Unwillingness of rheumatoid arthritis patients to risk adverse effects

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Abstract

Objective. To evaluate patient willingness to accept the risk of adverse effects (AEs) commonly associated with arthritis medications.

Methods. Rheumatoid arthritis patients were asked to rate their willingness to take a medication associated with 17 specific AEs using a visual analogue scale.

Results. We interviewed 100 patients. Eighty-one were currently using one or more disease-modifying anti-rheumatic drugs (DMARDs) and 29 had previously experienced AEs related to DMARDs. Seventy-five stated that they were doing very well or well with respect to their arthritis compared with other people their age. Thirty-five per cent of those interviewed were unwilling to accept the risk of cosmetic changes, 38% were unwilling to accept the risk of temporary discomfort and 45% were unwilling to accept the risk of major toxicity. Patients who had previously experienced AEs were more willing to accept the risk of cosmetic changes (83 vs 58%, P = 0.02), temporary discomfort (79 vs 55%, P = 0.02) and major toxicity (83 vs 44%, P = 0.001) compared with those who had not previously experienced AEs.

Conclusions. Many rheumatoid arthritis patients are very concerned about potential drug toxicity. However, risk aversity appeared to be attenuated by past experience with AEs. Our results suggest that certain patients, especially those with milder disease activity, might be reluctant to accept commonly used arthritis medications if they are fully informed of their potential toxicity.

KEY WORDS: Drug toxicity, Patient attitudes.

Ethical and legal doctrines dictate that patient preferences should be the primary determinants of medical decisions. Examination of patient preferences is especially relevant in rheumatoid arthritis (RA), a disease for which there are several treatment strategies with no clear drug of choice, medications have frequent and often serious toxicity, and numerous doctor visits and blood tests are required to monitor toxicity.

The premise for this and other patient preference studies assumes that patients want to be fully informed of their options and to participate in their medical care. Previous studies have found that patients, including those with RA [1], have strong preferences for full disclosure of medication risks as well as treatment alternatives [2–4].

To elicit patient treatment preferences in clinical practice, physicians must first disclose the risks and benefits of appropriate options. Experts disagree, however, on which risks to disclose and how best to communicate this information. If physician and patient values were similar, it would be reasonable to disclose information reflecting physician values exclusively. However, comparisons of physician and patient values have consistently shown that these two populations differ with respect to what they judge to be important [5–8]. For example, Fries et al. [5] found that physician and patient scores for adverse events (AEs) related to the medications used to treat arthritis differed for 55% of the items studied.

In the study of Fries et al. [5], patient values for toxicity-related factors were ascertained by asking a small number of patients with rheumatic diseases to rate the ‘severity’ of AEs. While the severity of AEs certainly reflects patient values, this concept does not necessarily reflect patient willingness to accept the risk of toxicity. For example, the fact that patients rated ‘impotence’ and ‘trouble thinking’ as equally severe in the study of Fries et al. does not necessarily indicate that they would be just as willing to take a medication associated with ‘impotence’ as one associated with ‘trouble thinking’. In order to determine whether patients are willing to accept the risk of a particular AE, other facets

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of toxicity in addition to severity, such as likelihood, sequelae and the expected benefit of the medication, must also be considered [9, 10].

Previous studies of willingness to accept risk in rheumatic disease have selected patients on the basis of their ‘presumed ability to complete a difficult questionnaire’ [11] and have not assessed patient values for specific AEs [11–13]. To further elucidate how patients value specific AEs, we sought to evaluate patient willingness to accept the risk of specific AEs commonly associated with corticosteroids, non-steroidal anti-inflammatory drugs (NSAIDs) and disease-modifying anti-rheumatic drugs (DMARDs) for a standardized medication benefit.

Methods

Patients

All rheumatologist-diagnosed RA patients belonging to a community rheumatology practice serving New Haven, CT and surrounding areas and who had an office visit between August 1998 and August 1999 were sent a letter describing the present study. Consecutive patients were contacted by telephone approximately 1 week after receiving the letter and asked to participate. Interviews were scheduled in patients’ homes or their doctor’s office, according to the patients’ choice. All interviews took place at least 2 weeks after seeing a rheumatologist, orthopaedist or primary care doctor. Patients were recruited and interviewed by a trained research assistant.

