Factors influencing the patient evaluation of injection experience with the SmartJect® autoinjector in rheumatoid arthritis

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Abstract

Objective

To evaluate factors influencing injection patterns and patient evaluations of an autoinjector device in biologic-naïve patients beginning golimumab (GLM) treatment.

Methods

GO-MORE was an open-label, multinational, prospective study in patients with active rheumatoid arthritis (RA) (28-joint disease activity score based on erythrocyte sedimentation rate [DAS28-ESR] ≥3.2). Patients injected 50 mg subcutaneous GLM once monthly for 6 months. Patients reported use preferences and autoinjector evaluations by questionnaire. Responses were analysed descriptively. Effects of patient variables were evaluated with chi-square tests or t-tests.

Results

Of 3,280 efficacy-evaluable patients, 67.7% self-injected with the autoinjector. Compared with patients who self-injected, patients who had someone else administer injections had greater baseline disease activity (e.g. DAS28-ESR 5.84 vs. 6.23, respectively), but not more tender/swollen joints in hands/wrists. Month 6 efficacy was greater for patients who self-injected. In those who self-injected, injection site (thigh [75.2%; 1,563/2,077], abdomen [17.4%; 363/2,077], upper arm [7.2%; 151/2,077]) was not associated with wrist swelling or tender/swollen joints in the hand used for injection. Autoinjector ratings were similar across injection sites, yet less pain/discomfort was associated with abdomen injection. Patient autoinjector ratings were favourable overall (e.g. ease of use, pain). Patients with baseline functional impairment had slightly less favourable ratings.

Conclusion

Biologic-naïve patients who self-injected had less baseline disease activity and higher response rates than patients who did not self-inject. Although patients prefer to inject in the thigh, injection in the belly may be less painful. Most patients who self-injected had favourable autoinjector evaluations; patients with functional impairment had slightly less favourable ratings.

Key words

rheumatoid arthritis, golimumab, biologic products, tumour necrosis factor-alpha

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Introduction

Previous studies have shown that treatment administration route plays a key role in the treatment choices for patients with rheumatoid arthritis (RA) and that patients generally prefer to receive treatment at home and as infrequently as possible (1–3). However, individual patients may differ in their preferences for route of administration, self-injection *versus* injection by another person, and injection locations. In a study of preferences among patients with RA for self-injection of tumour necrosis factor (TNF) alpha inhibitors, approximately half of patients reported that they preferred to self-administer their treatment. Younger patients were more likely to prefer self-administration than older patients, and younger patients reported greater confidence in their ability to self-administer (3). About a third of patients, however, reported that they prefer to receive their treatment in a clinical setting. This subgroup cited the opportunities for social interaction and the availability of staff in case of complications as their main reasons for this choice (3).

A variable that may influence ability or desire to self-administer RA medications is that administering injections may be difficult or painful if patients have inflammation and/or joint damage in the hands and fingers. Functional impairment of the hands may make it more difficult for RA patients to self-inject, and injection may be more difficult in certain body locations because of the functionality in the hands that is required. Such difficulties with injection, or concerns regarding these issues, could affect dosing consistency or overall patient compliance, either of which could decrease treatment effectiveness. To help give patients the best instruction on how to use injection devices, it would be helpful to have more information about patient characteristics and/or disease characteristics associated with difficulty or ease of use of injection devices, such as disease activity in the hands, level of overall functional impairment, age, and gender.

Autoinjection devices are designed to alleviate some of the difficulties of injection with syringes, but some patients may still be reluctant to use them either because of physical limitations, lack of confidence, or other factors. This may particularly be the case for patients with RA who are just beginning treatment with biologics because they generally have high disease activity and are not familiar with the autoinjector device. The current study evaluated the use of an autoinjector device for subcutaneous (SC) injection of golimumab (GLM) in patients being treated for 6 months in the GO-MORE study, a large, multinational study of patients with RA who were naïve to biologic treatment. The goals of this subanalysis were:

1. to explore baseline characteristics of patients who chose to self-inject *versus* those who had someone else perform their injections;
2. to compare the efficacy of GLM in patients who did *versus* those who did not self-inject;
3. to look at the relationships among autoinjector use preferences; patient evaluations of the autoinjector; and patient characteristics, including age, overall disease activity, disease activity in the hands and wrists, and functional impairment.

Methods

Study design

The GO-MORE study was an open-label, multinational, multicentre prospective trial (ClinicalTrials.gov identifier: NCT00975130) composed of 2 parts. Only results from Part 1 are reported here. The study received approval from appropriate Research Ethics Committees and was conducted in accordance with the Declaration of Helsinki and standards of good clinical research practice. After a screening phase of approximately 7 days, patients received 50 mg SC GLM by the SmartJect® autoinjection device (Janssen Biotech, Inc., Horsham, PA) once monthly for 6 months. Patients continued their current disease-modifying anti-rheumatic drug (DMARD) regimen. Patients were given the option to self-inject, have their injections administered by a properly trained caregiver, or have injections administered in the clinic.

