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Patient Experience of Informed Consent for Diagnostic Coronary Angiogram and Follow-On
Treatments: A Research Brief

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Abstract

Background/Aims: Coronary angiography requires a complex informed consent process, a legal and ethical requirement before treatment, which may allow percutaneous coronary intervention (PCI) to be completed as a continuation of a coronary angiography. Patients are routinely consented for both interventions, but over a quarter will only receive diagnostic angiogram. Therefore, the specific aim of this study is to describe patients' demography, views and understanding of the informed consent process, in patients who gave informed consent for coronary angiography and same setting PCI but were found to be ineligible for same setting PCI.

Methods: A descriptive cross sectional survey design was used to explore these patients' views. Participants completed a 36-item survey on the day after diagnostic coronary angiography.

Results: Data was collected from a convenience sample of 62 subjects, 73% male, 68% college-educated, 40% working with a mean age of 68.4 (11.4) years. Women reported; greater difficulty in recalling treatment information ($p < .03$) found discussions about alternative treatments more confusing ($p < .02$), and the disclosure of comprehensive risk information a deterrent to consent

for treatment ($p < .02$), when compared to men. Higher levels of education were associated with greater preference for information and involvement in treatment decisions ($p < .002$).

Conclusions: Patients who participate in an informed consent for diagnostic coronary angiography with, or without, a same-setting PCI need clear comprehensive information on alternatives. Recognizing patient's need for information is an opportunity for nursing to provide individualized explanation and reinforcement of the information provided during informed consent.

Introduction

Patients should be fully involved in informed consent discussions, but sometimes the complexity of treatment options can make it difficult for patients to fully engage and understand the purpose, risk, benefits, and alternative treatments. Research in the United Kingdom and United States has shown that patients with suspected coronary artery disease often misunderstand the nature of cardiac diagnostic procedures and potential treatment. From this we can see that the patient's pathway is complex because decisions about treatment cannot be made before the diagnostic procedure, which enables cardiologists to directly visualize any disease inside the lumen of coronary arteries.

Patients are known to overestimate benefits, perceive percutaneous coronary intervention (PCI) as a 'fix' and are often unaware of alternatives treatments for coronary heart disease (Lee et al., 2012; Probyn et al. 2017; Astin et al. 2019; Blanchard et al. 2020). This can lead patients to set an expectation of same setting PCI. Those who do not progress to same setting PCI may be upset and disappointed when expectations about this treatment are unfulfilled impacting their

quality of life (Probyn et al., 2017), but very little is known about the perspectives of this patient group who do not have same setting PCI.

However, because PCI can be done as a continuation of a coronary angiography, informed consent is sought for both stages simultaneously, but progression to same-setting PCI depends upon the outcome of coronary angiography. Importantly, up to 28.8% of patients consented for coronary angiography and PCI will have the diagnostic coronary angiography but will not be suitable for PCI because of the pattern of disease in their coronary arteries. (Williams et al. 2010). Alternative treatments and options maybe recommended as displayed in Figure 1

Several studies have reported patients' experiences and views of the informed consent process for coronary angiography and PCI. For some there was a lack of awareness of alternatives as well as the option of no treatment (Astin et al. 2019). Some patients recalled less serious complications with coronary angiography rather than life-threatening complications (Eran et al. 2010) and others did not fully comprehend the benefits and outcomes of coronary angiography and PCI (Dathatri et al. 2014; Astin et al, 2019; Blanchard et al, 2020). However, we are unaware of any studies reporting on the views and experiences of the informed consent process for people with suspected coronary artery disease, scheduled for planned coronary angiography and PCI, but who did not proceed to the same-setting PCI.

Aim

The specific aim of this study is to describe patients' demography, views and understanding of the informed consent process, in patients who gave informed consent for coronary angiography and same setting PCI but were found to be ineligible for same setting PCI.

Research Design

Sample

A descriptive cross-sectional study was conducted to collect the views and experiences of a convenience sample of English speaking, adult patients (>18 years of age) admitted to the cardiac catheterization laboratory of a single academic medical center for planned coronary angiography with possible PCI. Patients who received planned diagnostic coronary angiography but did not progress to have a PCI were identified by the cardiac catheterization laboratory scheduler and referred to the principal investigator. Patients were excluded if they were on contact precautions, medically unstable, intubated, or unwilling to complete the study survey.

