Understanding how patients (vs physicians) approach the decision to escalate treatment: a proposed conceptual model

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Abstract

Objective. We performed a qualitative study to better understand how patients with RA approach risk–benefit trade-offs inherent in the choice of remaining with their current treatment vs escalating care.

Methods. We used a think-aloud protocol to examine how patients with RA approach risk–benefit trade-offs inherent in the choice of remaining with their current treatment vs adding a biologic. The data emerging from the protocols were used to develop a conceptual model describing how patients approach the decision to escalate care.

Results. Participants who were strongly impacted by their disease were not open to considering alternative options. For some patients, being highly impacted by their disease results in a strong preference to escalate care. For others, the same level of distress is reason to unconditionally refuse additional medications. In contrast, those who were moderately impacted were more open to consider treatment options. Among these participants, however, subjects’ risk–benefit trade-offs were consistently modified by factors unrelated to medication, including sociodemographic characteristics, role responsibilities and the quality of the patient–physician relationship.

Conclusion. The conceptual model indicates that patients approach the decision to escalate care differently from physicians. In order to improve care in RA, it is important to recognize that many patients with moderate to high disease activity are not open to alternative treatments, which is a prerequisite to engaging in decision making. Routine clinical encounters should enable health care providers to identify these patients in order to tailor education prior to recommending treatment escalation.

Key words: rheumatoid arthritis, decision making, quality of care, patient preference, treat to target.

Introduction

Optimal care for RA patients with moderate to high disease activity includes regular monitoring and adjustment of medication in order to improve both short- and long-term outcomes [1]. Yet, recent studies have shown that treatment is frequently not adjusted in patients with active disease [2, 3]. This gap may be due, in part, to differences in how physicians and patients approach the decision to change or add medications [4].

Several papers have found that patients’ illness perceptions and medication beliefs are distinct from physicians’ explanatory models and that these beliefs predict adherence to prescribed medication [5–7]. Physicians are expected to escalate care using criteria informed by the results of high-quality randomized controlled trials demonstrating that the benefits of escalating care using treat-to-target protocols far outweigh the risks. Patients’ criteria to change treatment, however, differ from physicians’ criteria in consistent ways. Notably, in a large cohort study of patients with RA, 71% of patients who had high levels of disease activity stated that they...
preferred to continue with their current regimen rather than change medication [8]. In addition, a recent longitudinal study found that escalation of care in RA patients with high disease activity [as measured by the Routine Assessment of Patient Input Data 4 (RAPID4)] was likely to occur only in patients who also described being significantly physically and/or emotionally impacted by their disease [2]. These findings indicate that patients’ illness beliefs are an important determinant of treatment decisions that are not fully captured by the criteria used in treat-to-target protocols.

In order to decrease the gap between evidence-based recommendations and decisions made in clinical practice, it is important to understand how patients evaluate the relationship between their disease and the need to change treatment. Our objective was to qualitatively examine patient responses as they evaluated the risks and benefits inherent in the choice of remaining with their current treatment vs adding a biologic. We captured the patient perspective using a think-aloud protocol, which involves asking participants to verbalize their thoughts as they perform a specific task. Think-aloud procedures are commonly used to examine cognitive processing strategies during decision making and choice tasks [9]. The main advantage of this approach is that, unlike retrospective methods of obtaining feedback, concurrent think-aloud protocols are not influenced by omissions and systematic errors related to memory. The resulting narratives were used to develop a conceptual model describing how patients approach the decision to escalate care in the context of RA. A conceptual model reflecting how patients approach the decisions inherent in treat-to-target protocols may help improve shared decision making in clinical practice.

Methods

This study utilized an inductive approach in line with classic grounded theory to understand the patients’ subjective experiences as they make decisions about escalating care within the context of RA [10]. Classic grounded theory is based on the premise that the meaning of a phenomenon (e.g. the decision a patient makes about escalating RA care) is constructed, interpreted and modified by the individual and their social interactions. This methodology therefore attempts to glean a theory (or conceptual model) from the participants’ perceptions about the phenomenon, without a priori assumptions about the structure or content of the theory. Thus grounded theory can be considered a patient-centred form of qualitative research whose purpose is to develop a substantive theory that can be further tested in quantitative studies.

