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ORIGINAL RESEARCH

Association Between Nursing Support Levels and Effectiveness of Golimumab in the Management of Patients with Rheumatologic Diseases

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ABSTRACT

Introduction: The main objective of this study was to assess the level of nursing support received by biologic-naïve rheumatological patients treated with golimumab during their first cycle.

Methods: Adult patients ($N = 119$; aged 46.9 ± 13.4 years (mean ± standard deviation); 49.6% males), with rheumatoid arthritis ($N = 40$), ankylosing spondylitis ($N = 58$) or psoriatic arthritis ($N = 21$), and treated with golimumab (first tumor necrosis factor-α inhibitor) during a first reimbursement cycle were included by 17 Belgian centers. Patients were categorized in three levels of nursing support (intense, medium, or low). They filled in a non-validated and exploratory questionnaire about satisfaction, quality, and helpfulness of information.

Results: The nursing support was considered intense, medium, or low for 98 (82.4%), 10 (8.4%), and 11 (9.2%) patients, respectively. All disease activity scores improved versus baseline, and 90% of the patients qualified for treatment prolongation without major differences between nursing level groups. The proportion

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of patients able to self-inject golimumab was 88, 90, and 73% in the intense, medium, and low support groups, respectively. Satisfaction was high in all three nursing support groups.
Conclusions: This prospective open-label study has confirmed the short-term effectiveness of golimumab in three rheumatological diseases, with most of the patients qualifying for reimbursement renewal. The limited sample size and the fact that the vast majority of patients benefited from an intense nursing support did not allow drawing definite conclusions concerning the impact of the nursing level on the treatment effectiveness and changes in the disease activity. Nurses seem however to play a crucial role in this short-term study but this remains to be confirmed in a longer-term study.

Keywords: Ankylosing spondylitis; Belgium; Golimumab; Nursing; Psoriatic arthritis; Rheumatoid arthritis

Key Summary Points
Confirmation of the short-term effectiveness of golimumab in rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis patients in a real-life context.
Ninety percent of the patients qualified for treatment prolongation, without major differences between nursing level groups.
In this short-term study, nurses appear to manage patient care effectively. This should be confirmed in a longer-term study.
Nurses may provide support to physicians who may have less time to dedicate to their patients.

INTRODUCTION

Rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS) are the three most common inflammatory rheumatic diseases, sharing some key pathophysiological mechanisms. Tumor necrosis factor alpha (TNF-α) is a key player in the management of all three diseases [1].

Golimumab is a human immunoglobulin monoclonal antibody that forms high-affinity, stable complexes with the human TNF-α, thereby preventing its binding to its receptors [2].

The efficacy and safety of golimumab have extensively been demonstrated in pivotal randomized controlled trials, in RA [3], in AS [4], and in PsA patients [5]. These results have subsequently been confirmed for the three indications in real-life observational studies, both on a short-term (6 months) and long-term (2–3 years) treatment periods [6–9].

Patients who are treated for the first time with TNF-α inhibitors generally have many questions about the benefits and risks of their new treatment, as well as how to administer the injections [10–12].

A study conducted in UK [13] with a postal questionnaire has evaluated the attitudes of patients receiving drug counselling for RA medications. Overall, 39% of patients responded to the survey (median age 65 years, 66% female, median disease duration 15 years) and considered drug information from rheumatology nurses, rheumatologists, and leaflets as useful. More than one respondent out of three felt reassured by information received, but the same proportion felt more worried. Forty percent of subjects declared they were aware of the drug-adverse events. A total of 42–65% of patients understood that the TNF-α inhibitor therapy should be discontinued in case of infection, but most of them were ignoring the need for such a discontinuation in case of cancer. The conclusion of the authors was that there is potential for further improvement in drug counselling, to increase the patient's safety [13].

Nurses often spend more time with patients than doctors do. They are in a unique position to explore patient's needs; educate about treatment, administration, product storage, and self-injection technique; determine readiness for and understanding of treatment; monitor safety

and progress; and coordinate care within a multidisciplinary setting [14]. Additional nurse involvement may address patient's unmet needs, in particular about understanding the level of efficacy they can expect from their treatment and being aware of potential side effects, and concerns about physical pain, lost sleep, diminished functional capacity at work, difficulty with daily activities, and negative effects on home life and relationships [14]. In the nurse-led care (NLC) model, registered nurses, clinical nurse specialists, or nurse practitioners working in collaboration with physicians and other team members have their own patients to whom they provide services such as monitoring, educating, and support, thus taking on the primary responsibility for patient management. NLC for patients with RA is effective, acceptable, and safe as compared to other models. However, current evidence is insufficient to draw conclusions about its efficiency, accessibility, and appropriateness [15].