Survey

The survey was developed and has been used in other studies to assess views of informed consent for coronary angiography and PCI (Astin et al, 2019; Blanchard et al, 2020). The 36-item survey consisted of statements that participants rated on a five-point Likert scale indicating the level of agreement with each statement. Responses were scored 1 to 5 depending on the strength of agreement an individual had with a statement; a score of 1 corresponded with 'strongly agree' and a score of 5 with 'strongly disagree'. The items address the content of informed consent and are grouped into five distinct domains: purpose (9 items), attitude (8 items), risk (9 items), risk explanation (5 items) and outcomes (5 items) of coronary angiography and PCI. Cronbach alpha for the domain summary scores were 0.76 to 0.88.

Study Procedure

Following Institutional Review Board approval, the Principal Investigator approached eligible patients regarding their potential participation in the study. Patient were approached the day after coronary angiography while still hospitalized and discussions were occurring regarding treatment options. If interested, an informative letter was provided, reviewed with them, and the

Principal Investigator answered any questions they had about the research study. Consenting participants were given the survey to complete and a return envelope.

Data Analysis

Anonymized data from questionnaires were inspected before responses were entered into the Statistical Package for the Social Sciences (SPSS), version 24 (IBM, Armonk, NY) software. Responses were summarized descriptively and summary scores for each 'domain' calculated by summing mean of items for each domain and dividing by number of items for the domain. Frequency and percentages for each item response in the domains were calculated. Frequency distribution of demographic data, gender, age, employment, education, were assessed for comparisons to the summary scores of the survey. Mann Whitney tests were conducted to test the null hypothesis that the mean ranks of responses between different patient characteristics are equal (0.05 level).

Results

Seventy-six eligible patients were approached, and 62 questionnaires returned. Table 1 displays the demographic characteristics of the sample. Table 2 presents the item, summary categories and responses to the 36 items in the survey.

Almost all participants (95%) understood that a key '*purpose*' of the consent process was to inform patients about potential risks and benefits of the proposed treatment. However, most participants (85%) thought that by signing the consent form this provided evidence of them having 'choice' in their treatment. Participants '*attitudes*' showed their reliance on the doctor. Forty percent of participants agreed that most patients trust their doctor to decide for them and 38% depended upon the doctor to do so. Sixty percent of participants agreed that alternatives or other treatment options were discussed during their informed consent.

Information about the potential risks of treatment and alternatives are a required part of informed consent. About one fifth (20%) of participants agreed that such information could be worrying and/or confusing. Almost one third (31%) felt that the risk discussion could dissuade participants from having a potentially beneficial procedure. A similar proportion (48%) of participants agreed that patients do not usually understand all of the information provided to them or remember it (61%). Despite the aforementioned reservations about the disclosure of risk information, when participants were asked about '*preferences for risk information*' the majority agreed that patients should be told about the risk of death (87%) and significant disability (92%). In the 'domain' '*risk explanation*' the majority (90%) of participants agreed that a '*risk explanation*' should include all possible risks linked to treatment, whilst a few agreed that they would not want to know anything about potential risks (17%).

Most (70%), but not all recognized that the main treatment outcome of PCI was relief of angina symptoms. But a significant number of participants misunderstood some important treatment outcomes. Almost half (47%) agreed that the treatment was curative, would reduce their future risk of a heart attack (75%) and prolong their lifespan (77%).

Comparison by age groups and employment status across the five domain summary scores showed no significant difference in any of the informed consent summary scores. However, in comparing responses of men (n= 41) and women (n=16), women had a significant difference in the attitude summary score, men 3.14 (.90) versus women 2.57 (.74), ($p < .02$). Women felt information about risks may dissuade them from getting procedures (2.6 vs 3.5, $p < .02$), that information regarding alternatives was confusing (3.0 vs 3.9, $p < .02$), and women had difficulty recalling all information from informed consent (2.0 vs 2.7 $p < .03$).

In comparing difference in educational level, there was a significant difference in the attitude summary score ($p < .01$). Those subjects with a college education ($n = 22$) demonstrated a stronger desire to be a part of decisions about treatment ($< .002$) and have all potential risks discussed. ($p < .02$).

Discussion

This is the first study to provide data on patients who gave their consent for diagnostic coronary angiography and PCI which did not progress to same-setting PCI because the characteristics of their coronary artery disease made immediate PCI inappropriate. These participants are faced after coronary angiography with a significant health decision that had not been planned. This maybe at a time that they may not remember the information on alternatives from the pre-procedure informed consent process.

