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Patient Preferences for the Chemoprevention of Colorectal Cancer

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Abstract

Although evidence suggests that aspirin and celecoxib may reduce the risk of colorectal cancer (CRC), these drugs can also cause harmful side effects. The aim of this study was to characterize patient preferences for celecoxib and aspirin. Participants completed a computer-based patient decision-making questionnaire that included an educational component outlining the benefits and harms of celecoxib and aspirin. Under the base conditions 7.4% would take celecoxib and 43.6% would take aspirin; males were more willing than females to take aspirin. Patients identified the increased risk of myocardial infarction and gastrointestinal events as the primary reasons for their unwillingness to take celecoxib and aspirin, respectively. A majority of subjects would not take either drug, after considering their benefits and harms, although participants were almost six times more likely to take aspirin than celecoxib. These data serve to inform physicians and researchers regarding the variability and factors that affect patient preferences for CRC chemoprevention.

Keywords

Colorectal cancer; Chemoprevention; Aspirin; Celecoxib; Patient preferences

Introduction

As the second leading cause of cancer deaths in the USA, and with more than 150,000 new cases every year [1], colorectal cancer is an important target for screening and prevention efforts. Patients at risk of colorectal cancer face a steady increase in both the number and complexity of available preventive treatments.

There is evidence suggesting that both aspirin [2–4] and selective cyclooxygenase-2 (COX-2) inhibitors (coxibs) [5–7] can prevent colorectal cancer (CRC). However, this benefit comes with an increased risk of specific diseases or adverse events. Two large, randomized trials have confirmed both celecoxib's ability to reduce CRC risk and an associated increase in risk of cardiovascular events [5, 6]. In comparison, aspirin not only reduces CRC risk, but also lowers risk of primary cardiovascular events [8, 9]. The principal risk associated with aspirin use is gastrointestinal bleeding [10].

These chemoprevention options provide an opportunity to make a significant impact on the burden of this disease. However, while both of these interventions hold potential benefit, the risks involved are not trivial. It is therefore important to implement such interventions in a manner consistent with patient preferences. Decisions to initiate these treatments require discussions with patients to determine an individual's risk–benefit profile.

Although cost-effectiveness of CRC chemoprevention has been studied [11–14], little data exist regarding patient preferences for these drugs. The purpose of this study was to explore patient preferences with regard to chemoprevention of CRC, by specifically studying preferences for two drugs with different risk–benefit profiles: celecoxib and aspirin. Such information can inform healthcare providers, patients, and researchers as they consider chemoprevention and other interventions.

Methods

Overview of Study Design and Recruitment

The sample consisted of patients recruited from the Massachusetts General Hospital in Boston, MA. The study was approved by the Institutional Review Boards (IRB) and all study participants provided written, informed consent according to the approved protocol. Participants completed a computer-based questionnaire comprising preference elicitation, health history, and demographic components. This questionnaire was self-administered, with assistance available to subjects experiencing difficulties or having questions. Subjects were recruited in the waiting room of the endoscopy suite, intended as a representative sample of the general public. Target subjects were nonpatients present as escorts for patients undergoing endoscopic procedures with conscious sedation. Eligible participants were at least 18 years old, and were able to read and understand information presented in English on a laptop computer.

Survey Description

A text version of the computer-based questionnaire used in the interviews can be found in the Appendix. The survey consisted of three parts as described in detail below: an educational summary, patient preferences assessment, and demographic and related factors survey.

