Cardiovascular Screening for Family Members of People with Acute Coronary Disease: A Patient-Initiated and Family-Oriented Strategy
PI: Dr. Michael Goldfarb

Study Protocol

Patient Identification and Recruitment

The prospective study will be conducted at the Jewish General Hospital (JGH), an academic tertiary care referral centre in Montreal, Quebec. The JGH's acute care cardiovascular unit has 16 beds equipped for advanced hemodynamic and ventilator support and 32 ward beds with continuous telemetry. An outpatient cardiology clinic is adjacent to the inpatient unit.

Patients admitted to the JGH over a 12-month period will be assessed for eligibility into the study by a member of the research team. Inclusion criteria are patient age ≤70 years old admitted with an initial diagnosis of an acute coronary event, such as acute coronary syndrome or myocardial infarction, and at least 1 first-degree family or household member age ≥ 18 years old. Exclusion criteria are no eligible family or household members, inability to contact family or household members, distance to study centre too far as determined by the patient, or family or household members who have been screened for CV disease in the previous 2 years. Family or household members with known coronary disease will also be excluded.

Household members of the patient will be included in the study. There is evidence that partners and other non-genetically related household members, who do not have the same hereditary predisposition as the patient with CV disease, share social and lifestyle influences such as smoking habits, low physical activity, and diet, and have higher rates of CV disease than would be expected.[1]

Younger relatives (≥18 years old) of the CV patient will be included as well. Younger relatives (typically under age 30) have been excluded from most prior screening studies.[2] The optimal screening and management strategy for younger relatives of CAD patients is unclear. Early risk factor assessment and counselling of younger patients may promote lifelong changes in lifestyle choices and behaviours with long-term benefits.[3]

Eligible patients will be given a letter containing instructions for the eligible family and/or household members on how to be referred for the initial screening visit and information about the importance of CV disease primary prevention (Appendix A). If there has been no contact from an eligible family or household member two weeks following the CV patient's hospital discharge, a member of the healthcare team will contact the CV patient by phone to remind him or her to contact eligible family or household members.

Informed consent for participation in the study will be obtained from the patient at the time of enrolment during index hospitalization and other participants at the time of the initial screening visit. Institutional research ethics approval will be obtained for this study.

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Risk Factor Screening and Treatment

An appointment will be offered within two to four weeks of the patient's hospitalization in order to maximize the motivation of family members who are willing to undergo screening. Prior to the initial visit, participants will receive blood test requisitions for a baseline complete blood count, electrolytes, creatinine, lipid profiles, hemoglobin A1c, fasting blood glucose levels, liver enzymes, and creatine kinase. At the initial screening visit, a targeted history and physical exam will be performed by a cardiologist and investigations will be ordered as needed. CV primary prevention assessment will follow the Canadian Cardiovascular Society's recommendations.[4] Weight and body-mass index will be recorded and blood pressure will be checked with the BPtru machine (BpTRU Medical Devices, Coquitlam, BC) in accordance to the Hypertension Canada's guidelines.[5] A modified 10-year Framingham risk score will be calculated.[4] In patients ≤ 30 years old, a 30-year Framingham risk score will also be obtained. Physical activity will be measured using the Paffenbarger physical activity questionnaire (Appendix B) and reported in kilocalories of energy expenditure per day (kcal/d).[6] A nutrition questionnaire (Food Frequency Questionnaire) will be administered (Appendix C)**.** Identified CV risk factors will lead to appropriate evidence-based, society-recommended management.[4, 5] Participants will be referred to nutritionists, smoking cessation programs, and to other allied healthcare professionals as needed. The results of the risk assessment will be shared with the participant in order to support shared decision making, which has been shown to improve the likelihood that patients will achieve target lipid levels.[4] If the participant has a primary care physician, the physician will be sent a letter explaining the screening findings and treatment plan.

