PRO Assessment of Rheumatoid Arthritis Patients' Experience With IV Administered Biologic Therapy

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ABSTRACT

Background: Patient-reported outcomes (PRO) are used to assess patient related benefit in clinical trials. It was recently reported that rheumatoid arthritis (RA) patients are equally receptive to intravenous (IV) or subcutaneous (SC) biologic treatment[1]. The objective of this study was to obtain PRO data to understand characteristics of patients who receive IV biologic agents for RA.

Methods: This was a questionnaire-based study conducted at a single rheumatology practice with extensive clinical trial experience. A total of 100 patients will be enrolled; 87 patients are included in this interim analysis. The inclusion criteria were: a diagnosis of RA with IV biologic use for >3 mo; ≥18 years age; able to read, write and speak English, willing to complete the questionnaire and a signed informed consent form. IV biologic treatment was per clinical practice; there were no treatment assignments and study drug was not supplied. The questionnaire had 30 questions; patients completed the questionnaire prior to receiving a regularly scheduled dose of IV biologic.

Results: The mean (±SD) age of patients in this interim analysis was 57.9 (±14.5) years with a mean disease duration of 10.6 (±8.5) years (range 0.7-45 years). Patients were Caucasian (36.8%), African American (28.7%), Latino/Hispanic (20.7%), Asian/Pacific Islander (1.1%) and 12.6% not identified. IV biologics used were infliximab (68%), rituximab (13%), tocilizumab (10%), abatacept (7%), golimumab (1%) and other (1%). The mean duration of current IV therapy was 4.0 (±3.2) years (range 0.1 to 16.0 years). Patients' favorability (1=Not Favorable, 5=Very favorable) perception of IV therapy BEFORE and AFTER starting IV therapy is shown. Amongst all patients (A), "Very Favorable" increased (p>0.05) from 31% to 65% after receiving IV therapy; the increase in "Very Favorable" was evident in patients with or without previous SC therapy (B).

The favorability scores (mean ±SD) of current IV therapies were: infliximab 4.7 (±0.6), abatacept 4.7 (±0.5), rituximab 4.3 (±1.0), golimumab 5 (n=1) and tocilizumab 3.9 (±1.5). Prior SC biologic users had similar responses to questions identifying advantages or disadvantages associated with receiving IV biologic therapy as those patients who were not previous SC biologic users.

Conclusions: These interim results suggest that among patients receiving IV biologic therapy for treatment of RA, there is a high degree of patient satisfaction, including a similar favorability perception of IV therapy among patients who switched from an SC to an IV biologic. Our results support the concept that when there is a shared decision making discussion with patients regarding biologic treatments, the option of IV therapies should be an essential part of that discussion and that the RA patient's perspective should be given meaningful consideration.

Note: The results presented in the poster represent the final study results with n = 100 patients enrolled. The final study results are consistent with the conclusions from the abstract interim results (n = 87 patients).

[1]Bolge SC et al. *Arthritis Rheum.* 2013;65 Suppl 10:1023

BACKGROUND

- Patient-reported outcomes (PRO) are increasingly used to assess patient related benefit in clinical trials and real world evidence-based studies
- A survey of rheumatoid arthritis (RA) patients showed similar receptiveness to receiving therapy by SC or IV routes: 16% were open only to SC therapy and 14% were open only to IV therapy (53% were open to either, 16% neither). Additionally, although 28% of RA patients preferred IV therapy, prescribers believed only 16% of RA patients preferred IV therapy.[1]
- More patients may be open to both SC and IV biologic therapy and more patients may prefer IV biologic therapy than rheumatologists currently believe[1]
- To further explore potential positive or negative attributes associated with intravenous administration of biologic therapies for inflammatory arthropathies (IA), we developed a questionnaire to explore patient perspectives regarding their treatment with an IV biologic to treat IA

OBJECTIVE

- The primary objective of this study was to obtain PRO information that may be used to better understand the characteristics of patients who have opted to receive IV biologic agents for their inflammatory arthritis

