
Remote collection of questionnaires

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ABSTRACT

Rheumatoid arthritis (RA) is an autoimmune inflammatory disease associated with rapid loss of function and radiographic damage. Treatment is targeted to achieve low disease activity/remission, as measured by various pooled indices comprised of laboratory measures, patient-derived, and physician-derived measures. Outside clinical trials, it can be difficult to obtain all these components at the time of the visit to provide immediate guidance. Subsequently, several pooled indices of patient reported outcomes (PROs) have been developed and shown to be equally and sometimes more effective as traditional assessor- and laboratory-derived measures in detecting treatment group and predicting long-term outcomes. With growing use of electronic medical record (EMR) and technology, many of these PROs can now be obtained remotely and directly incorporated into EMR to facilitate target to treat approach. Remotely collecting PROs through the internet allows better data capture, easier incorporation into EMR, and more frequent monitoring of patient's disease activity in between clinic visits for quicker assessment of adverse events and therapeutic efficacy. Adapting remotely collected PROs into clinical trials, clinical care, and long-term database has the potential for restructuring medical care while reducing costs and improving quality of care to achieve disease remission.

Introduction

Rheumatoid arthritis (RA) is an autoimmune inflammatory disease affecting approximately 0.5–1% of the US population. It can lead to rapid loss of function, but early, aggressive treatment improves disease outcome and can potentially halt irreversible radiographic damage. The goal of treatment for patients with RA is to achieve remission (1). With the lack of gold standard measures such as blood pressure in hypertension, haemoglobin A1C

in diabetes, or Brain Natriuretic Peptide (BNP) in heart failure, pooled indices comprised of laboratory measures, patient-derived and physician-derived measures are often used to guide diagnosis, management, and prognosis for patients with RA (2). Key components of these pooled indices are patient-derived measures of disease activity. We will review the role of remotely monitoring these questionnaires in clinical care, clinical trials, and long-term databases.

Several pooled indices have been validated for assessing patients with RA: American College of Rheumatology (ACR) Core Data Set, 28 joint Disease Activity Score (DAS28), Simplified Disease Activity Index (SDAI), Clinical Disease Activity Index (CDAI), Routine Assessment of Patient Index Data (RAPID), and Rapid Assessment of Disease Activity in Rheumatology (RADAR.) In clinical trials, the ACR Core Data set and DAS28 are the most commonly used indices. The ACR Core Data Set includes seven disease activity measures to assess outcomes in clinical trials for the treatment of RA. These include 3 assessor-derived measures – tender joint count (TJC), swollen joint count (SJC), and physician global assessment of disease activity; 1 laboratory test for acute phase reactants – erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP); and 3 patient-derived measures – functional disability, pain, and global assessment (3). Unfortunately, in clinical practice and long-term databases, it is often not feasible to obtain all core measures at the time of the visit leading to missing data and an incomplete ACR/DAS28 score. Even when all components are available, it is difficult to calculate the ACR/DAS28 score without a specific calculator/programme making it less friendly for providers to interpret and use for their patients. Subsequently, several simpler and quicker pooled indices have been developed to aid pro-

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viders in assessing their patients including the SDAI, RADAR, RAPID3 (4), and CDAI (5). Most of these are some combination of assessor-derived TJC/SJC, assessor and patient global assessment, patient assessment of pain, and function, all of which can be obtained at the time of the visit for immediate interpretation.

Although patient-derived measures are often regarded as subjective or less valid than assessor-derived joint counts and laboratory tests, there is ample evidence to support the use of self-report questionnaires in standard care of patients with RA. First, patient questionnaires address the concerns of patients directly and quantitatively with regards to health-related quality of life (HRQoL) including pain, psychosocial distress, physical function, and fatigue. These measures are important to obtain as many physicians often underestimate or ignore factors that are considered more important from a patient's perspective including depression, functional disability, pain, and fatigue (6). Second, patient reported physical function, pain, and global status correlate significantly with other traditional "objective" measures of disease activity: TJC/SJC, radiographic scores, laboratory tests, and physical measures of functional status (*e.g.* grip strength and walking time) (7, 8). A pooled index of patient self-report questionnaires was equally effective in distinguishing between active treatment and placebo treatment as ACR20 responses, DAS28 and pooled indices of all and assessor-derived Core Data Set measures (8, 9). In addition, individual patient reported outcomes that measure function, pain, and physical aspect of the disease by themselves performed equally well as assessor and laboratory-derived measures in differentiating treatment group. In several studies, patient global assessment and patient pain scale were more responsive to treatment group differences than physician-derived tender joint count (9-12). Patient-derived questionnaires can also predict long-term outcomes including functional declines, disability, and death (8, 13-18). The most significant predictor of mortality has been repeatedly shown to be patient questionnaires