In Belgium, nurses are increasingly involved in rheumatology practices to explain the disease and medication (posology, expected treatment effect, precautions, and safety) to patients. However, the level of support provided by nurses has not been well described. In addition, the impact that this nursing support has on the extent to which patients are satisfied with their health status and treatment information they received is not known.

This study was designed to evaluate the effectiveness of golimumab on a short-term basis (4–6 months), in a real-life situation with biological-naïve RA, PsA, and AS patients, to assess the education and nursing support provided to patients, and to measure the levels of patient's satisfaction, the quality, and the helpfulness of provided information. In Belgium, patients need to return to their rheumatologist 4–6 months after initiating TNF-α inhibitor therapy to determine if they qualify for prolongation of reimbursement. Only patients who respond to the treatment without significant adverse experiences are allowed to continue treatment. This mandatory visit provided an ideal opportunity to investigate these questions in a real-life and observational environment.

METHODS

This was a prospective, observational, national (Belgian) and cross-sectional study in RA, AS, and PsA patients (17 centers) who started golimumab as their first TNF-α inhibitor treatment and who returned at the end of the first reimbursement cycle for a planned check-up visit, to determine if they qualified for further reimbursement.

The primary objectives of the study were to assess the level of nursing support received by biologic-naïve patients treated with golimumab at the end of the first reimbursement cycle (i.e., after 4–6 months of treatment), according to the patient's perception, and to assess the demographic and disease characteristics of patients receiving intense, medium, or no nursing support during this cycle. The secondary objectives were to assess the extent to which the level of nursing support as perceived by the patient is associated with the patient's satisfaction, and their disease and treatment knowledge at the end of the first reimbursement cycle (i.e., after 4–6 months of treatment), and to assess the proportion of patients deemed appropriate by their rheumatologist to continue treatment on golimumab in the next reimbursement cycle (i.e., to continue treatment after 4–6 months).

Adult ($\geq$ 18 years) patients, suffering from RA, AS, or PsA, living in Belgium and treated with golimumab during a first reimbursement cycle (4 ± 1 months for AS; 6 ± 1 months for RA and PsA) were included in the study. Patients who previously received golimumab or any other biological agents were excluded from the study. All patients gave their written informed consent and the study was conducted in agreement with GCP/ICH guidelines and the Declaration of Helsinki. The protocol was submitted to the Ethics Committees of each center (Supplementary Material) and was approved by the central Ethics Committee (Erasme Hospital, Université Libre de Bruxelles, Brussels, Belgium, 29 March 2016).

The following variables were evaluated: patients' demographics (gender, age, disease duration, educational level, language, distance

from home to center, nursing support offered to the patient); disease severity (at baseline and at the check-up visit—Disease Activity Score (DAS) 28 and Health Assessment Questionnaire (HAQ) for RA; Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and HAQ for AS; 76/78 Tender Joint Count (TJC)/Swollen Joint Count (SJC) and HAQ for PsA); characteristics of the treatment center (region; university, non-university center or private practice; availability of nursing support in the center).

Patients filled in a first questionnaire about nursing support they received at the start of their new treatment. This questionnaire had been designed by clinicians, based on the criteria defined by an advisory board. It had not been validated and has therefore to be considered as exploratory. Based on this questionnaire, they were categorized in three levels of nursing support (intense, medium or absent) as defined in Table 1. If the physician performed all the tasks himself/herself, the answer to the first questionnaire was 'No' and the patient was classified in the category 'None' (no nurse support).

Then, patients filled in a second questionnaire about satisfaction (three questions), quality of information (nine questions), and helpfulness of information (one question). This questionnaire had also been designed by clinicians, based on the criteria defined by an advisory board. Again, it had not been validated and has to be considered as exploratory (Supplementary material).

It should be noted that these questionnaires asked for satisfaction in general, including if support was provided by the physician instead of the nurse. Therefore, a patient with no nursing support (based on 1st questionnaire) could still have received all support and all information and still be very satisfied.

