Adjunctive Use of Halobetasol Propionate–Tazarotene in Biologic-Experienced Patients With Psoriasis

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PRACTICE **POINTS**

- Although monotherapy with biologic agents is effective to treat psoriasis, some patients do not achieve a satisfactory response.
- Adjunctive therapy with halobetasol propionate (HP) 0.01%–tazarotene (TAZ) 0.045% lotion can improve responses to biologic treatment in patients whose psoriasis symptoms could not be adequately controlled by biologic monotherapy.
- Adjunctive use of HP-TAZ lotion in addition to biologics was well tolerated.
- Compared with switching to a new biologic regimen, adding a topical regimen of HP-TAZ lotion to ongoing biologics may be a more cost-effective approach to enhance treatment effects.

Not all patients with psoriasis achieve a satisfactory response to their initial biologic monotherapy. Switching to a new biologic may be associated with new safety issues and additional costs. In this study, we assessed the effectiveness and safety of adjunctive halobetasol propionate (HP) 0.01%–tazarotene (TAZ) 0.045% lotion in adult patients with moderate to severe plaque psoriasis who had been receiving biologic monotherapy for 24 weeks or more but had inadequate responses. All participants received HP-TAZ lotion once daily for 8 weeks, then once every other day for 4 weeks, in addition to their ongoing biologics. This real-world study demonstrated that HP-TAZ lotion adjunctive to ongoing biologics is safe and effective and potentially a more economical alternative to switching biologics for patients with psoriasis with inadequate responses to biologic monotherapy.

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Psoriasis is a common chronic immunologic skin disease that affects approximately 7.4 million adults in the United States[1] and more than 100 million individuals worldwide.[2] Patients with psoriasis have a potentially heightened risk for cardiometabolic diseases, psychiatric disorders, and psoriatic arthritis,[3] as well as impaired quality of life (QOL).[4] Psoriasis also is associated with increased health care costs[5] and may result in substantial socioeconomic repercussions for affected patients.[6,7]

Psoriasis treatments focus on relieving symptoms and improving patient QOL. Systemic therapy has been the mainstay of treatment for moderate to severe psoriasis.[8] Although topical therapy usually is applied to treat mild symptoms, it also can be used as an adjunct to enhance efficacy of other treatment approaches.[9] The National Psoriasis Foundation (NPF) recommends a treat-to-target (TTT) strategy for plaque psoriasis, the most

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common form of psoriasis, with a target response of attaining affected body surface area (BSA) of 1% or lower at 3 months after treatment initiation, allowing for regular assessments of treatment responses.[10]

Not all patients with moderate to severe psoriasis can achieve a satisfactory response with systemic biologic monotherapy.[11] Switching to a new biologic improves responses in some but not all cases[12] and could be associated with new safety issues and additional costs. Combinations of biologics with phototherapy, nonbiologic systemic agents, or topical medications were found to be more effective than biologics alone,[9,11] though long-term safety studies are needed for biologics combined with other systemic inverventions.[11]

A lotion containing a fixed combination of halobetasol propionate (HP) 0.01%, a corticosteroid, and tazarotene (TAZ) 0.045%, a retinoid, is indicated for plaque psoriasis in adults.[13] Two randomized, controlled, phase 3 trials demonstrated the rapid and sustained efficacy of HP-TAZ in treating moderate to severe plaque psoriasis without any safety concerns.[14,15] However, combining HP-TAZ lotion with biologics has not been examined yet, to our knowledge.

This open-label study evaluated the effectiveness and safety of adjunctive HP-TAZ lotion in adult patients with moderate to severe plaque psoriasis who were being treated with biologics in a real-world setting. Potential cost savings with the addition of topical HP-TAZ to ongoing biologics vs switching to a new biologic also were assessed.

Methods

Study Design and Participants—A single-center, institutional review board–approved, open-label study evaluated adjunctive therapy with HP 0.01%–TAZ 0.045% lotion in patients with psoriasis being treated with biologic agents. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and in compliance with Good Clinical Practices. All patients provided written informed consent before enrollment.

Male and nonpregnant female patients (aged ≥18 years) with moderate to severe chronic plaque psoriasis and a BSA of 2% to 10% who were being treated with biologics for at least 24 weeks at baseline were enrolled. Patients were excluded if they had used oral systemic medications for psoriasis (≤4 weeks), other topical antipsoriatic therapies (≤14 days), UVB phototherapy (≤2 weeks), and psoralen plus UVA phototherapy (≤4 weeks) prior to study initiation. Concomitant use of steroid-free topical emollients or low-potency topical steroids and appropriate interventions deemed necessary by the investigator were allowed.

