

Patient and Caregiver Experiences with Molluscum Contagiosum: Results from an Exit Interview Conducted with Phase 3 Study Participants

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Synopsis

- Molluscum contagiosum (MC) is a common, highly contagious viral skin infection often characterized by persistent lesions and bothersome symptomatology.
- B-SIMPLE4, (Berdazimer Sodium In Molluscum Patients with Lesions; NCT04535531) the largest phase 3 MC interventional trial (n=891), investigated the efficacy and safety of berdazimer gel 10.3% for the treatment of patients with MC.
- There is no US Food and Drug Administration-approved prescription treatment and a watch-and-wait strategy is often employed. Lack of therapeutic intervention may spur clinical trial participation to address MC symptoms.
- The B-SIMPLE4 included participant- and investigator-assessments of MC lesion clearance and overall improvement in 891 patients with MC. Assessments of participant- and investigator-perceptions of complete lesion clearance were collected at weeks 12 and 24 of B-SIMPLE4, along with Global Impression of Change (GIC) scores from 1 (very much improved) to 7 (very much worse). Results indicate that lesion reduction, even without complete clearance, is meaningful to patients.
- A qualitative exit interview was conducted in a subset of 30 B-SIMPLE4 patients or caregivers to gather input about bothersome signs and symptoms and psychosocial aspects of MC, expectations regarding clinical trial participation, and meaningfulness of lesion reductions. The mean duration of participant-reported MC was nearly 2 years. The most frequently reported MC-related signs and symptoms were itch (n = 20), scarring (n = 18), and pain (n = 13)
- The most frequently reported psychosocial impacts were self-consciousness (n = 15) and embarrassment (n = 14). Lesion clearance was an expectation of 28 of 30 study participants. Overall, 26 of 30 reported being very satisfied (n = 18) or satisfied (n = 8) with the changes in their disease over the duration of the trial; 23 of 30 stated that the change in lesion count was meaningful. A mean reduction of 18 lesions (76% decrease) from baseline lesion count was reported by participants (n=28). Although 22 of 28 had less than complete lesion clearance, 17 of 22 reported that the reduction in the number of lesions was meaningful. MC lesion reductions, with or without complete clearance, may be considered a therapeutic "success" by the patient/caregiver.

Objective

- To better understand patients' and caregivers' experiences with MC.

Methods

- B-SIMPLE4 included participant- and investigator-assessments of MC lesion clearance and overall improvement in 891 patients with MC. Assessments of participant- and investigator-perceptions of complete lesion clearance were collected at weeks 12 and 24 of B-SIMPLE4, along with GIC scores from 1 (very much improved) to 7 (very much worse).
- For the qualitative exit interview, all English-speaking B-SIMPLE4 participants at select sites who had less than complete MC lesion clearance from baseline to their week 12 visit as determined by the investigator were eligible for qualitative exit interviews. The goal was to engage ~30 participants (balanced between berdazimer gel 10.3% and placebo groups), including ~20 participants with lesion count reductions ranging from 75% to <100% and ~3 to 4 participants with reductions in each of the following ranges: from 50% to <75%, 25% to <50%, and 0% to <25%. The 60-minute qualitative interviews of participants (patients or caregivers were interviewed, depending on patient age) were conducted using an interview guide by one of 2 RTI Health Solutions staff members via telephone 2 to 4 weeks after their week 12 visit.
- GIC data were summarized descriptively.
- Analysis of the exit interviews was facilitated by ATLAS.ti 9 using a coding framework developed and adapted as the analysis progressed. Interview results were analyzed using a thematic analysis approach using transcripts and interviewer notes; dominant trends in each interview were identified and compared across interviews, thus generating themes describing participants' observations and experiences.

