MASTER THESIS

Patient Preferences for Radial versus Femoral Vascular Access Options by Coronary Angiography and Intervention (PREVAS)

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Patient Preferences for Radial versus Femoral Vascular Access Options by Coronary Angiography and Intervention

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March, 2015

SUMMARY

BACKGROUND Coronary artery disease (CAD) can lead to a symptomatic vascular blockage. Angiography (CAG) is used to diagnose the vascular blockage that may then be treated by a percutaneous coronary intervention (PCI). Both CAG and PCI require arterial access in order to reach the coronary arteries. While trans-femoral access (TFA) had been the universal default since the late 1970s, there is an increasing interest in trans-radial access (TRA) as it is associated with a reduction in haemorrhagic entry site complications and permits earlier patient ambulation. Both access-sites have advantages and disadvantages. When the study was designed neither approach was generally proven to be superior in clinical outcome, which complicates the task for vascular choice. Literature suggests that the systematic incorporation of patient preferences into the decision could be regarded of supplementary importance, as a mutual involvement of the physician and the patient in the decision may provide directions for selecting procedural options and planning health care services. However, little is known about patient preferences within CAG and/or PCI procedures.

OBJECTIVES The aim of this study was to determine patient preferences over procedural characteristics and benefits and risks of vascular access sites in CAG and/or PCI. A secondary aim is to determine patients' perspective on shared decision-making for the scheduled catheterization procedure.

METHODS In a collaboration between Thoraxcentrum Twente (TCT) of the Medisch Spectrum Twente (MST) and the University of Twente (UT), a single-centre cross-sectional prospective study was carried out. A patient preference questionnaire (PPQ) was constructed and applied among a consecutive series of patients (n=148) who were, in the period from July 2014 to august 2014, electively admitted for CAG and/or PCI procedures in the MST hospital. The PPQ consisted of four parts and focused on background characteristics of patients, patient preferences for vascular access, and patients' informational and decisional agreement regarding procedure. The choice-based method Case 2 Best-Worst Scaling (BWS) was used to elicit patients' preferences on six attributes of care: length of hospital stay, peri-procedural changing of access-site, suitability of the vessel for next procedure, post-procedural patient comfort, peri-/post-procedural bleeding, and post-procedural mobilisation. The attributes had two or three levels. Eight choice sets were presented to patients, with patients indicating the 'best' and 'worst' attribute-level in each choice set. Best-minus-worst-scores (B-W method) and conditional logistic regression (Clogit) scores were calculated to assess which attributes and attribute-levels matter most to patients and to assess the overall utility of the radial or femoral procedural option. In addition, overall preference was measured within a direct question format. Informational and decisional agreement were assessed by using an 'agree-disagree' statement-format and independent multiple choice questions.

RESULTS Patients generally preferred the femoral approach (59%) over the radial approach (41%) ($p<0.05$). The BWS method showed that patients considered the peri-/post-procedural bleeding as most important procedural characteristic, followed by the length of hospital stay and post-procedural mobilisation. More specifically, patients valued most that the procedure takes place in day-care (0.585), that there are no bleedings after procedure (0.364) and that the procedure through the vessel succeeds (0.390). Least preferred were that there will be a major bleeding which requires blood-transfusion (-0.705), the incidence of hematoma (-0.398) or that patients need to lie flat for up to 6 hours (-0.344) ($p<0.05$). Most patients indicated to understand the information about the

benefits (IQR=1) and risks (IQR=0) of procedure and knew which benefits and risks were most important to them (Mdn=2). When considering decisional agreement, patients were satisfied with the course of procedure (Mdn=1; IQR=1) and had post-procedural preferences for the current access route (84.2%). A significant amount of patients in this study desired to have more, or less decisional power in the procedure than they actually had, but only a few individuals would like the physician or themselves to be the only decision owner ($p<0.05$).

DISCUSSION & CONCLUSION Patients were slightly in favour of the femoral approach, except from those who experienced both vascular routes, who were in favour of the radial approach. Besides, patients were able to express their preferences on the most important procedural characteristics and potential benefits and risks of procedure through the BWS method. Most important to patients were peri-/post-procedural bleeding, the length of hospital stay and post-procedural mobilisation – characteristics that are positively associated with the radial access route. No evident preferred procedural access option could be elicited from patients in this study; this contributes to the fact that the decision for vascular access is a preference-sensitive decision in which the characteristics of procedure can be of different importance to individual patients or subgroups. Therefore, the study may provide insight and clinical awareness on existing patient preferences. Although different opinions were noted on the extent to which the decision should be shared, the perceived decisional agreement in this study indicates that patients appreciate to participate in (or share) the decision on vascular access in CAG and/or PCI. The findings in this study may provoke discussion on the capability and desirability of shared decision-making (SDM) in cardiology by both health care professionals and patients and may lead to better defensible choices and a more patient-centered care.

PREFACE

The preferences of patients regarding their own treatment options and the feasibility of incorporating their choice into everyday health care are subjects of current debate and recurring themes in the professional and academic career of many colleagues, as well as my own. During my former bachelor study of Higher Education in Nursing and after certification in 2010, I gained an interest in topical issues with a focus on new (technologic) innovations, especially in those that may result in improved quality of care. During an internship as a nurse trainee at a day care department, I gathered valuable experience into the field of this thesis, while I was providing aftercare to cardiologic patients who had underwent conventional trans-femoral CAG and/or PCI procedures.

For me, as a (former) nurse, it was very natural to look beyond the clinical focus into patients' perspectives and opinions. In the past I have often found myself as a middle-man in the patient-physician relationship in order to seek after quality of care, with regard to the psychical and mental well-being of patients. This project forms a bridge between my bachelor and master education, as it combines hospital work-floor knowledge and research knowledge.

The collaboration of the University of Twente and the Medical Spectrum Twente-hospital permitted a prospective data collection. The findings of study provide new data that may have potential for further research use in the Health Technology and Services Research department of the University Twente and the Thoraxcentre Twente and may eventually be of practical use in the Medical Spectrum Twente-hospital or other health care institutions.

Anneloes Fens

Enschede, March 2015

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1. INTRODUCTION

Cardiovascular disease (CVD) is a general term for diseases affecting the heart and blood vessels. According to the World Health Organization (WHO), 17.3 million people died of CVDs in 2008, representing about a third of all deaths; as a result, CVD is the number one cause of non-communicable deaths globally (Alwan, 2011).

In countries with a Western lifestyle, the accumulation of plaques in the coronary arteries is the most important cause of mortality in patients with cardiac diseases. In the early and pre-clinical stage of the disease, the accumulation of plaques in the coronary artery, also called coronary artery disease (CAD), is generally asymptomatic. Later on, limited vessel obstruction may cause mild myocardial ischemia and thoracic pain during exercise, which may first be addressed by appropriate medical therapy and lifestyle changes (Bertrand, de Palma, & Meerkin, 2010). The scope of this study is directed at the stage in which the disease has (or is presumed to have) led to a (partial) vascular blockage that can be detected with coronary angiography (CAG), which may also include Fractional Flow Reserve (FFR), and may be treated with angioplasty. During this procedure, which is also called percutaneous coronary intervention (PCI), interventional cardiologists use small inflatable balloon catheters to open the vessel and implant stents to keep the lumen open (Bertrand et al., 2010).

CAG with or without PCI requires arterial access, which can be achieved at two vascular access sites, the femoral and radial arteries. Due to its high success rate and the superior support of the guiding catheter, and despite a certain risk of serious bleeding complications, the trans-femoral access (TFA) achieved the universal default status in the late 1970s (Bertrand et al., 2010; Jolly, Amlani, Hamon, Yusuf, & Mehta, 2009; Jolly et al., 2011; Kiemeneij, Laarman, Odekerken, Slagboom, & van der Wieken, 1997). During the 1990s, the trans-radial approach (TRA) was developed. Initially only a limited number of centres used this technique as their primary approach for CAG procedures (Campeau, 1989; Jolly et al., 2009; Kiemeneij & Laarman, 1994).

During the last decade, the refinement and miniaturization of stents permitted the use of guiding catheters with smaller diameters that were better suited for use through the (relatively small) radial artery. In parallel to recent improvements in the procedural success of PCI with modern devices (Lam et al., 2014; Man & Birgelen, 2012; von Birgelen et al., 2014), the focus of attention is shifting from the technical success of the coronary intervention to the prevention of access site complications. As a result, there is a growing interest in an alternative to TFA (Bertrand et al., 2012). Randomized controlled trials and a meta-analytic study have suggested that radial access for CAG and/or PCI is a safe and effective alternative to the femoral approach, while the radial technique is associated with a reduction in haemorrhagic entry site complications and permits earlier patient ambulation (Bertrand et al., 2012; Bertrand et al., 2010; Jolly et al., 2009; Jolly et al., 2011).

A debate regarding the optimal vascular access site for CAG and/or PCI procedures is ongoing, since both access-sites have their advantages and disadvantages (Rao, Bernat, & Bertrand, 2012), but when the study was designed, neither one was proven to be generally superior in terms of clinical outcomes (Bertrand et al., 2010; Jolly et al., 2009; Jolly et al., 2011). It was previously shown that the benefits and risks of different health care procedures can be valued differently by patients and physicians (Schwalm, Stacey, Pericak, & Natarajan, 2012; Sepucha & Mulley, 2009). As a result, the decision on vascular access is considered a preference-sensitive decision, though in practice, this decision is commonly based on the surgeon's expertise. Literature suggests that taking into account patient preferences into the decision-making can complement to the body of clinical and procedural evidence regarded in the choice for procedural option (Brennan & Strombom, 1998; Russell-Johnson, 1995; Ryan & Farrar, 2000; Woolf et al., 2005). Furthermore, the Dutch health care system has placed an emphasis on shared decision-making since it has been reformed in 2006, to make care more patient-oriented and demand-driven (van der Weijden et al., 2011).

RELEVANCE OF THE STUDY

The expanding role of patients in medical decision-making (MDM) is driven by several contemporary developments such as an increased patient autonomy (patient empowerment), broader access to informational resources, increase of chronic illnesses as vascular diseases, expanding clinical options and accompanying trade-offs, and a growing appreciation for personal values in health care (Sepucha & Mulley, 2009; Woolf et al., 2005). In addition, patient communication became an integral part of medical school, allowing for more democratic dialogue in the clinical encounter.

Literature suggests that in usual care patients are involved in a brief discussion with the treating cardiologist regarding the potential vascular access options; however the extent of patient-involvement in the decision is not always clearly reported and can differ between health care practices and between health care professionals (DosReis et al., 2014; MST, n.d.; Schwalm et al., 2012; Sepucha & Mulley, 2009). As vascular access is a preference-sensitive-decision this complicates comparing the benefits and harms of procedure. A systematic incorporation of patient preferences, along with professional expertise, may provide directions for selecting procedural options and planning care services (Brennan & Strombom, 1998; Pieterse, Berkers, Baas-Thijssen, Marijnen, & Stiggelbout, 2010; Ryan & Farrar, 2000; Zimmermann et al., 2013). The inclusion of patient values into the decision may lead to more patient-centered treatment plans which correspond to the priorities of the individual and may lead to better defensible choices in the care setting (DosReis et al., 2014).

RESULTS FROM EARLIER STUDIES

Through literature review it was found that a few prior studies studied patient preferences in relationship to the vascular access route in CAG procedures. In a study by Cooper et al. (1999) 200 patients were randomized to either the radial or femoral procedure and a significant amount of patients had a strong preference for trans-radial catheterization. In the ACCESS-study 75% of the patients who underwent diagnostic trans-femoral CAG and trans-radial PCI preferred the radial approach because of the more rapid post-procedural ambulation (Kiemeneij et al., 1997). However, the corresponding survey data remained unpublished. According to the RIVAL study, in which patients were randomly assigned to a vascular route, patients preferred radial vascular access to femoral access for subsequent CAG procedures (Jolly et al., 2011). Of those who underwent the radial route, 90.2% had a radial preference, and those who underwent the procedure through the femoral route, 50.7% preferred the radial route. A more recent publication by Schwalm et al. (2012) assessed the use of a patient decision aid in the choice for vascular access, and 150 patients were randomized to use a decision aid or not. In both groups a majority of patients (73.7% and 78.8% respectively) preferred the radial access route. The decision aid consisted of a description of the vascular options and the associated risk and benefits, as: serious bleedings, procedural failure (access-site crossover), required bed rest following procedure, procedural time (amount of contrast / radiation exposure) and access-site complications (vascular blockage / bruising). In a value clarification exercise patients valued six statements on an 'agree-disagree' scale; 3 in favour for one of the vascular access routes, and then made a final decision for vascular access or withdrawal from the decision. The use of the decision aid was associated with reduced decisional conflict, improved patient knowledge on procedural options and improved value agreement between desired and chosen procedure. A total of 76.3% patients selected actively their access route of choice compared to 39.2% without the decision aid. The authors state to be the first to report on the concept of formally involving patients in the decision-making process regarding vascular access in CAG and/or PCI procedures. Except from this study, no literature was found that assessed patients' valuation to participate in (i.e. share) the decision on vascular access in CAG.

RESEARCH QUESTION

The primary aim of study is to assess the optimal procedural option for CAG and/or PCI from a patients' perspective by establishing the relative importance of the distinct attributes of TFA and TRA. A secondary aim is to determine patients' perspective on shared decision-making.

The following central research question of this master assignment will be answered by means of four sub-questions.

"What is the preferred access-route for elective angiography and/or intervention according to patients and how do patients appreciate shared decision-making?"

1. Which favourable and unfavourable attributes of femoral and radial angiography can be distinguished and to what extent do they occur?
2. What is the relative importance of the attributes of femoral and radial angiography from a patient perspective?
3. Which vascular access-route is preferred by patients?
4. How do patients appreciate shared decision-making?

A literature review was applied in order to develop a theoretical framework, which is presented in the next section of this report. Based on the framework a quantitative measurement instrument, the 'Patient Preference Questionnaire', was developed in order to elicit patient preferences. Data were collected and were analysed with the aid of a statistical analysis plan. The results are presented and discussed in the final sections of this study.

2. THEORETICAL FRAMEWORK

2.1 PATIENT PERSPECTIVE

MEDICAL DECISION-MAKING APPROACHES

Hunink & Glasziou (2012) state that medical decision-making (MDM) comprises the process of making trade-offs between benefits, risks, costs and preferences in health care by integrating the best available evidence from literature. Several approaches for medical or treatment decision-making exist, which have different implications for the patients' and physicians' role in the professional relationship and on the type and flow of information between them. The professional paternalistic approach, in which the physician makes the decision in the best interest of the patient without exploring individual values, has been the most common approach in health care for centuries. The extent of patients' involvement in medical decision-making has been limited to both the micro-level of patient-physician consultation, as well as to the macro-level of planning and developing health care services (Charles, Gafni, & Whelan, 1997). Literature suggests however that the dependent relationship in which decisions are made on behalf of the patient without patients' involvement does not fit modern democratic society and has therefore been rejected by organizations as the World Medical Association (WMA). From a political point of view, patients have the right to participate in decisions that affect their own life (Williams, 2009). The international code of medical ethics states that patients have jurisdictions to choose the preferential treatment if more suitable and by law approved treatment options are available (Campeau, 1989; Elwyn, Edwards, Kinnersley, & Grol, 2000). In the trend towards more patient decision-making responsibilities, rigorous models as informed choice are described in literature, in which the patient makes an informed-decision without professional guidance (Sepucha & Mulley, 2009; Woolf et al., 2005), however a more moderate model is most advocated in which preference-sensitive decisions are shared. Within a shared decision-making approach, physicians have more interactive relationships with patients and their families, by developing a treatment recommendation which is consistent with the individual preferences and values, and where both parties can agree upon (Elwyn et al., 2000). A prerequisite for the approach is the sharing of information. While the physician is well informed about the diagnostic techniques, treatment options and prognosis, the patient has information about one's physical condition and one's own values and preferences. In the professional relationship information exchange from physician to patient is especially important to ensure the patient is well informed of treatment options and accompanying risks and benefits (Russell-Johnson, 1995). Information exchange from patient to physician is valuable as it may result in a more personalized care plan that is consistent with patient's values and, as a result, increases the legitimacy and the accountability of the vascular decision (DosReis et al., 2014). Both types of knowledge are required to organise health care services successfully and both parties should therefore be prepared to take the reciprocal responsibility to share all relevant information for the subsequent treatment decision.

The difficulties surrounding the decision-making process have already resulted in the development, evaluation and implementation of shared decision-making in some areas of care, as the chronically ill (Schwalm et al., 2012). In cardiology more patients will be diagnosed and treated for cardiovascular disease compared to the current situation, and more health care practices will provide both the radial and femoral approach in CAG procedures. The usual patient-physician consultation regarding vascular access options comprises a brief explanation or discussion on arterial access options and the associated benefits and risks. Since the cardiologic field has entered an era of patient-care optimisation, a more systematic involvement of patients' values in the preference-sensitive decision process of vascular choice (TFA versus TRA) is a contemporary and notable field of attention (Rao, Cohen, Kandzari, Bertrand, & Gilchrist, 2010).