Although participants maintained their prescribed biologics for the duration of the study, HP-TAZ lotion also was applied once daily for 8 weeks, followed by once every other day for an additional 4 weeks. Participants then continued with biologics only for the last 4 weeks of the study.

Study Outcome Measures—Disease severity and treatment efficacy were assessed by affected BSA, Physician Global Assessment (PGA) score, composite BSA×PGA score, and participant-reported Dermatology Life Quality Index (DLQI). The primary end point was the proportion of participants achieving a BSA of 0% to 1% (NPF TTT status) at week 8. Secondary end points included the proportions of participants with BSA of 0% to 1% at weeks 12 and 16; BSA×PGA score at weeks 8, 12, and 16; and improvements in BSA, PGA, and DLQI at weeks 8, 12, and 16.

Adverse events (AEs) that occurred after the signing of the informed consent and for the duration of the participant's participation were recorded, regardless of causality. Physical examinations were performed at screening; baseline; and weeks 8, 12, and 16 to document any clinically significant abnormalities. Localized skin reactions were assessed for tolerability of the study drug, with any reaction requiring concomitant therapy recorded as an AE.

The likelihood of switching to a new biologic regimen was assessed by the investigator for each participant at baseline and weeks 8, 12, and 16. Participants with unacceptable responses to their treatments (BSA >3%) were reported as likely to be considered for switching biologics by the investigator.

Pharmacoeconomic Evaluation—Potential cost savings were evaluated for the addition of HP-TAZ lotion to ongoing biologics vs switching to a new biologic. Cost comparisons were made in participants for whom the investigator would likely have switched biologics at baseline but not at the end of the study. For maintaining the same biologic with adjunctive topical HP-TAZ, total cost was estimated by adding the cost for 12 weeks (once daily for 8 weeks and once every other day for 4 weeks) of the HP-TAZ lotion to that of 16-week maintenance dosing with the biologic. The projected cost for switching to a new biologic for 16 weeks of treatment was based on both induction and maintenance dosing as recommended in its product label. Prices were obtained from the 2020 average wholesale price specialty pharmacy reports (BioPlus Specialty Pharmacy Services [https://www.bioplusrx.com]).

Data Handling—Enrollment of approximately 25 participants was desired for the study. Data on disease severity and participant-reported outcomes were assessed using descriptive statistics. Adverse events were summarized descriptively by incidence, severity, and relationship to the study drug. All participants with data available at a measured time point were included in the analyses for that time point.

Results

Participant Disposition and Demographics—Twenty-five participants (15 male and 10 female) were included in

the study (Table 1). Seven participants discontinued the study for the following reasons: AEs (n=4), patient choice (n=2), and noncompliance (n=1).

The average age of the participants was 50 years, the majority were White (76.0% [19/25]) and non-Hispanic (88.0% [22/25]), and the mean duration of chronic plaque psoriasis was 18.9 years (Table 1). Participants had been receiving biologic monotherapy for at least 24 weeks prior to enrollment, most commonly ustekinumab (32.0% [8/25])(Table 1). None had achieved the NPF TTT status with their biologics. At baseline, mean (SD) affected BSA, PGA, BSA×PGA, and participant-reported DLQI were 4.16% (2.04%), 2.84 (0.55), 11.88 (6.39), and 4.00 (4.74), respectively.

TABLE 1. Participant Characteristics at Baseline (N=25)

Characteristic	Participants
Age, y	
Mean (SD)	50.0 (11.9)
Median (range)	51 (29–68)
Gender, n (%)	
Male	15 (60.0)
Female	10 (40.0)
Race, n (%)	
White	19 (76.0)
Black	3 (12.0)
Asian	3 (12.0)
Ethnicity, n (%)	
Non-Hispanic	22 (88.0)
Hispanic	3 (12.0)
Psoriasis duration, y	
Mean (SD)	18.9 (10.6)
Median (range)	20 (2–41)
Biologic, n (%)	
Ustekinumab	8 (32.0)
Guselkumab	5 (20.0)
Secukinumab	4 (16.0)
Ixekizumab	3 (12.0)
Adalimumab	2 (8.0)
Risankizumab-rzaa	2 (8.0)
Brodalumab	1 (4.0)
NPF TTT status, n (%)	0 (0.0)

Abbreviations: NPF, National Psoriasis Foundation; TTT, treat-to-target.

