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Drug free holiday in patients with rheumatoid arthritis: a qualitative study to explore patients' opinion

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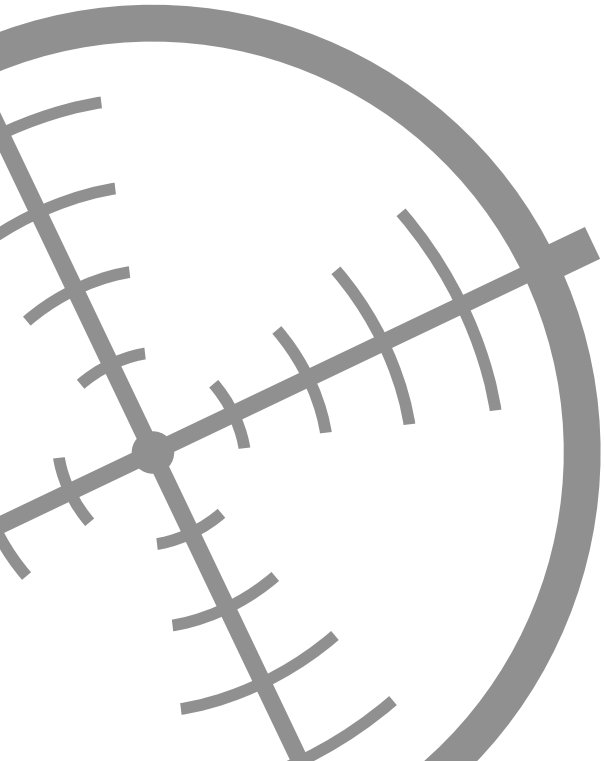

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ABSTRACT

Objective

Clinical trials have shown that in patients with longstanding low disease activity tapering and/ or stopping antirheumatic medication is a realistic option.
To explore patients' opinion about tapering and discontinuing antirheumatic drugs.

Methods

This qualitative study is based on interviews with twenty patients with rheumatoid arthritis (RA) about RA treatment and treatment discontinuation through structured interviewing. Interviews were tape-recorded, transcribed verbatim and screened by three assessors independently for meaning units.

Results

Positive emotions about drug discontinuation as hope, happiness and relief were mentioned, but also fear and disappointment. Some patients expect that drug discontinuation will be possible in other patients and/ or themselves, while others do not expect this. The concept of increase in disease activity after discontinuing medication was mentioned, and while patients expect that disease activity will decrease again after restarting medication, they expect that this will take (too much) time.

Conclusions

Positive emotions about the option to taper and discontinue antirheumatic medication, but negative expectations is a common combination in these RA patients. In particular patients expect that disease activity will flare and that improvement upon restarting medication will take time. Patients' expectations and feelings should be addressed before drug tapering is attempted in a clear strategy of continued monitoring of disease activity.

INTRODUCTION

Last decades, treatment strategies for rheumatoid arthritis (RA) have been changed dramatically. Treatment is commonly steered by disease activity scores, with treatment adjustments until the disease activity is sufficiently suppressed. Evidence from clinical trials shows that in patients with longstanding low disease activity or remission, antirheumatic medication can often be tapered and sometimes permanently discontinued.[1–6]

In daily practice tapering and discontinuation of medication is not yet routine. It is our impression that many patients are reluctant to taper or discontinue their medication when suggested by the rheumatologist, even if longstanding low disease activity or remission has been achieved. It is known that patients' expectations have a strong effect on efficacy of treatment: high expectations can augment the effect size of therapy.[7] Hence, patient expectation bias could influence whether drugs can be successfully tapered and stopped. To explore the patients' knowledge about tapering and discontinuation, their expectations and emotions, we performed this qualitative study based on interviews with unselected patients who visited the rheumatology outpatient clinic.

