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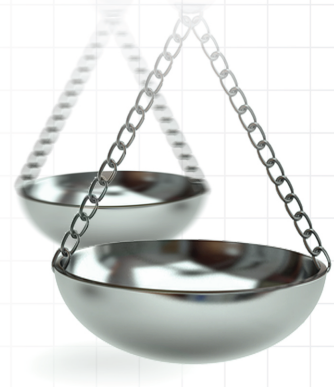

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Outcome domains and measures for pain in psoriasis used in registered trials: analysis of studies on ClinicalTrials.gov

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Aim: Psoriasis includes unpleasant symptoms such as pain. This study aimed to investigate whether clinical trials have domains related to pain in their study designs. **Materials and methods:** We analyzed all clinical trials about interventions for psoriasis treatment registered on ClinicalTrials.gov and the frequency of pain-related outcomes. **Results:** Our analysis included 1033 registered clinical trials. They had 1329 primary outcomes and 5457 secondary outcomes. The pain was used in six (0.6%) protocols as a primary outcome and 68 (6.5%) protocols as a secondary outcome. **Conclusion:** Pain as an outcome was used in few registered clinical trial protocols for the treatment of psoriatic conditions. Future studies should investigate why the trialists do not include pain among primary or secondary outcomes.

Lay abstract: Psoriasis is a chronic skin disease that presents with various symptoms, including pain. Our study aimed to investigate whether the pain is measured in planned clinical studies of patients with psoriasis and how. We analyzed publicly registered protocols of clinical studies and extracted data about the number and type of outcomes (measures of results) that the protocol authors planned to use. Our analysis included 1033 protocols. The pain was found in six (0.6%) protocols as the main outcome and 68 (6.5%) protocols as a secondary outcome. In conclusion, few authors of clinical studies included pain among results they plan to measure in patients with psoriasis. Future studies should investigate why is pain not measured more often in such clinical studies.

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Keywords: outcomes research • pain • psoriasis

Psoriasis is a common polygenic, inflammatory skin disease triggered by different environmental factors in suitable individuals with a prevalence of 2% of the population [1]. It is known today that psoriasis is not only a skin disease but a systemic disease that affects many systems, among which there is a gradual high incidence of psoriatic arthritis in even 20–30% of these patients [2]. Psoriatic lesions mainly occur in the area of the scalp, extremities and sacral regions, but we should also keep in mind their less frequent occurrence in other places which, due to their specificity, may have a strong influence on individuals (e.g., breast, intertriginous regions and face) [3,4]. Psoriasis is commonly associated with other comorbidities such as psoriatic arthritis, obesity and chronic infections. The choice of appropriate biologic therapy for a patient is very often determined by the presence of comorbidities [5,6].

These days it is very well known that this disease has unavoidably important effect on the quality of life (QoL) of affected patients [2], comparable with that of other important chronic medical conditions, with an expression of skin pain and skin discomfort among reported physical skin symptoms [7,8] in almost half of these patients [9]. Given the fact that many patients with psoriasis suffer from other systemic diseases, including psoriatic arthritis, it is not surprising that many patients with psoriasis, besides pain in the skin area, also emphasize the occurrence of pain in other areas of the body, especially in the musculoskeletal system [10]. Pain that occurs in patients with psoriasis leads to a distortion of their QoL, including different aspects of basic life needs [11,12], to functioning in business life [13] and everyday interpersonal relationships [11,12].

Future Medicine

Callis Duffin *et al.* have recently proposed a core domain set to assess psoriasis in clinical trials, with the aim to achieve international consensus about the core set of outcome domains that should be measured in all psoriasis clinical trials [14]. The proposed core domain set includes six domains: skin manifestations, psoriasis and psoriatic arthritis symptoms, health-related QoL, investigator global assessment, patient global assessment and treatment satisfaction [14]. The investigators behind this study concluded that the next step should be to focus on the development of a core outcome measurement set for psoriasis trials [14]. The pain was not explicitly mentioned among the domains proposed by Callis Duffin *et al.* [14].