METHODS

- This was a single center, observational, noninterventional, patient-based questionnaire study
- The study was conducted over approximately 8 weeks at a single rheumatology practice with a large in-office infusion center and extensive clinical trial experience
- There were no restrictions with respect to the IV biologic used to treat patients' inflammatory arthritis
- IV biologic treatment was per clinical practice; there were no treatment assignments and study drug was not supplied
- A total of 100 patients were enrolled and completed the questionnaire
- Eligible patients met the following inclusion criteria: (1) had a diagnosis of inflammatory arthritis and were receiving IV biologic treatment for at least 3 months prior to screening, (2) were male or female of at least 18 years of age, (3) had the ability to understand and sign an informed consent form (ICF), (4) were willing to complete a paper questionnaire, and (5) had the ability to read, write, and speak English
- Patients were ineligible if they did not meet the inclusion criteria or met any of the following exclusion criteria: (1) had a serious concomitant illness that could otherwise interfere with the patient's ability to complete the questionnaire, or (2) were participating in any interventional investigational clinical trial
- The questionnaire had 30 questions developed to characterize and quantify the IV biologic patients' experience of receiving an IV administered therapy to treat their IA; patients completed the questionnaire prior to receiving a regularly scheduled dose of IV biologic

Statistical Analyses

- Version 3.2.1 of R was used for all analyses. Descriptive statistics were calculated for all variables in the study. Patients' favorability on IV treatment before and after starting IV therapy was compared using McNemar's test.

RESULTS

Demographics, Patient Characteristics and Current IV Infusion Therapy:

- The demographic characteristics of the patients enrolled in the study are shown in **Table 1**
- Health insurance status was reported as Medicare (39%), Medicaid (7%), Private (72%) (patients could have >1 type of insurance coverage). One patient (female aged 18 years) reported not having insurance.
- 31% of the patients had received a SC biologic prior to starting an IV biologic

Table 1. Demographic Characteristics of Patients Completing the PRO IV Questionnaire

Assessment (n=100 patients)	
Age, years (mean ± SD)	58.35 ± 14.64
Gender, M/F (%)	34/66
BMI, kg/m^2 (mean ± SD)	30.29 ± 5.98
Disease Duration, years (mean ± SD)	10.1 ± 8.13
Disease duration range (yrs)	0.67 - 45
Disease Diagnosis	
Rheumatoid Arthritis	68%
Ankylosing Spondylitis	9%
Psoriatic Arthritis	21%
Crohn's Disease/Inflammatory Arthritis	2%
Ethnicity	
Caucasian	38%
African American	28%
Latino/Hispanic	22%
Asian/Pacific Islander	1%
Not identified	11%
Percent of Patients Counseled on Medication Treatment Prior to Start	97%
Patients Counseled by:	
Doctor	97%
Nurse Practitioner or Nurse	37%
Provided Pamphlets to Read	60%
Provided Other Reading Material	32%

- BMI of patients was distributed across weight classifications as follows: Normal weight (BMI=18.5-24.9) 19%, Overweight (BMI=25.0-29.9) 39%, Obese Class I (BMI=30.0-34.9) 21%, Obese Class II (BMI=35.0-39.9) 12%, and Obese Class III (BMI=40+) 9%

Table 2. Patients' Reported Medical History

Medical History	Number of Subjects (n=100)
Heart Disease	7
Congestive Heart Failure	1
Hypertension	44
Insulin Dependent Diabetes	4
Non-Insulin Dependent Diabetes	11
Stroke	2
Peripheral Vascular Disease	5
Skin Cancer	8
Cancer	5
Hepatitis	3
Tuberculosis	0
Chronic Infection	3
Stomach/Duodenal Ulcer	9
COPD/Emphysema	5

Table 3. Patients' Reported Health Status (during the month prior to completing the PRO IV questionnaire)

Current Health	% of Patients (n=100)
1 (very poor health)	2
2	5
3	24
4	43
5 (perfect health)	26

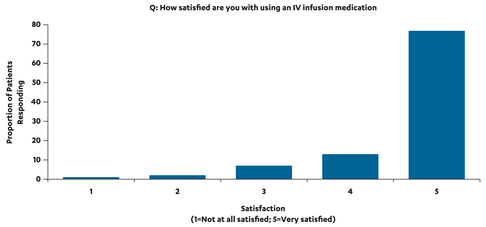
Table 4. Current IV Biologic Use

Current IV Biologic	% of Patients (n=100)	Duration of Use (years) Mean ± Std Dev	Range of Years of Use
Infliximab	71%	4.74 ± 3.45	0.33 - 16
Rituximab	12%	2.94 ± 1.86	0.08 - 6
Tocilizumab	10%	1.43 ± 1.58	0.08 - 4
Abatacept	6%	3.44 ± 2.49	0.25 - 6
Golimumab	1%	0.42 (n=1)	-

Patient-Reported Perceptions of IV Infusion Therapy:

