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Concise Report

## Factors associated with knowledge and safety skills of arthritis patients receiving biologics: A survey of 677 patients



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### ABSTRACT

**Objective:** We aimed to determine patient and rheumatologist factors associated with the safety skills of patients receiving bDMARDs for inflammatory arthritis.

**Methods:** Data were obtained from a descriptive observational cross-sectional nationwide survey performed in 2011 in France. Community- and hospital-based rheumatologists were selected at random. The BioSecure questionnaire was used to collect information on patient safety skills.

**Results:** Of the 677 patients included (mean age  $53 \pm 13$  years old; 452 (67%) women, 411 (61%) had RA; 421 (64%) received subcutaneous bDMARDs). Patients had received information about their treatments from their physician 610 (90%), a nurse 207 (31%), by a written booklet 398 (59%), and/or during therapeutic patient education (TPE) sessions 99 (15%). The median BioSecure total score was 72/100 (IQR 60–82). In total, 99 (16.4%) patients had a low skill level; 321 (53.2%) a moderate skill level and 183 (30.3%) a high skill level. On multivariate regression analysis, as compared with high safety skills, low skills were associated with living alone (OR 2.8 [95% CI 1.3–6.0]), low educational level (OR 4.3 [2.1–8.9]), living in a large city (OR 3.1 [1.2–8.2]), being unemployed (OR 3.3 [1.6–6.7]) and not receiving written information, participating in TPE sessions or consulting a nurse (OR 3.8 [1.6–8.8]). One rheumatologist-related factor was a high number of patients receiving bDMARDs in the practice.

**Conclusion:** We reveal factors associated with low safety skills of patients receiving bDMARDs for inflammatory arthritis, which should be addressed to improve safety skills in this population.

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Biological disease-modifying antirheumatic drugs (bDMARDs) are widely used [1,2] and are the most efficient treatment for

inflammatory arthritis (IA). They slow the progression of structural lesions and improve health-related quality of life (HRQoL). However, bDMARDs entail specific risks (e.g., infections); therefore, patients must have decision-making and safety skills for situations such as fever, dental care, and planned surgery. Skills include not injecting the bDMARD, consulting a physician or seeking advice from other healthcare professionals.

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Therapeutic patient education (TPE) is of increasing interest [3,4] and the European League Against Rheumatism (EULAR) has highlighted its importance [5–7]. According to the 1998 World Health Organization definition “TPE aims to help patients acquire or maintain the competencies they need to manage as well as possible their lives with a chronic disease” [8]. TPE includes patient acquisition and maintenance of self-care skills, including life-saving self-care skills [9]. These skills implement cognitive, practical and behavioural knowledge and interpretation of data and problem solving.

Healthcare professionals pay particular attention to core safety skills at the initiation and during the follow-up of bDMARD treatment. A flexible attitude is needed to choose adequate and individualized methods of TPE and account for the patient’s specific needs and resources [8,9]. However, no published data are available on factors associated with acquisition of knowledge and skills by patients receiving bDMARDs. Knowing which skills are difficult for patients to learn and what factors hamper acquiring these skills can provide a concrete evidence basis to improve TPE programs and patient information.

The main objective of this study was to determine factors associated with the level of knowledge and behavioural safety skills of patients with inflammatory arthritis treated with bDMARDs in France. A secondary objective was whether better HRQoL and self-efficacy perception are associated with a high rather than low level of knowledge and safety skills.

## 1. Patients and methods

### 1.1. Design

Data were obtained from a descriptive observational cross-sectional nationwide survey in France between September 2010 and September 2011 [10]. All patients completed a 54-item questionnaire addressing safety competences (BioSecure) [11] and provided additional information, including sociodemographic data, types of information received, quality of life and self-efficacy data. The patients were informed of the study objectives and the anonymous data collection and analysis and gave their consent to be in the study. All applicable regulations were respected and the project was conducted in accordance with ethical standards in France.

