
Health-related outcomes of importance to patients with Takayasu's arteritis

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ABSTRACT

Objective. *The need to include patients' perspectives as key outcomes in clinical trials is widely accepted. No disease-specific patient-reported outcomes have been developed in Takayasu's arteritis. This project was designed to identify outcomes of importance to patients with Takayasu's arteritis during active disease and remission across 2 different cultures.*

Methods. *Patients with Takayasu's arteritis from the US and Turkey were recruited to participate in semi-structured, one-on-one interviews or focus groups. The interviews and group sessions were recorded, transcribed, and entered into an Nvivo database. A line-by-line review of narrative data was used to develop themes describing the impact of Takayasu's arteritis on patients' life. US Patients were invited to freelist terms that they associated with disease states (active disease and remission). The Smith's Saliency Index (SSI) was used to identify the most salient terms.*

Results. *A total of 31 patients with Takayasu's arteritis participated in this study. Interviews and focus groups identified pain, fatigue, and emotional impact as common themes. Outcomes did not differ between the 2 countries. The most salient terms identified through freelisting were pain/discomfort and fatigue/low energy levels (SSI=0.56 and 0.33, respectively) during active disease and pain/discomfort and emotional impact (SSI=0.51 and 0.37, respectively) during remission.*

Conclusion. *Patients with Takayasu's arteritis report a range of disease-specific symptoms across different cultures and disease states that are generally not specifically captured by generic patient-reported outcome tools currently used in research. Identifying disease-specific outcomes would advance clinical trials methodology to best capture*

the full spectrum of disease activity in Takayasu's arteritis.

Introduction

Patient-reported outcomes (PROs) are patient-derived assessment tools describing patients' feelings, perceptions, and functions related to health conditions and treatment (1). An international need exists for more "patient-centered care" and PROs in rheumatology as well as in clinical trials of rheumatic diseases (2, 3). Variations in rheumatic conditions may necessitate development of disease-specific PROs for use in research in rheumatology.

Takayasu's arteritis (TAK) is a chronic, large-vessel vasculitis occurring predominantly in females in the second and third decades of life (4). Chronic vascular inflammation, disease-related damage and treatment toxicities can severely impact quality of life (QoL) and functional status of patients with TAK. It is important to develop validated measures of health-related QoL to determine and follow the effects of TAK and its treatments. Impaired QoL in TAK was shown in a few studies using traditional metrics. For example, impaired 36-item short-form health survey (SF-36) scores, a generic tool for assessment of health-related QoL, were decreased in patients with TAK (5-7). However, generic measures such as SF-36 lack the granularity and ability to capture essential disease-specific domains to assess treatment response or better understand the natural history of the disease. The purpose of developing disease-specific PROs is to capture highly patient-relevant outcomes related to specific conditions. As QoL may be impacted by both individual and cultural factors, it is important to explore differences across cultures when looking to implement PRO measures internationally.

In this study, individual interviews and focus groups were conducted, as well as freelist and pilesorting techniques, to describe patient experiences and perceptions of burden related to TAK at disease onset, and during periods of remission or active disease (flare). The aim of this study was to identify disease-specific PROs and to compare reported domains of TAK-related QoL from a sample of patients in the United States (US) and Turkey to determine the implications for an international PRO measure. This work is part of the broader research agenda of the OMERACT (Outcome Measures in Rheumatology) Vasculitis Working Group to explore the patient perspective in TAK and work towards the development of a core set of outcomes for use in clinical trials in TAK and large-vessel vasculitis (3).

Methods

Sample

Purposive sampling was used to recruit participants with TAK in the US with a range of disease durations from the population of patients with TAK cared for at the Vasculitis Center of the University of Pennsylvania. In Turkey, purposive sampling was used to recruit participants with TAK from the rheumatology patient population from Marmara University School of Medicine.

Freelisting and pilesorting

US patients were invited to freelist and then pilesort terms that they associated with TAK. Freelisting was not conducted in the Turkish sample due to the timing of alignment of study aims between the two US and Turkish study teams. Freelisting allows the exploration of the elements that form the shared cultural knowledge of a particular cultural domain while pilesorting allows the understanding of how these elements relate to each other by examining the ways in which people categorise items within a cultural domain (8). In this study, participants were asked to provide three separate lists of the words they associate with their TAK symptoms at different points in their experience with the disease: 1) onset, 2) remission, and 3) active disease (flare). The responses to

each of these questions were recorded in a database by the interviewer.