In this study, we aimed to investigate whether trialists planning clinical trials include outcome domains related to pain in their study designs. We analyzed all clinical trials about interventions for the treatment of psoriasis registered on ClinicalTrials.gov and analyzed the frequency of pain-related outcome domains and outcome measures used in those trial protocols.

Materials & methods

Study design

This was a primary methodological study, in other words, research-on-research study that included analysis of protocols of publicly available registered trials.

Ethics

In this study, we did not include any humans and; therefore, approval of a research ethics committee was not necessary.

Inclusion criteria

We included protocols of randomized clinical trials registered on ClinicalTrials.gov about interventions for the treatment of psoriasis. All types of psoriasis were eligible. We excluded nonrandomized study designs. The study design was determined by analyzing the field 'study design' and 'study type' in ClinicalTrials.gov protocols.

Search strategy

We searched ClinicalTrials.gov on the date 4 May 2019, using the search phrase 'psoriasis or psoriatic' in the field 'condition or disease' on the web site of ClinicalTrials.gov. We did not use any restrictions.

Screening

One author (Ana Sanader Vucemilovic) screened all results to confirm their eligibility for inclusion and another author (Livia Puljak) checked all screening results of the first author.

Data extraction

One author (Livia Puljak) extracted all results available for export by using the download option of ClinicalTrials.gov. The following information had to be extracted manually: which outcomes were primary and which were secondary. One author (Ana Sanader Vucemilovic) conducted manual extraction and another author (Livia Puljak) verified all manual extractions.

We analyzed the following data: unique number of the trial registration (National Clinical trial [NCT] number); type of psoriasis (condition); category of intervention (pharmacological, nonpharmacological, a combination of both pharmacological and nonpharmacological); date of the initial protocol registration; pain-related outcome domains and outcome measures; whether pain-related outcome domains and measures were analyzed as primary or secondary outcomes; all other outcome domains and outcome measures; type of funding (commercial or noncommercial). Extracted data were analyzed and categorized by Ana Sanader Vucemilovic and Livia Puljak.

We analyzed the frequency of use of pain-related outcome domains and outcome measures and the number and type of other outcome domains and outcome measured used. When trials used the same outcome/outcome measure multiple times for different time points, in our analysis of the frequency of individual outcomes/outcome measures, we counted it only once for that particular study and not multiple times for different periods.

Data synthesis

We performed descriptive data analysis and presented data as frequencies and percentages. We conducted analyses using MedCalc statistical software, v 15.2.1 (© MedCalc Software bvba, Ostend, Belgium). Statistical significance was set at $p < 0.05$.

Results

Among the 1493 clinical trial registrations that were retrieved via the search of ClinicalTrials.gov, we excluded 292 observational trials and 168 trials with conditions other than psoriasis or combinations of indications that were not eligible. Finally, we included 1033 clinical trial registrations into our analysis.

Among those 1033 registered trials about the psoriatic disease, the most commonly included indications, as reported by trialists, were: psoriasis (n = 442; 43%), plaque psoriasis (n = 123; 12%), psoriasis vulgaris (n = 87; 8.4%), psoriatic arthritis (n = 96; 9.3%) and chronic plaque psoriasis (n = 29; 2.8%).

Primary & secondary outcomes in analyzed trials

The 1033 trial protocols had 6786 listed outcomes, including 1329 primary outcomes and 5457 secondary outcomes. Among primary outcomes, the most commonly used outcomes and outcome measures were those related to pharmacokinetics and pharmacodynamics, Psoriasis Area Severity Index, Physician's Global Assessment, adverse events (AE) and Dermatology Life Quality Index (Table 1).

