Acute Ischemic Heart Disease

Influence of cardiovascular absolute risk assessment on prescribing of antihypertensive and lipid-lowering medications: A cluster randomized controlled trial

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Background Guidelines for management of hypertension and lipids recommend using cardiovascular absolute risk (CVAR) to manage patients. This randomized controlled trial investigated the impact of CVAR assessment in family practice on management of cardiovascular risk, including prescription of antihypertensive and lipid-lowering medication.

Methods A cluster randomized controlled trial was conducted from 2008 to 2010 in Sydney, Australia. Family practices were randomized, and patients aged 45 to 69 years were invited to participate. Intervention family physicians (FP) were trained in use of CVAR, provided with an electronic CVAR calculator, and assessed their patients' absolute risk in a dedicated consultation. Control practice patients received a general health check. Primary outcome analyzed was the proportion of patients in each group on antihypertensive and/or lipid-lowering medication at 12 months. Multilevel logistic regression was performed to explore variables influencing changes in pharmacologic therapy.

Results The study recruited 36 FPs from 34 practices and 1,074 patients, of which 906 (84.4%) completed 12-month follow-up. At 12 months, there was no significant difference between the intervention and control groups in proportion of patients on antihypertensives (31.2% vs 34.3%, $P = .31$), but control group patients were more likely to be on lipid-lowering medications (30.2% vs 22.7%, $P = .01$). After multilevel analysis, this difference was not present. Intensification or reduction of pharmacologic therapy was associated with meeting treatment targets for blood pressure and lipids but not with the CVAR or intervention group.

Conclusions Single-risk factor management remains a strong influence on FP prescribing practices. Shifting to an approach based on CVAR will require more intensive intervention. (Am Heart J 2014;167:28-35.)

Background

Cardiovascular disease (CVD) is the leading cause of mortality worldwide, accounting for 12.9 million deaths in 2010.[1] Prevention of CVD is dependent on managing modifiable risk factors, 2 of which are blood pressure (BP) and lipids. Control of BP and lipids often involves pharmacologic treatment, medicines being a major cost to the community. The annual medicines cost for hypertension alone in the United States is $21.3 billion[2]; the Australian government spends approximately $3 billion annually on BP and lipid-lowering medicines.[3] Given these costs, it is important to ensure that they are directed at those who will benefit most.

Guidelines for the management of hypertension and lipids no longer focus on BP or lipid levels in isolation, rather they recommend assessing cardiovascular absolute risk (CVAR) to guide management decisions.[4-7] CVAR takes into account multiple cardiovascular (CV) risk factors (age, sex, smoking, diabetes status, BP, and lipids) to provide an estimated percentage risk of an individual with a CV event over a 5- or 10-year period. Pharmacologic therapy is targeted to those at high absolute risk, defined as an estimated risk greater than 15% or 20% depending on the guideline. However, management of high-risk patients has been shown to be suboptimal.[8,9] Systematic CVAR assessment may improve this, but to date, research exploring the impact of CVAR on prescribing has shown minimal effect,[10,11] with only 2

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The trial was registered with the Australian New Zealand Clinical Trials Registry (http://www.anzctr.org.au; trial no: ACTRN12608000387325).

Submitted March 25, 2013; accepted October 5, 2013.

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0002-8703/$ - see front matter

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http://dx.doi.org/10.1016/j.ahj.2013.10.002

randomized trials showing a modest increase in prescribing of CV medications for high-risk patients.[12,13]

The use of CVAR assessment in clinical practice is increasing but by no means routine.[14-16] This Australian trial aimed to test the impact of a program of implementation of CVAR assessment on family physician (FP) management of CV risk, patient lifestyle behaviors, physiological parameters, new diagnoses of CV disease, and clinical process in family practice. This article presents the findings of the impact of CVAR assessment on prescribing of antihypertensive and lipid-lowering medications.

