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The Questionnaire Survey Method in Medicine on the Example of Treatment Adherence Scales

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Aim. Development, testing and validation of the original questionnaire "Adherence Scale" (AS) in the PRIORITY and ANTEY observational studies (OS).

Materials and methods. The OS PRIORITY assessed adherence to statins in 298 patients with high and very high cardiovascular risk for 3 months. The OS ANTEY assessed adherence to oral anticoagulants in 201 patients with non-valvular atrial fibrillation for 1 year. Adherence was assessed using the original AS questionnaire, for which external validation was performed (with the calculation of the Cohen's Kappa coefficient). The reference methods were the validated questionnaire and direct medical interview. And internal validation was performed (consistency of questions on the AS using Spearman's correlation analysis). The sensitivity, specificity (ROC analysis) and retest reliability of the adherence scale (Cronbach's alpha) were also determined.

Results. In the OS PRIORITY Cohen's kappa for the AS and the reference method of direct medical survey was 0.76 (high consistency), and for the AS and the reference method of the validated questionnaire=0.28 (low consistency). High internal consistency of the questionnaire questions (correlation coefficient=0.78, $p<0.0001$) confirms the internal validity of the adherence scale. Evaluation of the main characteristics of the modified AS in the OS ANTEY showed high consistency between the results of the AS and the validated questionnaire: Cohen's kappa=0.94 (high external validity of the AS). The retest reliability of the AS was 0.76 (Cronbach's alpha). The internal consistency of the questionnaire was confirmed by a strong and statistically significant correlation between the test questions: Spearman's correlation coefficient=0.80, $p<0.0001$. The sensitivity of the test, determined using the ROC analysis, was 89%, and the specificity was 62%.

Conclusion. The developed and tested new original questionnaire (modified version) – the AS – showed high indicators of reliability, validity and sensitivity. This ensures its reliability and ease of use for assessing various types of adherence and determining the leading factors of non-adherence, and also allows its use in scientific studies and clinical practice.

Keywords: questionnaire, adherence, validation, observational studies.

For citation: Lukina Y.V., Kutishenko N.P., Martsevich S.Y., Drapkina O.M. The Questionnaire Survey Method in Medicine on the Example of Treatment Adherence Scales. *Rational Pharmacotherapy in Cardiology* 2020;17(4):576-583. DOI:10.20996/1819-6446-2021-08-02.

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Received: 13.02.2021
Accepted: 24.05.2021

Introduction

The use of a variety of questionnaires and scales is widespread in medicine. Questionnaires have been developed to assess the quality of life of patients with various chronic noncommunicable diseases (Seattle questionnaire on the quality of life of patients with exertional angina, universal questionnaire Medical Outcomes Study 36-Item Short-Form Health Survey [MOS SF-36], etc.), as well as hospital scale for assessing anxiety and depression (The Hospital Anxiety and Depression Scale [HADS]), erectile dysfunction (International Index of Erectile Function [IIEF]), urinary disorders, pain, mood, etc. [1-4]. The questionnaire method is also widely used to assess patient adherence to the recommended treatment: dozens of different questionnaires and scales have been developed for the diagnosis of adherence [5]. The authors of systematic reviews of adherence note the following points that should be paid attention to when choosing a questionnaire to assess adherence: was the questionnaire validated and for which categories of patients, for which nosologies it was done, and which method was chosen as a reference (external validation); what are the indicators of internal consistency (internal validity), retest reliability, sensitivity, how the questions are formulated (are they acceptable and understandable to patients) – facial validity; and also whether the questionnaire identifies barriers to adherence [6, 7].

Some of the most famous and widely used questionnaires for assessing patient adherence to treatment are the Morisky's scales: a 4-question version and its revised version, consisting of 8 questions (4-item & 8-item Morisky Medication Adherence Scale [MMAS-4, MMAS -8]) [8,9]. The advantages of these questionnaires, which made them popular with researchers around the world, include brevity, versatility, satisfactory indicators of reliability, sensitivity and specificity, as well as confirmed validity [8,9]. Validation of the Morisky's scales, translated into Russian, was not carried out. In addition, an attempt to preserve negative statements in questions in the Russian-language version of MMAS-4 (which is considered a correct psychological technique) is recognized as unsuccessful due to the presence of double negation, which complicates the interpretation of answers in Russian. The text MMAS-4 (unsuccessful anonymous translation), circulated on the Russian Internet, reads as follows: "1. Have you ever forgot to take your medications? 2. Do you sometimes be inattentive to the time of taking medications? 3. Do you miss taking medications if you feel well? 4. If you feel unwell after taking medication, do you miss your next taking medications?". The result of applying this translated

version of MMAS-4 may be distortion of information due to the same meaning of negative and positive answers to questions with double negation in Russian [5].

