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Study Protocol for A Matter Of Heart:

A qualitative study of patient factors driving overuse of cardiac catheterization

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Abstract

Introduction:

Overuse of cardiac catheterization (CC) for stable coronary artery disease (CAD) is documented in Germany and other regions, although percutaneous coronary interventions (PCI) do not provide a benefit over medical therapy for stable patients. Various studies investigated health system, physician and patient factors driving non-adherence to guidelines which recommend a step-wise approach with invasive procedures only in case of signs of ischemia in non-invasive testing. In a larger-scale project we aim to better understand the patients' perspective in order to develop an intervention that enhances patient's acceptance of step-wise diagnostic approach for stable CAD. As a first step, this qualitative study aims to identify patient factors that prevent and promote the described overuse.

Methods and analysis:

The exploratory qualitative interview study will include about 20 patients with stable CAD and a history of acute coronary syndrome (ACS) from two German teaching practices. Narrative, structured interviews designed to last 30 to 90 minutes will be conducted. The interviews will be analyzed using qualitative content analysis by Mayring. The analysis will address the following questions: (1) What are reasons for stable patients to undergo CC? (2) How do patients deal with their heart disease (secondary prevention)? (3) Which processes do patients describe regarding decision making for non-invasive and invasive coronary procedures? (4) What information needs exist on behalf of patients to better understand the step-wise diagnostic approach outlined in guidelines and thereby avoid low-appropriate CCs? Based on these data, empirical typification will be conducted.

Ethics and dissemination:

Ethical approval for the study was obtained. All participants will provide written informed consent. Data will be pseudonymized for analysis. The findings will contribute to the development of an appropriate intervention. Results will be disseminated by conference presentations and journal publications.

Strengths and limitations of this study

- Limited research focused on the patient’s perspective; our study will bring a new perspective on the overuse of cardiac catheterization.
- Large number of interviews ensure a wide range of factors.
- New insights on how to communicate with patients are expected.
- Preselection by physicians may cause a bias.
- The study will be conducted in one geographical region; it may not be representative for other health systems or areas.

Introduction

Overuse of cardiac catheterization (CC) with and without interventions for asymptomatic patients with stable coronary artery disease (CAD) is documented for Germany, the US and Canada [1, 2]. It is estimated that 4-18% of coronary angiography procedures in the US and Canada are inappropriate according to guidelines [2]. Although conflicting data of the scope of overuse in Germany are reported, country comparisons show markedly higher rates compared to nations such as Sweden and the Netherlands, without any difference in cardiovascular mortality [3, 4].

Evidence shows that percutaneous coronary interventions (PCI) do not provide a benefit in quality of life compared to medical therapy in stable CAD [5, 6]. Therefore, guidelines recommend a step-wise approach with invasive testing for patients with signs of ischemia in non-invasive testing [2, 7–10]. A 2015 Swiss study from Chmiel et al. revealed that 37.5% (n=1018) of 2714 stable patients had not received non-invasive diagnostics prior to coronary angiography. In a retrospective study of 147 individual patient careers spanning back up to 28 years, we showed that patients with more than ten CCs in a lifetime had a higher rate of procedures classified as ‘low appropriateness’ (72%) compared to those with fewer procedures (20% in 1-5 procedures and 52% in 6-9 procedures) [11].

Analyzing factors that drive an overuse of CC studies describe three aspects, i.e. patient, physician and health system factors. Health system factors comprise, for example, the availability of and access to CC laboratories as well as economic incentives within health systems [12, 13]. A 1994 study in three UK cardiac centers showed that the use of CC varied significantly, with a higher rate of CC in the two centers with in-house cardio-thoracic surgery. The authors assumed that the physicians’ philosophy as well as the availability of surgery play a role [14]. A national cohort study of 158831 elderly patients followed for up to 7 years after a hospital stay for acute myocardial infarction showed marked differences by region of residency regarding the medical management and the intensity of invasive procedures: patients in regions with more CC laboratory capacities were more likely to receive interventional procedures, regardless of their age, clinical indication, or risk profile [15]. Similarly, a 2003 Canadian study examining payment claims for physician services in 47036 inpatients with acute myocardial infarction found that hospitals with on-site catheterization laboratories, those with university affiliations, and those closer to tertiary institutions showed a higher 90-day angiography use [16].