Results

Table 1: Participant-reported GIC by Lesion Reduction

Efficacy Assessment	Vehicle once daily (N = 447)		Berdazimer gel, 10.3% once daily (N = 444)	
	Improvement (n = 331)	No improvement (n = 63)	Improvement (n = 371)	No improvement (n = 21)
Patients with ≥75% reduction from baseline in MC lesion count	141 (42.6)	0	232 (62.5)	3 (14.3)
Patients with ≥90% reduction from baseline in MC lesion count	106 (32.0)	0	189 (50.9)	1 (4.8)

Table 2: Participant Characteristics Reported at the Time of the Exit Interview

Characteristic	Patients (n = 2)	Caregivers (n = 28)	Total (N = 30)
Gender, n (%)			
Male	1 (50)	2 (7.1)	3 (10)
Female	1 (50)	26 (92.8)	27 (90)
Age, years			
Mean (range)	30 (12-48)	36.9 (27-59)	36.4 (12-59)
Age of caregiver's child, years			
Mean (range)	NA	5.6 (2-11)	5.6 (2-11)
Self-reported duration of MC at study entry, months			
Mean (range)	90 (36-144)	15.2 (1-48)	20.2 (1-144)
Estimated number of lesions at study entry			
Mean (range)	14.5 (9-20)	22.2 (5-67)	21.7 (5-67)
Race, n (%)			
White	2 (100)	28 (100)	30 (100)

- Week 12 participant-reported GIC revealed 82% (322/392) of the berdazimer group and 60% (237/394) of vehicle patients reported MC lesions were either very much improved or much improved; Week 24 participant GIC scores of very much improved or much improved were 84% (313/374) vs. vehicle 71% (270/378) (Figure 1A). Results for the investigator-reported GIC were similar (Figure 1B). For participants with ≥75% reduction in MC lesion count from baseline at week 12, most reported improvement regardless of treatment assignment (Table 1).

Table 3: Impacts of MC Reported by Participants

Impact	Patients (n = 2)	Caregivers (n = 28)	Total (N = 30)
	n	n	n (%)
Self-consciousness	1	14	15 (50.0)
Embarrassment	2	12	14 (46.7)
Worry about others noticing or commenting	2	8	10 (33.3)
Avoiding certain clothing (eg, shorts or bathing suits)	2	6	8 (26.7)
Physical activities	1	5	6 (20.0)
Worry about contagiousness	1	1	2 (6.7)
Teased or treated meanly	1	2	3 (10.0)
Bath time	1	1	2 (6.7)
Daily activities	–	2	2 (6.7)
Sleep ^a	–	1	1 (3.3)
Interpersonal or social relationships ^a	1	1	2 (6.7)
Work ^a	1	–	1 (3.3)

^a Impact not probed during interview but spontaneously reported by participants.

Figure 1A: Participant-reported GIC Over Time

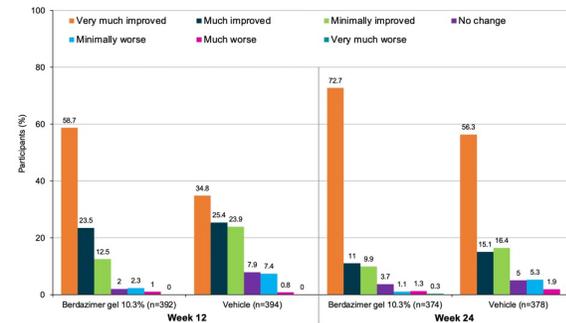
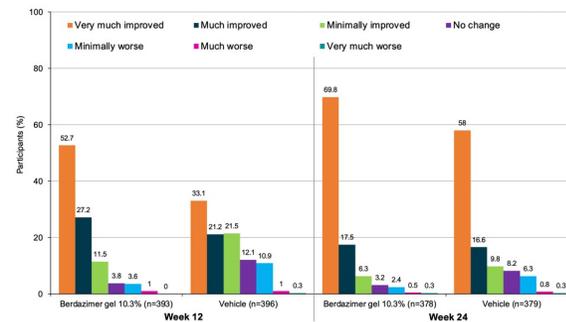


