Weighing the Risks and Benefits of Clinical Interventions

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CME Covered in *FPM* Quiz

FPM Tool inside

Should your patient be taking an aspirin a day to prevent heart attack? Here's how to decide.

A 62-year-old male patient presents to your office for a routine checkup and asks whether he should be taking an aspirin a day to prevent heart attack. His wife apparently read this recommendation in a women's magazine and asked him to seek your advice. The patient has no history of cardiovascular disease but does have mild hypertension. What would you recommend to him, and how would you arrive at your recommendation?

High-quality medical care requires a careful balance of risks and benefits, whether you're helping a patient decide if he should take an aspirin a day to prevent cardiovascular (CV) events, undergo a prostate-specific antigen (PSA) screening or have a biopsy to examine a suspicious lump. To make the best decisions in these clinical situations, you must engage your patient in a cost-benefit discussion, taking current evidence and the patient's needs, values and preferences into account. Using aspirin as the example, this article will walk you through the necessary steps.

1. Understand the evidence

Not since Hippocrates ground up willow bark and Friedrich Bayer's employee Felix Hoffman tinkered with the salicylate molecule to create ASA to alleviate his father's arthritis pain has aspirin enjoyed such notoriety. The beneficial effects of aspirin in secondary prevention of CV and cerebrovascular disease have been well established since the 1970s. Recently, the U.S. Preventive Services Task Force (USPSTF), usually a very conservative ("we'll be the last to jump on the bandwagon") organization, recommended that those patients without known cardiovascular disease but with at least a five-year 3-percent risk for a CV event be treated with 81mg of aspirin daily.[1] The task force gave this intervention its highest rating, an "A," meaning it is strongly recommended. The data suggest that aspirin reduces the risk of CV events by 28 percent.

(To view USPSTF recommendations on other clinical topics, visit http://www.ahrq.gov/clinic/uspstf/uspstopics.htm. To access a comprehensive database of clinical guidelines, visit the National Guideline Clearinghouse at http://www.guidelines.gov, and to access systematic reviews of the evidence on a variety of clinical topics, visit the Cochrane Reviews at http://www.cochrane.org/cochrane/revabstr/mainindex.htm.)

2. Understand the risks and benefits

While daily aspirin use promises certain benefits, it is clearly not without risks, including hemorrhagic stroke

ESTIMATES OF BENEFITS AND HARMS OF DAILY ASPIRIN USE OVER FIVE YEARS

The following estimates, from the U.S. Preventive Services Task Force,[1] are based on a relative risk reduction of 28 percent for coronary heart disease events in aspirin-treated patients and assume that risk reductions do not vary significantly by age.

Benefits and harms associated with daily aspirin use	Baseline risk for coronary heart disease over five years		
	1 percent	3 percent	5 percent
Total mortality	No effect	No effect	No effect
Coronary heart disease events	1-4 avoided	4-12 avoided	6-20 avoided
Hemorrhagic strokes*	0-2 caused	0-2 caused	0-2 caused
Major gastrointestinal bleeding events**	2-4 caused	2-4 caused	2-4 caused

1. U.S. Preventive Services Task Force. Aspirin for the primary prevention of cardiovascular events: recommendation and rationale. *Ann Int Med.* 2002;136:157-160.

* Data from secondary prevention trials suggest that increases in hemorrhagic stroke may be offset by reductions in other types of stroke in patients at very high risk for cardiovascular disease (≥10 percent risk over five years).

** Rates may be two to three times higher in people older than 70 years of age.

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CORONARY DISEASE RISK PREDICTION SCORE SHEET FOR MEN BASED ON TOTAL CHOLESTEROL LEVEL

FPM Tool

Step 1

Age	
Years	Points
30-34	-1
35-39	0
40-44	1
45-49	2
50-54	3
55-59	4
60-64	5
65-69	6
70-74	7

Step 2

Total Cholesterol		
(mg/dl)	(mmol/L)	Points
<160	≤4.14	-3
160-199	4.15-5.17	0
200-239	5.18-6.21	1
240-279	6.22-7.24	2
≥280	≥7.25	3

