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Patient Perspectives on Intravenous Biologics for Rheumatologic Disease

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Objective. Two surveys were conducted with patients with rheumatologic diseases to evaluate perceptions of different routes of administration (intravenous [IV] or subcutaneous [SC]) for biologic therapy.

Methods. In Survey I, patient preferences toward biologic treatment were evaluated at a rheumatology practice in Buffalo, New York. In Survey II, Canadian patients enrolled in the BioAdvance patient support program and scheduled to receive IV biologic therapy were asked about their opinions of IV treatment.

Results. In Survey I, 243 rheumatology patients participated. Median patient age was 60 years, 76% were female, and 44% were naive to treatment with biologic agents. Among biologic-naive patients, the majority (56%) were open to either SC or IV treatment; biologic-naive women were more likely than men to express a preference for the route of administration. In Survey II, 1,598 patients from the BioAdvance program (including 306 rheumatology patients) completed the full survey. Among the rheumatology patients, the median age was 49 years, 58% were female, and 61% had not previously taken biologics before enrolling in the BioAdvance program. The median rating of IV favorability (on a 10-point scale, with higher numbers indicating increased favorability) recalled by rheumatology patients was 5 prior to their first program infusion, which increased to 9 after multiple treatment infusions.

Conclusion. These survey results indicate that patients with rheumatoid arthritis are generally open to IV treatment and express high satisfaction with IV therapy. Additional patient and provider education may improve shared decision-making regarding biologic therapy administration options.

INTRODUCTION

Biologic therapies are the treatment of choice for moderate-to-severe cases of many rheumatologic diseases, including rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS), particularly in patients with an inadequate response to conventional disease-modifying antirheumatic drugs (DMARDs) (1–4). For RA patients with active disease despite conventional DMARDs, current recommendations do not specify a treatment of choice from among approved anti–tumor necrosis factor (anti-TNF) inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab, or infliximab) or the non-TNF options (e.g., abatacept, anakinra, rituximab, sarilumab, tocilizumab, and tofacitinib) in some cases (1,2). The choice of biologic therapy for each patient is generally based on consideration of patient-related factors, disease-related factors, the mechanism of action of the prescribed medication, and patient preferences for treatment (5–9).

One of the key factors influencing patient preference for biologic therapy is the route of administration (i.e., intravenous [IV] or subcutaneous [SC]) (9–11). Biologics generally exhibit comparable efficacy, despite differences in route of administration (12). Thus, patients' and rheumatologists' preferences for route of administration may play a role in driving the choice of biologic treatment; however, rheumatologists' and patients' perspectives on various routes of administration may differ. In 1 study in the US, evaluating perceptions of biologic therapy among patients with RA and

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SIGNIFICANCE & INNOVATIONS

- A general preference for subcutaneous biologic therapies has previously been reported among rheumatology patients.
- Results of the current surveys indicate that rheumatoid arthritis patients, including biologic-naive patients, are generally open to intravenous or subcutaneous treatment.
- Patients receiving intravenous therapy express high satisfaction with this route of administration.

rheumatologists, 53% of patients reported being open to both IV infusion and SC injections, while only 41% of rheumatologists reported that patients would be open to either route of administration (10). Approximately 28% of surveyed patients reported preferring IV treatment, while the rheumatologists reported that only 16% of their patients would prefer IV therapy (10).

Although a general preference for SC biologic therapies has been reported among rheumatology patients, among those who have experienced IV therapy, there is some evidence that most have favorable opinions of the IV route of administration (13–15). In a Danish study, IV therapy was preferred by 85% of patients already receiving IV treatment (15). In another recent study evaluating the characteristics of US patients with inflammatory arthritis (e.g., RA, PsA, or AS) who had been receiving IV biologic treatment ($n = 100$) ranging in duration from 0.08 to 16 years, approximately 80% of patients reported being very satisfied with their IV infusions (16). In that study, patients' perception of IV therapy improved considerably after starting treatment; only 33% of patients reported an extremely favorable view of IV therapy prior to treatment, while 71% reported an extremely favorable view after receiving therapy. Advantages of IV therapy reported by patients included medication administration by a health care provider in the infusion setting, as well as having regular on-site monitoring of health status and potential side effects. In general, patients did not consider the time required for travel to infusion centers, infusion durations, or time missed from work or school to be major disadvantages of IV therapy.