Efficacy Assessment—Application of HP-TAZ lotion in addition to the participants' existing biologic therapy reduced severity of the disease, as evidenced by the reductions in mean BSA, PGA, and BSA×PGA. After 8 weeks of once-daily concomitant HP-TAZ use with biologic, mean BSA and PGA dropped by approximately 40% and 37%, respectively (Figures 1A and 1B). A greater reduction (54%) was found for mean BSA×PGA (Figure 1C). Disease severity continued to improve when the application schedule for HP-TAZ was changed to once every other day for 4 weeks, as mean BSA, PGA, and BSA×PGA decreased further at week 12. These beneficial effects were sustained during the last 4 weeks of the study after HP-TAZ was discontinued, with reductions of 57%, 43%, and 70% from baseline for mean BSA, PGA, and BSA×PGA, respectively (Figure 1).

The proportion of participants who achieved NPF TTT status increased from 0% at baseline to 20.0% (5/20) at week 8 with once-daily use of HP-TAZ plus biologic for 8 weeks (Figure 2). At week 12, more participants (64.7% [11/17]) achieved the treatment goal after application of HP-TAZ once every other day with biologic for 4 weeks. Most participants maintained NPF TTT status after HP-TAZ was discontinued; at week 16, 50.0% (9/18) attained the NPF treatment goal (Figure 2).

The mean DLQI score decreased from 4.00 at baseline to 2.45 after 8 weeks of concomitant use of once-daily HP-TAZ with biologic, reflecting a 39% score reduction. An additional 4 weeks of adjunctive HP-TAZ applied once every other day with biologic further decreased the DLQI score to 2.18 at week 12. Mean DLQI remained similar (2.33) after another 4 weeks of biologics alone. The proportion of participants reporting a DLQI score of 0 to 1 increased from 40% (10/25) at baseline to 60% (12/20) at week 8 and 76.5% (13/17) at week 12 with adjunctive HP-TAZ lotion use with biologic. At week 16, a DLQI score of 0 to 1 was reported in 61.1% (11/18) of participants after receiving only biologics for 4 weeks.

Safety Assessment—A total of 19 AEs were reported in 11 participants during the study; 16 AEs were considered treatment related in 8 participants (Table 2). The most common AEs were retinoid dermatitis (28% [7/25]), burning at the application site (8% [2/25]), and pruritus at the application site (8% [2/25]), all of which were considered related to the treatment. Among all AEs, 12 were mild in severity, and the remaining 7 were moderate. Adverse events led to early study termination in 4 participants, all with retinoid dermatitis as the primary reason.

Likelihood of Switching Biologics—At baseline, almost 90% (22/25) of participants were rated as likely to switch biologics by the investigator due to unacceptable responses to their currently prescribed biologics (BSA >3%) (Figure 3). The likelihood was greatly reduced by concomitant HP-TAZ, as the proportion of participants defined as nonresponders to their biologic decreased to 35% (7/20) with 8-week adjunctive application of once-daily HP-TAZ with biologic and further decreased to 23.5% (4/17) with another 4 weeks of adjunctive HP-TAZ applied every other day plus biologic. At week 16, after 4 weeks of biologics alone, the proportion was maintained at 33.3% (6/18).

Pharmacoeconomics of Adding Topical HP-TAZ vs Switching Biologics—In the participants whom the investigator reported as likely to switch biologics at baseline, 9 had improvements in disease control such that switching biologics was no longer considered necessary for them at week 16. Potential cost savings with adjunctive therapy of HP-TAZ plus biologic vs switching biologics were therefore evaluated in these 9 participants, who were receiving ustekinumab, adalimumab, guselkumab, ixekizumab, and secukinumab during the study (Table 3). The estimated total cost of

