

Within-the-Clinic Shared Decision for an Over-the-Counter Medication

Ju H. Kim, MD; William B. Borden, MD

Aspirin and its relatives are some of the oldest and most widely used drugs, dating back thousands of years and treating aches, pains, and fevers. Since the 1980s, aspirin has been regularly used to prevent and treat heart disease and stroke. Unlike the robust data supporting the use of aspirin in secondary prevention of cardiovascular disease, uncertainty remains regarding its role in primary prevention. The uncertainty behind aspirin use in primary prevention is mainly due to imprecision underlying the relative size of the risk and benefit of aspirin use in a low-risk, otherwise healthy population.¹ Despite this, nearly every major cardiovascular health organization has published guidelines and statements on the use of aspirin in primary prevention of cardiovascular disease. Controversy and complexity of the available research combined with the over-the-counter accessibility of aspirin make translation of the evidence into practice particularly challenging for both clinicians and patients alike.

In 2009, the United States Preventive Services Task Force (USPSTF) assigned grade-A recommendations for the use of aspirin in men ages 45 to 79 years for the prevention of myocardial infarction (MI) and in women ages 55 to 79 years for the prevention of ischemic stroke, in both cases where the prevention risks outweigh the risk of gastrointestinal (GI) bleeding.² These recommendations are echoed to varying degrees in multiple cardiovascular disease prevention guidelines, including those of the American Heart Association (AHA).³ Conversely, the United States Food and Drug Administration (FDA) in 2014 declared that the available evidence does not support the general use of aspirin for

primary prevention. These conflicting statements can be confusing for both healthcare providers and patients to digest, potentially leading to underutilization of aspirin for primary prevention.⁴ The key for appropriate use of aspirin in primary prevention lies in the identification of the correct candidate for whom aspirin use is truly beneficial. This can be a complex task as consensus on assessment of cardiovascular risk remains elusive, and integrating bleeding risk with cardiovascular risk further complicates the decision-making process.

In this issue of the *Journal*, Luepker and colleagues share results from the Minnesota Heart Survey that showed age-adjusted aspirin use for primary prevention increased from 1980 to 2009 for both men (from 3.7 to 20.8%) and women (from 1 to 12%).⁵ The authors also found no indication of increases in gastrointestinal (GI) bleeding or intracranial hemorrhage despite the increase in overall aspirin use. Importantly, although this survey-based study cannot confirm the appropriateness of aspirin use in this population, increases in aspirin use were noted even among those for whom it is not recommended for primary prevention (men aged 35–44 years and women aged 45–54 years).

Also in this issue, Hirsch and colleagues show that a decision analytic model based on a statewide public awareness campaign supports the use of a population-based intervention to increase aspirin use for primary prevention among the USPSTF target population.⁶ Using data extrapolated from a regional campaign piloted in Hibbing, Minnesota,⁷ the authors developed a model with estimates of population-based aspirin use data and state-specific rates of MI, stroke, and GI bleeding to evaluate the costs and benefits of a statewide public awareness campaign. The campaign would include a public media component aimed at encouraging a dialogue between patients and their healthcare providers on whether aspirin use for primary prevention would be a fit for that patient. This model predicted that a statewide public awareness campaign would be both clinically and economically beneficial with quality-adjusted life year (QALY) gains and net cost savings achieved through decreasing the incidence of MIs in men and strokes in women.

These studies together highlight an important opportunity to bridge the gap that exists between the evidence for aspirin in primary prevention and its implementation. While the

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

From the Division of Cardiology, Department of Medicine, George Washington University School of Medicine and Health Sciences, Washington, DC.

Correspondence to: William B. Borden, MD, George Washington University, 2150 Pennsylvania Avenue, NW, Washington, DC 20037. E-mail: wborden@mfa.gwu.edu

J Am Heart Assoc. 2015;4:e002927 doi: 10.1161/JAHA.115.002927.

© 2015 The Authors. Published on behalf of the American Heart Association, Inc., by Wiley Blackwell. This is an open access article under the terms of the Creative Commons Attribution-NonCommercial License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited and is not used for commercial purposes.

primary prevention use of aspirin has increased substantially, there are clearly individuals who would potentially benefit but are not receiving aspirin, and conversely, lower-risk individuals for whom the risks outweigh the benefits but who are taking a daily preventive aspirin. Increasing appropriate aspirin use through innovative outreach campaigns can achieve public health benefits and significant cost savings, but with appropriate use being of paramount importance. Whether such approaches will lead to the message targeting the right patients remains unclear. The Minnesota public awareness program importantly promotes dialogue between individuals and their care providers about aspirin, rather than suggesting that patients independently decide to initiate aspirin for prevention. To best apply the evidence-based recommendations while minimizing potential harm, the unique medical and preference characteristics of each individual must be considered—not a simple task for either the patient or the clinician. While aspirin is an over-the-counter medication, the use of aspirin for primary prevention should be a within-the-clinic decision.