Data collection

Participants were presented with descriptions of AEs commonly associated with NSAIDs, low-dose (≤10 mg per day) prednisone and commonly used DMARDs of comparable efficacy, including methotrexate, sulphasalazine, azathioeprine and leflunomide [14, 15] (Appendix 1). Tumour necrosis factor antagonists were not available as first-line agents at the time of this study and therefore related AEs, such as injection site reactions, were not included. AEs were chosen on the basis of those reported in clinical trials and long-term follow-up studies [15–18]. We excluded laboratory abnormalities because Fries et al. [5] found that patients had difficulty judging the importance of abnormal blood tests. AEs were presented in random order without reference to specific medications in order to minimize bias due to personal knowledge or experience with medications.

Using lay terminology adapted from patient information sheets published by the Arthritis Foundation (USA), each AE was described in terms of the severity and reversibility of symptoms, likelihood of occurrence, and sequelae (Appendix 1). In view of the literature documenting significant variability in patients’ ability to interpret probabilities [19] and patient preferences for the presentation of probabilistic information [20], we used both verbal phrases (‘high chance’, ‘low chance’ and ‘very low chance’) and proportions (‘ten in a hundred’, ‘one in a hundred’ and ‘one in a thousand’) to describe the likelihood of AEs [21]. These levels were chosen on the basis of a previously published scale designed to facilitate communication of probabilistic information to patients [21]. We also provided participants with the following familiar examples to facilitate their understanding of less common events [9]: ‘The risk of a side-effect happening in 1 person in 100 (one in a hundred) is the same as the risk of being audited by the IRS over the next year’; ‘The risk of a side-effect happening in 1 person in 1000 (one in a thousand) is the same as the risk of a frequent motorcycle rider being killed in an accident in the next year or an average 65 year old man dying over the next two weeks’ [22].

The likelihood of each AE was chosen on the basis of those reported in the textbook Rheumatology [23–25]. For each AE, we chose a conservative estimate of risk.

For each AE, participants rated their willingness to take a medication associated with it on an anchored visual analogue scale (VAS), where 0 = not willing under any circumstances and 100 = definitely willing, assuming that the medication offered the following benefits: (i) ‘The medication relieves most of your pain and stiffness’; (ii) ‘The medication helps with your arthritis so you can eat, take a bath or a shower, climb stairs, do housework, and shop with minimal difficulty’; and (iii) ‘While taking the medication you aren’t worried about your arthritis, but once in a while you are concerned about how your arthritis will affect you in the future’.

Participants were asked to assume the same medication benefit for each AE. In addition patients were asked to assume the following: (i) ‘The medication is given as a pill once a day’; (ii) ‘While on the medication you need to have blood tests done about once every two months’; and (iii) ‘The medications can all cause side-effects, but are well tolerated by most patients’.

We collected sociodemographic data and information regarding medication use, personal experience with AEs and perceived arthritis-related health status [26]. Preference for disclosure of information was determined using four questions from a validated questionnaire: ‘Even if the news is bad I should be well informed’; ‘It is important for me to know all the side-effects of my medications’; ‘When there is more than one way to treat a problem, I should be told about each one’; and ‘I should be given information only when I ask for it’ [3]. Each question was coded on a five-point Likert scale (ranging from ‘strongly agree’ to ‘strongly disagree’), the strongest preference for disclosure of information being assigned a score of 5 (scoring for the last question was reversed). Scores were summed across the four questions and expressed on a scale adjusted from 0 to 100, where 100 reflected a strong preference for full disclosure [3].

Analysis

We described patient characteristics and the distribution of patient willingness to take medication associated with specific AEs using univariate statistics. Test–retest reliability was examined by comparing median ratings
of willingness to take medication with each AE on questionnaires administered 2–4 weeks apart in 10 subjects. On repeat evaluation, median scores were within 10 points for 15 of the 18 AEs studied.

