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BRIEF REPORT

Efficacy of new treatments for dactylitis of psoriatic arthritis: update of literature review

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Abstract

Dactylitis is a frequent disabling feature of psoriatic arthritis (PsA). Therapeutic strategy on dactylitis is not really codified. We performed a complementary literature review (since a previous one in 2014) of efficacy of new treatments recently used in PsA on this specific clinical manifestation. Eleven publications were retained (4697 patients). In the randomized double-blind placebo-controlled trials analyzed, authors declared ustekinumab, ixekizumab, adalimumab, and apremilast efficient. Secukinumab, clazakizumab, abatacept, and tofacitinib were promising. Brodalumab was ineffective. Calculations of odds ratios for residual dactylitis were significant for clazakizumab 100 mg and secukinumab in anti-TNF-naïve population. Homogenization of dactylitis assessment and use of this criterion as primary outcome are necessary to have better data on treatment efficacy in the future.

Keywords Dactylitis · Literature review · Psoriatic arthritis · Treatment

Introduction

Dactylitis is a frequent (16–48%) manifestation of psoriatic arthritis (PsA) and is classically the association of distal and proximal interphalangeal arthritis with flexor tenosynovitis. Dactylitis is a marker of the severity of PsA, and its treatment is empirical [1]. Historically, non-steroidal anti-inflammatory drugs (NSAIDs) and conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) have been used to treat this peripheral manifestation of PsA with limited efficacy [2]. Biological treatments appear to be more effective than csDMARDs [3] for dactylitis, which justified their early use for this disorder [1]. In 2014, Rose et al. [4] published a systematic literature review on the efficacy of all available treatments for dactylitis at that time, notably csDMARDs and biological drugs. Due to the recent arrival of new drugs to treat PsA [5], we decided to update the literature with new data for the specific management of dactylitis.

Methods

We performed a literature review of the clinical trials listed in PubMed from June 2014 (the date of acceptance of the latest paper in Rose's review) to October 2017 using the search terms "psoriatic arthritis" and "treatment." A total of 89 English language publications were identified. We only selected randomized, double-blind, placebo-controlled trials in which the dactylitis analysis was available. Finally, 11 papers were selected for full review [6–16] (Fig. 1). Two reviewers (XG and MS) independently extracted the data regarding study design, duration, population, therapeutic agents, outcome data, *p* value, and effect size when available. Our research and calculations were based only on data that were available in the publications (and in the supplementary appendix), and as such, consultation from an ethics advisory board was not required. Statistical analyses were performed using GraphPad Prism 5 software.

Results

We found 11 trials [6–16], which compared the efficacy of new drugs versus placebo for the treatment of PsA dactylitis (Table 1). All studies were multicenter, randomized controlled trials (RCT) with crossover designs at 12–24 weeks, with or

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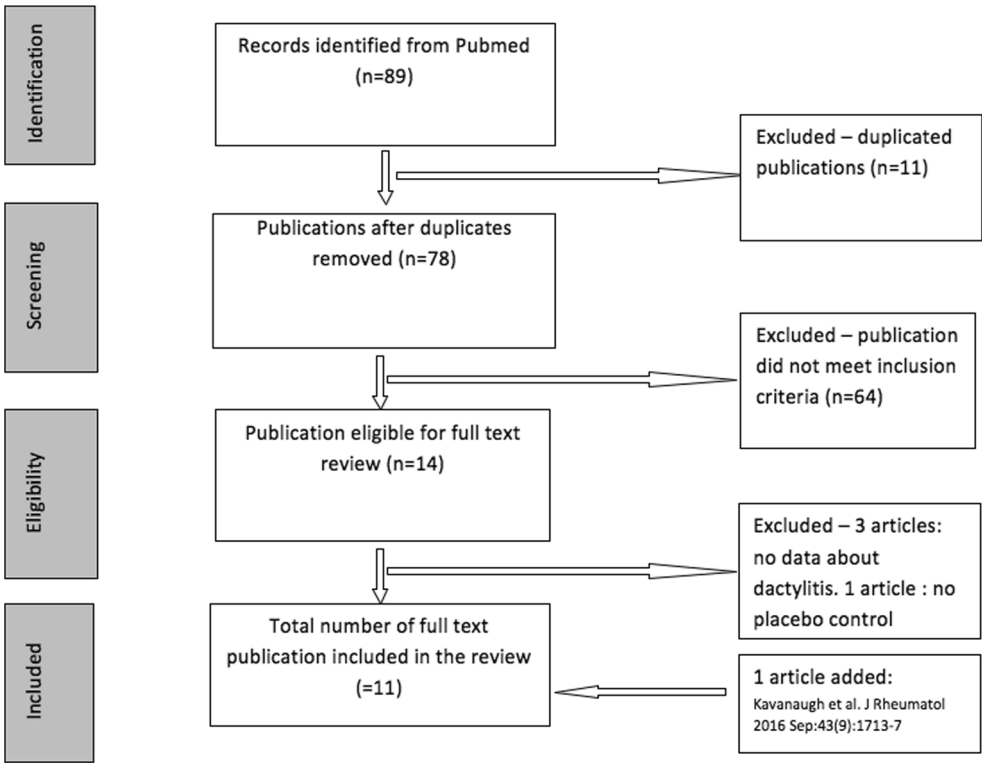