For pilesorting, the study team selected a patient partner group that represents 25% of the US interview sample size. Patients were asked to clean the list of items by combining similar terms into discrete categories and by creating as many categories as necessary but as few as possible in order to organise all of the items. Disagreement was addressed through discussion and consensus building within the patient partner group. The sorted data were entered into ANTHROPAC (Analytic Technologies, Lexington, KY, USA) to determine a Smith's Salience Index (SSI), a calculation of the item's frequency in all lists over its mean position across lists (9). The SSI scores range from 0 to 1 with higher scores indicating terms frequently mentioned and highly ranked by patients.

Interviews and focus groups

US patients participated in qualitative semi-structured, one-on-one interviews to elicit experiences, attitudes and beliefs about TAK. Turkish patients with various clinical manifestations, disease durations, and therapies were recruited for participation in three focus groups. Focus group sizes ranged from 4–8 participants and were used to conduct discussions among patients related to their experiences, attitudes, and beliefs about TAK.

While different methods and guides were deployed at each site prior to collaboration of the study teams, the combination of interview and focus group data in a non-hierarchical, side-by-side comparison can reveal complementary findings and a more nuanced depiction of a patient experience (10).

Participants in both countries were asked open-ended questions about the impact of TAK and its therapies on their QoL. The responses were audio recorded, transcribed, and entered into an NVivo database for analysis (NVivo qualitative data analysis Software; QSR International Pty Ltd. v. 10, 2012.). Transcripts from Turkey were translated from Turkish to English. Through a close reading and exhaustive review of all transcripts, key themes were identi-

fied and developed into a set of codes using the constant comparison method. The data was coded by two researchers (EE and TD) for quality control and the inter-rater reliability was assessed for each transcript. Coding discrepancies were addressed until a high interrater reliability was reached (agreement = 98.2%; kappa score >0.92). A modified grounded theory approach was used to interpret the data, identify common themes, and compare PROs from each cultural group in order to develop an understanding of the conceptual model patients use to describe their experiences with TAK. After open coding of the data, the study team reviewed and summarised interview and focus group data related to the most salient concepts identified through the freelist and pilesorting.

Statistical methods

The SSI scores were calculated using similar methods previously described by Smith *et al.* (9). Interrater reliability between the transcripts coders was measured using kappa statistics. The University of Pennsylvania Institutional Review Board and Marmara University Committee on Human Subjects Protection approved the study (protocol numbers 817899 for the University of Pennsylvania and 09.2011.0016 for Marmara University).

Results

Freelisting and pilesorting

A total of 124 items across the three disease states (*i.e.* onset, remission, and flares) were generated by freelist with the 12 US patients and 18 categories were created through pilesorting by the patient partner group. Table I shows the different categories with the associated freelisted terms. Several categories including pain and discomfort, fatigue and low energy levels, emotional impact, memory and mental state contained the majority of the listed terms. Figure 1 shows the SSI scores of the various categories obtained from the freelist and pilesorting activities across disease states.

Interviews and focus groups

A total of 31 patients with TAK participated in this study: 12 patients com-

Table I. Items included in “cleaned items” after pilesorting among patients with Takayasu’s arteritis in the United States.