Statistical analyses were performed using SAS® (version 9.3) and were only descriptive. Continuous variables were described using the number of observations, the number of missing observations, the arithmetic mean, the standard deviation (SD), the median, the minimum, the maximum, and the first and third quartiles (Q1–Q3). Discrete variables were described using number of observations, number of missing values, and percentages in each of the scores or categories. Missing values were not replaced, nor extrapolated.

RESULTS

A total of 120 patients were enrolled in the study and 119 patients (99.2%) were analyzed in the full analysis set, including all enrolled patients who took at least one dose of the study treatment and who completed the nursing support questionnaire.

Demographics and other baseline characteristics of the patients are presented in Table 2. Patients (49.6% males) were 46.9 ± 13.4 years (mean ± SD) (minimum–maximum (min–max) = 18–84 years; 10.1% aged over 65 years). The distribution of patients in the three diseases was 40 RA (33.6%), 58 AS (48.7%) and 21 PsA (17.6%). The average disease duration was 6.0 ± 7.7 years (min–max = 0.2–41 years).

The nursing support was considered intense, medium, or absent for 98 (82.4%), 10 (8.4%), and 11 (9.2%) patients, respectively. In particular, approximately 90% of the patients reported that they received explanations and instructions on their illness and the use of golimumab, 87% reported having a nurse that they could contact for information about the drug, 59% reported that a nurse had injected them with golimumab, and 75–80% reported receiving educational materials about the treatment and the safety aspects of biologic agents.

The percentage of patients with a post-graduate level was equal to 20.9% in the intense nursing support group versus 0% and 10% in the medium and no nursing support groups, respectively.

The percentage of patients benefiting from an intense nursing support was 90, 81, and 71% in RA, AS, and PsA patients, respectively.

General characteristics of the rheumatology practices are summarized in Table 3. The practices for the intense and medium nursing support groups were evenly distributed among university centers, non-university centers, and private practices. All patients treated in a private

Table 1 Definition of the three nursing support levels

Nursing support level	Definition
Intense	A nurse, either from the center or private practice, or a home care nurse, was the main person to contact for the patient during the first 4–6 months of treatment (Note: a person who was not a graduated nurse but who took the same responsibilities was considered as a nurse)
	At least five out of the seven following actions were performed by a nurse during the first 4–6 months of treatment:
	(1) Injection of golimumab by a nurse at least once
	(2) Instruction on golimumab injection (how to inject golimumab)
	(3) Instruction on golimumab posology (amount of golimumab to inject and how often to inject it)
	(4) Explanation of the treatment with golimumab
	(5) Provision of patient educational material about the treatment with golimumab
	(6) Education about safety recommendations for biological agents like golimumab
	(7) Explanation of the illness
Medium	At least three out of the four following actions were performed by a nurse between the start of therapy and the check-up visit at 4–6 months:
	(1) Injection of golimumab by a nurse at least once
	(2) Instruction on golimumab injection (how to inject golimumab)
	(3) Instruction on golimumab posology (amount of golimumab to inject and how often to inject it)
	(4) Explanation of the treatment with golimumab
None	None of the criteria of intense and medium nurse support were fulfilled
	This does not necessarily mean that there was no intervention or actions performed by a nurse

practice received at least medium nursing support. Nursing support availability at the treatment center was 96.9% for the intense nursing support group, 70.0% for the medium nursing support group, and 54.5% for the no nursing support group. Most patients at all types of centers had intense nursing support (82.4%). The proportion of patients with no nursing support was 18.4% for patients at non-university centers versus 9.5% at university centers and 0% in private practices.

Disease activity at treatment initiation and at the end of the first reimbursement cycle is summarized in Table 4. All scores improved relatively equally in the three nursing support groups. In RA patients, the mean (± SD) DAS28-ESR score decreased from 5.0 ± 1.0 to 2.3 ± 1.5, and the mean DAS28-CRP score decreased from 4.6 ± 0.7 to 2.8 ± 1.0. In AS patients, the mean BASDAI score decreased from 6.8 ± 1.4 to 3.6 ± 2.1. In PsA patients, the mean 76 SJC decreased from 7.0 ± 4.9 to 1.1 ± 1.9, and the mean 78 TJC decreased from 8.7 ± 9.5 to 1.7 ± 2.1. In all three rheumatological conditions, the mean HAQ total score decreased from 21.1 ± 10.9 to 7.8 ± 8.1.