Participants generally understood the key principles of informed consent similar to other patients who had PCI (Astin et al., 2019; Blanchard et al., 2020). Over one third of the participants in this study agreed that they deferred to the doctor's knowledge to determine the decision for treatment while same setting PCI studies found up to 60% depended on their doctor to make decisions for them (Coulter and Collins, 2011; Probyn et al., 2016; Astin et al., 2019). This probably reflects the imbalance in power and expertise between doctor and patient but acknowledges the trust in their doctor to know what best treatment for them would be to treat their coronary heart disease.

Knowledge of alternatives is an important part of patients being fully informed. For same setting PCI studies, 65 to 80% of participants wanted to know about alternatives, compared to 60% of participants in this study (Astin et al., 2019; Blanchard et al., 2020). Knowing about alternatives treatment options is a part of being fully informed and has been found to be

consistently not explored. For these study participants this potentially set an expectation of a PCI (Probyn et al, 2016).

There was some dissonance about risk disclosure as there was agreement that such discussions could cause concern and potential put patients off a treatment. However, most, but not all wanted to know about potential risks. The use of subjective terms such as ‘low risk’ and the patient’s emotions and previous experience should be considered when discussing risks of procedures (Paling 2003).

Around half of participants agreed that patients did not understand or remember the health information provided similar to results from same setting PCI studies (Astin et al., 2019; Blanchard et al., 2020). Three quarters of participants misunderstood the treatment outcomes. Research supports symptom relief as current treatment outcome with no data supporting reduction in risk of heart attack, that PCI is curative and decreases mortality (Chacko et al, 2020; Taglieri et al. 2020; Lerman et al. 2021).

This adds to the international body of research that shows patients tend to overestimate benefits and underestimate risks of coronary angiography and PCI (McLean et al. 2011; Whittle et al. 2014; Kureshi et al. 2014; Donovan et al. 2015). The complex nature of a ‘bundled’ consent in which the diagnostic procedure, determines whether PCI is indicated can set an expectation of intervention (McLean et al. 2011; Dathatri et al 2014; Whittle et al. 2014).

Gender and level of education influenced participants’ responses. Women were more likely to report health-related information as being difficult to remember, risk discussions as a deterrent to agreeing to PCI and confusion about alternative treatments, as compared to men (Probyn et al. 2017). This may be because women tend to have greater levels of anxiety across the life course than male counterparts (McLean et al. 2011).

Participants with a higher level of education wanted more information, therefore education play a role in participation in shared decision making (Kureshi et al. 2014; Donovan et al. 2015). People with higher levels of health literacy tend to want more health-related information (Kickbusch et al. 2013).

Limitations

The survey used in this study was modified from the original for use with a patient population who did not progress to same setting PCI. There were patients who qualified for the study, who shared compelling stories but declined participation and therefore are not represented.

This study is an exploratory study in a single center with a small sample. We did not exclude patients who had previous experience with coronary angiography, and who may have had a better initial understanding of the coronary angiography and PCI consent process. Participants were required to be English speaking, were from a single center but do appear to mirror those reported elsewhere. The gender differences should be viewed with caution as this was a small sample with fewer women than men. This study did not capture the totality of the patient experience of consent for coronary angiography and PCI, having coronary artery disease and not appropriate for a same setting PCI.

Conclusion

A significant proportion of patients undergoing coronary angiography without same-setting PCI agree that they rely upon their doctor to determine treatment decisions which mitigates against the notion of patients taking the lead in shared decision making. Health information resources need to be simplified and be potentially revisited more than once in the patient journey to support comprehension and recall of components of informed consent especially benefits and alternative treatments. Decision aids that focus on early education with

simplified information have been shown to increase patient knowledge of options and outcomes of coronary angiography encouraging patients to take a more active role in the decision-making process (King and Moulton 2006).

Teach-back would be a useful technique to implement particularly around discussion about treatment outcomes where some confusion exists (Zipkin et al. 2014; Ha Dinh et al. 2016). The teach-back technique starts by providing health information to patients in small 'chunks' and in plain and simple language. The health professional then asks the patient to share the information 'back' to them in their own words. This allows the nurse to assess whether his/her teaching has achieved its aim and enables the clarification and correction of any misunderstandings and an opportunity for the patient to ask questions (Kornburger et al., 2013; Peter et al., 2015).

Gender and level of education were important variables in the understanding of the views of patient experience after this complex consent. Nurses should consider these characteristics when determining the amount of detailed information that is to be provided during the complex consenting of patients for coronary angiography and PCI. Awareness of patient uniqueness throughout informed consent is supportive of their informed decision-making.