Domain	Items included
Emotional effects	Annoying, Calmness, Confident that doctors knew about the disease, Scary, Relieved, Fear, Strange, Struggling, Anticipation, Fine, Manageable, Livable, Difficult, Feel better, Hate my medicine, Dread, Severe, Sudden, Trial and error, Lengthy process.
Pain and discomfort	Pain, Pain In neck and ear, Painful everywhere, Neck pain, Back pain, Arm pain, Muscle soreness, Pain in arms, Less painful, Not as painful, Pain in left leg, Sometimes pain, Pain in left arm, back and neck pain, Chest pain, Sore, Pain in the arm, Some pain in right arm, Less chest pain, Left arm pain, Tender, Increase in arthritis, Chronic migraine, Muscles are tense, Tense muscles, Throbbing, Radiating, Stiffness, Indigestion, Heartburn, Intermittent Throbbing, Chest pain, Headaches, Less pain, Painful.
Fatigue and energy levels	Tired, Fatigue, Physical tiredness, Sometimes lacking energy, More Energetic, Very tired, Fatigued, Exhausting, Run down, Less Fatigue, Difficulty getting up.
Lung and chest problems	Shortness of breath, Out of breath, Less shortness of breath, Short winded.
Skin problems	Worsening skin condition.
Appetite or weight changes	Loss of weight, Gain of weight.
Ear Symptoms	Muffled Hearing.
Independence and loss of Function	Functional, Less activities, Old lady.
Memory and mental state	Foggy, Fogginess, Memory trouble, Concentration difficulty, Distracted, Mental fatigue, Memory loss.
Sensory problems	Numbness, Numbness in arm, Tingling in arm, Tingling, Coordination difficulty.
Test Results	Blood tests, Blood test.
Sleeping problems	Sleep problems, Difficulty waking up.
Weakness and strength	Weakness, Weaker on left side, General weakness, Muscle weakness in arms, Less weakness.
Body temperature	Hot flashes, Sweat, Sweating.
No symptoms	No symptoms, Seldom, Few, Minimal.
Vision and head symptoms	Blacked out, Blurred vision, Dizziness changing position, Light headed when changing position, Light headed, Fainting, Dizzy, Change in vision.
Hospital and doctor visits	Lengthy procedure, Hospital admissions, Hospitalisation.
Blood circulation problems	Blue hands, Stroke, Anaemia.

pleted individual interviews in the US and 19 patients participated in a total of three focus groups in Turkey. The common disease-specific domains of illness that emerged from both countries are listed in Table II. In both the US and Turkey, participants reported similar symptoms and aspects of the overall social and psychological experience of life with TAK. Participants in both populations reported difficulty walking, going outside, feeling limited in participating in various activities including school or employment. The identified PRO domains were most frequently related to arterial ischaemia

causing extremity pain (claudication), fatigue, and low energy levels. Both US and Turkish patients described experiencing depression or anxiety related to their experience with TAK. US patients, reported some outcomes absent in the Turkish data, including impact on finances, social avoidance, and stress and frustration.

The most salient domains identified across disease states include pain and discomfort, fatigue and low energy levels, and emotional impact. Each of these domains identified through freelist and pilesorting activities were described in interview and focus group

data in both the US and Turkish samples. The sections that follow utilise all data to provide a detailed review of patient perspectives on the most salient PRO domains identified through freelist and pilesorting.

Detailed review of pain and discomfort

Across all three disease states pain and discomfort was the most salient term. For disease onset, symptoms categorised as pain and discomfort had an SSI score of 0.489 and was mentioned by 83% of respondents. At disease remission, pain and discomfort had an SSI score of 0.515 and was mentioned by 82% of respondents. For disease flares, pain and discomfort had an SSI score of 0.56 and was mentioned by 82% of respondents. Of the terms included in pain and discomfort, “chest pain,” “pain,” “painful,” “pain in neck and ear,” and “pain in the arm” were most frequently mentioned.

US interviewees described how these symptoms impacted their function and ability to participate in various activities. Pain was often described as pervasive and inhibitive throughout disease phases: “*And then, the – I just happened to mention to my doctor in my – in the visit where they did the blood work and everything that my arm hurt, you know, when I was doing the – I mean, doing anything with it (Patient (PT) 401)*”. Turkish focus group participants reported similar affects: “*Well, of course when I do even a bit of work, my arm feels numb and painful right away*” (Focus Group (FG) 1). “*My disease started with arm pain and is active when I have arm pain*” (FG3). Across contexts, in both US interviews and Turkish focus groups, pain reportedly affected participants’ work and school: “*When I work my arms ache. But my feet are fine. Only the arms are causing a bit of problem. When I put up curtains or iron them, my arms get tired*” (FG1).