At the end of the first reimbursement cycle, 90% of RA patients ($N = 36$ out of 40) met EULAR criteria based on DAS28 of a moderate-to-good response, 86.2% of AS patients ($N = 50$ out of 58) had a reduction of at least 2 points of their BASDAI score, 100% of oligo-PsA patients

Table 2 Demographics and other baseline characteristics of the patients: overall and in the three nursing support groups

	Intense nursing support (*N* = 98)	**Medium nursing support (*N* = 10)**	**No nursing support (*N* = 11)**	**Overall (*N* = 119)**
Age (years)				
Mean (SD)	46.1 (13.1)	52.7 (12.6)	49.0 (16.0)	46.9 (13.4)
Median	45.5	53.5	46.0	46.0
Min–max	18.0–76.0	29.0–67.0	28.0–84.0	18.0–84.0
Q1–Q3	37.0–55.0	46.0–64.0	35.0–58.0	37.0–55.0
$\geq$ 65 years, *n* (%)	10 (10.2)	1 (10.0)	1 (9.1)	12 (10.1)
Male, *n* (%)	49 (50.0)	4 (40.0)	6 (54.5)	59 (49.6)
Education level, *n*	91	8	10	109
Primary school, *n* (%)	3 (3.3)	0	2 (20.0)	5 (4.6)
Secondary school, *n* (%)	40 (44.0)	4 (50.0)	3 (30.0)	47 (43.1)
Graduate school, *n* (%)	29 (31.9)	4 (50.0)	4 (40.0)	37 (33.9)
Post-graduate, *n* (%)	19 (20.9)	0	1 (10.0)	20 (18.3)
Native language, *n*	98	10	11	119
French, *n* (%)	28 (28.6)	4 (40.0)	4 (36.4)	36 (30.3)
Dutch, *n* (%)	69 (70.4)	5 (50.0)	6 (54.5)	80 (67.2)
Distance from home to center (km)				
n	98	10	11	119
Mean (SD)	25.7 (29.2)	30.4 (31.9)	18.7 (13.0)	25.4 (28.3)
Median	16.0	22.2	25.0	19.0
Min–max	0.0–215.0	2.0–108.0	3.0–43.7	0.0–215.0
Q1–Q3	7.1–35.0	5.0–45.0	5.2–25.0	7.0–32.0
Disease duration at start of golimumab treatment (year)				
n	97	10	11	118
Mean (SD)	6.3 (8.2)	5.5 (5.4)	4.1 (3.9)	6.0 (7.7)
Median	3.0	2.5	2.3	3.0
Min–max	0.2–41.0	1.0–16.4	0.5–11.0	0.2–41.0
Q1–Q3	1.1–7.9	1.9–9.0	1.0–9.0	1.1–8.0
Type of pathology				
n	98	10	11	119
RA, *n* (%)	36 (36.7)	1 (10.0)	3 (27.3)	40 (33.6)

Table 2 continued

	Intense nursing support (*N* = 98)	Medium nursing support (*N* = 10)	No nursing support (*N* = 11)	Overall (*N* = 119)
AS, *n* (%)	47 (48.0)	5 (50.0)	6 (54.5)	58 (48.7)
PsA, *n* (%)	15 (15.3)	4 (40.0)	2 (18.2)	21 (17.6)
Oligo PsA, *n* (%)	4 (4.1)	1 (10.0)	1 (9.1)	6 (5.0)
Polyarticular PsA, *n* (%)	11 (11.2)	3 (30.0)	1 (9.1)	15 (12.6)

SD standard deviation; *Q1-Q3* interquartile range; *RA* rheumatoid arthritis; *AS* ankylosing spondylitis; *PsA* psoriatic arthritis

Table 3 Practice characteristics of the rheumatologists: overall and in the three nursing support groups

	Intense (*N* = 98)	Medium (*N* = 10)	None (*N* = 11)	Overall (*N* = 119)
Type of practice, *n*	97	10	11	118
University center, *n* (%)	35 (36.1)	3 (30.0)	4 (36.4)	42 (35.6)
Non-university (peripheral) center, *n* (%)	27 (27.8)	4 (40.0)	7 (63.6)	38 (32.2)
Private practice, *n* (%)	35 (36.1)	3 (30.0)	0 (0.0)	38 (32.2)
Availability of nursing support, *n*	98	10	11	119
Yes, *n* (%)	95 (96.9)	7 (70.0)	6 (54.5)	108 (90.8)