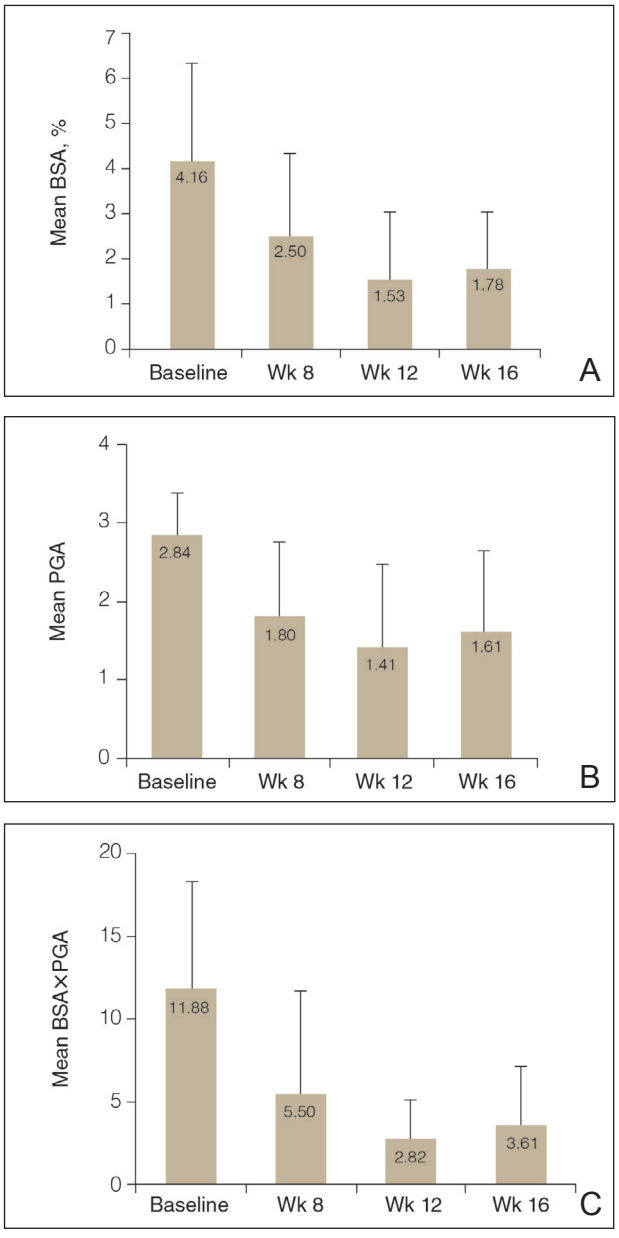

FIGURE 1. A, Mean (SD) values of affected body surface area (BSA). B, Mean (SD) values of Physician Global Assessment (PGA). C, Composite BSA×PGA scores. Means were calculated based on number of participants (n) with data available at each study visit (baseline, n=25; week 8, n=20; week 12, n=17; week 16, n=18).

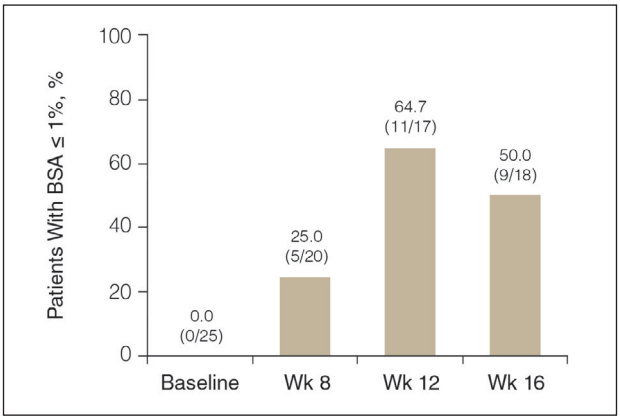

FIGURE 2. Proportion of participants achieving National Psoriasis Foundation target-to-treat status (body surface area [BSA] ≤1%) at baseline and weeks 8, 12, and 16. Percentages were calculated based on number of participants (n) with data available at each study visit (baseline, n=25; week 8, n=20; week 12, n=17; week 16, n=18).

TABLE 2. Summary of AEs (N=25)

AE	All causality	Treatment related
No. of AEs	19	16
Participants with ≥1 AE, n (%)	11 (44)	8 (32)
Retinoid dermatitis	7 (28)	7 (28)
Burning at application site	2 (8)	2 (8)
Pruritus at application site	2 (8)	2 (8)
Knee replacement repair	1 (4)	0 (0)
Worsening of diabetes	1 (4)	0 (0)
Worsening of hypertension	1 (4)	0 (0)

Abbreviation: AE, adverse event.