More recently, studies focused on physician factors driving overuse. A 2007 qualitative study asked 20 US cardiologists in focus groups about their intentions to use PCI for stable CAD. The authors showed that physicians had a firm belief in the benefits of the new technologies, such as PCI, they feared bad outcomes and being sued if they did not use PCI, and some reported negative experiences like a young patient dying of CAD. Also, physicians argued with the ‘oculostenotic reflex’ (i.e., better to visualize the coronary arteries than to rely on non-invasive results) and stated that they aim to reduce patients’ anxieties and wish to match patients’ requests [17].

In addition, studies identified various patient and physician-patient factors that drive overuse of CC. Reviewing several studies we identified four different patient factors that play a role, alone or in combination: (1) patient-physician interactions, (2) patients’ autonomy, (3) patients’ lack of knowledge and misconceptions, and (4) patients’ emotional factors. In a qualitative US study, 40 physician-patient interactions from the Verilogue Point-of-Practice Database between cardiologists and patients with stable angina were analyzed. In general, cardiologists overstated the benefits of coronary interventions and understated the associated risks and alternatives. The authors concluded that this physician communication may contribute to patients’ misperception and influence patients’ (mis-)understanding of their disease [18]. This is supported by a study from Rothberg et al. (2010), who compared US cardiologists’ and patients’ beliefs about the effects of PCI in 153 patients with elective CC. Almost three quarters of the patients were convinced that they would suffer from a myocardial infarction within the next five years without PCI; 88% believed that PCI could actually reduce their risk for a myocardial infarction, and 16 patients had CC to reduce their anxieties [19]. Both studies conclude that patients need better information strategies, especially in preference-sensitive intervention decisions. According to a US study of 472 patients undergoing coronary artery stenting, the majority of patients was not involved in joint decision-making at all: physicians discussed an alternative intervention including coronary artery bypass graft surgery or medication management in only 10% of the cases (n=43), and the physician asked about the patient’s preference in only 16% of the cases (n=69). [20]. A qualitative study in 100 participants analyzed the perceptions of CAD among Hong Kong Chinese people. The study concluded that CAD is underestimated and that there is an inadequate understanding of the disease due to a lack of public health education programs [21]. The role of emotional factors is supported by a study by Ockene at al. (1980) in 57 patients in whom normal coronary arteries and no other heart disease were diagnosed by CC. Prior to the diagnostic procedure, 79% (n=45) were convinced of suffering from heart disease; 16 months after CC, 44% (n=25) were still convinced of an undiagnosed heart disease. The study concluded that uncertainties and fears play a major role, and that this should be addressed by adequate patient information. However, such an intervention is missing [22]. Also, it is unclear whether there are different types of patients which may require different information strategies.

We assume that, to prevent overuse of CC, it is important to understand which factors influence patients' decisions for invasive procedures being asymptomatic. Therefore, this qualitative study uses a transdisciplinary approach well established in sociology and social sciences. Based on the reasons of stable patients to opt for CC, we will conduct an empirical typification to describe the relationship between a patient's attitude towards medical information and their trust in suggested treatments and decisions for CC with low appropriateness. To ensure a targeted information strategy that will match the needs of patients with stable CAD, we will integrate findings of a 2007 German study addressing patients' normative values and behavioral patterns in the health care system. Based on about 1500 randomly selected participants from the general population four types of patients were characterized: (1) the indifferent patient, who has little interest in gathering medical information and little trust in medical treatment, (2) the accepting patient, who has little interest in gathering medical information and high trust in medical treatment, (3) the skeptical patient, who has high interest in gathering medical information and little trust in medical treatment and (4) the co-physician, who has high interest in gathering information and high trust in medical treatment [23]. We expect that these four different types of patients can also be found among patients with stable CAD, and that these deal differently with their heart disease, describe different processes in decision making, have different reasons to undergo CC, and need different information strategies to avoid CCs of low appropriateness.

