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Research Article

How are pediatricians treating molluscum contagiosum? results from in-depth interviews

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Abstract

Molluscum contagiosum is a common, often persistent viral skin infection affecting children, and spread by infected individuals or objects. No molluscum management guidelines exist and only two FDA treatments have been approved in the last year, thus placing pediatricians in a clinical conundrum if molluscum treatment is warranted. When MC is particularly bothersome or persistent, parental anxiety may influence treatment. In-depth interviews with 25 pediatricians provided insight into the current MC treatment landscape and drivers of therapeutic intervention. This study reveals the important influence parental anxiety, patient characteristics, and parental involvement have on pediatrician's molluscum management and treatment intervention practices. Professional society endorsed molluscum management guidelines and the use of safe and efficacious FDA-approved therapies would fill therapeutic gaps.

Abbreviations

FDA: Food and Drug Administration; MC: Molluscum Contagiosum; SD: Standard Deviation

Introduction

Molluscum contagiosum is a viral skin infection caused by the *Molluscipoxvirus* and is characterized by flesh-colored bumps that are round, dome-shaped, and usually umbilicated [1]. Lesions commonly appear on the face, trunk, and extremities of children. The virus resides in the human epidermis and is transmitted by skin-to-skin contact with infected persons or contaminated objects; scratching may cause lesions to become more widespread or appear in other areas of the body through auto-inoculation.

Pediatricians may diagnose molluscum in either an annual well-child visit or through an office visit spurred by parental or caregiver concern. Per the Red Book[®], the standard of care for the treatment of MC infections is to “wait and see” or “watch and wait,” with an expectation that lesions will spontaneously resolve in a matter of months [2]; however, some episodes last months or years [3]. Treatment may be warranted for resistant MC cases, younger patients with large or numerous lesions, lesions in sensitive body regions, patients with bothersome symptoms such as itching, redness, secondary infection, and/or when there is concern about the potential for scarring or spreading to close contacts, such as siblings [4]. However, there is no consensus on the management of molluscum in children and adolescents, and until 2023, there were no United States Food and Drug Administration (FDA)-approved treatments. The lack of widely available treatment options



places pediatricians in a clinical conundrum, particularly if a parent or caregiver strongly advocates intervention.

The current gold standard for the treatment of MC is the physical destruction of lesions using curettage or cryotherapy. Chemical agents designed to trigger local inflammation are used to treat MC including cantharidin, off-label tretinoin, 25%–50% trichloroacetic acid, silver nitrate, potassium hydroxide, and imiquimod [2].

The most common treatments, cryotherapy, curettage, and cantharidin application, require multiple in-office visits, which can be time-consuming depending on the number and location of lesions. Further, potential adverse outcomes with cantharidin, including pain, burning, and discomfort after treatment, are more likely with the improper application or inadequate post-application care (ie, washing the cantharidin off a few hours following treatment) [2].

In the absence of MC treatment guidelines, and the off-label use of unapproved therapies, it is unknown how pediatricians typically manage and select therapies to treat children with MC. It is hypothesized that two recently approved treatments will fill an unmet MC therapeutic gap [5–7].

The purpose of this structured, in-depth interview of 25 pediatricians was to understand MC diagnosis and management strategies, gather information on factors that impact treatment decision-making, and gain physicians' perspectives on current treatment options and therapeutic gaps.

Materials and methods

From May 12 to 27, 2022, Syneos Health Consulting conducted in-depth telephone interviews with a cross-section of 25 pediatricians in the United States. This market research interview consisted of 35 questions (Table 1) to collect information about the location (state) of practice, practice characteristics (including the percentage of practice devoted to patient care), practice type, and monthly number of patients with MC. Pediatricians were also queried about their current MC diagnostic criteria, treatment practices (including a wait-and-see approach in which no treatment was initiated), or if the practitioner tended to treat patients with MC, use of pharmacologic therapy (eg, over-the-counter, prescription), physical removal, or both. Pediatricians were classified into one of three primary categories based on their MC management strategy: wait-and-see manager, treater, or referrer. Wait-and-see captured pediatricians who initiated no treatment upon MC diagnosis for most patients. Referrers captured pediatricians who referred > 50% of their patients with MC to a specialist (e.g., dermatologist) or another physician. Treater captured pediatricians who treated > 50% of their patients with MC. Interview responses were aggregated by category, and descriptive statistics were reported.

