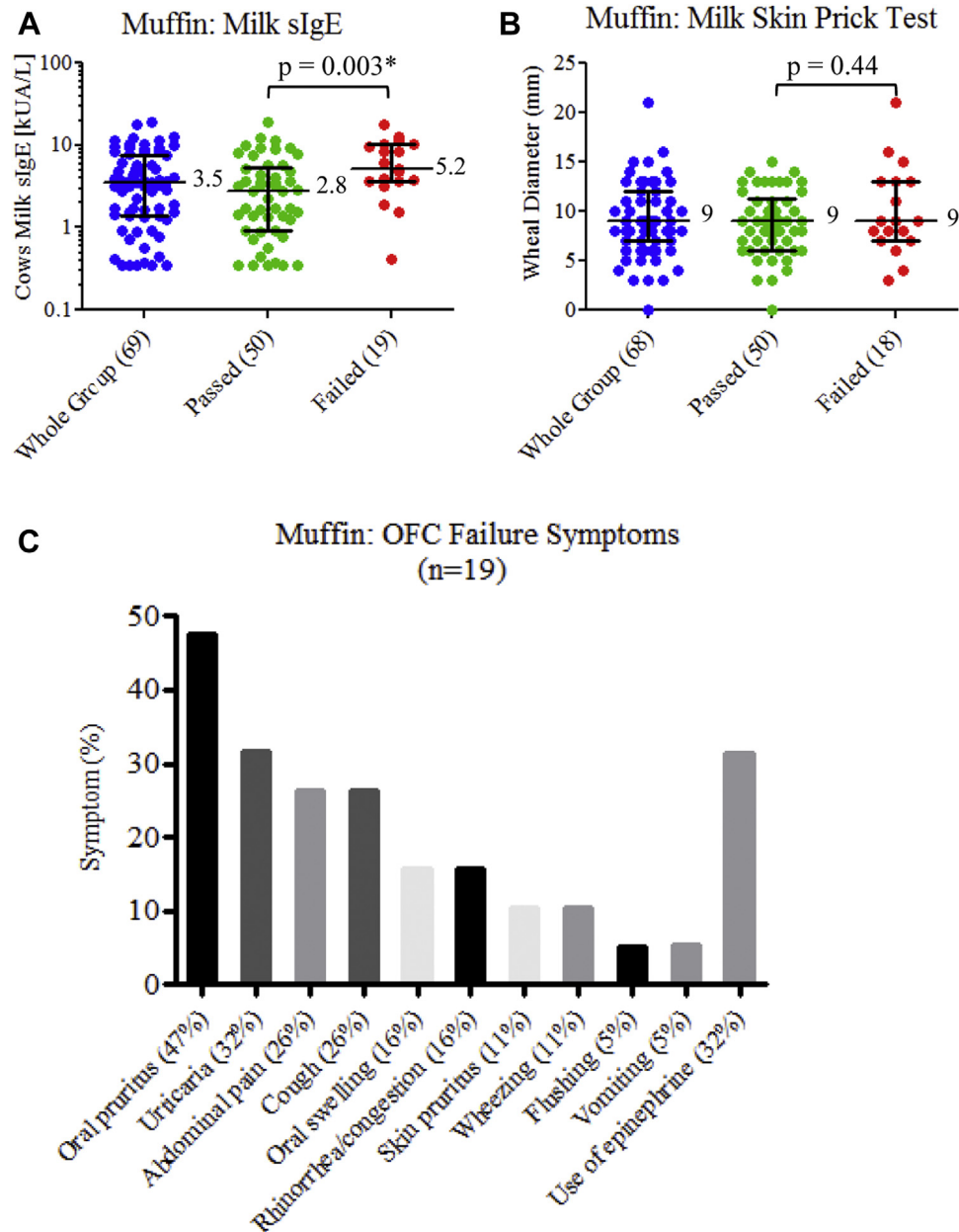
followed by a 2-hour observation. Challenges were stopped and patients were treated (with oral antihistamine, oral steroids, and/or intramuscular epinephrine) per the discretion of the physician if objective signs of reaction developed. Tolerant children were recommended to incorporate baked milk into regular diet.<sup>6</sup> Statistical significance was calculated using the Mann-Whitney *U* test for continuous variables and mid-P calculation for categorical variables with Graphpad Prism 7 statistical software.