Methods and Analysis

Study setting and design

The interviews will be conducted in two German teaching practices which are affiliated with our Institute for General Medicine. Teaching physicians will select patients with a history of acute coronary syndrome (ACS) who underwent at least one, or better yet multiple coronary catheterization procedures with or without intervention. The interviews will be conducted by a female researcher who is qualified and experienced in qualitative research methods and interview techniques. Each interview will last about 30 to 90 minutes.

Sample size

About 20-25 patients (ideally a 70/30 male/female ratio) will be interviewed.

Inclusion criteria

Patients with history of ACS or known CAD who have undergone at least one, or better yet multiple coronary procedures will be asked to participate. Patients must be able to communicate in German in order to understand the study information sheet, to provide informed consent and to answer questions of the interviewer.

Exclusion criteria

Patients with known anxiety disorders and those who do not match the inclusion criteria will be excluded.

Recruitment and sampling

The teaching physicians will ask patients who meet the study criteria as they come to the practice for routine care. Patients will be informed that participation is voluntary, that they can contribute to a better scientific understanding in the field and that non-participation has no adverse effect on their medical care. According to the patients' wishes, the practice will arrange an appointment for the interview, or the contact data will be passed on to the interviewer who will then contact the patient by phone. The recruitment will end after 20-25 interviews are conducted and saturation is reached.

Interview guide

We will use narrative, structured interviews as a survey method, which is known for high methodological standards such as comparability, objectivity, transparency [24, 25]. The interview guide (see Table 1) was prepared by a multidisciplinary research team which includes a sociologist (A.H.) (qualified in qualitative research methods and interview techniques) and a

Board-certified primary care physician and epidemiologist (B.W.). The interview guide was reviewed by an external Board-certified primary care physician specialized in psychotherapy and supervision. To familiarize herself with the field, the sociologist performed a participatory observation in a CC laboratory and interviewed cardiac patients in a general practice. The interview guide was based on these observations and conversations with patients as well as theoretical preparatory work from the field of qualitative research, our prior retrospective study and a systematic literature review.

Compensation

The participants will receive compensation in the form of a small gift worth 10 €.

Data analysis

The interviews will be tape-recorded and transcribed according to a simplified transcription system [26] by the research team prior to analysis. The transcripts will be anonymized so that no names or other identifying features will appear in any form of data reporting. Data will be analyzed by means of qualitative content analysis according to Mayring using the summarizing approach with a combination of inductive category development and deductive category application [27]. Two researchers will work independently on a system of categories with a subsequent discussion of the systems until a consensus is reached. The interpretation will focus on emotional and factual arguments that motivate patients with stable CAD to undergo CC. In addition, the patients' needs and wishes will be analyzed with regard to strategies for a future intervention. The following questions will guide our analysis:

(1) What are reasons for stable patients to undergo CC?

(2) How do patients deal with their heart disease (secondary prevention)?

(3) Which processes do patients describe regarding decision making for non-invasive and invasive coronary procedures?

(4) What information needs exist on behalf of patients to better understand a step-wise diagnostic approach and thereby avoid low-appropriate CCs?

In order to compare different types of patients and how they deal with their heart disease, an empirical typification of patients will be conducted [28]. Objectivity and reliability will be ensured by a second coder. Validity will be verified by construct validity, the verification of the results on the basis of proven theories and/or results from prior studies on plausibility [27].

Qualitative data analysis will be performed using the software ATLAS.ti.

Possible outcome of the analysis and benefits of the study

We assume that patients have a high level of uncertainty and fears regarding an adverse outcome. From everyday experience in general practices we also presume that there is a lack of confidence in non-invasive diagnostic procedures as well as a lack of detailed information about the disease and the effectiveness of secondary prevention (lifestyle changes, medication) as well as step-wise diagnostic algorithms. Our study is designed to provide the basis for interventions supporting the health literacy of patients with known CAD on the role of diagnostic algorithms. To meet this objective, we hypothesize that the confidence in guidelines will need to be strengthened and the understanding of pathological processes improved as well as uncertainties and fears addressed in order to minimalize them. On the basis of the study results, we are planning to develop an intervention in the form of an educational video. This intervention will empower patients to improve shared-decision making together with their physicians. Overall, we aim to promote guideline adherence, reduce the number of inappropriate CC procedures and thereby decrease the risk of minor and major adverse effects including severe arrhythmias and death as well as radiation exposure.