In addition, the high characteristics of the scales (sensitivity, specificity, reliability, internal consistency) declared by the authors of MMAS-4 and MMAS-8 were not always confirmed in the works of other researchers [10, 11].

And the main obstacle to the wide and accessible use of the validated Morisky's scales was the obligation of the author's permission for their use. The lack of permission led to the withdrawal of already published scientific papers that used the Morisky's scales. As a result, the world scientific community unofficially called for abandoning the MMAS-4 and MMAS-8 scales in favor of other adherence questionnaires [12].

The identified problems of using the Morisky's scales for the diagnosis of adherence, the main of which is the high cost of permission to use this author's technique, led to the fact that an attempt was made to develop an original questionnaire for assessing various types of adherence in patients with chronic noncommunicable diseases, in particular, in cardiac sick.

Thus, the aim and main objectives of the study were the development, testing and validation of the original questionnaire.

Implementation of the set objectives was carried out within the framework of two observational studies: PRIORITY and ANTEY.

Material and methods

Implementation of the objectives was carried out in the framework of two observational studies: PRIORITY and ANTEY.

Descriptions of the design, protocols, material and methods, as well as the main results of these observational studies are presented in previous publications [13, 14].

In the observational studies PRIORITY and ANTEY, the original questionnaire for assessing patient adherence to drug therapy was developed, tested, modified and validated, which was named the «Adherence Scale» (AS).

The observational study PRIORITY studied adherence to statins in patients with high and very high risk of cardiovascular complications. 298 people (143 [48%] women) took part in this program, the average age of which was 62.5 ± 9.2 years. The study was conducted over 12 weeks, during which 3 visits were performed: the inclusion visit (V0), visits of the 1st (V1) and 3rd (V2) months of observation.

During V0 and V2, patients completed the adherence scale questionnaire. The 8-question Morisky's scale (MMAS-8), validated and with high characteristics of sensitivity and specificity [9], as well as the method of direct medical survey, which determined whether the patient was taking the recommended medication [13], were chosen as the reference methods for validating the adherence scale.

The adherence scale was tested with an assessment of its main characteristics in the observational study ANTEY, which examined the adherence of patients with nonvalvular AF to taking new oral anticoagulants (NOACs). The study included 201 patients, of whom 83 were women (41.3%), and the average age of the patients was 71.1 ± 8.7 years. Before the start of the study, patients were recommended to take one of the NOACs medications. Patients were followed up for 1 year with an intermediate face-to-face visit after 6 months and a telephone contact 12 months after inclusion in the study [14].

The external validation method with the Cohen's kappa coefficient estimation using the statistical software package IBM SPSS Statistics 23.0 was used to validate the original questionnaire. A reliability analysis was carried out with the determination of the Cronbach's alpha coefficient, in addition, Spearman's correlation rank analysis was carried out to assess the internal validity of the questionnaire. Sensitivity and specificity were determined using the ROC analysis with the construction of the ROC curve of the binary classification of the trait (committed/not committed).

Results

The development of a new questionnaire for assessing adherence to drug therapy in patients with chronic noncommunicable diseases outlined the main positions that it had to satisfy. The adherence scale was developed, in particular, as an alternative to the Morisky's scales, therefore, an attempt was made to eliminate the shortcomings of the reference method,

while not losing the main characteristics in satisfactory values by which psychodiagnostic techniques are assessed: reliability, internal consistency, validity; and also to preserve the advantages inherent in MMAS scales: conciseness, simplicity of obtaining and interpreting the results. The questions on the adherence scale, by analogy with the Morisky's scales, were predominantly closed, using statements that reflect non-adherent behavior to exclude a person's psy-

