





Patient and Healthcare Professional Satisfaction, Acceptability, and Preference Experiences With Mirikizumab Administration for Ulcerative Colitis: An International Survey

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Background: There is a need to better understand ulcerative colitis (UC) patient and healthcare provider (HCP) treatment satisfaction, acceptability, and preferences.

Methods: Two international, cross-sectional, web-based surveys were conducted among participants of a phase 3 mirikizumab study (NCT03519945). The questions captured moderate-to-severe UC patients' experience, HCPs' perception of patients' experience, and HCPs' own experience with mirikizumab administration through intravenous (IV) infusions and subcutaneous (SC) injections.

Results: Respondents included 93 patients and 42 HCPs from 11 countries. The majority of patients had UC >4 years (74.2%), were bionative (68%), in remission at the time of the survey (63%). HCPs were primarily from the United States (57%), generally nurses (41%) or gastroenterologists (26%) with ≥6 years of experience in treating UC (57%). Most patients were "very satisfied/satisfied" (IV, 83%; SC, 91%), "completely/somewhat" accepting of mirikizumab administration (IV, 87%; SC, 97%), and agreed that improvement to their UC outweighed any administration dissatisfaction (90%). HCPs' perspectives of patients' experiences were higher: "very satisfied/satisfied" (IV, 93%; SC, 100%); "completely/somewhat" accepting (IV, 90%; SC, 98%). HCPs themselves were "very satisfied/satisfied" (IV, 81%; SC, 95%); gastroenterologists were "very satisfied" (IV, 82%; SC, 82%) more than nurses (IV, 29%; SC, 65%) who were generally at least "satisfied" (IV, 53%; SC, 35%). Two SC and monthly SC injections were "completely acceptable" by the patients (76% and 85%) and per HCPs' perceptions of patients' preferences (69% and 100%).

Conclusions: Both patients and HCPs were satisfied with and accepted mirikizumab IV induction followed by monthly maintenance SC injections. UC improvement outweighed any administration dissatisfaction.

Lay summary

Most patients with ulcerative colitis (UC) and their healthcare providers were satisfied and accepted mirikizumab intravenous infusion and subcutaneous injection, including monthly dosing with 2 injections. Over 90% of patients reported that UC improvement outweighed any administration dissatisfaction.

Key Words: administration, dosing, injection, infusion, mirikizumab

Introduction

Ulcerative colitis (UC) therapy options have significantly advanced during the past decades.¹ A large variety of treatment alternatives are available in different formulations, with different routes and frequencies of administration.^{2–5} These include conventional therapy with aminosalicylates, glucocorticoids, immunomodulators, and TNF- α inhibitors as well as the most recent biologics (IL-12/23, IL-23, and integrin inhibitors) and small molecules (Janus kinase inhibitors and sphingosine-1-phosphate receptor

agonists) that have improved the management of patients with UC because they addressed specific pathogenetic mechanisms.^{4–8}

However, many patients do not respond to induction therapy or lose response during the maintenance treatment period.^{9–11} Moreover, some of these targeted therapies may not be suitable for a specific patient due to their medical history or medication risk profile.^{2,6,9,12,13} Consequently, finding more effective medications is still a therapeutic need that has not been satisfied.¹⁴

Received for publication: April 18, 2024. Editorial Decision: August 26, 2024

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Mirikizumab is a humanized IgG4 monoclonal antibody directed against the p19 subunit of IL-23, a signaling cytokine involved in the inflammatory cascade associated with UC.¹⁵⁻¹⁷ Mirikizumab was recently approved for the treatment of moderately-to-severely active UC. It is administered intravenously (IV) during induction and subcutaneously (SC) during maintenance.^{18,19} Mirikizumab demonstrated significant clinical remission, compared to placebo, at week 12 of the induction trial (24.2% vs 13.3%, $P < 0.001$) and week 40 of the maintenance trial after 52 weeks of continuous treatment (49.9% vs 25.1%, $P < 0.001$), with an acceptable safety profile associated with a positive benefit-risk ratio.²⁰

Despite the many years of rigorous clinical research on novel medications, there is little evidence of UC treatment administration preferences and associated satisfaction with treatment administration. Such information is important for making educated treatment decisions, particularly when there are multiple alternatives available.¹ Moreover, perceptual differences between patients and their treating physicians may result in patients having suboptimal treatment.^{21,22}

To understand mirikizumab treatment administration satisfaction, acceptability, and preferences, 2 surveys were conducted: (1) a patient survey among patients with UC receiving mirikizumab and (2) a healthcare provider (HCP) survey to capture their perspectives on their patients' experiences as well as their own experiences. The study examined the differences in perceptions about treatment administration between patients and HCPs, explored differences between patients based on key clinical history and sociodemographic differences, and explored patient and HCP beliefs regarding benefit versus mirikizumab administration burden.

Methods

Study Design

This study involved 2 international, cross-sectional, non-interventional, web-based one-time surveys among patients with moderately-to-severely active UC and their treating HCPs.

The optional surveys were included as a protocol addendum substudy to LUCENT-3 (AMAP), a phase 3, multicenter, open-label, 160-week, long-term extension study evaluating the efficacy and safety of mirikizumab (NCT03519945).²⁰ All eligible patients and HCPs were offered the opportunity to complete the surveys, however, it was not a LUCENT-3 study protocol requirement.

The patient survey evaluated patients' experiences with mirikizumab administration. The HCP survey assessed HCPs' perceptions of patients' experiences as well as the HCPs' own experiences. Both surveys were administered from October 2022 to July 2023 and took approximately 30 minutes to complete.

Participants

Participants in the LUCENT-3 study were recruited from among the completers of 2 previous multicenter, double-blind, placebo-controlled mirikizumab studies in patients with moderately-to-severely active UC who were allowed to have prior exposure to a biological agent: (1) the phase 2 induction and maintenance study (AMAC, NCT02589665),^{18,23} and (2) the phase 3 withdrawal maintenance study (LUCENT-2 [AMBG], NCT03524092) in which the enrolled patients had completed a previous induction phase 3 study (LUCENT-1 [AMAN], NCT03518086; Figure 1). Mirikizumab was administered during induction as a 300 mg (20 mg/mL) intravenous (IV) infusion once every 4 weeks for 3 total infusions.¹⁸ During maintenance, mirikizumab was administered as a 200 mg subcutaneous (SC) injection delivered in 2 consecutive 100 mg/mL injections every 4 weeks (Figures 2 and 3).

Patients could participate in the survey if they gave written informed consent, were actively enrolled and participating in LUCENT-3, were willing and able to complete the web-based survey, were able to read and enter digital responses to complete the survey, and had access to the internet and a computer, tablet, or mobile device.

HCPs could participate in the survey if they were physicians, nurses, or other site support staff responsible for administering