PATIENTS AND METHODS

This qualitative study using an interviewing technique with structured interviews was performed in the Leiden University Medical Center (LUMC). Two investigators (IM and GA) identified consecutive RA patients who visited the rheumatology outpatient clinic during two weeks in May 2012, to include a diverse study population. Whereas the aim of qualitative research is to obtain meaningful in-depth and detailed data to gather understanding (e.g. in behavior, experience or opinions),[8] mostly in small sample sizes,[9] sampling is continued until data saturation is achieved.[10] Initial analysis sample size was set at twenty patients based on earlier qualitative studies in patients with rheumatoid arthritis.[11,12] Data saturation was defined as at least three consecutive interviews revealing no new insights. Twenty-two patients were invited to participate in the interview. Twenty patients gave their consent; two patients refused participation because of lack of time. Data saturation was checked retrospectively, evaluating the interviews in chronological order. The 18th to the 20th interview did not contain new data, and therefore data saturation was achieved. The patients' opinion about tapering or discontinuing their RA medication was asked through a structured interview in Dutch consisting of twelve open-ended questions, with some questions including several sub items (Table 1). To ensure the patients understood the intention of the questions, a quality check was performed by comparing the answers with predefined answer options.

The interviews were tape-recorded and transcribed verbatim. Qualitative analysis was performed using the empirical phenomenological analysis.[9] First, texts were read by two interviewers and a rheumatologist (CA) independently to get a general impression. Second, natural meaning units were identified by the three assessors; subsequently dominating

themes were linked to the meaning units. Then, the identified meaning units and themes were considered from the perspective of the research questions. Last, the relevant themes contributing to answer our questions were combined to descriptive statements.
Notable citations were translated from Dutch into English with notice of the intention of the statements.

Table 1. Structured interview with open-ended questions.

1. When was your rheumatoid arthritis (RA) diagnosed?
2. Can you explain in your own words what the disease RA implies?
3. Do you take medication for the pain due to RA?
4. Do you take specific antirheumatic medication?
5. How do you feel the RA is currently suppressed by the antirheumatic medication that you use?
6. How would you feel if the disease activity and the antirheumatic medication you use today were the same next year?
7. What is your experience with the antirheumatic medications you use (effect on disease activity, presence of side effects, fear for side effects)?
8. Do you think other RA patients could stop- temporarily or permanently- using their antirheumatic medication?
9. Do you think you could stop your antirheumatic medication in the future? Under what circumstances would this be possible?
10. What do you think will happen if you stop taking the medication when your RA is quiet for a long time? What do you expect in case of an exacerbation? What do you expect if medication will be restarted?
11. What kind of feelings does the idea of stopping antirheumatic medication evoke?
12. Have you ever stopped your antirheumatic medication in the past? If so, how often and how did you experience this?

RESULTS

Twenty patients gave their consent to participate in this descriptive study and were interviewed. Demographic characteristics are shown in Table 2.

Table 2. Demographic characteristics.

	Participants
Female, n	13
Age, median (IQR) years	71 (52 – 74)
Disease duration, median (IQR) years	15 (4 – 25)
Currently using DMARD, n	17
Low disease activity or remission, n	13

DMARD, disease-modifying antirheumatic drugs; IQR, interquartile range.

After the first question to know the disease duration, the second question aimed at understanding how patients see their disease. Three different concepts were presented by the patients: RA as a chronic disease, RA as a disease that may not be chronic and RA as only a description of symptoms. Questions 3 to 7 were to identify use of antirheumatic drugs and patients' opinion about benefits and disadvantages of taking these medications (Figure

1). The last 4 questions asked about emotions and expectations about tapering and stopping antirheumatic drugs, in general, and for themselves (Figure 1). Patients either believed that other patients and/ or they themselves could discontinue RA medication in the future or thought they would have to take RA medication the rest of their lives ("I think that RA is so powerful in the immune system, that I think I can never stop the medication completely.";

