Atherosclerosis 242 (2015) 625–629

Contents lists available at ScienceDirect

Atherosclerosis

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

Validity of self-report of lipid medication use: The Atherosclerosis Risk in Communities (ARIC) Study

Sahiti Bhaskara [a], Eric A. Whitsel [b], Christie M. Ballantyne [c], Aaron R. Folsom [a, *]

[a] Division of Epidemiology and Community Health, School of Public Health, University of Minnesota, 1300 South Second Street, Suite 300, Minneapolis, MN 55454-1015, USA
[b] Cardiovascular Disease Program, Departments of Epidemiology and Medicine, University of North Carolina at Chapel Hill, Bank of America Center, Suite 301-B, 137 East Franklin Street, Chapel Hill, NC 27514, USA
[c] Department of Medicine, Baylor College of Medicine, 6565 Fannin Street, Suite A656, MS A601, Houston, TX 77030, USA

ARTICLE INFO

Article history:
Received 29 May 2015
Received in revised form
20 July 2015
Accepted 18 August 2015
Available online 20 August 2015

Keywords:
Lipid medication
Validation study
Medication use
Statins

ABSTRACT

Objective: To evaluate the validity of self-reported lipid medication use in an epidemiological study.
Methods: We studied medication self-reports compared with inventoried lipid medication containers at the fifth visit of the Atherosclerosis Risk in Communities (ARIC) Study in 2011–2013 (n = 6370). To assess the validity of self-reports, we computed sensitivity, specificity, positive and negative predictive values. We used multiple logistic regression to determine whether validity varied by participant characteristics. Comparisons were made with visit 4 (n = 11,531), to determine if there was a change in validity as the pattern and types of lipid medication used changed over time.
Results: The prevalence of lipid medication use, according to medication containers was higher at visit 5 (56%) than visit 4 (14.3%). Statins were increasingly used. The percentage of participants reporting use/non-use accurately was 91.8% at visit 5, lower than visit 4 (97.3%). The unadjusted kappa coefficient of agreement was 0.83 (95% CI – 0.82 to 0.85) at visit 5 and 0.89 (95% CI – 0.88 to 0.90) at visit 4. Agreement was higher, compared with their counterparts, for women, younger and more educated participants, and those using fewer total medications.
Conclusion: In this population sample, self-reported lipid medication use was highly accurate and therefore likely would be for similar epidemiological studies or clinical settings collecting this information.

1. Introduction

Epidemiological research studies or clinical settings often require people to self-report their medications. Understanding the validity and quality of self-reported medication data therefore is vital.

Some previous studies have documented the accuracy of recall of medication histories in clinical care settings. Hulka et al. [1] reported that only about 27% of study participants with congestive heart failure were able to accurately recollect their therapeutic regimes. Another study showed high accuracy of recall of duration of use and names of most recent oral contraceptive drug regimens [2]. Parental recall of children's inhaled corticosteroid use was found to be highly accurate [3]. Yet, only 68% of the drug use information collected at home from patients of a specialized geriatric outpatient care clinic agreed with the clinic data [4]. Of various medication types assessed, self-report of beta-blockers and centrally acting hypertensive medication use was more likely to disagree with clinic data than others [4]. Also, the presence of comorbidities and use of multiple drug regimens in this older population decreased recall accuracy [4]. The accuracy of patient recall is reported to vary by clinical care setting, type of medication under consideration, patient condition and disease severity, doctor–patient relationship, demographic characteristics, past or current medication recall, and clinical factors [1–11].

Few studies have reported the accuracy of cardiovascular medication recall data. The Cardiovascular Health Study showed modest levels of agreement between directed recall of use of beta-blockers and beta-agonists compared with a medication inventory

* Corresponding author.
E-mail addresses: bhask007@umn.edu (S. Bhaskara), eric_whitsel@unc.edu (E.A. Whitsel), cmb@bcm.tmc.edu (C.M. Ballantyne), folso001@umn.edu (A.R. Folsom).

http://dx.doi.org/10.1016/j.atherosclerosis.2015.08.026
0021-9150/

[12]. In addition to assessing reliability, authors also used physiologic markers of drug effect to assess validity and found that the medication inventory was superior to the directed recall [12]. Consistent with findings from similar studies on other medication types, in the Rotterdam Elderly Study [13], agreement between self-report and pharmacy records varied from poor to perfect by class of cardiovascular medication used. Commonly prescribed antihypertensive agents were self-reported with high accuracy (kappa = 0.90 to 0.96), while kappas of agreement for organo-heparinoids and nitroglycerin were low (kappa = 0.26–0.53).

Only a few studies have assessed the accuracy of recall of lipid medication use. Researchers found a generally high sensitivity of recall of statin medication used in the past 6 months among older female controls (Sensitivity = 0.93, Specificity = 0.98) and cases with breast cancer (Sensitivity = 0.85, Specificity = 0.98) [14]. This recall accuracy decreased slightly among both cases and controls for 2-year and 8-year recalls [14]. The study also noted that although accuracy of self-report was generally high for statins, it was lower than for antihypertensive drugs. Cardiovascular epidemiological studies often ask about the use of lipid lowering medications, but the accuracy of self-reported anti-hyperlipidemic medication is not well documented.