(*N* = 6 out of 6) had a decrease of 2 points on the NRS for the joint most affected (according to the patient's and the physician's perspective), and 100% of poly-articular PsA patients (*N* = 15 out of 15) had a 20% decrease in HAQ and SJC/TJC scores. The proportion of patients able to self-inject golimumab was 88% in the intense group, 90% in the medium group and 73% in the no support group. Overall, 90% of the patients (*N* = 107 out of 119) qualified for treatment prolongation according to their rheumatologist's assessment (Table 5).

The patient's satisfaction levels, according to the questionnaires (Supplementary material), for the three satisfaction questions are shown in Fig. 1. Satisfaction was high in all three nursing support groups and overall, with the following decreasing order: intense support, no support and medium support.

The quality (nine questions) and helpfulness (one question) (Supplementary material) of patient information scores are also shown in Fig. 1. Patients in all nursing support groups and overall gave generally high scores for the quality of the information they received on golimumab, with the following decreasing order: intense support, no support, and medium support. It should be noted that in the no support group, satisfaction was also very high. The lowest levels of satisfaction were measured for the question concerning the differences between golimumab and other medicines, and for the question concerning the safety aspects related to the long-term use of these medicines.

Table 4 Disease activity at initiation and at the end of the first reimbursement cycle: overall and in the three nursing support groups

	Intense (*N* = 98)	**Medium (*N* = 10)**	**None (*N* = 11)**	**Overall (*N* = 119)**
DAS28-ESR in RA				
Study initiation				
n	10	1	1	12
Mean (SD)	5.1 (1.0)	6.1	3.9	5.0 (1.0)
End cycle				
n	9	0	1	10
Mean (SD)	2.4 (1.5)	–	1.6 (NA)	2.3 (1.5)
DAS28-CRP in RA				
Study initiation				
n	26	0	2	28
Mean (SD)	4.6 (0.7)	–	4.4 (0.2)	4.6 (0.7)
End cycle				
n	27	1	2	30
Mean (SD)	2.8 (1.0)	3.2 (NA)	2.5 (1.5)	2.8 (1.0)
BASDAI in AS				
Study initiation				
n	46	5	5	56
Mean (SD)	6.8 (1.4)	7.0 (1.0)	6.7 (1.3)	6.8 (1.4)
End cycle				
n	46	5	5	56
Mean (SD)	3.3 (1.8)	5.0 (3.2)	4.6 (3.0)	3.6 (2.1)
76 SJC in PsA				
Study initiation				
n	15	4	2	21
Mean (SD)	7.5 (5.6)	5.5 (3.1)	6.0 (0.0)	7.0 (4.9)
End cycle				
n	15	4	2	21
Mean (SD)	1.1 (2.1)	1.3 (1.9)	0.5 (0.7)	1.1 (1.9)
78 TJC in PsA				
Study initiation				
n	15	4	2	21

Table 4 continued

	Intense (N = 98)	Medium (N = 10)	None (N = 11)	Overall (N = 119)
Mean (SD)	9.8 (11.1)	6.0 (3.5)	6.0 (0.0)	8.7 (9.5)
End cycle				
n	15	4	2	21
Mean (SD)	1.5 (1.8)	2.8 (3.6)	0.5 (0.7)	1.7 (2.1)
HAQ in RA, AS, and PsA				
Study initiation				
n	46	3	4	53
Mean (SD)	21.3 (11.0)	14.0 (13.1)	24.0 (7.1)	21.1 (10.9)
End cycle				
n	50	3	4	57
Mean (SD)	7.6 (8.2)	6.7 (4.5)	11.0 (10.7)	7.8 (8.1)

BASDAI Bath Ankylosing Spondylitis Disease Activity Index, *CRP* C-reactive protein, *DAS28* Disease Activity Score 28, *ESR* erythrocyte sedimentation rate, *HAQ* Health Assessment Questionnaire, *NA* not applicable, *SD* standard deviation, *SJC* swollen joint count, *TJC* tender joint count

DISCUSSION

The results of this real-life observational study corroborate the short-term efficacy of golimumab found in randomized controlled trials in RA [3], AS [4], and PsA patients [5], as well as in other observational studies [6–9]. In particular in the real-life, observational GO-NICE study, after 6 months of treatment, an improvement of 36% was measured in the DAS28-ESR in RA patients, an improvement of 51% was measured in the BASDAI score in AS patients and an improvement of 68% was measured in the PsA patients, which corresponds quite well to the improvements of 54, 47, and 63% in the scores measured for the three diseases in the current study.