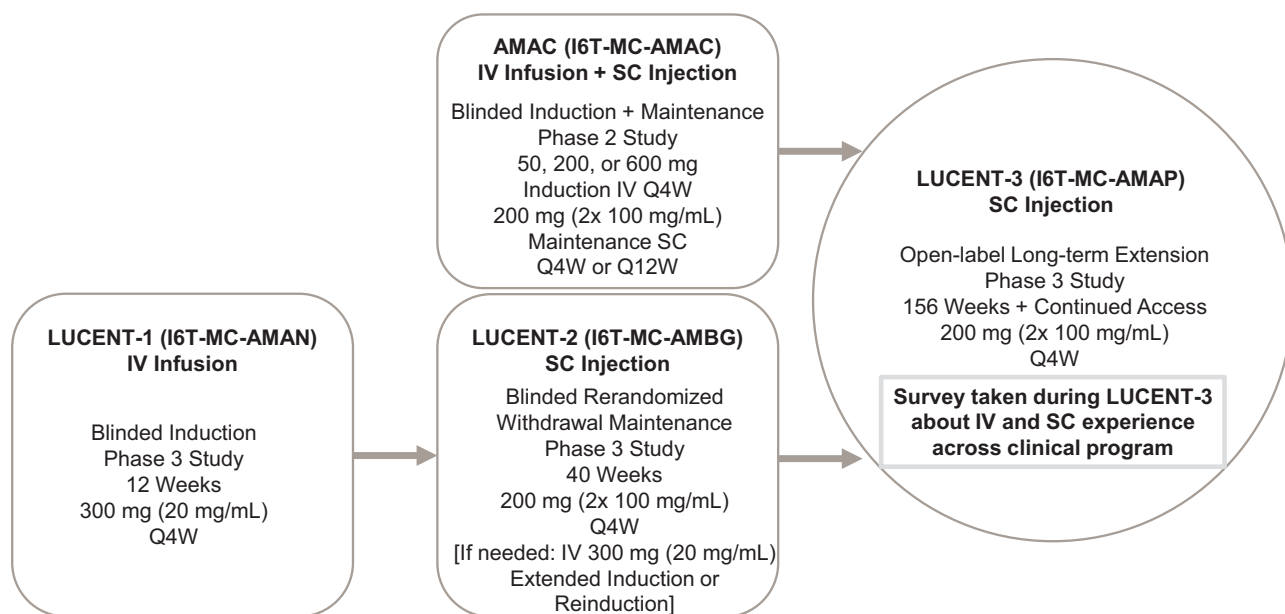


Figure 1. Patient flow and mirikizumab administration experience across the LUCENT clinical program. Abbreviations: IV, intravenous; Q4W, every 4 weeks; Q12W, every 12 weeks; SC, subcutaneous; UC, ulcerative colitis.

Mirikizumab Treatment Administration

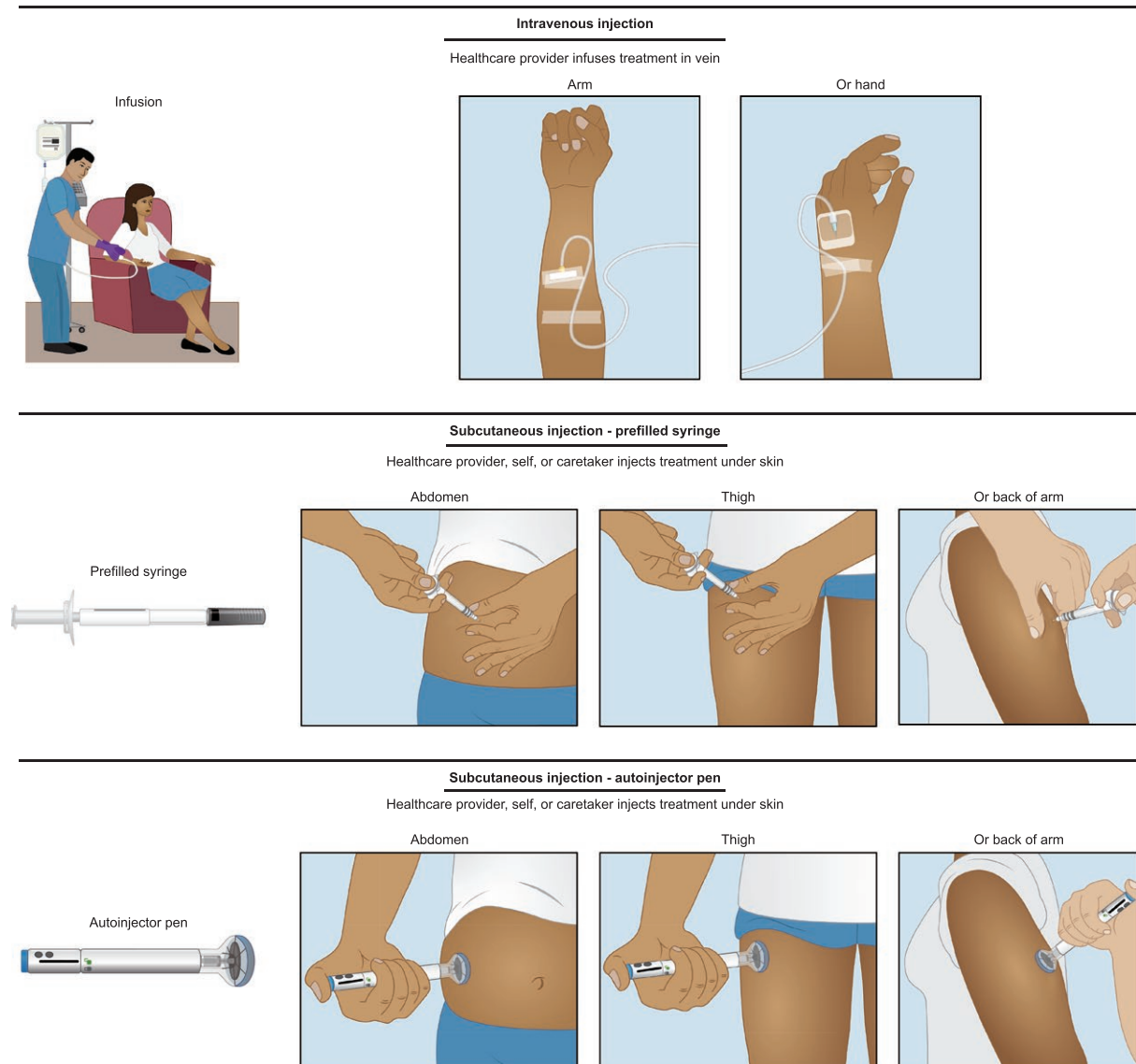


Figure 2. Illustrations for mirikizumab administration as intravenous infusion or subcutaneous injection. Infusion: 300 mg (20 mg/mL). Prefilled syringe or autoinjector pen (200 mg [2× 100 mg/mL]).

or overseeing administration of mirikizumab via IV infusion, SC injection, or both in AMAC, LUCENT-1, LUCENT-2, or LUCENT-3 studies for at least 6 months combined, and also met the criteria noted for patients.

Survey Structure and Content

The survey questions were designed to capture satisfaction with the mode of administration (IV and SC), acceptability of IV and SC, preferences for SC, and overall administration burden versus treatment satisfaction. Patients and HCPs were asked to answer the questions based on their holistic experiences across their participation in the clinical development program. Because IV infusions were not administered in LUCENT-3, patients and HCPs were asked to recall their experiences with IV infusions, administered every 4 weeks, in the induction periods of the LUCENT-3 parent studies. The SC injections' location and device were determined by study protocols across the induction, maintenance, and extension

studies. Patients were able to choose to self-inject only after they had completed 7 months in LUCENT-3; until that point, all SC injections were administered by the site staff (HCPs). Moreover, in the survey, the patients were asked to rank the SC injection options—HCP, self-injection, and caregiver—that they experienced during the study; if patients experienced only one method, this was ranked first, and if they experienced all 3 options, they were asked to rank them in order of preference.

Most survey questions were multiple-choice, with responses based on 5-point Likert-type scales. Some questions included ranked response options (e.g., patients' most and least preferred location to receive an SC injection) or a list of relevant response options. The survey was originally developed in English and then translated for each country. The surveys were pretested with 3 patients and 2 HCPs and revised based on their feedback (Supplementary Material, Survey Instrument Development).