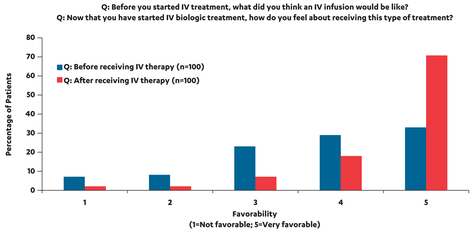
- The patient-reported level of satisfaction, based on a five point scale (1=Not at all satisfied, 5=Very satisfied) is shown in **Figure 1**
- 77% of patients were very satisfied with using an IV infusion medication and 1 patient (1%) indicated satisfaction as "not at all satisfied"
- The overall mean level of satisfaction with all currently used IV infusion therapies was 4.63 ± 0.79 (mean ± SD)
- Satisfaction scores (mean ± standard deviation) for individual current IV infusion therapies were: infliximab 4.76 (±0.60), abatacept 4.67 (±0.52), tocilizumab 4.00 (±1.41), rituximab 4.33 (±0.98) and golimumab 5.0 (n=1)

Figure 1. Satisfaction With IV Infusion Medication (n=100 patients)



- As recalled by patients currently receiving IV treatment, the mean favorability perception score of IV therapy prior to starting IV treatment was 3.73 ± 1.20 (mean ± standard deviation); the overall favorability perception score of IV treatment increased to 4.54 ± 0.87 after patients had started IV infusion therapy
- The distribution of reported favorability scores amongst all patients is shown in **Figure 2**
- There was a 2.15 fold increase in the reported level 5 (Very Favorable) score (from 33% to 71%) (p<0.0001)

Figure 2. Patients' Favorability Perception of Receiving IV Therapy: Before and After Starting IV Treatment



- Patients' favorability perception before and after initiating IV infusion therapy, based on whether patients had previously received an SC biologic to treat their IA is shown in **Figure 3**
- The increase in "Very Favorable" in patients with prior SC biologic use was from 32.26% of patients to 61.29% of patients (a 1.90 fold increase)
- Amongst patients without prior SC biologic use, "Very Favorable" increased from 33.33% of patients to 75.36% of patients (a 2.26 fold increase) after receiving IV infusion therapy

Figure 3. Patients' Favorability Perception of Receiving IV Therapy: by Prior SC Therapy Use

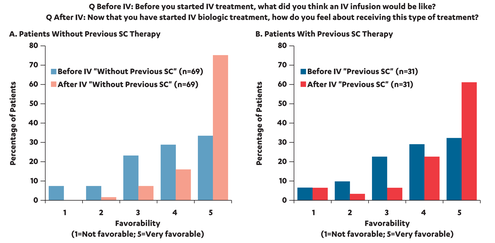


Figure 4. Distribution of Patient Responses to Questions Regarding Reasons Prior SC Biologic Users Switched From SC Administration to IV Administration

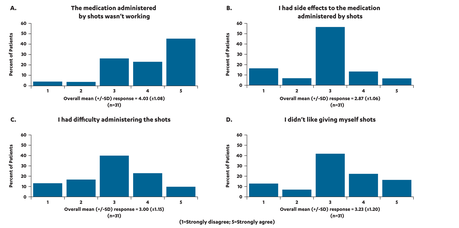


Table 5. Patient Responses to Perceptions of IV Medication to Treat Arthritis (Five point scale: 1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree)

Q: For each of the following statements about an IV medication for your arthritis, please indicate your response.	Mean ± SD (n=100)
My doctor felt strongly that an IV medication was the best choice for me.	4.55 (±0.67)
The doctor can adjust the dose of medication if needed.	4.49 (±0.82)
I believe that IV medications are strong medications.	4.24 (±0.78)
For my lifestyle, it is easier for me to schedule an appointment at an infusion center than to remember when to give myself shots.	4.17 (±1.10)
I believe an IV infusion would not be painful.	4.12 (±0.82)
Other medications did not control my symptoms.	4.06 (±0.91)
The infusion center is close to my home or office, making it convenient.	3.89 (±1.25)
I would be concerned about the risk of hurting or injuring myself if I had to give myself shots.	3.76 (±1.32)
I don't like needles and don't like the idea of having to give myself shots.	3.72 (±1.32)
My co-pay or out-of-pocket cost is lower with an IV infusion medication than medications that I would have to administer as shots.	3.53 (±1.00)

Table 6. Patient-Reported Potential Advantages to Receiving IV Infusion Therapy for IA (Five point scale: 1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree)