Overall, 90% of the patients qualified for treatment prolongation according to their rheumatologist's assessment and according to the strict Belgian drug reimbursement rules.

A total of 119 patients were analyzed in this study and the majority of these (82.4%) were in the intense nursing support group, rendering the groups sizes highly imbalanced. A possible reason for this is that for most patients (91%), nursing support was available at the facility where they enrolled, showing that nursing support is increasingly offered to patients in Belgium and that they are generally very well supported.

The limited sample size and the fact that the vast majority of patients benefited from an intense nursing support did not allow drawing definite conclusions concerning the impact of the nursing level on the treatment effectiveness and changes in the disease activity.

All patients were very satisfied and there was no trend for an impact of nursing support level on this variable. The same results applied for quality and helpfulness of patient's information. In conclusion, we can say that rheumatologists, in the absence of other nursing support, are doing an excellent job in supporting their patients, but that when the doctor has less time to devote to his/her patient, nurses are

Table 5 Number and percentage of patients achieving the objectives of treatment and benefiting from a prolongation of treatment with golimumab in the next reimbursement cycle: overall and in the three nursing support groups

	Intense (*N* = 98)	Medium (*N* = 10)	None (*N* = 11)	Overall (*N* = 119)
RA: patient meets EULAR criteria based on DAS28 of a moderate-to-good response, *N*	36	1	3	40
Yes, *n* (%)	32 (88.9)	1 (100.0)	3 (100.0)	36 (90.0)
AS: patient has a reduction of 2 points in BASDAI score, *N*	47	5	6	58
Yes, *n* (%)	44 (93.6)	2 (40.0)	4 (66.7)	50 (86.2)
Oligo PsA: patient has a decrease in 2 points on the NRS for the joint most affected (according to the patient's and the physician's perspective), *N*	4	1	1	6
Yes, *n* (%)	4 (100.0)	1 (100.0)	1 (100.0)	6 (100.0)
Polyarticular PsA: patient has a 20% decrease in HAQ score and a 20% decrease in SJC and TJC, *N*	11	3	1	15
Yes, *n* (%)	11 (100.0)	3 (100.0)	1 (100.0)	15 (100.0)
Rheumatologist's assessment whether the patient qualifies for reimbursement renewal, *N*	98	10	11	119
Yes, *n* (%)	91 (92.9)	7 (70.0)	9 (81.8)	107 (89.9)

NRS numeric rating scale, *SJC* swollen joint count, *TJC* tender joint count, *RA* rheumatoid arthritis, *AS* ankylosing spondylitis, *PsA* psoriatic arthritis

taking over this aspect in a very satisfactory way. Since time is becoming more and more an issue for rheumatologists, it is very important that nursing support is available, not only for the patient's satisfaction but also for the rheumatologist's satisfaction.

The nursing support was high in RA patients. This could be due to the fact that RA constitutes a big group of patients; there is a lot of information available to them by the nurse, the Internet, flyers, and brochures. The fact that the lowest levels of satisfaction were measured for the question concerning the differences between golimumab and other drugs, and for the question concerning the safety aspects related to the long-term use of these medicines are logical in a naïve population treated for the first time with a biological product and followed-up during a relatively short period of time, and shows that extra-attention might be needed for the dissemination of this information. This could also be related to the fact that the nurses are a little bit less comfortable to discuss about the biological products. For this reason, there should be a continuous possibility of training for nurses, even on items that are not directly assigned to them.

The main limitations of this study are intrinsic to its uncontrolled, open-label, and observational design. Since the groups were very unbalanced (80% in intense nursing support, 10% in the two other groups), group comparisons are inappropriate. In addition, the questionnaires used during the study were designed by clinicians, based on the recommendations of an advisory board, but were not validated.

