PATIENT SELF-REPORT ON AN MDHAQ (MULTIDIMENSIONAL HEALTH ASSESSMENT QUESTIONNAIRE) APPEARS TO PROVIDE SUPERIOR DOCUMENTATION OF POSSIBLE ADVERSE EVENTS OF METHOTREXATE THAN A PHYSICIAN NOTE IN AN ELECTRONIC MEDICAL RECORD

BY

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ABSTRACT

Objectives

To analyze the likelihood of self-report of 1 of 3 possible adverse events associated with methotrexate, the most widely used disease-modifying anti-rheumatic drug (DMARD) in patients with rheumatoid arthritis (RA), including headache, stomach pain, and hair loss, on a 60 symptom checklist on a patient self-report multidimensional health assessment questionnaire (MDHAQ); to recognize possible notation and/or action by the treating rheumatologist in the Epic electronic medical record (EMR) to the patient self-report of any of these 3 possible adverse events; to study possible differences in patients who met or did not meet criteria for fibromyalgia on a FAST3 (fibromyalgia assessment screening tool) cumulative index concerning the prevalence of the 3 possible adverse events and physician notation or actions.

Methods

All patients seen at Rush University Medical Center (RUMC) rheumatology clinic complete a 2- page MDHAQ at each visit to assess physical function, pain, fatigue, global status, and a self-report painful joint count. The MDHAQ also includes a 60-symptom checklist, which includes many specific symptoms which may be adverse events associated with medications used to treat RA (and other diseases).

A chart review of the Epic electronic medical record (EMR) of RA patients who were initially naïve to methotrexate was conducted for all visits to recognize whether patients reported 3 possible adverse events of methotrexate: headache, stomach pain or hair loss. We examined whether there was evidence that the treating rheumatologist recognized and/or acted in response to the symptom reported by the patient. A subset analysis was conducted to recognize the likelihood of patient report of 1 of the 3 symptoms and possible physician notation and/or actions

in response to the symptom in patients who met or did not meet criteria for fibromyalgia according to a fibromyalgia assessment screening tool (FAST3), to analyze the possible extent to which fibromyalgia may confound patient's self-report and physician response concerning possible adverse events.

Results

The study included 121 patients who completed an MDHAQ before taking any DMARD for RA and were then treated with methotrexate. Among the 121 patients, 79 reported headache, 40 stomach pain and 45 hair loss, including 40/80 (50%) who did not report headache prior to methotrexate use, 30/109 (28%) who did not report stomach pain prior to methotrexate use and 26/101 (26%) who did not report hair loss prior to methotrexate use. Documentation in the Epic EMR was seen for 9/40 patients who reported headache (9/19 who reported > 30% of visits), 14/30 who reported stomach pain (14/17 > 30% of visits) and 4/26 who reported hair loss (4/11 at > 30% of visits). Physician actions were seen in only 5/40 patients who reported headache (5/19 who reported > 30% of visits), 4/30 who reported stomach pain (4/17 who reported > 30% of visits) and 1/26 who reported hair loss (1/11 who reported > 30% of visits). Patients with fibromyalgia reported higher percentages for all symptoms, but physician recognition and action were higher in patients who did not meet criteria for fibromyalgia.

Conclusions

A 60 symptom checklist on a 2-page MDHAQ appears more sensitive to document possible adverse events to methotrexate than a physician note in the EMR, in which documentation and/or an action in response to patient self-report of a symptom was seen in only a minority of patients. New strategies to raise physician awareness of patient self-report of symptoms appear needed.

Key words

Rheumatoid arthritis (RA), multidimensional health assessment questionnaire (MDHAQ), routine assessment of patient index data (RAPID3), fibromyalgia assessment screening tool (FAST3), disease modifying antirheumatic drugs (DMARDs), electronic medical record (EMR).

