

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

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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

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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.

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