Fig. 1 Flow chart

without open-label extension. In total, 4697 adult patients with PsA were included. The range of treatments studied was heterogeneous, with biological treatments (adalimumab, golimumab, ustekinumab, clazakizumab, ixekizumab, brodalumab, and secukinumab), a selective T cell co-stimulation modulator (abatacept), an oral phosphodiesterase 4 inhibitor (apremilast), and an oral Janus kinase (JAK) inhibitor (tofacitinib). Treatment efficacy was evaluated at 24 weeks for all drugs except for brodalumab (a human monoclonal antibody against interleukin-17A receptor) and tofacitinib, which were evaluated at 12 weeks.

Dactylitis was always studied as a secondary outcome criterion. The assessments were heterogeneous. Assessments in the studies utilized the percentage of patients with dactylitis of the hands and feet, the Leeds Dactylitis Index (LDI) score and its simplified version (LDI basic) [17], as well as a dactylitis score 0–20 (swelling of the whole digit, with assessment of the number of all 20 digits that are affected) or 0–60 (0 = no dactylitis; 3 = severe dactylitis for each digit). Residual dactylitis was defined as the number of patients with the presence of one or more digits with dactylitis at the end of the study compared to the start of the study. There were no imaging evaluations.

A significant improvement in dactylitis ($p < 0.05$) compared to placebo was observed with the use of golimumab in GO-VIBRANT [6], ustekinumab in the PSUMMIT-1/PSUMMIT-2 trial [7], with apremilast (30 mg only) in PALACE 3 [8], and with ixekizumab and adalimumab in SPIRIT-P1 (post hoc analysis) [9].

However, the results were different for secukinumab. McInnes et al. (FUTURE 2) [10] found no significant efficacy with dactylitis resolution at 24 weeks in 47% of cases treated with secukinumab vs 11% for the placebo ($p = 0.9195$). In contrast, Kavanaugh et al. (FUTURE 2) [11] demonstrated the efficacy of secukinumab in anti-TNF-naïve (300 mg and 150 mg dosages) and anti-TNF-exposed patients (only 300 mg).

For the authors [12], treatment with clazakizumab (monoclonal antibody with high affinity and specificity for the interleukin-6 (IL-6) cytokine) resulted in a decrease in the mean incidence of dactylitis from baseline to weeks 16 and 24, but no statistical data are available in the report.

Similarly, recent publications have reported promising results for tofacitinib (JAK inhibitor) and abatacept, but no statistical data are available [13–15].