For subsequent analyses, AEs were grouped into three categories: (i) cosmetic changes (hirsutism, alopecia, weight gain and acne); (ii) temporary discomfort with no long-term sequelae (rash, stomatitis, mild nausea and vomiting, moderate to severe nausea and vomiting, mild diarrhoea, moderate to severe diarrhoea); and (iii) major toxicity (kyphosis, hip fracture, gastric ulcer, infection, pneumonitis, liver disease and cancer).

We created a dichotomous summary variable for toxicity in order to examine the association between patient characteristics and willingness to accept toxicity for each category of AEs. Patients with score 0 on the VAS (where 0 = not willing under any circumstances) for at least half of the AEs per category (at least two AEs for cosmetic changes, three for temporary discomfort and four for major toxicity) were classified as unwilling to accept the risk of AEs in that category. Associations between demographic and clinical characteristics with willingness to accept toxicity were ascertained using the t-test and χ² test for continuous and categorical variables respectively. Multivariate analyses were performed subsequently using multiple logistic regression. All analyses were performed using SAS software version 6.12 (SAS Institute, Cary, NC, USA).

Results

Patient characteristics

One hundred of the 170 patients (59%) approached agreed to participate. Non-participants were younger [mean (S.D.) age = 66 (14) yr] and a greater proportion were female (81 vs 73%), married (96 vs 58%) and currently employed (54 vs 18%) compared with participants. Current DMARD use did not differ between participants and non-participants.

Patient characteristics are described in Table 1. The mean (S.D.) age was 68 (12) yr (median 71, range 30–99); 73 were female and 58 were married. Eighty-one were currently using one or more DMARDs and 29 had previously experienced AEs related to DMARDs. Seventy-five stated that they were doing very well or well with respect to their arthritis compared with other people of their age. The mean (S.D.) score for preference for information disclosure was 86 (13) (median 88, range 44–100), reflecting a strong preference for full disclosure of risks and information regarding treatment alternatives.

Patient willingness to accept the risk of specific AEs

Using the VAS scores, willingness to accept the risk of AEs ranged from a median score of 0 (‘not willing under any circumstances’) for cancer to a median score of 20 for most cosmetic changes and mild gastrointestinal disturbances (Fig. 1). No AE median score was higher than 20. The percentage of respondents who were not willing to accept the risk of specific AEs under any circumstances (i.e. VAS score 0) ranged from 29% for acne to 60% for cancer (Fig. 2). Thirty-three per cent of those surveyed were not willing to accept the risk of any of the AEs studied (i.e. VAS score 0 for all AEs).

Using the dichotomous summary variable (which characterized persons as unwilling to accept the risk of toxicity if their scores were 0 for at least half of the AEs in a category), 35 patients were unwilling to accept the risk of AEs associated with cosmetic changes, 38 were unwilling to accept the risk of AEs associated with temporary discomfort, and 45 were unwilling to accept the risk of major toxicity.

In bivariate analysis, patients having previously experienced AEs were more willing to accept the risk of cosmetic changes (83 vs 58%, \(P = 0.02\)), temporary discomfort (79 vs 55%, \(P = 0.02\)) and major toxicity (83 vs 44%, \(P = 0.001\)) compared with those who had not experienced AEs previously. Age, gender, education level, marital and employment status, arthritis-related health status and preference for disclosure of information were not associated with willingness to accept toxicity (all \(P > 0.1\)).

In multivariate analyses controlling for age and preference for disclosure of information, patients who had previously experienced AEs remained more willing to

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In multivariate analyses controlling for age and preference for disclosure of information, patients who had previously experienced AEs remained more willing to
accept the risk of cosmetic changes [adjusted odds ratio (95% confidence interval) = 3.9 (1.3–11.9)], temporary discomfort [2.8 (1.0–8.0)] and major toxicity [6.0 (2.0–18)] compared with those who had not previously experienced AEs.