Two surveys were conducted to further assess trends regarding rheumatology patient preferences for SC and IV biologic treatment. The aim of Survey I was to evaluate preferences for route of administration of biologics among rheumatology patients at a clinical practice in the US, while the aim of Survey II was to evaluate perceptions of receiving IV biologic therapy among rheumatology patients in a Janssen-sponsored infusion clinic and treatment support program (BioAdvance). Results of both surveys are presented here.

PATIENTS AND METHODS

Survey I: In-office patient preferences for biologic route of administration in a rheumatology practice. Survey I was a 20-item survey assessing patient preferences and adherence to treatment (see Supplementary Appendix 1, available on the *Arthritis Care & Research* web site at http://onlinelibrary.wiley.com/doi/10.1002/acr.23758/abstract) and was administered to patients seen in a suburban rheumatology practice in Greater Buffalo, New York from January through March 2015. The survey was distributed at a single-specialty rheumatology practice consisting of 4 rheumatologists and 4 nurse practitioners at 2 offices. The survey was distributed to patients with rheumatic diseases, including RA, PsA, AS, systemic lupus erythematosus, and other diseases. This survey included biologic-naive patients as well as patients who were currently or previously receiving an IV or SC treatment. Patients completed the survey voluntarily in the waiting room prior to their visit. Surveys were reported anonymously; patients provided informed consent for demographic information to be captured from their chart (based on an identifying number) if they did not provide that data in their survey.

This survey was approved by the Mercy Hospital of Buffalo Institutional Review Board. Data analyses were performed using Excel software with the Data Analysis ToolPak. For demographic characteristics, continuous outcomes were summarized using descriptive statistics (median, range, mean, and SD), and categorical outcomes were summarized using percentages. For responses to survey questions about patient preference and adherence, results were summarized as percentages reporting each response. Statistical testing included *t*-tests and analysis of variance. *P* values less than 0.05 were considered significant.

Survey II: Patient perceptions of IV therapy in the BioAdvance treatment support program. During an approximately 2.5-month period (May 5 to July 18, 2014), nearly 10,000 patients were invited to participate in an online survey (Survey II) regarding their experiences with IV infusion and the Janssen-sponsored BioAdvance program (17). All invited patients were receiving infliximab treatment at 192 clinics across Canada and were enrolled in the BioAdvance patient support program, which provides support for Canadian patients scheduled to receive IV infusions of infliximab, golimumab, or ustekinumab for any approved indication (17). The BioAdvance program streamlines the care process for both the provider and patient, incorporating a prebiologic checklist, standard administration protocol for infusion clinic staff, injection/infusion education, continuous monitoring, and reminder calls for patients, while allowing patients to have a flexible clinic selection. Written informed consent was provided by all participants or their legal guardians (17).

Survey II included a total of 28 questions, including 11 related to patient characteristics and disease, health status, and treatment characteristics, and 17 questions related to patient perceptions of their experience prior to and after multiple IV administrations in the BioAdvance program (17).

The results of the full survey, which largely included patients with inflammatory bowel disease (e.g., Crohn's disease and ulcerative colitis) who were receiving IV treatment in the BioAdvance program, have been published previously (17). In the full survey, the majority of patients (75.5%) had received ≥1 year of infliximab treatment (to be taken every 8 weeks after induction doses at 0, 2, and 6 weeks) in the BioAdvance program (17). Patients completed the surveys online, and all identifying information was removed from the survey results (17). This survey was reviewed by an institutional review board. Data analyses were performed using SAS software, version 9.2 (17). For demographic characteristics, continuous outcomes were summarized using descriptive statistics (median, range, mean, and SD), and categorical outcomes were summarized using percentages. For responses to survey questions about patient preference and adherence, results were summarized as percentages reporting each response.

RESULTS

Survey I. *Patients.* A total of 243 rheumatology patients completed the patient preferences survey. Baseline and demographic characteristics are shown in Table 1. The majority of patients were female (76%), 49% were ages >60 years, 81% had a diagnosis of RA, and 44% of the 243 were biologic naive.