Educational Component/Summary of Risks and Benefits—The educational summary of the risk–benefit profiles for celecoxib and aspirin (referred to as “medicine A” and “medicine B,” respectively) were based on the current published data (Table 1). To describe the benefits and harms of each drug, participants were given information on four specific risks that could change with the use of celecoxib or aspirin: risk of CRC, risk of myocardial infarction (MI), risk of stroke, and risk of gastrointestinal event (GIE; ulcer or gastrointestinal bleeding). Studies have suggested that both celecoxib and aspirin are associated with a CRC risk reduction of approximately 33%, which we extrapolated to a change in lifetime risk from 6% to 4%. Because the baseline lifetime risk of MI differs by gender [15] and aspirin reduces stroke risk in women but MI risk in men [16], men and women were shown different risks. For celecoxib, the 50% increase (50% to 75% in men; 30% to 45% in women) in lifetime risk of MI presented is within the range of 30–160% described in the literature [5]. For aspirin, men were presented with a reduced risk of MI in the drug profile, while women were presented with a reduced risk of stroke.

To begin the survey, descriptions of celecoxib and aspirin (“medicine A” and “medicine B,” respectively), including both harms and benefits, were presented sequentially, in random order. In addition to the information about the benefits and harms of medicines A and B, participants were directed during the preference-elicitation exercises to view a pictorial representation of the risk reductions described (see Fig. 1 for example).

Preference Assessment and Patient Decision-Making—After each drug profile was presented, participants were asked whether or not they would be willing to take these drugs. They were then asked which benefit or harm most influenced their choice. To further explore patient preferences regarding CRC chemoprevention, subjects were asked to reconsider medicine A or B if a particular drug benefit was maximized or if a particular harm was minimized, while all of the other benefits and harms were held constant (referred to as the “improved drug profile analysis”). For example, a new “improved version” of medicine A would reduce the lifetime risk of CRC from 6% to 0% (6% to 4% in the base case) in one scenario, while all other risks (MI, stroke, GIE) would remain the same as in the base case.

Demographic and Related Factors—Finally, participants were asked about their medical histories and perceived risks of CRC, MI, and GI bleeds. They were also asked about current and past use of Vioxx and Celebrex, as well as current use of aspirin. Demographic information such as age, gender, race, and level of education were also collected.

Statistics

Descriptive statistics were used to present demographic data. A comparison of the proportion of patients who would be willing to take celecoxib versus aspirin was made using the McNemar’s test.

Results

Participant Characteristics

Of the 236 subjects asked to participate, 207 (88%) agreed to participate, and 202 (86%) completed the survey. Table 2 presents the participant characteristics. Median age was in the 45–54 years category, with 109 (54%) female subjects and 93 (46%) males. The sample was predominately White (88%) and highly educated, with 78% reporting at least some college, and more than a third (37%) saying they had received postgraduate education. Of those surveyed 37% were taking aspirin regularly while only 2% stated that they were currently

taking celecoxib (Celebrex) and 14% reported ever having taken celecoxib. Subjects had some past experience with cancer, cardiovascular conditions, and GI bleeds, with 10%, 17%, and 11% of respondents reporting a history of these conditions, respectively. The average time to complete the survey was 18.7 min (SD = 7.4 min).

Patient Decision-Making Results

Results of the decision-making portion of the study are presented in Table 3. After reading a description of benefits and harms associated with medicine A (celecoxib), 7.4% of participants stated that they would be willing to take the drug (7.3% of women and 7.5% of men). In comparison, 44% were willing to take medicine B (aspirin) (31% of women and 58% of men). This difference in the proportion of participants willing to take the two drugs was highly statistically significant ($P < 0.0001$). Additionally, men were more likely than women to accept medicine B ($P < 0.0001$), while there was no difference between genders in acceptance of medicine A.

None of the four participants who were currently taking celecoxib—and only one of the 29 who had ever taken it—were willing to take medicine A. Seventy-six of the 202 study participants (38%) answered that they currently take aspirin. Of these 76, 40 said they would take medicine B. However, nearly half (36) of those currently taking aspirin said that they would not be willing to take medicine B.

Most Important Factor Analysis/Decision-Making Determinants

A majority of participants who were not initially willing to take medicine A (73%; Table 4) identified the increased risk of MI as the most important factor affecting their decision. Participants who were willing to take medicine A (7.4%) cited the reduced risk of CRC cancer as the most important factor in their decision (93%). Most other participants (23%) selected increased risk of stroke as the most important factor in their decision not to take medicine A.