PREFERENCE ELICIATION THROUGH A CONJOINT METHOD

Patient preferences refer to statements made by individuals regarding the relative desirability of a range of treatment (characteristics) or health outcomes (Brennan & Strombom, 1998). Preferences can arise from a variety of aspects, such as the actual problem faced, personal values and norms, socio-demographic characteristics or the physician-patient interaction (Elwyn et al., 2000; Sepucha & Mulley, 2009). As patient preferences may influence choices, interest was developed into the elicitation of subjective values through decision theory, in a way that makes them actually accessible in a clinical encounter (Hansson, 1994). The conjoint analysis (CA) technique is based on Lancaster's theory of value which assumes that any good or service can be described by its characteristics or attributes (Lancaster, 1971). In the 1990s the conjoint analysis (CA) was developed in mathematical psychology. The technique has strong theoretical basis and is gaining widespread use in several areas of health care, for instance to elicit patients values on the optimum treatment strategy (Ryan et al., 2001).

Conjoint Methods can be classified as ranking, rating and choice-based techniques. In the ranking method, respondents are presented with a number of scenarios involving a combination of attribute-levels and are asked to list these in order of importance. The options which achieve the highest ranking are considered the most important. A second quantitative method is the rating technique, for which respondents are asked to assign a score to the scenarios on either a numeric or semantic scale in order to measure respondents' preferences. A common rating technique is the Likert scale in which individuals respond to statement on an 'agree-disagree' scale. A third quantitative method is choice-based in which respondents are presented with scenarios that involve different combinations of hypothetical but realistic choice options of the treatment options. Respondents are then asked to choose the preferred option in each scenario. All of the techniques elicit individual preferences and potential antecedent choices directly from respondents i.e. stated preferences (SP) in contrast to retrospective revealed preferences (RP) obtained from prior records (Ryan et al., 2001).

Although ranking or rating techniques have a relative ease to complete, in this study a choice based CA technique was applied because it poses actual choices and incite trade-offs in a decisional context (Brennan & Strombom, 1998). The CA choice based method involves five main stages (table 1) and starts with the identification of the independent attributes of the treatment options (stage I). Then a range of plausible levels on categorical or ordinal scale are assigned to the attributes (stage II). Then scenarios are constructed by selecting from every attribute an attribute-level by the use of experimental design (stage III). By conducting a survey, the preferences' for the attribute-levels in the choice experiments i.e. scenarios can be elicited (Stage IV). The final analysis is based on Random Utility Theory which assumes a latent utility scale in individuals when making decisions. When the attributes in the scenarios are competing a value utility function can be estimated. Regression techniques are used to analyse responses, by estimating the total individual utility value. Total utility is estimated from al the relative weights (utilities) assigned to the attributes of the treatment option

(Flynn, Louviere, Peters, & Coast, 2007; Ryan et al., 2001). In this study the technique enables to elicit overall patient preferences regarding femoral access and radial access in CAG and/or PCI procedures in order to determine the optimal treatment strategy from the patient perspective based on measures of the individuals in the sample.

Table 1. Five main stages in CA based on the choice-based method.

Stage I	Identification of attributes (i.e. characteristics) that are important in achieving the overall stated objective of the study
Stage II	Assigning levels to these attributes
Stage III	Using experimental designs to reduce the number of scenarios that individuals are presented with down to a manageable level
Stage IV	Eliciting preferences using choice experiments
Stage V	Analysing the data using a regression technique
Ryan et al. (2001)	

There is discussion on the CA method and discrete choice experiments (DCEs) as the methodologies are mixed-up in literature but are not considered to be synonymous (Louviere, Flynn, & Carson, 2010). In the context of this study the discussion will be disregarded and DCE will be seen as a specific form of CA, which will not be further specified.

BEST-WORST SCALING DESIGN

The conjoint technique Best-Worst Scaling (BWS) is based on the comparative judgements of individuals when facing choices and is developed and pioneered by Professor Jordan Louviere in 1987. Despite early resistance on the potential lack of added value, the technique receives much attention in preference research (Louviere, Hensher, & Swait, 2000). Traditional choice-based methods include a series of choice questions and respondents have to select the preferred alternative (Arons & Krabbe, 2013). A shortcoming of this conventional method is the need for a large amount of scenarios (i.e. choice sets) to enable estimating the overall preferred choice from the aggregated dataset (Flynn et al., 2007). BWS overcomes this shortcoming through requiring participants not only to report a 'top' choice in a probabilistic choice set, but also to report the 'bottom' choice, in order to quantify the attributes over which one can develop preferences (Flynn & Marley, 2012; Marley & Louviere, 2005). The bottom choice provides information about less attractive choice options in health care, which is crucial since societal interest is bipolar and is both directed to attractive health features as well as to negative features, such as very poor health states and negative side-effects of treatment (Flynn et al., 2007). BWS possesses higher discriminating power, since choice data obtained can be expanded into best-worst pairs (Flynn, 2010). The value utility function reflects the cognitive process of individuals when facing choices, in BWS this resembles the identification of the best-worst pairs of attribute-levels with maximum difference (MaxDiff) in terms of individual preferences (Marley & Louviere, 2005). In this manner BWS maximizes analytic efficiency, since both information on best and worst selection, as well as non-selection, is gathered from each individual.

BWS CASES

BWS could be applied for the purposes of data augmentation and process of theory (i.e. the psychological model for human choice making) (Lancsar, Louviere, Donaldson, Currie, & Burgess, 2013). In BWS three cases could be identified: the object case (Case 1), the profile case (Case 2) and the multi-profile case (Case 3), presented in ascending order of complexity between the choice options (Flynn & Marley, 2012).

In Case 1 BWS respondents make a simple ranking between objects without an attribute-level structure. How often one option is chosen over another indicates the respondent's value to that option. Although easy to apply, the case does not give information about the relative importance of options and cannot evoke trade-offs between competing alternatives. Health economists are generally not familiar with Case 1 BWS (Flynn et al., 2007). In Case 2 BWS a single and complete profile with varying attribute-levels is presented to respondents in each choice set. A profile is a complete health care good or health care outcome defined by attributes and levels. Respondents are asked to select the 'best' and the 'worst' attribute-levels within that profile. This case is often used in marketing and health economics for reasons that the impact of included attribute-levels associated with treatment can directly be compared on a common utility scale (Flynn et al., 2007; Flynn & Marley, 2012). Case 3 BWS is an extension of the more traditional choice-based methods, in which 'best' and 'worst' choices are made between multiple profiles (i.e. ≥2 treatments). The technique is increasingly popular in health economics, environmental studies and psychology since Case 3 BWS mirrors the selection of treatment options in a realistic setting and more information can be yielded than by presenting a single profile (Flynn et al., 2007).

RATIONALE CASE 2 BWS

In this study a Case 2 BWS was chosen as it has some advantages over the others. First of all, the impact of included attribute-levels associated with treatment can directly be compared on a common utility scale. In contrast Case 1 cannot be used to estimate overall utility as no profile is constructed and Case 3 uses multiple utility scales per attribute (Flynn, 2010). Although statisticians have shown that the optimum information is provided when a more complicated multi-profile Case 3 is applied (Louviere et al., 2000), this method is considered to be too cognitively demanding for specific subgroups as individuals within a high age category or people that are psychologically or physically vulnerable. The latter is especially important as respondents were asked to participate into the study just after the invasive procedure took place. For the same reason no extensive full ranking method as non-sequential or repeated BWS was considered suitable, regarding the higher time span and an increase in the psychological load. Case 2 BWS was perceived suitable in the context of this study as the Thorax Centrum Twente (TCT) posted a question on a comparison between two vascular access options (TFA and TRA) within CAG with or without PCI, which will be regarded to be a single procedure in context of this study and can therefore be compared within a single profile. In addition, the study is directed to measure overall preferences and is not concerned with the individual psychological process beyond the decisions made. In this study the treatment options were not specified to respondents, potentially making the choice less realistic comparing to real-life decision-making, meanwhile, the respondents were not able to direct the outcome of BWS, even when they were in possession of information on the treatment options (van Til, 2009).

2.2 CLINICAL BACKGROUND

When cardiovascular disease (CAD) has led to a (partial) vascular blockage, this can be detected with CAG and treated with PCI. During this procedure, a small inflatable balloon on a wired catheter is guided under X-ray imaging from the puncture site, through arterial blood vessels until the potential blockage in the epicardial coronary artery is reached (Bertrand et al., 2010). By PCI the vascular obstruction or occlusion will be removed by inflating the balloon to open the coronary artery lumen and by inserting drug-eluting stents to prevent the vessel from re-occlusion. The choice for vascular access by CAG and/or PCI is the first technical consideration of cardiovascular procedures and can influence its overall success (Bertrand et al., 2010; Schwalm et al., 2012).

In interventional cardiology, multiple access sites can be distinguished for CAG and/or PCI. In the pioneer era of PCI, the brachial artery (TBA) was the standard access-site, followed by the femoral artery (TFA) access which achieved the default status in the late 1970s (Bertrand et al., 2010; Kiemeneij et al., 1997). The Seldinger trans-femoral approach to cardiac catheterisation has dominated the explosive growth of invasive cardiology in the past decades. Continual evolution of device technology and antithrombotic regimen has resulted in the application of PCI to a wider population of patients. As current PCI procedural success rates are high and cardiac events relatively rare, evolution of PCI practice has led to an emphasis on minimizing peri- and post-procedural vascular complications (Agostoni et al., 2004; Rao et al., 2012). Bleeding complications after PCI are most commonly related to the vascular access site and associated with an increased risk of post-PCI morbidity and mortality (Rao et al., 2010). In the Netherlands, Dr. Kiemeneij and colleagues therefore applied the first trans-radial (TRA) angioplasty in the early 1990s, and currently there is a resurgence of interest in upper limb trans-radial CAG (Bertrand et al., 2012; Kiemeneij et al., 1997). Despite early enthusiasm for TRA, technical and material limitations confined the use of trans-radial PCI and restrained TRA to become a standard procedure (Agostoni et al., 2004; Rao et al., 2010). During the last decade, the refinement and miniaturization of stents permitted the use of guiding catheters with smaller diameters that were better suited for use through the relatively small radial artery (Safirstein, 2013). A consistent body of evidence, including the outcomes of the ACCESS and the RIVAL study, has suggested that radial access for CAG is a safe and effective alternative for the femoral route (Jolly et al., 2011; Kiemeneij et al., 1997). The vascular access site selection has ever since evolved with an increasing worldwide use of the TRA instead of the TFA, especially in Europe and Asia, were 48% and 42% of procedures are performed with the TRA respectively (Bertrand et al., 2010; Erbel & Wijns, 2014). In contrast, in the United States the TRA is used approximately in one out of six PCI procedures, and it is growing steadily (Safirstein, 2013).

PRINCIPAL BENEFITS AND HARMS OF TFA VERSUS TRA

Both TFA and TRA by catheterization procedures have principal benefits and harms (table 2). Since arterial puncturing and catheter insertion and manipulation can lead to injury and vascular complications the reduction of local access related bleeding is a principal benefit of the radial technique compared to the femoral technique (Jolly et al., 2009; Kiemeneij et al., 1997). Due to its superficiality the artery is easily to reach, which facilitates passive compression, both manual or by a pressure device to obtain haemostasis. No major veins or nerves are located in close proximity of the radial artery, minimising the risk of injury to surrounding tissues. Since the radial artery is accompanied by the ulnar artery to provide blood supply to the upper limb, arterial occlusion will not directly endanger the viability of the hand (Bertrand et al., 2010; Jolly et al., 2009; Jolly et al., 2011; Kiemeneij et al., 1997).

However, several vascular complications are related to the small size of the radial artery. The radial manoeuvre is more complicated due to anatomic variation and tortuosity of the artery and as a result TRA has more procedural failures and access-site crossovers than the technically straightforward femoral technique. Radial procedures therefore requires clinical experience, small diameter equipment, and should be carried out with delicacy (Bertrand et al., 2010; Kiemeneij et al., 1997). The radial artery is a muscular artery which can develop (severe) spasms, which may result in patient discomfort and may expend procedural time and radiation exposure (Jolly et al., 2011), although there are contradictory findings (Kuipers et al., 2012). Vascular complications after trans-radial PCI mainly are or lead to the occlusion of the radial arterial access site (Agostoni et al., 2004; Rao et al., 2012). For instance, a recent systematic overview by Jolly et al. (2009) states that the radial approach was associated with a trend towards a higher rate of contemporary or consistent inability to cross the coronary lesion with a wire, balloon, or stent, compared to the femoral approach. In addition, a significant number of patients have to undergo re-angioplasty (or a PCI of another coronary lesion at a later stage of the disease), which makes preservation of the patency of the arterial access site particularly important (Archbold, Robinson, & Schilling, 2004). The true incidence of radial artery occlusion and its clinical sequel for re-access are, however, still unresolved issues (Rao et al., 2012). In contrast, femoral access allows for procedures with larger diameter catheters and has demonstrated to have a shorter procedural time and consequently shorter X-ray exposure and a reduced volume of contrast (Erbel & Wijns, 2014; Jolly et al., 2011).

Overall, trans-radial access is considered a safe and effective alternative for trans-femoral access, since the technique enables a wide range of interventions and radial access is associated with fewer (haemorrhagic) vascular complications compared to the femoral vascular route. Complications after radial access PCI are considered relatively benign, and most can be managed conservatively. In contrast, serious vascular complications that may occasionally arise from femoral access PCI, such as large haematomas or retroperitoneal bleeding (Trimarchi et al., 2010), often require transfusions or surgical interventions (Jolly et al., 2009; Jolly et al., 2011; Kiemeneij et al., 1997). In addition, the femoral approach generally requires the use of an entry site closure device as Angioseal (a plug) or a Proglide (subcutaneous suture), which may cause peri- or post-procedural discomfort. Trans-radial catheterization allows for earlier patient ambulation, since it requires bed-rest for a significantly shorter period of time. Prospective recovery of the trans-radial approach may be achieved on cardiac day care department on chairs with specific arm boards or even by immediate mobilisation with a supportive sling. In order to sustain recovery and reduce the chance of inguinal access-site bleeding, the trans-femoral approach requires post-procedural flat bed-rest, which may cause discomfort, especially for those patients who suffer from lung diseases or back problems (Archbold et al., 2004). Although the predictability and stability of recent angioplasty allows for same-day discharge in elective patients for both the radial and femoral approach, literature suggest that procedures through the radial access-route may be associated with earlier hospital discharge (Agostoni et al., 2004; Bertrand et al., 2012; Erbel & Wijns, 2014).

Table 2. Advantages and disadvantages TFA and TRA.

	TFA	TRA
MAIN ADVANTAGES	Has the default status since late 1970s, much clinical experience, potential long-term effects known Straightforward technique through large diameter artery and therefore higher success rate Allows for procedures with large diameter sheaths, catheters and equipment Post-procedural occlusion of the femoral access site is extremely rare	Relatively few local access site complications and complications are mostly benign Artery easy palpable, which facilitates compression and haemostasis No veins or nerves located in proximate, minimising risk to surrounding tissues Backup of ulnar artery in case of radial artery occlusion, maintains arterial perfusion of the hand Relatively quick patient ambulation, no need for flat bed rest
MAIN DISADVANTAGES	Greater chance of significant access-related bleeding, due to large diameter of the artery Post-procedural flat bed rest to reduce inguinal access-site bleeding Requires entry site closure device (e.g. Angioseal, Proglide), which may cause peri- or post-procedural discomfort Occasionally causes large haematomas or (potentially lethal) retroperitoneal bleeding, which may require blood transfusion and/or surgical intervention	More complicated manoeuvre due to small diameter, anatomic variation and tortuosity, which may lead to procedural failure and access-sites cross-over Technique has a learning curve, and requires interventional cardiologists to be experienced in this approach Muscular artery with propensity of developing (severe) spasm, causing discomfort and increasing procedural time and radiation exposure Higher likelihood of developing an access site artery occlusion (radial artery occlusion)

3. METHODOLOGY

3.1 STUDY DESIGN

The study had three phases. At first attributes that were relevant to patients were identified and appropriate levels were selected. Then a measurement instrument 'the patient preference questionnaire' (PPQ) was developed and piloted to test for suitability and completeness. After some minor changes were made to the PPQ patient preferences for vascular access were gathered from a consecutive series of patients undergoing CAG and/or PCI procedures at a medium-volume secondary and tertiary care facility; the MST hospital (Enschede, the Netherlands). The hospital has a thorax centre and employs both procedures through the trans-radial and trans-femoral approach. From June 2014 till July 2014, all patients who were electively admitted for diagnostic CAG or therapeutic PCI procedures were approached by the author to participate in the survey. Patients with an insufficient command for the Dutch language in terms of reading and writing were excluded from study as they were considered to be unable to answer the rather complicated Dutch BWS choice questions in the questionnaire, and, consistent with the regulations of the Medische Ethische Toetsings Commissie (Medical Ethics Review Committee, METC), patients to which the questionnaire was likely to put a psychical emotional burden, were excluded from study. BWS does not allow for traditional statistical power calculation to determine the size of the statistical sample of the study population. In literature, heuristics for sample size determination and rules-of-thumb are suggested, based upon personal experience and judgement rather than statistical principles. A common rule of thumb is that for quantitative studies, were no subgroups are compared a quantity of about 300 respondents is required (Louviere et al., 2000; Orme, 2006). However, the sample size required to produce meaningful results in the context of this master thesis was set by the University of Twente on ≥100 respondents.

3.2 THE PATIENT PREFERENCE QUESTIONNAIRE (PPQ)

INSTRUMENT DEVELOPMENT

A literature review was conducted in order to develop a theoretical framework. Based on the consistent body of evidence a quantitative measurement instrument was constructed, existing of four parts (appendix I). In order to logically present the data in context of this study, the order is adjusted into; patient characteristics (part IV PPQ), preference elicitation for vascular access (part II,III PPQ) and informational and decisional agreement (part I, III PPQ).

