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Rating the Preferences for Potential Harms of Treatments for Cardiovascular Disease: A Survey of Community-Dwelling Adults

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Abstract

Background—The Institute of Medicine (IOM) has called for a new health care paradigm that integrates patient values into discussions of the risks and benefits of treatment. Although CVD affects one-third of Americans, little is known about how adults regard the potential harms or complications of treatment.

Objective—We sought to determine the preferences of community dwelling adults for 15 potential harms or complications resulting from treatment of cardiovascular disease (CVD).

Methods—In a telephone survey, adults over 18 years of age residing on Long Island, New York were asked to score the preferences for 15 potential harms or complications of treatment of CVD on a scale from 0 to 100. All statistical analyses were based on non-parametric methods. Multivariable general linear model analyses were performed to identify demographic factors associated with the score assigned for each adverse outcome.

Results—The 807 individuals surveyed generated 723 unique sequences of scores for the 15 outcomes. The ranking of scores from least to most acceptable was stroke, major myocardial infarction (MI), cognitive dysfunction, renal failure, death, prolonged ventilator support, heart failure, angina, sternal wound infection, major bleeding, re-operation, prolonged recovery in a nursing home, cardiac readmission, minor MI and percutaneous coronary intervention. Demographic factors accounted for less than 7% of the observed variation in the score attributed to each outcome.

Conclusions—Individual community-dwelling adults living on Long Island, New York assign unique values to their preferences for potential harms encountered following treatment of CVD. Thus, risk-benefit discussions and treatment decisions regarding CVD should be harmonized to the value system of each individual.

Historically, discussions of risk of harm and benefit of a particular treatment have incorporated the biases of the practitioner, the health care system or society (1). Harms or benefits of secondary importance to the individual patient may be emphasized or, conversely, important outcomes from the patient perspective may be minimized or not discussed at all. In its 2001 report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, the Institute of Medicine challenged the American health care system to

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reinvent itself (2). Specifically, the report called for a new care paradigm “that is respectful of and responsive to individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions (2).”

Prior studies have demonstrated that clinical decisions made by patients are often more sensitive to the potential risk of harm of treatment than to the potential benefit (3, 4). Thus, understanding how patients value the potential harms or complications of a particular treatment is of paramount importance in the new health care paradigm. Despite the fact that cardiovascular disease (CVD) affects 1 in 3 adults in the United States (5), little is known about the relative value assigned to the potential harms associated with the treatment of CVD. Prior surveys have assessed patient preferences regarding a single CVD outcome such as angina in the context of coronary heart disease (6) or of 2 related outcomes such as stroke and bleeding in the setting of atrial fibrillation (7). However no study has concurrently assessed the rating of a large number of commonly occurring harms associated with the treatment of CVD. The goal of the current study was to ascertain the values assigned to the preferences for 15 harms or complications commonly encountered after the treatment of CVD among a large cohort of community-dwelling adults.

Methods

After obtaining approval of the Human Subjects Committee of Stony Brook University Medical Center, the Stony Brook University Center for Survey Research conducted this survey by telephone between October 1 and November 6, 2010 as part of the Long Island Poll. The Long Island Poll is a twice yearly telephone survey of adults who reside in Long Island, New York to assess public opinion and attitudes. A list-assisted method of random-digit-dialing was used to obtain phone numbers of land lines in the sample. Within selected households, individuals 18 years of age and over were selected at random for participation. Up to 6 contact attempts at various times of the day and week were made at each household phone number. In order to assure a representative sample, all households and individuals who initially were not willing to participate in the survey were contacted again, and an attempt was made to persuade them to participate. A total of 807 interviews were conducted. The data are weighted to match population characteristics of Long Island on gender, age, educational attainment, and race/ethnicity based on the 2009 U.S. Census American Community Survey. Weighting was done using an iterative raking process developed to estimate joint weights for demographic variables for which population percentages are known.

In addition to providing information on sex, race/ethnicity, age, education, marital status, employment status, household income and answers to approximately 30 other questions, participants were asked to assign scores from 0 to 100 to 15 potential harms of treatment of CVD in relation to their desire to avoid those outcomes (“0 means you could relatively easily accept this consequence or outcome, and 100 means you absolutely could NOT accept this consequence or outcome”). The outcomes were those most frequently reported in articles retrieved by a computerized MEDLINE search for 1986–2010 using the combination of “outcome” or “complication” with coronary artery disease, acute coronary syndrome, congestive heart failure, percutaneous coronary intervention (PCI) and cardiac surgery. We then developed simple descriptions of the selected clinical outcomes (Table 1). The order of questions was randomly assigned for each respondent with the exception of “death” which was always asked last to reduce the potential for emotional stress and subsequent attrition by the respondent before the survey was completed.