Ethics and Dissemination

All participants will receive an information sheet outlining the study, their voluntary participation and how their personal data will be protected. All participants will provide written informed consent. Procedures for pseudonymization of the transcripts of the tape-recorded interviews will be outlined. Participants have the right to refuse answers to any question posed by the interviewer without disadvantages for the participants. The tapes will be erased on completion of the study. All electronic data will be stored in password-protected computers. Only the research team will have access to the data. Participants will not be identifiable in any publications or dissemination activities; confidentiality will be ensured by using study numbers to differentiate participant quotations. Ethical approval for the study was obtained from the Ethics Committee of the Faculty of Medicine at the University of Duisburg-Essen, Germany (15-6448-BO). The findings will contribute to the development of an appropriate intervention. Results will be disseminated within the academic field (conference presentations, journal publications) and beyond.

Authors' contributions

A. Herwig: complemented the study concept, wrote the first draft of the manuscript.

B. Weltermann: developed the study idea and concept, revised the manuscript.

Both authors critically reviewed the first draft and provided feedback on it. Both authors read and approved the final manuscript.

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Competing interests statement

The authors declare that they have no competing interests.

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Table 1: Interview guide

Topic	Question	Background
Starting the conversation	How is your heart? *Alternatively*: What happened to your heart? *Alternatively*: What have you gone through with your heart?	Patients are encouraged to speak. At the same time, as much information as possible is to be collected from the patient's point of view about the heart disease. The answer to the question is meant to show how patients deal with their illness and how they handle and process the steps of their treatment.
Understanding the disease	You have undergone cardiac catheterization. I have already seen the procedure in a heart catheter laboratory, but I cannot imagine how it feels lying there. Can you please tell me how it feels?	Patients are invited to share their experiences during the cardiac catheterization. The aim is to find out how the patients were informed about the procedure before and what impressions they were left with.
	Further question: What were your ideas/expectations regarding cardiac catheterization?	
	Further question: What did you think about the catheterization after the procedure?	
	Further question: What complications occurred during or after the procedure?	
	Further question: When did you feel most uncomfortable during the procedure?	
	Please tell me why the cardiac catheterization had to be carried out?	If it has not been explained in the narration before, the patients are asked to relate in their own words how they understood why the cardiac catheterization had to be done, what disease they are suffering from and what affects them on an emotional and factual level.
	Further question: What is your primary disease?	
	Further question: What complaints do you have?	
	Further question: When did you go to the physician regarding these complaints?	
	Further question if patient had heart attack: What did you feel when you had the heart attack?	
	Further question if patient had heart attack: What do you feel today when you think about that heart attack?	
	Further question: How did you feel when the physician told you about your disease?	
	Further question: How did you feel after you heard the results of your cardiac catheterization?	
	Please tell me, how healthy do you feel today?	The patients should talk about their state of health after the procedure and whether they are afraid of a new heart attack.
	Further question: Why do you feel unwell?	
	Further question: How big is your fear of having another heart attack?	
	What changed in your life after you had the cardiac catheterization?	The answer to this question is to find out whether the cardiac event