Participants and recruitment

Patients with RA were identified by the treating physician from four community-based rheumatology practices. The research assistant mailed all patients a letter briefly describing the study and notifying them that they would be telephoned by a research assistant. Potential subjects were offered the opportunity to refuse this contact by calling an answering machine and leaving a message. The research assistant contacted all patients who did not opt out by telephone to describe the study and confirmed additional inclusion criteria: being ≥ 18 years of age, having seen their rheumatologist at least twice over the past 12 months, having pain rated at least 3 on an 11-point numerical rating scale and currently prescribed at least one DMARD. Patients reporting a contraindication to biologics (diagnosis of cancer within the past 5 years, congestive heart failure, chronic lung disease, hepatitis B or C, open skin ulcers or a current infection) were excluded. This sampling method represents two strategies: purposive sampling of patients who could conceivably be faced with the decision-making paradigm under investigation, as well as a priori theoretical sampling of patients who both have and have not chosen to escalate care to incorporate biologics into their RA treatment regimen. An in-person interview was scheduled for patients who expressed interest in participating. Patients were given US$25.00 for their participation in the study. Subjects’ written consent was obtained according to the Declaration of Helsinki. The study was approved by the Yale Human Subjects Committee.

Decision-making task

We wanted to standardize the phenomenon or decision-making problem that patients responded to in this study. Therefore we used a conjoint analysis survey to present specific pairs of risk–benefit trade-offs (an example is provided in Fig. 1). Conjoint analysis is a commonly used task designed to elicit preferences for competing options that has been widely applied to health care decisions [11–14]. Participants evaluated the incremental risk and benefit of treatment escalation across eight medication attributes (e.g. ability to work, risk of infection; the full list can be found in supplementary Table S1, available at Rheumatology Online), each having three levels. Participants rated 10 paired-choice tasks using a 9-point rating scale (an example is provided in Fig. 1). The

![Example of a paired comparison task](image-url)
adaptive conjoint analysis software program SSI Web version 6.4 (Sawtooth Software, Orem, UT, USA) constructs pairs by examining all the possible ways the levels can be combined and then chooses pairs of options with similar utilities to which it expects respondents to be indifferent (based on previous responses). It ensures that the choices presented in each pair always have different levels of the same attribute and are displayed at random on either the right or left side of the screen. The program is interactive in that it uses the information obtained from each paired comparison to update the estimates of each respondent’s utilities and to select the next pair of options. Additional details regarding this methodology have been previously published [11, 15, 16]. The procedure lasted ~15–20 min.

Think-aloud protocol

Participants were audiotaped as they performed the conjoint analysis task described above. At the beginning of the protocol, a single trained research assistant asked each patient to think out loud as you answer the questions on the computer, just say out loud everything that comes into your head and remember there is nothing right or wrong to say. The research assistant reminded participants to say their thoughts aloud after silent periods of \( \geq 15 \) sec. This procedure allows the patient to identify and report self-perceptions about salient aspects of their decision making.

Analysis

Because the objective of this study was to develop a conceptual model describing patient decision making in escalating care in RA, this study utilized the classic grounded theory method using an inductive approach, as recommended by Glaser [10], which analyses data at four stages of analysis: substantive codes, concepts, categories and conceptual model (or theory in grounded theory terminology). An audit trail was created by audio recording each participant performing the think-aloud task. Recordings were transcribed verbatim by a private business specializing in transcription services (ASP.MD, Cambridge, MA, USA). The transcripts were independently evaluated and substantive codes identified and labelled line by line by at least two research team members (K.M., M.C., L.F.) with varying expertise (in clinical research, clinical rheumatology, medical decision making and qualitative research methods), thus fulfilling the requirements of investigator triangulation (using perspectives from varying investigators in qualitative research). A constant comparative approach was used to develop codes among research team members (K.M., M.C., L.F.). The resulting substantive codes with similar meanings were clustered together, leading to the emergence of concepts, which were further sorted into two comprehensive categories: factors related to approaching a risk–benefit trade-off and factors that influence decision making during a risk–benefit trade-off. Data from patients who demonstrated openness to approaching a risk–benefit trade-off were constantly contrasted with data from patients who demonstrated a closed stance towards engaging in a risk–benefit trade-off to identify similarities and differences in these two groups.