### 1.2. Patients

To obtain a representative sample of patients receiving bDMARDs for chronic IA, community- and hospital-based rheumatologists were selected at random from the directory of the French Society for Rheumatology to invite 3 to 5 consecutive eligible patients to complete a questionnaire. Eligible patients were > 18 years old; had a diagnosis of rheumatoid arthritis (RA), spondyloarthritis (SpA), or psoriatic arthritis (PsA) or a history of juvenile arthritis; were currently receiving one of the biologic agents, etanercept, adalimumab, infliximab, certolizumab, rituximab, abatacept or tocilizumab for at least 3 months, whatever the concomitant therapies; and were able to complete a questionnaire.

### 1.3. Collected data

#### 1.3.1. BioSecure questionnaire

The BioSecure questionnaire [11], which contains 29 items about knowledge and 7 specific problem cases (with 26 items), is designed to measure the self-care safety skills of patients receiving bDMARDs to treat joint disease. Each skill has one item for knowledge and another for coping with a specific problem case, grouped in 9 domains or skills. The response options are “yes”, “no”, and “I don’t know”. The skills are aggregated into dimensions (Table 1).

**Table 1**  
Description of the BioSecure questionnaire.

Dimensions	Domains/skills	No. items
bDMARDs management		6
	Background knowledge	4
	Communication	2
When to see a doctor		15
	Fever	11
	Symptoms	4
Specific situations		19
	Vaccines, wounds	8
	Dental care	2
	Surgery	7
	Birth control	2
Subcutaneous administration		3, including 2 short open-ended questions

Of the 55 items, 12 are “trick” questions. Scores are computed as a proportion of correct items. The final score and specific domain scores are from 0 to 100, higher scores indicating better skills [11].

#### 1.3.2. Other data collected

Patients provided the following data possibly associated with patient skills: sociodemographic data (age, gender, living arrangements [alone or not], educational level [below or above secondary school], occupational status [employed or not], size of residence [ $<$  or  $\geq$  200,000 people]), clinical data (diagnosis [RA, SpA, PsA], disease duration), type of follow-up (hospital physician, community physician, both), treatment characteristics (bDMARD duration and route of administration), information/TPE received about the bDMARDs (written information, oral information by a nurse or physician, TPE).

Furthermore, patients completed self-administered patient-reported outcome questionnaires, including a HRQoL questionnaire [Medical Outcomes Survey Short-Form 12-item version (SF-12), Physical Component Summary Score (PCS), Mental Component Summary scores (MCS); mean of 50 (SD 10) in the general population; scores ranging from 0 to 100, higher scores indicating better HRQoL] [12], a self-efficacy questionnaire [the General Self-Efficacy Scale (GSE, 0–40); scores range from 0 (worst) to 40 (best)] [13,14], and the global coping question of the Rheumatoid Arthritis Impact of Disease (RAID) questionnaire [“Considering your arthritis overall, how well did you cope (manage, deal, make do) with your disease during the last week”, scores ranging from 0 (best) to 10 (worst)] [15].

Rheumatologists provided the following information: estimated number of patients taking biologic agents in their practice, participation in a TPE program, awareness of a TPE program nearby, hospital- or community-based practice, age, and gender. The question “Do you think information and education are different?” was considered a proxy for knowing or not what TPE really was.

#### 1.4. Statistical analysis

For polytomous logistic regression, for an increase in odds ratio (OR) of 1.5 with  $P < 0.05$  and power 80%, we needed 644 patients [16].

Continuous data are summarized by mean (SD) or median (interquartile range) and categorical data by number (percentage). Because the distribution of the total skill score was highly skewed, we used multinomial logistic regression models to study factors associated with skill level. After determining the distribution of scores and the statistical law best fitting the distributions of the scores in each knowledge group, patients were a posteriori classified by observed values, and thresholds of skill levels were defined to form 3 levels by proportion of incorrect answers low, moderate and high. Variables significantly associated with skill level at  $P \leq 0.1$

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