PATIENT BACKGROUND CHARACTERISTICS

In the research protocol of study it was described that baseline patient information would be extracted from the digital information system of the MST. However, the need for only limited information and the possibility to guarantee respondents anonymity, advocated for the inclusion of the questions in the PPQ. The demographic characteristics of respondents were identified within four questions regarding: age, gender, highest educational level completed, and Dutch nationality. In addition, two questions were directed to the medical background of respondents regarding prior angiography or intervention (and the associated vascular access route), and the vascular access route of the current procedure. Patient characteristics were included in order to better understand existent preferences among respondents and to reveal potential differences between subgroups (Ryan & Farrar, 2000).

PREFERENCE ELCITATION FOR VASCULAR ACCESS

The preference elicitation part consisted of two phases. At first the attributes and attribute-levels for the trans-radial (TRA) and trans-femoral approach (TFA) for CAG and/or PCI were selected. Secondly, stated preferences were elicited in the PPQ. As described in section 2.1, BWS was the selected method for preference elicitation.

Since no existing classification model was found, the development of BWS instrument was supported by evidence from published literature, clinical practice guidelines and expert consultations, to ensure clinical and practical relevance. Multiple clinical and procedural characteristics which may be influential on patient vascular access choice were identified, operationalized and restructured into attributes. Six attributes were selected for study, these were; length of hospital stay, peri-procedural changing access-site, suitability vessel for next procedure, post-procedural patient comfort, peri-/post-procedural bleeding and post-procedural mobilisation (sub-question 1). The statistics from literature on these attributes are summarized in a quantitative consequence table (appendix II). A total of fifteen levels were assigned to the six attributes (table 3).

Table. 3 Consequence table on treatment attributes and associated levels.

ATTRIBUTE		LEVEL 1	LEVEL 2	LEVEL 3
1.	**Length of hospital stay**	The procedure will take place in day-care	After procedure, you will be admitted to the hospital for one night	After procedure, you will be admitted to the hospital for two nights
2.	**Peri-procedural changing access-site**	The procedure through the vessel succeeds, there will be no need to puncture another vessel	The procedure through the vessel does not succeed, another vessel will be punctured	
3.	**Suitability vessel for next procedure**	A potential next procedure can be performed in the same way	A potential next procedure will have to be performed through another vessel	
4.	**Post-procedural patient comfort**	After procedure, you will be limited in your daily activities for 24 hours	Till 3-4 days after procedure you will only be able to perform easy i.e. not heavy activities	
5.	**Peri-/post-procedural bleeding**	There will be no bleedings after procedure	You will get a hematoma and local pain after procedure	You will get a major bleeding which will be treated with a blood transfusion
6.	**Post-procedural mobilisation**	You will be able to directly mobilize after procedure	You will need to lie flat for 2-3 hours after procedure in order to recover	You will need to lie flat for up to 6 hours after procedure in order to recover

In order to increase the likelihood that from patients' 'best' and 'worst' selections in the BWS choice sets patients preferences could be elicited, suitable levels were identified in the attributes. Consequently some levels were ordinal (attributes 1,4,5,6) and others were categorical (attributes 2,3) (DosReis et al., 2014). Another distinction can be made between preferences measured by process aspects; the characteristics of treatment options (attributes 1, 4, 6), and preferences measured by the outcome aspects; the favourable and unfavourable or side-effects of treatment options (attributes 2, 3, 5).

Four versions of the PPQ were designed in order to prevent for version effect (Louviere et al., 2008). The versions were designed with the use of statistical software, which allocates the attribute-levels to the BWS choice sets (appendix IV, table 1). To get meaningful results, a sufficient number of scenarios had to be included, whilst not overburdening respondents. While the number of possible designs in this study was large (i.e. $\text{levels}^{\text{attributes}}$; 3^3*2^3= 216 scenarios) a subset of treatment designs from the original full factorial design was extracted, using a D-efficiency design (Louviere et al., 2000; Marshall et al., 2010). With this model it was estimated that when having 4 versions, 15 overall items (attribute-levels), 6 items per set (scenario), the number of sets (scenarios) in each design should be between 8 and 13. In order to limit the cognitively load it was chosen that each version of the questionnaire includes the minimum of 8 scenarios. Choice modelling is BWS is achieved through the aggregation of the selected best-worst pairs in the choice experiment. Attributes should be displayed in the same frequency in order to put equal focus on the attribute-levels, which have then a balanced statistical probability of being chosen in the choice experiments (Flynn & Marley, 2012). Although all attributes were presented in the BWS treatment scenarios, the levels within two-level attributes are logically more frequently shown (16 times) to respondents in the choice experiment than levels in the three-level attributes (10 or 11 times). Each attribute-level was shown between 1 up to 5 times in the 8 scenarios of each version (appendix IV, table 2).

After giving respondents an oral and written instruction on choosing the overall 'most desirable' and 'least desirable' attribute-level in the BWS choice sets, a sample question was given. This question had no direct relation to the study in order to prevent respondents from being influenced by the given answers. In order to counteract further inaccuracies special semantics were applied, which focus on the relation of words and phrases and the inclusion of smiley symbols to facilitate answering the BWS questions. In addition, a reminder was placed after the first question to emphasize that two opposing options should be selected in each choice scenario and the question is repeated within each choice scenario. Based on a series of trade-offs respondents made between hypothetical scenarios that contain different combinations of attribute-levels, utility scores for the attribute-levels and attribute importance scores could be obtained for the two vascular access routes (sub-question 2). By measuring the attribute weights (i.e. importance) at the end, the method will indirectly elicit the vascular access-site preferred by patients (Flynn & Marley, 2012; Ryan & Farrar, 2000).

After the BWS choice experiments, respondents were informed about the existence of the two safe and effective vascular-access routes for CAG and/or PCI procedure. A total of six variables were presented to respondents in a table, which were the probability of: hematoma on the lateral side of the lower limb, procedural failure, hematoma, major haemorrhagic complications, vascular occlusion and procedural success through the first selected vascular route. The variables differed slightly from the variables in the BWS choice experiments since: patient comfort, length of hospital stay and post-procedural ambulation were not included, and hematoma on lateral side of upper limb and procedural success were added. This alteration was applied in order to be able to add to all attributes, quantitative ranges of occurrence for both the radial and femoral vascular option. Respondents were asked to select the preferred treatment option, knowing which qualitative and quantitative ranges were belonging to which treatment option. This part enables to elicit direct stated preferences as expressed by the respondent, which could thereafter be compared to the indirect preference from the BWS questions. In a second open-ended question respondents were asked to state the incisive attribute for the expressed preference. The question provides additional information and allows for comparison with the weights assigned to the attribute-levels in the BWS choice experiments, in order to give a comprehensive answer on sub-question 3.

INFORMATIONAL AND DECISIONAL AGREEMENT

A Likert-Scale was used to elicit patient's level of agreement on a series of six statements (table 4). The statements focussed on satisfaction with the course of procedure, patients' perceived understanding of the advantages and disadvantages of procedure and their valuation of the information about procedure (table 4). The traditional Decisional Conflict Scale (DCS) has been used to select statements which are scaled within the satisfaction subscale (statement 6), the informed subscale (statements 1,2,4) and the values clarify subscale (statements 3,5) (O'Connor, 1993). Statements had six response categories on an 'agree-disagree' scale with in the middle a neutral 'neither agree nor disagree' option and at the end a 'not-applicable or no opinion' option, to prevent respondents from being forced to give incorrect answers. As only a part of the statements from the DCS instrument were incorporated into this study, no decisional conflict could be measured on a validated scale. However, the statement on satisfaction may give information on the willingness of patients to be part of the decision. Statements in the informed subscale and values clarify subscale may reveal information on patients' awareness on important procedural characteristics and their capability on valuing these characteristics (Sepucha & Mulley, 2009).

Table 4. Statements by subscale.

SUBSCALE	STATEMENT
Satisfaction subscale	6. I am satisfied with the course of my procedure
Informed subscale	1. I am sufficiently informed about my procedure 2. I am aware of the benefits of procedure 4. I know the risks and side-effects of my procedure
Values clarify subscale	3. I know what benefits are most important to me 5. I know what risks and side-effects are most important to me

Two other questions in the PPQ were directed to the decision owner of treatment. Respondents were asked to give their perception on the current decision owner of treatment and who the decision owner of treatment should be. The questions were Multiple Choice (MC) and the choices were ranging from solely the physician to solely me. The agreement between the questions may give implicit information about patients' valuation of their decisional power, hence to take part in the decision regarding their own treatment. The questions on informational and decisional agreement were incorporated to preliminary assess patients' view on shared decision-making (sub-question 4).

INSTRUMENT PILOT

After the construction of a paper-version instrument, its content and construct were evaluated with regard to its ability to elicit patient preferences by the supervisors of study and several health care workers of the cardiac research department. In addition, a small pilot phase was set up among the study population in order to access the feasibility of the questionnaire from a patients' perspective. The insights obtained were followed by some adjustments to the PPQ (appendix III). After the adjustments in the pilot phase a research protocol was provided to the Raad van Bestuur (Board of directions, RvB) for approval.

INSTRUMENT APPLICATION

The study was, by the author, introduced to the members of the cardiology department in a presentation, which aimed at information provision in order to cultivate acceptance and enthusiasm. The structure and activities on the cardiology department were assessed, and three possible survey moments were detected; prior to hospital admission at the information session, directly post-procedural at the hospital department, or several weeks after procedure. Due to logistic considerations, it was decided to contact patients directly after the scheduled procedure. Four versions of the questionnaire were about equally (not randomized) distributed to eligible patients in the cardiology department. Eligibility was verified with the responsible nurse. In order to inform patients about the survey a patient information folder (PIF) was provided to the patients at the moment of post-procedural encounter (appendix I). The provision of written patient information was supplemented with a short oral explanation on some objectives of study (to create acceptance and induce participation) and an explanation on the questioning technique in the BWS choice experiment (to increase a correct questionnaire fill-in). Only a small group of vulnerable patients received extensive guidance by filling in the questionnaire, for reasons of convenience or physical dysfunction. Patients, who were not able to finish the questionnaire during day-shift, could return the questionnaire to the medical staff or the secretary. Patients who were not able to complete the questionnaire during hospital admission received a postal envelope to return the questionnaire by mail to the cardiology department of the MST. A digital version of the PPQ was designed with the survey method tool LimeSurvey (Schmitz, 2012), in order to be able to store and process the upcoming data.

In addition, an online version of the PPQ was designed in order to expand data-collection. Due to the inquiries of the RvB the approval for the application of the PPQ was delayed, and the online version was set up to secure the attainment of the predetermined sample size (n≥100). The online PPQ was aimed at patients with coronary artery disease (CAD) and was posted online on three cardiac patients' fora: Patiëntenvereniging Hart&Vaatgroep (www.hartenvaatforum.nl), Stichting Hartpatienten (www.hartpatienten.nl), and Forum Hart Volgers (www.hart.volgers.org). Since the data-collection started shortly after the written approval of the METC and RvB in the end of May 2014 and the predetermined sample size (n≥100) was reached at the beginning of July 2014, the online data collection became of secondary importance.

3.3 DATA-ANALYSIS

In this study the gathered data were treated confidentially and were processed and analysed anonymously with regard to the Wet Bescherming Persoonsgegevens (Privacy laws, WBP) and the prevailing privacy regulations of the MST. Data were entered and stored in LimeSurvey (Schmitz, 2012). Data were processed and analysed in the database Microsoft Excel 2010, and using software packages IBM SPSS Statistics 20 and StataCorp LP STATA 13, to perform descriptive, correlation and regression analysis.

PATIENT INCLUSION

Patient statistics were registered throughout the data-collection period to get an accurate view on the study sample. Returned questionnaires were assessed to comply with minimal requirements on correctness and completeness and a registry was kept on the types of errors detected. One flaw in one part of the questionnaire is considered to be 1 error and more errors can be detected in each questionnaire. Since BWS analysis requires flawless choice-sets, 22 questionnaires were found unsuitable for analysis (appendix V).

Although an online survey was constructed, it was chosen to exclude the obtained data for analysis, since a large enough hospital data sample was obtained and to prevent the MST hospital sample to get contaminated with data from another sample, in which more than half of the data were incomplete.

PATIENT CHARACTERISTICS

At first descriptive univariate analysis was applied to get insight into the demographical features of respondents. The variables age, gender, Dutch nationality, and highest education completed were presented in a table with totals (no.) and percentages (%). Due to its high distribution the variable 'Age' was clustered into Low age category (30<50), Middle age category (50<70), and High age category (70<90). The same holds for the variable 'Highest education completed' in which the 7 educational streams were clustered into Low educated (Primary education, MAVO, LBO), Middle high educated (HAVO, MBO), and High educated (HBO, WO i.e. University). Secondly, univariate and bivariate analysis was applied on the medical history of respondents. Frequencies on earlier CAG and/or PCI procedure(s) and the current procedure were presented in a crosstabulation.

PREFERENCE ELCITATION FOR VASCULAR ACCESS

Descriptive analyses were applied on data of respondents explicit or direct choice for vascular access route (no.,%). To assess if there was an actual difference between the stated preferences for the radial and femoral vascular access option a statistical Chi-square test (for one variable) was applied to estimate a p-value. The p-value gives a probability between 0 and 1 and represents the strength of the association. Al statistical tests in this study were performed at a significance level of 5% ($p<0.05$) to conclude if there is strong evidence against the null-hypothesis (H^0), which states there is no relationship or no difference between one or more variables. In contrast, the alternative hypothesis (H^a) states there is an actual relationship or difference between the variable(s) (Huizingh, 2007). In a bivariate analysis stated preferences were measured by demographic factors (age, gender, education) and were presented in a table (no.,%). A Pearson Chi-square test (for independence) was performed to measure if the two nominal variables were independent (unrelated) or represent an actual relationship. Along with the stated preference respondents gave a rationale for their choice for vascular access. Data gathered from the standardized response options were presented in a table (no., %). Thereafter the data were clustered, along with responses given by respondents to the open-question format. The clusters are divided into factors that relate to: experience, concerns about haemorrhagic complications, chances of success, post-procedural mobilisation, and possible pain and discomfort associated with a particular vascular access route. Descriptive analysis was applied on the total respondents falling within each cluster and the most important categories within the clusters. In order to assess the relationship between stated preference and the current vascular access route, bivariate analysis was applied. Finally, the multivariate association between respondents' stated preference, the experience of earlier CAG and/or PCI procedures and the associated vascular access, and current vascular access, was analysed. The variables were presented in a table (no.). A Pearson Chi-square test was performed to assess if preferences in patients who experienced both vascular access routes was different to those in patients who experienced a single vascular access route. This analysis provides insight into the association between stated preference for vascular access and (prior) vascular experiences. Also the association with gender in these groups was assessed.

Analysis of best-worst data was conducted both by presenting best minus worst (B-W) scores, and by calculating a maximum likelihood based model; the conditional logistic regression (CLogit). Since the analysis was concerned with the elicitation of overall preferences for vascular access, the analysis was applied on the aggregated sample level.

Utility scores were estimated using the B-W scores method. Best and worst counts represented the times the attribute-level was chosen as best or worst within the 8 choice sets for all respondents in the sample. Proportions of best and worst counts were estimated by dividing the counts by the overall number of times the attribute-level was shown to respondents in the survey. B-W proportions (i.e. B-W scores) were subsequently estimated by subtracting the 'worst' proportion from the 'best' proportion. Data on the B-W analysis were presented in a table (no.,%). Proportion values can vary between 1 and minus 1, and a higher (positive) B-W proportion represents an attribute-level that was more often selected as best than worst and was likely to be more preferred relative to the other levels within the attribute. Conversely, a lower (negative) B-W score was chosen more often as worst than best, and was likely to be less preferred relative to the other levels in het attribute (DosReis et al., 2014). No statistical t-test could be applied to measure the significance of the B-W scores due to the choice for aggregated data-analysis instead of data-analysis on the level of the individual. In addition best and worst counts were presented in a scatterplot to assess the inverse relationship; as we expect attribute(levels) with high best counts to have minimal worst counts and those with high worst count to have minimal best counts (Flynn & Marley, 2012).

Once B-W scores were calculated for each attribute-level, within attribute variance was calculated by subtracting the lowest attribute-level proportion from the highest attribute-level proportion. Thereafter, the variation within the attribute was divided by the total variance of the attributes, to get the conditional attribute importance. Moreover, a subgroup-analysis was performed on the demographic factors (gender, age and education) to assess the impact of these variables on conditional attribute importance. Data were presented in a clustered bar-chart and in appendix VI.