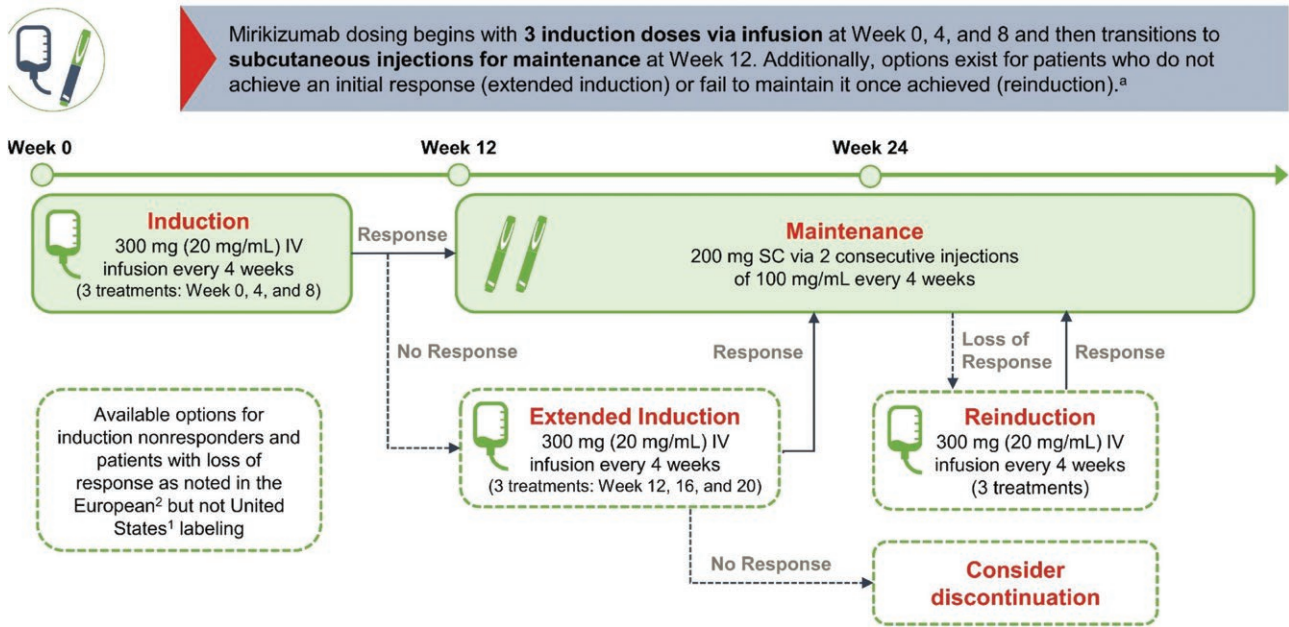


Figure 3. Mirikizumab dosing and administration. Mirikizumab IV infusion occurs over at least 30 minutes. Patients should be monitored for at least 1 hour after dosing, according to the local standard of care. Abbreviations: IV, intravenous; SC, subcutaneous. ^aSource: Mirikizumab summary of product characteristics.¹⁹

The patient survey (Supplementary Material, Patient survey) consisted of 28 closed-ended questions about participants satisfaction, acceptability, and preferences with different methods of study medication administration (SC or IV) as well as their satisfaction with overall treatment administration and injection device (prefilled syringe or autoinjector pen) usability. The survey did not contain questions on patients' demographic information and their clinical characteristics, as these data were captured as part of the clinical program.

The HCP survey (Supplementary Material, HCP survey) consisted of 32 closed-ended questions about the HCP's perception regarding their patients' treatment satisfaction, acceptability, preferences (Q1-Q25; Supplementary Material, HCP survey), and their personal experience administering the study medication (Q26-Q32; Supplementary Material, HCP survey). At the beginning of the HCP survey, 8 questions captured the HCPs' clinical background, including their specialty, their primary study role, the number of years they have provided care to patients with UC (excluding medical training), their primary practice setting, the percentage of working time spent actively interacting with patients (including patients with UC), their HCP experience with study medication administration methods, the number of infusions or injections they had administered or overseen during the mirikizumab clinical development program, and their country of origin.

Statistical Methods

Descriptive statistics were applied and presented for both patients' and HCPs' responses and were stratified by subgroups. The subgroup analyses were detailed and extended within the patient (Supplementary Table S1) and HCP (Supplementary Table S2) groups of survey participants. For all descriptive analyses, frequency distributions and cross-tabulations were constructed to evaluate and characterize

the distribution properties of each variable assessed in the surveys. Chi-square tests were used to evaluate differences between the subgroups for categorical data when specified. Analysis of variance was used to evaluate the differences between subgroups for continuous data when specified. All statistical tests were 2-tailed and were conducted with a type I error probability fixed at 0.05. No formal hypotheses were being tested, and, therefore, no multiplicity adjustment was performed. All data entered by patients and HCPs on the web-based survey platform was provided as a clean, deidentified, fully documented dataset. For subgroup analyses, survey variables were merged with the variables from the clinical trial, including baseline demographics and patient characteristics. The analysis was performed using the SAS Enterprise Guide 7.15 HF6 (SAS Institute Inc., Cary, NC).

Ethical Considerations

Country-specific and, where applicable, site-specific institutional review board (IRB) approval was obtained prior to any data collection efforts. All participants provided written (patients) or electronic (HCPs) informed consent. Data collection complied with ISO 27001 and the European Union Data Protection Directive 95/46/EC.

Results

There were 316 patients who completed the LUCENT-2 maintenance study and entered the LUCENT-3 extension study and an estimated 183 HCPs (investigators and study coordinators) involved in treatment administration participating in the LUCENT-3 study addendum from the 11 of 35 total participating countries (Australia, Austria, Czech Republic, Germany, Hungary, Japan, Mexico, Poland, Spain, Switzerland, and United States) that were invited to voluntarily respond to the survey (Table 1). Of these, survey respondents included 93 patients and 42 HCPs.

Table 1. Patient characteristics, *n* = 93.

Age, mean years (SD)	43 (11.8)
Male sex, <i>n</i> (%)	51 (55)
Region, <i>n</i> (%)	
Europe	41 (44)
North America	25 (27)
Asia	20 (22)
Central or South America	5 (5)
Rest of the world	2 (2)
Race, <i>n</i> (%)	
White	65 (70)
Asian	21 (23)
American Indian or Alaska Native	5 (5)
Black or African American	2 (2)
Disease duration ≥ 4 years, <i>n</i> (%)	69 (74)
Prior bionative before entering mirikizumab program, <i>n</i> (%)	63 (68)
Corticosteroid or immunomodulator use, <i>n</i> (%)	57 (61)
Symptomatic remission ^a achieved prior to entering LUCENT-3, <i>n</i> (%)	59 (63)
MMS Score, ^b <i>n</i> (%)	
Moderate (MMS = 4-6)	47 (51)
Severe (MMS > 6)	43 (46)
Missing	3 (3)
Mirikizumab SC injection experience through time of survey, <i>n</i> (%)	
>2 years to ≤3 years	32 (34)
>3 years	40 (43)
Missing	21 (23)
Mirikizumab IV infusion experience through time of survey, <i>n</i> (%)	
3 IVs (12 weeks)	47 (51%)
6 IVs (24 weeks)	32 (34)
Missing	14 (15)
Mirikizumab self-injection experience through time of survey, <i>n</i> (%)	41 (44)
Fear of needles prior to taking study medication, <i>n</i> (%)	
Not at all afraid	57 (61)
A little afraid	23 (25)
Moderately afraid	8 (9)
Very afraid	2 (2)
Extremely afraid	3 (3)

^aSymptomatic remission is based on Modified Mayo Score Stool Frequency (SF) and Rectal Bleeding (RB) components: SF = 0 or SF = 1 with a 1-point decrease in MMS from baseline; RB = 0.

^bUlcerative colitis severity subgroups were defined by the Modified Mayo Score: Moderate (MMS = 4-6) and Severe (MMS > 6).

Abbreviations: IV, intravenous; MMS, Modified Mayo Score; SC, subcutaneous; SD, standard deviation.

The subinvestigators may perform the endoscopic evaluations or fill in occasionally but they are more like the other partners in the practice referring patients and not the target population for this substudy.

Based upon the induction study baseline, 3 in 4 patients (69; 74%) had UC for more than 4 years. For 68% of patients, mirikizumab was their first biologic therapy, and 61% were receiving corticosteroids or immunomodulators (Table 1). Nearly all (97%) had either moderate or severe UC as indicated with modified Mayo Scores ≥4. Based

upon the last visit with symptomatic remission captured before entering LUCENT-3, the majority of patients (63%) had achieved symptomatic remission when they entered LUCENT-3. The survey was taken during LUCENT-3. At the time of the survey, patients were generally experienced in receiving injections, given that 85% had received at least 3 IV infusions and 77% had received mirikizumab SC injections for at least 2 years. As expected, based on the clinical study design, experience with self-injections was limited (44%). The majority of patients who took the survey did not report any fear of needles at the clinical study baseline (61%; Table 1).

