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 ORIGINAL ARTICLE

Management of Residual Psoriasis in Patients on Biologic Treatment

Wasim Haidari BS BA,[a] Adrian Pona MD,[a] and Steven R. Feldman MD PhD[a,b,c]

[a]Center for Dermatology Research, Department of Dermatology, Wake Forest School of Medicine, Winston-Salem, NC

[b]Department of Pathology, Wake Forest School of Medicine, Winston-Salem, NC

[c]Department of Social Sciences & Health Policy, Wake Forest School of Medicine, Winston-Salem, NC

ABSTRACT

While biologics are highly effective, most psoriasis patients do not achieve complete skin clearance with their biologic monotherapy. How to achieve complete skin clearance in psoriasis patients who fail their biologic is not well characterized. To describe treatment approaches in psoriasis patients who fail to achieve complete clearance from their biologic, we modeled and assessed the efficacy, cost, and safety of three treatment approaches– adding a topical agent with their biologic, escalating the biologic dose, and switching to a different biologic. Efficacy of each approach was obtained from literature identifying complete clearance defined as 100% improvement in Psoriasis Area and Severity Index and/or Physician's Global Assessment score of clear. Cost of each treatment approach was calculated using medication wholesale acquisition cost obtained from Medi-Span Price Rx. Safety was assessed by adverse event (AE) rates. Complete clearance in patients not cleared on their initial biologic was achieved when adding calcipotriene/betamethasone dipropionate (Cal/BD) foam (28%), switching to guselkumab (20%), and switching to infliximab (15.8%). Adding Cal/BD foam to the initial biologic ($3,780 per additional patient cleared) was a less costly approach compared to the lowest cost dose escalation (guselkumab; $73,370 per additional patient cleared) or switching the initial failed biologic to the lowest cost alternative biologic (infliximab; $88,250 per additional patient cleared). There were no treatment-related or serious AEs when adding Cal/BD foam. Adding a topical agent may be an efficacious, low cost, and safe approach to achieve complete clearing in psoriasis patients who previously failed to clear on their biologic.

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INTRODUCTION

Psoriasis impacts patients' quality of life as much as other major chronic diseases, including cancer.[1,2] Advancements in the treatment of psoriasis, particularly biologics, have allowed for better symptom control, reduction of adverse effects, and improved patient satisfaction, albeit at higher cost.[3] Biologic therapies have increased the ability of psoriasis patients to achieve complete skin clearance.[5] However, some patients may fail to respond to their biologic agent, and most do not achieve complete clearance.[4,11-14] Complete psoriasis clearing is desirable as complete clearance is associated with fewer symptoms and better quality of life compared to less than complete psoriasis clearing.[5]

There is no clear consensus about how to treat patients who fail to achieve complete clearing with a biologic. Treatment approaches include adding a topical agent, escalating the dose of biologic, or switching to a different biologic. We characterized the different treatment approaches for patients with psoriasis who improve but do not clear with their biologic treatment; we assessed efficacy, cost, and safety of each treatment approach using a model informed by the available literature.

METHODS

A systematic literature review was performed using MEDLINE to find articles discussing treatment approaches for moderate-to-severe plaque psoriasis patients who fail to achieve complete skin clearance on their biologic. Articles describing total psoriasis clearance, defined as 100% improvement in Psoriasis Area and Severity Index (PASI 100) and/or Physician's Global Assessment score of 0 (PGA 0), were considered. We then characterized the efficacy, cost, and safety of each approach to manage residual psoriasis in patients who failed to achieve complete psoriasis clearing on their biologic.

Efficacy

Efficacy for adding a topical agent as an adjunct was obtained from a published report.[17] We did not identify a similar report describing the efficacy of escalating the dose of a biologic in psoriasis subjects who previously failed to achieve complete skin clearance. However, since 18.6% of psoriasis subjects receiving ustekinumab 45 mg were able to achieve PASI 100 and 29.5% of psoriasis subjects were able to achieve PASI 100 on 90 mg of ustekinumab, we estimated that an additional 10.9% of psoriasis subjects would achieve PASI 100 on ustekinumab 90

FIGURE 1. Number needed to treat equation.