Participants who were willing to take medicine B identified the decreased risk of MI or stroke (men—57% for MI; women—53% for stroke; Table 4) as the most important factor affecting their decision. Among participants who were initially unwilling to take medicine B, the increased risk of GIE was the most cited reason (90%).

Improved Drug Profile Scenarios

Improving the CRC benefit to eliminate risk of CRC (0% lifetime risk) increased the proportion of participants willing to take celecoxib from 7.4% to 37% (Tables 5 and 6 present the data separately for men and women). Eliminating the increase in MI risk (no change, lifetime MI risk 50% in men, 30% in women) increased willingness to 35%, while eliminating increase in stroke risk increased willingness to 19%.

Improving CRC benefit to eliminate risk of CRC (0% lifetime risk) increased willingness to take aspirin from 44% to 69%.

Eliminating risk of MI (lifetime risk reduced from 50% to 0%, men only) increased willingness to take to 86% (among men), while eliminating risk of stroke (lifetime risk reduced from 20% to 0%, women only) raised acceptance to 66% (among women). Finally, eliminating the increase in GIE risk (lifetime risk remained 10%) increased willingness to take aspirin to 72%.

Discussion

As the second leading cause of cancer deaths in the USA [1], colorectal cancer is an important target for screening and prevention efforts. Patients at risk of colorectal cancer face a steady increase in both the number and complexity of available preventive treatments. Often, patients must decide between treatments whose benefits do not clearly outweigh their risks. In these situations, decisions must be based on individual patient preferences regarding the benefits and risks faced both with and without treatment. Because patients' preferences regarding the outcomes associated with such decisions may vary widely, it is important to understand patient preferences regarding preventive interventions.

Cost-effectiveness analyses studying aspirin [11, 12] and coxibs [13] as adjuncts to standard screening modalities for CRC chemoprevention have been published. Compared with screening alone, estimates for the cost-effectiveness of CRC prevention using aspirin range from US \$149,161 to US \$227,607 per life-year saved [11, 12] and from US \$404,700 to US \$823,800 per life-year saved for coxibs. These estimates are on the costly side; however, these analyses did not incorporate the effect, either positive or negative, of these drugs on cardiovascular disease. Another analysis studied the use of aspirin for primary cardiovascular prevention and found that it could be cost-saving (more effective and less costly) compared with no aspirin in a high-risk group of middle-aged men [17]. Finally, a cost-effectiveness study which directly compared celecoxib versus aspirin for CRC chemoprevention, incorporating the cardiovascular benefits of aspirin but not the harms of celecoxib, found that aspirin was superior [14]. These studies did not incorporate patient adherence to the chemoprevention drug into their models, which could have significantly affected the results of their analyses.

A majority of those surveyed in our study stated that they would take neither celecoxib (medicine A) nor aspirin (medicine B), although nearly six times as many (43.6%) participants were willing to take aspirin compared with celecoxib (7.4%). The increased risk of MI and the increased risk of GI event were the most important factors in determining preferences for celecoxib and aspirin, respectively.

Seventy-six of the 202 study participants (38%) were currently taking aspirin. Of these 76, 40 (53%) said they would take medicine B. However, the remaining 36 (47%) were concerned enough about the potential harm caused by medicine B that they would be unwilling to take it. In open-ended responses, most of these participants said they were taking aspirin because their doctor had recommended it to lower risk of cardiovascular events. A possibility is that many physicians are instructing patients to take aspirin without a comprehensive discussion regarding the potential benefits and harms of the drug. On the other hand, it is also possible that risk-averse patients in our study were unwilling to accept an increase in risk of any adverse event resulting from use of an unknown substance (medicine B). Because aspirin use is widespread in the USA, these same patients may perceive on the basis of experience—both personal and with friends and family—that aspirin is a “safe” drug.