It is important to use alternative approaches to assess whether the results obtained are consistent. Logistic analysis is used as the ranking depth of the dependent variable is dichotomous (radial vs. femoral) and het conditional element is based on the fact that the choice for the dependent variable depends on the features of that variable. Conditional logistic regression was used to determine the location of each attribute on the underlying latent scale. Therefore data were restructured, expanded and paired into all possible combinations of best-worst choice sets. Through applying Clogit a set of coefficients was calculated, that indicate the chosen choice set. A Likelihood Ratio (LR) Chi-square test was applied to assess if coefficients were statistically significant, and the coefficients, Standard Errors, and significance levels were presented in a table. As by the B-W method, the Clogit coefficients represent the impact of each attribute-level to the overall utility of the vascular access options. In order to get all utility coefficients on the same difference scale in the regression model, a reference value was set. Preliminary analysis on attribute-level importance, found the second level of the attribute 'suitability vessel for next procedure' (A3L2) to have a minimal impact on respondents' preference, and the level was therefore set on '0' as a reference attribute-level. This means the impact of each attribute-level is relative to the reference-level A3L2. Attribute variances were calculated and graphically depicted and the results were compared to those in the B-W method. Greater differences between minimum and maximum coefficients in the attribute, implicate a greater conditional importance of the attribute in respondents' choice for vascular access.

In order to elicit the actual implicit or indirect preference for vascular access following from the BWS analysis, the utility scores of attribute-levels that can be directly linked to the femoral or radial route were separately summed. Then the lowest score on a treatment option was subtracted from the highest score and divided by the total variance within the Clogit coefficients. The estimate represents the preferred vascular access route relative to the other access route (Flynn & Marley, 2012).

INFORMATIONAL AND DECISIONAL AGREEMENT

Responses on the statements in the Likert-scale regarding patients satisfaction with the course of procedure, their perceived understanding of the advantages and disadvantages of procedure and their valuation on the information about procedure, were presented in a table (no.,%). On the individual level of statements and on the aggregated level of the subscales a measure of central tendency (Median, Mdn) and a measure of dispersion (Interquartile range, IQR) was calculated. The median represents the value were half of the data is located below and half is located above, IQR represents the middle half of the data. Mdn values ≤2 indicated agreement and high values ≥4 indicated disagreement on the statement or subscale, and IQR≤1 Indicated that values are clustered around the Mdn. To further assess informational agreement, data analysis on individual patient level was applied into the distribution of respondents' disagreement on statements. Bivariate analysis was applied on data of the satisfaction statement and the current vascular access route. Descriptive analysis on patient perception and normative perception regarding the decision owner of treatment was applied (no., %), and results on decisional agreement were presented in a clustered bar-chart. To assess if answers in the two ordinal variables 'the current decision owner' and the 'normative decision owner' were significantly different in terms of median and distribution a non-parametric Wilcoxon Signed Rank test was applied (Huizingh, 2007). Thereafter, bivariate analysis was applied on respondents' perceived decisional power and the amount of decisional power respondents would like to have. The results were presented in a counts table with highlighted sections for both 'less' and 'more' decisional power than desired.

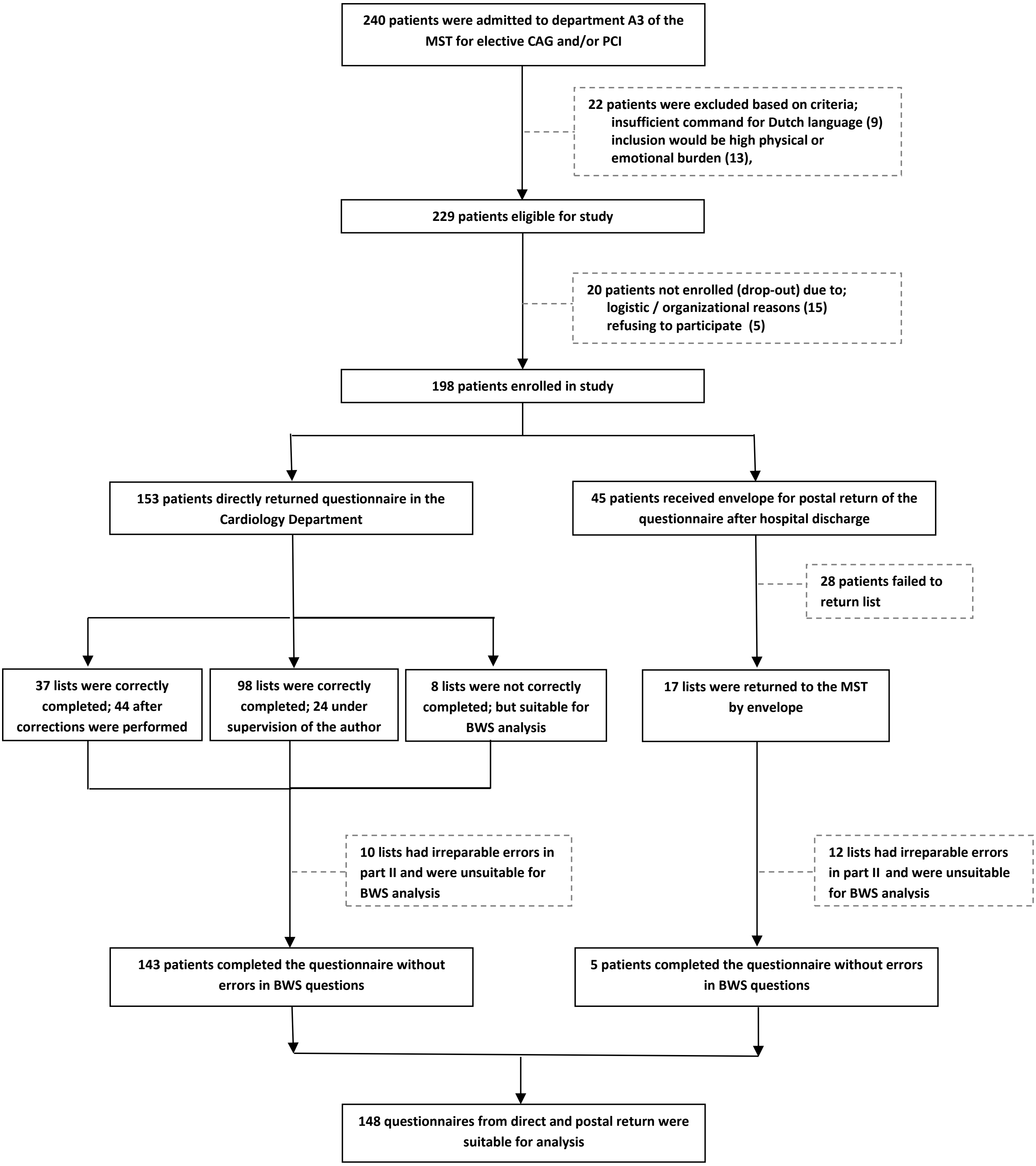
4. RESULTS

4.1 PATIENT INCLUSION

Between June 2014 and July 2014, all patients undergoing planned CAG and/or PCI at the MST hospital of Enschede (the Netherlands) were screened for their eligibility to participate in the patient preference study. From the 240 electively admitted patients in the hospital department, 22 patients (9.2%) were excluded from the study based on the predetermined exclusion criteria outlined in paragraph 3.1. Thereafter, another 20 (8.3%) eligible individuals dropped-out from study (figure 1) leaving a data collection of 198 patients.

Two ways of data-collection were performed; the mainstream data collection in the department (n=153, 77.3%) and a parallel data collection of distributed questionnaires for postal return after hospital discharge (n=45, 22.7%). In the department some patients received hands-on assistance filling in the questionnaire (n=24, 12.2%) because of physical constraints as a result of the trans-radial procedure (TRA; n=9), having flat bed rest following trans-fermoral procedure (TFA; n=7) or because of other reasons. Following the criteria outlined in paragraph 3.3, 148 out of 170 returned questionnaires (87%) were considered suitable for analysis (figure 1, appendix V). This represents 75% of the 198 enrolled patients.

Figure 1. Flowchart on patient inclusion.



Note: The questionnaire consisted of four parts; part II comprised the BWS choice questions.

4.2 BACKGROUND CHARACTERISTICS OF PATIENTS

All patients had been scheduled for CAG and/or PCI procedure in the MST hospital and underwent the procedure through the femoral or radial route before participating in the study. A total of 100 patients were male (67.6%) and 48 were female (32.4%) (table 5). Almost two-third of the patients (n=94, 63.5%) were between 50 and 70 years old, almost a third (n=43, 29.1%) was between 70 and 90 years old and only a few patients were between 30 and 50 years old (n=10, 6.8%). Few patients in the study (n=8, 5.4%) were born in a foreign country. When considering the educational level, most patients (n=65, 43.9%) were low educated, about a third (n=51, 34.5%) was middle high educated and the smallest group consisted of patients who were highly educated (n=30, 20.3%) (Table 5).

Table 5. Demographic characteristics of patients.

Characteristic	Total N=148
Gender	
Male	100 (67.6%)
Female	48 (32.4%)
Age	
30<50	10 (6.8%)
50<70	94 (63.5%)
70<90	43 (29.1%)
Nationality	
Dutch	139 (93.9%)
Foreign	8 (5.4%)
Education	
Low educated	65 (43.9%)
Middle high educated	51 (34.5%)
High educated	30 (20.3%)

Notes: Numbers do not always count to the total because of missing data. Education is classified into: low educated (primary education, MAVO, LBO), middle high educated (HAVO, MBO) and high educated (HBO, WO).

More than half of the patients (n=81, 54.7%) had previously undergone CAG and/or PCI procedure(s). From those procedures, almost all patients had femoral access procedures (n=79, 97.5%), while a minority had a previous radial access procedure (n=10, 12.3%). Some patients had previous CAG and/or PCI procedural through both vascular access options (n=8, 9.9%). Experience with both vascular access routes can be explained by the fact that patients had underwent two or more previous procedures or because they had to undergo both procedures during the same treatment.

In the current procedure, almost two-third (n=94, 63.5%) of the patients underwent a CAG and/or PCI procedure by the femoral access route and 55 patients had the radial access route (37.2%). Only two patients experienced both vascular access routes during the current procedure as arterial access through the first access route did not succeed (table 6).

When considering the current procedure and previous procedures, a total of six patients experienced the radial access route during an earlier procedure and the femoral access route in the current procedure. Conversely, 29 patients experienced the femoral route in an earlier procedure and the radial route during the current procedure. One patient did experience the femoral access route in a previous procedure and both the femoral and radial route during the current procedure. One patient did not undergo earlier procedures but underwent both femoral and radial vascular access during the current procedure. Therefore, a total of 36 patients experienced both vascular access routes in CAG and/or PCI procedures, which is about a quarter (24.3%) of all patients in this study.

Table 6. Crosstabulation on current performed procedure by previously performed procedure.

		Current procedure			TOTAL
		Femoral	**Radial**	**Femoral AND Radial**	
Previous procedure	**None**	41	24	1	66
	Femoral	45	25	1	71
	Radial	1	1	0	2
	Femoral AND Radial	5	3	0	8
TOTAL		92	53	2	147

Note: Numbers do not always count to the total because of missing data.

4.3 PREFERENCE ELICIATION FOR VASCULAR ACCESS

After patients were presented with the characteristics of the two vascular access options, more than half selected the femoral route as the preferred access route (n=88, 59.5%), which reflects a significant difference in preference among the patients (X^2=5.721; p=0.017; p<0.05). About three-quarters of female patients (n=47, 73.9%) preferred the femoral access route, while in male patients (n=100) preferences were evenly distributed among the two vascular access routes (X^2=5.722; p=0.017; p<0.05). A preference for femoral access was consistent across all age categories, and was strongest in patients between 30 and 50 years old and patients between 70 and 90 years old, in which categories approximately 70% preferred the femoral access route. The age groups had a comparable distribution of male and female patients. Although the age groups differed in preference, the difference is not large enough to be statistically significant. No noticeable differences in preferences were found within the educational levels (table 7).

Table 7. Frequencies on overall preference and preference by gender, age and education.

	Radial	Femoral	P-value
Overall preference	59 (39.9%)	88 (59.5%)	
Preference by gender			0.017
Male	47 (47.0%)	53 (53.0%)	
Female	12 (26.1%)	34 (73.9%)	
Preference by age			0.231
30<50	3 (30.0%)	7 (70.0%)	
50<70	43 (46.2%)	50 (53.8%)	
70<90	13 (30.2%)	30 (69.8%)	
Preference by education			0.653
Low educated	25 (38.5%)	40 (61.5%)	
Middle-high educated	22 (43.1%)	29 (56.9%)	
High educated	12 (41.4%)	17 (58.6%)	

Note: Numbers do not always count to the total because of missing data.

Less than a quarter of all patients (n=36, 24.3%) gave an explanation for the preferred vascular route, by selecting one of the standardized response options in the question (table 8). The other patients (n=112) gave an explanatory note in an open-ended question format (n=112), which were thereafter clustered along the six standardized response options and merged with the other responses (n=36). Most preferences of patients relate to the experience with vascular access (n=51), including, patient has good experience with the current access route (n=40), the preference is caused by lack of experience with the other vascular access option (n=8) and the preference is consistent with the physicians choice (n=3). About one quarter of the patients (n=38) expressed concerns about the incidence of haemorrhagic complications, including the risk of major bleeding (n=27), in the choice for the preferred vascular access route. Other patients (n=27) highlighted the probability of success as (one of the) decisive factor(s) for their preference; as they indicated to prefer a minimal risk of vessel occlusion (n=6) or procedural failure (n=21). Some patients expressed preferences based on post-procedural mobilisation (n=42), such as: faster mobilisation (n=25), no flat bed rest after procedure (n=11) or minimal other physical constraints (n=6). Finally, possible pain and discomfort (n=12) linked to the procedural access route was listed as reason for a particular vascular access choice. The duration of hospital stay was not mentioned in patients' rationale for vascular access.

Table 8. Patients' rationale for vascular access given in standardized response options.

Attribute	**Standardized response option**	**n=36**
Success probability vascular procedure	Success probability of procedure through first chosen access route	1 (0.7%)
	Risk of unsuccessful procedure	5 (3.4%)
	Risk of vessel occlusion	2 (1.4%)
Peri-/post-procedural bleeding	Risk of getting local hematoma	1 (0.7%)
	Risk of major haemorrhagic bleeding	27(18.2%)
TOTAL		36 (24.3%)

Note: The response option 'Risk of hematoma on the lateral side of the lower limb' within the peri-/post-procedural bleeding attribute was not incorporated into the table since the option was not selected by patients (n=0).

From the patients who experienced the femoral and/or radial access during current procedure (n=148) most patients expressed post-procedural preferences for that particular vascular access route (n=123, 84.2%). Some patients in the sample expressed a preference for vascular access that contradicts the procedural access choice of the current procedure (n=21, 14.4%). From the patients who experienced both vascular access routes, during previous and/or the currently performed procedure (n=36), a vast majority of 72.2% preferred the radial access route (table 9). When comparing this percentage to those of patients who experienced only one vascular access option (n=112) there was found a significant difference in preference as less than a third (30.6%) of these patients preferred the radial access route (X^2=96.381; $p<0.05$). Within patients who underwent both vascular access options no difference in preference was found between the sexes.

Table 9. Frequency counts on patients preferences for vascular access by the currently and previously performed procedures.

		Preference	
		Femoral	**Radial**
Previous procedure	**Current procedure**		
Previous None	Femoral	*36*	4
	Radial	2	*22*
	Both Femoral/Radial	0	1
Previous Femoral	Femoral	*39*	6
	Radial	6	*19*
	Both Femoral/Radial	1	0
Previous Radial	Femoral	*1*	0
	Radial	0	*1*
Previous Both Fem./Rad.	Femoral	*2*	3
	Radial	0	*3*
TOTAL		87	59

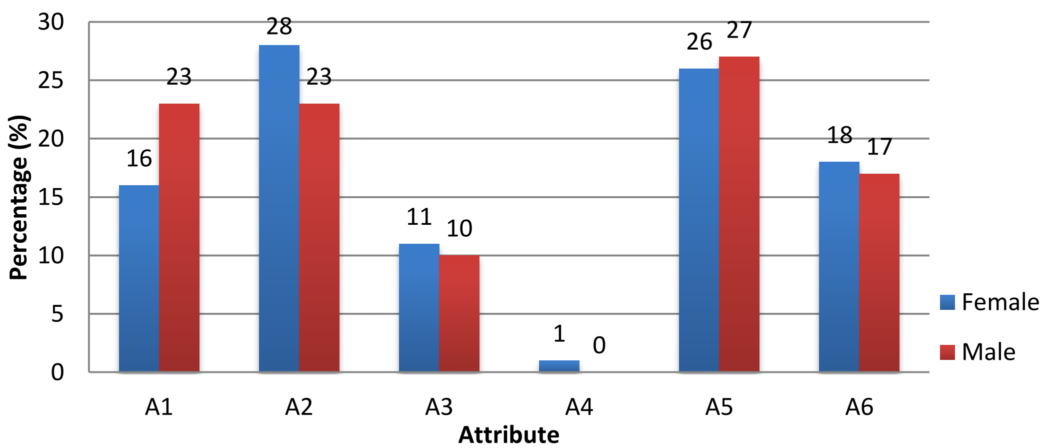
Notes: Numbers do not always count to the total because of missing data. Italic: patients preferred the currently performed vascular access route, Underlined: patients who preferred another access route than the currently performed one, Blue highlighted: Preferences of patients who experienced both vascular access routes.