Results

Of the 25 pediatricians interviewed, 13 (52%) were female and 12 (48%) male; 7 (28%) were from the Midwest, and 6 (24%) each from the Northeast, South, and West. Nine (36%)

were in a single specialty group practice; 7 (28%) in a multi-specialty group; 6 (24%) in private practice, and 3 (12%) in an Integrated Delivery Network. An average of 97.5% of the practices were devoted to patient care with a mean (\pm SD) of 72 (\pm 57.6) (median, 50) patients with MC per seen month.

Most pediatricians (\geq 90%) interviewed relied primarily on their residency training to manage patients with MC, followed by clinical experience and colleague consultations. Respondents estimated that nearly two-thirds (62%) of their patients with MC were diagnosed during a parent/caregiver-initiated office visit for lesion evaluation, and the remaining third (38%) were diagnosed during a well-child visit. The average time between a parent/caregiver first noticing the lesions and seeking an office visit was 2 to 4 months. More consultations occurred during warmer seasons. Pediatricians reported most parents were unfamiliar with molluscum unless through previous experience with an infected child's sibling. All respondents (n = 25, 100%) reported that the MC diagnosis was visual, without laboratory testing or biopsy. Pediatricians reported the most common lesion location(s) were extremities, including legs, arms, forearms, and hands (60%, n = 15), followed by the trunk (56%, n = 14), face/neck (40%, n = 10), sensitive locations, including the groin, axillary region, and behind the knees (16%, n = 4), and variable (4%, n = 1). Among pediatricians interviewed, a typical patient with MC was between 2 and 8 years of age with between 10 to 24 lesions.

Most pediatricians interviewed were classified as wait-and-see managers (68%, 18/25) and 32% (7/25) as treaters. When asked "What goes into your decision to treat or not to treat?" parental anxiety was reported as a key treatment decision driver (n = 23/25), followed by lesion number (n = 11/25), lesion location, (n = 9/25), patient discomfort (n = 7/25), and age (n = 2/25) (Figure 1).

Referrals to a specialist, like a dermatologist, were limited and in response to parents' desire for a referral or in cases where treatment may be challenging due to lesion location, high risk of patient discomfort, or MC treatment is not offered by the pediatrician.

If the pediatrician treated, over half used prescription topicals (56%, n = 14) followed by cryotherapy (52%, n = 13), over-the-counter topicals 36% (n = 9) and about one-third (32%, n = 8) curettage/physical removal. Homeopathy or natural medicine was used by 16% (n = 4). The type of MC therapy the pediatrician chose was influenced by case-specific factors including age, lesion location and count, and level of urgency for resolution; pediatricians generally present all options and leave the final decision to the patient/parent (Figure 2).

When queried about the need for new MC treatment options, most pediatricians interviewed agreed there is a therapeutic gap as current regimens have limited efficacy, are not FDA-approved, and are associated with bothersome side effects. A new MC therapy that could ease parental anxiety and reduce the duration of MC was desirable. Regarding the decision to prescribe, the three most important attributes of a potential new MC therapy were safety, efficacy, and side effects. The least important attribute was the onset of action.