Number Needed to Treat (NNT) to achieve clearance in one additional patient = (Number of subjects in the study) / (percentage of subjects achieving clearance)

FIGURE 2. Estimating cost per additional patient cleared when adding a topical agent to the initial biologic.

Cost per additional patient cleared
= (Cost of Cal/BD foam) x (NNT to achieve clearance for one additional patient)

FIGURE 3. Dose escalation approach calculations.

Medication cost/duration of study
= (Cost/unit of medication) x (Number of medication units administered during study)

Cost of Effectively Clearing One Biologically Naiive Subject with Standard Biologic Dosing
= (NNT) * (Medication cost/duration of study)

Estimated cost of effectively clearing one additional subject with dose escalation, previously not achieving complete clearance on standard dosing
= (Cost of Effectively Clearing One Biologically Naiive Subject with Standard Biologic Dosing) x 2

FIGURE 4. Switching to another biologic calculations.

Cost of new biologic loading dose
= (Cost/unit of medication) x (Number of units administed during loading phase with new biologic)

Cost per additional patient cleared with switch to another biologic
= (Cost of new biologic loading dose) x (NNT)

mg (29.5%-18.6% = 10.9%)[12] Since we could not find dose escalation clearing rates for other drugs, this rate also was applied for adalimumab, ixekizumab, and guselkumab dose escalations. Lastly, the rate of complete clearing for switching to another biologic was obtained from previous reported studies.[15,16]

Cost Considerations

In order to compare the cost per additional patient cleared for the different approaches, we assumed that the cost on the first biologic is their baseline cost and we determined the additional cost.

Adding a Topical Agent

The cost for topical Cal/BD foam (Enstilar, LEO Pharma Inc.), obtained from Medi-Span Price Rx, is $1,050 for 60 g.[9] Patients in the study evaluating Cal/BD foam efficacy in psoriasis patients with inadequate response to biologic therapy received Cal/BD foam once daily for 4 weeks.[17] The 28% of patients achieved total clearance of plaque psoriasis as early as week 4; we made an assumption that 60 g supply of Cal/BD foam is sufficient to last 4 weeks if applied once daily as reported in the study.[18] NNT to effectively clear one additional patient with topical treatment not achieving complete clearance on initial biologic was determined in the same manner as for the dose escalation and switching to another biologic approaches (Figure 1). In order to calculate the cost per additional cleared patient with addition of a topical agent approach, the cost of Cal/BD foam was multiplied by NNT to achieve clearance for one additional patient (Figure 2).

Dose Escalation Approach

Psoriasis clearance data on standard biologic dosing were available for adalimumab, ustekinumab, ixekizumab, and guselkumab.[11-14] These studies reported number of subjects and percentage of patients achieving PASI 100 allowing for the calculation of number needed to treat (NNT) to effectively clear one biologically naïve subject with standard biologic dosing (Figure 1). Cost/unit of medication for adalimumab, ustekinumab, ixekizumab, and guselkumab was obtained using available medication wholesale acquisition cost data retrieved from Medi-Span Price Rx.[9] Using the description of intervention completed in the studies, we counted the number of medication units administered over the duration of the study. Then, using the cost/unit of medication and total number of medication units administered during the study, medication cost/duration of study was determined (Figure 3). The next step was to calculate the cost of effectively clearing one biologically naive subject with standard biologic dosing. In order to do this, medication cost/duration of study and previously determined NNT were multiplied (Figure 3). Lastly, to estimate the cost of effectively clearing one additional subject with dose escalation, previously not achieving clearance on standard dosing, we made an assumption that it

would be double the cost of effectively clearing one biologically naive subject with standard biologic dosing (Figure 3).