Patients

Patients had active RA despite DMARD therapy and were biologic-naïve. The main inclusion criteria were a diagnosis of RA according to the 1987 revised American College of Rheumatology (ACR) criteria, active disease (28-joint disease activity score based on the erythrocyte sedimentation rate [DAS28-ESR] ≥3.2) despite DMARD treatment, and use of at least 1 DMARD at a stable dose for at least 1 month prior to entering the study. Details of patient inclusion/exclusion criteria have been described previously (4).

Outcome measures

Patient disease history characteristics were assessed at baseline. At the start of month 4 and the end of month 6, patients reported preferences and opinions related to autoinjector device use on a questionnaire. Patients were asked if they self-injected GLM (yes/no), which part of the body they preferred to self-inject (upper arm/thigh/belly), and which hand they used to self-inject (left/right/left and right equally). Appreciation of autoinjector use was assessed through a Likert scale with 5 categories using the following 5 questions: how easy it was to use the self-injection device, how much overall discomfort and pain/stinging they felt upon self-injection, how sure they were that the current treatment had been fully injected, how satisfied they were with the therapy's frequency of injections, and what was their overall impression of the self-injection experience.

Several efficacy and safety variables were measured throughout the study; these findings have been reported separately (4). Efficacy variables reported here included DAS28-ESR score and percentage of patients who achieved good or moderate European League Against Rheumatism (EULAR) DAS28-ESR response, DAS28-ESR remission, and DAS28-ESR low disease activity at the end of month 6.

Statistical methods

The efficacy-evaluable population consisted of all patients who received at least 1 dose of SC GLM and had DAS28-ESR scores at baseline and at 1 or more post-baseline visits. No formal statistical hypotheses were planned for this open-label study; however, the sample size in GO-MORE was planned for an 85% probability of detecting differences of at least 10% in the proportion of patients achieving DAS28-ESR EULAR response at 6 months among patient subgroups using an overall 2-sided alpha of 0.05 and controlling for multiplicity.

To evaluate adherence to recommended monthly dosing frequency, the average of the 5 intervals between doses was calculated for patients who had received all 6 doses of SC GLM. Proportions of patients with average dosing intervals of <29 days, 29 to 31 days, and >31 days were reported.

Baseline characteristics were summarised separately for patients who did and did not choose to self-inject. Six-month efficacy in these 2 groups was compared by using Cochran-Mantel-Haenszel chi-square tests. Efficacy variables evaluated were percentages of patients with DAS28 EULAR good or moderate response, DAS28-ESR remission (<2.6), DAS28-ESR low disease activity (<3.2), SDAI remission (≤3.3), and HAQ minimal or no functional impairment (≤.5).

Patient ratings of the autoinjector were analysed descriptively. If a patient did not respond to a particular question on the questionnaire, the data for that question were considered missing. Ratings were also analysed by patient age group (<48 years, 48–58 years, and >58 years) and by level of functional impairment at baseline (Health Assessment Questionnaire-Disability Index [HAQ-DI] >0.5 or HAQ-DI ≤0.5). To determine if disease activity might affect patient evaluations of the autoinjector, ratings and autoinjector use preferences (hand used for self-injection and site of self-injection) were analysed by patient characteristics, including handedness and hand-related disease activity levels.

Results

Patient disposition

Of 3,366 enrolled patients, 99.7% received ≥1 dose of study medication, and 91.7% completed 6 months of treatment. Details about reasons for discontinuation have been reported previously (4). The efficacy-evaluable population consisted of 3,280 patients.

Dosing frequency

Of patients who received 6 total doses of SC GLM (n=3,025), the average dosing interval was <29 days for 6.88% of patients; 29 to 31 days for 79.8% of patients; and >31 days for 13.32% of patients. In response to the autoinjector questionnaire item asking whether patients were satisfied with the autoinjection frequency, 92.1% of patients reported they were satisfied or very satisfied.

Self-injection pattern

Of the efficacy-evaluable population, 67.7% of patients (2,222/3,280) self-injected using the autoinjector device, and 32.3% had someone else administer their injections. Self-injection rates at month 6 varied widely by country, ranging from 45% to 100% (Table I). The 2 regions with the largest patient populations were Europe and Latin America, which had self-injection rates at month 6 of 69.7% (1,267/1,818) and 54.0% (489/906), respectively.

Patient demographics and baseline characteristics

The full study population has been described in detail previously (4). Overall, the efficacy-evaluable population had a mean disease duration of 7.6 years (SD=7.9), mean DAS28-ESR of 5.97 (SD=1.095), and mean HAQ-DI of 1.44 (SD=0.672) at baseline. Demographic and disease characteristics for the subgroups of patients who did and did not self-inject are shown in Table II. These subgroups did not differ in demographic characteristics of age, gender, or body mass index (BMI). The subgroups appeared to have differences in racial composition, likely related to country location.