Route of administration preference. When biologic-naive patients (n = 107) were asked whether they would be open to SC biologic therapy to be self-injected every 1 to 2 weeks, 63% reported being open to some degree: 31% reported being somewhat open, 13% were very open, and 18% were extremely open. When biologic-naive patients were asked whether they would be open to an IV biologic infusion every 1 to 2 months, 75% reported being at least somewhat open: 36% somewhat open, 21% very open, and 18% extremely open. In all, 56% of biologic-naive patients reported being open (i.e., somewhat, very, or extremely) to both SC and IV biologic therapy. A total of 7% of patients were open to SC treatment only, and 18% of patients were open to IV treatment only. Among biologic-naive patients who expressed a preference (n = 54), a significantly higher percentage of patients preferred IV biologic therapy (65%) compared with SC biologic therapy (35%; $P < 0.01$).

When route of administration preferences were evaluated by sex among biologic-naive patients, the proportion of patients who did not express a preference was higher among men (64%) than among women (43%), although the difference did not reach statistical significance ($P = 0.10$). Among biologic-naive women who expressed a preference, a significantly higher percentage preferred IV biologic therapy (65%) compared with SC biologic therapy (35%; $P < 0.01$). Among biologic-naive men expressing a preference, the percentage who preferred IV biologic therapy (63%) did not differ significantly from the percentage who preferred SC biologic therapy (38%; $P = 0.35$) (Figure 1A). Among all biologic-naive patients (both sexes) who expressed a route of administration preference, the proportion who preferred IV therapy increased with age, as nearly equal numbers of patients age ≤60 years endorsed SC and IV routes, while approximately 3.4 times as many patients age >60 years preferred IV (Figure 1B).

When route of administration preferences were evaluated for patients already receiving biologic therapy (i.e., biologics experienced), 50% of patients who were currently receiving SC preferred SC therapy, with 33% expressing no preference, while 58% of patients who were currently receiving IV therapy preferred IV therapy, with 29% expressing no preference.

In the overall cohort of patients who completed the survey and reported a preference, a significantly higher percentage of patients with RA preferred IV therapy (62%) compared with SC therapy (38%; $P = 0.0004$). In contrast, among patients with PsA, a significantly higher percentage of patients preferred SC therapy (82%) compared with IV therapy (18%; $P < 0.0001$). Only 6 patients with AS reported a preference, with 50% preferring SC therapy and 50% preferring IV infusion.

Adherence with SC therapy was assessed with the following question: "Assuming you are not having surgery and do not have an infection, how frequently do you give yourself your shot exactly as prescribed?" Patients who were not currently receiving home-based SC treatment were instructed to skip this question; of the 73 patients who did respond, most reported taking their shot (injection) exactly as they were

Table 1. Survey I: patient baseline and demographic characteristics*

Characteristic	Values (n = 243)
Age, years	
Median (range)	60 (19–92)
Mean ± SD	59.8 ± 12.8
Age group	
<40	7
40–60	44
>60	49
Sex	
Female	76
Male	24
Disease state†	
Rheumatoid arthritis	81
Psoriatic arthritis	13
Ankylosing spondylitis	5
Current medications	
Methotrexate	55
Biologics	50

* Values are the percentage, unless indicated otherwise.
† Patients could report >1 disease state. Percentages do not add up to 100%; 5 patients reported having systemic lupus erythematosus only, 6 patients reported having undifferentiated spondyloarthropathies, and 34 patients reported multiple diagnoses.