INTRODUCTION

Adverse events to medications are reported to be associated with 5% of U.S. hospital admissions, and 10% in elderly (Gandhi et al., 2003). Some adverse events are relatively obvious, such as a severe rash or severely abnormal laboratory test. However, many adverse events are common symptoms such as headache, stomach pain, hair loss, which may be overlooked in routine clinical care, particularly in elderly patients who have several chronic diseases and multiple comorbidities.

In clinical trials and other clinical research, proactive solicitation of adverse events is conducted using standard symptom checklists, which are recorded at programmed intervals, as well as in telephone contacts with patients and more recently through remote electronic monitoring between visits (Dueck et al., 2015). However, in routine care, recognition and recording of adverse events remains elicited by traditional communication between health professionals and patients, either elicited by health professionals at patient encounters or reported by patients through telephone or email contact between visits. This process remains highly variable, and many adverse events may be recognized only after prolonged delays or not recognized at all.

Several reports present strategies for remote electronic monitoring for adverse events in oncology, pulmonology, and other specialties, but not rheumatology (Basch et al., 2017; Johansen, Henriksen, Horsch, Schuster, & Berntsen, 2012). A recent case report indicated detection of adverse events to a biological agent on a remote electronic patient self-report multidimensional health assessment questionnaire (MDHAQ), including anorexia, weight loss, joint pain and insomnia (Schmukler & Pincus, 2019). These common symptoms appeared to remain unknown to the prescribing pulmonologist, but were detected on a remote, electronic

MDHAQ by a consulting rheumatologist, who had been contacted by the patient to try to explain the patient's distress. These observations suggest that proactive remote electronic MDHAQ monitoring may advance possible early detection of adverse events, to reduce their morbidity, costs, and mortality (Schmukler & Pincus, 2019).

At RUMC rheumatology, all patients complete an MDHAQ at all visits prior to seeing the rheumatologist to add to quality of care. The 2-page MDHAQ includes quantitative self-reported scales for physical function, pain, fatigue, global assessments (Pincus, Sokka, & Kautiainen, 2005; Pincus, 2008), a self-report painful joint count, and a 60-symptom checklist to facilitate review of systems (Castrejon et al., 2016; Pincus, 2008).

This study was designed to test a hypothesis that headache, stomach pain, and hair loss, 3 specific possible adverse events to methotrexate, the most widely used DMARD for treatment of RA, are documented by patient self-report on the MDHAQ 60-symptom checklist more than by physician notes and/or actions in the Epic electronic medical record (EMR), and elicit physician documentation and/or actions in only a minority of instances. We also analyzed the likelihood of report of symptoms by patients and physician recognition and/or actions according to whether patients met or did not meet criteria for fibromyalgia.

METHODS

MDHAQ

All patients seen at RUMC rheumatology clinic complete a 2-page MDHAQ. The MDHAQ includes quantitative self-reported scales for physical function, pain, fatigue, global assessments (Pincus et al., 2005; Pincus, 2008), a self-report painful joint count, and a 60-symptom checklist (Castrejon et al., 2016; Pincus, 2008). Two indices on the MDHAQ, RAPID3 (routine assessment of patient index data) and FAST3 (fibromyalgia assessment screening tool) are clinically useful. RAPID3 is a 0-30 index of a 0-10 scale for physical function, and two 0-10 visual numeric scales (VNS) for pain and patient global assessment (Pincus et al., 2005). RAPID3 is correlated significantly with traditional RA indices that include an "objective" physician joint count. RAPID3 is the most widely used index to monitor RA in routine care in the USA (Anderson et al., 2012), and has been found to be useful in all rheumatic diseases studied (Castrejon et al., 2016). FAST3 is a cumulative 0-3 scale, with 1 point each for pain score ≥ 6, symptom checklist ≥ 16, and painful self-report joint count ≥ 16. FAST3 of 2 or 3 agrees 80% of the formal criteria of fibromyalgia (Gibson, Castrejon, Descallar, & Pincus, 2019; Schmukler, Jamal, Castrejon, Block, & Pincus, 2019).