Keywords: percutaneous coronary intervention (PCI), patient experience, informed consent, health literacy, gender

Key Points:

Patients who are prepared for coronary angiography and PCI are participating in a complex informed consent. For those women who do not have a same-setting PCI, there is more confusing about alternatives, greater difficulty in recalling treatment information and concerns with risk information. Those with higher education prefer to be more involved in treatment decisions while those with less education defer decisions to their physician. Cardiovascular nurses are in a position to provide information and explanation during informed consent.

Reflective Questions:

1. Should nurses reinforce the alternatives if asked by a patient scheduled for a coronary angiography and PCI?
2. What is shared decision making and what actions can a nurse take to facilitate shared decision making during informed consent process?
3. How would nurses prepare the patient for informed consent for coronary angiography and PCI?
4. Do you think that information about the risk of complications should be individualized for patients with significant comorbidities?
. Does your service provide easy to understand health information well in advance of elective cardiology procedures to ensure that patients with different health literacy levels can understand them?
- 5, What teaching techniques do you use to enhance patient education sessions and how to do evaluate whether they are effective or not?

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Table 1 Sample Demographics

		N (%)
Gender	Male	45 (73)
	Female	17 (27)
Education	High School or less	20 (32)
	Completed or some college	19 (31)
	Advanced Degree	23 (37)
Age	68.4 (SD 11.4) years	62
Employment	Unemployed/Retired	37 (60)
	Working	25 (40)

Table 2. Domains, Items and Responses and Summary Score* of Survey

Domain	Item	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree		
		N (%)	N (%)	N (%)	N (%)	N (%)	N Missing	Mean (SD)
Purpose of informed consent	Inform the patient about possible risks/complications	51 (84)	7 (11)	1 (1.5)	1 (1.5)	1 (1.5)	1	1.3 (.73)
	Respect the patients right of autonomy (independence to choose)	42 (70)	16 (27)	2 (3)			2	1.3 (.54)
	Educate the patients about alternative treatment options	39 (66)	11 (19)	6 (10)	1 (2)	2 (3)	3	1.6 (.98)
	Provide the doctor with greater protection against medical litigation	26 (44)	13 (22)	16 (27)	1 (2)	3 (5)	4	2.0 (1.1)
	Inform the patient about the desired benefits of the procedure	39 (64)	19 (31)	2 (3)		1 (2)	1	1.4 (.72)
	Improve the doctor patient relationship	30 (49)	13 (21)	9 (15)	7 (11)	2 (3)	1	2.0 (.72)
	Improve the patient's compliance with medical care in general (help people to know and act on what the doctor wants them	26 (44)	19 (32)	10 (17)	2 (3)	2 (3)	3	1.9 (1.0)

Domain	Item	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree		
		N (%)	N (%)	N (%)	N (%)	N (%)	N Missing	Mean (SD)
	to do about their treatment)							
	Reduce patient anxiety (stress/worry) about the procedure	28 (47)	17 (28)	8 (13)	6 (10)	1 (2)	2	1.9 (1.0)
	The consent form provides evidence of a choice in treatment (By signing the form there is proof that a discussion about treatment choices took place)	37 (61)	14 (24)	5 (8)	4 (7)		3	1.6 (.9)
	Purpose Summary Score						6	1.66 (.55) Range 1 to 3
Attitude to informed consent	Most patients trust their doctor to decide for them	8 (13)	16 (27)	15 (25)	10 (17)	11 (18)	2	3.0 (1.3)
	Most patients depend on their doctor to make decisions for them	4 (7)	17 (29)	15 (25)	15 (25)	8 (14)	3	3.1 (1.1)

Domain	Item	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree		
		N (%)	N (%)	N (%)	N (%)	N (%)	N Missing	Mean (SD)
	Disclosing (sharing) information about potentially harmful risks may be worrying and be a disadvantage for the patient	8 (13)	4 (7)	12 (20)	20 (33)	16 (27)	2	3.5 (1.3)
	Informing patients about details of alternative treatments may be confusing	4 (7)	7 (12)	14 (24)	16 (27)	18 (30)	3	3.2 (1.2)
	Discussion of risks during informed consent may dissuade the patient from undergoing a procedure that may benefit them	7 (12)	11 (19)	12 (20)	19 (32)	10 (17)	3	3.2 (1.3)
	Most patients do not usually <u>understand</u> all the information given to them during the process of consent	11 (18)	18 (30)	11 (18)	11 (18)	9 (15)	2	2.8 (1.3)
	Most patients do not usually <u>remember</u> all the information given to them during the process of consent	14 (23)	23 (38)	6 (10)	11 (18)	6 (10)	2	2.5 (1.3)