Four participants (2%) also responded that they were taking celecoxib at the time of the survey, while 29 (14.4%) said they had taken it in the past. None of the four participants who were currently taking celecoxib—and only one of the 29 who had ever taken it—were willing to take medicine A. In all likelihood, these participants were taking or had taken celecoxib for pain relief, which was not included as a benefit of medicine A in our questionnaire. Furthermore, the cardiovascular risks associated with the coxibs were not identified until after the drugs had been approved and many prescriptions were filled, raising

the possibility that the patients were not aware of the increased risk of cardiovascular events or felt enough familiarity that they believed it to be “safe” for them.

The improved drug profile scenarios highlight the responsiveness of patients to changes in risk. Reducing risk of CRC for medicine A from 4% to 0% raised acceptance from 7.4% to 37.1%, while eliminating the risk of GI events for medicine B raised acceptance from 43.6% to 72.3%. Some patients remained unwilling to take a drug for chemoprevention even when there are no associated risks: more than a quarter of participants remained unwilling to take medicine B even when all of its described effects were beneficial. In open-ended responses, some patients said they prefer not to take anything “when they don’t have to,” and that “they’d rather change their lifestyle than take medication.” This unwillingness to take a drug with no downsides may also reflect disbelief on the part of participants who suspect that taking medication always carries risk.

Overall, participant response to medicines A and B (celecoxib and aspirin) seemed more consistent with risk-minimizing behavior as opposed to benefit maximization. For a few participants with a high perceived risk or great fear of colon cancer, even medicine A (celecoxib) was acceptable, while a large majority of participants rejected this higher-risk drug. Medicine B (aspirin), which had a more favorable benefit-to-harm ratio, was more widely accepted, particularly when the sole risk—increase in ulcer and GI bleed—was eliminated.

Our research has several limitations. The questionnaire was not a validated instrument. However, we incorporated established concepts and techniques from the disciplines of risk communication and survey science. Furthermore, the effort and cost to formally validate a survey instrument is prohibitively high and impractical for study of a clinical issue as specific as chemoprevention for colorectal cancer. Our questionnaire design attempted to achieve medical accuracy while avoiding cognitive burden [18].

The descriptions, particularly the quantitative values, were based on the published literature but were still simplifications of medical knowledge. The process of distilling large amounts of complex medical data into information that is comprehensible and does not overwhelm an individual without medical training could lead to biases, or “framing effects.” We followed published recommendations on methods to minimize “framing manipulation” such as presenting benefits and harms in the absolute risk format as well as the use of visual aids [19].

Our study population, although demographically diverse, may not be representative of the general public. In particular, our sample was predominately White, and the level of education was much higher than the population average.

In conclusion, many participants were interested in CRC chemoprevention. However, the amount of protection offered and the side-effect profile of a drug determine whether or not it is acceptable. These data provide insights into the tradeoffs patients are willing to consider and can inform physicians and researchers regarding factors that affect patient preferences for chemoprevention and aid in the process of shared decision-making.

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Appendix

Colon Cancer Prevention Survey (Male Version)

[Celecoxib Description]

Scenario

We will ask you to think about your health and colon cancer prevention and then ask you to make some choices.

Colon Cancer

Colon cancer is cancer in the large intestines (large bowel). 6% of people will get colon cancer in their lifetime. 3% of people will die of the disease. There are medicines available that can help prevent colon cancer. Each medicine has its own risks and side effects. Not everything is known about these medicines. Please read some of the best information available about one of these medicines, Medicine A, and answer the imaginary choices in the questions.