In the principal investigator's center, care was taken that the study was not performed by the same nurse as the one who gave the support, because this might bias the answers. This

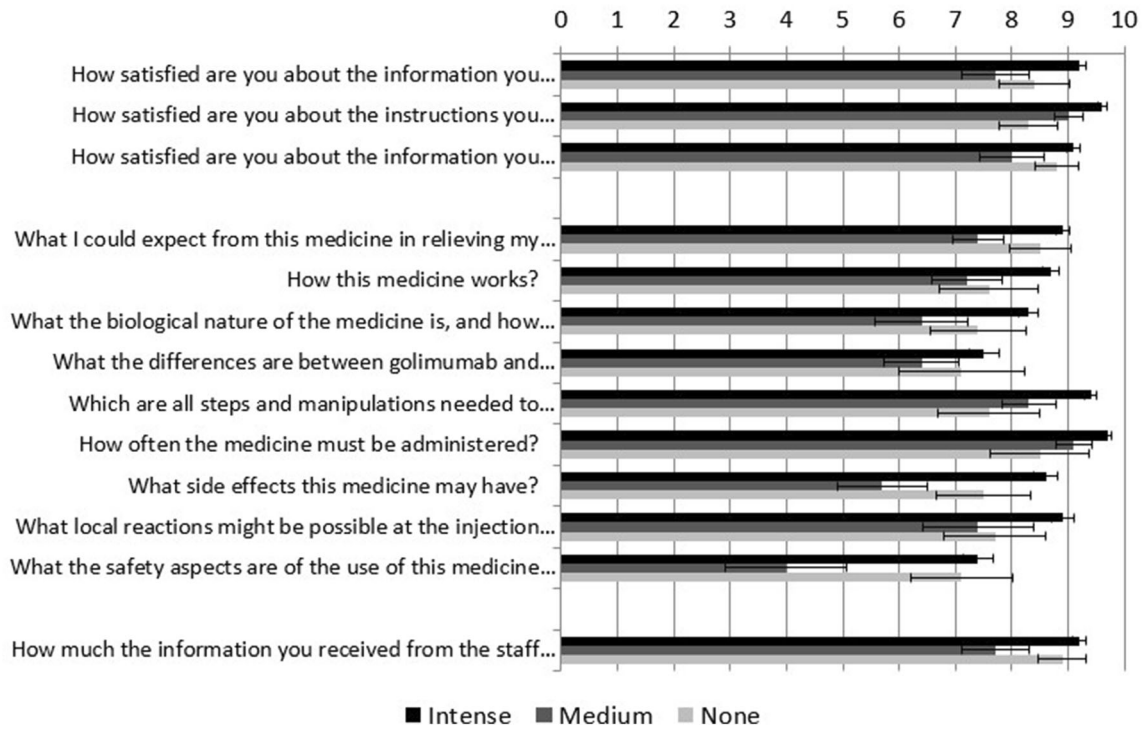

Fig. 1 Level of patient satisfaction (three questions), and quality (nine questions), and helpfulness (one question) of patient information scores (mean ± SE) in the three nursing support groups (intense, medium and none). Patients provided responses using a numeric rating scale from 0 for not satisfied at all/not at all informed by the clinic staff to 10 for very satisfied/very well informed by the clinic staff

was not systematically requested in the other centers and could induce a bias in the study.

CONCLUSIONS

This large cohort painted a real-life presentation of RA, AS, and PsA patients in the context of their treatment with golimumab, in academic and non-academic centers in Belgium. The short-term effectiveness of the drug has been confirmed overall and in all nursing support groups, in agreement with published randomized controlled trials and observational studies. Most patients with RA, AS, or PsA were offered nursing support and most of them received it at a high level. However, despite different levels of nursing support, most patients were satisfied with the information and instruction they received about their disease and golimumab treatment, whether they were delivered by nurses or other medical personnel, and most were able to perform self-injections. Golimumab was effective for most patients, resulting in 90% of patients qualified for reimbursement renewal. Longer-term studies in a higher number of patients are recommended to see how the nursing level can modulate the benefit/risk ratio of golimumab and other TNF-α inhibitors.

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Compliance with Ethics Guidelines. All patients gave their written informed consent and the study was conducted in agreement with GCP/ICH guidelines and the Declaration of Helsinki. The protocol was submitted to the Ethics Committees of each center (Supplementary Material) and was approved by the central Ethics Committee (Erasme Hospital, Université Libre de Bruxelles, Brussels, Belgium, 29 March 2016).

Data Availability. The datasets analyzed during the current study are available from the corresponding author on reasonable request.

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