Switching to Another Biologic Approach Cost Considerations

Studies evaluating switching to another biologic approach reporting clearance as PASI 100 or PGA 0 were identified for infliximab and guselkumab only.[15,16] Similar to dose escalation approach, the number of subjects in the study and percentage of patients achieving clearance were used to determine NNT to achieve clearance in one additional patient (Figure 1). We assumed that the baseline cost on the first biologic would equal the cost of the switched biologic except the additional cost of loading dose of the new biologic. To determine the additional cost with this approach, we needed to estimate cost of the new biologic loading dose. For infliximab, the loading dose of 5 mg/kg is administered at weeks 0, 2, and 6. We used the price of reconstituted 100 mg intravenous infliximab solution ($1,167) obtained from Medi-Span Price Rx,[9] and the average weight was assumed to be 80 kg, which would require a 400 mg infliximab dose. The cost/unit of medication ($1,167*4 = $4,668) was multiplied by the number of medication units (three) administered during loading period of infliximab: $4,668*3 = $14,004 to estimate cost of the new biologic loading dose. Multiplying this cost by the NNT provides additional cost required to effectively clear one more patient not achieving complete clearance on initial biologic: $14,004 x 6.3 = $88,225 when switching to infliximab (Figure 4).

In the study evaluating switching to guselkumab, patients were administered guselkumab at weeks 0 and 4 during the loading phase after an inadequate response to ustekinumab. We multiplied the cost/unit of medication ($10,859) by the number of medication units (two) administered during loading period to estimate cost of the new biologic loading dose.[9,16] NNT and cost of effectively clearing one additional patient not achieving complete clearance on initial biologic was determined in the same manner as for the switch to infliximab (Figure 4).

For addition of topical treatment, the added cost was the price of Cal/BD foam when adding topical as an adjunct to the patient's existing biologic therapy. For the dose escalation approach, the added cost is the same as cost of standard maintenance biologic dosing as we have estimated dose escalation to double the price of standard dose (Figure 3). For the switch to another biologic approach, assuming the maintenance cost of the new biologic is equal to the baseline cost of the initial biologic, the added cost is simply the cost of the new biologic loading dose.

Time to Clearance and Safety

Secondary endpoints include time to clearing and adverse event rates. To determine time to clearing, we evaluated the time (number of weeks) it took patients to achieve psoriasis clearance on different treatments. Lastly, we looked at AE rates as another secondary endpoint and reported serious AE described in the studies to assess safety.

RESULTS

Complete clearance in those not initially cleared on their biologic was achieved in 28% (n=7) of subjects when adding calcipotriene/betamethasone dipropionate (Cal/BD) foam, 20% (n=135) of patients switching to guselkumab, and 15.8% (n=179) switching to infliximab (Table 1).[15-17] These rates represent clearance beyond what was accomplished by the initial biologic. There were limited data reporting efficacy of dose escalation in patient populations failing an initial biologic; we have estimated around 10.9% patients would achieve clearance with dose doubling of adalimumab, ustekinumab, ixekizumab, and guselkumab.

In addition to patient's baseline cost of initial biologic, adding a topical agent costs $3,780 per additional patient cleared (Table 1). Adding a topical agent is less costly than biologic dose escalation or switching biologic approaches. Guselkumab is the least costly option for achieving clearance with dose escalation with $73,370 being the added cost of effectively clearing one additional subject, whereas adalimumab is the most costly option at $290,900 per additional patient cleared (Table 2). Switching the initial failed biologic to infliximab ($88,225 per additional patient cleared) is least costly switching intervention; guselkumab was estimated to cost $108,590 per additional patient cleared (Table 1). No other studies were identified that reported complete psoriatic clearance after switching biologics.