Medicine A

- Medicine A is a pill that you take once a day
- Your doctor would give you a prescription for this medicine
- Medicine A reduces your risk of getting colon cancer by 30%. Since your lifetime chance of getting colon cancer is about 6%, this medicine reduces your lifetime risk to 4%. (See pictures on green sheet)

Harms and Side Effects

- Medicine A increases your chance of having a heart attack by 50%. Over a lifetime, 50% of men will have a heart attack, so Medicine A increases your chance of having a heart attack to 75%.
- Medicine A increases your chance of having a stroke by 50%. Since 20% of men will have a stroke in their lifetime, Medicine A increases your lifetime chance of having a stroke to 30%.
- Medicine A increases the chance of you having problems in your gut (stomach or intestines) by 50%. This may include getting an open sore in the gut, called an ulcer, or having bleeding in your stomach or intestines. The lifetime risk of having an ulcer or bleeding in your gut is 10%, so Medicine A increases your chance of having these problems to 15%.
- Medicine A increases your chance of having stomach upset or indigestion. About 10% of people taking Medicine A will stop taking it because of stomach upset.

Medicine A Summary

Benefits	Harms
<ul style="list-style-type: none"> • Lowers your lifetime chance of getting colon cancer from 6% to 4% 	<ul style="list-style-type: none"> • Increases your lifetime chance of a heart attack from 50% to 75% • Increases your lifetime chance of stroke from 20% to 30% • Increases your chance of having an ulcer or bleeding in the gut from 10% to 15% • Increases your chance of having stomach upset or indigestion

[Aspirin Description]

Scenario

Now please think about a DIFFERENT medicine that helps prevent colon cancer, Medicine B.

Medicine B

- Medicine B is a pill that you take once a day
- You can buy Medicine B over the counter (you don't need a prescription)
- Medicine B reduces your risk of getting colon cancer by 30%. Your lifetime chance of getting colon cancer is 6%, so this medicine reduces your lifetime risk to 4%.
- Medicine B reduces your chance of heart attack by 30%. Since 50% of men will have a heart attack in their lifetime, Medicine B lowers your chance of having a heart attack to 35%.

Risks and Side Effects

- Medicine B increases the chance of you having problems in your gut (stomach or intestines) by 75%. This may include getting an ulcer or having bleeding in your stomach or intestines. Over a lifetime, 10% of people will have an ulcer or bleeding in their gut. Medicine B increases your chance of having these problems to 18%.

Summary of benefits and harms of Medicine B

Pros (benefits)	Cons (risks)
<ul style="list-style-type: none">• Lowers your lifetime chance of getting colon cancer from 6% to 4%• Lowers your lifetime chance of having a heart attack from 50% to 35%	<ul style="list-style-type: none">• Increases the lifetime chance of having an ulcer or bleeding in your gut from 10% to 18%

Fig. 1.

Visual aid, representation of percentages. Patients were given visual representations of the risk and benefit percentages using a 10×10 icon grid format, with the unhappy faces representing heart attacks and the smiley faces representing no heart attack. The 30% absolute lifetime risk is without medicine A (average population risk for women) while the 45% risk is the presumed risk if one were to take celecoxib (increase risk by 50%)

Table 1

Descriptions of disease risks and effect of chemoprevention

	Men (%)	Women (%)	References
<i>Colorectal cancer</i>			
Base lifetime risk	6	6	SEER [1]
With celecoxib	4	4	Arber [5]; Bertagnolli [6]
With aspirin	4	4	Sandler [2]; Chan [3]
<i>Myocardial infarction</i>			
Base lifetime risk	50	30	Lloyd-Jones [15]
With celecoxib	75	45	Kearney [20]; Arber [5]; Bertagnolli [6]
With aspirin	35	30	Berger [16]; Hayden [10]; Sanmuganathan [9]
<i>Stroke</i>			
Base lifetime risk	20	20	Seshadri [21]
With celecoxib	30	30	Kearney [20]; Arber [5]; Bertagnolli [6]
With aspirin	20	17	Berger [16]
<i>Ulcer/GI bleeding</i>			
Base lifetime risk	10	10	Graham [22]
With celecoxib	15	15	Simon [23]; Deeks [24]
With aspirin	18	18	Sanmuganathan [9]; Hayden [10]