Participants will have a follow-up visit at 6-months during which they will undergo a history and physical exam and have lipid and glucose blood tests drawn. The Paffenbarger physical activity scale, Food Frequency Questionnaire, and an Information Assessment Method questionnaire (see section A3) will be administered. Interim follow-up appointments (maximum 2 per participant) may be scheduled if needed. At the 6-month visit, participants will receive an individualized report of CV risk factor control and their change in 10-year modified CV risk. Reports will be sent to the primary care physician if applicable. Participants without primary care physicians will be given resources on how to register for one.

The patient with coronary disease and all participating family and household members will be encouraged to attend the initial screening visit and all subsequent healthcare interactions. The history and physical exam will be done without other participants present in order to preserve confidentiality. Patients who accompany their family and household members to the appointments will also be encouraged to take their secondary preventive medications and continue follow-up with their treating physician, since half of patients who have a myocardial infarction stop taking their evidence-based preventative medications within 12 months of the index event.[7]

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Assessment of Participant Comprehension and Engagement in Care

At the 6-month clinic visit, the Information Assessment Method (IAM), a self-administered 1-page questionnaire (Appendix C**)**, will be distributed to participants (patients, family members, and household members). The IAM is will be used to systematically evaluate the (1) acquisition and relevance of new information, (2) practical impact, (3) expected health benefits, and (4) associated barriers or facilitators.[8, 9] Using a mixed-methods approach, we will review the IAM responses to understand the factors associated with the referral and screening program and to generate recommendations and feedback to the participants. The IAM is considered a knowledge translation tool by the Canadian Institute for Health Research.[10]

Data Collection

A research assistant will be based in the Division of Cardiology at the JGH and will have a dedicated space in the clinical research department with a computer-equipped workstation. The research assistant will be responsible for obtaining informed consent and extracting data from the patient record.

From the patient, we will collect the following data: age, sex, ethnicity, willingness to refer family members and reasoning, whether CV screening was done prior to hospitalization, CV risk factors (including family history of CV disease), description of the acute coronary event, cardiac unit and hospital length of stay, and approximate number of eligible family or household members.

From the family or household members, we will collect the following data: age, sex, gender, ethnicity, relationship with CV patient, whether the patient has a primary care physician and last time seen, CV symptoms on history, medications, weight, BP Tru recording, physical examination findings, physical activity, nutrition, and other CV risk factors identified (i.e., obstructive sleep apnea). Baseline and 6-month CV individual risk factor values will be recorded (i.e., blood pressure, lipid levels, HbA1c), as well as baseline and 6-month modified Framingham 10-year risk scores. A 30-year Framingham risk score will be recorded at baseline and 6-months for patients who are under age 30 at the time of study enrolment. Results from the IAM, nutrition, and physical activity at the 6-month visit will also be collected.

Measures

The effectiveness of the screening strategy will be measured by the total number of participants identified at intermediate or high risk on the modified Framingham CV risk score (>10% risk of a CV event over the following 10-year period). The effectiveness of the primary prevention intervention will be measured by the change in percentage of the mean modified Framingham 10-year CV risk score for family and household members between the initial visit and 6-month follow-up. The most recent Canadian Cardiovascular Society guidelines strongly recommend CV risk assessment using the modified Framingham 10-year risk score to guide therapy and to repeat the risk assessment when there is an expected change in risk status.[4]

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Data Analysis

Results will be stratified by age (<65; ≥65) and sex. Continuous data will be presented as mean with standard deviation or median with interquartile range and between group differences will be tested with the Student's t test and the Mann-Whitney U test, respectively. Categorical data will be presented as frequencies and percentages and will be compared using the chi-squared test or the Fisher exact test, as appropriate. All p values will be two-sided with values ≤ 0.05 indicating statistical significance. Statistical tests will be done using the SPSS 24.0 statistical software (IBM Corp, Armonk, New York). Statistical analysis will be performed by statisticians affiliated with the Lady Davis Institute for Medical Research (Montreal, Quebec).