Time to clearing was shortest for adding a topical agent approach as patients achieved total clearance of plaque psoriasis as early as week 4.[17] Time to clearance for dose escalation would be expected to be more than 24-28 weeks, as it takes 24 weeks to achieve clearance on adalimumab and guselkumab standard dosing, and 28 weeks to reach clearance on ustekinumab and ixekizumab standard dosing (Table 3). Time to clearance with switching to infliximab is 26 weeks while it's 36 weeks for switching to guselkumab, although we made an assumption in this paper that switch to guselkumab would also clear patients in 26 weeks.[15,16]

Lastly, serious AE were evaluated as another secondary endpoint to assess safety of treatments. Adding Cal/BD foam is safer than dose escalation or switching to another biologic, as there were no treatment-related AE or serious AE when adding a topical agent to biologic monotherapy.[17] AE rates for biologic dose escalation are expected to be at least as high as rates (1.7% – 4.9% serious AE) reported in studies evaluating standard biologic dosing.[11-14] 3.7% and 6.7% of patients experienced serious AE in studies evaluating switching to infliximab and switching to guselkumab, respectively (Table 3).[15,16]

TABLE 1.

Achieving Clearance by Switch to a Different Biologic or Addition of a Topical Agent										
Treatment Approach	Study	Design	Number of Subjects	Previous Therapy	Intervention	Duration (Weeks)	Key Results (% of Patients Achieving Either PASI 100 or PGA0)	Cost of Biologic Loading Dose or Cost of Topical Agent	NNT to Achieve Clearance in one Additional Patient	Additional Cost to Effectively Clear Another Patient not Achieving Complete Clearance on Initial Biologic
Switching to infliximab	Gottlieb et al., 2012	P, MC, OL	179	Etanercept	Received infliximab (5mg/kg) at weeks 0, 2, 6, 14, and 22 after a 2-week washout period	26	15.8	$14,004	6.3	$88,225
Switching to guselkumab	Langley et al., 2017	R, DB	135	Ustekinumab	Patients with IR to ustekinumab (45 or 90mg) administered at weeks 0 and 4 were randomized after 12-week washout period and received guselkumab 100mg at weeks 0, 4, 12, 20, 28	36	20	$21,718	5.0	$108,590
Adding a topical agent / Cal/BD foam	Bagel et al., 2018	P, OL	25	Ustekinumab (52%), adalimumab (20%), secukinumab (20%), etanercept (4%), ixekizumab (4%)	Received Cal/BD foam once daily for 4 weeks, followed by a maintenance regimen of 2 consecutive days weekly for an additional 12 weeks	16	28	$1,050	3.6	$3,780

P- Prospective; Open-label- OL; MC- Multicenter; R- Randomized; DB- Double Blind; PGA- Physician Global Assessment; PASI- Psoriasis Area and Severity Index; Cal/BD foam – Calcipotriene/Betamethasone Dipropionate foam; IR – Incomplete Response

TABLE 2.

Achieving Clearance Through Dose Escalation

Biologic	Author	Intervention	Number of Subjects	Duration (weeks)	Percentage of Patients Achieving PASI 100	# of Medication Units Administered Over Duration of Sstudy	Cost Per Unit of Med.	Med. Cost per Duration of Study	NNT	Cost of Effectively Clearing One Biologically Naive Subject with Standard Biologic Dosing	Est. Cost of Effectively Clearing One Additional Subject With Dose Escalation*
Adalimumab	Menter et al., 2008	Adalimumab 80mg at week 0, then 40mg EOW starting one week after initial dose	334	24	24.9	14	$5,174	$72,437	4.0	$290,900	$581,800
Ustekinumab	Papp et al., 2008	Ustekinumab 45mg at weeks 0 and 4, then every 12 weeks	397	28	18.6	4	$11,002	$44,009	5.4	$236,600	$473,200
Ixekizumab	Gordon et al., 2016	Ixekizumab 160mg initial loading dose at week 0; then 80mg every 4 weeks	195	28	49.50	9	$5,368	$48,312	2.0	$97,600	$195,200
Guselkumab	Blauvelt et al., 2017	Guselkumab 100mg at weeks 0 and 4, followed by injections every 12 weeks	329	24	44.4	3	$10,859	$32,578	2.2	$73,370	$146,740

TABLE 3.