Patients who did not self-inject had slightly greater baseline disease activity across a variety of measures, including DAS28-ESR, EULAR disease activity, 28-joint tender joint count (TJC28), and 28-joint swollen joint count (SJC28) (Table II). To determine if hand-related joint synovitis, in particular, might be related to the choice of self-injection,

Table I. Number and percentage of patients who reported at month 6 that they self-injected golimumab by region and country.

Region	Self-injection n (%)
Asia, n=133	20 (15.0)
India, n=105	0
South Korea, n=28	20 (71.4)
Canada, n=218	186 (85.3)
Europe, n=1818	1,267 (69.7)
Austria, n=82	71 (86.6)
Belgium, n=123	103 (83.7)
Czech Republic, n=115	78 (67.8)
Denmark, n=44	39 (88.6)
Finland, n=52	44 (84.6)
France, n=97	76 (78.4)
Germany, n=370	259 (70.0)
Greece, n=20	9 (45.0)
Hungary, n=71	41 (57.7)
Ireland, n=11	10 (90.9)
Italy, n=98	54 (55.1)
Netherlands, n=36	34 (94.4)
Norway, n=5	5 (100.0)
Poland, n=129	82 (63.6)
Portugal, n=25	20 (80.0)
Romania, n=51	14 (27.5)
Russia, n=59	28 (47.5)
Slovak Republic, n=1	1 (100.0)
Spain, n=140	74 (52.9)
Switzerland, n=26	17 (65.4)
United Kingdom, n=263	208 (79.1)
Latin America, n=906	489 (54.0)
Argentina, n=86	60 (69.8)
Brazil, n=169	127 (75.1)
Chile, n=34	31 (91.2)
Colombia, n=130	65 (50.0)
Ecuador, n=58	32 (55.2)
Guatemala, n=68	34 (50.0)
Mexico, n=197	96 (48.7)
Panama, n=35	1 (2.9)
Peru, n=129	43 (33.3)
Middle East, n=88	39 (44.3)
Israel, n=53	36 (67.9)
Turkey, n=35	3 (8.6)
South Africa, n=117	93 (79.5)

TJC and SJC were calculated with only hand and wrist joints (TJC28 and SJC28). With this method, there were no differences in SJC28 and TJC28 at baseline in patients who self-injected *versus* those who did not (mean SJC28 8.39 [SD=4.89] *vs*. 8.45 [SD=5.19], respectively; mean TJC28 10.31 [SD=5.85] *vs*. 10.41 [SD=5.75], respectively).

The physicians of patients who self-injected were slightly more experienced with biologic treatment than physicians of patients who did not self-inject. Of physicians whose patients did self-inject, 31.4% had 0 to 6 years of experience treating patients with biologics, 56.1% had >6 to 10 years of experience, and 12.5% had >10 years of experience.

Table II. Baseline characteristics: efficacy-evaluable population (n=3,280).