Statistical Analysis

The characteristics of the survey population were summarized by descriptive statistics (frequencies and percentages). The raw score of each adverse outcome was summarized by its observed median score and its 25th to 75th interquartile range (IQR). The percentage of missing values for the demographic factors was: gender, 0.0%; race/ethnicity, 2.9%; age, 5.8%; education, 0.7%; marital status, 1.5%; employment, 0.4%; and household income, 27%. Because of the large number of missing responses for household income, the missing values were replaced by mean household income values for the respondent's zip code based on 2000 United States census data and adjusted for inflation.

To assess the relation between rating scores for each of the 15 outcomes and each of the 7 demographic factors, univariate analyses were conducted with the Kruskal-Wallis test. Multivariable general linear model analyses were performed to identify demographic factors associated with the score assigned for each adverse outcome. Before performing the multivariable modeling, the observed raw scores of each cardiovascular outcome were first transformed into distribution-free, ranking-based scores to alleviate the potential impacts of non-normal distributions of the raw scores. The initial model used the transformed outcome and those demographic factors with a univariate $P < 0.2$ for that outcome to perform a backward, stepwise selection process. This primary multivariable modeling technique used an "available case" analysis strategy where the model included participants with missing data for some variables. All statistical analyses were performed using SAS software version 9.2 (SAS Institute Inc., Cary, NC). A 2-sided $P < 0.05$ was considered statistically significant.

Results

The household-level cooperation rate (the completion rate among all of those households reached in person by an interviewer) (8) for the survey was 38 % whereas the response rate (the number of completed interviews divided by completed interviews, non-interviews and an estimated number of how many unknown households that are eligible) (8) was 20 %. The demographic characteristics of the survey population were similar to that of the 2 constituent counties-Nassau and Suffolk- of Long Island, New York (Table 1 online).

The 807 individuals who participated in the survey generated 723 unique sequences of rating scores for the 15 outcomes. Characteristics of the participants are presented in Table 2. The survey population consisted of 60% females and 87% whites. Over half the participants were 50 years of age or above and about two-thirds had attained education beyond high school. Most (65%) respondents were married or living with a partner and most were employed (55%). The annual household income was less than \$60,000 for 45% of respondents, between \$60,001 and \$100,000 for 22%, between \$100,001 and \$150,000 for 18% and greater than \$150,001 for 16%.

The observed median rating score for each outcome along with the 25th and 75th percentile values are presented in Table 3 as is the rate of refusal to provide a score for each outcome. The rate of refusal to provide a score for each outcome ranged from 12–19%. The median scores for both stroke and major myocardial infarction (MI) were 100 and greater than the median score for death. The univariate associations between sex, age, education, marital status, employment status, household income and median scores for each of the 15 outcomes are presented in online Tables 2–7. Table 4 depicts the variables independently associated with the rating scores of each outcome on multivariable analysis. Female sex was associated with higher scores for 2 of the least acceptable outcomes-stroke and cognitive dysfunction-as well as with higher scores for prolonged ventilator support, sternal wound infection and

re-operation. Marital status (being married) was associated with higher scores for each of the 4 most unacceptable outcomes-stroke, major MI, cognitive dysfunction and death. Each age group (18–34, 35–49 and 50–64) found death significantly less acceptable than respondents aged 65 years and older. Employed individuals assigned significantly higher scores to renal failure, heart failure and re-operation-outcomes that received intermediate rating scores from the study population as a whole. For each outcome, the R^2 was 0.07 or less (Table 4) indicating that the demographic factors analyzed accounted for 7% or less of the observed variation for each outcome.

Discussion

Although 1 in 3 Americans has some form of CVD (5), to our knowledge this is the first study to document how individuals rate their preferences for many of the harms or complications that may result from treatment. The most important finding of this study is that adults residing in Long Island, New York differ significantly in their rating of the same complication associated with the treatment of CVD. Furthermore, as has been previously reported in the cancer literature (9,10), their preferences are not predicted by demographic factors such as age, sex, education, marital status employment or household income. If generalizable to the general population, these findings have important implications not only for clinical decision making, but for the informed consent process and clinical trial design as well.