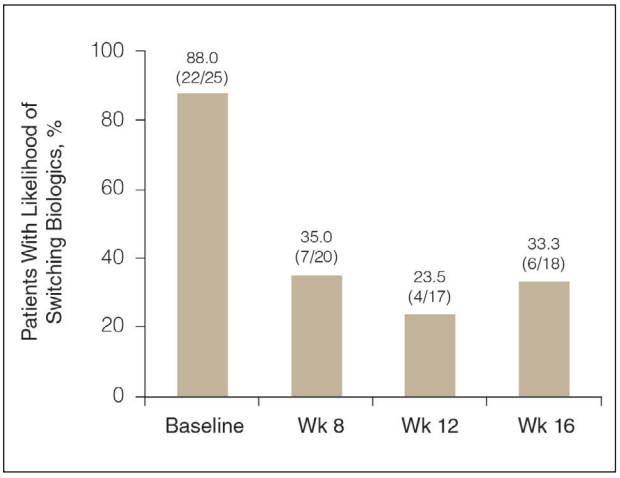

FIGURE 3. Proportion of participants for whom the investigator was likely to switch biologics at baseline and at weeks 8, 12, and 16. Percentages were calculated based on number of participants (n) with data available at each study visit (baseline, n=25; week 8, n=20; week 12, n=17; week 16, n=18).

16-week maintenance dosing of biologics plus adjunct HP-TAZ lotion ranged from $14,675 (ustekinumab 45 mg) to $54,025 (secukinumab 300 mg), while switching to other most commonly prescribed biologics for 16 weeks would cost an estimated $33,340 to $106,400 (induction and subsequent maintenance phases) (Table 3). Most biologic plus HP-TAZ combinations were estimated to cost less than $30,000, potentially saving $4816 to $91,725 compared with switching to any of the other 7 biologics (Table 3). The relatively more expensive maintenance combination containing secukinumab plus HP-TAZ ($54,025) appeared to be a less expensive option when compared with switching to ustekinumab (90 mg) ($83,097), ixekizumab (80 mg)($61,452), or risankizumab (150 mg)($57,030) as an alternative biologic.

Comment

Adjunctive Use of HP-TAZ Lotion—In the present study, we showed that adjunctive HP-TAZ lotion improved biologic treatment response and reduced disease severity in participants with moderate to severe psoriasis

TABLE 3. Estimated Costs for Switching to a New Biologic vs Maintaining Existing Biologics Plus HP-TAZ Over a 16-Week Treatment Period

		Estimated cost of treatment				
		Switching		Maintenance plus HP-TAZ[b]		
Biologics, dose	Cost/ dose, $[a]	No. of doses	Biologic, $[c]	No. of doses	Biologic, $[c]	Biologic[c] + HP-TAZ, $[d]
Ustekinumab, 45 mg	13,850	3	41,550	1	13,850	14,675
Ustekinumab, 90 mg	27,699	3	83,097	1	27,699	28,524
Adalimumab, 40 mg	3334	10	33,340	8	26,672	27,497
Guselkumab, 100 mg	13,670	3	41,010	2	27,340	28,165
Ixekizumab, 80 mg	6828	9	61,452	4	27,312	28,137
Secukinumab, 300 mg	13,300	8	106,400	4	53,200	54,025
Etanercept, 50 mg	1667	30	50,010			
Risankizumab, 150 mg	19,010	3	57,030			

Abbreviation: HP-TAZ, halobetasol propionate 0.01%–tazarotene 0.045% lotion.

[a]Cost estimates were based on prices from the 2020 average wholesale price specialty pharmacy reports (BioPlus Specialty Pharmacy [https://www.bioplusrx.com]).

[b]Includes biologics taken by participants considered likely to have their biologic switched at baseline but not at the end of the study.

[c]For maintaining existing biologics, the total costs of biologics reflect the cost of injections over a 16-week period (after at least 24 weeks of prior therapy), and for switching, the costs are based on injections for induction and subsequent maintenance dosing for a 16-week treatment course; numbers of injections are based on the dosing schedules recommended on product labels.

[d]Cost of HP-TAZ lotion was estimated at $825/100 g canister (the wholesale acquisition cost), with 1 canister/participant sufficient for a 12-week treatment period (once daily for 8 weeks and once every other day for 4 weeks).

whose symptoms could not be adequately controlled by 24 weeks or more of biologic monotherapy in a real-world setting. Disease activity decreased as evidenced by reductions in all assessed effectiveness variables, including BSA involvement, PGA score, composite BSA×PGA score, and participant-reported DLQI score. Half of the participants achieved NPF TTT status at the end of the study. The treatment was well tolerated with no unexpected safety concerns. Compared with switching to a new biologic, adding topical HP-TAZ to ongoing biologics appeared to be a more cost-effective approach to enhance treatment effects. Our results suggest that adjunctive use of HP-TAZ lotion may be a safe, effective, and economical option for patients with psoriasis who are failing their ongoing biologic monotherapy.