Demographic characteristics	SC GLM n=3,280	
	Did self-inject n=2,222	Did not self-inject n=1,058
Female, n (%)	1,793 (80.7)	923 (87.2)
Age, y		
Mean (SD)	52.0 (12.16)	52.8 (14.06)
Median (min, max)	53.0 (18, 88)	54.0 (18, 85)
Race, n (%)		
Caucasian	1,691 (76.1)	592 (56.0)
Multiracial	207 (9.3)	237 (22.4)
Other	140 (6.3)	71 (6.7)
Not allowed to collect this data	85 (3.8)	12 (1.1)
Asian	52 (2.3)	115 (10.9)
Black or African American	41 (1.8)	16 (1.5)
American Indian or Alaska Native	6 (.3)	15 (1.4)
BMI (kg/m^2)	n=2214	n=1057
Median (min, max)	26.3 (15.6, 54.5)	25.8 (14.0, 49.4)
Treatment history		
Concomitant MTX dose, n (%)	1,804 (81.2)	859 (81.2)
Any dose		
Low (<10 mg/week)	101 (4.5)	41 (3.9)
Medium (≥10 and <15 mg/week)	320 (14.4)	206 (19.5)
High (≥15 mg/week)	1,383 (62.2)	612 (57.8)
Concomitant CS use, n (%)		
Received CSs	1,370 (61.7)	708 (66.9)
DMARD combinations*, n (%)	n=2,216	n=1,054
MTX only	1,153 (52.0)	528 (50.1)
MTX + chloroquine derivatives	270 (12.2)	163 (15.5)
Leflunomide only	203 (9.2)	100 (9.5)
MTX + leflunomide	145 (6.5)	71 (6.7)
MTX + sulfasalazine	107 (4.8)	43 (4.1)
Sulfasalazine only	69 (3.1)	21 (2.0)
Chloroquine derivatives only	67 (3.0)	20 (1.9)
MTX + chloroquine derivatives + sulfasalazine	66 (3.0)	40 (3.8)
Number DMARDs failed, n (%)	n=2,221	n=1,058
1 DMARD	769 (34.6)	360 (34.0)
2 DMARDs	772 (34.8)	404 (38.2)
≥3 DMARDs	680 (30.6)	294 (27.8)
Disease characteristics		
Disease duration (y)	n=2,221	n=1,058
Mean (SD)	7.4 (7.5)	8.1 (8.6)
Median (min, max)	4.8 (0.02, 50.19)	5.0 (0.01, 56.56)
TJC28, mean (SD)	12.7 (6.8)	13.6 (6.7)
SJC28, mean (SD)	9.4 (5.4)	10.1 (5.9)
EULAR DAS28-ESR, n (%)	n=2,215	n=1,055
Moderate disease activity (3.2–5.1)	549 (24.8)	149 (14.1)
High disease activity (>5.1)	1,666 (75.2)	906 (85.9)
DAS28-ESR	n=2,222	n=1,058
Mean (SD)	5.84 (1.09)	6.23 (1.06)
DAS28-CRP	n=2,188	n=1,048
Mean (SD)	5.34 (0.99)	5.58 (1.00)
CRP (mg/L)	n=2,188	n=1,048
Mean (SD)	12.94 (18.22)	17.69 (23.96)
ESR (mm/hr)	n=2,222	n=1,058
Mean (SD)	31.4 (22.7)	42.2 (26.9)
Anti-CCP (U/mL)	n=2,185	n=1040
Mean (SD)	367.0 (543.5)	379.2 (502.8)
Rheumatoid factor (IU/mL)	n=2,188	n=1,046
Mean (SD)	206.7 (559.1)	281.1 (598.9)
HAQ-DI¥	n=2,221	n=1,056
Mean (SD)	1.37 (0.66)	1.59 (1.67)
EQ-5D index	n=2,215	n=1,053
Mean (SD)	0.44 (0.32)	0.36 (0.34)

*Each additional combination used by <3% of patients.
¥Lower HAQ-DI scores indicate better outcomes.
BMI: body mass index; CCP: cyclic citrullinated peptide; CRP: C-reactive protein; CS: corticosteroid; DAS28: 28-joint disease activity score; DMARD: disease-modifying anti-rheumatic drug; EQ-5D: EuroQol 5-dimension quality of life questionnaire; ESR: erythrocyte sedimentation rate; EULAR: European League Against Rheumatism; GLM: golimumab; HAQ-DI: Health Assessment Questionnaire Disability Index; IU: international unit; Max: maximum; Min: minimum; MTX: methotrexate; SC: subcutaneous; SD: standard deviation; SJC28: swollen joint count 28; TJC28: tender joint count 28; y: years.