ADHERENCE SCALE (modified version) «POTENTIAL ADHERENCE»	
1. Are you going to take medications recommended by your doctor at this visit?	
1 No	– potentially non-adherent patient
2 Rather no than yes	– potentially partially non-adherent patient
3 Rather yes than no	– potentially partially adherent patient
4 Yes	– potentially adherent patient

Figure 1. Adherence scale for determining potential adherence

ADHERENCE SCALE (modified version) «OVERALL ACTUAL ADHERENCE»	
1. Did your doctor prescribe drug therapy for you?	
1 No	
2 Yes	
2. Do you violate the recommendations of your doctor regarding taking medications (regularity of taking, adherence to the dosage of the medication, the frequency and time of taking the medication, etc):	
1 I didn't want to take the prescribed medications (4 points)	
2 I stopped taking medications (3 points)	
3 I take the medication irregularly, stop taking the medication on my own or change the dose, frequency and time of the medications (2 points)	
4 I sometimes forget to take the medications (1 point)	
5 I take the medications strictly according to the doctor's recommendations (0 points)	
3. If you didn't want to take or if you stopped taking your prescribed medications, what is the leading reason for this?	
1 I forget to take my medications	
2 I'm afraid of side effects and health risks with long-term medication	
3 I'm experiencing side effects of drug therapy	
4 Lack of tangible effect (improvement) from treatment	
5 I take many different medications	
6 I have a very complex medication regimen (many times a day, several pills)	
7 High price of the medications	
8 I doubt the need for my prescribed treatment	
9 I don't want to take the medications for a long time	
10 Other (specify) _____	
The Key to Adherence Scales	
0 points	– complete adherence;
1 point	– partial, incomplete adherence, unintentional violations of medical recommendations;
2 points	– partial, incomplete adherence, intentional violations of medical recommendations;
3 points	– partial, secondary non-adherence
4 points	– complete, primary non-adherence

Figure 2. Adherence scale for determining actual overall adherence

chological tendency to answer the question «yes» (in a modified version of the questionnaire).

There are many types of adherence/non-adherence, so several modifications of the adherence scale have been developed to diagnose them. With the help of the new questionnaire, we can determine

- potential (patient's intentions to take medications) (Fig. 1) and actual (actual actions of the patient in relation to taking medications) adherence;
- primary (refusal to start taking medications) and secondary (stopping medications) non-adherence;
- intentional (independent change, refusal or termination of treatment by the patient) and unintentional (due to forgetfulness) non-adherence;
- partial (taking medications with violations of medical recommendations) and complete (taking medications in full accordance with medical recommendations) adherence;
- partial and complete non-adherence (refusal or termination of started taking medications, respectively);
- and also identify the main barriers to adherence (Fig. 2).

The results of both scales (the adherence scale and MMAS-8) were presented dichotomously for comparison and external validation of the adherence scale according to the observational study PRIORITY. According to the results of MMAS-8, partially adherent patients were defined as adherent patients in connection with the excessively strict criterion of the author's key to MMAS-8 identified in the observational study PRIORITY for assessing fully adherent patients (who comply with all medical recommendations for taking medications) and unsatisfactory diagnostics

of this type of adherence [15]. Patients with any violation of adherence (partially adherent, partially non-adherent and completely non-adherent) were assessed on the adherence scale as non-adherent [14,15].

The results of assessing adherence using the original and validated adherence scales, as well as by direct medical survey (indirect methods for diagnosing adherence) are presented in Table 1. Potential adherence (the patient's intention to take the recommended drug) was determined using the adherence scale (n=281) and direct medical survey (n=298) when included in the study (V0). Baseline adherence to statins was determined on the adherence scale (n=181) provided that the doctor prescribed them. Also, the initial general adherence of patients to the implementation of medical recommendations was diagnosed based on the results of MMAS-8 (n=292).

The Cohen's kappa coefficient when choosing a direct medical survey as a reference method was 0.76 (high consistency); and 0.28 when comparing the data obtained on the adherence scale with the results of MMAS-8 (low consistency).