Summary of Primary and Secondary Endpoints of Treatment Approaches to Manage Residual Psoriasis

	Primary Endpoints		Secondary Endpoints	
Treatment Approach	Percentage of Patients Anticipated to Clear With Approach	Additional Cost Required to Effectively Clear One Additional Patient Not Achieving Complete Clearance on Initial Biologic	Time to Clearing (Weeks)	Adverse Event Rates
Adalimumab dose escalation	10.9	$290,900	>24	*
Ustekinumab dose escalation	10.9	$236,600	>28	Serious AE were seen in 2% of patients*
Ixekizumab dose escalation	10.9	$97,600	>28	1.7% of patients experienced serious AE*
Guselkumab dose escalation	10.9	$73,370	>24	4.9% of patients experienced at least one serious AE*
Switching to infliximab	15.8	$88,225	26	3.7% experienced serious adverse events, which were considered to be solved without sequelae
Switching to guselkumab	20	$108,590	36	6.7% of patients had at least one serious AE
Adding Cal/BD foam to biologic	28	$3,780	4	No treatment-related AE and no serious AE were reported in the study

Cal/BD foam – Calcipotriene/Betamethasone Dipropionate foam; AE – Adverse Event
*These AE rates reported are for studies evaluating standard biologic dose

DISCUSSION

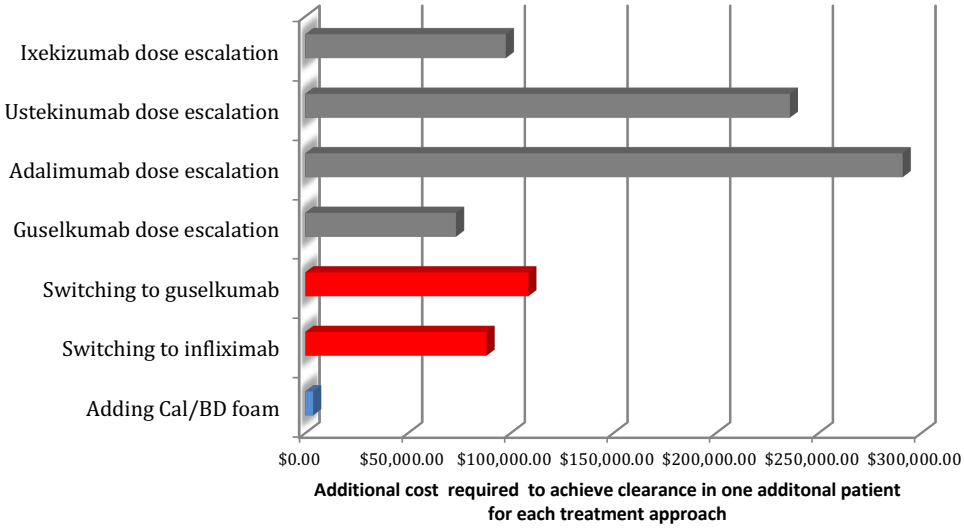
Although biologics are highly efficacious treatment options for psoriasis, initial therapy with a biologic usually fails to result in complete skin clearance.[4] To address incomplete psoriasis clearance, healthcare providers may add a topical medication while continuing the initial biologic, increase the dose of the initial biologic, or switch to a different biologic.[6]