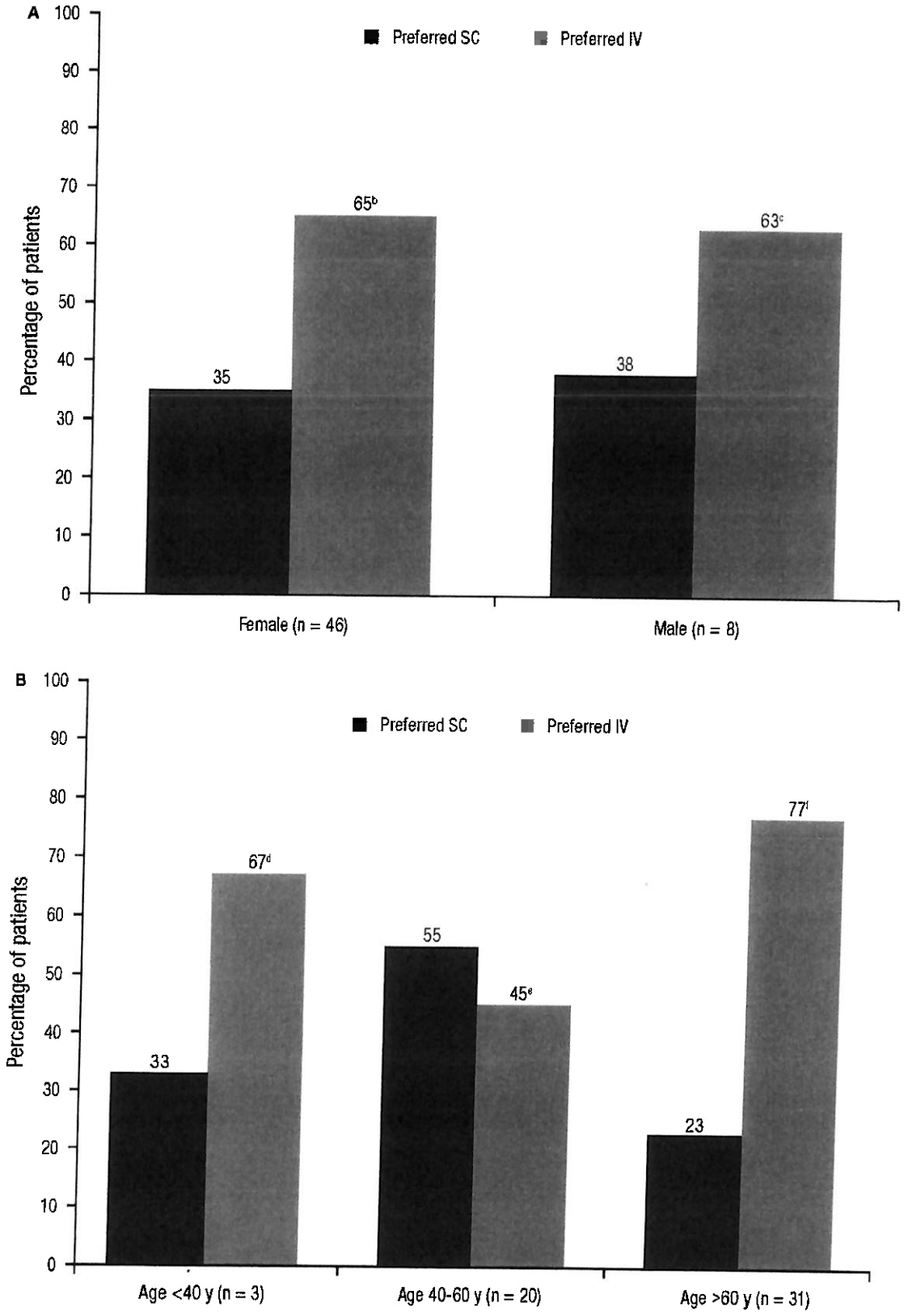

Figure 1. Survey I: biologic-naive patient preferences for subcutaneous (SC) or intravenous (IV) biologic therapy among patients who expressed a preference by sex (**A**) and age group (**B**). Patients who reported that they did not have a preference and would consider either option or were unwilling to consider either option were excluded from these analyses. b indicates $P < 0.01$ versus proportion preferring SC biologic therapy; c indicates $P = 0.35$ versus proportion preferring SC biologic therapy; d indicates $P = 0.52$ versus proportion preferring SC biologic therapy; e indicates $P = 0.54$ versus proportion preferring SC biologic therapy; f indicates $P < 0.01$ versus proportion preferring SC biologic therapy.