		had an influence on everyday life.
Information procurement	What did you discuss with your family regarding your cardiac catheterization?	We want to know how family and friends support the patient.
	Further question: How did your family react to your cardiac catheterization?	
	Further question: How did your friends react to your cardiac catheterization?	
	Further question: What did you think about **THAT SPECIAL ADVICE/OPINION**?	
	You seem to be quite well informed about your disease and the cardiac catheterization. How come?	We want to know if patients actively get informed about their disease and the treatment options and how the patients get this information.
	Further question: What do you read about your disease?	
	Further question: What advice does your family give you?	
	Further question: Do you talk about your disease with your family and friends a lot?	
	Further question: With regard to all the information you were given, what would you have said to the physician if he had told you that you do not need cardiac catheterization?	
Enlightenment by the physicians and patient-physician-relationship	Which physician did you initially contact because of your complaints?	We want to find out which physician the patients are most likely to trust and which recommendations they follow.
	Which medical examinations were done before you had your cardiac catheterization?	The intention is to analyze how familiar the patient is with other diagnostic procedures.
	How did the physician explain the need and the procedure of cardiac catheterization to you?	The aim of this question is to establish the satisfaction with the ambulatory patient’s education.
	Further question: How did the physician explain your disease?	
	Further question: What did you feel when your physician told you that you needed cardiac catheterization?	
	What did the physicians tell you during the procedure?	The aim is to ask about the satisfaction with the patient’s education as an inpatient as well as about the patient’s needs and wants regarding information.
	What do you think about the information the physicians gave to you?	
	Do you remember a situation in which you would have liked to have more information?	
	How satisfied are you with your treatment in general?	

Ending the conversation	Is there anything else you did not tell my yet but think may be of interest?	

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- Large number of interviews ensure a wide range of factors.
- New insights on how to communicate with patients are expected.
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Overuse of cardiac catheterization (CC) with and without interventions for asymptomatic patients with stable coronary artery disease (CAD) is documented for Germany, the US and Canada [1, 2]. It is estimated that 4-18% of coronary angiography procedures in the US and Canada are inappropriate according to guidelines [2]. Although conflicting data of the scope of overuse in Germany are reported, country comparisons show markedly higher rates compared to nations such as Sweden and the Netherlands, without any difference in cardiovascular mortality [3, 4].

Evidence shows that percutaneous coronary interventions (PCI) do not provide a benefit in quality of life compared to medical therapy in stable CAD [5, 6]. Therefore, guidelines recommend a step-wise approach with invasive testing for patients with signs of ischemia in non-invasive testing [2, 7–10]. A 2015 Swiss study from Chmiel et al. revealed that 37.5% (n=1018) of 2714 stable patients had not received non-invasive diagnostics prior to coronary angiography. In a retrospective study of 147 individual patient careers spanning back up to 28 years, we showed that patients with more than ten CCs in a lifetime had a higher rate of procedures classified as ‘low appropriateness’ (72%) compared to those with fewer procedures (20% in 1-5 procedures and 52% in 6-9 procedures) [11].

Analyzing factors that drive an overuse of CC studies describe three aspects, i.e. health care system, physician and patient factors. Health system factors comprise, for example, the availability of and access to CC laboratories as well as economic incentives within health systems [12, 13]. A 1994 study in three UK cardiac centers showed that the use of CC varied significantly, with a higher rate of CC in the two centers with in-house cardio-thoracic surgery. The authors assumed that the physicians’ philosophy as well as the availability of surgery play a role [14]. A national cohort study of 158831 elderly patients followed for up to 7 years after a hospital stay for acute myocardial infarction showed marked differences by region of residency regarding the medical management and the intensity of invasive procedures: patients in regions with more CC laboratory capacities were more likely to receive interventional procedures, regardless of their age, clinical indication, or risk profile [15]. Similarly, a 2003 Canadian study examining payment claims for physician services in 47036 inpatients with acute myocardial infarction found that hospitals with on-site catheterization laboratories, those with university affiliations, and those closer to tertiary institutions showed a higher 90-day angiography use [16].

More recently, studies focused on physician factors driving overuse. A 2007 focus group study asked 20 US cardiologists about their intentions to use PCI for stable CAD. The authors showed that physicians had a firm belief in the benefits of the new technologies, and they feared bad outcomes and/or being sued if they did not use PCI. Some even reported negative experiences like a young patient dying of CAD. Also, physicians argued that it is better to visualize the coronary arteries than to rely on non-invasive results (so called 'oculostenotic reflex'). Also, they aimed to reduce patients' anxieties and wish to match patients' requests [17]. In a qualitative study, 40 interactions between US cardiologists and patients with stable angina from the Verilogue Point-of-Practice Database were analyzed in detail. In general, cardiologists overstated the benefits of coronary interventions and understated the associated risks and alternatives [18].