The HCPs who responded to the survey were primarily from the United States (57%) and most frequently nurses (41%) or gastroenterologists (26%; Table 2). Most HCPs were experienced (≥6 years) in treating patients with UC (57%) and provided primarily office-based patient care (71%; Table 2). When asked about time spent actively seeing patients, HCPs most frequently reported 26%-50% (*n* = 15, 36%) or 76%-100% (*n* = 13, 31%).

Table 2. HCP characteristics, *n* = 42.

Type of HCP, <i>n</i> (%)	
Nurse ^a	17 (41)
Gastroenterologist ^b	11 (26)
Internal medicine or other physician	2 (5)
Other	12 (29)
Years providing care to patients with UC (excluding medical training), <i>n</i> (%)	
0-5 years	18 (43)
6-10 years	8 (19)
11-15 years	6 (14)
16-20 years	7 (17)
≥21 years	3 (7)
Primary medical practice setting providing care to patients, <i>n</i> (%)	
Office-based	30 (71)
Hospital-based (non-university)	7 (17)
University-based	5 (12)
Percentage of working time spent actively seeing patients, <i>n</i> (%)	
0-25%	4 (10)
26%-50%	15 (36)
51%-75%	10 (24)
76%-100%	13 (31)
Country, <i>n</i> (%)	
United States	24 (57)
Australia	4 (10)
Switzerland	4 (10)
Hungary	3 (7)
Japan	2 (5)
Poland	2 (5)
Austria	1 (2)
Germany	1 (2)
Spain	1 (2)

^aIncludes nurses, nurse practitioners, or other nurse specialists.

^bIncludes gastroenterologists or physicians with gastroenterology specialty. Abbreviations: HCP, healthcare provider; UC, ulcerative colitis.

Patients Survey Responses

IV Infusions

Satisfaction overall and by subgroups

Patients were generally either “very satisfied” or “satisfied” with the administration of IV infusion ($n = 77$, 83%; [Figure 4](#)). Only one patient reported being “dissatisfied” with IV infusions, and none of the patients reported being “very dissatisfied.” Subgroup findings of interest are:

- Women were more often “very satisfied” or “satisfied” ($n = 39$, 93%) than men ($n = 38$, 76%); only a few women ($n = 3$, 7%) were neither satisfied nor dissatisfied, as opposed to one in every 4 men ($n = 12$, 24%; $p = 0.0159$).
- Most patients were “very satisfied” or “satisfied” with IV regardless of their previous experience with corticosteroids or immunomodulators ($n = 51$, 89% vs $n = 26$, 72%; $p = 0.1104$).
- Similarly, most patients were “satisfied” or “very satisfied” with IV regardless of their experience with biologics ($n = 48$, 84% vs $n = 21$, 81%; $p = 0.4216$).
- Satisfaction with IV infusion did not change over time for most patients ($n=69$, 74%). Of patients who reported satisfaction improvement over time ($n=17$, 18%), this change was more frequent among patients with <4 years’ experience with UC ($n=9$, 38%) than patients with >4 years’ experience ($n = 8$, 12%; $p = 0.0374$).
- Asian patients were less likely to be “very satisfied” ($n = 4$, 19%), a trend in the data that should be interpreted with caution due to being underpowered.
- With similar caution, patients were more likely to be “very satisfied” if they had Inflammatory Bowel Disease Questionnaire (IBDQ) response (≥ 16 improvement from baseline²⁴⁻²⁶; $n = 37$, 49%); had severe UC at induction baseline ($n = 23$, 54%); had self-injection experience ($n = 21$, 51%); had achieved symptomatic remission ($n = 30$, 51%); were not afraid of needles ($n = 30$, 53%). Younger (<40 years) patients ($n = 20$, 67%) chose “scheduling the IV infusions was easy” as a reason for satisfaction more than older (≥ 40 years) patients ($n = 23$, 45%).

Acceptability overall and by subgroups

To the question about the acceptability of receiving medication through IV infusion, the most frequent responses were “completely acceptable” or “somewhat acceptable” ($n = 81$, 87%; [Figure 4](#)). Subgroup findings of interest are:

- Patients who found IV administration of study medication completely acceptable were older (≥ 40 years old; $n = 33$, 59%), men ($n = 29$, 57%), who had not experienced prior biologic failure ($n = 35$, 61%), were bionative ($n = 35$, 61%), had UC for <4 years ($n = 18$, 75%), had more severe UC ($n = 26$, 61%), had achieved IBDQ remission (IBDQ score ≥ 170 ²⁴⁻²⁶; $n = 40$, 56%), had achieved symptomatic remission in parent studies ($n = 34$, 58%), and had no fear of needles ($n = 32$, 56%). However, these subgroup comparisons were not statistically significant except for the comparison by disease duration (<4 years vs ≥ 4 years; $p = 0.0467$).
- When examining reasoning for the responses of “completely” or “somewhat acceptable” by subgroups, there

were a few response option trends that were clear. Nearly all patients with higher disease severity (ie, Modified Mayo Score [MMS] score > 6; $n = 35$, 92%) and most patients with moderate disease severity (MMS score 4-6; $n = 35$, 83%) at baseline of the parent induction studies selected “I feel it helped my UC.”

- Women answered “it allowed me to interact with HCPs” more often than men ($n = 17$, 45% vs $n = 10$, 23%; $p = 0.0407$).
- Patients with <4-year experience with UC more frequently selected the “length of time while receiving IV infusion was acceptable” than patients with ≥ 4 -year experience with UC ($n = 15$, 65% vs $n = 21$, 36%; $p = 0.0178$).

SC Injections

Satisfaction overall and by subgroups

Patients were generally either “very satisfied” or “satisfied” with SC injections ($n = 85$, 91%; [Figure 4](#)). Two patients were dissatisfied with SC injections; no one was very dissatisfied. Subgroup findings of interest are:

- Although subgroup comparison differences did not meet statistical significance, patients who were most frequently “very satisfied” were bionative ($n = 32$, 56%), had achieved IBDQ remission ($n = 37$, 51%), had moderate disease severity at baseline ($n = 28$, 60%), had achieved symptomatic remission at the end of the maintenance study LUCENT-3 ($n = 31$, 53%), and did not have a fear of needles ($n = 31$, 54%).
- Some patients reported their satisfaction improved over time ($n = 17$, 18%). This change was statistically significant by disease duration (33% <4 years vs 13% ≥ 4 years; $p = 0.0121$), IBDQ remission (74% yes vs 53% no; $p = 0.0035$), symptomatic remission achieved at the end of the maintenance study LUCENT-3 (76% yes vs 57% no; $p = 0.0195$).

Acceptability overall and by subgroups

Nearly all patients ($n = 90$, 97%) found SC injections “completely” or “somewhat acceptable” ([Figure 4](#)). Two patients found SC injection “neither acceptable nor unacceptable” and one patient found it “somewhat unacceptable.” When asked about the acceptability of receiving 2 SC injections, most patients found it “completely acceptable” ($n = 71$, 76%) or “somewhat acceptable” ($n = 19$, 20%). Only 3 patients selected “neither acceptable nor unacceptable” (3%; [Figure 4](#)). The patients were then asked about acceptability of receiving monthly SC injections, and most selected “completely acceptable” ($n = 79$, 85%). Fewer patients selected “somewhat acceptable” ($n = 12$, 13%) or “neither acceptable nor unacceptable” ($n = 2$, 2%; [Figure 4](#)).

