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ARTICLE



Network meta-analyses comparing the efficacy of biologic treatments for achieving complete resolution of nail psoriasis at 24–28 and 48–52 weeks

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ABSTRACT

Background: Available network meta-analyses (NMAs) comparing the efficacy of biologics in nail psoriasis (NP) have not included recently approved biologics such as bimekizumab nor have they provided comparisons up to 1 year.

Objective: We conducted two NMAs that update and extend results from a previous NMA comparing biologics for achieving complete resolution of NP.

Methods: Bayesian NMAs were performed using a generalized linear model with a logit link to model the binary outcome of nail clearance at weeks 24–28 and 48–52.

Results: For the NMA at weeks 24–28, which included seven biologics and placebo, the absolute probability of achieving complete resolution of NP was highest for ixekizumab (46.4%; 95% credibility interval [CrI] 35.2–58.0), followed by brodalumab (37.1%; 95% CrI 17.1–62.2) and bimekizumab (30.3%; 95% CrI 12.7–53.9). For the NMA at weeks 48–52, which included six biologics, the absolute probability was highest for ixekizumab (77.2%; 95% CrI 51.1–93.4), followed by adalimumab (75.6%; 95% CrI 61.5–87.3) and brodalumab (71.9%; 95% CrI 38.4–93.2).

Conclusion: Among biologics included in these two NMAs, ixekizumab has the highest absolute probability of achieving complete resolution of NP. Results may help to inform treatment decisions for patients with NP.

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Introduction

Nail psoriasis (NP) affects up to half of patients with psoriasis and most patients with psoriatic arthritis (1–4). NP is widely acknowledged as challenging to treat and, along with scalp psoriasis, psoriasis severity and other factors, it is an important predictor of the future development of psoriatic arthritis (5, 6). Biologics have proven efficacious in the treatment of NP, although limited comparative information is available and few network meta-analyses (NMAs) that compared the efficacy of biologic treatments have been performed (7–10). Moreover, available NMAs have not included recently approved biologics such as bimekizumab nor have they provided long-term comparisons up to 1 year. We conducted two NMAs that update and extend results from a previous NMA comparing biologics for achieving complete resolution of NP (9), herein providing new comparative efficacy data that include bimekizumab and secukinumab and long-term outcomes up to 52 weeks.

Methods

Methods have been previously described by Reich et al. (9). Briefly, the analysis included phase III randomized controlled trials of licensed biologics that focused on adults with moderate-to-severe chronic plaque psoriasis and concomitant fingernail psoriasis (Supplementary Table S1). Eligible clinical trials were identified from a targeted literature search conducted in May 2023 (with no specified start date for searches) and hand-searched from the bibliographies of published NMAs. The most recently reported clinical trial results included in the updated and extended analyses were from March 2023 (11–24). Similar to previous analyses (25), data were also extracted from posters (21, 23) in the absence of full manuscripts. Outcomes of interest in the analyses were the proportion of patients that achieved complete resolution of NP at weeks 24–28 in the updated NMA and at weeks 48–52 in a new/second NMA independent of the shorter-term analysis. Complete resolution of NP was defined as a score of zero on the Nail

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Psoriasis Severity Index (NAPSI), modified NAPSI or Physician's Global Assessment of Fingernails (PGA-F). Characteristics of the trials included in the updated NMA are provided in [Supplementary Table S2](#).

Comparators

Treatments included the anti-tumor necrosis factor (TNF) agent adalimumab (initial dose of adalimumab 80mg, followed by 40mg every second week starting 1 week later), the interleukin (IL)-17A and F inhibitor bimekizumab (320mg every 4 weeks [BE VIVID trial]; 320mg every 4 weeks until week 16 then rerandomized to 320mg every 4 weeks or every 8 weeks [BE RADIANT trial]), the IL-17 receptor A inhibitor brodalumab (210mg, at weeks 0, 1, 2, and every 2 weeks thereafter), the IL-23p19 inhibitor guselkumab (100mg, at weeks 0, 4, and every 8 weeks thereafter), the anti-TNF agent infliximab (5mg/kg at weeks 0, 2, 6, and every 8 weeks thereafter), the IL-17A inhibitor ixekizumab (160mg starting dose at week 0, followed by 80mg every 2 weeks from week 2–12 and every 4 weeks thereafter), the IL-17A inhibitor secukinumab (300mg every 1 week until week 4 then every 4 weeks), and the IL-12/23p40 antibody ustekinumab (45/90mg weight-based dosing at weeks 0, 4, and every 12 weeks thereafter) ([Supplementary Table S1](#)).