Between January 2008 and December 2015, 84 patients underwent BM-OFC to muffin; 15 subjects who did not consume the full challenge dose for reasons other than allergic reaction were excluded. All of the 69 subjects included in the analysis had milk-sIgE and milk SPT preceding OFC. Most sIgEs and SPT were performed within 1 year and within 6 months before OFC. There were no significant differences in baseline age, gender, or atopic illness between those tolerating and reacting (Table E2, available in this article's Online Repository at [www.jaci-inpractice.org](http://www.jaci-inpractice.org)).

Of 69 children included in muffin OFC analysis, 72% (n = 50) tolerated a full serving. sIgE levels (kU<sub>A</sub>/L) were significantly lower among tolerant children (CM-sIgE median 2.8, interquartile range [IQR] 0.9-5.3) compared with reactors (CM-sIgE median 5.2, IQR 3.6-10.2) (*P* = .003) (Figure 1, Table E2, available in this article's Online Repository at [www.jaci-inpractice.org](http://www.jaci-inpractice.org)). Sensitivity, specificity, and likelihood ratios of CM-sIgE for muffin OFC are given in Table I.

Among muffin reactors (n = 19), the most common symptoms were oropharyngeal pruritus (47%) and urticaria (32%) (Figure 1, C). Median cumulative dose before symptom onset was one-fourth muffin (IQR 1/8-1/2). Most reactions (63%) were treated with oral antihistamine. Eight children (12% of all challenged; 42% of subjects who reacted) developed symptoms of anaphylaxis, including one or a combination of the following symptoms: oral pruritus and swelling, vomiting, urticaria, cough with coarse breath sounds, and/or tachycardia. Of these, 6 were treated with intramuscular epinephrine; the remaining 2 were treated with oral antihistamine and oral steroids. None received more than 1 dose of epinephrine. No delayed reactions were reported after the 2-hour observation period. CM-sIgE (kU<sub>A</sub>/L) and SPT wheal diameters (mm) were similar among reactors given epinephrine (CM-sIgE median 4.3, IQR 3.6-11.3; SPT median 7.5, IQR 4-13) and reactors not given epinephrine (CM-sIgE median 6.2, IQR 3.4-10; SPT median 9, IQR 8-13) (*P* = .88 and .37, respectively).

In this retrospective study, we describe outcomes of 84 BM-OFC in the allergy office at a food-allergy referral center. As in previous studies, the majority (72%) of milk allergic children included in the analysis who underwent BM-OFC were BM tolerant.<sup>2,3,7</sup> Among this referral population, 42% of reactors (and 12% of all challenged) developed mild anaphylaxis. All reactions resolved quickly with in-office medications, and no children required monitoring after the 2-hour observation period. Milk-sIgE levels were significantly higher in reactive patients and appear useful in predicting tolerance.<sup>2,3,5,8,9</sup> In contrast to prior studies,<sup>2,3,5,8</sup> SPT wheal diameters were similar among those reacting and tolerating BM-OFC, and appear in



**FIGURE 1.** Specific IgE, skin prick tests, and symptoms associated with muffin oral food challenges (OFC). Serum cow milk-sIgE (**A**) and skin test results (**B**) before muffin OFC are shown. Median values are labeled and bracketed by interquartile ranges indicated by bars.  $P$  values (\*significance defined as  $<.05$ ) were calculated using the Mann-Whitney  $U$  test. Symptoms during failed OFC are shown in (**C**).

our analysis to have less utility in predicting tolerance when compared with sIgE.

Study limitations include the retrospective design, as well as the lack of follow-up to determine what portion of tolerant children continue to tolerate BM at home and if tolerance to unbaked milk was attained. As subjects were not challenged to unbaked CM to confirm the continued presence of unbaked CMA, we cannot exclude the possibility that some subjects may have already tolerated unheated CM at the time of BM-OFC.

Among patients at this referral center, we anticipate that food allergy is likely to be more prevalent and accompanied by reactions that are more severe than in the typical community-based allergy clinic. This limitation may provide reassurance that we have captured the more severe phenotype of potential reactions during BM-OFC.

In conclusion, we have summarized outcomes of in-office BM-OFC conducted outside the research setting. This study provides further evidence that BM-OFC can be safely conducted

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