Subgroup findings of interest are:

- Acceptability of monthly SC injections expressed as “completely acceptable” increased with years of injection experience from 75% ($n = 24$) among those with 2-3 years of experience to 93% ($n = 37$) among those with >3 years of experience ($p = 0.0354$).
- Asian patients favored the “somewhat acceptable” ($n = 11$, 52%) response rather than “completely acceptable”

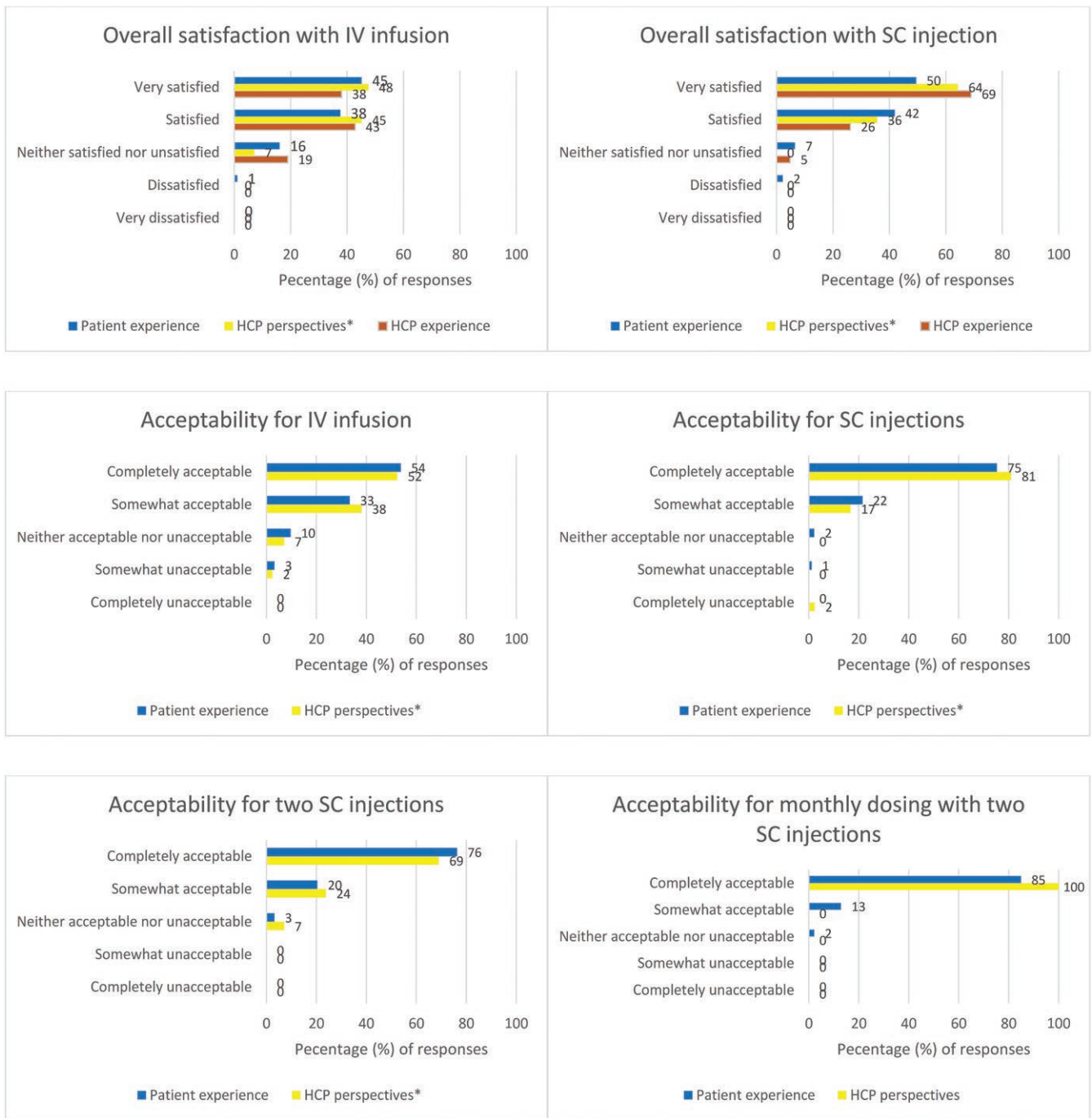


Figure 4. Satisfaction and acceptability rates associated with mirikizumab IV infusions and SC injections by patients’ actual experience ($n = 93$), HCP perspectives of patients’ experiences, and HCP own experiences ($n = 42$). Abbreviations: HCP, healthcare professionals; IV, intravenous; SC, subcutaneous. *HCPs’ perspectives of patients’ experiences.

($n = 9, 43\%$) that was favored by the patients from other geographic regions ($p = 0.0097$).

- Although comparisons were not statistically significant, those who believed that SC injections were “completely acceptable” were older (≥ 40 years old; $n = 46, 82\%$), men ($n = 39, 77\%$), did not experience prior biologic failure ($n = 43, 75\%$), were bionative ($n = 43, 75\%$), had UC for < 4 years ($n = 22, 92\%$), had moderate disease severity ($n = 37, 79\%$), had achieved IBDQ remission ($n = 56, 78\%$), had achieved symptomatic remission before en-

tering the LUCENT-3 study ($n = 48, 81\%$), and had no fear of needles ($n = 46, 81\%$).

Administration Options and Preferences

Patients most frequently preferred to receive their SC injections from HCPs ($n=78, 84\%$), followed by self-injection ($n=41, 44\%$), and caregivers ($n=8, 9\%$); however, for patients with self-injection experience, self-injection was the preference. Patients’ injection-site preferences were abdomen

($n = 72$, 77%), followed by the back of the upper arm ($n = 32$, 34%), and the thigh ($n = 8$, 9%).

The patients were then asked to rank by preference the administration options that they experienced during their clinical trial participation. The ranking data should be interpreted with caution because some patients might not have experienced all options. Those patients who only experienced receiving the injection from an HCP ranked HCPs as either first ($n = 56$, 72%) or third ($n = 22$, 28%) preferred option. However, when patients also had self-injection experience, they ranked this option as their first ($n = 31$, 76%), third ($n = 9$, 22%), or second ($n = 1$, 2%) preference. Younger patients ($n = 15$, 83%) were more likely to rank self-injection as their first preference. Almost all of those who experienced receiving the injection from a caregiver, ranked caregiver as their first ($n = 6$, 75%) preferred option. For patients who found SC injections acceptable, the reason most patients selected was “I feel it helped my UC” ($n = 87$; 97%); “I liked the self-injection option” ($n = 18$; 51%), and “I liked having the option to receive the injections at home” ($n = 19$; 54%) were chosen more by younger UC patients.

Most patients reported they “strongly agree” when asked about the convenience of using the self-injection device ($n = 24$; 59%). Thirteen patients reported “agree” ($n = 13$; 32%), while only one patient reported “neither agree nor disagree” ($n = 1$; 2%) and 3 patients reported “disagree” ($n = 3$; 7%). Moreover, when asked whether they found the device “easy to use,” most patients selected “strongly agree” ($n = 25$; 61%) and “agree” ($n = 14$; 34%). The patients responded “strongly agree” ($n = 34$; 83%) and “agree” ($n = 7$; 17%) when the patients were asked whether they understood instructions to self-inject. Similarly, they responded “strongly agree” ($n = 32$; 78%) and “agree” ($n = 7$; 17%) when asked whether they understood instructions to store the medication at home.

Overall, the most reported strategy used by patients to help with SC injection administration was to “let study medication warm to room temperature before injecting” ($n = 60$; 65%), followed by “pinch skin and squeeze while injecting” ($n = 47$; 51%). Nineteen patients (20%) did not use any strategies to ease the administration burden.

Treatment Satisfaction and Administration Burden

Nearly all patients indicated that they were “very satisfied or satisfied” (98%) with the overall study medication administration (Table 3). Similarly, most patients ($n = 88$, 95%) expressed complete acceptability to the medication’s administration (Table 3). Subgroup findings of interest are as follows:

- Overall satisfaction was statistically significantly higher among patients who had an IBDQ response (100% vs 86%; $p = 0.0054$).
- Complete acceptability was expressed more frequently among older patients (aged ≥ 40 years) than among younger patients (98% vs 89%, $p = 0.0369$).