Table 2. Survey II: patient baseline and demographic characteristics*

Characteristic	AS (n = 113)	PsA (n = 74)	RA (n = 119)	Overall rheumatic diseases (n = 306)
Age, years				
Median (range)	44 (18–69)	49 (23–69)	54 (20–81)	49 (18–81)
Mean ± SD	45.0 ± 11.4	49.0 ± 11.5	51.8 ± 14.0	48.6 ± 12.8
Age group				
<40	33	27	24	28
40–60	56	55	47	52
>60	12	18	29	20
Sex				
Male	68	35	21	42
Female	32	65	79	58
Health rating†				
Median (IQR)	7 (6–9)	7 (6–8)	7 (6–9)	7 (6–9)
Mean ± SD	7.2 ± 1.9	6.8 ± 2.0	6.9 ± 2.3	7.0 ± 2.1
Category				
1–4	6	12	14	11
5–6	26	35	15	24
7–8	39	35	44	40
9–10	29	18	27	25
Infliximab treatment, duration‡				
0–2 months	5	5	7	6
3–6 months	7	10	4	7
7–11 months	8	7	7	7
1–2 years	13	14	10	12
>2 years	66	64	72	68
No. of prior biologic therapies§				
None¶	66	42	69	61
1	18	27	16	20
2	12	19	8	12
3	2	10	3	4
>3	3	3	4	3
Employment status				
Full-time	49	27	37	39
Part-time	12	15	8	11
Student	3	1	3	2
Retired	12	15	29	19
Long-term disability	20	28	15	20
Unemployed	5	12	8	8

* Values are the percentage, unless indicated otherwise. Percentages may not total 100%, due to rounding. AS = ankylosing spondylitis; PsA = psoriatic arthritis; RA = rheumatoid arthritis; IQR = interquartile range.
† Possible health rating ranged from 0 to 10, with higher scores indicating better health.
‡ AS: n = 112; PsA: n = 73; RA: n = 118; overall rheumatic diseases: n = 303.
§ AS: n = 111; PsA: n = 72; RA: n = 116; overall rheumatic diseases: n = 300.
¶ Patients had received no prior biologics before initiating intravenous treatment in the BioAdvance program.

supposed to all of the time (58%), or most of the time (41%), with only 1 patient (1%) reporting a lack of adherence with SC treatment ("I'm somewhat casual about giving myself a shot, and I take it primarily when I feel I need it"). When the data were analyzed by age, all patients age <40 years (n = 11) and >60 years (n = 31) reported adherence with treatment most or all of the time; 97% of patients ages 40–60 years (n = 31) reported adherence with treatment most or all of the time.

Survey II. *Patients.* Of 10,000 invitations, 1,712 responses to Survey II were provided by patients receiving IV therapy for any indication from clinics enrolled in the BioAdvance program (17). A total of 1,598 patients completed the full survey. In all, 306 patients with rheumatic diseases completed the full survey (RA: n = 119; AS: n = 113; PsA: n = 74). Nearly all of these patients (99%) were receiving IV infliximab after enrolling in the BioAdvance program. Baseline and demographic characteristics for patients with rheumatic diseases who completed full surveys are shown in Table 2. Among patients with rheumatic diseases, the population with RA was the oldest (median age 54 years [range 20–81 years]) and had the smallest proportion of male patients (21%) (Table 2). The population with AS was the youngest (median age 44 years [range 18–69 years]) and had the highest proportion of male patients (68%). Fewer than 40% of patients with rheumatic diseases were employed full-time, 19% were retired, and 20% were on disability.

The proportion of patients with rheumatic diseases with a health rating of 7 or greater (possible score 0 to 10, with higher scores indicating better health) ranged from 53% (for patients with PsA) to 71% (for patients with RA) (Table 2). The majority of patients (80%) with rheumatic diseases had been receiving infliximab treatment for 1 year or more.

Patient perceptions of IV therapy in the BioAdvance treatment program. The proportion of patients with rheumatic diseases who felt that their time commitment to obtain IV biologic therapy was highly worthwhile (score of 9 of a possible total score of 10) increased after having received multiple IV infusions. Based on recall, 38.2% of patients reported that their time commitment to IV biologic therapy was highly worthwhile prior to therapy, compared with 66% who rated their time commitment as highly worthwhile after multiple IV infusions (Figure 2A). Patients with rheumatic diseases who believed that the time commitment required for IV therapy was highly worthwhile (score of at least 9) typically maintained that belief, while 84% of patients who did not see their time commitment as worthwhile (score of 1 to 6) prior to therapy increased their rating by at least 1 point, with 77% of patients increasing their rating to 7 or greater, after undergoing IV infusions in the BioAdvance program.