Other studies addressed patient factors that drive an overuse of CC. A questionnaire study from Rothberg et al. (2010) showed a marked discrepancy between US cardiologists' and patients' beliefs about the effects of PCI. While physicians aimed at symptom relief, three quarters of the 153 patients with elective CC believed in a prognostic benefit and were convinced that they would suffer from a myocardial infarction within the next five years without PCI; also, 88% believed that PCI could actually reduce their risk for a myocardial infarction, while a smaller group of 16 patients stated to elect a CC to reduce their anxieties [19]. According to a US mail survey among 472 patients who had undergone coronary artery stenting, the majority of patients stated that they were not involved in decision-making at all: only 10% of the patients said that physicians discussed an alternative intervention including coronary artery bypass graft surgery or medication management, and only 16% of the patients reported that the physician had asked about their personal preference [20]. Furthermore, the role of patients' emotional factors is supported by a study by Ockene at al. (1980) in 57 patients in whom normal coronary arteries and no other heart disease were diagnosed by CC. Prior to the diagnostic procedure, 79% (n=45) were convinced of suffering from heart disease; interestingly, 16 months after CC, 44% (n=25) were still convinced of an undiagnosed heart disease. In agreement with others, this study concluded that uncertainties and fears play a major role, and that these should be addressed by adequate patient information. However, interventions with proven effectiveness to address the various factors on behalf of patients with stable CC, e.g. lack of information, inadequate risk perception, and emotional factors, are missing [21]. Also, it is unclear whether there are different types of patients which may require different information strategies.

To better prevent overuse of CC, we assume that it is important to obtain a more in-depth understanding which factors influence stable patients' decisions for invasive procedures. Therefore, this qualitative study uses a transdisciplinary approach well established in sociology and social sciences. Based on the reasons of stable patients to opt for CC, we will conduct an empirical typification to describe the relationship between a patient's attitude towards medical information and their trust in suggested treatments and decisions for CC with low appropriateness. We assume that patients have different attitudes towards the health care environment and therefore act different in it and make various decisions in same situations. To show that, we will draw on and integrate findings of a 2007 German study which addressed patients' normative values and behavioral patterns in the health care system. Based on about 1500 randomly selected participants from the general population four types of patients were characterized: (1) the indifferent patient, who has little interest in gathering medical information and little trust in medical treatment, (2) the accepting patient, who has little interest in gathering medical information and high trust in medical treatment, (3) the skeptical patient, who has high interest in gathering medical information and little trust in medical treatment and (4) the co-physician, who has high interest in gathering information and high trust in medical treatment [22]. We expect that these four different types of patients can also be found among patients with stable CAD, and that these deal differently with their heart disease, describe different processes in decision making, have different reasons to undergo CC, and need different information strategies to avoid CCs of low appropriateness.

Methods and Analysis

Study setting and design

The interviews will be conducted in two German teaching practices which are affiliated with our Institute for General Medicine. Teaching physicians will select patients with a history of acute coronary syndrome (ACS) who underwent at least one, or better yet multiple coronary catheterization procedures with or without intervention. The interviews will be conducted by a female researcher who is qualified and experienced in qualitative research methods and interview techniques. Each interview will last about 30 to 90 minutes.

Sample size

About 20-25 patients (ideally a 70/30 male/female ratio) will be interviewed.

Inclusion criteria

Patients with history of ACS or known CAD who have undergone at least one, or better yet multiple coronary procedures will be asked to participate. Patients must be able to communicate in German in order to understand the study information sheet, to provide informed consent and to answer questions of the interviewer.

Exclusion criteria

Patients with known anxiety disorders and those who do not match the inclusion criteria will be excluded.

Recruitment and sampling

The teaching physicians will ask patients who meet the study criteria as they come to the practice for routine care. Patients will be informed that participation is voluntary, that they can contribute to a better scientific understanding in the field and that non-participation has no adverse effect on their medical care. According to the patients' wishes, the practice will arrange an appointment for the interview, or the contact data will be passed on to the interviewer who will then contact the patient by phone. The recruitment will end after 20-25 interviews are conducted and saturation is reached.

