Patient Involvement in Outcome Measures for Psoriatic Arthritis

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Abstract

Psoriatic arthritis (PsA) is a heterogeneous inflammatory arthritis with a varied clinical phenotype. There has been considerable international collaboration over recent years to develop and prioritise appropriate disease domains and outcome measures to capture all aspects of this complex disease. It has been recognised that patient reported measures and physician assessments are complementary and when used together allow an improved reflection of disease burden. Taking this concept one step further the experience in rheumatoid arthritis has demonstrated benefits of incorporating the patient perspective in the development of outcome measures. We report a systematic review demonstrating there has been little incorporation of the patient perspective in the development of outcome measures and domains in PsA, the proceedings from the preliminary patient involvement in outcome measures for PsA (PIOMPSA) meetings and a proposed roadmap for improving patient involvement.

Introduction

Psoriatic arthritis (PsA) is a complex disease with a varied clinical phenotype affecting the skin, joints, nails, entheses and axial skeleton. Historically disease outcome has been measured with tools adapted from related inflammatory diseases such as rheumatoid arthritis (RA) and axial spondyloarthritis.[1] It became apparent that such borrowed instruments did not capture all aspects of this multifaceted disease and considerable progress has been made in the development of disease domains and composite measures for PsA in recent years. The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) in collaboration with Outcome Measures in Rheumatology (OMERACT) have been actively involved with this process, defining appropriate domains of assessment and tools to measure them.[2, 3]

An obvious way of capturing all components of PsA has been an expansion in the use of patient reported outcome (PRO) measures assessing health related quality of life, physical function, work, pain, fatigue and global health.[1, 4] The use of PRO's arose from the realisation that the patient perspective brings a unique insight into the measurement of disease activity that was previously not captured by traditional, physician-centric outcome measures such as clinical examination and biomarkers. Moreover incorporating PRO's has the potential of reducing the impact of the known discordance in disease assessment between physician and patient, as demonstrated in RA[5, 6] and PsA[7]. There is consensus that both PRO's and physician assessed measures

are required to effectively capture all aspects of disease and that this combined approach results in a truer reflection of disease and thus both are incorporated in the OMERACT core set for PsA.[8]

In recent years we have seen the PRO's concept extended to the incorporation of the patient perspective in the OMERACT process.[9] Patients have brought a new perspective to how domains of disease should be prioritised and measured, thus enhancing the 'truth' aspect of the OMERACT filter.[10, 11] The European League Against Rheumatism (EULAR) has also recognised this issue and recommends the inclusion of the patient perspective in scientific projects.[12, 13] Furthermore the National Institute of Health Research (NIHR) in the United Kingdom has convened the INVOLVE group to promote patient involvement in all aspects of the NHS including research. Despite the growing recognition of the benefits of incorporating the patient perspective it has recently become apparent that there has been little patient involvement in the development of PsA domains and outcome measures. We report a systematic review of patient involvement in the development of outcome measures and domains in PsA, the proceedings from the preliminary GRAPPA special interest group for Patient Involvement in Outcome Measures for PsA (PIOMPSA) meetings and a proposed action plan for improving patient involvement.

Systematic review of patient involvement in PsA

We set out to establish the degree of patient involvement during the development of the original domain construct, outcome measure and disease activity indices used in psoriatic arthritis.

Methods

A literature search was performed of Medline and Embase (1970- present) and the Cochrane database on January 3rd 2013. Publications were identified using the following keyword or MeSH terms: “psoriatic arthritis” in combination with (AND) “Domain” OR “Outcome” OR “Assessment” OR “Validation” (AND) “Composite measure”, “physical function”, “skin activity”, “patient global”, “pain”, “health related quality of life”, “peripheral joint activity”, “enthesitis”, “dactylitis”, “fatigue”, “nails”, “physician global”, “spinal”, “participation” as listed in the OMERACT core set for PsA. Radiology, MRI, USS, CT, tissue analysis and acute phase reactants were not included in the search. The following limitations were applied; “Humans”, “English Language”, “published 1970 to present”.