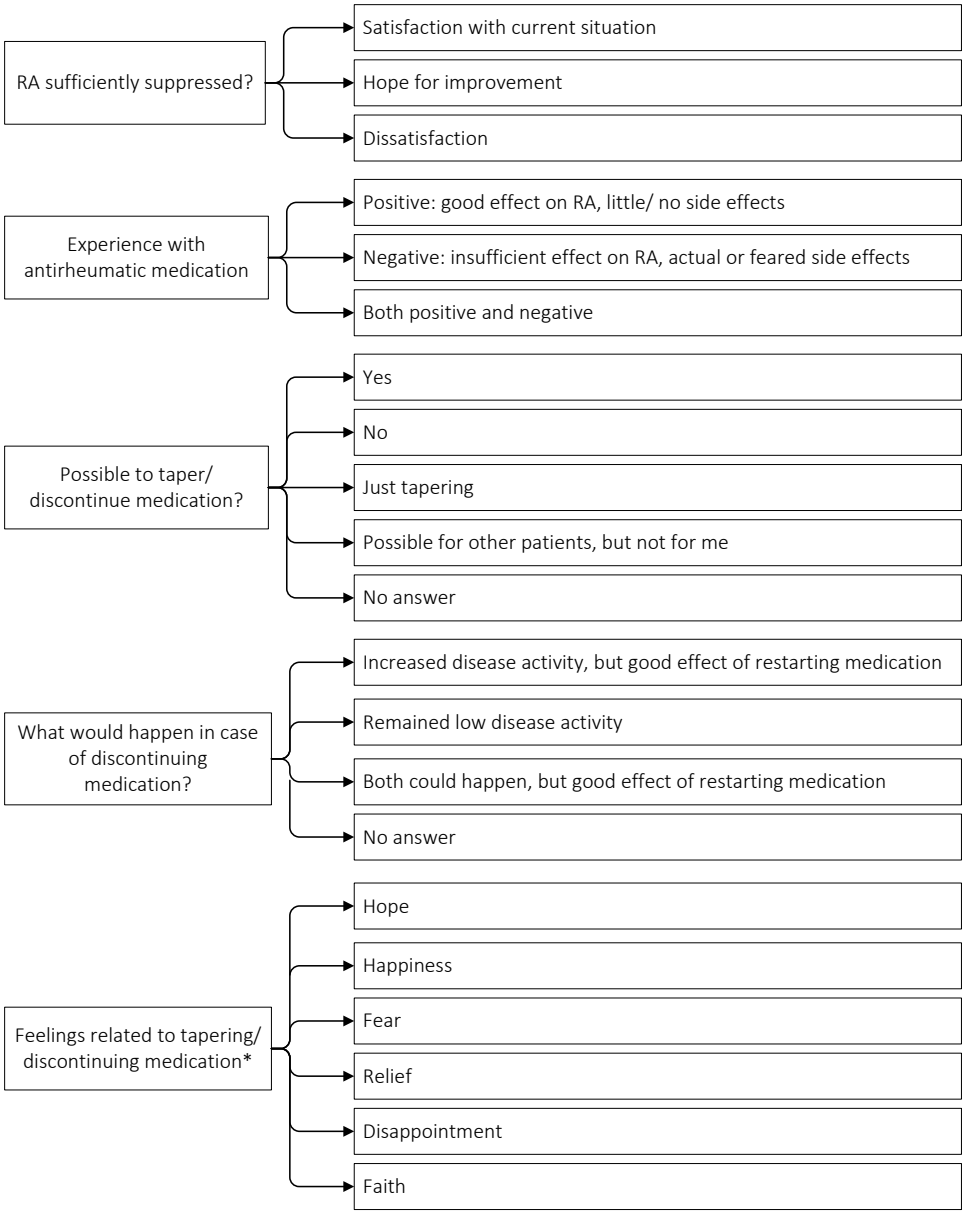

Figure 1. Concepts presented of answers to key questions in the interview.
*Multiple feelings could be mentioned per patient.

female patient, 39 years old, RA since 3 years). However, in this latter group, patients also said that they would taper or discontinue their drugs if their doctor suggests this. Notable is that some of the patients could not formulate an answer to one or both questions. Regardless of their previous answer, patients were asked under what conditions they would stop their medication. Multiple conditions could be mentioned per patient. One group of patients maintained that under no condition they would discontinue their medication. Other patients would stop medication in case of (severe) side effects, longstanding low disease activity, after a period of tapering and if additional monitoring is offered.

Answers to the question what patients expect to happen after discontinuing medication are also shown in Figure 1. Patients who mentioned a certain or possible disease flare were asked what would happen if medication would be restarted. Some expected that restarting antirheumatic drugs would result in relief of symptoms once again, others had no idea what would happen in case of restarting. However, the concept that improvement would take time was also mentioned, something patients would not want to risk ("I'm afraid I would have fallen behind: joint damage and the need to take more pills than before"; male patient, 74 years old, RA since 11 years).