Statistical analysis

The NMAs were conducted in the Bayesian framework and performed with R Statistical Software (v3.4.2; R Core Team 2021) using the R2jags package. A generalized linear NMA model with a logit link was used to model the binary outcome of nail clearance at weeks 24–28 and 48–52. Both fixed and random-effect models were assessed, and the best model was selected based on deviance information criterion (lower values indicating better fit) and comparing the number of data points to the residual deviance (larger differences between the two indicating poorer fit). Convergence for all models was assessed using trace plots as modified by Brooks and Gelman (26). Results are presented as a point estimate (posterior probability of nail clearance) and associated 95% credible intervals (CrI). For each outcome, the probability of each treatment being ranked best is also presented (27). To assess the potential impact of a zero-cell count event in Elewski et al. (13) on the overall week

24–28 NMA, a sensitivity analysis was performed following the guidance of the *Cochrane Handbook for Systematic Reviews of Interventions* (28). In this analysis, a fixed value of 1.0 was added to both the adalimumab and placebo arm before re-running the NMA to account for computational problems when no events are observed in one group of an individual study (28).

Results

Nail resolution NMA at weeks 24–28

A total of eight clinical trials provided comparative outcomes data at weeks 24–28 that connected to form an evidence network ([Figure 1a](#)). These phase III trials included two placebo-controlled trials (13, 14) and six head-to-head active comparator trials (11, 16–18, 20, 21) evaluating a total of seven active biologic treatments plus placebo.

The absolute probability of achieving complete resolution of NP at weeks 24–28 was highest for ixekizumab at 46.4% (95% CrI 35.2–58.0), followed by brodalumab (37.1%; 95% CrI 17.1–62.2), bimekizumab (30.3%; 95% CrI 12.7–53.9), adalimumab (28.3%; 95% CrI 24.3–32.4), guselkumab (27.7%; 95% CrI 21.0–35.0), ustekinumab (20.8%; 95% CrI 10.2–35.5), and infliximab (1.2%; 95% CrI 0.0–15.4) ([Figure 1b](#)). Aside from infliximab, all biologics were significantly better at achieving nail clearance than placebo. The Bayesian NMA also showed that ixekizumab had the highest absolute probability to be ranked best (79%), followed by brodalumab (17%) and bimekizumab (4%). Findings of the sensitivity analysis using a continuity correction for zero-event studies were largely consistent with the principal analysis for the top-ranking biologics. However, the response rate for infliximab was 23.8% higher than in the main analysis, resulting in a reversal of the order with ustekinumab ([Supplementary Figure S1](#)).

Nail resolution NMA at weeks 48–52

The evidence network for outcomes data at weeks 48–52 included five clinical trials, all head-to-head comparative studies (11, 17, 18, 21, 23), involving six different interventions ([Figure 2a](#)). For this network, the absolute probability of achieving complete resolution of NP at weeks 48–52 was highest for ixekizumab at 77.2% (95% CrI 51.1–93.4),