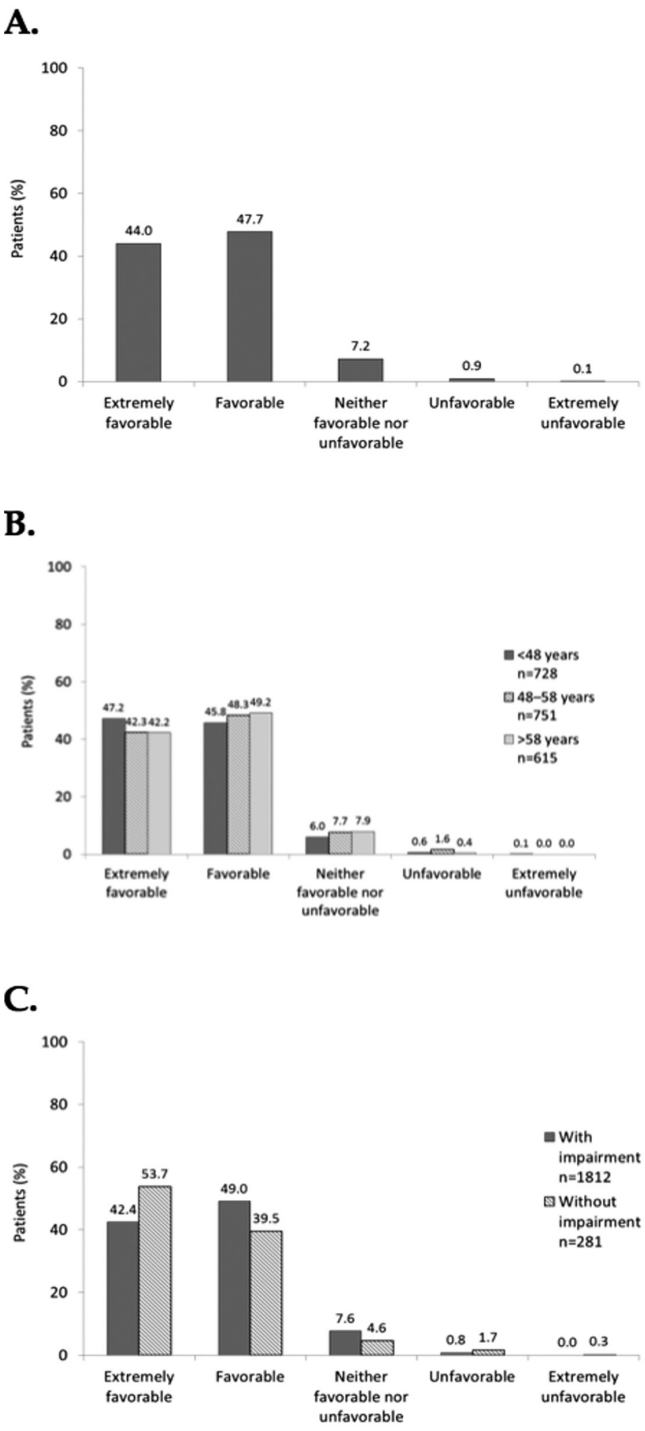

Fig. 1. Patient overall impressions of the autoinjector device at month 6 (**A**) overall (n=2,094) and by (**B**) patient age and (**C**) functional impairment.
The number of patients in each group only includes the patients who self-injected and responded to the given question at month 6.

Of physicians whose patients did not self-inject, 44.4% had 0 to 6 years of experience with biologics, 48.1% had >6 to 10 years of experience, and 7.4% had >10 years of experience.

Efficacy of SC-GLM in patients who self-injected versus those who did not

For all efficacy outcomes evaluated, patients who self-injected had greater efficacy at month 6 than patients who had someone else administer their GLM injection. Patients who self-injected were more likely to have DAS28-ESR good or moderate response (85.4% *vs*. 76.3%, $p<0.001$), DAS28-ESR remission (27.7% *vs*. 17.2%, $p<0.001$), DAS28-ESR low disease activity (42.7% *vs*. 28.1%, $p<0.001$), Simplified Disease Activity Index (SDAI) remission (15.7% *vs*. 11.4%, $p<0.001$), and HAQ ≤.5 (40.4% *vs*. 32.0%, $p<0.001$).

Autoinjector use preferences

The remaining analyses include only patients who chose to self-inject (n=2,222). At month 6, most patients reported they preferred to autoinject in the thigh (75.2%), followed by the abdomen (17.4%) and the upper arm (7.2%). Similar autoinjection preferences were reported at month 4.

Patients' choices of autoinjection site did not differ by patient age subgroup (<48 years, 48 to 58 years, and >58 years), hand-related disease activity level, or functional impairment (HAQ-DI >0.5 *vs*. HAQ-DI ≤0.5) at baseline. More patients in all age subgroups chose to self-inject in the thigh (77.2%, 75.3%, and 78.8% of patients aged <48 years, 48 to 58 years, and >58 years, respectively) than in the abdomen (17.8%, 17.3%, and 17.3% in the respective age groups) or the upper arm (9.9%, 7.4%, and 3.9% in the respective age groups). There was no relationship between choice of injection site and baseline wrist SJC (mean wrist SJC 0.38 [SD=0.67], .44 [SD=0.72], and .37 [SD=0.67] for patients who injected in the thigh [n=1554], abdomen [n=359], or upper arm [n=151], respectively). Of patients with functional impairment at baseline, 76.2% (1370/1797), 16.8% (302/1797), and 7.0% (125/1797) injected in thigh, abdomen, and upper arm, respectively; of patients without functional impairment at baseline, 68.8% (192/279), 21.9% (61/279), and 9.3% (26/279) injected in the thigh, abdomen, and upper arm, respectively.

The site that patients reported injecting into (abdomen, thigh, or upper arm) was not associated with the hand used for injection (right, left, both hands) or evaluations of the autoinjector (ease of use, certainty of complete injection, satisfaction with injection frequency, or overall impression of autoinjection experience), all $p>0.05$ at month 6. However, patients who responded that that they felt "no pain" upon injection were more likely than patients with other responses to have injected in the abdomen ($p<0.001$), and patients who responded that they felt "no discomfort" upon injection were more likely to have injected in the abdomen ($p=0.006$).