Prior to their first IV infusion, the median patient rating of IV favorability (based on recall) was 5 of a possible score of 10 (with higher numbers indicating increased favorability). After multiple treatment infusions, the median rating increased to 9 of 10. The proportion of patients with rheumatic diseases with a highly positive impression of IV infusions (score of 9) increased after having received multiple IV infusions. Based on recall, 16% of patients reported a highly favorable rating for their impression of IV therapy in general (score of at least 9) prior to treatment, while 57.2% reported a highly favorable rating after multiple IV infusions (Figure 2B). The proportion of patients with rheumatic diseases with a highly positive perception (score of at least 9) of IV therapy prior to initiating IV treatment mainly remained positive, while 94% of patients who had a negative perception (score of 1 to 6) prior to therapy increased their rating by at least 1 point, with 88% of patients increasing their rating to 7 or greater, after undergoing infusions in the BioAdvance program. On average, patients reported that having a health care practitioner on site at the BioAdvance clinic was very important to them (median score 9 [range 1–9]), based on a Likert scale of 1 (not important at all) to 10 (extremely important). Using the same Likert scale, patients rated the importance of spending time with other patients in the BioAdvance clinic as only moderately important (median score 5 [range 1–9]).

DISCUSSION

The 2 surveys presented here directly evaluated patient preferences regarding mode of administration (SC or IV) for biologic treatment among patients with rheumatic diseases in the US and Canada. Based on the results of Survey I, most biologic-naive patients (56%) were open to either SC or IV biologic therapy. These results were in keeping with findings of a previous study evaluating the perceptions of biologic therapy among US patients with RA, which showed that 53% of patients were open to either SC or IV therapy (10). In Survey I, a higher proportion of biologic-naive patients overall expressed a preference for IV therapy than for SC therapy, although preferences varied by age, sex, and disease state. Younger patients (age <40 years) showed a strong preference for SC therapy; however, younger patients with rheumatic diseases have previously been shown to be less adherent to SC biologic treatment than older patients (18,19). In general, female patients were more likely to state a preference for the route of administration of their biologic treatment than male patients, suggesting that men were more likely to allow their physician to decide the best route of administration. The specific disease state also appeared to affect patient preferences for route of administration; IV therapy was preferred by a higher proportion of patients with RA, while SC therapy was preferred by a higher proportion of patients with PsA. In a survey reported recently by Gaylis et al (16), patients with inflammatory arthritis reported a number of perceived advantages with IV therapy, including additional monitoring by health care staff, the immediate availability of health care resources, less frequent dosing, ease of scheduling administrations, and reduced fear of self-injection.

Results of Survey II were also consistent with previous data in the literature (16) regarding patients' acceptance of IV therapy; Canadian patients with rheumatic diseases surveyed generally reported very favorable perceptions of IV therapy and felt that the time commitment to obtain biologic therapy was highly worthwhile, and perceptions of IV therapy and the associated time commitment improved favorably after receiving multiple infusions in the program.