Inclusion criteria: Any study developing an outcome measure or core set of outcome measures for use in PsA. *Exclusion criteria:* Review articles, conference abstracts, articles not reporting data specific to PsA, articles not reporting any clinical outcomes (such as genetic, radiographic or laboratory measures), articles not developing an outcome measure for use in PsA. *Data extraction;* Abstracts were screened for the presence of exclusion criteria and the remaining articles were subject to full text review. A ‘pearl growing’

approach was then employed. For each outcome measure found the first article validating or using an outcome measure in PsA was selected along with any citing articles (citation tracking) and their references (reference tracking). This approach was felt to be the most effective and efficient way of identifying the literature. Articles were screened and reviewed for using a literature evaluation tool. The tool was developed through consensus by the authors based upon the INVOLVE and EULAR guidelines for patient involvement in research.[12, 14] The level and type of patient involvement was recorded; patient selection (for communication skills, motivation, constructive assertiveness), training (background information), consultation (patients consulted on their views through interview or focus groups), collaboration (on-going relationship such with the research team or advisory board), whether the research was user-led (patient directed and managed research) and finally recognition of the patient involvement.

Results

The search results are reported in Figure 1: 1238 articles were identified for abstract review. Twenty-six articles were selected as ‘pearls’. Two hundred and eight further articles were identified during the citation search and sixty three from the reference search. Two hundred and thirty four articles were excluded as duplicates, review articles, not related to PsA and not related to the development of an outcome measure. Thus, sixty three articles were selected for final inclusion, summarised in Table 1.

Six articles described some patient involvement. Only one outcome measure, the Psoriatic Arthritis Quality of Life (PsAQoL), described patient involvement during the initial development stage.[15] In this study the patients involvement was proportional and acknowledged but there was no evidence of patient selection, training or on-going collaboration in the tools refinement. Two further studies involved patients in the assessment (but not development of) existing measures.[16, 17]

Three articles reported the involvement of four patients during the development of the OMERACT core set for PsA. There were no patients at the first OMERACT 7 workshop where PsA domains were first discussed. Deliberations were based on two previous GRAPPA exercises to identify domains, a Delphi process[3] and a nominal group process[8]. The Delphi processes included thirty two rheumatologists and no patients. The group process included three groups reported to contain representatives from rheumatology, dermatology, patients and industry sponsors (without a vote) but exact numbers were not reported or available from records. As a result of these deliberations, a set of domains was identified. This data was reviewed in the OMERACT 7 workshop before participants were divided into twelve groups to discuss domains that should be included in PsA clinical trials. Domains suggested were then voted on and summarised into a summary table and presented at a plenary session. The final consensus on a core set of domains was made at OMERACT 8. One patient of four with PsA presented a personal story of living with PsA at this meeting amongst 137 physicians. After a plenary session at which current status of measures used

to assess PsA were reviewed, and discussion at breakout groups, the group achieved consensus on six domains for the inner circle of the core set.

In summary this systematic review establishes that much of the original domain construct, outcome measure, disease activity and responder indices were developed and prioritised without substantial incorporation of the patient perspective.

PIOMPSA Special Interest Group

The PIOMPSA Special Interest Group (SIG) was formed as part of a GRAPPA initiative to address the historic lack of patient involvement in the development of PsA outcome measures. The group brings together seven rheumatologists (AA, LC, OF, LG, PH, NJM and WT) one professor of rheumatology nursing (SH), one nurse practitioner (PM) and six representatives of the patient perspective (MB, WC, JJ, AR, DO'S and MdeW). The group had representatives from the UK, Ireland, Canada, France and the Netherlands.

Proceedings of the first PIOMPSA meeting

The first step was an initial meeting held in Dublin in August 2012. The aim of this meeting was to agree on a preliminary roadmap for involving the patient perspective in the further development of outcome measures and domains of PsA, with a view of incorporating this in an OMERACT 14 workshop proposal.

To this end a meeting was convened and introductory presentations were made to facilitate group discussion.

Introductory presentations

MdeW reviewed the role of patients in research, describing the opportunities for patient involvement at each step of the research process from design through to implementation and reporting. The EULAR recommendations clarify how this may be achieved including the roles patients may take, numbers, recruitment, selection, support, training and acknowledgment.[12] NJM reviewed the OMERACT core set of domains and the tools to measure them in PsA studies.[2] He highlighted the importance of PRO's as a reliable, patient centred, feasible and sustainable method of data collection in longitudinal observational studies. The importance of physician measures such as the joint count and skin score were also recognised but that they require relatively high levels of training. NJM indicated that the level of patient participation in the development of any existing measures or domains was likely to have been minimal and that there was a need for this to be established with a systematic review. PH discussed the role of composite measures as a method of capturing all aspects of disease activity in PsA. There is a lack of consensus currently on the three novel measures: the Composite Psoriatic Disease Activity Index (CPDAI), the Arithmetic Means of Desirability Functions (AMDF) and the Psoriatic Arthritis Disease Activity Score (PASDAS). Again it was felt likely there had been minimal patient involvement in the development of these scores. PM discussed the importance of fatigue as an outcome measure in RA and PsA but

acknowledged there was a current lack of a validated tool to use in PsA and that further research was required. Two studies developing novel instruments currently underway are incorporating the patient perspective; the Psoriatic Arthritis Impact of Disease (PsAID) study[18] and the disease flare initiative.