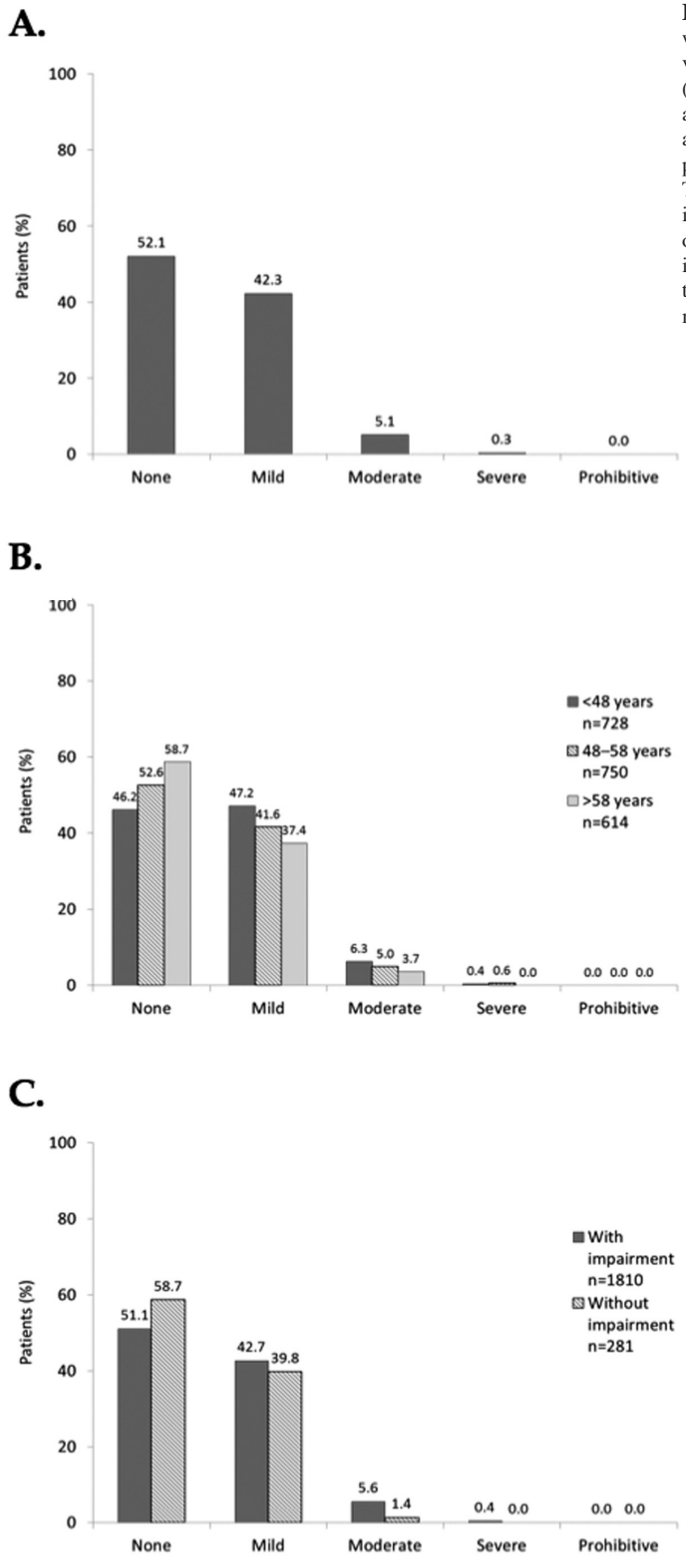

Fig. 2. Levels of pain with autoinjector device use at month 6 (**A**) overall (n=2,092) and by (**B**) patient age and (**C**) functional impairment.
The number of patients in each group includes only patients who self-injected and responded to the given question at month 6.

Overall, 87.8% of patients (1,818/2,070) indicated that they used their right hand for autoinjection. Of the patients who used their right hand for autoinjection, 97.9% reported that their right hand was their dominant hand. Of patients who used their left hand for autoinjection (202/1,988), 38.3% (77/201) reported that their left hand was their dominant hand. Use of the nondominant hand did not appear to be related to a greater number of tender or swollen joints; patients who used their nondominant hand had similar TJC22 and slightly lower SJC22 than patients who used their dominant hand (nondominant mean TJC22, 10.0 *vs*. dominant mean TJC22 10.4 [p=0.387]; nondominant mean SJC22 7.3 *vs*. dominant mean SJC22 8.5 [p=0.004]). The hand used for autoinjection (left *vs*. right) did not appear to vary with patient age or the presence of functional impairment at baseline.

Patient evaluation of autoinjector device

Patients evaluated the autoinjector device at the start of month 4 and end of month 6. Because responses at both months were very similar, only month 6 responses are reported. More than 90% of patients reported that the overall autoinjection experience was either favourable or extremely favourable (Fig. 1A), and this pattern held for all age groups (Fig. 1B). Overall ratings were slightly less favourable for patients with functional impairment than without functional impairment at baseline (Fig. 1C). Disease activity at month 6 appeared to be associated with autoinjector favourability. Of patients who did not give a favourable rating to the autoinjector, 76.3% (129/169) had DAS28-ESR ≥3.2 at month 6; of patients who did give a favourable rating to the autoinjector 55.5% (1,064/1,917) had DAS28-ESR ≥3.2.