Pain as a primary outcome

Pain as a stand-alone primary outcome was used in few studies; only six protocols out of 1033 (0.6%) used pain as a primary outcome. Nine (0.9%) protocols measured pain as an AE associated with the administration of intervention. Among six trial protocols that analyzed pain as a stand-alone primary outcome, only one protocol included patients with psoriasis (NCT02168244), one described eligible patients as having psoriasis and joint pain (NCT02047851), while the remaining four included patients with psoriatic arthritis (NCT02047851, NCT02436785, NCT01463189 and NCT03008590). Reported outcome measures for pain used in those six protocols were VAS in three protocols (NCT02168244, NCT03693833 and NCT02047851), numeric pain rating in one (NCT02436785), Brief Pain Inventory (BPI) in one (NCT03008590) and BPI short form (BPI SF) in one protocol (NCT01463189).

Among primary outcomes, thirty trial protocols used composite outcomes for which it was explicitly mentioned that pain intensity was part of the tool/assessment; these tools/outcomes used American College of Rheumatology (ACR) criteria (n = 25), minimal disease activity (n = 2), psoriatic arthritis response criteria (n = 1) and two tools for measuring the QoL – SF-36 (n = 1) and EQ-5D (n = 1). One protocol reported that they will analyze pain catastrophizing scale and pain awareness scale as a part of a primary outcome called 'change in cognitions'.

Pain as a secondary outcome

In 68 (6.5%) out of 1033 protocols, the pain was used as a secondary outcome; several of those protocols use more than one pain outcome measure and thus 74 outcome measures were used in those 67 protocols. The pain was measured with VAS in 49 (4.7%%) protocols and with NRS in nine (0.9%) protocols. Among the 58 protocols that measured pain with VAS or NRS, 31 (53%) specified what is exactly measured, in other words, joint pain, skin pain from psoriasis and nail pain).

The remaining outcome measures were used in one or two protocols. Most protocols with pain as a secondary outcome included patients with plaque psoriasis (n = 21/67; 31%), psoriatic arthritis (n = 19/67; 28%) and psoriasis (n = 9/67; 13%).

One protocol used two composite outcome measures for pain, BPI and painDETECT; this protocol included patients with chronic pain due to osteoarthritis, rheumatoid arthritis or psoriatic arthritis.

In 290 (28%) protocols, pain was used only as a part of a composite outcome measure; the most common among those outcome measures were SF-36 (n = 72/290; 25%), Maastricht Ankylosing Spondylitis Enthesitis Score (n = 35/290; 12%), ACR70 (n = 28/290; 9.6%), ACR20 (n = 25/290; 8.6%), EQ-5D (n = 20/290; 6.8%) and ACR50 (n = 18/290; 6.2%). The remaining outcome measures were used in less than ten protocols.

In ten protocols, the pain was used as the secondary AE (i.e., injection site pain or symptoms causing severe discomfort or pain).

Discussion

Our main finding is that only 7.2% of the analyzed registered clinical trial protocols about psoriatic conditions used pain as either a primary or secondary outcome. Considering that psoriatic conditions can cause substantial pain, this finding requires further consideration regarding outcomes that matter to patients.

Table 1. The most common outcomes and outcome measures used in analyzed clinical trial protocols about psoriatic disorders (total n of analyzed protocols = 1033).

Outcome or outcome measure	n (%)
PK-PD	327 (32)
PASI	314 (30)
PGA	262 (25)
AE	261 (25)
DLQI	227 (22)
PASI 75	197 (19)
SF-36	182 (18)
IGA	173 (17)
BSA	156 (15)
sPGA	130 (13)
PASI 50	120 (12)
PASI 90	104 (10)
PGA	82 (7.9)
ACR20	80 (7.7)
NAPSI	65 (6.3)
Hematological	54 (5.2)
PASI 100	52 (5.0)
HAQ-DI	52 (5.0)
VAS	52 (5.0)
EQ-5D	50 (4.8)
PASI change from baseline	47 (4.5)
ACR 70	47 (4.5)
DAS28	43 (4.2)
MASES	39 (3.7)
DSS	37 (3.6)
Safety and tolerability	37 (3.6)
Hematologic	36 (3.5)
NRS	36 (3.5)
AUC	36 (3.5)
PSSQ	36 (3.5)
PsARC	31 (3.0)
VAS	29 (2.8)
PSSI	29 (2.8)
FACIT-F	28 (2.7)
AE/SAE	27 (2.7)
PASI 50/75/90/100	25 (2.4)
TCS	25 (2.4)
GPP	23 (2.2)
ACR50	23 (2.2)
TSS	23 (2.2)
Erythema, induration, scaling	22 (2.1)
Relapse	22 (2.1)
PSI	22 (2.1)
LEI	21 (2.0)