With regards to the potential administration burden, almost all patients (90%) “agreed” or “strongly agreed” that the improvement in their UC outweighed any dissatisfaction they may have had with the administration of the medication (Table 3). These responses were more frequent among patients who achieved IBDQ response (92% vs 79% without

response; $p = 0.0287$) and achieved symptomatic remission (93% vs 83% without remission; $p = 0.0207$) at the end of the maintenance study before entering the LUCENT-3 study when the survey was administered.

Finally, almost all (97%) patients responded that they would recommend mirikizumab to someone with UC (Table 3). The willingness to recommend mirikizumab was stronger (ie, “strongly agree” answers) among non-Asian patients ($n = 62$, 85%) than among Asian patients ($n = 7$, 35%; $p = 0.0009$ vs other regions).

HCPs Survey Responses

IV Infusions

HCPs perspectives of patients’ experiences

HCPs believed that patients would be “very satisfied” or “satisfied” ($n = 39$, 93%) with IV infusions, and no one thought that there would be any dissatisfied patient (Figure 4). Subgroup findings of interest are as follows:

- HCP perspective of patient overall satisfaction with administration of IV infusion was statistically significant by HCP type ($p = 0.0048$), years providing UC care ($p = 0.0027$), and average IV infusion experience ($p = 0.0192$).
- When looking at HCP type, we found that all gastroenterologists ($n=11$, 100%) and nearly all nurses ($n=16$, 94%) believed that their patients were “very satisfied” or “satisfied”; however, the physicians’ answers were grouped within “very satisfied” ($n=10$), while nurses’ responses were more evenly divided between “very satisfied” ($n = 7$) and “satisfied” ($n = 9$).
- Despite this, the proportion of HCPs thinking patients were “very satisfied” or “satisfied” was similar between HCP types. However, some HCPs were potentially overestimating their patients’ satisfaction from “satisfied” to “very satisfied” compared to the patients’ actual satisfaction.
- HCPs with ≥ 16 years of providing UC care were more likely to believe that their patients were “very satisfied” ($n = 9$, 90%) with IV infusion compared with those who had < 5 years of experience ($n = 2$, 11%; $p = 0.0027$).
- Similarly, HCPs who had provided > 30 IV infusions ($n = 12$, 75%) were more likely to believe patients were “very satisfied” with IV infusion than HCPs who had administered < 10 infusions ($n = 4$, 36%; $p = 0.0192$).
- Most HCPs said that patients’ satisfaction with the administration of IV infusion “did not change over time” ($n=32$, 76%). Seven HCPs said patients’ satisfaction “improved over time” mostly after the second or third infusion ($n = 6$) while one HCP believed that change occurred already after the first infusion.

Regarding acceptability, HCPs reported that they thought patients found it “completely” or “somewhat acceptable” ($n = 38$, 90%) to receive the IV infusion (Figure 4). Subgroup findings of interest are as follows:

- Gastroenterologists were more likely to select “completely acceptable” than nurses ($n = 11$, 100% vs $n = 7$, 41%; $p = 0.0008$).

Table 3. Overall experience with administration of study medication.

	Patients' experiences (N = 93)	HCP perspectives of patients' experiences (N = 42)	HCP own experiences (N = 42)
Improvement in UC outweighed any dissatisfaction with the administration of mirikizumab, <i>n</i> (%)			
Strongly agree	67 (72)	20 (48)	26 (62)
Agree	17 (18)	17 (41)	14 (33)
Neither agree nor disagree	4 (4)	5 (12)	1 (2)
Disagree	4 (4)	0 (0)	1 (2)
Strongly disagree	1 (1)	0 (0)	0 (0)
Overall satisfaction with mirikizumab, <i>n</i> (%)			
Very satisfied	71 (76)	27 (64)	28 (67)
Satisfied	20 (22)	13 (31)	13 (31)
Neither satisfied nor unsatisfied	2 (2)	1 (2)	1 (2.4)
Unsatisfied	0 (0)	1 (2)	0 (0)
Very unsatisfied	0 (0)	0 (0)	0 (0)
Overall acceptability of administration of mirikizumab, <i>n</i> (%)			
Completely acceptable	88 (95)	39 (93)	NA
Somewhat acceptable	3 (3)	2 (5)	NA
Neither acceptable nor unacceptable	1 (1)	1 (2)	NA
Somewhat unacceptable	1 (1)	0 (0)	NA
Completely unacceptable	0 (0)	0 (0)	NA
Recommend mirikizumab to someone with UC, <i>n</i> (%)			
Strongly agree	69 (74)	28 (67)	NA
Agree	21 (23)	13 (31)	NA
Neither agree nor disagree	2 (2)	1 (2)	NA
Disagree	1 (1)	0 (0)	NA
Strongly disagree	0 (0)	0 (0)	NA
Found SC self-injection device easy to use, <i>n</i> (%)			
Strongly agree	25 (61)	23 (55)	32 (76)
Agree	14 (34)	9 (21)	5 (12)
Neither agree nor disagree	1 (2)	8 (19)	3 (7)
Disagree	1 (2)	2 (5)	2 (5)

Abbreviations: HCP, healthcare provider; NA, not applicable; SC, subcutaneous; UC, ulcerative colitis.

- HCPs in Western Europe did not select “completely acceptable” at all and were the most likely to select “somewhat acceptable” ($n = 6$, 86%; $p = 0.0296$ vs among geographical regions).
- HCPs believed that the main reason for acceptability was that the treatment helped patients with their UC ($n = 33$, 87%).

HCPs own experiences

HCPs themselves were mainly “very satisfied” ($n = 16$, 38%) or “satisfied” ($n = 18$, 43%) with IV infusions. Few HCPs ($n = 8$, 19%) were “neither satisfied or unsatisfied” and no one was unsatisfied or very unsatisfied (Figure 4). The gastroenterologists were mostly “very satisfied” ($n = 9$, 82%) while the nurses were mostly “satisfied” ($n = 9$, 53%) and to a lesser extent “very satisfied” ($n = 5$, 29%).

SC Injections

HCPs perspectives of patients' experiences

When asked about their perspective on patients' overall satisfaction with the administration of SC injections, the

HCPs believed that their patients were “very satisfied” ($n = 27$, 64%) or “satisfied” ($n = 15$, 36%; Figure 4); gastroenterologists preferentially selected “very satisfied” ($n = 9$, 82%) while nurses distributed their responses between “very satisfied” ($n = 10$, 59%) and “satisfied” ($n = 7$, 41%). Most HCPs ($n = 31$, 74%) believed that patients' satisfaction did not change over time. However, a few HCPs ($n = 9$, 21%) said their patients' satisfaction improved over time.

Overall, most HCPs perceived their patients found it “completely acceptable” ($n = 34$, 81%) or “somewhat acceptable” ($n = 7$, 17%) to receive study medication via SC injection. Most HCPs also believed that patients accepted SC injections mainly because they helped their UC ($n = 38$, 93%) and that it was easy to schedule the injections ($n = 29$, 71%).

HCPs perspective on patient acceptability of receiving 2 SC injections (“completely acceptable”: $n = 29$, 69%; “somewhat acceptable”: $n = 10$, 24%) were lower than patients' actual experience (Figure 4). Regarding the monthly dosing of 2 SC injections, all HCPs believed that their patients found it “completely acceptable” ($n = 42$, 100%; Figure 4).

HCPs own experiences

HCPs themselves were mainly “very satisfied” ($n = 29$, 69%) with SC injections. Some were “satisfied” ($n = 11$, 26%), only a few ($n = 2$, 5%) were “neither satisfied or unsatisfied” and no one was unsatisfied or very unsatisfied (Figure 4). The gastroenterologists were mostly “very satisfied” ($n = 9$, 82%) while the nurses were mostly “satisfied” ($n = 11$, 65%) and to a lesser extent “very satisfied” ($n = 6$, 35%).