No pain or mild pain with autoinjector use was reported by more than 90% of patients (Fig. 2A). The oldest patients (>58 years) tended to be more likely than the youngest patients (<48 years) to report feeling no pain upon autoinjection (Fig. 2B). Injection pain was comparable for patients with and without functional impairment, with a vast majority reporting little or no pain (Fig. 2C). The pattern of ratings for discomfort upon injection (not shown) was almost identical to the pattern for pain ratings.

More than 80% of patients found the autoinjector to be easy or extremely easy to use (Fig. 3A). The youngest patients (<48 years) and patients with minimal or no functional impairment at baseline tended to report slightly greater ease of injection (Fig. 3B-C). 96.9% (2,030/2,094) of patients were

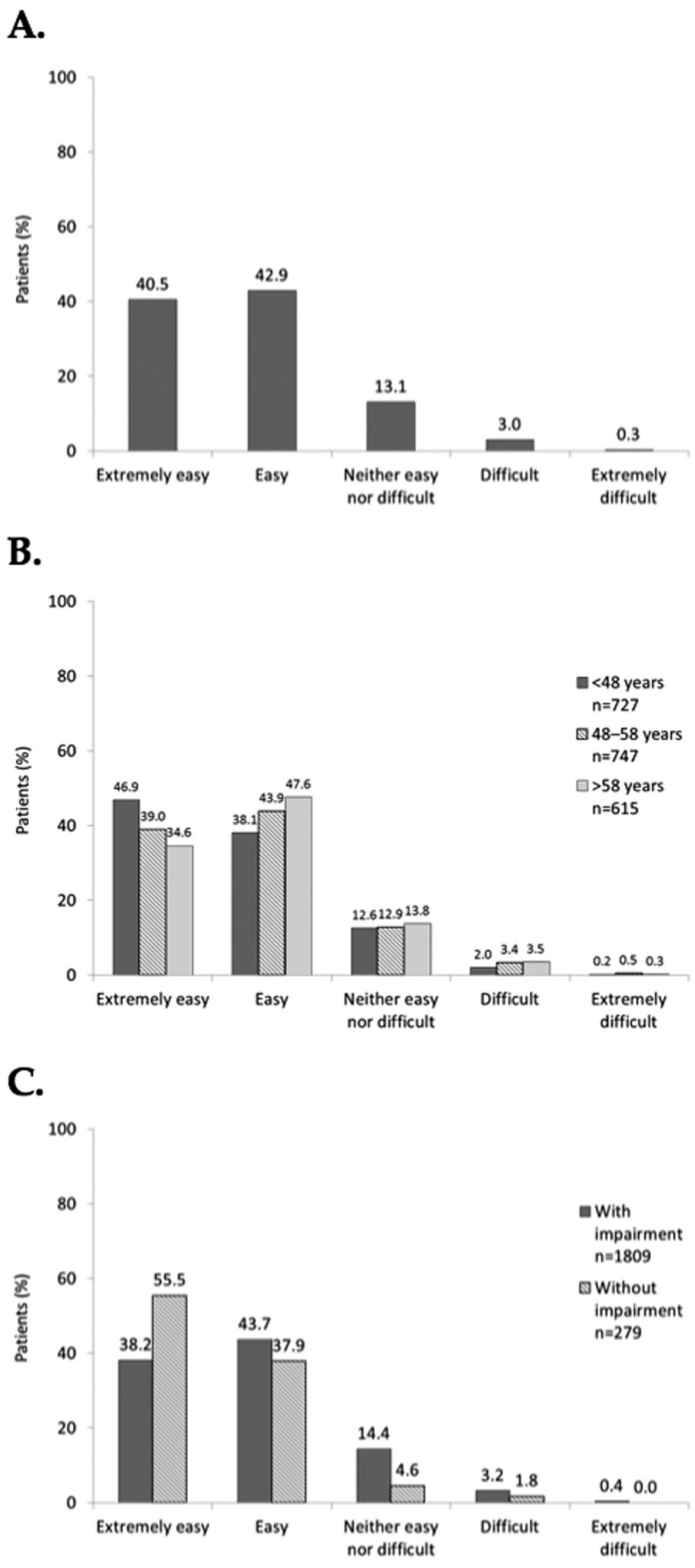

Fig. 3. Ease of autoinjector device use at month 6 (**A**) overall (n=2,089) and by (**B**) patient age and (**C**) functional impairment.
The number of patients in each group only includes the patients who self-injected and responded to the given question at month 6.

sure or very sure that when they used the autoinjector, the treatment had been fully injected.