measuring physical function (14, 19-21). Nonetheless, in most standard clinical care, the majority of clinicians do not collect patient questionnaire data (22), often leading to a descriptive rather than quantitative assessment that is only examiner dependent. Reasons for not collecting patient questionnaire data may include perceived lack of time and staff support in clinic settings for paper data collection. Paper forms are perceived as cumbersome, time-consuming and not cost-effective. Clinical decisions are therefore often based on empirical, rather than quantitative, assessment of clinical status (17, 23, 24). Quantitative patient-derived measures of disease activity obtained remotely could eliminate these perceived barriers and be incorporated into standard clinical care to assess and document clinical status and monitor responses to therapy.

Validity and feasibility of computerised questionnaires

In recent years, computerised patient-monitoring systems have been gaining popularity and have been validated in rheumatology. Significant correlation has been seen between paper and electronic versions of the ACR patient assessment (25) as well as the SF-36, RAQoL, HAQ, VAS pain/global, and TJC/SJC. While TJC had a significant correlation coefficient of 0.85, a slightly lower correlation coefficient (0.60) was noted for SJC, which may reflect the overall poorer reliability of the SJC (26) rather than a flawed system. Furthermore, computer systems can be more cost efficient with better data capture (27-29). For example, in one study of RA patients, 44% of participants had at least one missing or problematic response in the paper version, as patients are more likely to skip questions or mark more than one response (28). In contrast, a computer programme can alert patients to missing data with any attempt to proceed with or end an incomplete questionnaire. Additionally, computerised questionnaires can be easily incorporated into electronic medical records and reviewed to facilitate therapeutic decisions. With automatic scoring of computerised versions of questionnaires on completion, data is directly

available to both patients and physicians for sharing of information to improve patient-physician communication and clinical decision-making (27). Contrary to popular belief, many patients prefer electronic systems due to their ease of use as compared to paper questionnaires regardless of age, computer experience and education level (30, 31). Use of electronic questionnaires has even been shown to contribute to patient empowerment (32).

Remote collection of questionnaires

The combination of growing interest in electronic patient doctor communication (33) coupled with wider availability of computerised questionnaires has paved the way for remote collection of patient-derived questionnaires. According to a 2002 survey, 90% of internet-users desire to communicate with their physicians electronically, and their ability to do so may affect their choice of physician (34). Many patients are already using the Internet to communicate with their physicians using the messaging system built into many electronic medical record (EMR) systems. There are several potential methods for collecting questionnaires remotely, including traditional computers (*e.g.* PC, Mac), tablet PCs, telephone based monitoring system (*e.g.* Health Buddy), and smartphones. As of January 2014, 87% of US adults use the internet and about 40% of the world population has internet connection, with the number of internet users increasing tenfold from 1999 to 2013 (35). Further, more than 50% and 42% of American adults have a smartphone and a tablet computer, respectively, as of January 2014 (35).

Telephone-based remote monitoring system has already gained popularity in the management of heart failure, chronic obstructive pulmonary disease, and diabetes. Telemonitoring units such as the 'Health Buddy,' a portable device that patients use to record their health information using a telephone line, are commonly used in heart failure patients. Information from these units is then sent and reviewed by the provider from a remote location in real time. There are several advantages to this approach, including giving patients more

control in managing their problems and much more personalised health care, and improving patient compliance and engagement. While mobile phone-based remote monitoring systems can be relatively expensive depending on the phone service, it is convenient especially in providing medical services to people living in remote communities (36). In one prospective review of new consults assessed by a rheumatologist through a teleconsultation, patients were overall satisfied and 84% of patients felt that the care they received was as good as an *in person* visit, and was efficient in both time and cost savings (37).