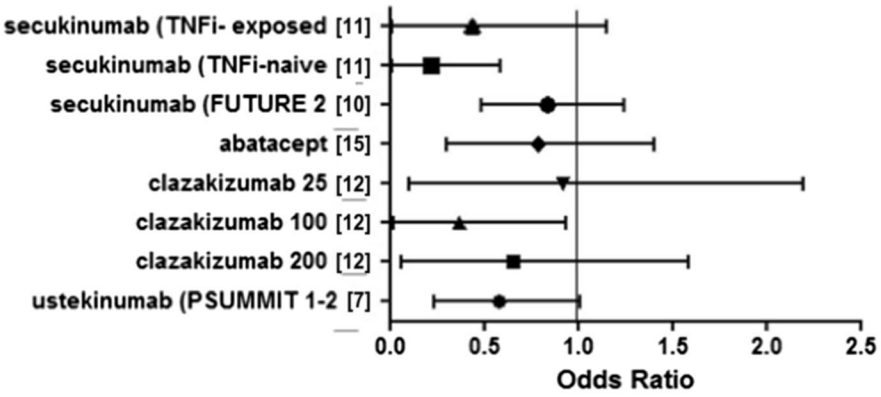
In contrast, no significant efficacy was demonstrated for brodalumab in a randomized controlled trial (RCT) [16].

Data on the effect size were only available in one study using secukinumab (FUTURE 2) [10], with resolution of 47% of dactylitis cases in the secukinumab-treated group (pooled data) vs 15% in the placebo group with an odds ratio (OR) of 4.35 [1.39–14.29] ($p = 0.9$). Calculation of the OR of residual dactylitis was possible in some of the studies with significant results for clazakizumab (100 mg dosing) [12] and secukinumab in an anti-TNF-naïve population [11] (Fig. 2), with ORs of 0.14 (0.02–0.93) and 0.07 (0.01–0.58), respectively. The OR was not statistically significant for

Table 1 Data of studies with evaluation of treatment efficacy on dactylitis

Article	Study population	Study type	Study size	Study medication	Outcome variable	Outcome data	Study duration	*p*	Effect size
Kavanaugh (GO-VIBRANT) [6]	Multicenter	DB-RPC	$n = 480$	GOL intravenous 2 mg/kg vs Pbo	Dactylitis score	Mean variation ± SD of dactylitis score: − 8.2 ± 8.9 GOL; − 5.0 ± 8.1 Pbo	24 weeks	< 0.001	N/A
Kavanaugh (PSUMMIT-1/PSUMMIT-2) [7]	Multicenter	DB-RPC, crossover at 24 weeks	$n = 927$	UST vs Pbo	% patients with dactylitis and dactylitis score (1–60)	% of dactylitis resolution: 24.4% Pbo vs 48.2% UST Mean variation ± SD of dactylitis score: 57.5 (62.84) % UST vs 11 (77.67) % Pbo	24 weeks	$p = 0.010$ for % of dactylitis resolution; $p < 0.001$ for dactylitis score variation	N/A
McInnes (FUTURE 2) [10]	Multicenter ($n = 76$)	DB-RPC, crossover at weeks 16 and 24	$n = 397$	SEC vs Pbo	% with dactylitis of hands/ft	% dactylitis improvement: 47% SEC (combined 75/150/300 mg) vs 15% Pbo.	24 weeks	0.9195	4.35
Edwards (PALACE 3) [8]	Multicenter	DB-RPC, crossover at 24 weeks	$n = 505$	APR 20 mg twice daily vs APR 30 mg twice daily vs Pbo	% with dactylitis of hands/ft	Mean variation of dactylitis score: APR 30 mg −2.4; APR 20 mg − 1.6; Pbo − 1.4	24 weeks	APR 30 mg: $p = 0.0399$; APR 20 mg: $p > 0.05$	N/A
Kavanaugh (FUTURE 2) [11]	Multicenter ($n = 76$)	DB-RPC, crossover at weeks 16 and 24	$n = 397$	SEC vs Pbo	% with dactylitis of hands/ft	Change at 24 weeks: % of dactylitis résolution: TNF-naive: 54.8% SEC 300 mg; 57.1% SEC 150 mg; 17.6% Pbo. TNF-exposed: 60.0% SEC 300 mg, 36.4% SEC 150 mg, 10% Pbo	24 and 52 weeks	< 0.05 for SEC 300 mg-150 mg TNF-naïve and SEC 300 mg TNF exposed	N/A
Mease [16]	Multicenter ($n = 29$) in USA and Canada	DB-RPC to 12 weeks, open-label 12–52 weeks	$n = 168$	BRO vs Pbo	Dactylitis score	Mean variation of dactylitis score: Pbo − 0.5, BRO 140 mg − 1.4, BRO 280 mg − 2.0	12 weeks	> 0.05	N/A
Mease [12]	Multicenter ($n = 44$) in 13 countries	DB-RPC to 24 weeks, then open-label long term-extension	$n = 165$	CLA ± MTX vs Pbo ± MTX	% with dactylitis of hands/ft	% patients with resolution of dactylitis: Pbo 38.5%; CLA 25 mg 66.7%; 81.8% CLA 100 mg; 57.1% CLA 200 mg	24 weeks	N/A	N/A
Mease (SPIRIT-P1) [9]	Multicenter in 15 countries	DB-RPC	$n = 417$	IXE vs Pbo vs ADA	% with dactylitis of hands/ft, LDI-B	Change at 24 weeks: % of complete resolution of dactylitis symptoms: 25% Pbo, 79.5% IXE 80 mg/4 weeks, 79.6% IXE 80 mg/2 weeks, 77.8% ADA 40 mg/2 weeks Mean variation ± SD of LDI-B from baseline a 24 weeks: Pbo − 33.7(9.7); IXE 80 mg/2 weeks − 66.1 (9.8); IXE 80 mg/4 weeks − 75.4 (8.1); ADA 40 mg/2 weeks − 76.0 (10.9)	12 and 24 weeks	< 0.001 for resolution of dactylitis; < 0.01 and < 0.001 for mean variation of LDI-B	N/A
Mease [14]	Multicenter in 126 countries	DB-RPC	$n = 422$	TOF vs Pbo vs ADA	Dactylitis severity score	Mean variation ± SD of dactylitis score: TOF 5 mg − 3.5 (1.0); TOF 10 mg − 5.5(0.9); ADA −4.0 (1.0); Pbo −2.0 (1.1)	12 weeks	N/A	N/A
Gladman (OPAL Beyond) [13]	Multicenter in 98 countries	DB-RPC	$n = 395$	TOF vs Pbo	Dactylitis severity score	Mean variation ± SD of dactylitis score: Pbo – 1.9(0.8); TOF 5 mg − 5.2(0.7); TOF 10 mg − 5.4(0.8)	12 weeks	N/A	N/A
Mease [15]	Multicenter in 76 centers worldwide	DB-RPC	$n = 424$	ABA vs Pbo	% of patients with dactylitis	% of patients with dactylitis resolution (95% CI): ABA 44.3% (31.8 to 56.7) vs Pbo 34.0% (20.9 to 47.1)	24 weeks	N/A	N/A