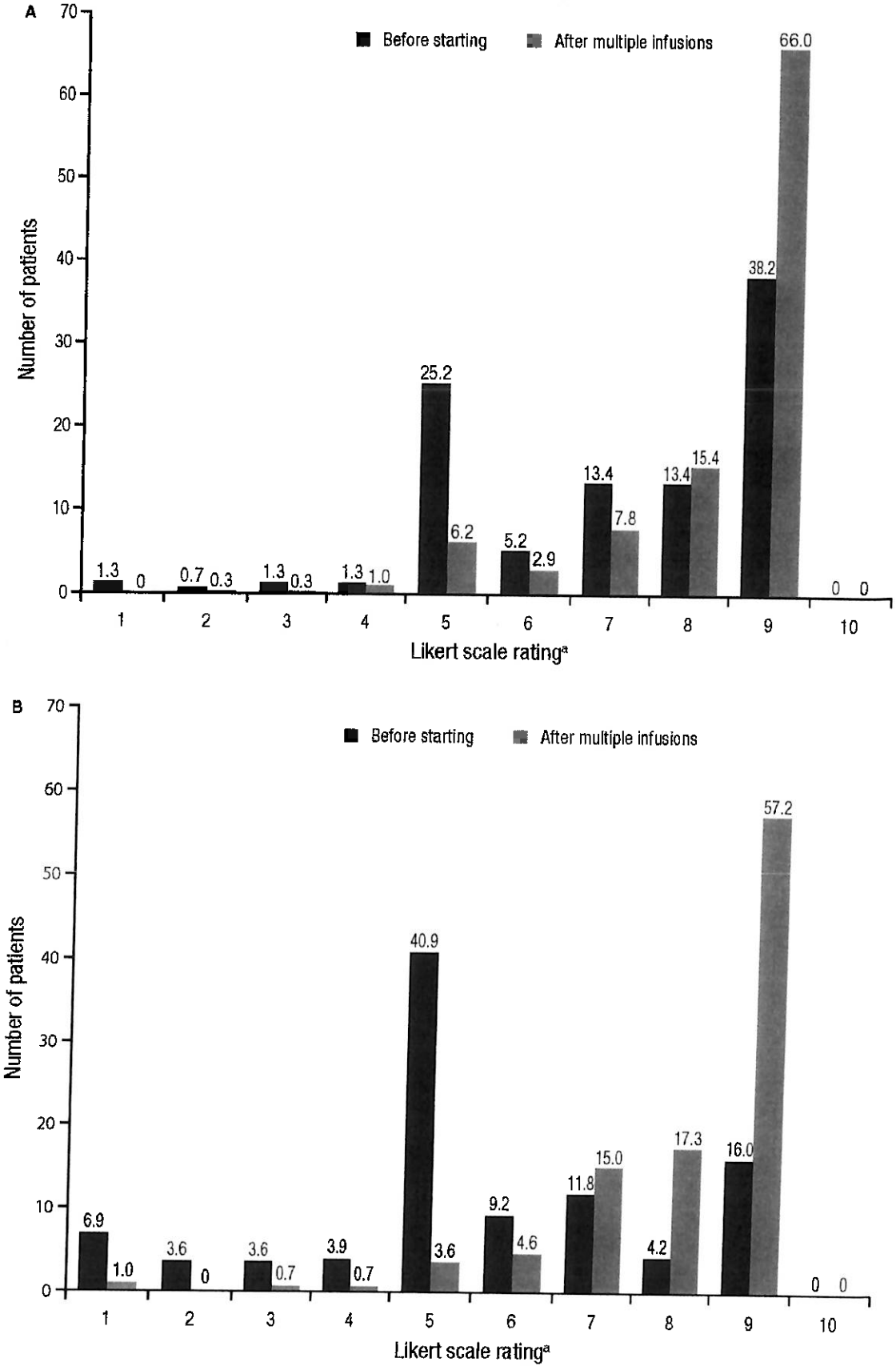

Figure 2. Survey II: proportion of patients with rheumatic diseases, with their impressions of time commitment required for intravenous infusion (**A**), and intravenous infusions in general (**B**). a = Scale of 0 to 10, with higher scores indicating a higher rating.

Results of both surveys reported here indicate that patients with inflammatory arthropathies generally have favorable perceptions of IV therapy. Based on the authors' clinical experience, patient education and convenience appear to be factors driving the choice of treatment modality; biologic-naive patients may be unaware of the option of IV biologic therapy or perceive home-based SC biologic therapy as a safer option than IV therapy. In a previous study of 500 patients with RA, less than half of patients reported receiving information about alternative biologic therapies (specifically, anti-TNF agents) from their physicians (20). Thus, patient education regarding IV biologics as an option for treatment could represent a key unmet need. Results from the previous literature on patient and physician preferences for biologic therapy suggest a disconnect in patient and physician perceptions (21). Results of the 2 surveys reported here, along with the results of previous patient preference studies (8–10,15,20–22) may address this disconnect by providing physicians with information regarding patients' attitudes and concerns around different rheumatology treatments. This understanding of the patient perspective may help guide physicians' discussions with their patients about different biologic therapy options.