The next phase of the analysis involved elaborating on these categories within each patient group. Emerging results from analysing these data served as the basis of the conceptual model (or theory in grounded theory terminology) developed by two research team members (L.F. and E.S.). All protocols were transcribed prior to analysis. Throughout the process of data analysis, emerging substantive codes, concepts, categories and the conceptual model were continuously compared with the data to ensure the grounded nature of the analysis. The categories and conceptual model that emerged from the data were also evaluated through peer debriefing with researchers and clinician experts in pain.

Results

Subject characteristics

Participants \( (n=88) \) ranged in age from 20 to 83 years [mean 55 years ± 13]; 68% were Caucasian, 74% were women and 53% were married. Approximately one-third had a college degree or higher education. On average, participants had been living with RA for nearly 12 years and 21% were currently on a biologic.

Overview of conceptual model

While we undertook this study to learn how patients with active RA approach the decision to escalate care, the most striking finding that emerged from the think-aloud interviews with patients was that many patients did not view that they had a choice or a decision to make. In other words, for many patients with RA, consideration of trade-offs was immaterial. Individual differences in the degree to which patients were impacted by their disease appeared to differentiate those patients who were open to considering options vs those who viewed themselves as having only one possible course of action (whether it was to change treatment or to remain with the status quo). The conceptual model (Fig. 2) that emerged from the think-aloud subject data posits that patients who are either

**Fig. 2** Relationship between disease impact and openness to engage in decision making
very highly impacted by their disease (e.g. disabled by current symptoms, very worried about future impact of symptoms) or not at all impacted by their disease (despite meeting guideline criteria for escalation of care) view themselves as having only one possible course of action and are therefore not open to considering alternative options. In contrast, patients who are moderately impacted by their disease appear to be more willing to consider trade-offs. The following sections describe each phenotype in more detail and representative quotations are provided in Tables 1 and 2.

Closed to alternative options

**Patients with high disease impact**

While patients who felt highly impacted by their disease viewed themselves as having only one option, they did not all agree on what that option was. Some patients with high disease impact viewed maintaining the status quo (i.e. leaving the current treatment regimen unchanged) as their only alternative (Table 1). They described high levels of difficulty coping with their illness, but also strongly believed that adding a medication would result in certain additional morbidity. Therefore, despite being strongly impacted by RA, these participants viewed adding another medication as an unacceptable alternative because they felt unable (too sick) to contend with any additional health threats. These patients did not demonstrate openness to considering trade-offs and have preferences that likely contribute to the lower than expected rates of treatment escalation observed in clinical practice.

In contrast, other patients reporting high disease impact felt that changing their status quo, i.e. escalating treatment, was their only option (Table 1). They described their suffering due to RA as oppressive and unbearable and viewed medication as their primary (or only) tool to manage RA symptoms. Medication was described as a lifeline, and medication escalation as the method to reduce disease-related distress and disability. These patients also did not demonstrate willingness to consider trade-offs; however, their preferences are concordant with treat-to-target protocols and therefore do not contribute to the gap between recommendations and observed clinical practice patterns.