Discussion

In summary, we found that 33% of the patients in our study were not willing to accept the risk of AEs commonly associated with medications used to treat RA. In general, patients were more willing to accept the risk of reversible cosmetic changes than temporary discomfort and least willing to take medications associated with a risk of major toxicity, such as pneumonitis (Fig. 1). These findings are in keeping with previous studies demonstrating a similar reluctance of arthritis patients to accept the risk of drug toxicity [11–13].

Interestingly, severe nausea and vomiting, which was defined as a reversible AE with no sequelae (Appendix 1), was considered to be less acceptable than potentially life-threatening complications. Aversion to this AE has also been found in cancer patients, who ranked nausea as the most severe out of 45 AEs associated with chemotherapy [27].

Despite the variability noted in our study, patient ratings tended to cluster at the ‘not willing to take a medication with a particular AE under any circumstances’ end of the scale. In contrast, in a seminal paper by Fries et al. [5], patient ratings of the severity of a list of AEs clustered at the milder end of a scale ranging from ‘very mild’ to ‘severe’. Direct comparison between the two studies is difficult because of the differences in sample sizes, the AEs studied and the specific question asked. In our study we measured the acceptability of AEs, which requires consideration not only of severity but also of probability, sequelae and expected benefits of the medication under consideration, whereas in the study of Fries et al. the AEs were listed in isolation without reference to other medication characteristics.

Recent reports demonstrate that, when faced with difficult decisions, patients prefer extensive disclosure regarding treatment options [2–4]. Therefore, we provided patients with comprehensive treatment descriptions which included details such as the route of administration, drug monitoring requirements and patient-oriented outcomes, including not only the

Fig. 1. Patient willingness to take medications associated with specific adverse effects. Willingness was measured on an anchored VAS on which 0 = ‘not willing under any circumstances’ and 100 = ‘definitely willing’. N/V, nausea and vomiting.
resolution of symptoms but also improvement in functional and emotional status. Furthermore, to optimize patient understanding of probabilities, we used numerical estimates as well as familiar verbal phrases and provided familiar examples to facilitate understanding of less common events [9, 22].

In our study, patients who had experienced AEs previously were more willing to accept the risk of toxicity compared with patients who had not experienced AEs. Similar results have been found in studies of cancer patients in which patient experience with chemotherapy was positively related to preference for more aggressive treatment [28–30]; these results suggest that the effects of AEs on quality of life that the patients anticipated might be worse than their actual effects. This hypothesis is based on studies in the psychology literature that show that people systematically exaggerate the impact of negative events on future well-being [31]. For example, assistant professors consistently overestimated how unhappy they would be in the future if they were denied tenure compared with former assistant professors who were actually denied tenure [32]. Similarly, Sieff et al. [33] found that patients’ predictions of their well-being after receiving a positive HIV test result were overly negative compared with patients who had actually received positive test results. This theory also explains why quality of life on dialysis is rated higher by dialysis patients than by healthy persons [34].

Inability to predict responses to negative events accurately is thought to be due to unawareness of one’s ability to adapt to negative events [31]. In our study, patients who had not experienced AEs previously might have overly exaggerated the impact of AEs on their quality of life, and consequently might have been more fearful of toxicity. Our data did not permit us to examine whether patients who had recovered more easily from previous AEs were more willing to risk toxicity compared with those who had worse outcomes.

Our results must be interpreted in view of the limitations of the study design. First, most of the patients in this study were doing well with respect to their RA, as reflected by their self-reported health status. Previous studies have shown that willingness to accept risk is related to current health status and disability [13, 35]. It is therefore likely that sicker patients are more willing to accept the risk of toxicity. Secondly, although medication benefit was described in terms of symptom relief as well as improvement in physical and emotional status, we did not include the impact of disease-modifying drugs on long-term prognosis, because we evaluated AEs related to NSAIDs and prednisone, in addition to DMARDs. Including the positive effects of DMARDs on long-term prognosis might affect willingness to accept toxicity, especially among younger patients. Thirdly, the participants in this study were recruited from a single community practice, thereby limiting the
generalizability of the results to persons with similar demographic characteristics. Our sample contained a relatively small number of men. Recruiting men for our study was difficult because of the much lower prevalence of men with RA attending this community practice.

