Contemporary Clinical Trials Communications 10 (2018) 42–49

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

Design and outcomes of the Patient Centered Outcomes Research Institute coronary heart disease cohort study

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A B S T R A C T

Background: The Patient Centered Outcomes Research Institute (PCORI) established Clinical Data Research Networks (CDRNs) to support pragmatic research. The objective was to electronically identify, recruit, and survey coronary heart disease (CHD) patients and describe their characteristics, health status, and willingness to participate in future research.

Methods: We developed a computable phenotype and assembled CHD patients 30 years or older and had visits or hospitalizations between 2009 and 2015. A sample of patients was surveyed between August 2014 and September 2015. Survey administration included the following methods: face-to-face, telephone, paper or web portal. Survey items covered broad domains including: health literacy and numeracy, and socio-demographics, physical and mental health, health behaviors, access to medical care, and willingness to participate in future research.

Results: Of 5517 approached patients, 2605 completed the survey. Participants were mostly white (~88%), male (68%) and had a median age of 69 years (interquartile range [IQR] 61–76 years). Most respondents' health literacy and numeracy were adequate (83.2% and 84.3%, respectively). Only 4% of respondents reported that their overall health or physical health was excellent. The majority (~58%) reported that their health was good or very good, while 40% reported that their general and physical health were fair or poor. The majority reported that their quality of life was good to excellent (81%). Limitations in physical health and function were common, including often/always having fatigue (25%), pain (38.7%), or sleep difficulty (19.7%). A patient sample (n = 1936) was provided with a trial summary which would randomize their aspirin dose; and 63% reported that they would consider participating.

Conclusion: Many patients with CHD had limitations in physical health. However, the majority reported a good or excellent quality of life.

1. Introduction

Over the past 30 years, there have been numerous randomized clinical trials to evaluate the impact of medications, procedural therapies, and management strategies on outcomes in patients with cardiovascular disease. In general, these trials have relied on traditional methods for identification and recruitment of patients using research nurses, which can be resource-intensive. In an era of big data and pragmatic clinical trials, more efficient and cost-effective approaches are needed [1]. The construction of cardiovascular disease cohorts from administrative systems could facilitate identification of a potentially large segment of patients willing to participate in future research. Furthermore, future studies could focus enrollment on populations often underrecruited in cardiovascular clinical trials; for example, women and minorities. However, broad definitions of coronary heart disease are often not validated in large administrative databases [2–5].

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https://doi.org/10.1016/j.conctc.2018.03.001
Received 22 September 2017; Received in revised form 16 February 2018; Accepted 8 March 2018
Available online 09 March 2018
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Abbreviations

ADAPTABLE trial	Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness
CDRN	Clinical Data Research Networks
CHD	Coronary heart disease
EHR	Electronic Health Record
ICD 9 CM	International Classification of Diseases, Ninth Revision, Clinical Modification
PCORI	Patient Centered Outcomes Research Institute
PHCS-2	Perceived Health Competence Scale
PROMIS	Patient Reported Outcomes Measurement Information System
RA	Research Assistant
RD	Research Derivative
REDCap	Research Electronic Data Capture
U.S.	United States
VHAN	Vanderbilt Health Affiliated Network
VUMC	Vanderbilt University Medical Center

Efficient recruitment of participants is paramount to the success of clinical research and is of particular importance in pragmatic clinical trials, including the ongoing Patient-Centered Outcomes Research Institute (PCORI) funded ADAPTABLE trial (Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness) [6]. Thus, starting with a broad cardiovascular disease population seen in clinical practice is likely to be an effective strategy in engaging a broader, more diverse pool of research participants. To this end, PCORI funded 13 Clinical Data Research Networks (CDRNs) to build infrastructure for comparative effectiveness research and pragmatic clinical trials. Each CDRN was tasked with developing a cohort for a common condition, a rare condition, and one for weight-related research [7–9]. Here we describe the identification, recruitment, and enrollment of the Mid-South CDRN common condition cohort of patients with Coronary Heart Disease (CHD). We present their sociodemographic characteristics, health status using patient-reported outcome measures, and willingness to participate in research.