DB-RPC double-blinded, randomized, placebo-controlled trial; *N/A* not applicable; *GOL* golimumab; *ADA* adalimumab; *Pbo* placebo; *IXE* ixekizumab; *CLA* clazakizumab; *MTX* methotrexate; *LDI-B* Leeds Dactylitis Index-Basic; *BRO* brodalumab; *DS* standard deviation; *SEC* secukinumab; *TOF* tofacitinib; *ABA* abatacept



Treatment	Ustekinumab (PSUMMIT 1-2, Kavanaugh ARD 2016) [7]	Clazakinumab 200 (Mease A&R 2016) [12]	Clazakinumab 100 (Mease A&R 2016) [12]	Clazakinumab 25 (Mease A&R 2016) [12]	Abatacept (Mease ARD 2016) [15]	Secukinumab (FUTURE2, Mc Innes, Lancet 2015) [10]	Secukinumab (anti TNF naïve) (FUTURE 2, Kavanaugh JOR 2016)[11]	Secukinumab (anti TNF-exposed) (FUTURE 2, Kavanaugh JOR 2016)[11]
Lower range	0.23	0.06	0.02	0.10	0.30	0.48	0.01	0.01
Mean	0.48	0.31	0.14	0.47	0.65	0.77	0.07	0.13
Upper range	1.01	1.58	0.93	2.19	1.40	1.24	0.58	1.15

Fig. 2 Odds ratios for residual dactylitis in treatment/placebo groups

ustekinumab, clazakizumab (25 and 200 mg), abatacept, or secukinumab in anti-TNF-exposed patients.