The best minus worst (B-W) proportions (table 10) represent the strength of patients' preferences for specific treatment characteristics and for potential benefits and risks. A higher (positive) best-worst proportion for a specific characteristic (i.e. attribute-level) means it was selected more often as best than as worst and is likely to be preferred by patients relative to the other levels in the same attribute, a lower (negative) best-worst proportion means the attribute-level was selected as worst more often than as best and therefore is likely to represent a characteristic least preferred by patients. B-W scores ranged from positive to negative within all attributes, except from the post-procedural patient comfort attribute, in which both a 24 hour limitation in daily activities and a 3-4 days restriction to easy activities, were not desired by patients (-0.034; -0.024). When considering the length of hospital stay, patients preferred the procedure to take place in day care (0.585) more than any other treatment characteristic. A successful vessel puncture at the first attempt was the second most preferred characteristic (0.390). The third most preferred characteristic by patients was that there are no bleedings during and after the procedure (0,333). The incidence of peri-/post-procedural bleeding was very important to patients, since, except from the characteristic 'no bleeding' as best characteristic, the incidence of a major bleeding which will be treated with a blood transfusion (-0,588) was least preferred by patients and the incidence of a hematoma with local pain after procedure (-0,364) was second least preferred compared to the other characteristics. The need to lie flat for up to 6 hours was the third lowest valued by patients (-0,315). Patients attached little value to the suitability of the vessel for the next procedure and no noticeable preferences were found for the potential that the next procedure will have to be performed through another vessel (-0.076), therefore this characteristic was chosen to be the reference value in the conditional logistic regression model.

Conditional attribute importance, based on the within attribute variance of the B-W proportions was estimated (table 10). The incidence of peri-/post procedural bleeding was most important to patients (31%), followed by 'length of hospital stay' (23%), 'post-procedural mobilisation' (20%), and 'peri-procedural changing of access-site' (18%). Patients attached little value to the suitability of the vessel for the next procedure (8%), and almost no value to post-procedural comfort.

In addition, conditional attribute importance was estimated for the demographic subgroups; gender, age and education. A difference in the importance of treatment characteristics was found within male and female patients, as male selected peri-/post-procedural bleeding as most important characteristic (27%) followed by length of hospital stay and suitability of the vessel for the next procedure (both 23%). Conversely, female patients selected peri-procedural changing of access-site (28%) as most important characteristic, followed by peri-/post-procedural bleeding (26%) and post-procedural mobilisation (18%) (figure 2). No noticeable differences in preferences were found within the subgroups based on age and education (appendix VI).

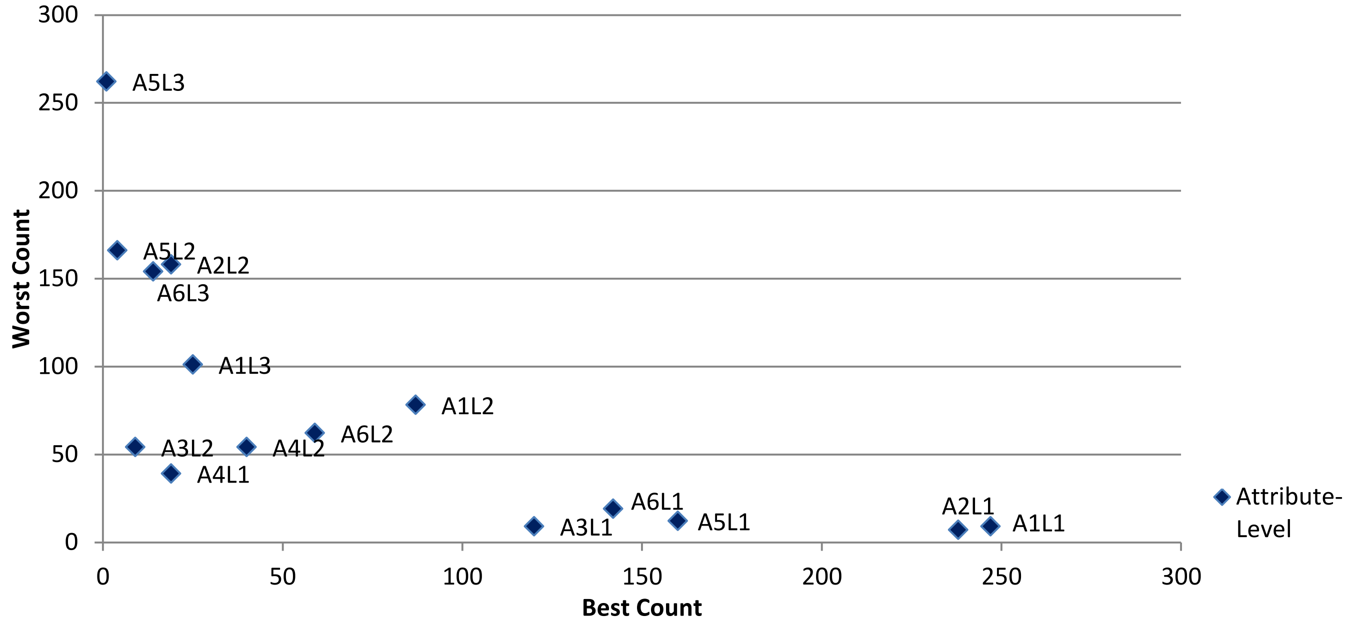
Figure 2. Distribution of attribute importance with regard to male and female patients.



Note: Codes in the horizontal axis represent attributes: Length of hospital stay (A1), Peri-procedural changing access-site (A2), Suitability vessel for next procedure(A3), Post-procedural patient comfort (A4), Peri-/post-procedural bleeding (A5), Post-procedural mobilisation (A6).

The scatterplot (figure 3) shows a moderate negative (not linear) association between the best and worst characteristics of the procedure (i.e. attribute-levels) chosen by patients as presented in table 10. Best and worst counts are distributed among patients as expected, since the line shows an inverse relationship; those characteristics with high best counts have minimal worst counts and are most desired by patients, and characteristics with high worst counts have minimal best counts and are least desired by patients. The plot shows that patients most preferred to have the procedure with a same day discharge (A1L1; 0.585). Remarkably though, an approximate indifference was seen for the prospect of having to be hospitalized for one night (A1L2; 0.022), which is explained by the fact that patients chose the characteristic inconsistently as most (87 times) and least (78 times) preferred characteristic. There is a middle group of characteristics which were not often selected as best or as worst and to which patients attached little value as compared to the other characteristics.

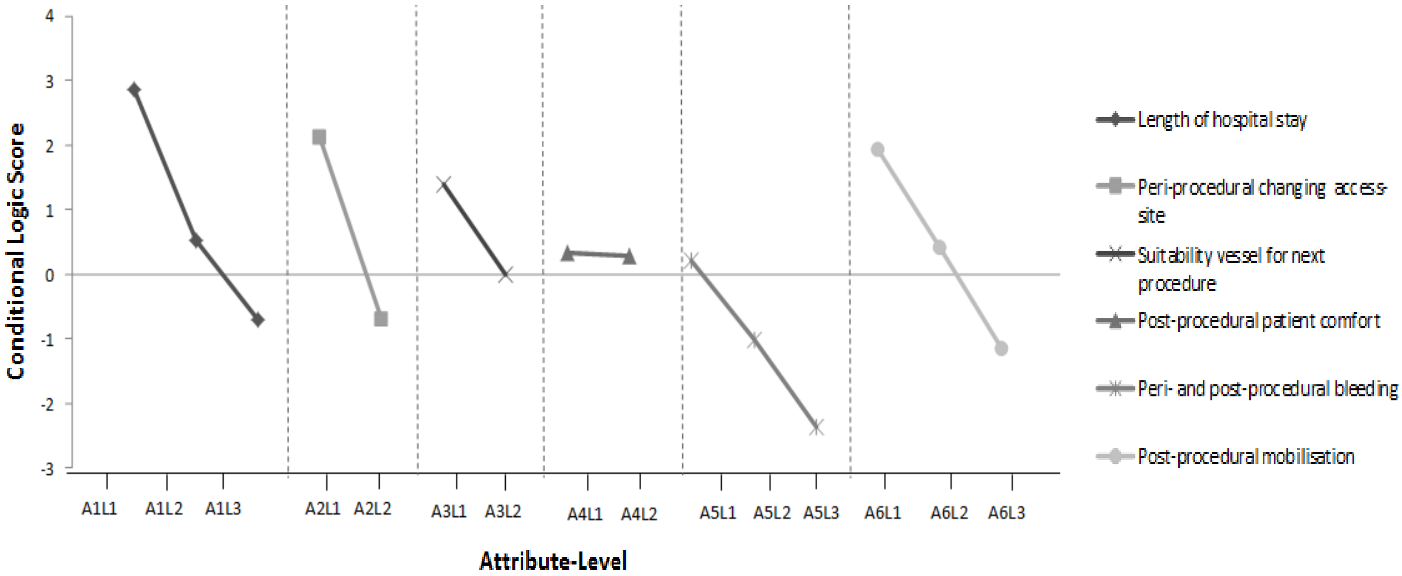
Figure 3. Scatterplot on the distribution of best and worst counts.



Through applying Clogit, a set of coefficients of attribute-levels was estimated (table 11). Higher (positive) coefficients had a positive impact on the choice for vascular access, and lower (negative) coefficients had a negative impact on patients' choice for vascular access. All Clogit coefficients were found to be statistically significant at $p<0.05$, which concludes that patients were able to make a difference between the characteristics of the procedure compared to the reference characteristic. Clogit did not differ to the B-W method in estimating the most and least influential characteristics to patients. However the order of the second and third most preferred attribute-level switched from position. Patients preferred most that the procedure could take place in day-care (2.859), followed by that there are no bleedings after the procedure (2.121) and that the procedure through the vessel succeeds (2.114). Patients least preferred to get a major bleeding after the procedure which requires a blood transfusion (-2.359), to lie flat for up to 6 hours after the procedure (-1.158), or to get a hematoma and local pain after the procedure (-1.020).

Moreover, some negative values in the B-W method became positive in the Clogit. This holds for the characteristic that patients need to lie flat for 2-3 hours after the procedure (-0.007; 0.407), that patients are limited in their daily activities for 24 hours (-0.034; 0.320), and that patients are restricted to perform easy activities till 3-4 days after procedure (-0.024; 0.292). However, these characteristics had no major impact on patients' preferences and the differences observed, did not contradict the results of the B-W method.

Figure 4. Variance within the conditional logistic regression scores with regard to attribute(levels).



Note: Attribute-levels are represented in codes, from A1L1 (Attribute 1 level 1) to A6L3 (Attribute 6, level 3), the attribute-levels are the same as presented in table 6 and table 7.

Figure 4 shows the Clogit regression coefficients for each attribute-level, showing the amount of attribute variation. The greater the difference between minimum and maximum coefficients, the greater the relative importance of the attribute to patients' preference for vascular access by CAG and/or PCI procedures. There is a sharp downward trend on the ascending levels of the procedural characteristics, except from post-procedural patient comfort in which the levels remain about the same, reflecting a low relative importance of this characteristic to patients compared to the other characteristics of the procedure. When plotting the same figure on the B-W proportions, small differences were seen in the importance of characteristics, however the order of the most important characteristics in B-W and Clogit remains unaltered; which means peri-/post-procedural bleeding (29%) is most important to patients, followed by length of hospital stay (23%) and post-procedural mobilisation (20%).

From the six attributes two relate directly to existing procedural characteristics for one of the access routes in CAG and/or PCI. While, after the radial procedure patients are able to mobilize directly after the procedure (1.933) and are limited in their daily activities for 24 hours (0.320), in the femoral procedure patients need to lie flat for 2-3 hours after the procedure in order to recover (0.292) and are only able to perform easy i.e. not heavy activities till 3-4 days after the procedure (0.407). When considering these characteristics, patients' preferences were slightly in favour of the radial access route (1.554, 8.7%). However, the other four attributes reflect probabilities of benefits and risks associated with procedural access and can, although more plausible by one of the access routes, not directly be associated with a preference towards a particular access route.

4.4 INFORMATIONAL AND DECISIONAL AGREEMENT

Patients' satisfaction with the course of the procedure, their perceived understanding of the benefits and risks of the procedure and their valuation on the information about the procedure, are presented in table 12. These were measured along six statements which are categorized into the satisfaction-, informed- and values clarify subscale. All patients were satisfied with the course of the procedure, as 44.6% of the patients were satisfied and 55.4% of patients were very satisfied (Mdn=1; IQR=1). When the level of satisfaction was measured among the current vascular access route, comparatively more patients (n=35, 63.6%) who were treated through the radial route expressed to be 'very satisfied', compared to patients who were treated through the femoral access route (n=47, 50%). About a third of the patients (33.1%) agreed on all statements in the subscales. Within the information and valuation subscale most patients agreed with the statements (Mdn=2). Patients were most divided on the statements regarding their understanding on the risks of procedure and their valuation of the most important risks of procedure, as a substantial part of the patients reacted neutral (9.5% and 12.8%) or disagreed with the statements (both 4.0%) (IQR=0). More consistency was found within patients perceived understanding on the benefits of procedure and their valuation of the most important benefits of procedure, where 92.6% and 87.9% agreed respectively (IQR=1). Most patients (95.9%) agreed to be sufficiently informed about the current procedure (IQR=1).

Nine patients disagreed upon statements in the informed- and values clarify subscale. One patient disagreed to be sufficiently informed and was unable to value the most important benefits of the procedure. Two patients were unaware of the risks of procedure and two were unable to value the risks. Four patients were both unaware of the risks of the procedure and were unable to value the most important risks of the procedure. A total of 28 patients felt statements in the informed and values clarify subscale were not applicable to their situation or had no opinion.

Patients were asked about the current decision owner of procedural choice. According to almost two-third of the patients the decision owner for treatment was the physician (n=49, 33.1%) or mainly the physician (n=43, 29.1%). Another large group believed the decision was made both by the physician and themselves (n=46, 31.1%). Only a small group of patients perceived themselves as the main decision owner (n=8, 5.4%) or as the only decision owner in the decision-making process (n=2, 1.4%). Patients were also asked who should be the decision owner for treatment (table 13). Again a majority (n=85, 58%) of patients chose the physician, however a smaller amount of patients wanted the physician to be the only decision owner (n=29, 19.6%). More patients agreed the decision should be made both by the physician and themselves (n=59, 39.9%) and fewer patients found themselves to be the main or only decision owner (both n=2, 0.7%). There is a significant difference between the answers given by patients on the question about the 'current decision owner' and the 'normative decision owner' (Z=-2.420; p=0.016; $p<0.05$), which indicates that from a patient's view, there is a difference between the actual decision owner of treatment and the preferred decision owner of treatment.

Table 13. Distribution of patients' perception and normative perception on decision ownership for treatment.

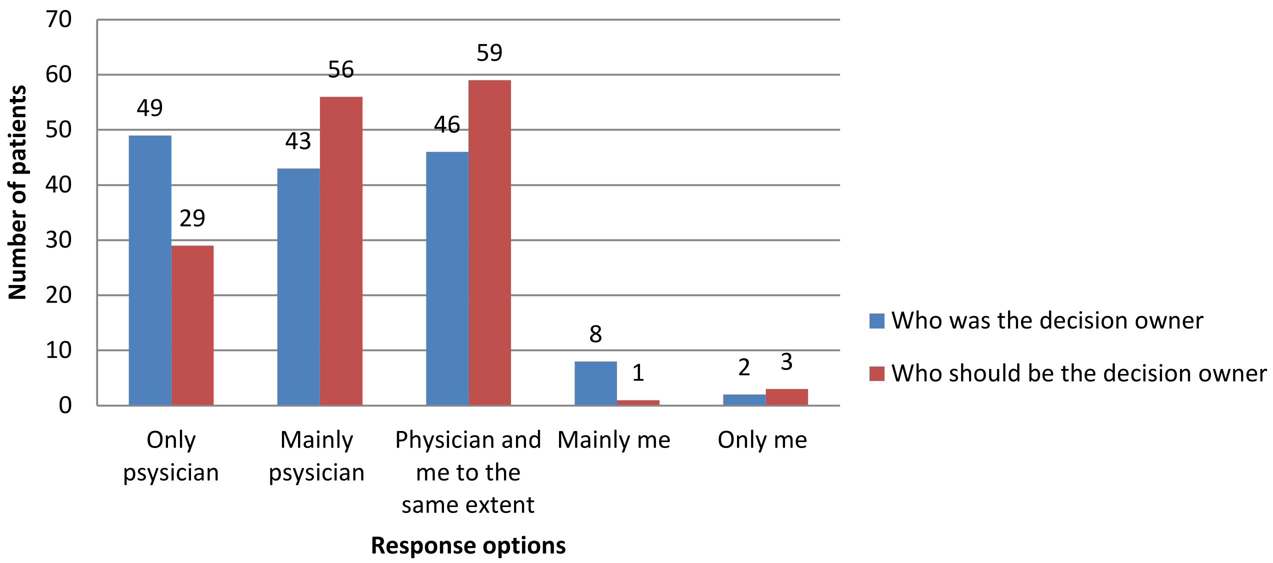


Table 14 shows that from all patients, about a quarter received less decisional power than they would like to have (n= 36, 24.3%). Conversely, another group of patients received more decisional power in the decision for treatment than they would like to have (n=17, 11.5%).

Table 14. Decisional power following from frequency counts within the response options.

		Who should be the decision owner for treatment?					
		Only physician	Mainly physician	Physician and me to the same extent	Mainly me	Only me	Total
Who was the decision owner for treatment?	Only physician	23	21	5	0	0	49
	Mainly physician	4	30	9	0	0	43
	Physician and me to the same extent	2	4	39	0	1	46
	Mainly me	0	1	6	1	0	8
	Only me	0	0	0	0	2	2
	Total	29	56	59	1	3	148

Note: Salmon-pink highlighted section represents patients with less decisional power than they would like to have. Conversely, the grey highlighted section represents patients with more decisional power than they would like to have.