Domain	Item	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree		
		N (%)	N (%)	N (%)	N (%)	N (%)	N Missing	Mean (SD)
	Patients having urgent angioplasty are focused on thinking about their survival	25 (41)	17 (28)	8 (13)	7 (11)	4 (7)	1	2.1 (1.3)
	Attitude Summary Score						5	2.98 (.89) Range 1 to 2.9
Preference for risk information	What the procedure entails (involves)	47 (80)	12 (20)				3	1.2 (.4)
	What the procedure aims to achieve	48 (80)	12 (20)				2	1.2 (.4)
	Additional procedures that are likely to be necessary	40 (68)	16 (27)	2 (3)	1 (2)		3	1.4 (.6)
	What alternative/other treatment options are available	38 (64)	19 (32)	1(2)	1 (2)		3	1.4 (.6)
	A realistic outcome/results for the procedure	40 (67)	15 (25)	3 (5)	2 (3)		2	1.4 (.7)
	A realistic outcome/results if procedure refused	30 (51)	20 (34)	5 (8)	4 (7)		3	1.7 (.9)

Domain	Item	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree		
		N (%)	N (%)	N (%)	N (%)	N (%)	N Missing	Mean (SD)
	The possibility of death	36 (60)	16 (27)	6 (10)	2 (3)		2	1.6 (.7)
	The possibility of significant disability (e.g., heart attack, stroke, bypass surgery)	39 (65)	16 (27)	3 (5)	2 (3)		2	1.5 (.6)
	The possibility of less significant disability (e.g., bleeding, bruising, pain)	33 (56)	23 (39)	2 (3)	1 (2)		3	1.4 (.8)
	Risk Information Summary Score						7	1.4 (.5) Range 1 to 2.3
Risk Explanation	To be told about <u>all</u> of the possible risks linked to my treatment	46 (77)	8 (13)	3 (5)	3 (5)		2	1.4 (.8)
	To be told about <u>common things</u> that can go wrong linked to my treatment	47 (78)	12 (20)	1 (2)			2	1.2 (.6)
	To be told about <u>uncommon things</u> that can go wrong linked to my treatment	38 (63)	13 (22)	5 (8)	3 (5)	1 (2)	2	1.6 (1.0)

Domain	Item	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree		
		N (%)	N (%)	N (%)	N (%)	N (%)	N Missing	Mean (SD)
	To be told about <u>life threatening</u> things that can happen linked to my treatment	45 (75)	12 (20)	3 (5)				1.3 (.6)
	<u>Not</u> to be told anything about the possible risks linked to treatment	7 (12)	3 (5)	1 (2)	12 (20)	36 (61)	3	4.1 (1.4)
	Risk Explanation Summary Score						4	1.9 (.6) Range 1 to 4.2
Treatment Outcomes	The relief of symptoms	24 (41)	17 (29)	6 (10)	5 (9)	6 (10)	4	2.2 (1.3)
	Widening of narrowed coronary arteries	37 (64)	18 (31)	2 (3)	1 (2)		4	1.4 (.6)
	A cure for coronary heart disease	17 (30)	10 (17)	10 (17)	7(12)	13 (23)	5	2.8 (.5)
	A reduced risk of future heart attack	23 (39)	21 (36)	5 (8)	2 (3)	8 (14)	3	2.2 (1.3)
	A longer life span	27 (46)	18 (31)	4 (7)	1 (2)	8 (14)		2.0 (1.4)
	Treatment Outcomes Summary Scores						9	2.1 (1.0)

Domain	Item	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree		
		N (%)	N (%)	N (%)	N (%)	N (%)	N Missing	Mean (SD)
								Range 1 to 4.4

*Summary Score calculated by adding mean score for each item and dividing by number of items in each

Table 3. Gender differences in Summary Scores

	Men	Mean (SD)	Women	Mean (SD)	p
Purpose	41	1.59(.08)	15	1.85(.58)	.11
Attitude	41	3.14(.90)	16	2.57(.74)	.02
Risk	41	1.36(.43)	14	1.56(.53)	.32
Risk Explanation	44	1.94(.63)	15	1.92(.55)	.98
Outcomes	39	2.23(.99)	15	1.94(1.0)	.22