Discussion

Our review, with heterogeneous results, confirmed that it is difficult to evaluate the therapeutic response for dactylitis in PsA patients. We found confirmation for the efficacy of golimumab (in an intravenous form), ustekinumab, and ixekizumab for treating PsA-related dactylitis. A new study on apremilast (PALACE 3) demonstrated efficacy for dactylitis, in contrast with a previous study [18]. These promising results for this new small molecule indicate a potential place for it in the therapeutic strategy for PsA. Contrary to previous data, adalimumab was effective for treating dactylitis in the SPIRIT-P1 study [9]. Secukinumab, clazakizumab, abatacept, and tofacitinib are potential candidates, but further studies are required to confirm their efficacy. In our study, the ORs were significant only for clazakizumab (100 mg dosing) and secukinumab in anti-TNF-naïve patients. The OR for secukinumab in FUTURE 2 [10] should be interpreted cautiously because of the use of a sequential hierarchical testing method, which could introduce bias into the study.

There are currently no data on the efficacy of baricitinib for dactylitis in patients with PsA, and brodalumab may be ineffective for this specific clinical manifestation.

Surprisingly, we did not find any evaluation of the treatment efficacy for dactylitis in peripheral spondyloarthritis compared to PsA. Indeed, these two conditions are very similar, so patients are sometimes gathered into the same group. In PSUMMIT-1/PSUMMIT-2 [7], patients had spondylitis associated with their PsA, and we are unaware of their human leukocyte antigen typing or their sacroiliac imaging, so we may suppose that patients could be classified equally as mixed spondyloarthritis (axial and peripheral) and PsA. Carron et al. (in the CRESPA study) [19] demonstrated the efficacy of golimumab for dactylitis in early peripheral spondyloarthritis at 12 and 24 weeks compared to the placebo. The most frequent extra-articular manifestation in this group of patients was skin and/or nail psoriasis (41.6%); this raised the question of coexisting real PsA. Another study [20] demonstrated a lack of efficacy for adalimumab on dactylitis at 12 weeks in patients with non-psoriatic peripheral spondyloarthritis. Studies evaluating treatment efficacy on dactylitis in this population should be conducted.

This update of the literature, in line with the previous review of Rose et al. [4], was warranted due to new drugs for

treating PsA and a lack of evidence for the efficacy of most treatments on dactylitis. Rose et al. highlighted the efficacy of ustekinumab and certolizumab, as well as the promising potential of infliximab and golimumab [4]. The efficacy of NSAIDs, local corticosteroid injections, csDMARDs, etanercept, adalimumab, anakinra, and new small molecules was uncertain or absent. In a recent study, Coates et al. [21] demonstrated the efficacy of methotrexate after 12 weeks with significant improvement in LDI basic scores ($p = 0.0033$) and complete dactylitis resolution in 63% of patients with PsA. This study was not included in our literature review due to the absence of a placebo control group.

As suggested by Rose et al., clinical evaluation of dactylitis should be standardized, and LDI is not used systematically in different studies despite its validation [22]. The heterogeneous evaluation of dactylitis induced limitations in interpreting literature results, as well as their use as secondary outcome criteria only. Conclusions regarding the treatment efficacy of dactylitis in PsA should be cautious.

Sequential high-field conventional MRI showed good efficacy in detecting an early response to biologic therapy; however, it is not applicable in current practice [23]. Another study showed that the relationship between clinical and MRI scores is not strong, highlighting the limits of clinical evaluation. Musculoskeletal ultrasonography is of course a good imaging tool to diagnose and evaluate the therapeutic response [24] but was unfortunately not used in the studies.

Dactylitis is currently recommended in individualized therapy as a target only by the GRAPPA (Group for Research and Assessment of Psoriasis and Psoriatic Arthritis) [25]. TNF inhibitors (with the exception of etanercept) are recommended as first-line therapy. Several options are also available: corticosteroid injections, csDMARDs, etanercept, IL-12/23 inhibitor, IL-17 inhibitor, and PDE-4 inhibitor. Dactylitis management warrants further standardization. This invalidating clinical manifestation should be evaluated as a primary outcome and may be part of the research agenda in PsA treatments.

Compliance with ethical standards

Disclosures None.

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