References

1. Kardia SL, Modell SM and Peyser PA. Family-centered approaches to understanding and preventing coronary heart disease. *American Journal of Preventive Medicine*. 2003;24:143-51.
2. Goldfarb M, Slobod D, Dufresne L, Brophy JM, Sniderman A and Thanassoulis G. Screening Strategies and Primary Prevention Interventions in Relatives of People With Coronary Artery Disease: A Systematic Review and Meta-analysis. *Can J Cardiol*. 2015;31:649-57.
3. Montgomery AA, Fahey T, Ben-Shlomo Y and Harding J. The influence of absolute cardiovascular risk, patient utilities, and costs on the decision to treat hypertension: a Markov decision analysis. *Journal of Hypertension*. 2003;21:1753-9.
4. Anderson TJ, Grégoire J, Pearson GJ, Barry AR, Couture P, Dawes M, Francis GA, Genest J, Jr., Grover S, Gupta M, Hegele RA, Lau DC, Leiter LA, Lonn E, Mancini GBJ, McPherson R, Ngui D, Poirier P, Sievenpiper JL, Stone JA, Thanassoulis G and Ward R. 2016 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in the Adult. *Canadian Journal of Cardiology*. 32:1263-1282.
5. Leung AA, Nerenberg K, Daskalopoulou SS, McBrien K, Zarnke KB, Dasgupta K, Cloutier L, Gelfer M, Lamarre-Cliche M, Milot A, Bolli P, Tremblay G, McLean D, Tobe SW, Ruzicka M, Burns KD, Vallee M, Prasad GV, Lebel M, Feldman RD, Selby P, Pipe A, Schiffrin EL, McFarlane PA, Oh P, Hegele RA, Khara M, Wilson TW, Penner SB, Burgess E, Herman RJ, Bacon SL, Rabkin SW, Gilbert RE, Campbell TS, Grover S, Honos G, Lindsay P, Hill MD, Coutts SB, Gubitz G, Campbell NR, Moe GW, Howlett JG, Boulanger JM, Prebtani A, Larochelle P, Leiter LA, Jones C, Ogilvie RI, Woo V, Kaczorowski J, Trudeau L, Petrella RJ, Hiremath S, Drouin D, Lavoie KL, Hamet P, Fodor G, Gregoire JC, Lewanczuk R, Dresser GK, Sharma M, Reid D, Lear SA, Moullec G, Gupta M, Magee LA, Logan AG, Harris KC, Dionne J, Fournier A, Benoit G, Feber J, Poirier L, Padwal RS and Rabi DM. Hypertension Canada's 2016 Canadian Hypertension Education Program Guidelines for Blood Pressure Measurement, Diagnosis, Assessment of Risk, Prevention, and Treatment of Hypertension. *Can J Cardiol*. 2016;32:569-88.
6. Paffenbarger RSJ, Hyde R, Wing AL and Hsieh C-c. Physical Activity, All-Cause Mortality, and Longevity of College Alumni. *N Engl J Med*. 1986;314:605-613.
7. Choudhry NK, Avorn J, Glynn RJ, Antman EM, Schneeweiss S, Toscano M, Reisman L, Fernandes J, Spettell C, Lee JL, Levin R, Brennan T and Shrank WH. Full coverage for preventive medications after myocardial infarction. *N Engl J Med*. 2011;365:2088-97.

8. Pluye P, Grad RM, Johnson-Lafleur J, Bambrick T, Burnand B, Mercer J, Marlow B and Campbell C. Evaluation of email alerts in practice: Part 2. Validation of the information assessment method. *Journal of Evaluation in Clinical Practice*. 2010;16:1236-43.
9. Pluye P, Granikov V, Bartlett G, Grad RM, Tang DL, Johnson-Lafleur J, Shulha M, Barbosa Galvao MC, Ricarte IL, Stephenson R, Shohet L, Hutsul JA, Repchinsky CA, Rosenberg E, Burnand B, Legare F, Dunikowski L, Murray S, Boruff J, Frati F, Kloda L, Macaulay A, Lagarde F and Doray G. Development and content validation of the information assessment method for patients and consumers. *JMIR Research Protocols*. 2014;3:e7.
10. Information Technology Primary Care Research Group. *The Information Assessment Method*. Department of Family Medicine, McGill University. http://www.mcgill.ca/iam. Accessed October 20, 2017.