Clinical Decision Making

Traditionally, clinical decision making has involved the framing of potential risks and benefits associated with various treatment options by the clinician (1). If patient preferences were considered at all they were inferred by the clinician based on his or her rapport with the patient. The ultimate decision was largely based on the judgment of the clinician. Although current concepts of patient-centered care recognize the variation in patient preferences and advocate shared decision making that incorporates these preferences (1), this model is far from universal. Shared decision making involves 3 steps, the first of which is information transfer. Information transfer requires bidirectional sharing of information between patient and clinician (11). Included in this transfer is information regarding potential risks and benefits as well as patient preferences and values regarding the various treatment options, including the option of no treatment. The second step is deliberation over the options that ultimately leads to the third step which is coming to a consensus regarding a decision.

Information transfer should allow for individualized risk estimation (12) of not only the obvious outcomes such as death but other outcomes important to patients such as those considered in the current study. Unfortunately discussions of the multiple dimensions involved in informed decision making cannot generally be accomplished within the time constraints of a clinical encounter. Integration of patient-specific risk and preferences in a point-of-care risk calculator might improve the efficiency of information transfer but no such instrument currently exists. Likewise, the integration of decision aids into discussions of treatments may increase patient involvement and lead to more informed and value-based decisions (13).

Although the philosophy of evidence-based medicine mandates clinicians to incorporate not only the best available evidence but also the patient's values, preferences and circumstances in the decision making process, clinical guidelines generally do not incorporate patient preferences into treatment recommendations (14) setting up a potential collision between evidence-based care and patient-centered care. Nease and colleagues first pointed out that the 1991 American College of Cardiology/American Heart Association (ACC/AHA) guidelines for management of chronic stable angina did not allow for the integration of

patient preferences into decisions regarding treatment of this common condition (6). Specifically, the guidelines did not incorporate the degree to which patients are concerned or bothered by their symptoms. The current study, in which angina received a median score of 70 with significant variability (IQR, 40–100), complements the study by Nease and colleagues who found that patients with the same degree of angina varied in their willingness to tolerate their symptoms. Understanding patient-specific tolerance of angina or other symptoms has important implications for the referral to more invasive treatment options which carry with them significant risk. Although coronary artery bypass graft surgery (CABG) is an effective treatment for angina (15), it is associated with adverse outcomes that many individuals in this study find significantly more unacceptable than angina including stroke, major MI, death (16) and cognitive dysfunction (17).

As another example, atrial fibrillation is the most common chronic arrhythmia and is a major risk factor for stroke (18). Oral anticoagulation dramatically reduces the risk of stroke (19) but also increases the risk of bleeding (20). Thus the prescription of oral anticoagulants needs to balance the benefit of stroke prevention against the risk from bleeding. The underutilization of oral anticoagulants in patients with atrial fibrillation (21, 22) may be due to the excessive concern about bleeding risk. However in the current study, serious bleeding was significantly more acceptable than stroke suggesting that incorporating patient values into the risk-benefit analysis would result in more patients being treated with oral anticoagulants. Devereaux et al confirmed that patients at high risk of atrial fibrillation placed more value on the avoidance of stroke and less value on the avoidance of the bleeding complications associated with anticoagulation than did physicians who treat atrial fibrillation (7). Physicians, who make treatment recommendations based on their own values without accounting for the preferences of the individual patient, even while following the recommendations of guidelines, may not be acting in the best interests of the patient.

Informed Consent

Ideally, the process of informed consent should codify the discussions involved in the process of shared decision making. But because informed consent is frequently obtained by a clinician (or their surrogate) not involved with the shared decision making process, it has been referred to as a “perfunctory” process (23) that consists of rote listing a number of risks and benefits that most patients do not recall after the process (24). In fact, studies of patients undergoing elective surgery have demonstrated that although patients believe they are adequately informed during the consent process, they cannot recall the information that was provided (25–29). Patients consenting for cardiac catheterization tend to overestimate the benefits of PCI (30, 31) and to forget the risks of the procedure (30, 32). Without a personalized presentation and understanding of risks, benefits and alternatives to treatment, patients cannot provide truly informed consent.

A recent study has attempted to integrate patient-specific data to calculate a more personalized assessment of bleeding, mortality and restenosis risks following PCI for inclusion in the informed consent process (23). Although a step in the right direction, these risks may not be those of most importance to an individual patient. In fact, the current study would suggest that the risk of stroke and major MI are of greater concern to most community-dwelling adults in Long Island, New York than bleeding and restenosis (manifested by angina or need for repeat PCI) even though they are less common. A preferred process would use patient-specific data to calculate the risks of outcomes that were of most concern to each individual.

