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Patient information and education

POS1497-PARE POST-TRIAL SURVEY OF PARTICIPANTS OF A PHASE 3 CLINICAL TRIAL IN SSC-ILD

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Background: The SENSISCIS® trial (2015–18) was a large clinical trial (n=576) investigating the efficacy and safety of nintedanib in patients with systemic sclerosis-associated interstitial lung disease.1 The clinical research sponsors (CRS) collaborated with the scleroderma patient community advisory board (CAB) regarding the design, implementation and conduct of the trial.2 As part of this collaboration, the CRS and CAB developed a post-trial survey for SENSISCIS® participants. The use of the developed patient-centric materials was optional for the sites.

Objectives: The objectives of the SENSISCIS® post-trial survey were to gain experience in collecting real-world information and trial satisfaction data from patients to inform and improve future patient centric clinical research.

Methods: SENSISCIS® trial participants who were involved in the extension trial SENSISCIS®-ON completed a post-trial survey covering nine multiple-choice questions about three main topics:

- [1] Recruitment – Where do patients usually search for clinical trials and how did they become aware of SENSISCIS®?
- [2] Motivation & Retention – What motivated patients to start and continue participation in SENSISCIS®?
- [3] Challenges & Wishes – What were the challenges during trial participation and how can future clinical trials be improved regarding patient centricity?

Results: A total of 125 participants completed all survey questions. Participants could select more than one option. A total of 51 patients reported that they are usually not actively looking for trials. For those actively searching, the most common sources to learn about trials were specialists/general practitioners (GPs) (46 patients) and internet search engines (20 patients), followed by patient organisations (12 patients). Of note, 78 patients would pay attention to printed materials, such as a card/flyer/poster in a doctor's office and get in touch with a trial/study site. Back in 2015–2017, during recruitment for the SENSISCIS® trial, the majority of the patients who answered the survey were made aware via their specialist/GP (116 patients), whereas 5 were made aware via patient organisations and 4 via the internet.

The most frequent motivations to join the trial were 'hope to receive an improved therapy' (98 patients), to help other patients (64 patients), and on the recommendation of their specialist/GP (81 patients). Similarly, the most liked aspects of the trial were the 'opportunity to receive an improved therapy' (92 patients) and 'to support the development of an improved therapy for my illness' (90 patients). More than half of patients reported 'continuous observation of general health' (72 patients) and 'advice from GPs/specialists' (71 patients) as motivation to stay in the trial (Figure 1).

'Concerns about side effects' (72 patients) and 'not knowing whether the trial medication will work for me' (63 patients) were reported as the least liked aspects of the trial. Travel to the site was reported as a challenge by 21 patients.

To improve clinical trials, patients requested more patient-friendly information (50 patients) and multiple formats of information material (46 patients). Finally, 48 patients expressed the desire to communicate with other trial participants.

Conclusion: The SENSISCIS® post-trial survey is a unique approach to receive real-world feedback from trial participants, and these pilot data will help improve future clinical trials and communication. The results highlight the importance of reaching patients who may not be actively looking for clinical trials.

Figure 1. Motivation to stay in the SENSISCIS® trial^{1,2}

¹More than one option could be selected.

²Data collected on 9th January 2021

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Building patient led organisations

POS1498-PARE LAUNCHING A NEW RELAPSING POLYCHONDRIITIS ("RP") PROGRAM

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Background: In 2011, I was diagnosed with relapsing polychondritis ("RP"), a debilitating and sometimes fatal rheumatic disease that is characterized by inflammation of cartilage and other tissues. The disease affects multiple organs, particularly cartilaginous structures such as the ears, nose, airways, and joints as well as eyes, skin, heart valves and brain. The cause of RP remains unknown and there currently is no cure for the disease.

As a patient, I had the opportunity to be evaluated by an incredible team of multidisciplinary expert medical professionals. While interacting with these experts, it was evident that there were tremendous unmet needs in the areas of diagnosis and treatments. As a retired Registered Nurse, it was clear that targeted research initiatives would be required to combat RP.

Objectives: After diagnosis, I realized that I could focus on my specific case or combat RP more broadly and help others. I decided to live my life with the purpose of helping others.

Methods: While fighting RP, I met many highly skilled, collaborative research scientists, especially at annual gatherings of rheumatology professionals. In 2017 in San Diego, I participated in an RP study group that received a tremendous response from participating clinicians, clinical and basic scientist researchers, patients, and patient advocacy groups.

In 2018 in Chicago, I helped organize the RP Foundation's reception, co-hosted an event with the University of Michigan Division of Rheumatology, participated on a podcast of a news source dedicated to the rheumatology field, and facilitated two exhibitor booths at a prominent rheumatology conference.

In 2019 in Atlanta, I participated in an RP investigator meeting, which provided an update on a classification criteria project, introduced a new project to modify the disease activity index, and summarized RP-related projects.

With knowledge gleaned at these sessions, my husband and I collaborated with the RP Foundation to provide a substantial gift in 2020 to establish the Penn RP Fund, which will support a unique partnership between the University of Pennsylvania and the National Institutes of Health sponsored Vasculitis Clinical Research Consortium.

Results: Living with the purpose of helping other patients continues to improve the quality of my life. It affords me the ability to be excited about the extraordinary advances in patient care and cutting-edge research.

Participating in these conferences has provided exceptional opportunities to learn and collaborate with highly skilled research scientists. Further, I was able to build relationships with these scientists, which played a key role in the launch of the Penn RP Program.