The proliferation of evidence-based medicine has greatly advanced the science of medicine and increased the need for the art of medicine to apply and communicate the wealth of data to an individual patient. In an age where this medical evidence is widely available in a variety of public formats, individuals become important advocates for their own health, but also potentially face making complex medical decisions alone. The patient-provider relationship is key to navigating this elaborate world of evidenced-based medicine, particularly when considering potentially high-consequence decisions like starting primary prevention aspirin. To practice true patient-centered care, providers must not only assist in interpretation of the often complicated medical evidence, but also in incorporating individual values, preferences, and needs of the patient into the clinical decision making process. This shared decision making⁸ involves the patient and the provider sharing their expertise on how a particular medical decision will impact the patient's life.^{9–11} Together, they mutually arrive at a decision that is in line with the best available evidence as well as the patient's preferences.

Many clinical decision-making tools have been developed and are commonly used to aid in shared decision making.¹⁰ Examples have been studied in a variety of cardiovascular diseases, including atrial fibrillation,¹² diabetes,⁹ and coronary artery disease.¹³ The AHA endorsed the importance of shared decision making in a scientific statement focused on advanced heart failure.¹⁴ A wide range of decision aid formats have been utilized, including interactive web-based tools,¹⁵ pamphlets,⁹ pictographs,^{12,13} and mobile apps. Specific to preventive aspirin use, the Mayo Clinic has free downloadable decision aids to be used during an office visit.¹⁵ These decision aids can facilitate communication between a patient and their provider

to include best available evidence-based medicine, available alternatives, risks, benefits, and how all of these data may be incorporated with the patient's preferences.

Success of a well-designed public awareness program should ideally be measured not by absolute increases in the number of patients using preventive aspirin, but by those who are doing so in line with their personalized potential benefit and risk, and their individual preferences. Shared decision making is particularly appropriate in the setting of aspirin use in primary prevention as the relative estimates of risks and benefits for a low-risk individual remain imprecise. Moreover, as clinical evidence continues to evolve with data from ongoing primary prevention trials arriving in coming years^{16–18} and with expected updated USPSTF recommendations,¹⁹ the process of shared decision making should be iterative with incorporation of changing data and patient preferences. Aspirin for primary prevention remains a complex topic. As public health efforts play an important educational role in encouraging patients to have evidence-based discussions with their healthcare providers, those providers must likewise embrace the importance of collaboration with their patients through shared decision-making to deliver true patient-centered care.

Disclosures

Dr Borden provides consulting to the Agency for Healthcare Research and Quality on a cardiovascular disease reduction program. The views expressed here are his own.

References

1. Fuster V, Sweeny JM. Aspirin: a historical and contemporary therapeutic overview. *Circulation*. 2011;123:768–778.
2. Aspirin for the prevention of cardiovascular disease: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2009;150:396–404.
3. Meschia JF, Bushnell C, Boden-Albala B, Braun LT, Bravata DM, Chaturvedi S, Creager MA, Eckel RH, Elkind MSV, Fornage M, Goldstein LB, Greenberg SM, Horvath SE, Iadecola C, Jauch EC, Moore WS, Wilson JA; on behalf of the American Heart Association Stroke Council, Council on Cardiovascular and Stroke Nursing, Council on Clinical Cardiology, Council on Functional Genomics and Translational Biology, and Council on Hypertension. Guidelines for the primary prevention of stroke: a statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2014;45:3754–3832.
4. Fiscella K, Winters PC, Mendoza M, Noronha GJ, Swanger CM, Bisognano JD, Fortuna RJ. Do clinicians recommend aspirin to patients for primary prevention of cardiovascular disease? *J Gen Intern Med*. 2015;30:155–160.
5. Luepker RV, Steffen LM, Duval S, Zantek ND, Zhou X, Hirsch AT. Population trends in aspirin use for cardiovascular disease prevention 1980–2009: the Minnesota Heart Survey. *J Am Heart Assoc*. 2015;4:e002320 doi: 10.1161/JAHA.115.002320.
6. Michaud TL, Abraham J, Jalal H, Luepker RV, Duval S, Hirsch AT. Cost-effectiveness of a statewide campaign to promote aspirin use for primary prevention of cardiovascular disease. *J Am Heart Assoc*. 2015;4:e002321 doi: 10.1161/JAHA.115.002321.
7. Oldenburg NC, Duval S, Luepker RV, Finnegan JR, LaMarre H, Peterson KA. A 16-month community-based intervention to increase aspirin use for primary prevention of cardiovascular disease. *Prev Chronic Dis*. 2014;11:e83.
8. Spatz ES, Spertus JA. Shared decision making: a path toward improved patient-centered outcomes. *Circ Cardiovasc Qual Outcomes*. 2012;5:e75–e77.