The use of telemonitoring in managing patients with heart failure has been shown in meta-analyses to significantly reduce the probability of hospitalisations, improve quality of life as well as reduce costs of care (38-40). However, two randomised controlled trials failed to demonstrate a clinical benefit for telemonitoring in heart failure (41), so further research is needed in this domain. Further, while telemonitoring through telephone calls can be very beneficial to patients, it is not without its limitations as it can be difficult to reach the patient at times and these calls can be time consuming and inefficient for staff, require additional documentation in the patient's medical record, and patients may feel time pressured leading to frustration and reduced quality of care. Internet-based computerised questionnaires may offer some solutions to these problems related to telephone based system, including better data capture, easier incorporation into EMR, and increased practice efficiency and productivity, and convenience to physicians. It similarly allows for more frequent monitoring of patient's disease activity in between clinic visits for quicker assessment of adverse events and therapeutic efficacy (29, 30). Regular disease activity measurements and documentation is paramount to the treat to target strategy, one that is now advocated as the optimal treatment strategy for control of inflammation in RA and has been supported by a number of clinical trials (42-48). In addition to allowing for more frequent assessments of disease activity, ena-

bling online communication between patients and healthcare providers has been shown to improve efficiency, patient satisfaction, and reduce costs (49, 50). Remote collection offers the additional advantage of convenience to patients especially those that are functionally incapacitated or who live far away from the nearest rheumatology clinic, as the forms can be completed at home. This becomes particularly important in smaller micropolitan areas of the U.S. that have very few or no practicing adult rheumatologists. According to a recent analysis of ACR data, in populations with less than 50,000 people, there was limited access to a practicing rheumatologist, with travel to the nearest practice in 50 of the 479 micropolitan areas being more than 100 miles (51). Electronic patient-doctor communication may soon achieve reimbursement. In fact, online consultations have received a designated CPT code, which facilitates billing for such services. Studies comparing self-assessments using a direct data entry on a tablet PC have illustrated that the majority of patients preferred remote data entry using this means with no difference in scores obtained as compared to paper-pencil questionnaires (32, 52). Further touch-screen computer systems take no longer to complete, and are rated significantly higher for ease of use even by computer naïve patients (30).

Although remote collection of questionnaires has multiple advantages, there are several potential drawbacks that are important to consider. The first and arguably greatest concern is assurance of patient privacy in accordance with the Health Insurance Portability and Accountability Act (HIPAA). Balancing conflicting interests of ensuring patient confidentiality with providing access to electronic medical data is a serious challenge (53). Leaked digital clinical data could compromise patients and expose medical practitioners to lawsuits (53-55). Thus, compliance is critical with the paramount security and privacy requirements for healthcare applications including maintaining data confidentiality and privacy, strong user authentication, and proper data integrity mechanisms. It is also impor-

tant that both patients and physicians comply with standard electronic safety techniques (55, 56). Secondly, practical concerns with electronic questionnaires exist, such as the feasibility of dependence on peripheral devices (*i.e.*, keyboard and mouse) in patients with rheumatoid arthritis-related chronic hand deformities. In one study, 77% of patients reported some discomfort related to computer use (57), although these problems are likely exaggerated when using a paper and pencil. Providing the option to choose among various devices (*e.g.* mouse, touch pad, touchscreen) enhances acceptability of the computer forms among those with hand disability (26) and contrary to popular belief, age was not significantly correlated with patient preferences regarding computer versions of forms (27, 58). Although growing number of people are computer literate, a minority of the population may still prefer paper questionnaires due to familiarity and lack of access to computers/smartphones and internet. Thirdly, since patient outcome measures can be remotely collected with ease and unlimited frequency, this abundance of data may lead to unnecessary treatment modification. Many rheumatic diseases have a fluctuating disease course that may revert to baseline without any interventions. Thus, it may become difficult to distinguish insignificant disease activity fluctuations from true worsening of the disease when outcome measures are measured too frequently. Lastly, questionnaires completed in the waiting room may prepare patients for the visit and provide a platform for open communication with their providers, which may be lost if patients complete them remotely in between their visits. However, this can be overcome by providing results of remotely collected data to both patients and providers to review at the time of clinic visit. If desired, patients can still complete patient-derived questionnaires at the time of their visit to augment the remotely collected data. In conclusion, incorporation of quantitative patient derived measurements is feasible and should be incorporated into standard clinical care, clinical trials, and long-term database to assess and

document clinical status and monitor responses to therapy for patients with RA. Numerous studies have already demonstrated the benefits of using telemedicine in novel ways to provide optimal care to patients with rheumatic diseases. Continued improvement in technology and electronic data security has paved the way towards incorporating patient-derived measures of disease activity into a patient's EMR for direct patient care as well as into case report forms for clinical trials. As illustrated, tele- and internet-based medicine has the potential for restructuring medical care while reducing costs and improving quality of care. By using remotely obtained questionnaires, patient assessment and therapeutic decision making can be facilitated in order to achieve low disease activity state or remission among patients with RA.

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