An alternative for patients who have not achieved complete clearing with biologic monotherapy may be to add a topical agent. Adding topical agents as an adjunct to biologics can improve clinical response in psoriasis patients who did not achieve complete clearance.[18] When comparing all treatment options for patients with psoriasis who failed to achieve complete clearance after their initial biologic, adding Cal/BD foam is the least-costly approach to achieve clearing of residual psoriasis in patients on biologic treatment and was considerably less costly compared to the lowest cost dose escalation (guselkumab; $73,370 per additional patient cleared) or switching the initial failed biologic to the lowest cost alternative biologic (infliximab; $88,225 per additional patient cleared). Patients may be hesitant to use a topical as they have often failed topicals before going on biologics. However, adding a topical with the best patient friendly properties (once daily, fast acting, effective treatment) will increase chances that the patient will adhere to the treatment. Based on the available evidence, adding a topical to a biologic can provide for complete clearing and may be a safe and lower cost alternative in managing patients with psoriasis who failed to achieve complete clearance from their initial biologic.

Dose escalation may assist in clearing a patient's residual psoriasis. Dose escalation for a biologic includes shortening of the dosing interval and/or increasing the medication dose per single administration. Dose escalation, although perhaps the simplest strategy, creates an economic burden as doubling the dosage likely doubles the cost.[8] Dose escalation approach to achieve clearance in one additional patient is more costly than switching to another biologic or adding a topical (Figure 5). Although we were able to estimate the successful clearance of residual psoriasis by dose escalating a biologic, our estimate was based on an assumption, as there were no studies evaluating dose escalation in patient population failing initial biologic. Our estimation was a reasonably conservative approach because clinical trials try to identify the effective dose.

If patients with psoriasis fail to achieve complete skin clearance from their initial biologic, they may switch to a different biologic.[7,10] Switching to another biologic agent can be effective for patients who have failed the first biologic.[7,10] Lack of efficacy of a specific biologic may not necessarily equate to resistance to other biologics (Table 1).[4] When clearing one additional patient, switching to guselkumab ($108,590 per additional patient cleared) is $20,365 more costly biologic to substitute than switching to infliximab ($88,225 per additional patient cleared) after an initial failed biologic. However, previous failed therapy in those switched to infliximab (etanercept) was different than previous failed biologic in those switched to guselkumab (ustekinumab). When you have a patient who has improved considerably, you know they are not a complete treatment failure. Switching does not guarantee better outcomes; some patients could experience worsening of their psoriasis or no improvement. Other potential problems associated with switching include the economic burden on a patient, the time to achieve complete clearance once initiated on a new biologic, and the length of time for a patient's

FIGURE 5. Added Cost Required to Achieve Clearance in One Additional Patient Based on Treatment Approach (this cost is in addition to patient's baseline cost)



insurance company to approve their new biologic; while waiting for an insurance company to approve a new biologic, patients continue to suffer from their residual psoriasis. Navigating through new insurance paperwork, when switching from a drug that was already authorized to a new one, also entails greater cost to the physician's practice, a cost that we did not include in our model. A limitation in this study is that the estimate of cost for switching a biologic may be low as failing one drug may make it more likely patients would fail a second one.

CONCLUSIONS

Adding a topical agent may be an effective, low cost, and safe approach to achieve clearing in patients with psoriasis who fail to achieve complete clearance from an initial biologic.

DISCLOSURES

This study received a research grant from LEO Pharma Inc. Dr. Steven Feldman has received research, speaking and/or consulting support from a variety of companies including Galderma, GSK/Stiefel, Almirall, LEO Pharma, Boehringer Ingelheim, Mylan, Celgene, Pfizer, Valeant, Abbvie, Samsung, Janssen, Lilly, Menlo, Merck, Novartis, Regeneron, Sanofi, Novan, Qurient, National Biological Corporation, Caremark, Advance Medical, Sun Pharma, Suncare Research, Informa, UpToDate, and National Psoriasis Foundation. He is founder and majority owner of www.DrScore.com and founder and part owner of Causa Research, a company dedicated to enhancing patients' adherence to treatment.

Wasim Haidari and Dr. Adrian Pona have no conflicts to disclose.

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AUTHOR CORRESPONDENCE

Wasim Haidari BS BA
E-mail:..... wh374@georgetown.edu