9. Tamhane S, Rodriguez-Gutierrez R, Hargraves I, Montori VM. Shared decision-making in diabetes care. *Curr Diab Rep*. 2015;15:112.
10. Elwyn G, Frosch D, Volandes AE, Edwards A, Montori VM. Investing in deliberation: a definition and classification of decision support interventions for people facing difficult health decisions. *Med Decis Making*. 2010;30:701–711.
11. Ting HH, Brito JB, Montori VM. Shared decision making: science and action. *Circ Cardiovasc Qual Outcomes*. 2014;7:323–327.
12. Seaburg L, Hess EP, Coylewright M, Ting HH, McLeod CJ, Montori VM. Shared decision making in atrial fibrillation: where we are and where we should be going. *Circulation*. 2014;129:704–710.
13. Coylewright M, Shepel K, Leblanc A, Pencille L, Hess E, Shah N, Montori VM, Ting HH. Shared decision making in patients with stable coronary artery disease: PCI choice. *PLoS One*. 2012;7:e49827.
14. Allen LA, Stevenson LW, Grady KL, Goldstein NE, Matlock DD, Arnold RM, Cook NR, Felker GM, Francis GS, Hauptman PJ, Havranek EP, Krumholz HM, Mancini D, Riegel B, Spertus JA; on behalf of the American Heart Association Council on Quality of Care and Outcomes Research, Council on Cardiovascular Nursing, Council on Clinical Cardiology, Council on Cardiovascular Radiology and Intervention, and Council on Cardiovascular Surgery and Anesthesia. Decision making in advanced heart failure: a scientific statement from the American Heart Association. *Circulation*. 2012;125:1928–1952.
15. Montori VM. Cardiovascular primary prevention choice. Mayo Clinic Shared Decision Making National Resource Center. Available at: <http://shareddecisions.mayoclinic.org/decision-aid-information/decision-aids-for-chronic-disease/cardiovascular-prevention/>. Accessed December 4, 2015.
16. A Study of Cardiovascular Events in Diabetes—A Randomized 2x2 Factorial Study of Aspirin Versus Placebo, and of Omega-3 Fatty Acid Supplementation Versus Placebo, for Primary Prevention of Cardiovascular Events in People With Diabetes (ASCEND). ClinicalTrials.gov Identifier: NCT00135226. Available at: <https://clinicaltrials.gov/ct2/show/NCT00135226?term=aspirin+primary+prevention&rank=7>. Accessed December 1, 2015.
17. A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Parallel Group Study to Assess the Efficacy (Reduction of Cardiovascular Disease Events) and Safety of 100 mg Enteric-Coated Acetylsalicylic Acid in Patients at Moderate Risk of Cardiovascular Disease (ARRIVE). ClinicalTrials.gov Identifier: NCT00501059. Available at: <https://clinicaltrials.gov/ct2/show/NCT00501059?term=aspirin+primary+prevention&rank=9>. Accessed December 1, 2015.
18. Effect of Aspirin in Primary Prevention of Cardiovascular Risk in Patients With Chronic Kidney Disease (AASER Study). ClinicalTrials.gov Identifier: NCT01709994. Available at: <https://clinicaltrials.gov/ct2/show/NCT01709994?term=aspirin+primary+prevention&rank=10>. Accessed December 1, 2015.
19. Draft Update Summary: aspirin to prevent cardiovascular disease and cancer. U.S. Preventive Services Task Force. September 2015. Available at: <http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryDraft/aspirin-to-prevent-cardiovascular-disease-and-cancer>. Accessed December 1, 2015.

Key Words: Editorials • aspirin • prevention • public policy



Within-the-Clinic Shared Decision for an Over-the-Counter Medication

Ju H. Kim and William B. Borden

J Am Heart Assoc. 2015;4:e002927; originally published December 23, 2015;

doi: 10.1161/JAHA.115.002927

The *Journal of the American Heart Association* is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Online ISSN: 2047-9980

The online version of this article, along with updated information and services, is located on the World Wide Web at:

<http://jaha.ahajournals.org/content/4/12/e002927>

Subscriptions, Permissions, and Reprints: The *Journal of the American Heart Association* is an online only Open Access publication. Visit the Journal at <http://jaha.ahajournals.org> for more information.