Completed paper MDHAQs from routine care are scanned into an Epic Electronic Medical Record (EMR) as a quality measure for that visit. Research studies have been conducted based on retrospective analyses of completed MDHAQs of selected patients, entered into a database called ClinDat. Among these studies have been a comparison of patient disease burden in rheumatoid arthritis (RA) vs osteoarthritis (OA), and development of FAST3.

The Rush University Institutional Review Board (IRB) approved a retrospective review of MDHAQs, provided the data were de-identified of patient name, medical record number, and date of birth.

Patients

Adult patients with a primary diagnosis of RA assigned by the treating rheumatologist seen between January 2011 (when the Epic EMR was introduced at RUMC) and December 2018 were studied. All medications of these patients were identified in the Epic EMR, and entered into the ClinDat database. Only patients who were DMARD-naive were included in the study. All MDHAQ's at all visits available in the Epic EMR for these patients were entered into the ClinDat database.

Patients were classified according to their FAST3 scores into two groups, as meeting criteria for fibromyalgia (with FAST3 scores 2 or 3), or not meeting these criteria (with FAST3 scores 0 or 1).

Medications and adverse events

Methotrexate is the most commonly used DMARD for RA, taken by more patients with RA and continued longer than any medication (Pincus, Cronstein, & Braun, 2010).

A list of adverse events, warnings and precautions associated with methotrexate was compiled from websites of the US Food and Drug Administration (FDA), and Up-to-date ®. The most common adverse events of methotrexate included headache, stomach pain, and hair loss.

Physician documentation of their patients' self-reported symptoms on the MDHAQ 60-symptom checklist were collected from review of the Epic EMR at each visit. The most frequently documented physician actions in response to possible medication adverse events were

increasing the dose of methotrexate, decreasing the dose of methotrexate, or discontinuation of the medication.

Statistical analysis

Descriptive statistical analyses were conducted to recognize the prevalence of self-report on the MDHAQ symptom checklist of headache, stomach pain or hair loss while taking methotrexate. Two sets of analyses were performed on patients who reported any of the 3 symptoms before initiation of methotrexate and a second set in patients who did not report the symptoms before taking methotrexate. The report of a symptom was conducted according to two criteria: any report of a symptom at any visit, and report of a symptom at more than 30% of visits, based on the possibility that single or 2 notations of these common symptoms could be less likely to be a result of an adverse event of methotrexate.

The number and percentages of physicians who documented recognition and/or pursued an action in response to the patient self-reported symptoms were calculated. These percentages of the 3 reported symptoms were compared in patients who met or did not meet criteria for fibromyalgia according to FAST3 (Schmukler et al., 2019).

RESULTS

Among the 121 RA patients identified, 83% were females, mean age was 53 (14.3) years, 40% were white, 33% black, 24% Hispanic and 3% "other". The mean number of years of formal education was 13.5 years (Table 1).

Among the 121 patients, at any visit, headache was reported by 79 (65%), stomach pain by 40 (33%), and hair loss by 45 (37%). A self-report of any of the three symptoms at more than 30% of visits was seen for headache in 49 patients (41%), and both stomach pain and hair loss in 23 patients (19%).

Among patients who did not report any of the 3 symptoms prior to taking methotrexate, headache was reported by 40 of 80 patients (50%), stomach pain by 30 of 109 patients (28%), and hair loss by 26 of 101 patients (26%). A symptom was reported at >30% of visits by 19 of 80 patients (24%) for headache, stomach pain was reported by 17 of 109 patients (16%), hair loss by 11 of 101 patients (11%) (Table 2).

Physician documentation of patient self-reported symptom was seen for headache in 9 of 40 patients for headache at any visit (23%), including 9 of 19 who reported headache at > 30% of visits (47%). Results for stomach pain indicated physician documentation in 14 of 30 patients who reported the symptom at any visit after methotrexate use (47%), including 14 of 17 at > 30% of visits (82%). Results for hair loss indicated physician documentation in 4 of 26 patients who reported the symptom at any visit (15%), including 4 of 11 patients at > 30% of visits (36%) (Table 3).