Interview guide

We will use narrative, structured interviews as a survey method, which is known for high methodological standards such as comparability, objectivity, transparency [23, 24]. The interview guide (see Table 1) was prepared by a multidisciplinary research team which includes a sociologist (A.H.) (qualified in qualitative research methods and interview techniques) and a

Board-certified primary care physician and epidemiologist (B.W.). The interview guide was reviewed by an external Board-certified primary care physician specialized in psychotherapy and supervision. To familiarize herself with the field, the sociologist performed a participatory observation in a CC laboratory and interviewed cardiac patients in a general practice. The interview guide was based on these observations and conversations with patients as well as theoretical preparatory work from the field of qualitative research, our prior retrospective study and a systematic literature review.

Compensation

The participants will receive compensation in the form of a small gift worth 10 €.

Data analysis

The interviews will be tape-recorded and transcribed according to a simplified transcription system [25] by the research team prior to analysis. The transcripts will be anonymized so that no names or other identifying features will appear in any form of data reporting. Data will be analyzed by means of qualitative content analysis according to Mayring using the summarizing approach with a combination of inductive category development and deductive category application [26]. Two researchers will work independently on a system of categories with a subsequent discussion of the systems until a consensus is reached. The interpretation will focus on emotional and factual arguments that motivate patients with stable CAD to undergo CC. In addition, the patients' needs and wishes will be analyzed with regard to strategies for a future intervention. The following questions will guide our analysis:

(1) What are reasons for stable patients to undergo CC?

(2) How do patients deal with their heart disease (secondary prevention)?

(3) Which processes do patients describe regarding decision making for non-invasive and invasive coronary procedures?

(4) What information needs exist on behalf of patients to better understand a step-wise diagnostic approach and thereby avoid low-appropriate CCs?

In order to compare different types of patients and how they deal with their heart disease, an empirical typification of patients will be conducted [27]. Objectivity and reliability will be ensured by a second coder. Validity will be verified by construct validity, the verification of the results on the basis of proven theories and/or results from prior studies on plausibility [26].

Qualitative data analysis will be performed using the software ATLAS.ti.

Possible outcome of the analysis and benefits of the study

We assume that patients have a high level of uncertainty and fears regarding an adverse outcome. From everyday experience in general practices we also presume that there is a lack of confidence in non-invasive diagnostic procedures as well as a lack of detailed information about the disease and the effectiveness of secondary prevention (lifestyle changes, medication) as well as step-wise diagnostic algorithms. Our study is designed to provide the basis for interventions supporting the health literacy of patients with known CAD on the role of diagnostic algorithms. To meet this objective, we hypothesize that the confidence in guidelines will need to be strengthened and the understanding of pathological processes improved as well as uncertainties and fears addressed in order to minimalize them. On the basis of the study results, we are planning to develop an intervention in the form of an educational video. This intervention will empower patients to improve shared-decision making together with their physicians. Overall, we aim to promote guideline adherence, reduce the number of inappropriate CC procedures and thereby decrease the risk of minor and major adverse effects including severe arrhythmias and death as well as radiation exposure.

Ethics and Dissemination

All participants will receive an information sheet outlining the study, their voluntary participation and how their personal data will be protected. All participants will provide written informed consent. Procedures for pseudonymization of the transcripts of the tape-recorded interviews will be outlined. Participants have the right to refuse answers to any question posed by the interviewer without disadvantages for the participants. The tapes will be erased on completion of the study. All electronic data will be stored in password-protected computers. Only the research team will have access to the data. Participants will not be identifiable in any publications or dissemination activities; confidentiality will be ensured by using study numbers to differentiate participant quotations. The findings will contribute to the development of an appropriate intervention. Results will be disseminated within the academic field (conference presentations, journal publications) and beyond. Our study report will adhere to the consolidated criteria for reporting qualitative studies (COREQ).