Discussion

Current treatment in RA with TNF inhibitors and other biologics involves SC injections routinely administered by the patient herself/himself (1). Although this treatment approach is convenient, there are concerns that appropriate dose administration via self-injection devices may be difficult for patients whose hands are affected by RA (5). Ready-to-use syringes and ready-to-use autoinjector devices have been introduced to ease this problem.

This analysis of the GO-MORE study explored factors that influence patient evaluations of an autoinjector device that was used for SC injection of GLM in patients who were biologic-naïve. Two-thirds of patients chose to self-inject with the autoinjector, and they generally found it very easy to use and reported little pain or discomfort. The third of patients who chose not to self-inject were similar to those who did self-inject on most baseline characteristics, including age and gender. However, they had slightly greater overall disease severity and were more likely to have functional impairment at baseline. Surprisingly, they did not have significantly greater disease in the hands, as assessed by TJC22, SJC22, and wrist SJC. Functional impairment is likely to improve during anti-TNF treatment (6); and in fact, both function and disease activity improved in the GO-MORE study (4). It is not clear whether patients who are initially reluctant to self-inject would consider this option later in treatment.

It is possible that hand and wrist inflammation may affect the ability or perceived ability of patients with RA to self-administer medication. Patients who had greater overall functional impairment at baseline rated the autoinjector slightly less favourably. Such difficulties and concerns could affect dosing consistency or compliance, thereby decreasing treatment effect. Although complete medication delivery was not measured directly, patients who self-injected reported being confident that the full dose had been injected. When efficacy was directly compared in patients who self-injected *versus* those who had someone else perform their injections, patients who self-injected had greater efficacy. It has been shown in patients with RA that coping strategies of cognitive reframing and active problem-solving contribute to coping effectiveness, which is positively related to the perception of general health (7). These data suggest that certain coping strategies used by RA patients are effective in influencing quality of life (7). In a

previous report from the GO-MORE study patient expectations of treatment at baseline were also associated with effectiveness of treatment at 6 months (8). The association we found between self-injection and treatment efficacy may suggest that self-injection is an expression of active coping, which may be a patient characteristic that leads to better outcomes. It is also important to note that these patients who self-injected had lower disease activity at baseline before the start of treatment than patients who did not self-inject. The previously reported overall results of the GO-MORE study indicated that achieving low disease states or remission were more likely in patients with lower baseline disease activity (4). This may be an alternative explanation for the observed differences in efficacy.

Patients had a clear preference for injection in the thigh rather than the abdomen or upper arm. These preferences did not vary by age, disease activity in the hand, or functional impairment at baseline. Although most patients choose the thigh as the injection site, it may not have been the least painful site. The patients who reported feeling no pain at the time of injection were more likely to have injected in the abdomen than patients who reported that they had some pain upon injection.

Patients who are satisfied with their treatment show greater adherence to their treatment plan, which, in chronic diseases, can improve treatment effectiveness (9). In the current study, 80% of patients who had 6 doses during the 6 months of the study stayed within the recommended monthly dosing frequency (within 29 to 31 days between doses, on average); and after 6 months of SC GLM treatment, 82% of patients had good or moderate EULAR responses and 24% of patients had attained remission (4). More than 90% of patients in the GO-MORE study reported being either satisfied or very satisfied with the monthly frequency of SC GLM autoinjection.

These findings support previous reports of positive patient experiences with the autoinjector device that is used for SC GLM delivery. In a study of patient-reported pain upon injection of TNF-alpha inhibitors (etanercept [ETA], adalimumab [ADA], and GLM) *versus* a control influenza injection, GLM injections were reported to be less painful than those of the other two TNF-alpha inhibitors (10). Similarly, in a study of patients receiving TNF-alpha inhibitor treatment for RA, psoriatic arthritis, or ankylosing spondylitis, patients who received GLM reported less stinging and burning upon injection than did patients who received ADA or ETA (11). In the GO-SAVE study, in which patients with active RA despite methotrexate and either ADA or ETA were switched to SC GLM autoinjector device, 70.6% of patients reported they preferred the GLM autoinjector to their previous injection device after 8 weeks of GLM treatment (12).

Strengths of this analysis of the GO-MORE study are that it includes a large number of patients in real-world settings and a diverse population in several countries receiving a variety of concomitant treatments. The study did not directly assess why some patients chose to self-inject and some did not. Although there were some baseline differences in the patients who did *versus* did not choose to self-inject, the reasons why some patients did not self-inject are unclear; and additional studies would be required to determine if educational interventions would help these patients and their treating physicians determine ways they could successfully use the autoinjector device with confidence. Given the wide variability of self-injection rates by country, there may have been practice differences or cultural factors that influenced patients' willingness or capability to self-inject.

Overall, patients who used the autoinjector device for GLM treatment in the GO-MORE study found administration of treatment to be easy, involve little pain, and felt confident that the full dose had been injected. Patients had good compliance with the suggested monthly dosing interval, and also good rates of efficacy.

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