Detailed review of fatigue and energy levels

Fatigue and low energy levels was the second most salient term collected during freelist for both disease onset and flare (SSI score: 0.394 mentioned

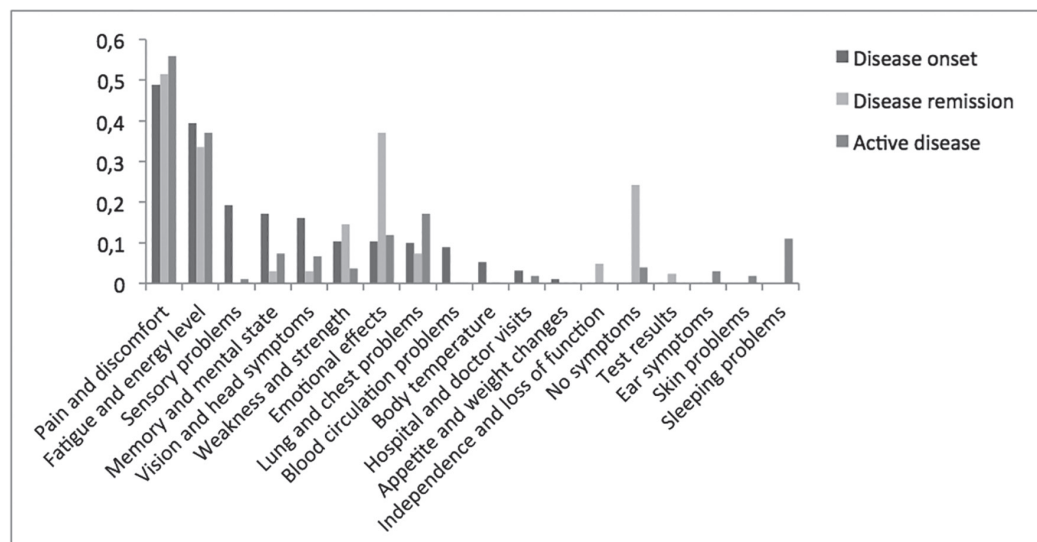


Fig. 1. Smith's Saliency Index scores of the categories pilesters associated with different disease time points in Takayasu's arteritis: disease onset, disease remission, and active disease.

by 58.3%; and SSI score: 0.336 and mentioned by 54.5% for disease onset and flare respectively). When responding about disease remission, participants did not use terms related to fatigue and low energy levels with such high frequencies. Only 36.4% of participants referred to fatigue and low energy levels with an SSI score of 0.218 as a descriptor of the disease remission state. The most frequently mentioned items included in the fatigue and low energy levels category were "fatigue" and "physical tiredness."

In qualitative interviews and focus groups, fatigue and physical tiredness were attributed to several negative outcomes. Several participants explained how the fatigue they experienced at disease onset affected school or work. When asked how the physical symptoms of vasculitis began participants responded, "I was 17, my senior year in high school. I started to feel very tired all the time, like I didn't want to get out of bed in the morning and then as soon as I came home from school, I wanted to go to sleep" (PT407); "It is tiring to work... When I am doing my work, I get tired quickly and leave it to rest and then continue to work" (FG3). Both US and Turkish participants explained that fatigue affected their ability to walk: "Walking seemingly insignificant distances up a slight hill at school or at work or wherever it is, going up steps, how I'd have to catch my breath at the top for a minute or feel a little lightheaded or something like that"

(PT401). "I take a couple of steps and get tired. I get tired quickly" (FG3).

Detailed review of emotional impact

Emotional impact was the fourth most salient term when describing disease onset but the second most salient term used to describe symptoms at disease remission. Emotional impact was not one of the most salient terms for disease flare. For disease remission, emotional impact was used to describe disease symptoms for 63.6% of participants and had an SSI score of 0.371. In general the impact was both negative and positive and the common used terms included "stress," "frustrated," "relieved," "manageable," "fine," and "livable."

