Research Article

Interventional Cardiology

Does the type of treatment affect who makes the decision? Secondary data analysis of patients undergoing angioplasty *vs.* medical treatment for high cholesterol levels

Objectives: The objective of our study is to compare decision-making preferences regarding who makes the final treatment decision comparing two conditions: (1) Use of medication for high cholesterol and (2) angioplasty or/and bypass for coronary artery disease.

Methods: We used data from the National Survey of Medical Decisions (the DECISIONS study). All subjects completing the DECISIONS survey modules on high cholesterol medication and cardiac procedures (angioplasty or/and bypass) for coronary artery disease were included in our analysis. Our primary outcome of interest was the person who made the final decision (provider or patient). Our analyses were adjusted for the corresponding set of weights (multipliers relating the sample to the total population) and strata (subpopulations). These adjustments allow for the inference of results to a population rather than being limited to our study sample.

Results: The estimated target population comprised of 144,807,605 individuals, with a mean age of 62.2 years ± 0.53, 45.3% being female, and most were white (73.4%). Only 24.4% of all patients reported that the decision was mainly theirs. When comparing the primary outcomes between patients in both groups, a majority of individuals in the high cholesterol medication group expressed that the therapeutic decision was mainly theirs unlike those in the cardiac procedures group (24.4%±2.1% *vs.* 16.1%±5%). This finding was more pronounced among women (21.7%±2.8% *vs.* 6%±3.5%).

Conclusion: The nature of a medical intervention modifies the decision patterns and preferences of patients in the field of cardiology. Shared decision-making was not predominant among cardiac conditions.

Keywords: Shared decision making ▪ Medical decision making ▪ Coronary artery disease ▪ Angioplasty

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Introduction

When considering how to prevent and treat conditions related to coronary artery disease (CAD), patients have to make a wide range of decisions from medical therapy to angioplasty or cardiac bypass surgery. These decisions often involve discussions with primary care physicians about the benefits, risks, and alternative approaches, ultimately aimed at a balance between risks and benefits. In this context, shared decision-making (SDM) has gained a lot of attention in the past decades given its ability to increase patients' active involvement, knowledge, treatment

satisfaction, and clinical outcomes [1]. Despite positive results, findings vary considerably given the vast heterogeneity in interventions supporting shared decision making across studies. Further explanations for these conflicting results are the risks and complications of different interventions, making the outcomes difficult to compare. To our knowledge, however, no previous studies have evaluated the impact of whether a decision-making process made in the context of a medical *vs.* interventional therapy in cardiology might affect the choice of whom, the patient or the physician might make the final treatment decision.

Clinical guidelines for the prevention of cardiac diseases recommend initiating therapy in patients with a 10-year risk of a cardiovascular event of 7.5% [2,3]. Genetically determined and metabolically induced disturbances in lipid metabolism, as manifested in several types of dyslipidemia, have demonstrated to be causally related to the development of coronary artery disease [4]. Treatments for dyslipidemia are associated with adverse effects, including inflammatory muscle disease [5]. Although the adverse effects of the treatment for dyslipidemia are perceived as moderate, some authors have recommended that the decision to initiate treatment should consider patient values [6]. Shared decision-making is therefore important to have patients' input in their course of prevention of cardiovascular diseases. Despite its importance, at this point we have no information on how much value patients might attach to shared decision making when faced with treatments with different risk profiles. For example, it is unclear how patients having to decide on the use of medications for high cholesterol compared to those making decisions regarding an invasive cardiac procedure.

To address this gap in the literature, our study is aimed at comparing who the patient identifies as the final medical decision maker across two conditions and interventions: (1) The use of medication for high cholesterol, and (2) Cardiac procedures (angioplasty or/and bypass) for coronary artery disease, using the National Survey of Medical Decision Making Study (the DECISIONS study), a national sample of United States (US) adults identified by random digit dialing. Our study made use of the DECISIONS study sampling design to make inferences to the entire US population rather than restricting our conclusions to the study sample. This dataset was chosen since, although the study was conducted a decade ago, the perceived risk associated with a drug *vs.* interventional treatment is unlikely to have changed [7]. We hypothesize that the shared decision making will be predominant among patients undergoing cardiac procedures.