Spearman's rank correlation analysis showed the presence of a strong and statistically significant correlation characterizing the internal consistency of the questionnaire questions (correlation coefficient=0.78, $p < 0.0001$), which confirms the internal validity of the questionnaire. Correlation analysis was performed for variables of the adherence indicator (adherent/non-adherent) and the presence of adherence barriers (no barriers/there are barriers) due to the specifics of the wording of the adherence scale questions. The retest reliability indicator Cron-

Table 1. Results of assessing adherence using the adherence scale, MMAS-8 and medical survey in the observational study "PRIORITY"

Number of surveyed patients/ Adherent patients/ Non-adherent patients, n (%)	Adherence scale Total/adherent patients/ non-adherent patients	MMAS-8 Total/adherent patients/ non-adherent patients	Medical survey Total/adherent patients/ non-adherent patients
Potential adherence (Visit 0), n (%)	281 (100)/ 244 (86.8)/ 37 (13.2)	–	298 (100)/ 286 (96)/ 12 (4)
Visit 0 (inclusion)*, n (%)	181 (100)/ 118 (65.2)/ 64 (34.8)	292 (100)/ 106 (36.3)/ 186 (63.7)	–
Visit 2 (3 months of the observation), n (%)	294 (100)/ 260 (88.4)/ 34 (11.6)	188 (64.4)/ 104 (35.6)	298 (100)/ 262 (88)/ 36 (12)
*assessment of baseline adherence to statin therapy as prescribed by the doctor			
MMAS – Morisky Medication Adherence Scale			

ADHERENCE SCALE (modified version) «ACTUAL ADHERENCE TO SPECIFIC MEDICATIONS»	
1. Did your doctor prescribe drug therapy for you?	
1	No
2	Yes
2. Do you violate the recommendations of your doctor regarding taking medications (regularity of taking, adherence to the dosage of the medication, the frequency and time of taking the medication, etc):	
1	I didn't want to take the prescribed medication (s). Indicate which medication (s) you didn't want to take _____
2	I have stopped taking the medication (s). Indicate which medication (s) you started but stopped taking _____
3	I don't take the medication (s) regularly, stop taking the medication myself, or change the dose, frequency and time of taking the medication. Indicate what kind of medication (s) it is _____
4	I sometimes forget to take the medication (s). Indicate which medication (s) you forget to take _____
5	I take the medications strictly according to the doctor's recommendations
3. If you didn't want to take or if you stopped taking your prescribed medications, what is the leading reason for this?	
1	I'm afraid of side effects and health risks with long-term medication. Indicate what kind of medication (s) it is _____
2	I'm experiencing side effects of drug therapy. Indicate which medication (s) caused you side effects _____
3	I'm afraid of side effects and health risks with long-term medication. Indicate what kind of medication (s) it is _____
4	Lack of tangible effect (improvement) from treatment. Indicate what kind of medication (s) it is _____
5	I take many different medications
6	I have a very complex medication regimen (many times a day, several pills)
7	High price of the medications. Indicate what kind of medication (s) it is _____
8	I doubt the need for my prescribed treatment (indicate what kind of medication (s) it is _____)
9	I don't want to take the medications for a long time (indicate what kind of medication (s) it is _____)
10	Other (specify) _____
The Key to Adherence Scales	
0 points	– complete adherence;
1 point	– 1 point – partial, incomplete adherence, unintentional violations of medical recommendations;
2 points	– partial, incomplete adherence, intentional violations of medical recommendations;
3 points	– partial, secondary non-adherence
4 points	– complete, primary non-adherence

Figure 3. Adherence scale for determining actual adherence to specific medications (points are calculated for each medication separately, similar to the adherence scale key to assess overall actual adherence)

bach's alpha for the adherence scale was 0.38.

The questionnaire was modified to take into account the deficiencies of the adherence scale identified in the observational study PRIORITY, which included positive affirmations of the test questions (a «yes» answer implied a good patient adherence to treatment). The inversion of a positive (in relation to adherence) affirmation to a negative affirmation was performed while maintaining the general structure of the questionnaire, to exclude the psychological tendency of the person to answer «yes» (for example, question 2 in the original wording read as follows: «Do you follow the recommendations of your doctor regarding taking medications?» In a modified version, the same question is phrased as follows: «Are you violating your doctor's recommendations for taking medications») (Fig. 2). In addition, the modified version of the questionnaire contained refinements to assess adherence to specific medications as part of a multicomponent drug therapy (Fig. 3).

The observational study ANTEY used a classification of responses similar to the classification used in the observational study PRIORITY. The results of assessing patients' adherence to oral anticoagulants (using MMAS-8 and the adherence scale) after 6 and 12 months of the observation (visit after 6 months and telephone contact, respectively) are shown in Fig. 4.