This program will allow researchers to pursue important projects, including the development of a world-class referral center to examine the impact of the microbiome on RP disease activity. Additionally, patients with RP will have the opportunity to be evaluated by multiple subspecialties in a coordinated patient-centered manner.

Conclusion: The RP Foundation, University of Pennsylvania, and the Vasculitis Clinical Research Consortium (VCRC) Created a Powerhouse Healthcare Coalition. The Penn RP program will significantly improve the quality of my life and other RP patients for years to come.

Nancy Linn

The Relapsing Polychondritis Foundation formed a powerhouse healthcare coalition with the University of Pennsylvania and the NIH sponsored Vasculitis Clinical Research Consortium

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Arthritis research

POS1499-PARE PATIENT PERSPECTIVES OF BIOLOGIC TREATMENTS FOR AXIAL SPONDYLOARTHRITIS: SATISFACTION, WEAR-OFF BETWEEN DOSES, AND USE OF SUPPLEMENTAL MEDICATIONS

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Background: Biologic disease-modifying antirheumatic drug (bDMARD) therapy has been shown to be effective in the treatment of axial spondyloarthritis (axSpA).^{1,2} Little is understood about patients' experience of axSpA treatment from their own perspective.

Objectives: To characterize patient experiences and perspectives with bDMARD treatments for axSpA, including satisfaction, and use of supplementary treatments when wear-off between doses is perceived among those currently treated with bDMARD therapy.

Methods: Adult US participants (pts) within the ArthritisPower registry with physician-diagnosed axSpA were invited to complete electronic PRO measures, such as the BASDAI (0-10 scale, score ≥ 4 indicates suboptimal disease control), and an online survey about their perspectives of treatment. Analysis compared pt characteristics and treatment satisfaction by whether or not pt reported wear-off between bDMARD doses.

Results: 128 pts with axSpA and on bDMARD therapy met inclusion criteria of whom 82.8% were female, with mean age of 47 years. Mean BASDAI scores indicated poor disease control (6.4, SD 1.8), worse for those perceiving wear-off between doses compared with those who did not [6.8 (1.6) vs. 5.9 (2.0), $p=0.01$]. A majority of pts on a bDMARD reported being somewhat (57.8%) or very satisfied (26.6%) with their current axSpA treatment, and about 53.1% were satisfied with how well it controls axSpA-related pain. However, 60.9% ($n=78$) of pts reported that their current bDMARD typically wears off before the next dose. Treatment satisfaction was lower for pts experiencing wear-off compared to pts without wear-off (highly satisfied: 21.8% vs. 34%; somewhat satisfied: 60.3% vs. 54%; dissatisfied: 17.9% vs. 12%). 82.1% ($n=64$) of pts reporting wear-off used additional medications or supplements when that happened, chiefly NSAIDs (68.8%, $n=44$), muscle relaxers (42.2%, $n=27$) and/or opioids (37.5%, $n=24$). Among the 20 pts not satisfied with current axSpA treatment, side effects (6/20, 30.0%), or worry about risk of side effects (2/20, 10%) were the main reasons.

Conclusion: In a predominantly female sample of bDMARD-treated axSpA patients with high disease activity, most expressed satisfaction with treatment. However, most experienced wear-off between doses and took supplementary medications, including opioids, to manage.

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Table 1. Demographic and clinical characteristics by wear-off between bDMARD doses (n=128)

	Pts currently on bDMARD doses (N=128)	Wear-off between bDMARD doses (N=78)	No wear-off / Not sure (N=50)	p-value
	Number or mean (% or SD)			
Age	46.9 (10.3)	46.1 (9.2)	48.2 (11.8)	0.25
Female	106 (82.8)	69 (88.5)	37 (74.0)	0.03
White	115 (89.8)	70 (89.7)	45 (90.0)	0.96
Body Mass Index	30.9 (7.8)	31.2 (8.5)	30.4 (6.6)	0.57
Current Medications, addition to bDMARD				
Conventional Synthetic DMARD (e.g. methotrexate, sulfasalazine)	17 (13.3)	15 (19.2)	2 (4.0)	0.01
Prescription NSAID	59 (46.1)	39 (50.0)	20 (40.0)	0.27
Other prescription medication [*]	70 (54.7)	44 (56.4)	26 (52.0)	0.62
Noticed improvement in symptoms related to axSpA since starting current bDMARD	80 (62.5)	51 (65.4)	29 (58.0)	0.40
Noticed improvement in symptoms NOT related to axSpA since starting current bDMARD	40 (31.3)	22 (28.2)	18 (36.0)	0.35
BASDAI [‡]	6.4 (1.8)	6.8 (1.6)	5.9 (2.0)	0.01
PROMIS Pain Interference [‡]	65.3 (5.7)	66.0 (5.1)	64.3 (6.4)	0.09
PROMIS Physical Function [‡]	36.7 (5.6)	36.1 (5.3)	37.7 (5.8)	0.11
PROMIS Sleep Disturbance [‡]	59.8 (8.5)	61.2 (7.7)	57.6 (9.3)	0.02

^{*} Statistical significance between groups of pts who experienced wear-off between bDMARD or not, $p < 0.05$ [‡] Other prescription medications: muscle relaxers, nerve pain medications or anti-depressants, and opioids[‡] BASDAI is scored on a 0-10 scale with score ≥ 4 indicating suboptimal control of disease. PROMIS measures use T-score metric in which 50 is mean, 10 is standard deviation (SD), of US population; higher T-score = more of concept measured

Figure 1. Satisfaction with axSpA treatment by wear-off between bDMARD doses (n=128)