5. DISCUSSION & CONCLUSION

5.1 DISCUSSION

This is one of the first studies that examined the existence of patients' preferences in access site selection in CAG and/or PCI procedures with a methodological-based preference elicitation method (BWS). Since no pre-existing validated classification model was found to compare the attributes of trans-radial and trans-femoral CAG, a total of six attributes and fifteen levels were identified from literature review (section 3.2). The BWS choice sets comprise actual treatment characteristics as well as potential benefits and risks of treatment, which may influence vascular access choice. Although the traditional BWS technique is characterized by posing actual choices between the treatment options (Brennan & Strombom, 1998), in this study the patient preference for a vascular option was measured indirectly by letting patients select the 'best' and 'worst' treatment characteristic from a list of competing attribute-levels. The choice for vascular access may depend on specific patient characteristics such as, values and norms, (personal) experience and (actual available) knowledge. In this study some demographic characteristics, prior experiences with CAG and/or PCI procedure and patients' perceived understanding of the information about the procedure were measured.

An important finding was that the preference of patients was slightly in favour of the femoral access route (59.5%; $p<0.05$). Most patients chose the currently performed vascular access as the preferred route, irrespective of earlier experiences, and about a third of the patients actually expressed that the current experience with vascular access was the main rationale behind the choice for vascular access. Notably, within patients who experienced both vascular access routes a majority of patients stated to prefer the radial access route (72.2%) and this percentage differed significantly from patients who only experienced a single vascular access route, where less than a third preferred the radial route. In contrast to the results in this study, prior studies found that patients had a preference for trans-radial catheterization (Cooper et al., 1999; Schwalm et al., 2012). In addition, patients in the RIVAL study, in which patients were randomly assigned to a vascular access route, preferred radial vascular access to femoral access for subsequent CAG procedures (Jolly et al., 2011), however, of those patients who underwent the radial route 90.2% had a radial preference and among those who underwent the procedure through the femoral route preferences were about evenly distributed to the femoral and radial route. The different preference found in this study may be explained by the fact that patients were better aware of the treatment characteristics and benefits and risks of procedure through the information in the questionnaire and were able to make a balanced decision. However, when considering that two-third of the patients in this study underwent the procedure through the femoral route, and a large percentage of patients chose the current procedure as the preferred one, consistent with the RIVAL study, the difference may also be explained by the fact that patients tend to opt for a treatment option that is familiar to them. This presumption is strengthened by the fact that most patients actually expressed 'experience with a treatment option' to be an important rationale behind the decision made. In addition, several aforementioned studies were performed at centres that are publicly known to prefer the radial access route and/or were designed to assess the potential advantage of the radial access route. Therefore, in these studies patients may have been unconsciously or formally aware of socially desirable answers. In the present study, much effort was taken to approach patients in a neutral way, and the cardiology centre of the MST is not known to be a strong advocate of one or the other vascular access approach. Nevertheless, the results of the present study on preferences in patients who experienced both vascular access routes, was consistent with those of two other studies, in which 80% and 75% of the patients preferred the radial vascular route, respectively (Archbold et al., 2004; Kiemeneij et al., 1997).

The range of attributes (i.e. treatment characteristics) within the BWS choice sets is considered to be the strength of the instrument. When considering the attribute-levels, patients valued these conform expectation, which means the instrument was able to determine that preferences can vary by the frequency and severity of the attribute ($p<0.05$). An important finding in this study was that the attribute peri-/post-procedural bleeding was most important to patients. The level 'no bleeding' was valued within the three most preferred and the levels 'get heamatoma' and 'get major bleeding' within the three least preferred. This attribute may therefore have overpowered the others, but does provide valuable information on its importance to patients. The second most important attribute to patients was length of hospital stay and the level 'the procedure will take place in day-care' was among the top three most preferred. Noticably there was inconsistency in the level 'hospitial admission for one night after procedure' as the attribute-level was many times selected as best and worst. This conceivably reflects that most patients within the sample preferred same-day discharge, although others did not mind to stay (when the attribute is compared to the other possible characteristics) or found it reassuring to be admitted to the hospital for one night. The relative importance of the attributes 'post-procedural bleeding' and 'length of hospital stay' from a patient perspective are valuable, as no prior data on these attributes were found in published literature. The third most important attribute was 'post-procedural mobilisation' and the level 'having flat bed rest for up to six hours' was among the least preferred levels. The findings on the relative importance of post-procedural mobilisiation in this study was consisent with other studies, which state that post-procedural mobilisation was the most important attribute to patients in their choice for radial access (Archbold et al., 2004; Kiemeneij et al., 1997). Although no overall preference can be obtained from the BWS choice set, both mobilisation as well as the other high valued attributes 'post-procedural bleeding' and 'length of hopsital stay' are virtually in favour of the radial approach.

From subgroup analysis, male and female patients were found to have significantly different preferences. About three-quarters of female patients preferred the femoral access route, while in male patients preferences were evenly distributed among the two vascular access routes. Moreover, the opinion on the most important attributes differed between sexes, as male patients agreed on the first two overall most important attributes, but selected 'suitability of the vessel for next procedure' as the third important attribute. In contrast, female patients selected 'peri-procedural changing access-site' as most important attribute, followed by the overall preferred attributes 'post-procedural bleeding' and 'post-procedural mobilisation'.

In addition to the assessment on patient preferences for vascular access, investigation was conducted into patients' readiness and willingness to take decision-making responsibilities. Findings in this study suggest that there was no to minimal informational conflict, as most patients state to be sufficiently informed about the procedure (Mdn=1, IQR=1), had a sufficient understanding about the risks and benefits of procedure, and were able to value the information about the procedure (Mdn=2). Noticeably, patients were less consistent regarding their understanding and valuation of information on the risks of the procedure (IQR=0) compared to the benefits of the procedure (IQR=1). Another remarkable point is that 28 patients felt that statements regarding the informational understanding of the procedure were not applicable to their situation or they state to have no opinion, while statements directly relate to the procedure all patients in the sample had just undergone. This may be attributable to the fact that some patients are not particularly concerned about treatment information as they transfer responsibilities to the care professionals, or because the construct or theory behind the question may not be well understood. Although decisional conflict could not be measured on a validated scale, decisional agreement was assumed, as most patients expressed post-procedural preference for the current vascular access route performed and all patients stated to be satisfied with the course of the procedure. Nonetheless, about a quarter of the patients received less decisional power than they would like to have (n= 36, 24.3%), and more than a tenth (n=17, 11.5%) received more decisional power than they would like to have. In view of the fact that only a few patients chose the extremes 'only the physician' and 'only me' or 'mainly me' as response option, it may be fair to conclude that patients do not necessarily want to be the bigger part in the decision process, but do appreciate to participate in it or share the decision on treatment.

5.2 LIMITATIONS

Some limitations of study can be detected. Although the measurement instrument was reviewed multiple times and piloted among the study population, some potential concerns can be expressed upon the design. Four versions of the questionnaire were developed with experimental design software in order to achieve a balanced attribute selection. Despite compliance to the design, some attribute-levels were underpowered and may therefore have a statistically smaller chance of being chosen in the choice sets (appendix IV). While this could have affected the validity of the findings, preliminary analysis suggests that the inequalities seem not to have had a significant influence on patients' choices. Another potential concern is response bias. Individual patients may have responded to the construct of the questionnaire, the phrasing of the questions, the provided information or the interpersonal interaction with the author of study. Theoretically, the latter could have provoked patients to provide socially desirable responses, even though the survey was conducted in a neutral way and patients' responses were anonymous and identities are irretraceable.

Although the attribute-identification process consisted of a rigorous iterative process, in the BWS analysis, only the attributes 'patient comfort' and 'post-procedural mobilisation' delivered utility scores that could be directly linked to a vascular route and therefore no overall preference for vascular access could be obtained. It is possible that important attributes which can pose a direct choice between the treatment options are left unidentified. As only directly stated preferences were identified, no head-to-head comparison could be made with the implicit preferences, concerning patients preferences on vascular access based on the attributes of treatment. The identified attributes in this study did however provide valuable information on the favourable and unfavourable treatment characteristics from a patient's view.

Another limitation of this study was that the questionnaire, especially the BWS choice sets, was too complicated for some patients in the sample. This was observed through the expressed comments during data collection, the sometimes extensive verbal instruction and hands-on assistance to patients and the incorrect responses (n=22) (appendix V). Since a golden standard in measuring the preference utility is absent, the best suitable preference elicitation technique was selected in order to answer the research questions, without using complex multi-profile (Case 3) or full ranking choice sets. Flynn & Marley (2012) state however, that the simplest conjoint method may not be suitable for 'vulnerable patients' (e.g. high age category) as the technique is cognitively demanding.

As a common rule of thumb for quantitative studies in which no subgroups are compared a quantity of about 300 respondents is required (Louviere et al., 2000; Orme, 2006). Nevertheless, the sample size (n=148) and response rate of patients enrolled in the present study (75%) was considered sufficient to get statistically meaningful results in the context of this pilot study. There are however concerns on the external validity of the findings. Generalizability problems may arise as no random sampling techniques were applied for patient inclusion, as this was impractical within the given time frame of this study. Nevertheless, sample demographics (e.g. age and the distribution of gender) of this single-centre study, that addressed a consecutive series of patients, who underwent planned CAG or PCI procedures, were comparable to other patient preference studies for vascular access (Cooper et al., 1999; Kiemeneij et al., 1997; Schwalm et al., 2012), we cannot exclude that the sample characteristics may differ from other random or non-random samples. Moreover, some patients were excluded from the study or dropped-out after inclusion. We cannot exclude that these patients may have had fundamentally other characteristics and preferences than found in this study. A final generalizability problem may be that the stated preferences measured reflect those of patients who had just undergone CAG and/or PCI procedure. Post-procedural preferences may be different from those prior to the procedure or in earlier stages of treatment plan development, as patients may be influenced by the newly acquired experience. However, timing of the present survey in the post-procedural phase was deliberately chosen, as otherwise patients might have been influenced by the information in the questionnaire which then could have interfered with the physician-patient information exchange or the scheduled course of treatment.

5.3 RECOMMENDATIONS

Forthcoming research is recommended to further investigate on potential unidentified treatment attributes that enable a comparison of patients' preference scores (i.e. utilities) regarding the femoral and radial access route. With these attributes a preference-elicitation instrument can be developed in order to measure stated preferences for procedural characteristics and potentially for vascular access. Similarly to this study, direct preferences can be measured in order to assess patients' consistency in choice.

In section 5.2, some concerns were postulated on the feasibility of the chosen preference-elicitation technique, as some patients had difficulties with the BWS choice questions. Although most patients handed in correct questionnaires (n=148), the BWS technique may not be suitable for direct post-procedural application as patients are recovering from the procedure, or the elicitation technique was unsuitable for specific subgroups in the sample, for instance patients within the high age category. In this study incorrect responses were processed (appendix V), but no meaningful statements could be drawn from the small sample (n=22). It is recommendable that future research should focus on the feasibility of Case 2 BWS in patients eligible for CAG and/or PCI procedure (Flynn & Marley, 2012), and into patients informational and instructional requirements.

This study was useful for identifying preferences and decisional agreement; however the limitations of study emphasize the need for a multi-centered and higher sample volume study to confirm results in this study. As a higher volume quantitative study allows for decent subgroup analysis (Orme, 2006), it is recommended that future research focuses further on the background characteristics underlying the observed preferences for vascular access; especially on the presence and strength of an association with gender for which a significant relationship was found in this study.

Although the present study was predominantly applied on the aggregated sample level, it is recommended that future research will focus more extensively on the subgroup level and individual patient level. A study into the latter may reveal important information on individual preferences and on the (psychological) decision-making process behind the vascular choice. It may also be interesting to further assess values and norms or (prior) actual available procedural knowledge, (prior) vascular access experiences of individual patients or patient subgroups, as these could be predictors for specific preferences regarding vascular access (Schwalm et al., 2012).

In addition, it is recommended that future research should focus more thoroughly on patients' readiness and willingness to take decision-making responsibilities regarding vascular access in CAG and/or PCI through a shared decision-making concept. The elicited patient preferences are only valuable if patients understand the actual risks and benefits of the procedure and if patients are willing to take responsibilities into the decision. Moreover, it is not known if the stated preference is a predictor for future vascular choice. More research is needed into how stated preferences for vascular access choice can meaningfully inform or be included in care activities through a systematic approach, and on its implications for the organization of the future health care infrastructure (Schwalm et al., 2012).

5.4 CONCLUSION

In addition to the cumulative literature comparing trans-radial and trans-femoral vascular access from the technical and clinical perspective, this study compares the two vascular access routes based on a patient perspective. At the time of this study, no access route was superior and the decision for vascular access is therefore considered to be a preference-sensitive decision, in which the characteristics of the procedure can have a different importance with regard to the individual patient. In this study patients were slightly in favour of the femoral approach, except from those who experienced both vascular routes, as they were in favour of the radial approach. Through the BWS method patients were able to express that the characteristics 'peri-/post-procedural bleeding', 'the length of hospital stay' and 'post-procedural mobilisation' were most important to them. These characteristics are virtually in favour of the radial access-route. Since no evident preferred procedural access option could be elicited from a patients' perspective, this study may provide insight and clinical awareness on existing patient preferences on procedural characteristics and on the associated benefits and risks of the procedure. Although different opinions were noted on the extent to which the decision should be shared and there was a perceived decisional agreement with the chosen procedure, the findings of study indicate that patients appreciate to participate in (or share) the decision on vascular access in CAG and/or PCI. The findings in this study may provoke discussion on the capability and desirability of shared decision-making (SDM) in cardiology by both health care professionals and patients. The need for discussion is strengthened as in the field of interventional cardiology a shift is ongoing towards more trans-radial CAG and/or PCI procedures due to their clinically beneficial characteristics, such as the virtual absence of access-site complications and rapid patient mobilisation. Hence, information on existing preferences and attitudes among patients is valuable for assessing current health care needs and for planning future health care services. The results of this study may, with respect to ethical and legal regulations, contribute to a more patient-centered care in cardiology regarding the vascular access choice.

ACKNOWLEDGEMENTS

This master graduation project is the concluding study part of the Master Health Sciences at the University of Twente and hence, most likely, the dawning of the era of working life. A few people have significantly contributed to this accomplishment. At first I offer significant gratitude to my internal supervisor Dr. Janine van Til and co-supervisor Marieke Weernink for their constructive feedback, support and patience throughout the research project. Without their knowledge and guidance I was not able to design and applicate the patient preference survey, and analyse the obtained data within the established theoretical background. Secondly, I am sincerely grateful to my external supervisors Dr. Clemens von Birgelen and Dr. Ming Kai Lam who offered me a platform for carrying out my survey in the hospital setting of the MST and had a very meaningful contribution with regard to the design, evaluation and application of the patient preference questionnaire. Thirdly, I am indebted gratitude to all the research participants, for their dedication and readiness to participate in the study by filling in a questionnaire, hence giving me the input to base upon the conclusions of my master thesis.

My graduation was a learning period, not only in terms of the acquired knowledge and expertise, also in terms of personal issues. I have followed a mindfulness course on performance anxiety, and I want to express gratitude to Drs. Engberts and Drs. Ploszaj for their successful mental stimulation throughout my graduation.

Ultimately, the greatest motivation throughout the research project came from my friends and family, especially my friend Dennis, who showed unconditional understanding and encouragement throughout the project. Moreover, I want to thank my parents for their faith in my competences and their generous support, and my brother Richard and his friend Laura for providing meaningful advices and feedback on my thesis report. A final special acknowledgement I would like to dedicate to my beloved grandfather Lambert Fens, who has passed away at the time of my graduation, but who had always proved to be of great support.

REFERENCES

Agostoni, P., Biondi-Zoccai, G. G., De Benedictis, M. L., Rigattieri, S., Turri, M., Anselmi, M., Hamon, M. (2004). Radial versus femoral approach for percutaneous coronary diagnostic and interventional proceduresSystematic overview and meta-analysis of randomized trials. *Journal of the American College of Cardiology, 44*(2), 349-356.

Alwan, A. (2011). *Global status report on noncommunicable diseases 2010*: World Health Organization.

Archbold, R. A., Robinson, N. M., & Schilling, R. J. (2004). Radial artery access for coronary angiography and percutaneous coronary intervention. *BMJ: British Medical Journal, 329*(7463), 443.

Arons, A. M., & Krabbe, P. F. (2013). Probabilistic choice models in health-state valuation research: background, theories, assumptions and applications.

Bertrand, O. F., Bélisle, P., Joyal, D., Costerousse, O., Rao, S. V., Jolly, S. S., Joseph, L. (2012). Comparison of transradial and femoral approaches for percutaneous coronary interventions: a systematic review and hierarchical Bayesian meta-analysis. *American heart journal, 163*(4), 632-648.

Bertrand, O. F., de Palma, R., & Meerkin, D. (2010). Vascular Access Vol. 1. *Percutaneous Interventional Cardiovascular Medicine* (pp. 1-16). Retrieved from http://www.pcronline.com/eurointervention/textbook/pcr-textbook/chapter/3-24.php

Brennan, P. F., & Strombom, I. (1998). Improving Health Care by Understanding Patient Preferences The Role of Computer Technology. *Journal of the American Medical Informatics Association, 5*(3), 257-262.