To facilitate patient-centered, collaborative care of rheumatology patients, the choice of IV versus SC therapy should be discussed as part of a shared decision-making process. In Survey II, most patients, particularly those who had received multiple infusions, perceived the time commitment required for IV therapy as highly worthwhile, which may be related both to the effects of consistent biologic treatment and regular contact with a health care provider.

As previously noted, there is often a disconnect between patient and physician perceptions of IV therapy, with physicians presenting a more negative perception of IV therapy than that of patients who have been receiving IV therapy (10,21). Bridging this gap in patient and provider communication to ensure that the benefits, as well as risks, of both IV and SC options are presented to patients, to allow for a more balanced decision-making process, could assist with improving biologic treatment adherence and outcomes.

Another key aspect of biologic therapy to be considered is adherence to therapy. Adherence to treatments for RA remains problematic; in a recent meta-analysis, an overall adherence rate of 66% for all evaluated therapeutics (biologics, conventional DMARDs, steroids, and nonsteroidal antiinflammatory drugs) was reported (23). Adherence to treatment could be more readily monitored for patients receiving IV therapy at an infusion center than for those self-administering SC therapy; however, studies of the impact of the different routes of administration on adherence are generally lacking. In addition to the perceived benefit for potentially improving patient adherence to treatment, increased oversight of patients by health care providers in an infusion center may allow better management of patients' overall health and the ability to rapidly address any potential side effects of treatment. This concept is supported by the results of Survey II, in which patients reported that having a health care provider on-site at the infusion center was important to them. In addition, a recent study by Gaylis et al (16) showed that patients believed that medication administration by a health care provider in the infusion setting, as well as having regular on-site monitoring of health status and potential side effects, were key benefits of IV therapy. However, while patients perceived an advantage to receiving treatment at an IV center, more research will be needed to demonstrate an association with general health or rheumatology outcomes.

The findings of the current surveys in patients with rheumatic diseases could potentially be applied to other specialties. For example, in patients with inflammatory bowel disease, findings regarding patient preference for IV or SC treatment are conflicting (24,25). In 1 survey evaluating preferences for route of administration of anti-TNFs in 78 patients with Crohn's disease, 42% of patients preferred the IV option while 24% preferred the SC option (25). In a separate survey of 100 patients with Crohn's disease, 64% preferred an SC anti-TNF, while 25% preferred an IV anti-TNF (24). These conflicting results suggest that patients with inflammatory bowel disease may experience similar challenges in treatment decision-making as those identified for patients with rheumatic diseases, and that broad education about IV and SC biologic options could be valuable for this patient population as well.

The results of these 2 surveys were subject to certain limitations. Some of the questions in these surveys were based on patient recall. Patient preferences for mode of administration may have been affected by experiences with prior or current treatments for other conditions. In Survey I, the results for the overall cohort of rheumatology patients may have been influenced by other factors (e.g., sex, disease state). Survey II included only patients in the BioAdvance program. Their perceptions may have been influenced by multiple different factors specifically related to the program, such as interactions with the BioAdvance coordinator and participating physicians. Furthermore, there may be systemic differences in how health care is administered in Canada that may not be applicable in other countries.

Taken together, results of the current surveys indicate that rheumatology patients are generally open to IV treatment and express high satisfaction with IV therapy. Based on these data and the authors' many years of combined clinical experience, we believe that additional patient and provider education may contribute to an improved shared decision-making process for the patient.

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AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published. Dr. J. Grisanti had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. L. Grisanti, Kwiatkowski, Dyrda, J. Grisanti, Gaylis.

Acquisition of data. L. Grisanti, Dyrda, J. Grisanti, Dehoratius, Gaylis.

Analysis and interpretation of data. L. Grisanti, Kwiatkowski, Dyrda, Field, J. Grisanti, Hatem, Dehoratius, Gaylis.

ROLE OF THE STUDY SPONSOR

Employees of Janssen, Inc., were involved in the design of Survey II and the collection, analysis, and interpretation of the data from that survey. All authors participated in the writing of the manuscript and decision to submit the manuscript for publication. Publication of this article was not contingent upon approval by Janssen, Inc.

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