Materials and Methods

Our study compares the final medical decision maker between two conditions: Use of medication for high cholesterol and cardiac procedures (angioplasty or/and bypass) for coronary artery disease in the DECISIONS study using a nationwide sample of the US. Specifically, we evaluate whether the medical decisions were made primarily by participants, by their HCP or shared. The results were generalized to the population of persons aged 40 and older in the US. This study is described per the Reporting of Observational Studies in Epidemiology (STROBE) statement [8].

Ethics

The Institutional Review Board of the Hospital Ruy Azeredo, Brazil approved our study. The database is publicly available for analysis by researchers of any institution.

Settings

We used data from the National Survey of Medical Decisions (the DECISIONS study), a nationwide random-digit-dial telephone survey of 3,010 English-speaking adults aged 40 years and above, conducted between November 2006 and May 2007 at the University of Michigan. Participants completed a set of screening questions to determine their eligibility for precise decision-specific modules. Eligible individuals reported if they had taken a medical action or discussed taking any such action with a healthcare provider (HCP) for any of ten common medical decisions in the past two years. The modules included decisions related to (1) Prescription medication for hypertension, high cholesterol, and depression, (2) Cancer screening tests for colorectal, breast and prostate and (3) Surgical interventions for knee/hip replacement, cataracts, low back pain and coronary artery disease. To define the respondent burden, eligible participants were randomized to two decision modules, with the probability of inversely relating assignments to the expected prevalence of each condition. Trained interviewers conducted telephone interviews and data was collected through a computer-assisted telephone interview (CATI) mechanism. A detailed discussion of DECISIONS study sampling procedures, survey methodology, and survey instruments was described elsewhere [9]. Our present study focused on patients providing positive answers to the following two

modules: High cholesterol medication and cardiac procedures for coronary artery disease.

Participants

All subjects completing the DECISIONS modules on high cholesterol medication and cardiac procedures (angioplasty or/and bypass) for coronary artery disease were included in our analysis.

Outcomes

Outcomes of interest were the participants' decision-making preferences about the final decision maker including patients, healthcare providers, or a decision made involving both patients and healthcare providers.

Predictors

Our main predictors were the two specific condition modules of the DECISIONS study: High cholesterol medication and cardiac procedures for coronary artery disease.

Potential confounders

The following potential confounders were selected based on evidence from the previous literature: Age, gender, race, education, marital status, income, health status, having a personal healthcare provider, and health insurance coverage [10-12].

Strata

Models, especially the final decision maker including patients, healthcare providers, and both patients and providers were evaluated within strata.

Statistical analysis

We commenced with an exploratory analysis to evaluate distributions, frequencies, and percentages for each of the numeric and categorical variables, assessing categorical variables for near-zero variation [13]. Extensive graphical displays were used for both univariate analysis and bivariate associations. Missing data were explored using a combination of graphical displays involving univariate, bivariate and multivariate methods. Imputation was performed using a k-nearest neighbors algorithm (n=5) [14].

Since this dataset is representative of a larger population, the United States population, we adjusted all of our analyses for the corresponding set of weights (multipliers relating the sample to the total population) and strata (subpopulations). These adjustments allow for inferring our results to the larger population rather than being limited to our study sample. In our study, these inferences have two significant implications. First, for each of our frequencies, we report on the number of individuals in both our study sample and the corresponding overall population to whom these results apply. Second, we adjusted our confidence intervals for the target population. In other words, our results represent the correlation between the final medical decision maker relating to medical treatment and invasive interventions across two conditions in the United States population. Comparisons between groups were made by verifying the overlap in confidence intervals between different estimates, with significant differences indicated by non-overlapping confidence intervals. All analyses were performed using the R language [15] and the following packages: ggplot2, survey, and rmarkdown.