**Table 1:** Survey questions.

1. Please provide a brief description of your practice and medical background (for example, geographic location, type of practice, specialty)
2. How would you characterize where you practice? <i>For example, an IDN, provider network, or independent office? How many providers and what licensure? [MD/DO or PA/NP etc, for example]</i>
3. How large is the practice you work at in terms of number of annual patients?
4. How many molluscum patients do you see a month? a. What % of those patients do you diagnose yourself?
5. How do patients who suffer from molluscum typically come to you?
6. Can you describe the typical patient that presents to you with molluscum? a. What is the typical age range? b. What is the range of lesion numbers that patients present with? What is the average number of lesions? c. Where on the body can the lesions form? What location(s) do you see most often? d. How long does the infection last? e. Do you think the disease is more prevalent among certain populations? (e.g., socio-economic conditions, ethnicities)
7. How are patients with molluscum currently diagnosed? a. What diagnostic testing is routine? How do you come up with a differential diagnosis of molluscum? b. Overall, how confident are you in the ability to recognize and correctly diagnose molluscum? c. How frequently is this testing used in your patients? d. Do you anticipate the diagnostic process to remain the same or might there be any new diagnostic procedures available in the next 3-5 years?
8. How is the topic of molluscum typically brought up in the interaction with a patient? Is it usually something that is brought up by the parents/caregivers or is it something that you proactively identify? h. Do molluscum patients come through well-visits or visits specifically for their molluscum? Can you estimate the split of molluscum patients that come in for each? i. What happens when you are unsure of a molluscum diagnosis? j. When seeing a molluscum patient, do you typically code the diagnosis? If so, for what percentage of diagnosed patients to you code?
9. How do you classify/segment your patients for treatment and management of molluscum? a. Do you typically use mild, moderate, and severe classifications for molluscum in clinical practice? b. If so, what are the typical criteria you use for each classification?
10. Once diagnosed, how do you typically manage your molluscum patients? (<i>classify as "wait and see," "treater" or "referrer"</i>) a. What goes into your decision to treat or not to treat? <i>e.g., disease severity (number and size), disease location, parent influence, well-visit vs. molluscum-specific visit, household spread</i> b. How much influence does the caregiver have? c. What is your typical strategy for "wait & see" patients that you do not treat at first visit? What is your typical follow-up for a wait-and-see patient? d. Do you ever choose to refer a molluscum patient? Why? e. Who do you normally refer to? f. How do you manage the molluscum contagiosum patients you diagnose over a typical 12-month period? Please provide the approximate % breakdown for the following options: Pharmacologic therapy (prescription or over-the-counter) _____ % Lesion removal procedure (cryotherapy, curettage, etc.) _____ % Pharmacologic therapy & lesion removal procedure _____ % NOT treated & referred to specialist (e.g., dermatologist) _____ % NOT treated & NOT referred (i.e., watch & wait) _____ % Other _____ % Total 100%
11. What is the typical conversation that you have with a patient/caregiver regarding their molluscum and treatment/management options? a. Is the decision ultimately up to the parent in how to manage molluscum? How often does the parent choose what you recommend? b. Is the decision ultimately up to the parent in how to manage molluscum? How often does the parent choose what you recommend? i. If they disagree with your recommendation, do they usually want to treat vs wait or wait vs treat?
12. What percentage of your molluscum patients do you treat? a. How do you typically treat molluscum? Are there any guidelines or protocols that you follow? b. Do you prefer pharmacological treatments, physical procedures (e.g., curettage, cryotherapy), or a combination? What impacts your decision in how to treat a molluscum patient? c. Can you remember what you were taught/shown in residency? What has influenced you since then?
13. What are the strengths/weaknesses/unmet needs with currently available molluscum treatment options?
14. Can you describe the access and reimbursement situation for molluscum treatments?
15. If there was an FDA-approved drug therapy for molluscum, how would that change your management behavior of molluscum?
16. Are you aware of new therapies being developed for the treatment of molluscum? If so, what?
17. What sources do you typically rely on for information on new drug therapies?
Questions 18-34 were related to target product questions and unrelated to this analysis

Respondents were not aware of MC management guidelines but said they would find guidelines useful, particularly if issued by the American Academy of Pediatrics or the American Academy of Dermatology.