Lastly, although we chose to use a VAS in order to avoid clustering, the respondents’ ratings were highly skewed towards unwillingness to accept the risk of toxicity under any circumstances. Similar problems have been found using Likert scales [2], however, and having respondents rank the AEs was not possible because of the number of items included in the questionnaire.

Elicitation and incorporation of patient preferences into medical decision-making is based on the assumption that patients want to be fully informed about their medical options. The participants in this study, despite their general reluctance to accept the risk of toxicity, had a strong preference for full disclosure of treatment-related risks. This finding is consistent with a growing literature demonstrating that the vast majority of patients, independent of the disease under consideration, prefer to be fully informed [3, 4, 36–38], and underscores the importance of effective communication in clinical practice.

The majority of RA patients in our study were very concerned about medication toxicity, as indicated by the high proportion of respondents who were unwilling to risk AEs. Patient willingness to risk AEs, however, depends not only on the specific AEs and the expected benefits of a medication, but also on the physician–patient relationship. This explains why DMARD use in actual clinical practice is much greater than one would have predicted on the basis of our results. Nonetheless, the results of this study imply that certain patients, especially those with milder disease activity, might be reluctant to accept commonly used arthritis medications if they were fully informed of their potential toxicity. In addition, risk aversity appeared to be attenuated by past experience with AEs, indicating a possible discrepancy between the anticipated and the actual impact of AEs on quality of life.

Our results suggest a potential opportunity to improve the quality of medical decisions in clinical practice. Specifically, physicians might facilitate patients’ acceptance of treatment risks by clarifying the consequences of AEs to alleviate fear of the unknown.

These findings, together with other evidence [2, 39], also suggest that future studies of patient preferences should provide supplementary information (e.g. in the form of images or patient testimonials) to help patients understand the implications of a given health risk and to standardize the anticipated effects of AEs on quality of life [39].

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References


Appendix 1

Description of AEs included in the study

The same VAS scale was used for all AEs and is therefore presented only once.

1. The arthritis medication can cause severe diarrhoea (you have stomach cramps and need to run to the bathroom every 2–3 hours during the day and night). The diarrhoea goes away if the arthritis medication is stopped. How willing are you to take this medication if there is a:

   - Low chance (approximately 1 person in 100) of getting this side-effect.
   - Very low chance (approximately 1 person in 1000) of getting this side-effect.
   - High chance (10 or more people out of 100) of getting this side-effect.

2. The arthritis medication can weaken your bones, which increases your risk of breaking your hip if you fall. Patients with a broken hip need to be admitted to the hospital for major surgery. Patients having this surgery are in the hospital for about 3 days and then spend between 2 and 6 weeks in a rehabilitation facility. Most patients walk with a cane or walker for about 3 months after the surgery. How willing are you to take this medication if there is a:

   - Very low chance (approximately 1 person in 1000) of getting this side-effect.
   - High chance (10 or more people out of 100) of getting this side-effect.

3. The arthritis medication can cause mild or moderate nausea and vomiting (you sometimes feel a little queasy and vomit about once a week). The nausea and vomiting go away if the arthritis medication is stopped. How willing are you to take this medication if there is a:

   - Very low chance (approximately 1 person in 1000) of getting this side-effect.

4. The arthritis medication can cause a stopped posture (or a hump on your back) from...
osteoporosis. The stooped posture is painless. It is permanent and doesn’t go away even if the medication is stopped. How willing are you to take this medication if there is a:

Very low chance (approximately 1 person in a 1000) of getting this side-effect.

5. The arthritis medication can cause a red itchy rash. The rash can be treated with medications and creams to stop the itch. The rash goes away if the arthritis medication is stopped. How willing are you to take this medication if there is a:

High chance (10 or more people out of 100) of getting this side-effect.