2. Methods

2.1. Setting

At the time of this study, the Mid-South CDRN was comprised of Vanderbilt University Medical Center (VUMC), the Vanderbilt Health Affiliated Network (VHAN), and Greenway Prime Research Network. VUMC is a tertiary care academic medical center in Nashville, TN, which includes large cardiology and primary care practices. The VHAN is a clinically integrated network which includes more than 40 hospitals and 300 ambulatory practices, with an estimated reach of more than 3 million patients in the Mid-South area. Greenway Health provides electronic health record (EHR) and practice management software to more than 2000 sites around the country. For the present CHD cohort, only VUMC and nearby VHAN clinical sites were used.

2.2. CHD computable phenotype

We used the VUMC Research Derivative (RD) to develop a computable phenotype to identify a population of patients with CHD between January 2009 and 2014. The RD is one component of the PCORI Mid-South common data model database and is composed of clinical and related data derived from VUMC's enterprise data warehouse and restructured for research [10]. The RD includes data from the EHR, ORMIS (Operating Room Management Information System), scheduling systems, and medication prescribing and administration. Data types include inpatient and outpatient encounters, clinical notes and documentation, nursing records, medication data, laboratory data, and vital signs. Data may be structured (ICD-9 CM codes [11]), semi-structured (laboratory tests and results), or unstructured (patient summaries and physician progress reports). The medical record number, other person identifiers, and dates are preserved within the database. Patient vital status is derived from data available through the Social Security Death Index.

CHD computable phenotype definitions were developed using an iterative process, and a sample of 50 charts was reviewed by 2 physicians until consensus was achieved on the presence of coronary disease. The computable phenotype identified patients with CHD, on the basis of outpatient or inpatient billing codes. Patients fit the phenotype by fulfilling either an outpatient case definition for coronary heart disease (case type 1) or having a revascularization procedure (case type 2). Case type 1 was defined as having two outpatient visits on separate days for prior myocardial infarction (ICD 9-CM diagnosis code 410.*; 412.*; 429.7*) or obstructive coronary artery disease (411.*; 413.*; 414.*; V45.81; V45.82). For case type 2, a revascularization procedure for CHD was defined as having one inpatient or outpatient procedure code for coronary artery bypass or percutaneous transluminal coronary angioplasty (CPT codes 33140; 33533–36; 33510–23; 33530; 33533–33536; 92920–92921; 92924–92925; 92928–92929; 92933–92934; 92937–92938; 92941; 92943–92944; 92980–82; 92984; 92995–6; 92974 or ICD-9 CM Procedure code: 36.01; 36.02; 36.03; 36.05; 36.09; 36.10–36.19). We then validated the final above algorithm. Research assistants abstracted 470 charts. The recorded diagnosis of CHD in the patient record or discharge summary was considered the reference standard for validation. The positive predictive value of the final above definition was 98.5% (192 true positives/195 algorithm positive) and the sensitivity was 94.6% (192 true positives/203 coronary disease positive patients) [12].

2.3. Study sample

To identify a pool of potentially eligible patients, we applied the phenotype to patient records from VUMC, as well as patients seen by Vanderbilt cardiologists at nearby VHAN sites whose data were available in the RD. To increase the likelihood that identified patients would have accurate contact information on file and feel a greater sense of engagement with the medical center, we limited the search to patients with inpatient or outpatient clinical encounters within the last 5 years (January 2009 through June 2014). Two updates were performed to capture additional newly diagnosed CHD patients. Thus, the end search dates were modified to be through December 2014 and April 2015. We restricted the sample to patients aged 30 years or older, to exclude patients likely to have non-traditional (non-atherosclerotic) coronary conditions, including patients with congenital heart disease. We also excluded patients who had an unknown date of birth or sex, were receiving hospice care, or who had a recorded date of death at the time of the search. The institutional review board of Vanderbilt University approved this study. Study participants were enrolled between August 2014 and September 2015. All surveyed participants provided informed consent and were offered $10 for survey completion.

2.4. Study procedures

Patients who met the computable phenotype definition of CHD and had any form of contact with the VUMC health system were recruited for survey participation. Research assistants further excluded patients if the medical record reported impaired cognition (dementia or severe psychiatric illness), legal blindness, significant hearing loss, if the

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