Discussion

MC is a contagious skin infection primarily affecting children and adolescents. Pediatricians are often the first healthcare providers to diagnose molluscum; however, most

take a watch-and-wait approach to treatment. Although MC lesions may clear in a few months, some episodes may last several months to years, with the infected child remaining contagious while active lesions are present.

To date, there are no professional practice guidelines endorsed for the management of MC, and only two recently approved therapies, Y-Canth™ (0.7% cantharidin, Verrica, Westchester, PA), a drug-device combination of a blistering agent requiring application in a healthcare provider's office and post-application wash off [5] and Zelsuvmi™ (berdazimer topical gel, 10.3%, LNHC, Durham, NC), a first-in-class topical nitric oxide-releasing prescription medication approved in January 2024, that is applied by the patient or caregiver once a day and does not require post-application removal [6,7]. Prior to these approvals, there had been an unmet need for a well-studied, safe, effective, and convenient MC treatment. This study sought to capture pediatric practices in the treatment of MC, to understand key drivers in therapy initiation, and to identify therapeutic gaps.

Consistent with Red Book guidance [2], this exploratory in-depth interview revealed most pediatricians take a wait-and-see approach for patients with MC. However, clinicians are more willing to treat if desired by a parent/caregiver. The most commonly cited treatments were topical prescription therapies followed by cryotherapy. Treatment selection varied based on patient attributes, including age, anatomical location of lesions, and number of lesions. Referrals to other specialists were limited but more likely if the patient required more extensive therapy, suggesting a multidisciplinary approach to challenging MC cases.

Parental anxiety was revealed to be the primary reason MC therapy was initiated. This result was consistent with Olsen and colleagues [8] finding that 82% of parents (23/30) were moderately or greatly concerned about their child's molluscum, and physician-driven reassurance about the child's MC disease course was paramount to alleviating parental concern.

In clinical challenges such as these, professional practice guidelines often prove helpful in standardizing care and avoiding unnecessary off-label use of ineffective therapies. MC management guidelines exist in the European Union but not in the United States [9]. Development of US MC management guidelines, spearheaded by the American Academy of Pediatrics and/or the American Academy of Dermatology, could help clinicians better communicate and reassure parents about effective treatment strategies aimed at reducing the risk of re-infection or viral spread and provide much-needed guidance regarding evidence-based standards of care, particularly in cases of widespread, persistent, or bothersome MC.

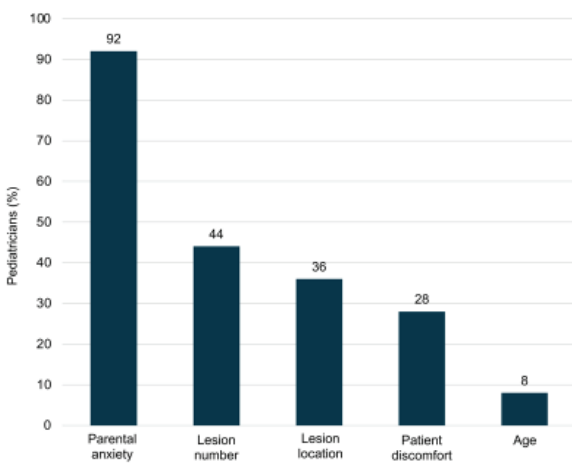
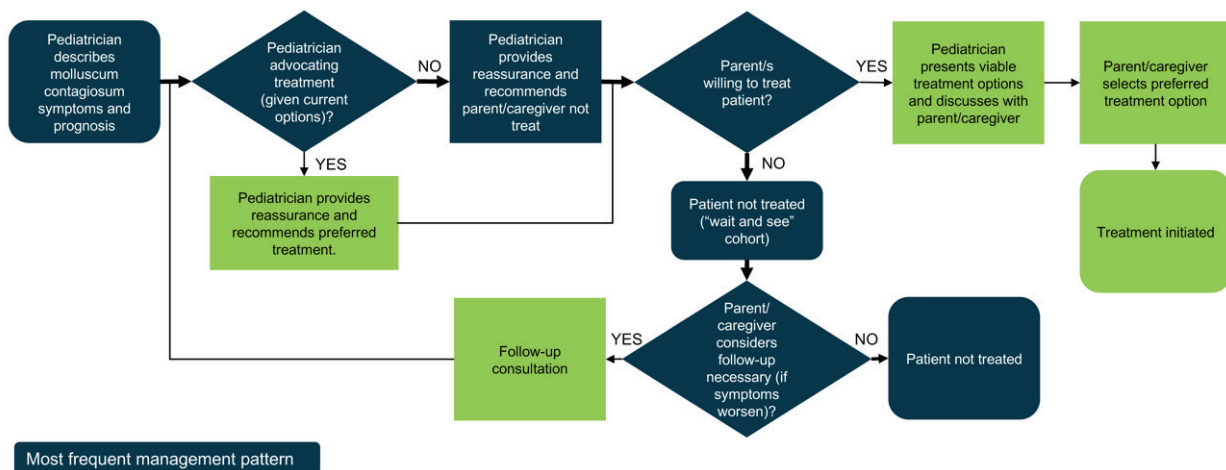