Ethical approval for the study was obtained from the Ethics Committee of the Faculty of Medicine at the University of Duisburg-Essen, Germany (15-6448-BO).

Authors' contributions

A. Herwig: complemented the study concept, wrote the first draft of the manuscript.

B. Weltermann: developed the study idea and concept, revised the manuscript.

Both authors critically reviewed the first draft and provided feedback on it. Both authors read and approved the final manuscript.

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Competing interests statement

The authors declare that they have no competing interests.

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Table 1: Interview guide

Topic	Question	Background
Starting the conversation	How is your heart? *Alternatively*: What happened to your heart? *Alternatively*: What have you gone through with your heart?	Patients are encouraged to speak. At the same time, as much information as possible is to be collected from the patient's point of view about the heart disease. The answer to the question is meant to show how patients deal with their illness and how they handle and process the steps of their treatment.
Understanding the disease	You have undergone cardiac catheterization. I have already seen the procedure in a heart catheter laboratory, but I cannot imagine how it feels lying there. Can you please tell me how it feels?	Patients are invited to share their experiences during the cardiac catheterization. The aim is to find out how the patients were informed about the procedure before and what impressions they were left with.
	Further question: What were your ideas/expectations regarding cardiac catheterization?	
	Further question: What did you think about the catheterization after the procedure?	
	Further question: What complications occurred during or after the procedure?	
	Further question: When did you feel most uncomfortable during the procedure?	
	Please tell me why the cardiac catheterization had to be carried out?	If it has not been explained in the narration before, the patients are asked to relate in their own words how they understood why the cardiac catheterization had to be done, what disease they are suffering from and what affects them on an emotional and factual level.
	Further question: What is your primary disease?	
	Further question: What complaints do you have?	
	Further question: When did you go to the physician regarding these complaints?	
	Further question if patient had heart attack: What did you feel when you had the heart attack?	
	Further question if patient had heart attack: What do you feel today when you think about that heart attack?	
	Further question: How did you feel when the physician told you about your disease?	
	Further question: How did you feel after you heard the results of your cardiac catheterization?	
	Please tell me, how healthy do you feel today?	The patients should talk about their state of health after the procedure and whether they are afraid of a new heart attack.
	Further question: Why do you feel unwell?	
	Further question: How big is your fear of having another heart attack?	
	What changed in your life after you had the cardiac catheterization?	The answer to this question is to find out whether the cardiac event

		had an influence on everyday life.
Information procurement	What did you discuss with your family regarding your cardiac catheterization?	We want to know how family and friends support the patient.
	Further question: How did your family react to your cardiac catheterization?	
	Further question: How did your friends react to your cardiac catheterization?	
	Further question: What did you think about **THAT SPECIAL ADVICE/OPINION**?	
	You seem to be quite well informed about your disease and the cardiac catheterization. How come?	We want to know if patients actively get informed about their disease and the treatment options and how the patients get this information.
	Further question: What do you read about your disease?	
	Further question: What advice does your family give you?	
	Further question: Do you talk about your disease with your family and friends a lot?	
	Further question: With regard to all the information you were given, what would you have said to the physician if he had told you that you do not need cardiac catheterization?	
Enlightenment by the physicians and patient-physician-relationship	Which physician did you initially contact because of your complaints?	We want to find out which physician the patients are most likely to trust and which recommendations they follow.
	Which medical examinations were done before you had your cardiac catheterization?	The intention is to analyze how familiar the patient is with other diagnostic procedures.
	How did the physician explain the need and the procedure of cardiac catheterization to you?	The aim of this question is to establish the satisfaction with the ambulatory patient's education.
	Further question: How did the physician explain your disease?	
	Further question: What did you feel when your physician told you that you needed cardiac catheterization?	
	What did the physicians tell you during the procedure?	The aim is to ask about the satisfaction with the patient's education as an inpatient as well as about the patient's needs and wants regarding information.
	What do you think about the information the physicians gave to you?	
	Do you remember a situation in which you would have liked to have more information?	
	How satisfied are you with your treatment in general?	

Ending the conversation	Is there anything else you did not tell my yet but think may be of interest?	