Results

Of the 3010 interviewed respondents, 1141 were eligible for the high cholesterol module and 421 for the cardiac procedures for coronary artery disease module. The analyses present the characteristics of participants adjusted for the corresponding set of weights, strata and primary sampling units and can be generalized to the United States population aged 40 and older. For example, frequencies are described for the target population of the United States, with significant differences between groups indicated by non-overlapping confidence intervals. When comparing baseline characteristics across both conditions, our estimated number for the overall target population was 144,807,605 subjects, with a mean age of 62.2 years, 45.3% being female, and most white (73.4%). Comparing both groups of individuals, those in the group of users of medication for high cholesterol presented a greater proportion of women (47.1% *vs.* 40.3%), were younger (60.6 *vs.* 66.6 years old), more educated, more frequently married, more frequently employed (49.9% ±2.5% *vs.* 29.6%±3.4%), with a higher income, and higher general health status levels (Table 1).

In the following table, we compared percentages across the three groups, inferring all results to the US population. Results were considered statistically significant when confidence intervals did not overlap between different estimates. Comparing the primary outcomes between patients in both groups, a higher proportion of patients in the medication group expressed that the decision was mainly theirs (24.4%±2.1% which does not overlap with 16.1%±5%) (Table 2).

When focusing the analysis on women, more patients in the high cholesterol medication group expressed that the decision was mainly theirs (21.7%±2.8%) compared

Table 1: Study sample baseline characteristics along with inferences for the United States population.

Variable	Use of medication for high cholesterol (105,906,517)	Cardiac procedures (angioplasty or/ and bypass) for CAD (38,901,088)
Female	49,891,991 (47.1%)*	15,665,204 (40.3%)*
Age (years)	60.59 (±0.44)*	66.63 (± 0.74)*
Education		
-High school or less	10,246,190 (9.7%)	6,334,186 (16.3%)*
-High school graduate	38,343,942 (36.2%)	16,092,151 (41.4%)*
-Some college	20,510,980 (19.4%)	6,933,250 (17.8%)*
-College graduate	20,076,407 (19%)	4,889,847 (12.6%)*
-Postgraduate	16,728,999 (15.8%)	4,651,655 (12%)*
Marital status		
-Married/Living together	72,695,518 (68.6%)*	22,413,412 (57.6%)*
-Separated	1,045,649 (1%)*	985,205.7 (2.5%)*
-Divorced	12,484,766 (11.8%)*	5,682,086 (14.6%)*
-Widowed	14,223,969 (13.4%)*	7,404,360 (19%)*
-Never married	5,456,616 (5.2%)*	2,416,025 (6.2%)*
Currently have health insurance	98,746,068 (93.2%)*	36,340,524 (93.4%)*
Income		
-Less than $25,000	23,530,445 (22.2%)	13,850,885 (35.6%)*
-Between $25,000 and $49,999	29,160,506 (27.5%)	12,274,114 (31.6%)*
-Between $50,000 and $74,999	19,646,759 (18.6%)	6,254,985 (16.1%)*
-Between $75,000 and $99,999	11,697,245 (11%)	2,088,485 (5.4%)*
-More than $100,000	21,871,562 (20.7%)	4,432,620 (11.4%)*
Race		
-Black	16,183,801 (15.3%)	5,441,037 (14%)
-Other	11,741,331 (11.1%)	5,194,758 (13.4%)
-White	77,981,385 (73.6%)	28,265,294 (72.7%)
Hispanic ethnicity	6,140,776 (5.8%)	1,917,153 (4.9%)
Employed	52,803,745 (49.9%)*	11,504,245 (29.6%)*
Health status		
-Excellent	11,763,196 (11.1%)*	2,081,426 (5.4%)*
-Very good	33,517,800 (31.6%)*	8,669,884 (22.3%)*
-Good	37,909,536 (35.8%)*	13,474,384 (34.6%)*
-Fair	15,560,978 (14.7%)*	8,720,130 (22.4%)*
-Poor	7,155,008 (6.8%)*	5,955,264 (15.3%)*
Has a primary care provider	101,568,524 (95.9%)*	36,911,995 (94.9%)*

Table 2: Primary outcomes comparing patients receiving medications for high cholesterol versus those receiving an intervention for CAD.