Treat-to-Target Status—The NPF-recommended target response to a treatment for plaque psoriasis is BSA of 1% or lower at 3 months postinitiation.[10] Patients in the current study had major psoriasis activity at study entry despite being treated with a biologic for at least 24 weeks, as none had attained NPF TTT status at baseline. Because the time period of prior biologic treatment (at least 24 weeks) is much longer than the 3 months suggested by NPF, we believe that we were observing a true failure of the biologic rather than a slow onset of treatment effects in these patients at the time of enrollment. By week 12, with the addition of HP-TAZ lotion to the biologic, a high rate of participants achieved NPF TTT status (64.7%), with most participants being able to maintain this TTT status at study end after 4 weeks of biologic alone. Most participants also reported no impact of psoriasis on their QOL (DLQI, 0–1[16]; 76.5%) at week 12. Improvements we found in disease control with adjunctive HP-TAZ lotion plus biologic support prior reports showing enhanced responses when a topical medication was added to a biologic.[17,18] Reductions in psoriasis activity after 8 weeks of combined biologics plus once-daily HP-TAZ also are consistent with 2 phase 3 RCTs in which a monotherapy of HP-TAZ lotion used once daily for 8 weeks reduced BSA and DLQI.[15] Notably, in the current study, disease severity continued to decrease when dosing of HP-TAZ was reduced to once every other day for 4 weeks, and the improvements were maintained even after the adjunct topical therapy was discontinued.

Safety Profile of HP-TAZ Lotion—The overall safety profile in our study also was consistent with that previously reported for HP-TAZ lotion,[15,19-21] with no new safety signals observed. The combination treatment was well tolerated, with most reported AEs being mild in severity. Adverse events were mostly related to application-site reactions, the most common being dermatitis (28%), which was likely attributable to the TAZ component of the topical regimen.[15]

Likelihood of Switching Biologics—Reduced disease activity was reflected by a decrease in the percentage of participants the investigator considered likely to change biologics, which was 88.0% at baseline but only 33.3% at the end of the study. Although switching to a different biologic agent can improve treatment effect,[22] it could lead to a substantial increase in health care costs and use of resources compared with no switch.[5] We found that switching to one of the other most commonly prescribed biologics could incur $4816 to $91,725 in additional costs in most cases when compared with the combination strategy we evaluated over the 16-week treatment period. Therefore, concomitant use of HP-TAZ lotion with the ongoing biologics would be a potentially more economical alternative for patients to achieve acceptable responses or the NPF TTT goal. Moreover, combination with an adjunctive topical medication could avoid potential risks associated with switching, such as new AEs with new biologic regimens or disease flare during any washout period sometimes adopted for switching biologics.

Study Limitations—Our estimated costs were based on average wholesale prices and did not reflect net prices paid by patients or health plans due to the lack of known discount rates. Inherent to the nature of its design, the study also had a relatively small patient population and lacked control groups. Although lack of a control group may limit the conclusions of our study, our goal was to examine real-world patient experience, and the efficacy of HP-TAZ lotion as well as the baseline disease state for each participant using a biologic was well known. Statistical inference on the differences in efficacy between biologics with and without adjunctive HP-TAZ lotion, or between combination therapy and a new biologic monotherapy, was not possible. Additionally, a longer follow-up after discontinuation of HP-TAZ is needed to evaluate the long-term maintenance of responses. Nevertheless, the results here demonstrated that participants responded better when adjunctive HP-TAZ lotion was added to the ongoing biologics in a clinical practice setting.

Conclusion

In this real-world study, patients with psoriasis that failed to respond to biologic monotherapy had improved disease control and QOL and reported no new safety concerns with adjunctive use of HP-TAZ lotion. Adding HP-TAZ to the ongoing biologics could be a more cost-effective option vs switching biologics for patients whose psoriasis symptoms could not be controlled with biologic monotherapy. Taken together, our results support the use of HP-TAZ lotion as an effective and safe adjunctive topical therapy in combination with biologics for psoriasis treatment.

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