Administration Options and Preferences

HCPs perspectives of patients’ experiences

HCPs were asked to provide a ranking for all administration options. They were asked to rank what they believed were patient preferences for who (self, caregiver, or HCP) administered the SC injections. When looking at the total sample, HCPs most frequently chose “HCP” ($n = 29$, 69%) followed by “caregiver” ($n = 22$, 52%), and “self-administration” ($n = 20$, 48%). Based on these results, HCPs believed that patients preferred the HCP to give the injection, while patients who had performed self-injections primarily preferred the “self-injection” option, suggesting an HCP-patient disconnect on the topic of preference for who should do the injections.

HCPs were also asked to rank what they believe were the patients’ preferences for the location (abdomen, thigh, and back of upper arm) of SC injections. As the first preferred option, they ranked “abdomen” ($n = 26$, 62%), which was aligned with the patients ranking. As the second preferred option, they reported “thigh” ($n = 16$, 38%) and “abdomen” ($n = 14$, 33%). As the third preferred option, they reported “thigh” ($n = 24$, 57%) and “back of upper arm” ($n = 16$, 38%).

HCPs own experiences

When HCPs were asked to rank their own preferences for the preferred administration method of SC injections, as the first preferred option, they most frequently ranked “SC injection, administered by the patient” ($n = 18$, 43%); as the second preferred option, they ranked “SC injection, administered by HCP” ($n = 23$, 55%); and, as the third preferred option, they ranked “SC injection, administered by caregiver” ($n = 20$, 48%).

Treatment Satisfaction and Administration Burden

HCPs perspectives of patients’ experiences

Most HCPs believed that patients were “very satisfied” or “satisfied” with the administration of the study medication (95%) and considered it “completely” or “somewhat acceptable” (98%; Table 3). In the opinion of the HCPs, patients believed that the therapeutic advantages of the medication outweighed any dissatisfaction they had with its administration (88% “agree” and “strongly agree”; Table 3). This opinion was expressed by all gastroenterologists ($n = 11$, 100%) but not by all nurses ($n = 9$, 75%; $p = 0.0746$). In concordance with patients’ experiences, almost all HCPs (98%) agreed that their patients would recommend the study medication to someone with UC (Table 3).

Regarding HCP perspectives of patients’ beliefs of injector usability, patients responded that injector device was convenient (90% “strongly agree” and “agree”) and easy to use (95% “strongly agree” and “agree”) more than HCPs believed they would (79% and 76% respectively). Patients also responded that the injector device instructions were understood (100%

“strongly agree” and “agree”) more than HCPs (91%) believed they would. Patients (54%) used injection instruction documents less than HCPs (95%) believed they did. Patients felt responses from their HCPs to their questions were more helpful (100%) than HCPs (94%) believed they were. Patients felt more confident they were using the injection device correctly (98%) and getting a full dose (100%) than HCPs (81% and 86%, respectively) believed they were.

HCPs own experiences

HCPs responses about their own opinions showed that most HCPs were “satisfied” or “very satisfied” with IV infusions ($n = 34$, 81%), SC injections ($n = 40$, 95%), and with overall mirikizumab treatment ($n = 41$, 98%). Most HCPs ($n = 40$, 95%) “agreed” or “strongly agreed” that the treatment benefits of mirikizumab outweighed any dissatisfaction with its administration (Table 3). Subgroup findings of interest are as follows:

- Subgroup analysis revealed that gastroenterologists were “very satisfied” ($n = 9$, 82%) with IV infusions, whereas the nurses were “satisfied” ($n = 9$, 53%; $p = 0.0153$).
- Similar differences, although not statistically significant, were seen in “strongly agree” responses that treatment benefits outweighed any dissatisfaction with the administration: 82% among gastroenterologists ($n = 9$) vs 53% among nurses ($n = 9$), $p = 0.2186$.
- Lastly, HCPs with longer experience providing care to patients with UC (≥ 16 years) were more frequently very satisfied ($n = 9$, 90%) with SC injections than the HCPs with less experience ($n = 13$, 72%) although this was not a statistically significant difference ($p = 0.2090$).

Regarding strategies recommended by HCPs to patients to ease the administration burden, only 79% of HCPs selected warm medication before injecting, despite the label recommending doing. Moreover, this suggestion was more frequently given by nurses than gastroenterologists (82% vs 73%; $p = 0.0494$). Choosing a different injection location was recommended by 69% of HCPs, but only 9% of patients noted choosing a different injection location as a method to ease the administration burden, suggesting an HCP-patient disconnect.

Discussion

This international web survey demonstrated that patients with moderately-to-severely active UC and their HCPs were predominantly satisfied and accepting of mirikizumab treatment administration, whether administered via IV infusion or SC injection including monthly SC dosing with 2 injections. Gastroenterologists were more likely than nurses to think patients were “very satisfied” with and “completely acceptable” of IV infusion and SC injections. HCPs overall were more likely to overestimate the proportion of patients with the highest degree of satisfaction or acceptance of IV infusions and SC injections. However, the overall satisfaction range responses (very satisfied + satisfied) and overall acceptability range responses (completely acceptable + acceptable) for IV infusion and SC injection were similar across patients’ experiences, HCPs perspectives of patients’ experiences, and HCPs’ personal experiences. HCPs and patients were closely

aligned that the abdomen was the preferred site for injections. HCPs were less likely than patients to respond that patients fully understood administration instructions and indicate that the self-injection option was easy and convenient. There was also a disconnect between patients and HCPs regarding methods for helpfulness with SC injection in which HCPs recommended choosing a different injection site, but almost no patients selected this as an option.

Importantly, patients and HCPs believed that the benefits of mirikizumab therapy outweighed any potential burdens associated with the administration method. Patients were satisfied with and accepted both the IV and SC routes of administration because they felt mirikizumab treatment helped their UC. These results offer some insight into patients' preferences regarding UC treatment attributes and the treatment administration burden they are willing to accept for therapeutic success. They suggest acceptance of the administration burden for therapies that offer clinically relevant therapeutic benefits. This is in alignment with previous studies showing that the administration route is of lesser concern to patients and their HCPs than treatment effectiveness and safety profile.²⁷⁻³¹ For example, a conjoint analysis assessing biologics treatment preferences among patients with IBD showed that patients, either naïve or experienced in biologics, rated route of administration as the third important treatment characteristic after efficacy and safety. Another study on biologic naïve patients with moderate-to-severe UC found that patients primarily cared for long-lasting effectiveness, and they considered of "no real importance" or "completely irrelevant" the route of administration (25.3%) and the dosing frequency (32.3%).²⁸ There are data available from 4 discrete choice experiments among patients with IBD that included route of administration as one of the treatment attributes assessed.²⁹⁻³² Two of those studies found that the administration route was not among patients' primary considerations.^{29,31} In the third study, some patients were willing to accept 10.3% (95% CI, 6.6%-14.0%) added risk to replace IV administration at a hospital with an injection at home.³⁰ The most recently published study reported that patients with UC preferred oral or SC administration over IV ($P < 0.001$).³² The current data does suggest a similar patient preference for SC injection over IV infusion: satisfied or very satisfied (IV, 83%; SC, 91%) and completely acceptable or somewhat acceptable (IV, 87%; SC, 97%). Finally, in a structured interview with patients of a UK hospital with IBD, patients with prior biological therapy experience were more receptive to SC or IV therapies than bionative patients.³³

For several survey questions, HCPs' and patients' responses were not aligned. For example, the HCP perspective of patient overall satisfaction with IV infusions was elevated compared with what was reported by patients. Similarly, HCPs believed that patients preferred the HCP to give the SC injections, whereas patients reported that they preferred to self-inject. In addition, the HCP survey demonstrated a disconnect between gastroenterologists and nurses. This was observed with patient satisfaction for IV infusion and SC injection, patient acceptability for IV infusion, and overall HCP satisfaction with the administration of study medication. While gastroenterologists' responses tended to aggregate around "very satisfied" or "completely" acceptable, nurses' responses were divided between these 2 categories and were closer to patients' responses. For example, gastroenterologists

were "very satisfied" (IV, 82%; SC, 82%) more than nurses (IV, 29%; SC, 65%). This discrepancy appears to be influenced by the finding that nurses were less likely to respond that patients felt their treatment "helped my ulcerative colitis" (IV: gastroenterologist 100% vs nurse 81.3%; SC: gastroenterologist 100% vs nurse 87.5%). Nurses were also less likely to believe patients found the self-injection device easy to use (strongly agree: gastroenterologist 81.8% vs nurse 41.2%) or that patients felt confident using the SC self-injection device (strongly agree: gastroenterologist 81.8% vs nurse 58.8%). The similarity of nurses' responses to patients' responses was previously shown in a Spanish study assessing the satisfaction of patients with IBD with healthcare services received.³⁴ Although not specific to treatment administration preferences like the current study, the Spanish study highlighted the essential role of nurses in the management of patients with IBD that brings them closer to patients and ultimately the understanding of their needs. A role has been suggested to involve them in IBD care management as patients' educators.³⁵