One interviewee described the relief associated with disease remission: "I think it makes me feel relieved that I don't have to worry about waking up and having the symptoms and not feeling good for the day. And not worrying if I can go through the day without getting tired..." (PT408). While this participant and several others described some positive emotional impact, the qualitative data revealed more negative emotional impact of TAK during disease remission than was evident in the freelisting data. Stress and frustration were among the negative emotional symptoms. At times stress was attributed to a trigger during remission: "I would say stress is a big one. I guess I'm under a lot of stress and work and relationships, which

also contributes to when I'm under stress and taking not as good care of my body..." (PT407); "...long-term is also hard to hear that I'm gonna be on drugs pretty much the rest of your life to deal with this. So I'm kind of long-term, a little lost, which is also frustrating because I don't know what the long-term treatment plan is. I feel like for other diseases – and that was the other part, too. For remission, when they said you're in remission, isn't that awesome? And it doesn't – you know, I feel like someone with cancer, you're in remission, you stop treatment. It's a great feeling. I feel like, for me, I'm in remission, but yet, I'm still on drugs. So it doesn't really feel like I'm in remission. It doesn't feel like – I thought I'd feel so much better. It doesn't feel that way" (PT403).

The chronicity of the disease led to negative emotional impact other than stress. Participants described fear and sadness when confronting the chronic nature of the disease: "My rheumatologist here – told me that I would likely have a shortened life, but prognosis for five plus years was good. That's very scary to hear" (PT402); "And it's hard to hear you have something that you're gonna have the rest of your life. Like, it's not something you can just take a medication or have a surgery and get rid of. It's something that you're chronically gonna have to deal with" (PT403). Reinitiating treatment during a flare was also described as a hopeless experience: "I felt sad again

Table II. Comparison of domains of illness commonly reported by patients with Takayasu's arteritis in the United States and Turkey.

Domain	Definition	Turkish Focus Groups	US Interviews
Impact on Family and Home Management	Participants discuss how their disease limits their ability to participate in family activities (including chores), manage household roles/responsibilities, or interact with family members including children	X	X
Impact on Finances	Participants describe the financial burden associated with insurance/medication for their care		X
Impact on Future	Participants describe how the disease affects their understanding of their future and how it has led them to change or abandon life plans		X
Impact on Participation in Activities	Participants describe how TAK symptoms affect their ability or desire to participate in activities i.e. going to the beach/park or walking	X	X
Impact on School or Work	Participants describe how TAK symptoms affect their performance or ability to carry out specific tasks at work	X	X
Impact on Self-care and Hygiene	Participants describe how TAK symptoms affect their ability to carry out various personal care tasks i.e. doing hair	X	X
Limited Interactions	Participants explain that TAK limits the amount or quality of interactions they have with family members or friends	X	X
No Impact on Function or Activities	Participants explain that TAK had little or no impact on their functioning	X	X
Social Avoidance	Participants explain that they avoid social settings in attempt to limit risk of exposure to germs that could cause illness		X
Coping	Participants talk about the different ways they cope with the changes brought on by TAK including coping with the chronic nature of the disease and engaging in activities to alleviate symptoms	X	X
Depression and Anxiety	Participants talk about experiencing depression or anxiety in relation to their experience with TAK	X	X
Psychological Treatment and Support	Participants talk about the psychiatric support they receive or have received or the lack thereof	X	X
Response to Diminished Function and Mobility	Participants talk about coming to a realisation that they cannot do the things that they think they should be able to	X	X
Social Support	Participants describe the effects that social support (or the lack thereof) had on their experience with TAK	X	X
Stress and Frustration	Participants discuss stress and/or frustration brought on by symptoms, diagnosis, and treatment		X

TAK: Takayasu's arteritis; "x" indicates whether patients in that country mentioned the domain.

because like according to the previous blood test and doctors kind of gave very positive response saying I probably could be off the medication, but then it came back again and it made me feel kind of hopeless" (PT404).

Discussion

This study identifies for the first time several health-related domains of high importance to patients with TAK from their perspective using and contrasting three different qualitative methods. In addition, study findings illustrate similarities and differences between two

cultures of patients experiencing TAK highlighting the commonalities of TAK experience among international patients but also the impact a culture may have on that experience. These results will set the foundation to create a disease-specific patient-reported outcome measure that accurately reflects patients' experience and burden of TAK. PROs have recently become an integrate part of any set of outcome measures in clinical trials (11). There currently exists no disease-specific PRO to measure domains of interest to patients with TAK. Previous studies have

utilised generic PRO tools, such as the SF-36, to capture disease experience and burden in TAK (5-7). The questions used in the SF-36 are general and meant to capture the experience and burden of any disease or its treatment on patients, however in the case of TAK it can miss TAK-specific effects. For example, several of domains identified in this study as important to patients with TAK are not readily captured by the SF-36 survey; these include disease-specific symptoms, impact on future and self-care, stress and frustration, and limited interactions.