ACR20: American College of Rheumatology 20; ACR50: American College of Rheumatology 50; ACR 70: American College of Rheumatology 70; AE: Adverse event; AE/SAE: Adverse event/serious adverse event; AUC: Area under the curve; BSA: Body surface area; DAS28: Disease activity score 28; DLQI: Dermatology life quality index; DSS: Dactylitis severity score; EQ-5D: EuroQol- 5 dimension; FACIT-F: Functional assessment of chronic illness therapy-fatigue; GPP: Generalized pustular psoriasis; HAQ-DI: Health assessment questionnaire disability index; IGA: Investigator's global assessment; LEI: Leeds enthesitis index; MASES: Maastricht ankylosing spondylitis enthesitis score; NAPSI: Nail psoriasis severity index; NRS: Numeric rating scale; PASI: Psoriasis area and severity index; PASI 50: Psoriasis area and severity index 50; PASI 75: Psoriasis area and severity index 75; PASI 90: Psoriasis area and severity index 90; PASI 100: Psoriasis area and severity index 100; PGA: Physician's global assessment; PK-PD: Pharmacokinetics/pharmacodynamics; PsARC: Psoriatic arthritis response criteria; PSI: Psoriasis severity index; PSSI: Psoriasis scalp severity index; PSSQ: Patient psoriasis satisfaction questionnaire; SF-36: 36-item short form survey; sPGA: Static physicians global assessment; TCS: Total clinical score; TSS: Total symptom score; VAS: Visual analogue scale.

Pain can be assessed as a part of the composite patient-reported outcomes that analyze the QoL, or psoriasis-specific outcomes, but it is unclear whether the assessment of pain within those tools will be reported separately to highlight patients' pain in the subsequent research reports. Furthermore, some of those tools lack psoriasis specificity, which is limiting fine assessments such as differentiating between symptoms such as pain and pruritus [15].

The most frequent outcome measures used in the analyzed protocols were Psoriasis Area Severity Index and Physician Global Assessment. However, pain and pruritus, symptoms that can be highly debilitating for patients affected with psoriatic conditions, may fail to be addressed if assessments made by physicians rely solely on those outcome measures [15]. This can be explained by research findings that show discrepancies between what patients and physicians consider as burdensome symptoms.

Lebwohl *et al.* surveyed 1005 patients, 101 dermatologists and 100 rheumatologists in 2012 and reported discrepancies between symptom burden perceived by patients and physicians. For example, more than half of patients diagnosed with psoriasis alone reported suffering from joint pain. On the contrary, less than 20% of dermatologists reported that their psoriasis patients suffered from joint pain [16].

This potential disregard for the pain in psoriasis patients can also have clinical consequences in daily practice, as assessing pain in patients with psoriasis can help diagnose psoriatic arthritis. Lebwohl *et al.* have shown that most dermatologists and rheumatologists surveyed agreed that psoriatic arthritis might go undiagnosed because skin and joint symptoms were not concomitantly considered; less than 60% of dermatologists indicated that they discussed the risk of psoriatic arthritis with all of their psoriasis patients [16].

Few studies have systematically analyzed the use of outcomes in psoriatic conditions. Busard *et al.* extensively searched the literature published up to 2015, to analyze outcomes used in randomized controlled trials on nail psoriasis; they found that only 8% of analyzed trials analyzed pain and discomfort, using VAS or NRS [17]. The authors concluded that these findings are striking, as nail psoriasis lesions can be painful and impair the use of the hands [17]; this is particularly relevant because such symptoms can seriously impact patients' emotional, social or working life [18].