Clinical Trial Design

Clinical trials in cardiovascular disease often utilize composite endpoints to reduce the required sample size and related cost by increasing the event rate in the control group (33–35). Composite endpoints generally combine death with other endpoints that vary in their degree of importance to individual patients such as stroke, major or minor MI, bleeding, hospitalization, angina or PCI (33–35). The sample size calculations are performed under the assumption that the individual components of the composite outcomes are weighted equally. In most trials, the majority of subjects who experience an outcome event will experience one of the less severe events resulting in the estimated treatment effect being weighted toward events that are less severe (34, 35) and of relatively less significance to the patient. Although some investigators have called for the weighting of endpoints (34, 35), as this study shows, no single weighting value would reflect the preferences of all patients. However, if clinical trials were designed from the perspective of the patient, endpoints would be weighted according to the beliefs and values of the individual patients at the time of randomization. Although sample sizes would no longer be able to be calculated prospectively, this paradigm shift in clinical research would yield clinical trial results that are reflective of patient preferences rather than extraneous factors such as trial cost.

Limitations

This study has certain limitations that should be borne in mind. First, we have no knowledge of the prior medical history of the population surveyed. Given the prevalence of CVD and the ages of the respondents, they likely consist of a mixture of adults with and without known CVD as is encountered in clinical practice. The acceptability of outcomes by patients with established CVD may differ from individuals with no CVD and is the subject of a current study. Second, there are many methods for assessing patient preferences. Because of the scope and nature of this telephone survey, a rating scale method was used for this study. Although, rating scale metrics are felt to accurately reflect the values of the general public (36), the best method for assessing preferences has not been established. Our results might have been different if other methods of health utility measurement such as time trade-off or standard gamble had been utilized (37). Third, the definitions of the outcome provided to the respondents were, by necessity, simplistic without an opportunity for discussion. Responses might have been different had more detailed definitions and subsequent discussions taken place as could occur in a clinical encounter. Fourth, we have no information on the stability of an individual response over time. It is possible that scores of an individual fluctuate significantly over time. Fifth, given the low response rate, we cannot exclude the possibility of participation bias. Finally, the preferences expressed by this study population may not apply to other populations.

In conclusion, the current study demonstrates that community-dwelling adults assigned unique preference values to the potential harms of CVD treatment that cannot be inferred from demographic data. In light of these findings, we suggest fundamental changes in clinical decision making, informed consent and clinical trial design that will incorporate individual patient preferences and values in each process.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Survey descriptions of harms/complications.

Usual Term	Description for Survey Participants
Death	Death from any cause
Myocardial infarction (major)	Heart attack which would result in permanent loss of heart function
Myocardial infarction (minor)	Heart attack which would result in no loss of heart function
Stroke	Stroke which would result in permanent loss of brain function
Cognitive dysfunction	A reduction in mental abilities such as memory, understanding and concentration.
Cardiac readmission	Readmission to the hospital for heart-related problems
Angina	Chest pain from a blocked artery in the heart
Percutaneous coronary intervention	Non-surgical treatment using small tubes placed through an artery in the leg to fix a blocked artery or arteries in the heart, also known as angioplasty or stent procedure
Re-operation	Having a repeat heart operation after a first heart operation
Heart failure	The development of heart failure, such as difficulty breathing and swelling of the legs
Renal failure	Kidney failure which would require placement on an artificial kidney machine, also known as dialysis
Prolonged ventilator support	Prolonged time, or more than 24 hours, on a ventilator
Sternal wound infection	Chest wall infection after heart surgery which would require prolonged antibiotic treatment and/or surgical removal of infected tissue
Major bleeding	Bleeding in the eye or brain or bleeding which would require a blood transfusion or surgery to stop the bleeding
Prolonged recovery in a nursing home	Prolonged, or more than 2 weeks, recovery in a nursing home

Table 2

Characteristics of the Survey Population.