Figure 1B: Investigator-reported GIC Over Time



- The exit interview revealed MC episodes with a mean of nearly 2 years (Table 2). The most frequently reported MC-related signs and symptoms were itch (n = 20), scarring (n = 18), and pain (n = 13) (Table 4). Visibility and contagiousness of MC were the most bothersome aspects. The most frequently reported psychosocial impacts were self-consciousness (n = 15) and embarrassment (n = 14) (Table 3). Lesion clearance was an expectation of 28/30 and 26/30 reported being very satisfied (n = 18) or satisfied (n = 8) with the changes in MC disease over the duration of the trial; 23/30 stated that the change in lesion count was meaningful. A mean reduction of 18 lesions (76% decrease) from baseline lesion count was reported by participants (n=28). Although 22/28 had less than complete lesion clearance, 17/22 reported that the reduction in the number of lesions was meaningful to them.

Table 4: Signs, Symptoms, and Characteristics of MC Reported by Participants

Reported sign, symptom, or characteristic	Patients (n = 2)	Caregivers (n = 28)	Total (N = 30)
	n	n	n (%)
Raised skin (bump, spot, wart)	2	28	30 (100.0)
Location	2	28	30 (100.0)
Number	2	27	29 (96.7)
Size	1	27	28 (93.3)
Contagiousness	1	20	21 (70.0)
Itch	1	19	20 (66.7)
Visibility	1	19	20 (66.7)
Scarring	1	17	18 (60.0)
Pain	1	12	13 (43.3)
Pustules or inflamed ^a	1	12	13 (43.3)
Sore or blister ^a	1	6	7 (23.3)
Bleeding ^a	0	1	1 (3.3)
Looks infected ^a	0	2	2 (6.7)

^a Impact not probed during interview but spontaneously reported by participants.

Table 5: Select Quotes Grouped by Interview Topic

Signs, symptoms, and characteristics
Itch "They're itchy and quite bothersome."
Pain "They also turn into big sores and pustules, and they're very painful when they get to that point."
Scarring "Yes, we have scarring. They pretty much look like chickenpox scars, which are like a lighter-skin, circular scar."
Location "Before the study he had some all over his eyebrows and around his eyes, and he had them on...a couple near his hands in the study, and then on his legs. He had a lot on his legs, lower extremities."
Size "Most of them were little. Some of them were medium and then some of them were big and huge."
Number "There was probably at least 10 on his face, probably at least 10 more on his legs. I mean, I'd say a good 20 lesions on his body at least." "Yes. I think on our first visit I counted 67 bumps."
Contagiousness "It was primarily because he has a sister. They are 20 months apart and they used to bathe together all the time. That was a big thing because they had to stop taking a bath together. And they really enjoyed bathing together and playing in the tub." "It definitely spread. It was spread through contact. Her largest molluscum were on her left shoulder and upper arms. And they continued to spread to up her arm and started to form on her chin and jaw line on that side."
Visibility and contagiousness as bothersome aspects of MC "The fact that they turn into these sores, and they leave scars. That's the most bothersome, because every time a molluscum, I guess, bump turned into a sore or turned into a pustule it would leave somewhat of a scar, and it wouldn't go away quickly." "I didn't like it being on her face, because she is in school, and I'm a schoolteacher, and I know how mean kids are. And so, I didn't want people making fun of her either. And I didn't want it to keep spreading and not...the spreading them, the contagiousness."
Self-consciousness/embarrassment/worry "It definitely made her more self-conscious." "He would just make comments like, 'I hate them so bad; they look so gross, I don't want people to see them, I wish they would just go away,' things like that. And then when we'd go swimming, he'd be like, 'I don't want to take off my shirt.' Just things like that."
Meaningfulness of change "The most important improvement is the resolution of the spots with a lack of scarring."

Conclusion

- These results and interviews reveal MC lesion count reductions are important to MC patients/caregivers regardless of complete clearance.

Reference: Data on file. Novan 2022. in preparation for publication