Group discussions

Whilst it was recognised that all domains are important on an individual basis some may not be sufficiently responsive to change to warrant inclusion in an activity measure. Conversely domains that are subject to little variation may not be suitable as response measures and better incorporated 'impact' or severity measures. There was a feeling amongst the group that despite these variances all items should be tracked as part of the research agenda.

There was recognition that some aspects of disease important to patients are not currently included in the existing composite measures (fatigue, pain, work, participation) and it was agreed that the patient perspective was essential in justifying the inclusion and exclusion of individual items. The patient participants wondered what rationales are behind the novel composite measures and why these scores do not include all OMERACT PsA core domains. The group summarised with the following agreements and action plan:

- There was a need to definitively confirm the level of patient involvement in outcome measure and domain development with a systematic review.

- In order to inform a roadmap to improve future patient involvement the group should meet again to review;
    - The OMERACT experience of incorporating the patient perspective in choosing and developing instruments in RA.
    - The findings of the systematic review.
    - The preliminary findings of the PsAID project and Flare studies

Proceedings of the Bath follow up meeting

The meeting took the following structure; MdeW prepared pre-meeting reading material for all members of the group covering the project background, concepts of outcome measurement, OMERACT and its process and a glossary of terminology, introductory presentations were made to inform discussions and concluded in a summary action plan.

Introductory presentations

OF reviewed the Dublin meeting outcomes and the group discussed the opportunity of raising the issue of improved patient participation at GRAPPA through a workshop at the forthcoming Toronto meeting. AA drew the groups' attention to INVOLVE, a UK based body promoting patient involvement in the NHS and particularly research.[14] This national profile for patient involvement was further support for the PIOMPSA groups' objectives.

MdeW presented a patients perspective of ten years involvement with OMERACT. He outlined the need to understand the impact of disease through the patient perspective before selecting domains, a core set, tools for

measurement and cut off values for treatment response. Layered into this process he described the historic discrepancies between the physician and patient perspectives of disease activity. Fatigue was used as an example of an outcome important to patients, but not included in the existing inner circle of the OMERACT core set that was selected and prioritised by physicians. Finally he drew attention to the poor reporting of the core set and the importance that all domains are reported with none left out, as recently systematically reviewed by Palominos *et al*.[4] Discussions ensued on the importance of individual domains, the historic omission of fatigue and the on-going development of the Bristol Rheumatoid Arthritis Fatigue (BRAF) scale.

AA raised the potential issue of how disagreement between physicians and patients in prioritising domains for core-sets or composite measures would be addressed. LC used the RA flare group experience to describe a method of avoiding conflict and achieving agreement through a Delphi process of ranking and consensus to incorporate all perspectives.

PH presented the preliminary findings from the PsAID[18] and Flare studies (unreported findings). The EULAR PsAID initiative was conceived from the belief that the patient perspective is not fully reflected in existing tools and has the aim of addressing this through appropriate involvement during the development of a new disease impact measure, the PsAID. The group is made up of patients, rheumatologists, dermatologists and allied health professionals from 13 countries. He went on to describe the study starting with the identification and selection of sixteen domains identified by patients at

the first meeting. The domains were then prioritised by a ranking exercise including more than 130 patients. After excluding four domains with low sores in the ranking exercise two weighting systems were employed to create two versions, one for nine domains and one for twelve. A longitudinal study of >400 patients in thirteen countries found the feasibility, reliability and sensitivity of the two tools to be good.[18]

PH then went on to discuss the Flare study. Flare is a very different experience for every patient and there is a need for a standardised definition. SH led on an international qualitative study that identified the core elements of RA flare, which prompted discussion from the patient representatives in the group on the experience of flare.[19] The local Bath PsA group (named PsAZZ) meet to exchange views and flare had recently been discussed. The group emphasised the importance of two particular aspects of flare; the systemic feelings of ill health found in flare dubbed the 'yuk factor' and ability to work.

WT presented the findings of the systematic literature review. The group went on to discuss how the patient perspective may influence the existing domain selection and outcome measures.