Characteristic	N (%)
Total	807 (100)
Female	481 (60)
Race/Ethnicity	
White	702 (87)
Black	35 (4.3)
Asian	25 (3.1)
Hispanic	21 (2.6)
Other	1 (0.1)
Refused	23 (2.9)
Age	
18–34	64 (8.0)
35–49	180 (22)
50–64	276 (34)
65	240 (30)
Refused	47 (5.8)
Education	
High School or less	186 (23)
Some College or college degree	395 (49)
Advanced Degree	220 (27)
Don't Know/Refused	6 (0.7)
Marital Status	
Married	528 (65)
Not married	267 (33)
Don't Know/Refused	12 (1.5)
Employment Status	
Currently employed (full or part-time)	444 (55)
Unemployed/Homemaker/Student/Disabled	115 (14)
Retired	245 (30)
Don't Know/Refused	3 (0.4)
Household Income	
< \$60,000	364 (45)
\$60,001–\$100,000	174 (22)
\$100,001–\$150,000	141 (18)
>\$150,000	128 (16)
Don't Know/Refused	214 (27) *

* Prior to replacement of missing values.

Table 3

Values of potential harms/complications.

Outcome	Median (Interquartile Range)	Refusal Rate (%)
Stroke	100 (90–100)	13
MI - major	100 (75–100)	12
Cognitive dysfunction	90 (50–100)	12
Death	90 (10–100)	19
Renal failure	80 (50–100)	13
Prolonged ventilator support	80 (50–100)	14
Heart failure	75 (50–100)	13
Angina	70 (40–100)	13
Sternal wound infection	70 (30–100)	15
Major bleeding	70 (25–100)	14
Re-operation	60 (30–95)	12
Prolonged recovery in a nursing home	50 (25–90)	12
Cardiac readmission	50 (1–75)	12
MI - minor	30 (0–75)	13
PCI	20 (0–50)	12

MI, myocardial infarction. PCI, percutaneous coronary intervention.

Table 4

Variables independently associated with preference rating of each harm/complication.

Outcome	R ²	Coefficient	Standard Error	P Value [†]
Stroke	.02			
Female		34.3	12.6	0.007
Hispanic		64.5	31.0	0.04
Married		33.8	13.1	0.01
MI-major	.01			
Married		36.6	14.2	0.01
Cognitive dysfunction	.03			
Female		48.4	14.9	0.001
Married		50.2	15.5	0.001
Death	.07			
Married		56.0	15.2	<0.001
Age (years)				< 0.001
18 to 34 vs. 65		102.3	26.1	< 0.001
35 to 49 vs. 65		87.6	19.5	< 0.001
50 to 64 vs. 65		41.0	17.2	0.02
Renal failure	.01			
Employed		33.3	15.0	0.03
Prolonged ventilator support	.01			
Female		46.4	14.9	0.002
Heart failure	.03			
Employed		55.4	15.6	<0.001
Income				0.03
\$60,000 to \$100,000 vs. <\$60,000		37.5	19.7	0.06
\$100,000 to \$150,000 vs. < \$60,000		-18.3	21.1	0.39
\$150,000 vs. \$60,000<		40.6	21.8	0.06
Angina	.01			
Employed		48.5	15.1	0.002
Sternal wound infection	.04			
Female		43.8	15.5	0.005
Age (years)				0.002
18 to 34 vs. 65		75.5	28.6	0.009
35 to 49 vs. 65		67.0	21.0	0.002
50 to 64 vs. 65		62.8	18.8	<0.001
Major bleeding	.02			
Age (years)				0.005
18 to 34 vs. 65		80.8	28.9	0.005
35 to 49 vs. 65		60.2	21.2	0.005

Outcome	R ²	Coefficient	Standard Error	P Value [†]
50 to 64 vs. 65		20.4	18.8	0.28
Re-operation	.03			
Employed		40.6	17.5	.02
Female		40.6	15.8	0.01
Age (years)				0.02
18 to 34 vs. 65		35.3	30.5	0.25
35 to 49 vs. 65		71.8	23.3	0.002
50 to 64 vs. 65		38.7	20.6	0.06
Prolonged recovery in a nursing home	.004			
None				
Cardiac readmission	.02			
Age (years)				0.003
18 to 34 vs. 65		88.5	28.9	0.002
35 to 49 vs. 65		44.7	21.2	0.04
50 to 64 vs. 65		59.9	18.9	0.002
MI-minor	.01			
None				
PCI	.02			
Age (years)				0.009
18 to 34 vs. 65		98.3	29.3	< 0.001
35 to 49 vs. 65		32.4	21.2	0.13
50 to 64 vs. 65		17.3	18.8	0.36

MI, myocardial infarction. PCI, percutaneous coronary intervention.

[†] Multivariable general linear model analysis with backward, stepwise selection among demographic factors with univariate P<0.2 for each outcome.