Key	
Color	Risk
green	Very low
white	Low
yellow	Moderate
rose	High
red	Very high

Step 3

HDL - Cholesterol		
(mg/dl)	(mmol/L)	Points
<35	≤0.90	2
35-44	0.91-1.16	1
45-49	1.17-1.29	0
50-59	1.30-1.55	0
≥60	≥1.56	-2

Step 4

Blood Pressure					
Systolic (mmHg)	Diastolic (mmHg)				
	<80	80-84	85-89	90-99	≥100
<120	0 pts				
120-129		0 pts			
130-139			1 pt		
140-159				2 pts	
≥160					3 pts

Note: When systolic and diastolic pressures provide different estimates for point scores, use the higher number.

Step 5

Diabetes	
	Points
No	0
Yes	2

Step 6

Smoker	
	Points
No	0
Yes	2

Risk estimates were derived from the experience of the NHLBI's Framingham Heart Study, a predominantly Caucasian population in Massachusetts, USA.

Step 7 (sum from steps 1-6)

Adding up the points	
Age	_____
Total Cholesterol	_____
HDL Cholesterol	_____
Blood Pressure	_____
Diabetes	_____
Smoker	_____
Point Total	_____

Step 8 (determine CHD risk from point total)

CHD Risk	
Point Total	10 Yr CHD Risk
≤-1	2%
0	3%
1	3%
2	4%
3	5%
4	7%
5	8%
6	10%
7	13%
8	16%
9	20%
10	25%
11	31%
12	37%
13	45%
≥14	≥53%

Step 9 (compare to men of the same age)

Comparative Risk		
Age (years)	Average 10 Yr CHD Risk	Low* 10 Yr CHD Risk
30-34	3%	2%
35-39	5%	3%
40-44	7%	4%
45-49	11%	4%
50-54	14%	6%
55-59	16%	7%
60-64	21%	9%
65-69	25%	11%
70-74	30%	14%

*Low risk was calculated for a man the same age, normal blood pressure, total cholesterol 160-199 mg/dL, HDL cholesterol 45 mg/dL, nonsmoker, no diabetes.

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"Weighing the Risks and Benefits of Clinical Interventions" Mohler P. *Family Practice Management.* January 2003:53-56, http://www.aafp.org/fpm/20040100/53weig.html.

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CORONARY DISEASE RISK PREDICTION SCORE SHEET FOR WOMEN BASED ON TOTAL CHOLESTEROL LEVEL

FPM Tool

Step 1

Age	
Years	Points
30-34	-9
35-39	-4
40-44	0
45-49	3
50-54	6
55-59	7
60-64	8
65-69	8
70-74	8

Step 2

Total Cholesterol		
(mg/dl)	(mmol/L)	Points
<160	≤4.14	-2
160-199	4.15-5.17	0
200-239	5.18-6.21	1
240-279	6.22-7.24	1
≥280	≥7.25	3

Key	
Color	Risk
green	Very low
white	Low
yellow	Moderate
rose	High
red	Very high

Step 3

HDL - Cholesterol		
(mg/dl)	(mmol/L)	Points
<35	≤0.90	5
35-44	0.91-1.16	2
45-49	1.17-1.29	1
50-59	1.30-1.55	0
≥60	≥1.56	-3

Step 4

Blood Pressure					
Systolic (mmHg)	Diastolic (mmHg)				
	<80	80-84	85-89	90-99	≥100
<120	-3 pts				
120-129		0 pts			
130-139			0 pt		
140-159				2 pts	
≥160					3 pts

Note: When systolic and diastolic pressures provide different estimates for point scores, use the higher number.

Step 5

Diabetes	
	Points
No	0
Yes	4

Step 6

Smoker	
	Points
No	0
Yes	2

Risk estimates were derived from the experience of the NHLBI's Framingham Heart Study, a predominantly Caucasian population in Massachusetts, USA.

