

Study protocol

Association with inflammatory bowel disease in patients with psoriasis and psoriatic arthritis: A systematic review and meta-analysis

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Table of Contents

Table of Contents	2
List of abbreviations	3
Abstract	4
Rationale and Background.....	5
Aim.....	5
Research Methods.....	5
Study design	5
Eligibility criteria	5
Literature search	5
Quality assessment.....	6
Data synthesis.....	6

List of abbreviations

CD	Crohns disease
IBD	Inflammatory Bowel Disease
NOS	Newcastle-Ottawa Scale
OR	Odds ratio
PRISMA	Preferred Reporting Items for Systematic Review and Meta-Analysis
PsA	Psoriatic arthritis
PsO	Psoriasis
UC	Ulcerative colitis

Abstract

Rationale and background: Inflammatory bowel disease (IBD) has been reported to frequently co-occur in patients with manifest psoriasis (PsO) and psoriatic arthritis (PsA), and vice versa. To date, no systematic review and meta-analysis has robustly assessed the prevalence of IBD in among patients with PsO.

Research question and objectives: To determine the association with IBD among patients with PsO and/or PsA.

Study design: Systematic review and meta-analysis.

Data sources and methods: Three databases (Pubmed, Web of Science and Embase) will be systematically searched for studies reporting on the proportion of patients with PsA among PsO patients. Key terms used for search are “psoriasis”, “psoriatic arthritis”, “inflammatory bowel disease”, “crohns”, and “ulcerative colitis”.

Data analysis: A meta-analysis is done, calculating the pooled odds ratio estimates for the association with IBD in PsO and PsA, and vice versa.

Rationale and Background

In light of new psoriasis (PsO) and psoriatic arthritis (PsA) therapies that may either exacerbate, cause, or treat inflammatory bowel disease (IBD), data on the association between these diseases are warranted. Several observational studies have been conducted to investigate this, but no comprehensive review with a meta-analysis has been done estimating the exact prevalence.

Aim

To examine the prevalence of PsA among PsO patients.

Research Methods

Study design

Systematic review and meta-analysis.

Eligibility criteria

Published studies in English language, from any year, are eligible to be included. To be eligible, studies must report the proportion of PsO or PsA patients that have IBD (either unspecified, Crohns disease [CD], or ulcerative colitis [UC]) or vice versa, and may be cohort, case-control or cross-sectional designs, from any healthcare setting, with any length of follow-up. The examination is bidirectional, so the exposure of interest can be either PsO, PsA, or IBD (CD, UC, or unspecified/any) and the outcome is IBD (CD, UC, or unspecified/any), PsO or PsA, respectively. We will exclude case series (including retrospective clinic populations), ecological studies, and reviews.

Literature search

We will search databases Pubmed, Web of Science and Embase from their date of inception through February 2018. Key terms used for search will be “psoriasis”, “psoriatic arthritis”, “inflammatory bowel disease”, “crohns”, and “ulcerative colitis”.

Selection of studies and data extraction

Initially, all titles and abstracts resulting from the literature search will be screened, and duplicates will be removed. Two reviewers (FA and HGT) will independently screen all titles and all abstracts. The full-text articles will be retrieved for studies that fulfill the inclusion criteria, as well as for studies where there is any ambiguity of the potential eligibility. Any disagreement between the two reviewers regarding a potential study inclusion will be resolved through discussion with a third reviewer (AE) if needed. If applicable, authors are contacted to obtain additional information that are missing from the studies. No reviewer-blinding will be performed regarding the journal titles or study authors. The literature selection and the reasons for study exclusion will be documented in a PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) flow diagram. For included studies, the reference lists are reviewed to identify additional studies that may have been missed in the initial search.

Each of the two reviewers will, independently and in duplicate, extract the manuscript data in order to minimize bias and errors. The following data will be sought for each publication:

- 1) study details: author information, publication year, design, country
- 2) population characteristics: for example, mean and median age and sex
- 3) exposure: definition of PsO, PsA, or IBD (CD, UC, or unspecified/any) as an exposure, number of exposed subjects, details of diagnostic method (physician, dermatologist, rheumatologist, gastroenterologist etc.)
- 4) outcomes: definition and identification of PsO, PsA, or IBD (CD, UC, or unspecified/any), number of subjects with the outcome, and details of diagnostic method.

Quality assessment

To allow comparison by study quality, a critical appraisal will be independently performed by the reviewers. The Newcastle-Ottawa Scale (NOS) is used for quality assessment. Full results of this quality assessment will be presented in the final manuscript, and quality assessment will be discussed in the narrative data synthesis.

Data synthesis

We will group studies in the following groups and analyze data accordingly:

- 1) All studies (in the following groups PsO, PsA, IBD, CD, UC)
- 2) Stratified by sex
- 3) Children-only
- 4) Adults-only
- 5) By disease severity
- 6) Stratified by population size ($n < 500$, $500-999$, ≥ 1000)
- 7) Clinical trials
- 8) Register-based (database) studies
- 9) Population based studies
- 10) By geographic area (Africa, Asia, Europe, North America, South America)
- 11) By NOS Score

We will perform a meta-analysis to obtain a pooled effect estimate (pooled odds ratio [OR]). We will assess statistical heterogeneity using the I^2 statistic. The pooled OR and its 95% CI will be calculated using random effects models. If substantial heterogeneity is observed, we will perform sensitivity analyses to explore the reasons for such heterogeneity. Study characteristics and the effect estimates for the association between PsO, PsA and IBD will be presented in full (in tabular form), either in the manuscript or as supplementary materials. We will attempt to assess publication bias by standard approaches including funnel plots and Egger tests. PRISMA guidelines will be used to report the results of this study.