Q: To better understand what you consider to be the advantages of receiving your medication at an infusion center, please indicate your responses to the following.	All Patients (n=100)	No Previous Self-Injection: (n=69)	Previous Self-Injection: (n=31)
The medication is being administered by professionals who can monitor for any side effects.	4.79 (±0.50)	4.77 (±0.52)	4.84 (±0.45)
The staff at the infusion center keeps track of when I need my next dose of medication, and my next doctor's appointment and keeps me on schedule.	4.69 (±0.61)	4.67 (±0.68)	4.74 (±0.44)
The staff of medical professionals can assess how I am doing.	4.68 (±0.57)	4.67 (±0.59)	4.71 (±0.53)
The visit for my infusion provides another assessment beyond my regular doctor visit.	4.45 (±0.70)	4.36 (±0.75)	4.65 (±0.55)
I want to have a healthcare professional administer the medication to me.	4.44 (±0.81)	4.55 (±0.74)	4.19 (±0.91)
Infusion therapy is more consistent with my lifestyle.	4.21 (±0.99)	4.39 (±0.84)	3.81 (±1.17)
With IV therapy, I don't have to fear about injecting myself.	4.20 (±1.03)	4.48 (±0.87)	3.58 (±1.12)
I like being able to socialize with the staff and other patients at the infusion unit.	4.15 (±0.90)	4.22 (±0.91)	4.00 (±0.89)
The staff of medical professionals at the infusion center can also monitor my other medical conditions.	4.13 (±0.96)	4.16 (±0.93)	4.06 (±1.03)
The infrequent dosing is an advantage.	4.09 (±0.90)	4.22 (±0.81)	3.80 (±1.03)
Infusion therapy is less costly.	3.42 (±1.12)	3.58 (±1.12)	3.06 (±1.06)
I take advantage of other activities such as shopping or going out to eat on days when I have to go to the infusion center.	3.32 (±1.18)	3.39 (±1.24)	3.16 (±1.04)

Data shown are the mean ± SD.

Table 7. Patient-Reported Potential Disadvantages to Receiving IV Infusion Therapy for IA (Five point scale; 1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree)

Q: What do you consider to be the potential disadvantages of getting your medication by IV infusion? Please indicate your responses to the following.	All Patients (n=100)	No Previous Self-Injection: (n=69)	Previous Self-Injection: (n=31)
I have to travel to an infusion facility.	2.79 (±1.31)	2.74 (±1.29)	2.9 (±1.37)
The cost of the infusion, such as the co-insurance or co-pay costs.	2.55 (±1.22)	2.57 (±1.23)	2.52 (±1.21)
The infusion itself takes too much time.	2.47 (±1.15)	2.46 (±1.17)	2.48 (±1.12)
Frequent scheduling issues, such as time off work, finding a babysitter, etc.	2.30 (±1.16)	2.33 (±1.18)	2.23 (±1.12)
The cost of going to the infusion center, such as gas, parking, etc.	2.26 (±1.14)	2.22 (±1.15)	2.35 (±1.14
Missing several hours from work or school.	2.23 (±1.12)	2.32 (±1.13)	2.03 (±1.08)
I don't like seeing the IV needle.	2.22 (±1.12)	2.26 (±1.17)	2.13 (±0.99)
The loss of vacation days from work.	2.15 (±1.09)	2.23 (±1.11)	1.97 (±1.02)
The need for IV treatment reminds me that I am sick.	2.15 (±1.15)	2.13 (±1.16)	2.19 (±1.14)
I don't like being in a setting with other people who may be very ill.	1.97 (±0.95)	1.97 (±1.00)	1.97 (±0.84)
The IV infusion is difficult since I have poor veins.	1.92 (±1.08)	1.94 (±1.11)	1.87 (±1.02)

Data shown are the mean ± SD.

CONCLUSIONS

- The final study results (n=100) reported in this poster are consistent with the results from the abstract interim analysis (n=87)
- Compared to how they felt about IV therapy before they received it, there was a >2 fold increase in the "very favorable" rating after patients were receiving IV therapy
- Results suggest that among patients receiving IV biologic therapy for treatment of IA, there is a high degree of patient satisfaction, including a similar favorability perception of IV therapy among patients who switched from a SC to an IV biologic
- The results also indicate that patients regarded the IV biologic infusion experience as a positive opportunity to engage health care professionals, receiving an additional layer of hands on health care
- Our results support the concept that when there is a shared decision making discussion with patients regarding biologic treatments, the option of IV therapy should be an essential part of that discussion and that the IA patient's perspective should be given meaningful consideration

REFERENCE

1. Bolge SC, et al. Openness to and Preference for Biologic Therapy Among Patients With Rheumatoid Arthritis Prior to Biologic Initiation: Patient and Prescriber Perspectives. [abstract]. *Arthritis Rheum.* 2013;65(Suppl 10):1023 DOI: 10.1002/art.2013.65.issue-s10

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