Table 2

Patient characteristics

	Percentage
Gender	
Female	54.0
Male	46.0
Age (years)	
18–24	3.0
25–34	3.0
35–44	14.4
45–54	33.7
55–64	27.2
65+	18.8
Ethnicity	
White	87.6
Black/African American	3.0
Hispanic	3.5
Asian or Pacific Islander	2.5
Other	1.0
Multiracial	2.0
Declined to answer	0.5
Education level	
Some high school or less	2.0
High school/GED	19.8
Some college/college	41.1
Postgraduate	37.1
Aspirin dose (tabs/week)	
None	63.4
1–5	17.3
6–14	19.8
14+	0.5
Take celebrex	
Currently	2.0
Ever	14.4
Medical history	
Hx of cancer	10.0
Hx of heart condition	16.8
Hx of GI bleed	10.9

Percentage may not add up to 100% as a result of rounding

Table 3

Base case results

Willing to take drug (%)	F (%)	M (%)	Both (%)
Celecoxib	7.3	7.5	7.4
Aspirin	31.2	58.1	43.6

Difference between two drugs: $P < 0.0001$

Table 4

Most important factor analysis

	Willing to take		Unwilling to take	
<i>Celecoxib</i>				
Most important factor (%)	F (8)	M (7)	F (101)	M (86)
Decreased CRC risk	87.5%	100%	2.0%	1.2%
Increased risk of MI	0%	0%	67.3%	79%
Increased risk of stroke	0%	0%	26.7%	17.4%
Increased risk of GI event	12.5%	0%	4.0%	2.3%
<i>Aspirin</i>				
Most important factor (%)	F (34)	M (54)	F (75)	M (39)
Decreased CRC risk	41.2%	38.9%	6.7%	0%
Decreased risk of MI	–	57.4%	–	10.3%
Decreased risk of stroke	52.9%	–	4.0%	–
Increased risk of GI event	5.9%	3.7	89.3%	89.7%

CRC, colorectal cancer; *MI*, myocardial infarction; *GI*, gastrointestinal. Results are presented for males and females separately

Table 5

Improved drug profile scenarios—medicine A (celecoxib) *

Scenario	Acceptors (%)	
	F (109)	M (93)
Base case (risks: CRC ▼33%; MI ▲50%; stroke ▲50%; GIE ▲50%)	7.3	7.5
Scenario 1: improved CRC risk (0% lifetime risk of CRC; MI, stroke, GIE risks as in base case)	29.4	46.2
Scenario 2: improved MI risk (no increase in MI risk; CRC, stroke, GIE risks as in base case)	29.3	41.9
Scenario 3: improved stroke risk (no increase in stroke risk; CRC, MI, GIE risks as in base case)	22.2	13.3

CRC, colorectal cancer; *MI*, myocardial infarction; *GIE*, gastrointestinal event

* M + F separately

Table 6Improved drug profile scenarios—medicine B (aspirin)^{*}

Scenario	Acceptors (%)	
	F (109)	M (93)
Base case (risks: CRC ▼33%; MI ▼33%; stroke ▼15%; GIE ▲75%)	31.2%	58.1%
Scenario 1: improved CRC risk (0% lifetime risk of CRC; MI, stroke, GIE risks as in base case)	60.1%	79.6%
Scenario 2: improved MI risk (0% lifetime risk of MI; risk of CRC, stroke, GIE risks as in base case)	–	86.0%
Scenario 3: improved stroke risk (no increase in stroke risk; CRC, MI, GIE risks as in base case)	66.1%	–
Scenario 4: GIE risk (no increase in GIE risk; CRC, stroke, MI risks as in base case)	64.2%	81.7%

CRC, colorectal cancer; *MI*, myocardial infarction; *GIE*, gastrointestinal event^{*} M + F separately