6. The medication can make you more susceptible to serious infections, such as pneumonia and blood or joint infections. Patients with these infections need to be admitted to the hospital for treatment with intravenous antibiotics for 1 to 2 weeks. Most people get better. Rarely, when severe, this type of infection can be life-threatening. How willing are you to take this medication if there is a:

Very low chance (approximately 1 person in 1000) of getting this side-effect.

This type of infection may be life-threatening in approximately 1 person in 10 000.

7. The arthritis medication can cause lung problems that cause a dry cough, shortness of breath, and fever. Patients with this side-effect need to be admitted to the hospital for treatment with oxygen and intravenous medications (steroids by vein). Treatment takes an average of 2 weeks. Most patients get better. Rarely, when severe, this side-effect can be life-threatening. How willing are you to take this medication if there is a:

Very low chance (approximately 1 person in 1000) of getting this side-effect.

These lung problems may be life-threatening in approximately 1 person in 10 000.

8. The arthritis medication can cause a bleeding stomach ulcer. Patients with bleeding stomach ulcers need to be admitted to the hospital for treatment. Most patients get better with fluids and blood transfusions, but sometimes major surgery is needed. Rarely, when severe, this side-effect can be life-threatening. How willing are you to take this medication if there is a:

Low chance (approximately 1 person in a 100) of getting this side-effect.

Bleeding ulcers may be life-threatening in approximately 1 person in 10 000.

9. The arthritis medication can cause cancer that might occur even after the medication is stopped. If this does happen you will be referred to a cancer specialist for treatment. How willing are you to take this medication if there is a:

Very low chance (approximately 1 person in a 1000) of getting this side-effect.

10. The arthritis medication can make you gain weight. The weight gain is due to water retention and increased body fat. The increased body fat occurs mainly in the face (giving a round or moon face), the stomach and the back of the neck. These changes will slowly go away if the medication is stopped. How willing are you to take this medication if there is a:

High chance (10 or more people out of 100) of getting this side-effect.

11. The arthritis medication can cause painful mouth sores. The sores feel like canker sores. The sores can be treated with a gel or a mouth rinse. The sores go away if the medication is stopped. How willing are you to take this medication if there is a:

High chance (10 or more people out of 100) of getting this side-effect.

12. The arthritis medication can cause increased hair growth on your face and arms. This hair doesn’t usually go away, even after the medication is stopped. The hair can be bleached, or removed permanently with electrolysis or laser therapy. How willing are you to take this medication if there is a:

High chance (10 or more people out of 100) of getting this side-effect.

13. The arthritis medication can cause mild to moderate diarrhoea (you have occasional stomach cramps and have watery bowel movements about 2 or 3 times per week). The diarrhoea goes away if the medication is stopped. How willing are you to take this medication if there is a:

High chance (10 or more people out of 100) of getting this side-effect.

14. The arthritis medication can cause severe nausea and vomiting (you often feel queasy and have vomited 1 or 2 times every day since starting the medication). The nausea and/or vomiting go away if medication is stopped. How willing are you to take this medication if there is a:

Low chance (approximately 1 person in 100) of getting this side-effect.

15. The arthritis medication can cause liver damage. People with liver damage may become tired and weak and may lose their appetite. Many patients don’t get other symptoms, but in some the liver...
damage gets worse and can cause yellow skin, intense itching, and bloating of the stomach. Rarely, when severe, liver damage can be life-threatening. How willing are you to take this medication if there is a:

Very low chance (approximately 1 person in 1000) of getting this side-effect.
Liver damage may be life-threatening in approximately 1 person in 10 000.

16. The arthritis medication can cause acne (pimples). The pimples go away if the medication is stopped. How willing are you to take this medication if there is a:

High chance (10 or more people out of 100) of getting this side-effect.

17. The arthritis medication can cause you to lose some of your hair. Your hair will slowly grow back if the medication is stopped. How willing are you to take this medication if there is a:

High chance (10 or more people out of 100) of getting this side-effect.