**Patients with low disease impact**

Despite meeting guideline criteria to escalate care, these patients were not sufficiently impacted by their current disease, or concerns regarding future consequences of untreated disease, to perceive a need for additional treatment. They were able to maintain their level of function despite having signs of active RA, and had a strong belief that medications would cause side effects that would interfere with their ability to work or to engage in the recreational activities they enjoyed. These patients focused on preserving their status quo (i.e. avoiding additional medications) in order to protect their current quality of life. They did not demonstrate openness to considering alternatives and expressed an unwillingness to add or change medication despite meeting criteria for treatment escalation.

Open to alternative options

**Patients with moderate disease impact**

Participants who were moderately impacted by their disease and/or medications were more likely to perceive a decision and thus more open to considering the pros and cons related to possible alternatives. In all cases, however, evaluations of the presented trade-offs were made in the context of factors external to the medication characteristics included in the paired comparison tasks. These factors included personal characteristics (sociodemographic characteristics and role responsibilities) and elements of the patient–physician relationship. Notably, none

<table>
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<th>Level of impact</th>
<th>Representative quotations</th>
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<td>High disease impact + prefer the status quo</td>
<td>The risk for a neurologic disease when I already have severe RA is a very, very significant risk and for me and we would want to prevent that at all cost even if at the expense of having more joint pain or more bony destruction. I am a sick person. I just think about things like that [medication risks] because I have no choice since I already have sickle cell anemia ... and the list goes on and on.</td>
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<tr>
<td>High disease impact + prefer to escalate</td>
<td>I don’t want to deal with the crap of these biological medications, but I really do not have any options. Deal with the pain or deal with a biologic because that is all we have available. Well if you are really sick, depending how badly you are suffering but if you are suffering a lot, I got to the point it is not worth living, you know, when you cannot do what you want and you know, you are just a mess of yourself, you know, you can hardly move here and there.</td>
</tr>
<tr>
<td>Low disease impact + prefer the status quo</td>
<td>... but physically, just to be able to go do the things in the world, you know, pursue my interest. I am fairly active so I do not think I would fare well if I could not go climb on things, make things, ride boats all over the ocean, and stuff like that (because of medication side effects). So, that is really what drives my decisions.</td>
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of these factors consistently increased or decreased willingness to escalate care.

**Personal factors.** Although ethnicity and gender are frequently cited as predictors of risk perception, in this study the only sociodemographic characteristic brought up by patients was age. While older adults with RA are generally viewed as being more risk averse [17], participants cited older age as a reason to both accept and refuse the risks associated with additional medication. Some believed that their advanced age made it easier for them to accept the possible risks of adverse events since they had less to lose, whereas others felt that older age decreased their ability to cope with drug toxicity and were therefore more risk averse.

Role responsibilities were frequently raised as an important factor influencing how patients evaluated competing risks and benefits. As with age, responsibilities could be associated with either a positive or negative attitude towards changing medication. Some expressed concern about the impact of toxicity on their ability to work or care for their children as a reason to maintain the status quo. The same responsibilities motivated others to escalate RA medication in order to improve function and to prevent future morbidity.

**Patient-physician relationship.** Participants also described trust in one’s physician and communication between the patient and physician as factors that influenced their trade-offs. Lack of trust was most frequently described as a barrier to escalating medication. Mistrust of medical providers and suspicions related to medications themselves deterred several participants from trying new RA treatments. Some did not believe that physicians were fully aware of all the potential risks associated with medications, while others felt that physicians did not take into account their personal past medical experiences when prescribing new medication. Several noted that they felt like guinea pigs as their physicians experimented with different medication to treat their RA. Others expressed an unwillingness to try new medications because they felt that their providers did not adequately inform them of the expected risks and benefits. Many participants described working with multiple physicians and some were concerned that providers were not fully aware of what others were prescribing. The perceived lack of
communication between providers amplified some participants’ concerns regarding potential interactions between prescribed medications.

Only one participant described her relationship with her physician as a facilitator towards escalating RA medication. This participant described both trust and open communication between herself and her physician as key to facilitating escalation of RA medication (Table 2).