Methods

This cluster randomized controlled trial was conducted in urban family practice in Sydney, Australia, in 2008 to 2010. The protocol for this study has been previously published but is summarized below.[17]

Recruitment

Family physicians. Family physicians and practices were recruited from 4 Divisions of General Practice (geographically based FP organizations that support clinical practice) in Sydney. Practices were eligible if they used electronic prescribing software and were not involved in other CVD research. Family physicians were eligible if they worked 4 or more sessions (1 session = 3-4 hours) per week.

Patients. Patients were eligible if they were aged 45 to 69 years, had no history of CVD, and had attended the practice in the previous 12 months. Electronic records of participating FPs were searched, and a list of patients who met the eligibility criteria was generated; from this, 160 patients were randomly selected and sent letters of invitation. Patients who had insufficient English or were cognitively impaired were excluded.

Randomization

Randomization was conducted at the practice level to avoid contamination between intervention and control FPs and patients. A person (U.J.) independent of the intervention and data collection conducted the allocation using a computer randomization program. It was done in 2 blocks of 4 practices within each division with an extra block of 2 practices from one of the divisions. Research staff collecting practice data were blinded to group allocation, as were patients.

Intervention

This was a multifaceted intervention in family practice involving 3 components: training of FPs, patient consultation to assess and manage CVAR, and practice support for intervention implementation.

Intervention FPs were provided with a 3-hour training workshop covering assessment of CVAR, use of the New Zealand CV risk calculator[18] (based on Framingham risk score), and current recommendations for management of CV risk based on Australian guidelines for hypertension and lipid management and the New Zealand calculator guidelines.[6,7] The New Zealand CV risk calculator was used because there was no Australian calculator available at the time the study commenced.

Intervention patients received a dedicated 20- to 30-minute consultation that involved calculating the CVAR and then providing appropriate management based on risk level and current guidelines.[6,7,18] Patients in the control group had a general health check. At the 12-month health check, FPs were asked to reassess the CVAR of intervention patients.

Data collection

Data were collected by patient questionnaire, blood test results (fasting lipids and glucose), and medical record audit. Questionnaires were administered at baseline and 12 months, and a medical record audit was conducted after the 12-month health check.

Outcomes

A full set of primary and secondary outcomes was outlined in the protocol paper.[17] This paper is focused on pharmacologic management of CV risk. The primary outcomes were the proportion of patients in each group at 12 months prescribed

- Antihypertensive medication
- Lipid-lowering medication
- Both antihypertensive and lipid-lowering medication

Sample size

The sample size calculation was based on the ability to detect a difference of 20% between the control and intervention groups in the prescribing of antihypertensive and lipid-lowering medication, with a design effect of 2.0 because of clustering and an expected 10% loss to follow-up. For 80% power at the 5% significance level, this gave a sample size of 16 practices (20 FPs) and 660 patients in each group.

Analysis

Univariate analysis (χ^2 and McNemar test) of the data was conducted with SPSS software (v18; SPSS, Chicago, IL) to examine medications prescribed within and between the intervention and control groups at baseline and 12 months. Medication data were analyzed for all patients for whom there was both baseline and 12-month medication data to allow for within-group analysis. The researchers calculated CVAR scores where all necessary input variables (age, sex, smoking status, BP, lipid levels, and diabetes status) were available. For patients where a CVAR score was calculated, pharmacologic management was stratified by risk. Analysis was on an intention-to-treat basis.

Data were subject to multilevel logistic regression analysis to explore factors associated with intensification (commenced, increased dose, or number of medications) and reduction (ceased, decreased dose, or number of medications) of BP and lipid-lowering therapy. Intensification and reduction were based on the difference between baseline medications and those at 12 months, thus accounting for baseline differences. Multilevel analysis was chosen to take account of the potential for clustering of medication changes around the individual FPs, given that prescribing is an individual FP's decision. Multilevel logistic regression models were used with 4 potential

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