Most patients mentioned multiple feelings related to tapering and stopping drugs: hope (to achieve low disease activity), happiness (about achieving a condition in which discontinuation would be possible), fear (for return of symptoms and joint damage after drug discontinuation), relief (from no longer having to take medication), faith (in the recommendation of the treating rheumatologist) and disappointment (about her current condition, a patient who had stopped medication) were mentioned (Figure 1). A frequently mentioned combination of concepts was positive feelings with negative expectations when thinking about stopping medication.

The question about previous experience with tapering and stopping antirheumatic medication resulted in the following concepts: no previous experience, a negative experience, with an increase in symptoms (some patients had stopped on their own initiative) and positive experiences, such as the opportunity to get pregnant, lasting low disease activity and the relief of not taking drugs and one patient mentioned both good and bad consequences of tapering or stopping drugs. At the moment of interviewing, one patient was tapering his medication and three patients didn't take medication at all, one against doctor's advice.

DISCUSSION

Recent trials demonstrated that patients with prolonged low disease activity or remission can often taper and sometimes permanently stop their antirheumatic medication, even in some patients with longstanding disease.[1–6,13] This qualitative study was undertaken to explore patients' knowledge, opinions and expectations about this topic. The main outcome of this study is that the combination of positive feelings and negative expectations about the option of tapering and stopping medication were frequently present.

Feelings such as hope to achieve longstanding low disease activity, happiness on achieving a condition in which discontinuation would be possible and relief of no longer having to take the medication were mentioned, and besides these positive feelings, fear for increase in disease activity. It is likely that this fear influences patients' expectations about tapering and discontinuing medication. The expectation that tapering and discontinuation of antirheumatic drugs is a realistic option for the patient themself was not commonly mentioned. It could be that positive feelings are expressed as a desire for an ideal situation, but that expectations are based on acquired information. Possibly, since the possibility of drug tapering and discontinuation has become apparent through relatively recent trials, patients previously have been given conservative information about what to expect about the disease course and treatment strategies. This may affect expectations on drug tapering and discontinuation. Informing patients that drug tapering and discontinuation may be considered at some time, not only at the moment of diagnosing RA but also at the moment of treatment adjustments, could be important to create awareness of and confidence in a drug tapering and discontinuation strategy.

In an earlier study in 6,135 RA patients who completed a questionnaire about willingness to change (not taper or discontinue) therapy, most patients were reluctant to change their medication as long as their situation was stable. Fear to lose disease control and (fear for) side effects of medication are named as reasons for this resistance.[14] An example in another area of medicine of patients preferring to continue medication while physicians may want to stop is the use of benzodiazepines. It has been shown that a single intervention to inform patients, such as a letter or a consultation by the GP, can result in decreased use of benzodiazepines.[15] This supports the idea that a lack of information may lie behind patients' unwillingness discontinue medication.

A randomized trial could compare the effect of an intervention with an additional method of information with routine care and information. Outcome parameters might be the patients' perspective on drug tapering and discontinuation through questionnaires or interviews.

The current study is based on only twenty patients. However, based on their characteristics and based on data saturation, they seem to be a fair representation of the variation in patients in our outpatient clinic. Interviewer bias could possibly play a role in the analysis of the data, i.e. expectancies of the interviewer may influence the interpretation of the results. Two methods to reduce this risk of bias were used; first, the interviewers were independent investigators without a therapeutic relationship with the interviewees or experience in treating patients with RA. Second, meaning units and accompanied terms were assessed by three investigators. Because this qualitative study was based on data saturation, interpreting exact numbers and percentages from this study is not possible. Nevertheless, the outcome does show the variation in opinions and expectations of patients.

In conclusion, since there is evidence from recent studies in RA that drug tapering and discontinuation in case of longstanding low disease activity or remission may be possible, current treatment recommendations include the possibility of tapering and discontinuing

antirheumatic therapies. We found that many patients feel positive about this option. Nevertheless, a minority sees this as a realistic option, as a disease flare and a long wait until restarted medication will regain effect are expected and feared. We believe that the results of this study indicate that we need to address patients' expectations and emotions when discussing the possibility of drug tapering and discontinuation in daily practice.

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