Campeau, L. (1989). Percutaneous radial artery approach for coronary angiography. *Catheterization and cardiovascular diagnosis, 16*(1), 3-7.

Charles, C., Gafni, A., & Whelan, T. (1997). Shared decision-making in the medical encounter: what does it mean?(or it takes at least two to tango). *Social science & medicine, 44*(5), 681-692.

Cooper, C. J., El-Shiekh, R. A., Cohen, D. J., Blaesing, L., Burket, M. W., Basu, A., & Moore, J. A. (1999). Effect of transradial access on quality of life and cost of cardiac catheterization: a randomized comparison. *American heart journal, 138*(3), 430-436.

DosReis, S., Ng, X., Frosch, E., Reeves, G., Cunningham, C., & Bridges, J. F. (2014). Using Best–Worst Scaling to Measure Caregiver Preferences for Managing their Child's ADHD: A Pilot Study. *The Patient-Patient-Centered Outcomes Research*, 1-9.

Elwyn, G., Edwards, A., Kinnersley, P., & Grol, R. (2000). Shared decision making and the concept of equipoise: the competences of involving patients in healthcare choices. *British Journal of General Practice, 50*(460), 892-899.

Erbel, R., & Wijns, W. (2014). The Year in Cardiology 2013: coronary intervention. *European heart journal, 35*(5), 313-320.

Flynn, T. N. (2010). Valuing citizen and patient preferences in health: recent developments in three types of best-worst scaling. *Expert review of pharmacoeconomics & outcomes research, 10*(3), 259-267.

Flynn, T. N., Louviere, J. J., Peters, T. J., & Coast, J. (2007). Best–worst scaling: what it can do for health care research and how to do it. *Journal of health economics, 26*(1), 171-189.

Flynn, T. N., & Marley, A. A. (2012). Best worst scaling: Theory and methods. *Sydney, CenSoC Working Paper*(12-002).

Hansson, S. O. (1994). Decision theory. *A brief introduction. Department of Philosophy and the History of Technology. Royal Institute of Technology. Stockholm*.

Huizingh, E. (2007). *Aplied Statistics with SPSS* (Vol. 1st edition). London Sage publications

Hunink, M. M., & Glasziou, P. (2012). *Decision Making in Health and Medicine with CD-rom: Integrating Evidence and Values* (12 ed. Vol. 1): Cambridge University Press.

Jolly, S. S., Amlani, S., Hamon, M., Yusuf, S., & Mehta, S. R. (2009). Radial versus femoral access for coronary angiography or intervention and the impact on major bleeding and ischemic events: a systematic review and meta-analysis of randomized trials. *American heart journal, 157*(1), 132-140.

Jolly, S. S., Yusuf, S., Cairns, J., Niemelä, K., Xavier, D., Widimsky, P., Lewis, B. S. (2011). Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): a randomised, parallel group, multicentre trial. *The Lancet, 377*(9775), 1409-1420.

Kiemeneij, F., & Laarman, G. J. (1994). Percutaneous transradial artery approach for coronary Palmaz-Schatz stent implantation. *American heart journal, 128*(1), 167-174.

Kiemeneij, F., Laarman, G. J., Odekerken, D., Slagboom, T., & van der Wieken, R. (1997). A randomized comparison of percutaneous transluminal coronary angioplasty by the radial, brachial and femoral approaches: the access study. *Journal of the American College of Cardiology, 29*(6), 1269-1275.

Kuipers, G., Delewi, R., Velders, X. L., Vis, M. M., van der Schaaf, R. J., Koch, K. T., Tijssen, J. G. (2012). Radiation exposure during percutaneous coronary interventions and coronary angiograms performed by the radial compared with the femoral route. *JACC: Cardiovascular Interventions, 5*(7), 752-757.

Lam, M. K., Sen, H., Tandjung, K., van Houwelingen, K. G., de Vries, A. G., Danse, P. W., Linssen, G. (2014). Comparison of 3 biodegradable polymer and durable polymer-based drug-eluting stents in all-comers (BIO-RESORT): Rationale and study design of the randomized TWENTE III multicenter trial. *American heart journal, 167*(4), 445-451.

Lancaster, K. (1971). Consumer demand: A new approach.

Lancsar, E., Louviere, J., Donaldson, C., Currie, G., & Burgess, L. (2013). Best worst discrete choice experiments in health: Methods and an application. *Social science & medicine, 76*, 74-82.

Louviere, J. J., Flynn, T. N., & Carson, R. T. (2010). Discrete choice experiments are not conjoint analysis. *Journal of choice modelling, 3*(3), 57-72.

Louviere, J. J., Hensher, D. A., & Swait, J. D. (2000). *Stated choice methods: analysis and applications*: Cambridge University Press.

Man, F., & Birgelen, C. (2012). Usefulness and safety of the GuideLiner catheter to enhance intubation and support of guide catheters: insights from the Twente GuideLiner registry. *EuroIntervention, 8*(3), 336-344.

Marley, A. A., & Louviere, J. J. (2005). Some probabilistic models of best, worst, and best–worst choices. *Journal of Mathematical Psychology, 49*(6), 464-480.

Marshall, D., Bridges, J. F., Hauber, B., Cameron, R., Donnalley, L., Fyie, K., & Johnson, F. R. (2010). Conjoint Analysis Applications in Health—How are Studies being Designed and Reported? *The Patient: Patient-Centered Outcomes Research, 3*(4), 249-256.

MST. (n.d.). Thoraxcentrum Twente. Een dotter- en stentbehandeling (PCI). Patienten informatie map (PIM) Enschede

O'Connor, A. (1993). User Manual-Decisional Conflict Scale. Retrieved from http://decisionaid.ohri.ca/eval.html#DecisionalConflictScale

Orme, B. K. (2006). Getting started with conjoint analysis: Strategies for product design and pricing research.

Pieterse, A. H., Berkers, F., Baas-Thijssen, M., Marijnen, C. A., & Stiggelbout, A. M. (2010). Adaptive conjoint analysis as individual preference assessment tool: feasibility through the internet and reliability of preferences. *Patient education and counseling, 78*(2), 224-233.

Rao, S. V., Bernat, I., & Bertrand, O. F. (2012). Remaining challenges and opportunities for improvement in percutaneous transradial coronary procedures. *European heart journal, 33*(20), 2521-2526.

Rao, S. V., Cohen, M. G., Kandzari, D. E., Bertrand, O. F., & Gilchrist, I. C. (2010). The Transradial Approach to Percutaneous Coronary InterventionHistorical Perspective, Current Concepts, and Future Directions. *Journal of the American College of Cardiology, 55*(20), 2187-2195.

Russell-Johnson, H. (1995). Paternalism to partnership. *Paediatric nursing, 7*(3), 9.
Ryan, M., & Farrar, S. (2000). Using conjoint analysis to elicit preferences for health care. *BMJ: British Medical Journal, 320*(7248), 1530.
Ryan, M., Scott, D., Reeves, C., Bate, A., Van Teijlingen, E., Russell, E., Robb, C. (2001). Eliciting public preferences for healthcare: a systematic review of techniques. *Health technology assessment (Winchester, England), 5*(5), 1-186.
Safirstein, J. (2013). Radial Access in Practice *Cardiologys toda'y Intervention*
Schmitz, C. (2012). Lime Survey: the free & open source survey software tool: Available on: http://www.limesurvey.org/. Accessed: May 2014.
Schwalm, J.-D., Stacey, D., Pericak, D., & Natarajan, M. K. (2012). Radial Artery Versus Femoral Artery Access Options in Coronary Angiogram Procedures Randomized Controlled Trial of a Patient-Decision Aid. *Circulation: Cardiovascular Quality and Outcomes, 5*(3), 260-266.
Sepucha, K., & Mulley, A. G. (2009). A perspective on the patient's role in treatment decisions. *Medical Care Research and Review, 66*(1 suppl), 53S-74S.
Trimarchi, S., Smith, D. E., Share, D., Jani, S. M., O'Donnell, M., McNamara, R., Moscucci, M. (2010). Retroperitoneal hematoma after percutaneous coronary intervention: prevalence, risk factors, management, outcomes, and predictors of mortality: a report from the BMC2 (Blue Cross Blue Shield of Michigan Cardiovascular Consortium) registry. *JACC: Cardiovascular Interventions, 3*(8), 845-850.
van der Weijden, T., van Veenendaal, H., Drenthen, T., Versluijs, M., Stalmeier, P., Koelewijn-van Loon, M., Timmermans, D. (2011). Shared decision making in the Netherlands, is the time ripe for nationwide, structural implementation? *Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen, 105*(4), 283-288.
van Til, J. A. (2009). *Integrating preferences in decision making. The treatment of ankle-foot impairment in stroke.* PhD thesis University of Twente Enschede
von Birgelen, C., Sen, H., Lam, M. K., Danse, P. W., Jessurun, G. A., Hautvast, R. W., Louwerenburg, J. W. (2014). Third-generation zotarolimus-eluting and everolimus-eluting stents in all-comer patients requiring a percutaneous coronary intervention (DUTCH PEERS): a randomised, single-blind, multicentre, non-inferiority trial. *The Lancet, 383*(9915), 413-423.
Williams, J. R. (2009). World Medical Association; Medical ethics manual Retrieved from http://www.wma.net/en/30publications/30ethicsmanual/pdf/ethics_manual_en.pdf
Woolf, S. H., Chan, E. C., Harris, R., Sheridan, S. L., Braddock, C. H., Kaplan, R. M., Tunis, S. (2005). Promoting informed choice: transforming health care to dispense knowledge for decision making. *Annals of internal medicine, 143*(4), 293-300.
Zimmermann, T. M., Clouth, J., Elosge, M., Heurich, M., Schneider, E., Wilhelm, S., & Wolfrath, A. (2013). Patient preferences for outcomes of depression treatment in Germany: A choice-based conjoint analysis study. *Journal of affective disorders, 148*(2), 210-219.

GLOSSARY

ATTRIBUTE In choice models the characteristics that comprises a treatment or health care service can be translated into attributes. Attributes vary systematically across hypothetical scenarios in order to observe the choices individuals make and estimate the strength of the individual preference (Flynn et al., 2007; Louviere et al., 2000).

LEVEL Within the attributes different levels can be identified. The strength of the individuals' preference for a treatment or a health care service is measured by means of the selection of the attribute-levels (Flynn et al., 2007).

MEDICAL DECISION-MAKING
"The process of making trade-offs between risks, benefits, costs, and preferences in health care, by integrating the best available evidence with the values relevant to patient and society" (Hunink & Glasziou, 2012).

PREFERENCE Preferences refer to statements made by individuals regarding the relative desirability of a range of treatment (characteristics) or health outcomes (Brennan & Strombom, 1998).

SHARED DECISION-MAKING
"A process between the patient and physician, and their networks of family or professional colleagues, in which both parties participate in the decision and agree on the final decision"(Elwyn et al., 2000).

UTILITY Single summary score that represents the strength of an individual's preference for a specific health-related outcome (Louviere et al., 2000; Ryan et al., 2001).

VASCULAR ACCESS Coronary angiography (CAG) with or without intervention (PCI) is accomplished primarily with vascular access obtained via the radial artery at the wrist or the femoral artery in the groin (Bertrand et al., 2010).

LIST OF ABBREVIATIONS

BWS	Best-worst scaling
CA	Conjoint analysis
CAD	Cardiovascular disease
CAG	Coronary angiography
Clogit	Conditional logistic regression
MAXDIFF	Maximum difference model
MDM	Medical Decision-making
MST	Medical Spectrum Twente
PCI	Percutaneous coronary intervention
PIF	Patient information folder
PPQ	Patient preference questionnaire (no official abbreviation)
SDM	Shared decision-making
TFA	Trans-femoral approach
TRA	Trans-radial approach

APPENDICES

APPENDIX I PATIENT PREFERENCE QUESTIONNAIRE (VERSION 1)

Medisch Spectrum △Twente

TCT THORAX CENTRUM TWENTE

UNIVERSITEIT TWENTE.

Onderzoek naar behandelingsvoorkeuren bij hartcatheterisatie of dotterbehandeling

Geachte heer/mevrouw,

Mede namens cardioloog dr. C. von Birgelen en de hele maatschap **cardiologie,** wil ik u graag uitnodigen om deel te nemen aan een onderzoek over de behandeling van mensen die een hartcatheterisatie of dotterbehandeling hebben ondergaan. Dit onderzoek wordt verricht in samenwerking met de Universiteit Twente.

Het onderzoek bestaat uit het eenmalig invullen van een **vragenlijst.** De vragenlijst gaat over uw huidige hartcatheterisatie of dotterbehandeling. Met dit onderzoek proberen wij te ontdekken wat u belangrijk vindt voor, tijdens en na de ingreep, o.a. door te onderzoeken wat volgens u de voor- en nadelen van behandeling zijn. Door beter inzicht te krijgen in uw voorkeuren kan de zorg in de toekomst beter worden afgestemd op de behoeften van patiënten die dezelfde procedure als u zullen ondergaan.

Het invullen van de vragenlijst vindt plaats onder begeleiding van de onderzoeker en duurt ongeveer **15 minuten.**

Deelname aan dit onderzoek is geheel **vrijwillig** en u kunt op elk gewenst moment uw medewerking stopzetten.

Al uw gegevens zullen **vertrouwelijk** worden behandeld en **anoniem** worden verwerkt en zijn daarom niet te herleiden op u als persoon. Dit betekent ook dat andere personen, zoals bijvoorbeeld uw cardioloog, de cardioloog die de ingreep heeft uitgevoerd of uw huisarts niet zullen weten wat u heeft ingevuld.

Alvast hartelijk dank voor uw medewerking,

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Mede namens
Dr. J.A. van Til (Universiteit Twente)

Onderzoek behandelingsvoorkeuren bij hartcatheterisatie of dotterbehandeling

Deze vragenlijst bestaat uit 4 onderdelen. Wanneer in een vraag of stelling wordt gesproken over de 'ingreep' wordt hiermee uw hartcatheterisatieonderzoek en de eventuele dotterbehandeling die u heeft ondergaan bedoeld.

Bij het beantwoorden van een vraag of stelling kunt u telkens 1 antwoord aankruisen, tenzij anders staat aangegeven. Bij de vragen in deel 1, 2 en 3 wordt gevraagd naar uw persoonlijke mening.

Het beantwoorden van een vraag / stelling		
Kruis het hokje aan waarmee u de vraag of stelling wilt beantwoorden	☐	☒
Wanneer u verkeerd heeft gekozen kunt u het hokje zwart maken en het goede hokje aankruisen	■	☒

Deel 1 Algemeen deel

Het eerste deel bestaat uit 6 stellingen over uw ingreep. Geeft u achter elke stelling aan in welke mate u het eens of oneens bent met de stelling. Wanneer de stelling niet op u van toepassing is of u geen mening heeft over de stelling dan kunt u de laatste antwoordoptie aankruisen.

	Zeer mee eens	Mee eens	Niet eens/ niet oneens	Niet mee eens	Zeer mee oneens	N.v.t *of* Geen mening
1. Ik ben voldoende geïnformeerd over mijn ingreep	☐	☐	☐	☐	☐	☐
2. Ik ken de voordelen van mijn ingreep	☐	☐	☐	☐	☐	☐
3. Ik weet welke voordelen het meest belangrijk voor mij zijn	☐	☐	☐	☐	☐	☐
4. Ik ken de risico's en bijwerkingen van mijn ingreep	☐	☐	☐	☐	☐	☐
5. Ik weet welke risico's en bijwerkingen het meest belangrijk voor mij zijn	☐	☐	☐	☐	☐	☐
6. Ik ben tevreden over het verloop van mijn ingreep	☐	☐	☐	☐	☐	☐

Deel 2 Kenmerken van de ingreep

Het tweede deel bestaat uit 8 vragen. Elke vraag beschrijft een ingreep aan de hand van 6 voor- en nadelen van de behandeling. U wordt gevraagd het meest wenselijke en minst wenselijke kenmerk van de ingreep aan te kruisen. U kruist per vraag dus **2 antwoordhokjes** aan.

In onderstaand **voorbeeld** wordt in het midden een supermarkt beschreven. In de kolom links is bij het meest wenselijke kenmerk 'Er is een groot aanbod van producten' aangekruist. In de kolom rechts is het kenmerk 'De supermarkt in op 5 km afstand ' als minst wenselijke kenmerkt aangekruist.

Wat vindt u het **meest wenselijke kenmerk** van deze supermarkt? ☺	Voorbeeldvraag **Supermarkt**	Wat vindt u het **minst wenselijke kenmerk** van deze supermarkt? ☹
☒	Er is een groot aanbod van producten	☐
☐	De supermarkt is op 5km afstand	☒
☐	De supermarkt is duur	☐
☐	De supermarkt is logisch ingedeeld	☐

1. Stelt u zich voor dat uw ingreep er als volgt uitziet. Geeft u <u>links</u> aan wat u het <u>meest wenselijke kenmerk</u> van deze ingreep vindt en <u>rechts</u> wat u het <u>minst wenselijke kenmerk</u> van de ingreep vindt.