Our study therefore measured the validity of patient self-report of lipid medication use in a population-based cohort study, the Atherosclerosis Risk in Communities (ARIC) Study. We also examined whether there was a change in validity as patterns of lipid medication use evolved between 1996–98 and 2011–13.

2. Methods

The ARIC study is a prospective cohort study comprised of 15,792 men and women in 4 communities: Forsyth County, NC, Jackson, MS, suburban Minneapolis, MN and Washington County, MD. At baseline, in 1987–1989, the participants were between 45 and 64 years and were selected either by list or area probability sampling [15]. ARIC performed four examinations of the cohort between 1987 and 1998, and conducted annual telephone interviews. The present study is mainly based on the fifth visit in 2011–2013, but with some data from the fourth visit in 1996–1998. Among 10,036 ARIC original cohort members deemed alive, 6538 participated in visit 5 resulting in an overall response rate of 65% [16]. The visit 4 response rate was 80%. The institutional review board at each site approved the ARIC study protocol, and each participant supplied informed consent.

Study participants were instructed to bring to visit 5, the containers of all medications used in the past four weeks. If a participant forgot to bring any medication containers, he/she was telephoned later for this information. The medication containers were used to create a detailed medication inventory which is being used in this analysis as the gold standard to evaluate the validity of self-reports. The inventory was created by scanning barcodes on medication containers, with the scanning system directly linked to a medication database. When a barcode was missing, a medication was not identified by the database, or unmarked containers/loose pills were to be inventoried, the interviewer manually transcribed the medication using a pre-determined protocol. Medication inventories have been found to be a reasonably accurate method for ascertaining cardiovascular medication use in the elderly, even though this method may generate higher estimates of prevalence of medication use as compared to serum levels [11,16]. Self-report of lipid medication use was ascertained from the question, “Were any of the medications you took during the last four weeks for high blood cholesterol?” which was recorded as “Yes”, “No” or “Unknown”. We excluded participants whose medication container record was missing (n = 26); self-report of medication use was missing (n = 39) or ‘Unknown’ (n = 89); or both medication records and self-reported were missing (n = 14). Our final analytic sample for Visit 5 included 6370 participants (97% of all visit 5 participants, Fig. 1).

Comparisons were made with medications reported and recorded at ARIC visit 4 to determine whether there was a change in validity as the pattern and types of lipid medication used changed over time. At visit 4 staff entered medication names by hand and they were linked to a medication database. The fourth visit analytic sample, after excluding observations with missing or unknown medication information (n = 125), included 11,531 participants (99% of all visit 4 participants).

2.1. Statistical analysis

We computed the sensitivity, specificity, positive predictive value and negative predictive value to determine the validity of the self-reported use of lipid medication as compared to the gold standard, the medication container records. Sensitivity represents the proportion of those who brought in a lipid medication container who reported use. Specificity represents the proportion who had no lipid medication container who reported no use. The positive predicative value represents the proportion who reported use who actually had a lipid medication container. The negative predictive value represents the proportion who reported not using a lipid medication who had no lipid medication container. We also calculated unadjusted, and prevalence- and bias-adjusted, kappa coefficients [17] (measures of agreement) and their respective 95% confidence intervals. To study factors related to accurate self-reporting, we created a dichotomous variable of agreement (Yes/No) between self-report and medication containers. Using multiple logistic regression, we examined whether accuracy varied by the number of medications used, age, sex, race, education, combined variable of prevalent cardiovascular disease (CVD) and CVD risk, and study center. The combined variable of prevalent CVD and CVD risk was created as follows. Study participants were first categorized based on the presence of prevalent CVD by ARIC criteria. Those without prevalent CVD were further categorized by CVD risk ($\geq$ 7.5% or < 7.5%) based on American College of Cardiology and American Heart Associations' combined guidelines on the assessment of CVD risk [18]. The three resultant categories of this combined variable were: 1) Prevalent CVD, 2) No prevalent CVD, but CVD risk $\geq$ 7.5% and 3) No prevalent CVD, and CVD risk <7.5%. All analyses were performed using SAS (version 9.3).

3. Results

The mean (range) of participant ages was 76.7 (66–90) years at visit 5 and 62.8 (52–75) at visit 4, and the percentages of women were 56% and 59%, respectively. As shown in Table 1, according to the medication containers, 61.6% of visit 5 participants currently used some lipid medication, as compared with only 14.6% at visit 4. Statins were the most commonly used type of lipid medication at both visits (85.0% and 75.7% at visits 5 and 4 respectively), followed by fibrates, ezetimibe, niacin, bile sequestrants and other types during visit 5. Other lipid medications included omega-3 fatty acids, etc. The relative use of statins increased and that of fibrates, niacin and bile sequestrants decreased from visit 4 to visit 5.

At visit 5, 91.8% of the participants accurately self-reported the use or non-use of lipid medication (Table 2). On the other hand, 97.3% of participants had correctly self-reported lipid medication use at visit 4, fifteen years earlier. At visit 5, the sensitivity and specificity of self-reported lipid medication use when compared with the medication containers was 0.91 and 0.93 respectively (Table 3). These measures of agreement were slightly higher at