Also, primary and secondary non-adherence was assessed using the adherence scale (refusal to start or stop taking the recommended medication). After 12 months of the observation, 15 (7.6%) cases of primary non-adherence were diagnosed using the adherence scale. Based on MMAS-8 results, only 9 (60%) of these 15 patients were identified, and 6 people were considered adherents, although they didn't start taking the medication.

Evaluation of the main characteristics of the modified adherence scale (ref-

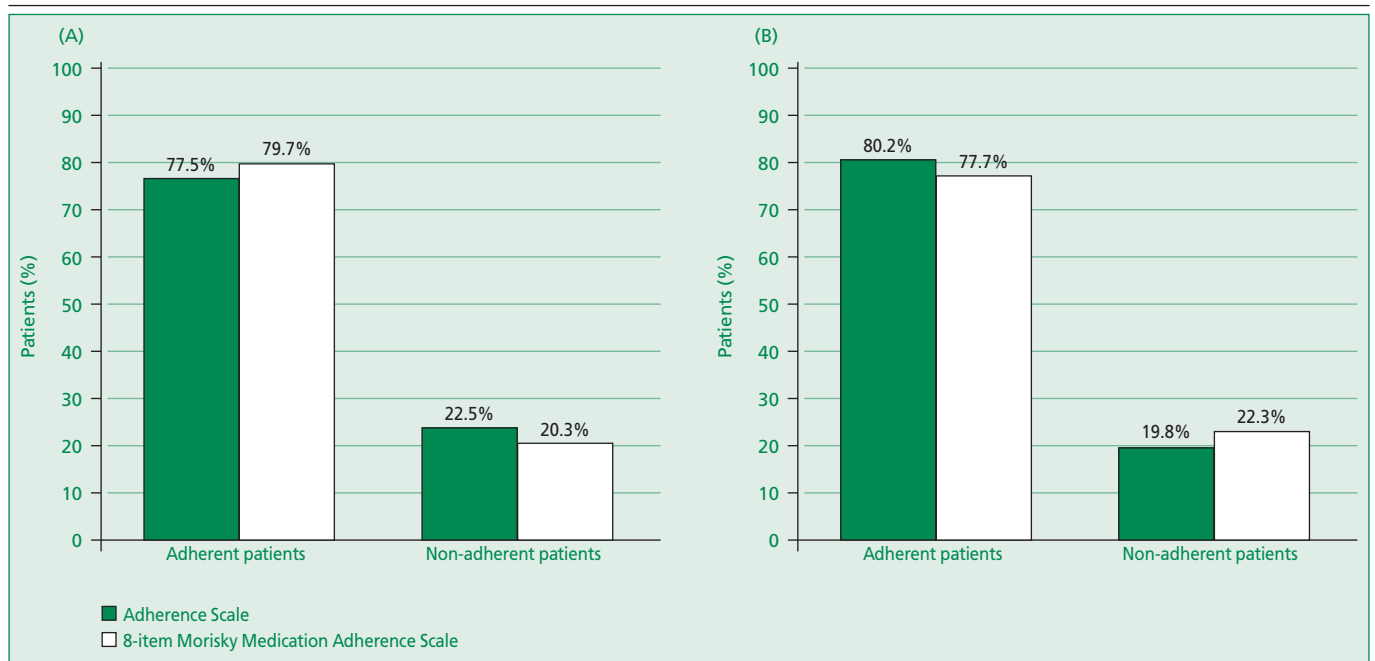


Figure 4. Results of assessing patients' adherence (using MMAS-8 and the adherence scale) to oral anticoagulants after 6 and 12 months of observation

erence method - MMAS-8 with dichotomous gradation of responses) showed high consistency between the results of the validated and the original questionnaire: Cohen's kappa=0.94 (high external validity of the adherence scale). The retest reliability of the adherence scale was 0.76 (Cronbach's alpha). Internal consistency of the questionnaire was confirmed by a strong and statistically significant correlation between the test questions (a transformation similar to that in the observational study PRIORITY was performed): Spearman's correlation coefficient=0.80 ($p < 0.0001$).