Figure 1: Molluscum treatment decision drivers as reported by the 25 pediatricians interviewed. Based on Q10. Once diagnosed, how do you typically manage your molluscum patients? What goes into your decision to treat or not to treat?

Limitations

A small sample of pediatricians was queried, and the survey questionnaire was not validated. Nevertheless, the results provide important insights into the usual care of patients with MC in pediatric practices. This interview (conducted in 2022) highlighted the lack of FDA-approved MC treatment options at the time, the desire for safe, effective, and convenient treatments, and the strong influence of parental



Most frequent management pattern

Figure 2: Flow chart of usual care for patients molluscum contagiosum in pediatric practices. Based on questions 11, 11a, 11b.



engagement in MC treatment selection. A larger study using a validated questionnaire may be useful to identify specific educational gaps or strategies that could be used by clinicians to foster adherence to MC mitigation practices among parents/caregivers and those infected with molluscum. No pediatric dermatologists at academic medical centers were surveyed to discern if this specialty manages MC differently from local pediatricians.

Conclusion

The interview data herein shed light on practice patterns among pediatricians and confirm that most do not treat MC infection but rather wait for it to resolve. However, when prompted by parental concern, treatment, albeit off-label, is sometimes initiated. None of the treatments used by pediatricians at the time of the survey were FDA-approved and there appeared to be no specific criteria regarding which cases of MC merited treatment. MC management practice patterns are expected to change with the recent approval of two FDA-approved therapies. The development of expert-driven, evidence-based MC management guidelines is encouraged to standardize the treatment of MC in children.

Conflicts of interest

Drs. Cartwright and Maeda-Chubachi and Ms. Enloe are employees of Pelthos (previously Novan, Inc.). Dr. Stripling is a clinical investigator and advisor for Pelthos, and a clinical investigator for Arcutis Biotherapeutics. Dr. Hebert has received research grants paid to the McGovern School of Medicine from AbbVie, Arcutis, Pelthos, and Pfizer; has received honoraria from Pfizer, Arcutis, Incyte, Pelthos, Ortho Dermatologics, Amyrt, Galderma, Almirall; and is a member of Data Safety Monitoring Boards for GSK, Ortho Dermatologics, and Sanofi Regeneron.

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Author contributions: Drs. Cartwright and Maeda-Chubachi conceptualized and designed the study. Dr. Cartwright drafted the initial manuscript. Drs. Maeda-Chubachi, Stripling, and Hebert, and Ms. Enloe critically reviewed the manuscript for important intellectual content. All authors approved the final manuscript as submitted and agreed to be accountable for all aspects of the work.

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