Step 7 (sum from steps 1-6)

Adding up the points	
Age	_____
Total Cholesterol	_____
HDL Cholesterol	_____
Blood Pressure	_____
Diabetes	_____
Smoker	_____
Point Total	_____

Step 8 (determine CHD risk from point total)

CHD Risk	
Point Total	10 Yr CHD Risk
≤-2	1%
-1	2%
0	2%
1	2%
2	3%
3	3%
4	4%
5	4%
6	5%
7	6%
8	7%
9	8%
10	10%
11	11%
12	13%
13	15%
14	18%
15	20%
16	24%
≥17	≥27%

Step 9 (compare to women of the same age)

Comparative Risk		
Age (years)	Average 10 Yr CHD Risk	Low* 10 Yr CHD Risk
30-34	<1%	<1%
35-39	1%	<1%
40-44	2%	2%
45-49	5%	3%
50-54	8%	5%
55-59	12%	7%
60-64	12%	8%
65-69	13%	8%
70-74	14%	8%

*Low risk was calculated for a woman the same age, normal blood pressure, total cholesterol 160-199 mg/dL, HDL cholesterol 55 mg/dL, nonsmoker, no diabetes.

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and major gastrointestinal bleeding. Table 1 (page 53) outlines the benefits and harms associated with daily aspirin use that were noted in the five studies that the USPSTF used to make its recommendation noted above.

But before you can understand a patient's real risks and benefits of daily aspirin use, you must understand his or her risk of CV events. To do this, clinicians should become familiar with a coronary heart disease risk calculator such as the Framingham tool.[2] There are paper versions (see page 54) and online tools (see the box below). Most of the CV calculators create a 10-year risk, so the result needs to be divided by two. Risk calculators that include age, gender, total cholesterol, HDL, smoking and treated or untreated blood pressure are more accurate than simply counting risk factors. According to the score sheet on page 54, a 62-year-old man has at least a 4-percent, five-year risk of CV events, making our fictitious patient a candidate for daily aspirin use.

3. Understand your patient

To weigh the risks and benefits associated with an intervention, you need to do more than consult the evidence and risk calculators. You also need to talk with your patient and find out what his or her needs, concerns, values and preferences are. Some patients may fear a hemorrhagic stroke more than an MI and will elect not to take aspirin. Others may have absolute or relative contraindications that will preclude them from the standard treatment. Only you, their family physician, can help patients weigh these issues and arrive at an informed decision that takes into account both the scientific and human sides of medicine. FPM

Send comments to fpmedit@aafp.org. Send Improving Patient Care manuscript submissions to bwhite@aafp.org.

RISK CALCULATORS ON THE INTERNET

The following risk calculators, all available on the Internet, can help you and your patients assess their risk for a variety of clinical conditions and then use the information to formulate a shared care plan.

Breast cancer
http://bcra.nci.nih.gov/brc/q1.htm
http://www.halls.md/breast/risk.htm

Cancer (general)
http://www.yourcancerrisk.harvard.edu/

Coronary heart disease
http://hin.nhlbi.nih.gov/atpiii/calculator.asp
http://www.intmed.mcw.edu/clincalc/heartrisk.html
http://www.med-decisions.com/cvtool/index.html (also offers a version for the handheld computer)

Diabetes-related
http://www.dtu.ox.ac.uk/riskengine/download.html
http://www.healthandage.com/tools/diab/indexdiab.jsp
http://www.footandankle.com/DMfoot/start.html

Osteoporosis
http://www.indiadiets.com/calculators/risk_osteoporosis.htm

Prostate cancer
http://www.prostatecalculator.org/introduction.html

Smoking-related
http://www.medindia.net/patients/calculators/ciger_smoke.asp

Strep throat
http://www.aafp.org/fpm/20030900/sorethroatencounterform.pdf

1. U.S. Preventive Services Task Force. Aspirin for the primary prevention of cardiovascular events: recommendation and rationale. *Ann Int Med.* 2002;136:157-160.

2. Wilson PW, D'Agostino RB, Levy D, Belanger AM, Silbershatz H, Kannel WB. Prediction of coronary heart disease using risk factor categories. *Circulation.* 1998;97:1837-1847.