Furthermore, some of the SF-36 scales such as physical functioning, which is centered on walking activities, may miss disease-specific activities, particularly activities using the upper extremities such as using a dryer or comb for hair care, that result from ischaemic complications commonly affecting the upper extremities in TAK.

TAK is a relapsing disease and determining state-specific disease impact may identify PROs that discriminate between disease states (*e.g.* active vs. remission). In this study patients with TAK reported a wide range of symptoms and health-related domains across different disease states. Pain and discomfort emerged as a common theme during the interviews and was the most salient term across all disease states (*i.e.* onset, remission, and active). Many of the common symptoms reported in TAK such as pain and claudication often persist during periods of remission due to vascular damage. This may explain why pain and discomfort was the most salient term in this study during active disease and remission. However, the presence of new or worsening pain can indicate active disease. Fatigue and low energy levels were another term commonly mentioned by patients in the interviews and the second most salient term identified by freelisting and pile-sorting during disease onset and active disease but not as salient during remission. This suggests that fatigue and low energy levels differentiates between disease states. While fatigue may result from the disease or its therapy, new or worsening fatigue may herald disease activity.

Lastly, emotional impact was the second most salient term in disease remission and included both positive and negative impacts, ranging from stress, frustration, and hopelessness to feeling fine, relieved, and livable. Of interest, emotional impact was not markedly salient in either disease onset or active disease and may have been overshadowed by physical symptoms that are frequently prominent during disease activity.

When considering the development of outcome measures, contextual factors such as sex, age and geographical

locality should be considered (11-13). These important factors may affect the interpretation of PROs regardless of the disease type or state. While the demographics and pathophysiology of TAK do not greatly vary by geography, the experience of patients with TAK may differ based on a patient's culture and surrounding normative responses to disease states. Patients in the US and Turkey reported similar health-related domains that they considered important. However, US patients reported some outcomes absent in the Turkish data, including impact on finances and social avoidance. There were no domains mentioned by Turkish patients that did not exist in the US data. These differences between the two countries are likely related to cultural differences rather than TAK-specific factors and illustrate the importance of considering the patient's culture and geographical locality when assessing patient-reported outcomes in TAK.

This project is part of the broader research agenda of the OMERACT Vasculitis Working Group to develop core set of outcomes and disease-specific outcome measures for use in clinical trials in TAK. As next steps, we plan to: a) identify the best candidate tools to measure the domains identified by patients, b) generate a disease-specific PRO measure with substantial input from patients, c) test the validity and reliability of this measure in patients with TAK, and d) test the disease-specific PRO measure in clinical trials.

This study has several strengths. This is the first study in TAK to determine health-related domains of importance to patients with TAK from patients' perspectives. The study used three different qualitative methods, including individual interviews, focus groups, and freelisting with pilesorting, resulting in a highly comprehensive assessment of the patient experience of the disease and its burden. Furthermore, this study examined the culture impact of the disease experience on patients with TAK from different countries to permit greater representation of the full spectrum of patient experiences with this disease.

The study also has limitations to consider. The sample number may be

considered small. Sample size will always be challenging in the study of rare diseases such as TAK. However, the analyses appeared to have reached saturation, but a larger sample may have illustrated additional themes not otherwise identified. Additionally, the narrative data were derived from two different methods (*i.e.* individual interviews and focus groups) in the US and Turkey. This was a pragmatic challenge that presented itself to the study team whose collaboration on this area of inquiry began after primary data collection methods had been deployed. However, the guide for interviews and the moderation guide for the focus groups were quite comparable and similarities were mostly found across both cultures indicating agreement between the two cultures.

In summary, patients with TAK report a range of disease-specific symptoms across different cultures and disease states that are generally not well captured by generic patient-reported outcome tools such as SF-36 or measured at all by the usual physician-based measures used in clinical research in TAK. Developing methods to capture outcomes of high importance to patients would promote research methodology to best capture the full spectrum of disease activity in TAK and advance the development of a core set of outcomes for use in clinical trials in TAK and large-vessel vasculitis.

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