Furthermore, other studies have shown that pain negatively impacts sleep quality in patients with psoriatic arthritis [19] and psoriasis [20], thus leading to impaired QoL, which brings us to the importance of adequately evaluating and treating pain in psoriatic patients.

There are validated instruments for measuring the QoL, including pain, in patients with scalp and nail psoriasis [21,22], but no such instrument has yet been confirmed for genital psoriasis [23]. The finding that 20% of genital psoriasis patients were most burdened by pain [23] further highlights the extreme importance of proper evaluation of pain among other parameters for measuring the impact on the QoL of these patients. Even though currently there are no systematic reviews about the burden of pain in psoriasis patients [24], multiple individual primary studies indicate that pain is the neglected symptom in psoriasis patients.

The pain was not among the core domain set proposed for assessing psoriasis in clinical trials in 2018 [14], but the report about the development of that core domain set was not sufficiently transparent and may not have been methodologically conducted in a way that would allow identification of outcomes that are important to patients.

Callis Duffin *et al.* have reported that their development of the core domain set for psoriasis trials started with a 'literature review', but it was not reported how that literature review was conducted, whether the search was systematic and which outcomes were considered in the process [14]. Thus, it is unknown whether pain was considered and how it was scored in this process of creating recommendations. Furthermore, the involvement of physicians and patients in this development was highly disproportionate, with patients involved in the Delphi rounds making less than 15% of the participants. Also, the patients were not ethnically diverse [14].

Our study offers suggestions for future trials. In our study, most of the protocols that used pain as a primary or secondary outcome used VAS as an outcome measure. The Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) has recommended that NRS should be used for assessing chronic pain, as NRS tend to be preferred over VAS by patients. Furthermore, VAS measures usually are associated with higher amounts of missing and incomplete data than NRS measures, presumably because NRS measures are less abstract and easier to understand [25]. This is also something that should be considered in further trials assessing pain.

Furthermore, only about half of the trial protocols in our sample that have measured pain with VAS or NRS have specified what is exactly measured, in other words, joint pain, skin pain from psoriasis and nail pain. Thus, this should be specified in future trials.

Conclusion

In conclusion, pain as an outcome was used in few registered clinical trial protocols for the treatment of psoriatic conditions. Given the perceived importance of pain in patients with psoriatic disorders, we believe that it is imperative in future research that pain is one of the factors investigated as part of important and extremely aggravating symptoms in patients with psoriasis.

Future studies should investigate why the trialists do not include pain among their primary or secondary outcomes, improve the choice of pain outcome measures used and specify what is exactly measured with those measures.

Summary points

- Psoriasis is a chronic inflammatory disease known today as one of the most common immune-mediated diseases, affecting about 2% of people worldwide.
- In addition to the affected skin areas, psoriasis also includes other unpleasant symptoms such as pain.
- A recent study reported that skin pain is strongly associated with other concomitant medical conditions.
- Pain present in psoriatic patients was shown to have a major negative effect on a patient's quality of life.
- Given the reports indicating a high prevalence and burden of pain in psoriasis, it is important to pay more attention to this ailment.
- We analyzed the frequency of use of pain-related outcome domains and outcome measures, as well as the number and type of other outcome domains and outcome measures used.
- Pain as an outcome was under-represented, found in only a few registered clinical trial protocols for the treatment of psoriatic conditions.
- Given that it has been observed that psoriatic conditions can cause significant pain to patients, our data warrant future consideration regarding outcomes that are important to patients with psoriasis.

Author contributions

Both authors gave their contributions to the design of the work, the acquisition, analysis and interpretation of data for the work, drafting the work and revising it critically for important intellectual content. Both authors gave their final approval of the version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Financial & competing interests disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

No writing assistance was utilized in the production of this manuscript.

Ethical conduct of research

The proposed study is not conducted with human participants. We only used published data and therefore approval of a research ethics committee is not required.

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