Group discussion on the OMERACT core set of PsA domains

The group posed the question that in light of the findings of the very low levels of patient involvement identified in the systematic review was it necessary to review the core domains and the tools to measure them? Were there domains that were not included in the inner circle that perhaps should be, such as

dactylitis and fatigue?[2] It was noted that there was little difference in the scores at OMERACT 8 between those domains finally included in the inner circle and those not.[2] Originally only domains with validated measures were included in the inner circle leaving those without to the outer circle or research agenda. The group discussed the examples of fatigue and dactylitis.

The domain of fatigue had caused much debate at the OMERACT workshops but was finally placed in the outer circle because there was no agreed instrument to measure it. Since OMERACT 8 there has been considerable work in the development of many outcomes in PsA which may influence the ranking of domains.[2] The patients in the group commented that although fatigue had been identified as an important outcome from the patient perspective, and despite the fact that a validated instrument was lacking, no research was initiated at that stage to develop a measure of fatigue in PsA. Moreover the evidence that will be reported in the PsAID study suggests fatigue ranks third of sixteen domains behind pain and skin disease from the patient perspective indicating its place in the core set may need to be reconsidered. However, a validated instrument to measure fatigue in PsA is still lacking.

The group felt that it was important to reconsider the place of dactylitis in the core set, currently in the outer circle. It was suggested that the measurement of dactylitis is covered through within the existing joint count or within the assessment of physical function, both included in the inner circle, and as such separate measurement was not required. An alternate view point voiced by

the group was that dactylitis is a characteristic and frequent manifestation of PsA rarely seen in other diseases so specific measurement is warranted. Additionally there is a validated measure available in the Leeds Dactylitis Index (LDI) for its measurement.[20]

The group then posed the question; should domain selection be based on areas affecting ‘a significant proportion’ of patients as in the RA model? Whilst this seems reasonable to include domains affecting a significant proportion of patients there was agreement that this approach was flawed in PsA. The variable clinical phenotype may mean such an approach would miss disease activity amongst those affected in less common domains. Furthermore if treatment decisions are being made on the basis of core set outcome measures the domains included become critically important.

In summary there was a feeling that all important domains should be included in the core set thereby forcing the development of appropriate measures and that this proposal should be taken forward for discussion at the GRAPPA Toronto Workshop.

Outcome measurement

There are many measures now available for the measurement of domains in the inner circle of the OMERACT core set but a lack of consensus on which were most discriminatory. The advantages and limitations of the currently available measures, including the novel composite indices were outlined by physicians within the group. By example the advantages of composite

measures were outlined, including; the ability to capture multiple domains, better quantification of the total burden of disease in someone with low activity but in multiple domains and their sensitivity to change enabling smaller, less expensive and quicker studies. Limitations include factors such as; they are often time consuming to complete, require training and have the potential of masking fluctuation in a single disease area by other domains. PH introduced the idea that the arithmetically derived AMDF could be adapted to incorporate different domains to reflect changes in the inner circle of the core set then be re-validated. The group proposed that there may be a need for a minimal 'inner circle' composite index and a second 'expanded' composite to incorporate broader domains. The possibility of revising the CPDAI, with patient involvement, was also discussed including the possibility of expanding the index to include a patient global score.

The group discussed the lack of objective evidence that incorporating the patient perspective improves outcome measures. Such a study would be very difficult to design and taken with the theoretical advantages is arguably not required. Perhaps the first argument is that incorporating the patient perspective ensures that PsA outcomes research remains patient centred. An example of the success of this approach may be found in the improved profile and measurement of fatigue in RA.[13] Furthermore there are advantages on individual and group/ association level whereby patients may feel a greater sense of empowerment through more involvement with research.[21] Such relationships may bring additional advantages such as improved participation in future research projects and the implementation of research findings.

The group acknowledged difficulties in incorporating the patient perspective.[12] In summary these include, but are not limited to; overcoming the asymmetrical nature of the physician/ patient relationship and the importance of creating a supportive and equal partnership; achieving ‘representativeness’ of the patient perspective through appropriate selection of patients and finally avoidance of relying solely on long term patient partners who may become professional with time thereby bring another medical opinion rather than the true patient perspective.

Conclusion

We report a systematic review of patient involvement in the development of outcome measures and domains in PsA together with the proceedings of the first meetings of the PIOMPSA group. We have outlined the background and aims of this special interest group together with discussion around the potential advantages and difficulties of incorporating the patient perspective in developing instruments for measuring disease outcome. These group discussions have identified research topics around domain selection and outcome measurement where the patient perspective may influence future research. The group concluded with agreement on the following action points;

- There is a historic underrepresentation of the patient perspective in the development of PsA domain selection and outcome measures, demonstrated in this systematic review and discussions.