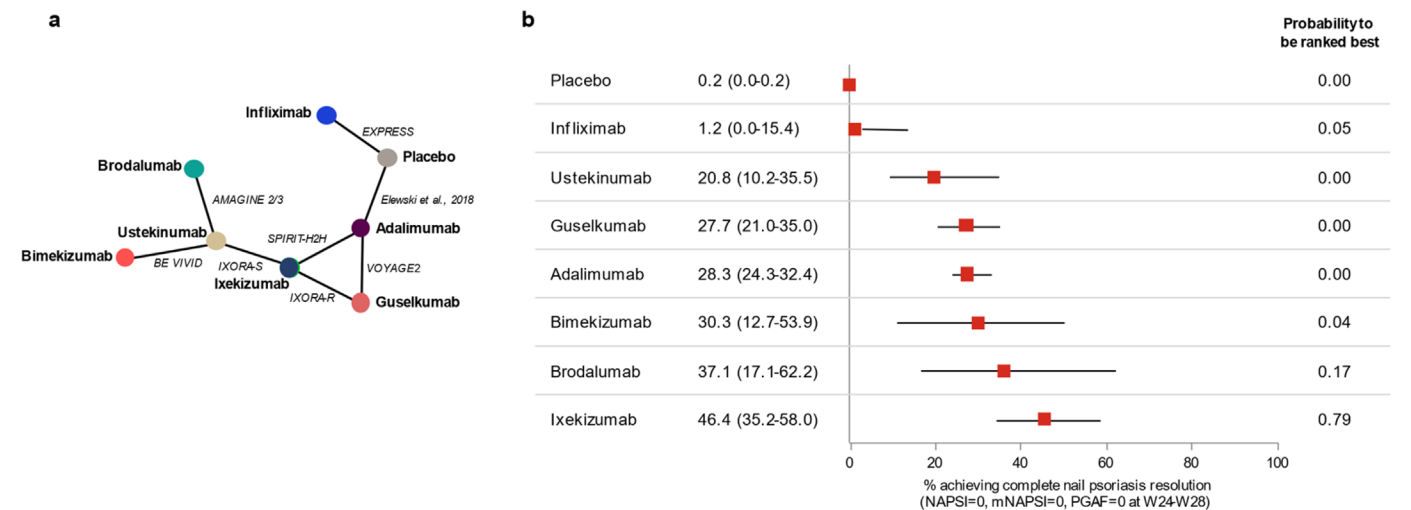


Figure 1. Network diagram (a) and forest plot of absolute treatment effects (with 95% credibility intervals) (b) for complete resolution of nail psoriasis at weeks 24–28. mNAPSI, modified NAPSI; NAPSI, Nail Psoriasis Severity Index; PGA-F, Physician's Global Assessment of Fingernail Psoriasis.

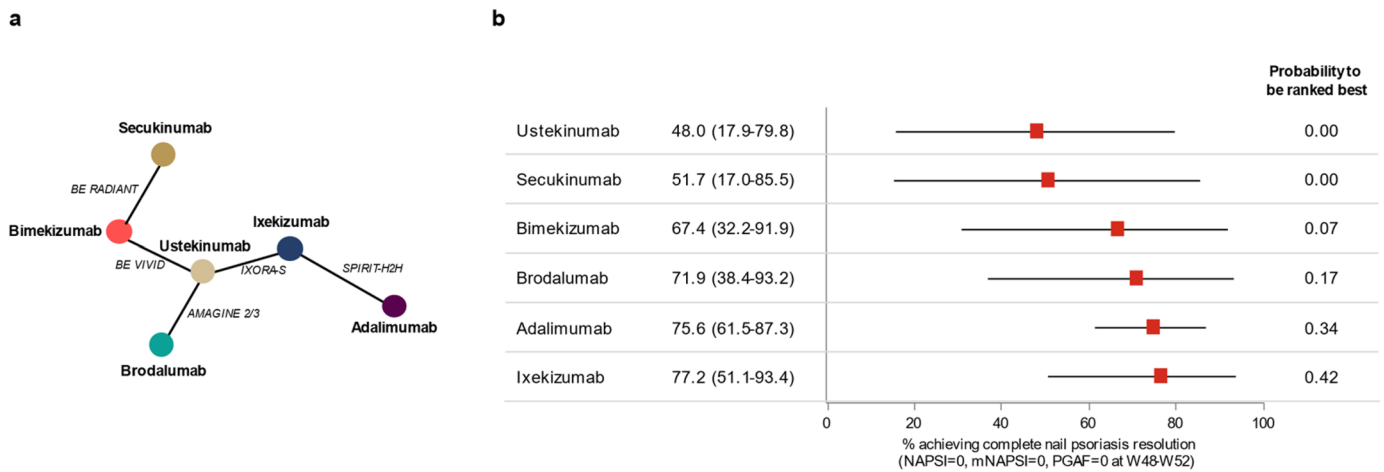


Figure 2. Network diagram (a) and forest plot of absolute treatment effects (with 95% credibility intervals) (b) for complete resolution of nail psoriasis at weeks 48–52. mNAPSI, modified NAPSI; NAPSI, Nail Psoriasis Severity Index; PGA-F, Physician's Global Assessment of Fingernail Psoriasis.

followed by adalimumab (75.6%; 95% CrI 61.5–87.3), brodalumab (71.9%; 95% CrI 38.4–93.2), bimekizumab (67.4%; 95% CrI 32.2–91.9), secukinumab (51.7%; 95% CrI 17.0–85.5), and ustekinumab (48.0%; 95% CrI 17.9–79.8) (Figure 2b). Based on the Bayesian NMA, ixekizumab was associated with the highest absolute probability to be ranked best (42%), followed by adalimumab (34%), brodalumab (17%), bimekizumab (7%), secukinumab (0%), and ustekinumab (0%).

Discussion

These NMAs compared the efficacy of biologic treatments in achieving complete resolution of NP in patients with moderate-to-severe psoriasis and concomitant fingernail psoriasis. Results showed that ixekizumab had the highest probability of achieving complete resolution of NP at weeks 24–28 in the updated NMA and at weeks 48–52 in the new/extended analysis. For biologics included in both the short- and long-term NMAs, the probability of achieving complete resolution of NP was higher overall in the long-term NMA, although differences between biologic treatments were smaller (and not statistically significant) than in the short-term NMA, potentially indicating that duration of treatment regardless of the neutralized cytokine pathway is a key determinant of treatment success (29).

