Evaluation of a prospective cohort event monitoring model for patient-reported adverse drug reactions attributed to biological DMARDs: Validity of the patient-reported information and representativeness of the participants

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Background

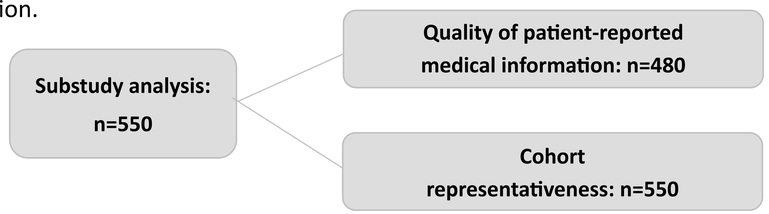
To gain knowledge on the prevalence, course and treatment of adverse drug reactions (ADRs) attributed to biological DMARDs (bDMARDs) and the experienced impact of ADRs on patients, an ADR-focused online questionnaire system was developed by Netherlands Pharmacovigilance Centre Lareb (*Dutch Biologic Monitor*).

Objective

- Assessment of the quality of patient-reported medical information in the *Dutch Biologic Monitor.*
- Evaluation of the representativeness of the sampled participants.

Method

Consecutive adult patients using a bDMARD for an immune-mediated inflammatory disease were included in eight Dutch centres. For this substudy, data of 550 patients with inflammatory rheumatic diseases was used. Patient-reported bDMARD, indication and combination therapy were verified for patients that permitted access to their electronic health record (EHR) using percentage agreement and/or Cohen's kappa (n=480). Population representativeness was tested for the entire substudy population by comparing age, gender and prescribed bDMARD to the centres' reference populations using Mann-Whitney U test, Chi-Square Goodness-of-Fit or Fisher's exact test with Monte Carlo simulation.



CONCLUSIONS

- Patients with inflammatory rheumatic diseases can adequately report their medical information.
- The included inflammatory rheumatic diseases patients in the *Dutch Biologic Monitor* represent their reference populations regarding age, gender and prescribed bDMARD.
- Patient report-based questionnaire systems appear an appropriate method to extract health-related data from patients.

Table 1: Comparison between the patient- and clinician-reported prescribed clinical information. Data is represented as amount of patients (n, %) or the level of interrater agreement (κ).

	Agreement n (%)	No agreement n (%)	Interrater agreement Level (κ)
bDMARD	459 (95.8)	20 (4.2)	N/A
Indication	434 (90.4)	46 (9.6)	Strong (0.832)
Combination therapy	346 (79.7)	88 (20.3)	Moderate (0.725)

Results

Quality of patient-reported medical information

The active substance and brand name of the prescribed bDMARD was correctly reported by 459 patients (95.8%), as shown in Table 1. Eleven patients (2.3%) reported an incorrect active substance and brand name, whereas nine (1.9%) had only mistaken the brand name. Agreement between patient-reported and clinician-reported information was strong for the reported indications and moderate for combination therapy.

Representativeness of the substudy population

The substudy population was representative for the reference populations from which they were sampled based on gender (38.4% vs. 38.8% male; $\chi 2(1, n=550)=0.038$, $p>0.05$) and bDMARD use (both subpopulations $p>0.05$). Median age was statistically not representative (58.0 vs. 56.0 years; U=962872, p=0.04, Fig. 1), since the median age of male participants originating from subpopulation 1 was higher compared to the reference population (U=18322.5, p=0.002).

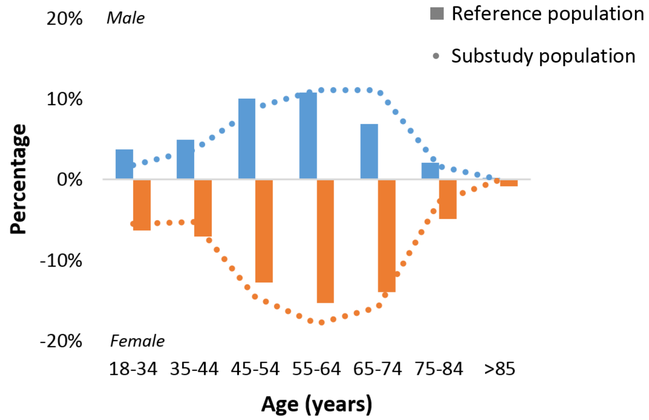


Figure 1: Age distributions of participating inflammatory rheumatic disease patients compared to the reference population.

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