Physician documentation in the Epic EMR and/or an action concerning possible medication adverse events was seen for 5 of 40 patients who reported headache at any visit (12.5%) and 5 of 19 patients who reported headache at >30% of visits (26%). For stomach pain,

Physician action was seen for 4 of 30 patients who reported the symptom at any visit (13%) and 4 of 17 patients who reported it at >30% of visits (23.5%).and for hair loss, physician action was seen for 1 of 26 patients who reported the symptom at any visit (4%) and 1 of 11 patients who reported it at >30% of visits (9%) (Table 3).

In analyses according to fibromyalgia, headache, stomach pain, and hair loss were reported at >30% of visits by 62%, 27% and 30% of patients who met criteria, respectively, compared to 30%, 15% and 11% of patients who did not meet criteria (Table 4), indicating a prevalence about two fold greater in patients who met criteria for fibromyalgia. Physician documentation and/or action was seen in 45%, 90%, and 43% for headache, stomach pain, and hair loss, respectively at more than 30% of visits in patients who did not meet fibromyalgia criteria compared to 57%, 50%, and 36%, , respectively at more than 30% of visits in patients met fibromyalgia criteria. An action of decreasing the dose of methotrexate or discontinuation of the medication, was seen in 56%, 33%, and 33% for headache, stomach pain, and hair loss, respectively, in patients who did not meet fibromyalgia criteria, compared to 23%, 20%, and 25% for headache, stomach pain, and hair loss, respectively, in patients who met fibromyalgia criteria (Table 4). Therefore, a change was seen in only about half of the patients who met fibromyalgia criteria compared to patients with did not meet these criteria.

Table 1. Demographic measures of study population.

Demographic measures	Total N=121
Age, years	53 (14.3)
Female gender	100 (83%)
Ethnicity	
White	48 (40%)
Black	40 (33%)
Hispanic	29 (24%)
Others	4 (3%)

Formal education, years	13.5 (3.16)

Table 2. Prevalence of symptoms on MDHAQ 60-symptom checklist in methotrexate-treated RA patients.

	Headache	Stomach pain	Hair loss
Subjects who reported the symptom at any visit	79	40	45
Subjects who reported the symptom at > 30% of visits	49	23	23
Subjects who did not report the symptom before the initiation of methotrexate	80	109	101
Subjects who did not report the symptom before methotrexate use then reported the symptom at any visit after methotrexate use	40	30	26
Subjects who did not report the symptom before methotrexate use then reported the symptom at > 30% of visits after methotrexate use	19	17	11

Table 3. Physician responses to patient self-reported symptoms.

	Headache	Stomach pain	Hair loss
Physicians who documented patient self-reported symptom at any visit	9	14	4
Physicians who documented patient self-reported symptom at > 30% of visits	9	14	4
Actions taken by the physician in response to patient self-reported symptom	5	4	1

Table 4. Comparison between RA patients with fibromyalgia and RA patients without fibromyalgia with their self-reported symptoms on MDHAQ 60-symptom checklist.

	FAST3 0 or 1	FAST3 2 or 3
Total:	66	37
Headache:		
Subjects who reported the symptom at any visit	40 (61%)	28 (76%)
Subjects who reported the symptom at >30% of visits	20 (30%)	23 (62%)
Physicians who reported patient self-reported symptom at any visit	9 (23%)	13 (46%)
Physicians who reported patient self-reported symptom at > 30% visits	9 (45%)	13 (57%)
Actions taken by physicians in response to patient self-reported symptom	5 (56%)	3 (23%)
Stomach pain:		
Subjects who reported the symptom at any visit	16 (24%)	18 (49%)
Subjects who reported the symptom at > 30% of visits	10 (15%)	10 (27%)
Physicians who reported patient self-reported symptom at any visit	9 (56%)	5 (28%)
Physicians who reported patient self-reported symptom at > 30% visits	9 (90%)	5 (50%)
Actions taken by physicians in response to patient self-reported symptom	3 (33%)	1 (20%)
Hair loss:		
Subjects who reported the symptom at any visit	18 (27%)	18 (49%)
Subjects who reported the symptom at > 30% of visits	7 (11%)	11 (30%)
Physicians who reported patient self-reported symptom at any visit	3 (17%)	4 (22%)
Physicians who reported patient self-reported symptom at > 30% visits	3 (43%)	4 (36%)
Actions taken by physicians in response to patient self-reported symptom	1 (33%)	1 (25%)