- Ideas introduced in the PIOPMSA meetings could be refined in a GRAPPA special interest group with voting on a roadmap for achieving meaningful incorporation of the patient perspective in future research.
- There is a case for reviewing the OMERACT PsA core set with meaningful patient representation.
- The AMDF or CPDAI could be revised to incorporate domains included in the inner circle.

Conflicts of interest

AA, MB, LC, WC, OF, SH, PH, JJ, PM, AR, WT, MdeW have no conflicts of interest to declare. LG Received EULAR funding for the PsAID study.

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Table 1: Systematic literature review of PsA outcome measures by domain

Core set	Domain	Outcome	Primary article (number of Pubmed citations)	Articles included from the Citation/ Reference search
Inner circle	Physical function	HAQ	*Blackmore 1995 (11)*[22]	Pincus 1999[23] Husted 1995/ 2001/5/7[24-27] Leung 2008[28] Brodsky 2010[29] Mease- 2011[30] Kwok2010[31] Wolfe 2004[32] MacKenzie 2011[17] Daltroy 1990[33] Stamm 2007[16]
		SF36	*Husted 1997(11)*[34]	Stamm 2007[16] Taylor 2007[35] Husted 2001[24] Leung 2010/ 08[28, 36] Kvamme 2009[37] MacKenzie 2011[17] Shikiar 2003[38]
		AIMS	*Husted 1996 (5)*[39]	Husted 1996[40] Duffy 1992[41] Stamm 2007[16]
	Health related Quality of Life	EQ5D	*Sokoll 2001 (22)*[42]	Brodsky 2010[29] Singh 2009[43] Kvamme 2009[37] MacKenzie 2011[17] Shikiar 2003[38]
		PsAQol	*McKenna 2004 (9)*[15]	Stamm 2007[16] Brodsky 2010[29] Healy 2008[44] Billing 2010
		DLQI	*Nicol 1996 (4)*[45]	Stamm 2007[16] MacKenzie 2011[17] Shikiar 2003[38]
		ASQUol	*Nil in PsA*	
	Patient global	Patient global VAS/ Numeric	*Cauli 2011 (0)*[46]	Kwok 2010[31] Leung 2012[47] Dandorfer 2012[7]
	Peripheral joint activity	Joint count	*Gladman 2007 (5)*[48]	Nil
	Skin activity	PASI	*Fredriksson 1974(64)*[49]	Louden 2004[50] Feldman 1996[51] Shikiar 2003[38] Carlin 2004[52]
	Pain	Pain VAS	*Kwok 2010 (1)*[31]	Nil
Outer circle	Physician global	PGA	*Nil in PsA*	Nil
	Fatigue	BASFI	*Leung 2008 (2)*[28]	MacKenzie 2011[17]
		FACIT-fatigue	*Chandran 2007 (4)*	Nil
	Enthesitis	LEI	*Healy 2008- (3)*[53]	Nil
		MASES	*Gladman 2007 (5)*[48]	Nil
		SPARCC	*Maksymowych 2009 (3)*[54]	Gladman 2007[55]
	Dactylitis	LDI	*Heliwell 2005 (1)*[56]	Healy 20007[20] Gladman 2007[48]
	Spinal	BASMI	*Gladman 2007 (3)*[55]	Leung 2011[57] Fernandez-Sueiro 2009[58]
		BASDAI	*Taylor 2004 (2)*[59]	Stamm 2007[16] Leung 2008[28] Fernandez-sueiro 2010[60] Eder 2010[61] MacKenzie 2011[17]
	Nails	NAPSI/ mNAPSI	*Rich 2003 nil (4)*[62]	Aktan 2007[63] Cassell 2007[64] Maejima 2010[65]
Research agenda	Participation			
OMERACT core set	Core domains		*Gladman 2007 (4)*[2]	Taylor 2005[3] Gladman 2005[8] Gladman 2005[66]
Composite measures	Composite measures	CPDAI	*Mumtaz 2011 (0)*[67]	Fitzgerald2012[68]
		DAPSA/ DAREA	*Nell-Duxneuner 2010 (1[69])*	*Schoels* 2010 *(1)*[70]
		MDA	*Coates 2010 (0)*[71]	Coates 2010 [72] Coates 2010 [73]
		PsAJAI	*Gladman 2010- 1892-7 (1)*[74]	Gladman 2010[75] Nell-duxneuner 2010[69]
		PASDAS & AMDF	*Helliwell 2012 (0)*[76]	Nil

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