The association between the recall period and the amount of information about reported adverse drug reactions in patients using biologicals

Alexandra Laurijssen[1], Jette van Lint[2], Bart van den Bemt[3,4], Lilian Beijer[1], Naomi Jessurun[2]

THU0637-HPR

Background

In order to monitor the safety of medicines, it is important that patients report their adverse drug reactions (ADRs). Theoretically, the quality of the reported information might be affected by the elapsed time between the onset of the ADR and the moment of reporting. Real-life evidence demonstrating a negative relationship between this recall period and the quality of reported ADRs is however lacking.

Objective

To assess the effect of recall period on the amount of information that patients report about their ADR (information density) in patients using a biologic for an immune-mediated inflammatory disease (IMID).

Methods

The Dutch Biologic Monitor is a multi-center cohort ADR monitoring system collecting data on reported ADRs by patients using a biologic for an IMID. Per patient, every first unique reported ADR between 1 February 2017 and 1 September 2019 was eligible. ADR reports were selected by stratified random sampling based on length of recall period and biologic. The recall period was defined by the number of days between the onset and reporting date of the ADR. The amount of information in an ADR report (information density) was determined based on eleven domains: specification, location, frequency, time-to-onset, course, causality, cause or consequence, health care professional (HCP) visits, HCP action, patient action and ADR burden. Information density was calculated by the number of reported domains divided by the number of domains deemed relevant in the ADR report. The association between the information density of the ADR reports and different recall periods was compared using a one-way ANOVA test. One-way ANOVA and independent t-tests were used to assess the impact of gender, age, type biologic and burden of the ADR on the information density of the reported ADRs.

Results

Out of 1109 reported ADRs by 531 IMID patients, we included 402 ADR reports of 294 patients (55%) (Table 1). Included reports were equally divided over seven different recall periods: 0-1, 1-2, 2-4, 4-8, 8-12, 12-26 and 26-52 weeks. Results have shown no association between the information density in patient-reported ADRs and the length of recall period (p=0.805) (Figure 1). However, the proportion of reported information about HCP visits for the ADR increased with increasing recall period: 0-1 week (14%), 1-2 weeks (24%), 2-4 weeks (34%), 4-8 weeks (40%), 8-12 weeks (48%), 12-26 weeks (50%) and 26-52 weeks (46%).
Female patients reported more information about their ADR (p=0.002), whereas the patient's age was not associated with information density (p=0.221). Etanercept users report significantly more information than adalimumab users (p=0.019). The number of patients using other biologics was too low for further analysis. A higher ADR burden tended (p=0.120) to result in more reported ADR information (Figure 2).

Table 1: Characteristics of included patients with adverse drug reactions

Characteristics (N=294)	N (%)
Gender (female)	202 (69%)
Age (years) (mean ± SD)	53 ± 13
Smoking	59 (20%)
BMI (kg/m^2) (mean ± SD)	25.7 ± 5.3
Reported ARDs (mean ± SD)	1.4 ± 0.8
Indication	
Rheumatoid arthritis	129 (44%)
Psoriatic arthritis	51 (17%)
Axial spondyloarthritis	43 (15%)
Crohn's disease	42 (14%)
Other indications	29 (10%)
Biologic	
Adalimumab	97 (33%)
Etanercept	72 (24%)
Infliximab	27 (9%)
Tocilizumab	16 (5%)
Secukinumab	15 (5%)
Rituximab	14 (5%)
Other biologics	53 (18%)

Figure 1: No effect of length of recall period on information density in patient-reported ADRs

Figure 2: The effect of ADR burden on information density in patient-reported ADRs

Patients reported their ADR burden on a 5-point scale, ranging from 1 (no burden) to 5 (very high burden)

Conclusion

The length of recall period did not affect the amount of information that patients report about their ADR(s). The recall period was longer for patients reporting information about their HCP visit. Furthermore, female patients tend to report more information about their ADR than male patients and etanercept users tend to report more than adalimumab users.

E-Mail: j.vanlint@lareb.nl

1. *Radboud University, Faculty of Science, Nijmegen, The Netherlands*
2. *Pharmacovigilance Centre Lareb, 's-Hertogenbosch, The Netherlands*
3. *Sint Maartenskliniek, Nijmegen, The Netherlands*
4. *Department of Pharmacy, Radboudumc, Nijmegen, The Netherlands*

netherlands pharmacovigilance centrelareb