According to the results of the observational study ANTEY, an attempt was made to perform a ROC analysis. The construction of a qualitative logistic regression model turned out to be impossible due to the small number of non-adherent patients; therefore, the dichotomous results of the adherence scale were used as probabilities; the reference method was MMAS-8 with a dichotomous gradation of responses. The ROC curve of the binary classifier was used (adherent/non-adherent) with values of 0 or 1, so the graph looks like two segments (0.0) → (1 – Specificity, Sensitivity) → (1.1). The sensitivity of the test, determined using the ROC analysis, was 89%, and the specificity was 62% (cut-off point 0.7).

Discussion

The postulate of the sufficient complexity of developing a high-quality and convenient questionnaire [16,17], in particular, to determine adherence to

treatment, is confirmed by the results of the work performed. Several difficulties arise from the inherent antagonism between various important characteristics of the questionnaire. For example, the indicators of the sensitivity and specificity of the questionnaire, as a rule, are inversely related. The reliability of the questionnaire is in direct proportion to the number of questions included in it, and it's directly proportional to the square root of this number [16-19]. On the contrary, the convenience of using this psychodiagnostic method in real clinical practice is largely due to the shortness of the questionnaire [7]. Of great importance is the observance of the rules for the formulation of questions due to the peculiarities of human psychology: it's recommended to present the questions of the questionnaire in the form of statements of the negative aspect of the problem under study (for example, a person violates medical recommendations for taking medications or doesn't take a medication at all) due to the psychological tendency of people to respond to questions are positive. Also, closed-ended questions allow you to get more formalized and easily interpreted information, but at the same time, they inevitably coarse the data. The information obtained on the basis of open-ended questions is more accurate and reliable, but it's difficult to formalize and statistically process, and also difficult to interpret.

The dynamics of the main characteristics of the adherence scale (indicators of reliability, external and internal validity of the questionnaire) revealed by us

is probably explained in accordance with the above reasons, modification of the questionnaire, as well as with different samples of patients from two observational studies, which influenced some indicators, in particular, reliability and internal consistency of the adherence scale.

Validation of questionnaires used to assess adherence to medication is complicated by the lack of a diagnostic method of the “gold standard”. As a result, validation is performed according to the recommendations of specialists in psychodiagnostics, including on the basis of comparing the results obtained with the data of already validated and used questionnaires, which are not without their own shortcomings [2,5].

An additional difficulty that researchers face in assessing adherence to treatment is the multicomponent nature of modern drug therapy and different patient adherence to different medications, confirmed by the authors of several studies [20,21]. Probably, the revealed inconsistency between the results of assessing primary non-adherence using MMAS-8 and the adherence scale can be explained by this fact. MMAS-8 measures the patient's overall behavioral response to pharmacotherapy, and the modified adherence scale measures adherence to a particular medication. According to the observational study ANTEY MMAS-8 identified only 60% of cases of primary non-adherence to new oral anticoagulants, diagnosing non-adherent patients who didn't start taking the recommended oral anticoagulant (that is, they were not initially adherent) as adherent to treatment.

The revealed differences in the indicator of retest reliability according to the results of the observational studies PRIORITY and ANTEY are probably due to

the more pronounced dynamics of adherence in the first study [15] compared with ANTEY, where changes in adherence indicators were noted, but on average, about 80% of patients remained adherent to the recommended therapy during the entire one-year observation period [14].

Also, the adherence scale allows diagnosing the main types of adherence/non-adherence with the maximum brevity of the developed questionnaire, and also determines the leading barriers to adherence, that is, it meets the main criteria for assessing various questionnaires on adherence [7].

The validated adherence scale was approved by the National Society for Evidence-Based Pharmacotherapy (NSEPh), which was reflected in the change in the name of the questionnaire – «Adherence scale of NSEPh». It was recommended by the eponymous society for the diagnosis of adherence in patients with chronic noncommunicable diseases.

Conclusion

Thus, the developed and tested new original questionnaire (modified version) «Adherence scale of NSEPh» demonstrated high reliability, validity and sensitivity indicators, and it's also laconic. This ensures its reliability and ease of use for assessing various types of adherence and determining the leading factors of non-adherence and allows us to recommend its use in scientific studies and clinical practice.

Relationships and Activities: none.

Funding: The observational studies ANTEY and PRIORITY were performed with the sponsorship of Bayer and OZON.

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