DISCUSSION

This study reports that 3 common adverse events associated with methotrexate, headache, abdominal pain, and hair loss, are documented by many patients on a 60 symptom checklist found on an MDHAQ. The MDHAQ is completed by every patient at every visit in routine care at our RUMC rheumatology, and offers a feasible and inexpensive approach to documentation of adverse events associated with medications.

The study also documents that the symptom reported by the patient on the self-report questionnaire is documented and/or associated with an action on the part of the physician in many fewer instances in the EMR. If a symptom was reported by patient at more than 30% of her or his visits, it was more likely to be noted and/or acted upon by the physician. These observations provide face validity to the self-report of symptoms by the patient. However, in many instances, patient self-report of a symptom was not noted or acted upon by the physician, suggesting a need for improved methods for conveying information concerning the symptom to the physician.

The data indicate that patient self-report appears a more sensitive strategy to recognize possible adverse events than traditional interactions between patients and physicians. This observation appears contrary to a traditional "biomedical model" (Abelson, Rupel, & Pincus, 2008; Callahan & Pincus, 1997; McCollum & Pincus, 2009; Pincus & Castrejon, 2019), the dominant paradigm of modern medical care. In this model, information from patients is "subjective", less significant in diagnosis, management and outcomes than "objective" information from laboratory tests, radiographic imaging, and physician's physical examination. In RA, patient self-report of physical function is far more significant in the prognosis of

disability and mortality than radiographs or laboratory tests, contrary to the "biomedical model." Our findings illustrate further limitations of this model.

Furthermore, in RA, patient level of formal education is more significant than laboratory tests, radiographic imaging in prognosis of disability and mortality, again contrary to the biomedical model (McCollum & Pincus, 2009; Pincus & Callahan, 1985; Pincus & Castrejon, 2019). Formal education level or another variable indicative of socioeconomic status (such as occupation or income) is more significant than age or duration of disease in prognosis. A variable of socioeconomic status may serve as a surrogate for patient actions that affect disease outcome (Pincus, 2007). Patient variables may be relatively unimportant in acute care, in which health professionals control the agenda and outcomes, but in may be as important as or more important than health professionals in long-term outpatient management and outcomes.

Patients who met criteria for fibromyalgia reported higher likelihood of all 3 symptoms than patients who did not meet criteria. Physicians were more likely to note or take an action in response to patient self-reported symptoms in patients who did not meet fibromyalgia criteria than in those who met criteria. These observations reflect that patients with fibromyalgia report more symptoms than other patients (Schmukler et al., 2019), so self-report of a symptom by a patient who does not meet criteria for fibromyalgia is more likely to evoke documentation and/or action by the physician.

The study has several limitations. First, only a small number of patients were studied. Second, methotrexate was the only medication analyzed. Third, only 3 symptoms on the MDHAQ 60-symptom checklist were analyzed for patient self-report and physician responses. Fourth, physicians may have noted the symptom and possibly even pursued an action concerning the medication without documentation in the Epic electronic medical record.

Nonetheless, the study documents two fundamental observations: frequent patient self-report of symptoms that are recognized as adverse events of methotrexate, and generally superior documentation by patients than doctors of these symptoms. The findings suggest a need for improved strategies to help the physician to be aware of the symptom which may be an adverse event (Schmukler & Pincus, 2019). One approach would involve an electronic MDHAQ with software to call attention to specific symptoms which may be specific adverse events of specific medications in a report to the doctor. A program involving completion of a weekly remote electronic MDHAQ at home for 12 weeks after initiation of a new medication may be a cost-effective approach for early recognition of efficacy and detection of adverse events.

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