Outcome	Use of medication for high cholesterol (105,906,517)	Cardiac procedures (angioplasty or/and bypass) for CAD (38,901,088)
Who made the final decision		
-Mainly my decision	17,802,574 (24.4%±2.1%)*	1,121,562 (16.1%±5%)*
-Mainly the healthcare provider decision	12,381,186 (17%±1.9%)	980,201.6 (14.1%±5.5%)
-We made the decision together	42,847,128 (58.7%±3.1%)	4,857,516 (69.8%±12.1%)

to those in the cardiac procedure group (6%±3.5%) presenting a statistically significant difference with non-overlapping confidence intervals (Table 3).

When stratifying the results by age, we observed that patients over the age of 57 years old (median age for this sample) did not demonstrate any statistically significant differences in relation to decision-making preferences for the final decision maker, as the result showed overlapping confidence intervals in relation to their predicted means (Table 4).

Table 3: Decision outcome variables in women stratified by condition/intervention categories.

Variable	Use of medication for high cholesterol (49,891,991)	Cardiac procedures (angioplasty or/ and bypass) for CAD (15,665,204)
Who made the final decision		
-Mainly my decision	7,341,520 (21.7% ±2.8%)*	134,790.1 (6%±3.5%)*
-Mainly the healthcare provider decision	5,325,471 (15.7% ±2.3%)	224,273.6 (10%±5.4%)
-We made the decision together	21,181,391 (62.6%±4.5%)	1,881,403 (84%±20.7%)

Table 4: Decision outcome variables stratified by age and condition/intervention categories.

Variable	Use of medication for high cholesterol (62,054,250)	Cardiac procedures (angioplasty or/ and bypass) for CAD (29,558,256)
Who made the final decision		
-Mainly my decision	7,888,061 (19.3%±2.2%)	733,765.5 (16.6%±5.2%)
-Mainly the healthcare provider's decision	8,718,741 (21.3%±2.6%)	719,234.1 (16.3%±7.9%)
-We made decision together	24,255,981 (59.4%±3.7%)	2,970,072 (67.1%±13.7%)

Discussion

To our knowledge, this is the first study comparing patients' preferences for a final decision maker across two conditions and interventions, namely the use of medication for high cholesterol and cardiac procedures (angioplasty or/and bypass) for coronary artery disease. We found that a majority of the individuals especially females in the high cholesterol medication group expressed that the therapeutic decision was mainly theirs unlike those in the cardiac procedures group. Additionally, the patients' ages did not influence their preference for a final decision maker when stratified by different interventions.

Evidence-based medicine has facilitated the establishment of clinical guidelines in an attempt to provide patients with the best available therapies. These guidelines will, often place little emphasis on priorities from a patient perspective; causing decisions to rest on available evidence primarily [16]. Besides the accumulation of data in clinical studies, patient-oriented benefits need to be integrated into the decision-making process. In the field of cardiology, patients and physicians share decisions on a wide range of medical conditions, both of high and low risk. These options range from medical therapy to angioplasty or cardiac bypass surgery, all of which entail different risk levels. For instance, patients and physicians make choices about how to prevent and treat conditions related to coronary artery disease [17]. Patients are encouraged to discuss decisions with care providers regarding available choices to balance these risks with their potential benefits. In this context, SDM has gained attention in the past decades given their beneficial outcomes. However, findings regarding these benefits vary considerably since SDM interventions tend to differ across studies [18].

Our results demonstrate that 30% of the decisions in the cardiac procedures intervention group were not a result of SDM. This is alarming, considering the high rate of misleading beliefs among patients who underwent PCI: 88% of them believed that it would reduce the risk of myocardial infarction, while three out of four patients thought that not having this procedure would predispose them to myocardial infarction [19]. Moreover, a considerable percentage of patients were unaware of the potential adverse effects of the percutaneous coronary intervention [20]. Therefore, our results underscore the value of SDM given its ability to improve clinical outcomes, increase patients' active involvement, knowledge, and treatment satisfaction [21].