Results of this study update and extend findings of the NMA conducted by Reich et al. (9), which showed ixekizumab had the highest probability of achieving complete resolution of NP and of being ranked best at weeks 24–26, being consistent with other NMAs (7, 8, 10). In the updated NMA at weeks 24–28, the ranked order from highest to lowest absolute probability of achieving complete resolution of NP was the same as in the original NMA for the biologics included. In addition to the clinical trial data used in the previous NMA, our updated analysis included clinical outcomes data for the recently approved biologic bimekizumab in the shorter-term nail resolution NMA at 24–28 weeks; bimekizumab was among the top three biologics evaluated at this period. The new/extended analysis also provides comparative efficacy data for six biologics in a long-term nail resolution NMA at 48–52 weeks. The evidence network for this NMA included data from two recently reported head-to-head comparative trials with bimekizumab (21, 23) and secukinumab (23). Unfortunately, we were unable to include other modern biologics, such as risankizumab (30) and tildrakizumab (31) in our NMAs, as the authors are not

aware of any head-to-head or placebo-controlled studies that have reported on complete resolution of NP at the study time points required for integration into the network.

To the best of our knowledge this is the first published NMA providing short- and long-term (up to 1 year) relative comparisons of biologic efficacy in achieving complete resolution of NP at the same time. The study also includes two biologics not included in previous NMAs—bimekizumab in both the short- and long-term NMA, and secukinumab in the long-term NMA. In addition, the analysis focused on complete resolution of NP as the key outcome. Complete nail resolution is a common outcome to multiple trials and only minimally affected by the scale or scoring system used (9, 20). It is also the least subjective and ambiguous outcome in NP and arguably the most important treatment goal for physicians and patients. We intend to continue to monitor NP disclosures/publications and update our NMAs on a regular basis as new information becomes available, in a similar way as other “living” literature reviews/NMA updates (32).

The study has several limitations. Studies included in the updated and extended NMAs, like the previous NMA conducted by Reich et al. (9), were identified using a targeted literature review rather than a systematic literature review (SLR). However, the authors have validated their search results against other NP NMAs that used SLRs (7, 8) and did not identify any additional clinical trials from those NMAs that were not included in our NMAs. Severity of NP varied across studies in the NMA; therefore, some patients may have had relatively mild disease at baseline and their improvement may not have been clinically significant. Ixekizumab has demonstrated similar efficacy in achieving complete resolution of NP regardless of the level of NP severity at baseline in adults (33) and pediatric patients (≥ 6 years old) (34), although this effect has not been reported (i.e., is unknown) for most other biologics. In IXORA-S, the efficacy of ixekizumab on NP clearance was only minimally affected irrespective of whether there was significant NP (defined as NAPSI ≥ 16 and ≥ 4 fingernails involved) or not (17). It can be assumed that studies with a higher degree of NP probably lead to an underestimation of the calculated response rate for drugs from these studies, although the exact magnitude of this effect cannot be ascertained and needs to be estimated in future studies. Other cross-trial differences in study design and patient characteristics may also influence the treatment effect and introduce bias in the comparisons. Missing data were also handled differently, potentially leading to an overestimation of treatment effects in studies using multiple imputation or

as observed rather than non-responder imputation. It can be assumed that studies employing non-responder imputation tend to underestimate the true response rate, whereas studies reporting multiple imputation or as observed results tend to overestimate the treatment effect of the investigated biologic (a factor that becomes more pertinent in long-term analyses). Another limitation is that the new information included in the NMA for bimekizumab was derived from clinical trials that used more frequent administration than the approved/labelled regimen for bimekizumab (35), potentially overestimating the treatment effect of this biologic. In addition, the relevant data from the bimekizumab clinical trials (BE VIVID and BE RADIANT) have been reported in posters (21, 23) and are not fully published, although the use of data from posters is not unprecedented in NMAs (25). Finally, the study was somewhat limited by the scarcity of clinical trial data and low sample sizes of patients also affected by NP, which in some cases resulted in wide 95% CIs. In particular, the treatment effect of infliximab was likely underestimated in the shorter-term NMA because of the connection to the network *via* placebo through the EXPRESS trial (14) and Elewski et al. (13), with the latter having a placebo response rate of 0%. This relatively low placebo response in the trial with adalimumab (13) compared with the EXPRESS trial with infliximab (14) was likely because patients entering the adalimumab trial were required to have more severe NP, whereas those entering the infliximab trial could have any degree of NP severity. A sensitivity analysis was run to account for this zero-count event and the computational issues associated with it (28). While this sensitivity analysis did not alter the ranking and performance of the top five biologics, confirming the robustness of the principal analysis, it resulted in the reversal of the order of ustekinumab and infliximab. As a result, the estimated response rate for infliximab aligns closely with what has been reported in the EXPRESS trial (14).

In conclusion, this updated NMA showed that, among biologic treatments included in the analysis, ixekizumab has the highest probability of achieving complete resolution of NP. Results of this study may help to inform treatment decisions for patients with NP.

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Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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