Discussion

In this study we used qualitative methods from a classic grounded theory perspective to gain insight into how patients consider trade-offs related to the risks and benefits of escalating treatment. Our findings support a U-shaped relationship between patients’ perceived disease impact and openness to engaging in a decision-making process. The conceptual model that emerged from our data suggests that patients who are either strongly or minimally impacted by their disease are not open to considering alternatives. Those who are strongly impacted describe themselves as having only one viable option; however, there is significant disagreement as to which option is the viable option. For some patients, being highly impacted by their disease results in a strong preference to escalate care. For others, the same level of distress is reason to unconditionally refuse additional medications. Patients who are not impacted by their disease are also closed to considering alternatives; however, they uniformly report remaining with the status quo as their preferred option. This observation is concordant with the literature suggesting that patients with chronic illnesses who meet guideline criteria to escalate care will need to perceive a significant impact of their disease on their current and/or future health in order for an escalation of treatment to occur in clinical practice [2, 18].

The conceptual model outlined in this article may be helpful in guiding treatment discussions for patients meeting guideline criteria to escalate care (Fig. 3). First, patient perception regarding the impact of disease should be explicitly assessed. For patients who perceive low disease impact because of a lack of symptoms or because they have adapted to their current symptoms and disability, further education regarding the consequences of untreated disease (to ensure that patients are effectively informed) may be required in order to increase impact, and consequently willingness to engage in decision making. For patients who perceive a high impact of their disease on quality of life and perceive treatment escalation as their only viable option, an informed consent process is sufficient. For patients who perceive a high impact of their disease on quality of life, but who are also committed to protecting their status quo because they perceive a high negative impact of escalation of RA treatment on their quality of life, additional interventions to increase openness to considering trade-offs prior to describing treatment alternatives should be investigated.

Once open to considering alternatives, it is important to recognize that patients use factors distinct from those used by physicians in their decision making. This finding is consistent with previous qualitative as well as quantitative studies [4, 19, 20]. In addition, we observed that the same factors could influence participants towards or away from considering new medication. For example, role responsibilities and age motivated some patients to take treatment and others to avoid it. Patient-physician relationship variables could also theoretically act to increase or decrease uptake of additional medication. However, in this study participants most frequently reported the effect of lack of trust and poor perceived communication on their decision making. Only one participant described her relationship with her physician as a facilitator towards escalating treatment. The influence of these factors on patients’ decision making highlights the need to broaden treatment planning discussions beyond risk–benefit trade-offs and reinforce that trust is a necessary, albeit not sufficient, requirement for patients to accept physician recommendations.

There are several limitations of this study. While we conducted a large number of interviews, our sample was recruited from a single county, thereby limiting the generalizability of the themes discussed to this group. Further, we were not able to continue theoretical sampling in the context of emerging data, as data collection was completed prior to analysis. We feel that a qualitative study was the best approach to meet our objective, however, this approach does preclude quantitative analyses of the data and assessment of the relative importance that patients attach to each of the factors discussed. We strongly encourage researchers to attempt to replicate these findings in further qualitative studies and validate and/or modify this conceptual model based on quantitative studies.

Despite these limitations, the findings have important clinical implications. Our conceptual model emphasizes that many patients are not open to evaluating trade-offs between alternative treatment options, which is an essential component of a high-quality decision-making process.
It also provides a framework to guide interventions aimed at improving shared decision making in clinical practice. Successful implementation of evidence-based recommendations may be best enhanced by having health team members assess disease impact prior to the patient-physician encounter. Providing the appropriate support for patients closed to considering alternatives, whether through further education, motivational interviewing or peer counselling, to increase patient openness to decision making is likely to be an effective and more efficient way to improve the quality of the subsequent shared decision-making process between patients and their physicians [21, 22].

Rheumatology key messages

- Understanding how RA patients approach treatment decisions is critical to improving adherence to guidelines.
- Many patients with active RA are not open to considering alternative treatment options.
- Education should be individualized based on RA patients’ readiness to change their current treatment plan.

Supplementary data

Supplementary data are available at Rheumatology Online.

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