A higher proportion of patients undergoing medical treatment expressed that the therapeutic decision was mainly theirs. They were, however, less confident about the accuracy of their decisions than patients undergoing a cardiac procedure. Since an invasive procedure involves a higher risk compared to medical therapy, it is likely that these patients might experience higher stress levels. Stress makes individuals feel more confident about uncertain decisions in experimental settings [22], which may explain why participants presented greater confidence levels in the cardiac procedure intervention group. It is also possible that patients with higher perceived risks are more prone to cognitive biases that limit their decision-making capacity with sufficient information [23]. The relationship between risk perception, real-life stressful scenarios, cognitive biases, as well as the potential of decision aids should thus be further investigated to address this issue.

Our stratified analysis demonstrated differences between men and women regarding decision patterns. It is surprising that only the subgroup of women would prefer to be more involved in a medical treatment decision. It seems paradoxical that this group also prefers less involvement in angioplasty and/or bypass cardiac procedure decisions. These imbalances could be explained since men and women may use different underlying decision-making processes, women being more risk adverse [24]. An alternative hypothesis is that women might have received less information than men after an ischemic coronary event [25], which could translate into higher levels of uncertainty and different decision-making patterns. Decision aids may be a useful tool to change this disparity.

Decision-making patterns differed across different age groups. Contrary to the general population, the risk of the intervention did not influence the proportion of patients over 57 years old who expressed that the decision was mainly theirs. This finding is interesting in that autonomy is a point of concern among the elderly [26]. For example, risk perception to falls is different between the senior population and younger individuals [27].

Despite its novelty, our study does have limitations. First, our study is observational with an analysis involving association rather than causal models. We, therefore, argue that our results should be interpreted with caution and in light of other experimental or causal models. For instance, experimental studies exploring decision aids across diseases associated with different risk-perception levels will be helpful to bring further clarity into this area. Second, taking into account data regarding physicians' behaviors exclusively relying on patients' perceptions, our results could not be validated. Future studies should address this issue. Third, although the DECISION study is a decade old and might therefore not represent the most current changes in interventions, similar interventions are still being performed, and therefore the conclusions should hold for patients at the time of our study.

Conclusion

In conclusion, our study suggests that the nature of an intervention modifies the decision patterns and preferences of patients in the field of cardiology. Shared decision-making was not predominant among cardiac conditions. Given the benefits associated with shared decision-making, future clinical practice guidelines and healthcare policies should devise mechanisms to enhance its use in all circumstances. Reasons for the limited use of shared decisions in critical conditions, along with its consequences for the quality of healthcare should be described in subsequent studies. Our data also point to the need to develop and test tools that optimize the process of shared decision-making, recognizing that different characteristics across subpopulations should guide personalized decision aids. Ultimately, the goal should be to further engage patients in decisions about their health.

Executive summary

Objectives: The objective of our study is to compare decision-making preferences regarding who makes the final treatment decision comparing two conditions: (1) Use of medication for high cholesterol and (2) angioplasty or/and bypass for coronary artery disease.

Methods: We used data from the National Survey of Medical Decisions (the DECISIONS study). All subjects completing the DECISIONS survey modules on high cholesterol medication and cardiac procedures (angioplasty or/and bypass) for coronary artery disease were included in our analysis. Our primary outcome of interest was the person who made the final decision (provider or patient). Our analyses were adjusted for the corresponding set of weights (multipliers relating the sample to the total population) and strata (subpopulations). These adjustments allow for the inference of results to a population rather than being limited to our study sample.

Results: The estimated target population comprised of 144,807,605 individuals, with a mean age of 62.2 years±0.53, 45.3% being female, and most were white (73.4%). Only 24.4% of all patients reported that the decision was mainly theirs. When comparing the primary outcomes between patients in both groups, a majority of individuals in the high cholesterol medication group expressed that the therapeutic decision was mainly theirs unlike those in the cardiac procedures group (24.4%±2.1% *vs.* 16.1% ± 5%). This finding was more pronounced among women (21.7%±2.8% *vs.* 6%±3.5%).

Conclusion: The nature of a medical intervention modifies the decision patterns and preferences of patients in the field of cardiology. Shared decision making was not predominant among cardiac conditions.

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