Considerations, Strengths, and Limitations

When interpreting these findings, the study's limitations and strengths should be acknowledged. Strengths include that this web-based survey provides the first evidence regarding the level of patients' and HCPs' satisfaction and acceptability of mirikizumab treatment administration in UC. Moreover, beyond some reports on satisfaction with conventional therapies,^{28,36} there is no apparent research evidence on satisfaction with other biological treatments. This is also the first research to look at patient and HCP drug administration preferences for a specific medicine used to treat UC.

Among the study's strengths is that its findings are not geographically limited, as participants were recruited from varying countries. The fact that the treatment under evaluation was administered within a clinical trial helps to overcome disparities in prescription patterns, pharmaceutical costs, reimbursement, and general therapeutic approaches between countries.

The main study limitation was its small sample size. Because of this, the study was underpowered, and all comparative results and subgroup analyses should be interpreted with caution. These findings may only apply to patients with UC who meet the eligibility criteria to enroll in a phase 3 study in UC; such criteria usually exclude many patients attending routine clinical practice. Patients' participation in LUCENT-3 was voluntary so it was unlikely and expected that no patients in the survey would have found the study medication completely unacceptable. Since the questionnaire was administered a long time after the induction IV administration, patients who discontinued during or shortly after induction treatment may have had different opinions of mirikizumab administration than those who did not discontinue, and those insights thus may not have been captured. Thus, patients who found the study medication administration unacceptable might have discontinued study participation before LUCENT-3; however, study discontinuation data do not suggest this was an issue.^{18,20,37,38} Of note, only 3.8% of mirikizumab-treated patients discontinued the LUCENT-1 induction study due to any reason—1.7% due to adverse event; 0.6% due to lack of efficacy; 0.3% due to withdrawal by subject.²⁰ During the LUCENT-2 maintenance study: amongst both mirikizumab induction responders and non-responders 25% discontinued

due to any reason—1.7% due to adverse event, 19.0% due to lack of efficacy, and 1.6% due to withdrawal by subject.²⁰

The currently described survey was added to an ongoing extension study (LUCENT-3). The patient population in LUCENT-3 represented a subset of patients who were originally in the induction and maintenance studies, LUCENT-1 and LUCENT-2. This survey was conducted as a protocol amendment offered to a subset of participating countries. Participation in the survey was voluntary. Because only a subset of eligible patients and HCPs completed the questionnaire, this could have introduced bias into the results. Similarly, since the questionnaire was administered to a patient population that successfully entered the extension study (LUCENT-3), the majority of patients were experiencing clinical benefit from treatment, introducing bias regarding acceptance of the administration route versus acceptance due to the clinical improvement presented. Many experienced patients had transitioned to a hybrid of on-site and remote study visits and dosing, which decreased their access to this site-based survey, and this may also have added bias. Additionally, the voluntary nature of survey participation could have introduced selection bias, which could have leaned toward more satisfied patients.

The survey study did not allow open-ended responses, and no adverse event questions were asked; therefore, there is no way to align adverse events and survey respondents nor ascertain how these might have influenced patient satisfaction and acceptability. Of note, 0.4% of mirikizumab-treated patients reported infusion-site reactions during IV induction, 8.7% reported injection-site reactions during maintenance treatment, and 5.5% during the first year of extension treatment.^{20,39}

Future discrete choice experiment research designs may give more detailed information about patients' preference drivers and the trade-offs they are willing to make between different treatment attributes.

Conclusion

For the administration of mirikizumab, this study revealed some aspects of discordance between patients' experiences and HCPs' perspectives of patients' experiences, such as patient preference for self-administration, as well as some differences amongst HCP subgroups such as gastroenterologists and nurses. However, overall, both HCPs and patients reported satisfaction with and acceptance of mirikizumab IV and SC administration. Nevertheless, it may be important for HCPs to fully understand patients' treatment administration preferences and perspectives. Importantly, most patients felt that UC improvement outweighed any administration dissatisfaction. These findings may aid patients and HCPs in their treatment choices if they are seeking information on prior patients' experiences.

Supplementary Data

Supplementary data are available at *Crohn's & Colitis 360* online.

Acknowledgments

Stephanie Woerner (study execution), Richard Moses (medical peer review), Deborah Fisher (medical peer review), and

Jordan Johns (stat peer review) from Eli Lilly and Company; Patrick Daniele (stat analysis, Evidera). Athanasia Benekou (Evidera) and Phil Leventhal (Evidera) provided medical writing services, which were funded by Eli Lilly and Company, in accordance with Good Publication Practice (GPP) guidelines (Good Publication Practice (GPP) Guidelines for Company-Sponsored Biomedical Research: 2022 Update. *Ann Intern Med*).

Authors' Contributions

David Clemow: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Supervision; Validation; Writing—review & editing; Christine Radawski: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Supervision; Validation; Writing—review & editing; Joe Milata: Conceptualization; Investigation; Methodology; Validation; Writing—review & editing; Karla Alaka: Conceptualization; Investigation; Methodology; Writing—review & editing; Theresa Hunter Gible: Conceptualization; Methodology; Writing—review & editing; Adam Schaum: Conceptualization; Investigation; Methodology; Supervision; Writing—review & editing; Obi Ezennia: Data curation; Investigation; Writing—review & editing; Nicholas Martinez: Writing—review & editing; Tibor Szaloki: Writing—review & editing; Yuka Ito: Writing—review & editing; Danielle Rodriguez: Formal analysis; Investigation; Methodology; Validation; Writing—original draft; Writing—review & editing; Katherine Kirk: Formal analysis; Investigation; Methodology; Validation; Writing—original draft; Writing—review & editing. All authors approved the final version of the manuscript.

Funding

Eli Lilly and Company was the current study sponsor, funded the original research as well as the medical writing and editing services.

Conflicts of Interest

David Clemow, Christine Radawski, Joe Milata, Karla Alaka, Theresa Hunter Gible, Adam Schaum, and Obi Ezennia are employees of Eli Lilly at the time the study was conducted and the manuscript developed. Danielle Rodriguez and Katherine Kirk are employees of Evidera, which was contracted by Eli Lilly for work relating to this study. Tibor Szaloki is an employee of Javorszky Hospital and was contracted by Eli Lilly to assist as an external collaborator for this study. Nicholas Martinez is an employee of Gastroenterology Research of America and was contracted by Eli Lilly to assist as an external collaborator for this study. Yuka Ito is an employee of NHO Mito Medical Center and was contracted by Eli Lilly to assist as an external collaborator for this study. Medical writing support was provided by Athanasia Benekou, Principal Medical Writer, from Evidera's Medical Writing and Healthcare Communications, and funded by Eli Lilly.

Data Availability

Eli Lilly and Company provides access to all individual participant data collected during the study, after anonymization.

Data are available to request 6 months after the indication studied has been approved in the USA and EU and after primary publication acceptability, whichever is later. No expiration date of data requests is currently set once data are made available. Access is provided after a proposal has been approved by an independent review committee identified for this purpose and after receipt of a signed data sharing agreement. Data and documents, including the study protocol, statistical analysis plan, and study report will be provided in a secure data sharing environment. For details on submitting a request, see the instructions provided at [www.vivli.org].

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