Wat vindt u het **meest wenselijke kenmerk** van deze ingreep? ☺	**Ingreep 1**	Wat vindt u het **minst wenselijke kenmerk** van deze ingreep? ☹
☐	De ingreep vindt plaats in dagopname	☐
☐	De ingreep via de ader <u>mis</u>lukt, er wordt nog een ader aangeprikt	☐
☐	Een eventuele volgende ingreep moet via een andere ader	☐
☐	Na de ingreep bent u 24 uur beperkt in uw dagelijkse activiteiten	☐
☐	U krijgt een grote bloeding die behandeld wordt met een bloedtransfusie	☐
☐	U zult tot 6 uur na de ingreep plat op bed moeten liggen voor herstel	☐

U heeft bovenstaande vraag juist beantwoord als u **1 hokje in de linkerkolom <u>en</u> 1 hokje in de rechterkolom** heeft aangekruist. De volgende 7 vragen beantwoord u op dezelfde wijze.

2. Stelt u zich voor dat uw ingreep er als volgt uitziet. Geeft u links aan wat u het meest wenselijke kenmerk van deze ingreep vindt en rechts wat u het minst wenselijke kenmerk van de ingreep vindt.

Wat vindt u het **meest wenselijke kenmerk** van deze ingreep?	**Ingreep 2**	Wat vindt u het **minst wenselijke kenmerk** van deze ingreep?
☐	U zult na de ingreep voor twee nachten in het ziekenhuis worden opgenomen	☐
☐	De ingreep via de ader lukt, er hoeft geen andere ader aangeprikt te worden	☐
☐	Een eventuele volgende ingreep kan op dezelfde manier	☐
☐	Na de ingreep kunt u 3-4 dagen alleen lichte werkzaamheden uitvoeren	☐
☐	Er treden geen bloedingen op na de ingreep	☐
☐	Na de ingreep mag u direct mobiliseren	☐

3. Stelt u zich voor dat uw ingreep er als volgt uitziet. Geeft u links aan wat u het meest wenselijke kenmerk van deze ingreep vindt en rechts wat u het minst wenselijke kenmerk van de ingreep vindt.

Wat vindt u het **meest wenselijke kenmerk** van deze ingreep?	**Ingreep 3**	Wat vindt u het **minst wenselijke kenmerk** van deze ingreep?
☐	U zult na de ingreep een nacht in het ziekenhuis worden opgenomen	☐
☐	De ingreep via de ader mislukt, er wordt nog een ader aangeprikt	☐
☐	Een eventuele volgende ingreep moet via een andere ader	☐
☐	Na de ingreep kunt u 3-4 dagen alleen lichte werkzaamheden uitvoeren	☐
☐	Er treden geen bloedingen op na de ingreep	☐
☐	U zult tot 6 uur na de ingreep plat op bed moeten liggen voor herstel	☐

4. Stelt u zich voor dat uw ingreep er als volgt uitziet. Geeft u links aan wat u het meest wenselijke kenmerk van deze ingreep vindt en rechts wat u het minst wenselijke kenmerk van de ingreep vindt.

Wat vindt u het **meest wenselijke kenmerk** van deze ingreep? ☺	**Ingreep 4**	Wat vindt u het **minst wenselijke kenmerk** van deze ingreep? ☹
☐	U zult na de ingreep een nacht in het ziekenhuis worden opgenomen	☐
☐	De ingreep via de ader mislukt, er wordt nog een ader aangeprikt	☐
☐	Een eventuele volgende ingreep kan op dezelfde manier	☐
☐	Na de ingreep kunt u 3-4 dagen alleen lichte werkzaamheden uitvoeren	☐
☐	U krijgt een bloeduitstorting en heeft lokale pijn na de ingreep	☐
☐	U zult 2 tot 3 uur na de ingreep plat op bed moeten liggen voor herstel	☐

5. Stelt u zich voor dat uw ingreep er als volgt uitziet. Geeft u links aan wat u het meest wenselijke kenmerk van deze ingreep vindt en rechts wat u het minst wenselijke kenmerk van de ingreep vindt.

Wat vindt u het **meest wenselijke kenmerk** van deze ingreep? ☺	**Ingreep 5**	Wat vindt u het **minst wenselijke kenmerk** van deze ingreep? ☹
☐	U zult na de ingreep voor twee nachten in het ziekenhuis worden opgenomen	☐
☐	De ingreep via de ader lukt, er hoeft geen andere ader aangeprikt te worden	☐
☐	Een eventuele volgende ingreep moet via een andere ader	☐
☐	Na de ingreep kunt u 3-4 dagen alleen lichte werkzaamheden uitvoeren	☐
☐	U krijgt een bloeduitstorting en heeft lokale pijn na de ingreep	☐
☐	U zult tot 6 uur na de ingreep plat op bed moeten liggen voor herstel	☐

6. Stelt u zich voor dat uw ingreep er als volgt uitziet. Geeft u links aan wat u het meest wenselijke kenmerk van deze ingreep vindt en rechts wat u het minst wenselijke kenmerk van de ingreep vindt.

Wat vindt u het **meest wenselijke kenmerk** van deze ingreep? ☺	**Ingreep 6**	Wat vindt u het **minst wenselijke kenmerk** van deze ingreep? ☹
☐	De ingreep vindt plaats in dagopname	☐
☐	De ingreep via de ader lukt, er hoeft geen andere ader aangeprikt te worden	☐
☐	Een eventuele volgende ingreep moet via een andere ader	☐
☐	Na de ingreep bent u 24 uur beperkt in uw dagelijkse activiteiten	☐
☐	U krijgt een bloeduitstorting en heeft lokale pijn na de ingreep	☐
☐	Na de ingreep mag u direct mobiliseren	☐

7. Stelt u zich voor dat uw ingreep er als volgt uitziet. Geeft u links aan wat u het meest wenselijke kenmerk van deze ingreep vindt en rechts wat u het minst wenselijke kenmerk van de ingreep vindt.

Wat vindt u het **meest wenselijke kenmerk** van deze ingreep? ☺	**Ingreep 7**	Wat vindt u het **minst wenselijke kenmerk** van deze ingreep? ☹
☐	U zult na de ingreep voor twee nachten in het ziekenhuis worden opgenomen	☐
☐	De ingreep via de ader lukt, er hoeft geen andere ader aangeprikt te worden	☐
☐	Een eventuele volgende ingreep kan op dezelfde manier	☐
☐	Na de ingreep bent u 24 uur beperkt in uw dagelijkse activiteiten	☐
☐	U krijgt een grote bloeding die behandeld wordt met een bloedtransfusie	☐
☐	U zult 2 tot 3 uur na de ingreep plat op bed moeten liggen voor herstel	☐

8. Stelt u zich voor dat uw ingreep er als volgt uitziet. Geeft u links aan wat u het meest wenselijke kenmerk van deze ingreep vindt en rechts wat u het minst wenselijke kenmerk van de ingreep vindt.

Wat vindt u het **meest wenselijke kenmerk** van deze ingreep? ☺	**Ingreep 8**	Wat vindt u het **minst wenselijke kenmerk** van deze ingreep? ☹
☐	De ingreep vindt plaats in dagopname	☐
☐	De ingreep via de ader mislukt, er wordt nog een ader aangeprikt	☐
☐	Een eventuele volgende ingreep kan op dezelfde manier	☐
☐	Na de ingreep bent u 24 uur beperkt in uw dagelijkse activiteiten	☐
☐	Er treden geen bloedingen op na de ingreep	☐
☐	U zult 2 tot 3 uur na de ingreep plat op bed moeten liggen voor herstel	☐

Deel 3 Voorkeuren voor de ingreep

Het derde deel bestaat uit 2 vragen over uw voorkeur voor de ingreep en 2 vragen over de beslissing voor de gekozen ingreep.

1. Uw ingreep kan op twee manieren plaatsvinden; via de pols en via de lies. Beide manieren zijn veilig en effectief. In deel 2 heeft u gekeken naar de voor- en nadelen van de ingreep, in dit deel worden de twee aanprikplaatsen naast elkaar gezet op basis van deze voor- en nadelen. Kunt u aangeven welke aanprikplaats uw voorkeur heeft?

	Ingreep via de Pols	**Ingreep via de Lies**
Bloeduitstorting flank (behandeling met medicatie of een bloedtransfusie of een extra ingreep)	0%	2%
Kans op mislukken van operatie (ingreep moet alsnog via een andere route)	7%	1%
Kans op een bloeduitstorting (lokale pijn na de ingreep)	1%	4%
Kans op een grote bloeding (behandeling met bloedtransfusie en een extra overnachting in het ziekenhuis)	1%	3%
Kans op afsluiting van het bloedvat (een volgende ingreep moet misschien via een andere route)	6%	1%
Kans op succes van de ingreep via de eerst gekozen route	93%	99%
Voorkeursbehandeling graag aankruisen	☐	☐

2. Op welk kenmerk van de ingreep baseert u deze voorkeur?

....

....

....

3. Wie maakte de beslissing voor de huidige ingreep?

☐ alleen de arts

☐ vooral de arts

☐ de arts en ik in gelijke mate

☐ vooral ik

☐ alleen ik

4. Wie zou volgens u de beslissing voor de ingreep moeten maken?

☐ alleen de arts

☐ vooral de arts

☐ de arts en ik in gelijke mate

☐ vooral ik

☐ alleen ik

Deel 4 Achtergrondvragen

Het vierde deel bestaat uit 6 vragen over uw achtergrond.

1. Wat is uw leeftijd: ...... jaar

2. Wat is uw geslacht? ☐ man ☐ vrouw

3. Wat is de hoogste opleiding die u heeft afgerond?

☐ geen opleiding

☐ lagere school/basisschool

☐ lager beroepsonderwijs

☐ middelbaar algemeen voortgezet onderwijs

☐ hoger algemeen voortgezet onderwijs

☐ middelbaar beroepsonderwijs

☐ hoger beroepsonderwijs

☐ wetenschappelijk onderwijs (universiteit)

4. Bent u in Nederland geboren? ☐ ja ☐ nee

5a. Heeft u al eens eerder een hartcatheterisatie of dotterbehandeling gehad?

☐ ja ☐ nee ☐ weet ik niet

b. Zo ja, is dit gebeurd via de pols of via de lies?

☐ pols ☐ lies ☐ geen van beide ☐ weet ik niet

6. Hoe werd de huidige hartcatheterisatie of dotterbehandeling uitgevoerd?

☐ pols ☐ lies ☐ geen van beide

Dit is het einde van de vragenlijst. Wij willen u hartelijk bedanken voor uw medewerking.

I

APPENDIX II QUANTITATIVE CONSEQUENCE TABLE

Domain	Attribute	Radial approach	Femoral approach	Lowerbound level	Upperbound level
Vascular success	Success rate	93%	97%	**90%**	**100%**
	Procedural failure Failure to cannulise by puncturing, failure passing the wire, failure to perform the intervention	5.3%[5] 4.7%[3] 7.2%[1]	3.6%[5] 3.4%[3] 2.4%[1]	**1%**	**7%**
	Access-site crossover Access-site crossover from radial to femoral approach or vice versa	5.9[3] *7.2%*[4] *6.2%*[5]	1.4[3] *2.0%*[4] *0%*[5]	**1%**	**7%**
Post-procedural complications	Major access-site haemorrhagic complications Complications requiring blood transfusion /vascular intervention/prolonged hospital stay	0%[4] 0.05%[3] 1.4%[4]	2%[4] 2.3%[3] 3.7%[4]	**1%**	**4%**
	Minor access site haemorrhagic complications Post-procedural haematoma	2.9%[4]	3.4%[4]	**1%**	**3%**
	Arterial Thrombosis Post-procedural asymptomatic or	3% -6%[1]	0.2-0.4%[2]	**1%**	**6%**

	permanent reduction in vessel diameter				
Patient comfort	Post-procedural patient comfort	Wrist should be secured with sling for 1 day and thereafter the patients should carefully return to normal activity[6]	Patients are not allowed to drive, swim, cycle, and may only perform easy (i.e. not heavy) activities (MST)[6]	**-**	**-**
Patient mobilisation (in hours)	Post-procedural mobilisation	No feed for (flat) bed rest[2]	2-3 hours flat bed rest[2] Flat bed rest 2-4uur (MST) 6-8 hours bedrest *(after manual compression)*[2]	**0 hours**	**8 hours**
Length of hospital-stay (in days)	Time from hospital admission to discharge	0.5- 1 day (CAG) or hospital stay for one night (PCI)[6] 1.5 days[5] 1.8 days[1]	1 day (CAG) or hospital stay for one night (PCI)[6] 1.8 days[5] 2.4 days[1] + 0.4 days[3]	**0.5 day(s)**	**2.5 days**
1 Agostoni et al. (2004) 2. Betrand (2010) 3. Jolly et al. (2009) 4. Jolly et al. (2011) 5. Kiemeneij et al (1997) 6. MST (n.d.)					

APPENDIX III ADJUSTMENTS FOLLOWING PILOT STUDY

ADJUSTMENTS FOLLOWING PILOT BY PATIENTS

- It was estimated that the time to complete the survey was between 15 and 20 minutes, which falls within the predetermined time margins.
- Patients who had procedure through TFA are best approached after completing flat bed rest. Between flat bed rest and mobilisation, patients have half an hour seating bed rest in which they are capable of filling in the questionnaire. Also at time of mobilisation patients can be recruited for the survey. Patients who had TRA procedure could be approached directly post-procedural, since flat bed rest is not required. Other possibilities mapped for the conduction of the survey were less suitable due to logistical reasons.
- It was found that patients who had procedure through TRA may not be able to fill in the questionnaire due to physical dysfunction. These patients will be supported by their relatives or may receive hands-on assistance by the author of study.
- It was found that the questionnaire can best be filled in by the patients themselves, without (much) interference of the author of study. To focus on the comments in the questionnaire and to answer the relative complex BWS questions, patients need time and rest to answer them. The author will be at the department and can at any time be reached for questions.
- Another argument for self-completing questionnaires is that extensive support by filling in the questionnaire turned out to be very timely or sometimes impossible and therefore only a limited number of patients, predominantly with psychical limitations and those able to designate the answers will get this support.
- Besides the information in the patient information folder (PIF) of the questionnaire, it was determined that patients should get limited oral information on the study-owners and on a covered aim of study. In order to prevent steering respondents' preferences, the actual aim of study was left unrevealed to the patients.
- Besides the general oral information the pilot suggest that patients should get additional instruction on the BWS questions, since four out of six were not able to answer the questions correctly during the first time. Instead, patients were selecting 'one' or 'all' items instead of a 'best' item and a 'worst' item. It was also criticized by some that the choice sets 'were very much alike' and others stated that all items in a scenario were tolerable, which hinders decision-making. Therefore, the instructions (with smileys) are repeated by every choice set and the written instructions as well as the sample question in part II of the questionnaire will in addition be orally explained.
- From the pilot it became clear that it should be emphasized that the BWS questions involves hypothetical treatments, to prevent (uninformed) patients' to get upset about the unattractive characteristics of treatments, such as 'bleeding', as mentioned in the questionnaire.
- Some patients handed in a questionnaire that was incomplete or incorrect. In order to restore the errors, the questionnaires should be controlled directly after collection at the department, because in a later stage no errors could be corrected due to the anonymously nature of the questionnaire. This means patients will be asked whether they agree upon a quick check on their given answers in the questionnaire.

- When errors are detected patients are asked if they have read the information and the additional instructions. Patients are then once asked if they are willing to restore the errors.
- For patients who were unable to fill in the questionnaire during hospital admission a postal return option was suggested. Patients with physical impairments could receive the questionnaire with a stamped envelope to take home. Those patients will get in advance the same oral information and instruction as those filling in the questionnaires at the department.

ADJUSTMENTS FOLLOWING PILOT BY HOSPTIAL CARE STAFF

- In two nurse-practitioners (NPs) remarks were made on the attribute-level 'You get a large bleeding, which will be treated with blood-transfusion', since the complication is very rare. It was therefore considered to alter the attribute into the surpassing level 'You get a severe hematoma on abdomen, buttocks and legs, however, this level may violate discriminating power since two attribute-levels will focus on hematoma. A second possibility was to replace the level with a level on the occurrence of aneurysm or a hematoma on the flank of the lower limb; since for both the incidence are higher. It was chosen to adopt neither of the attributes; however the complication of hematoma on the flank was included in part III of the questionnaire, since it is related only to procedures applied through TFA. The occurrence of an aneurysm was left out, since the concept requires too much explanation to patients.
- The attribute 'pain' was suggested for inclusion. Although pain could pose discriminating power between the treatment options, as the placement of an Angioseal or Proglide system by the TFA can cause pain or vasovagal reactions, it was chosen not to substitute an existing attribute or to add pain as the seventh attribute. Pain may be highly variable as it can vary between the actions of the responsible cardiologist and between the perceptions of the patient. No information was found in literature on the variable pain by vascular choice.
- Some nurses and NPs noticed the absence of a clear aim in patient information folder (PIF). Since patients should not be able to consciously force a preference outcome for access-site, it was decided to give patients additional information on the two-different access-sites in part III of the questionnaire and not in part II, which comprises the BWS choice sets.
- The term 'ingreep' may not be suitable since CAG is not a treatment, however to be consistent and to avoid multiple repetition and confusion of the terms: CAG and/or PCI, and because patients were estimated not to be influenced, the term was maintained.
- Another point of discussion was on the table in part III of the questionnaire. Literature had suggested that both CAG and PCI procedures can be provided in day care, which is in contrast to the legislation of the MST hospital that requires patients after PCI to stay for one night. In order to avoid confusion by patients, the qualitative measures were excluded and only six quantitative attribute-levels are presented. It was also stated that 3-4 hours or up to 6 hours flat bed rest are not conform MST guidelines; however these numbers were not altered in order to measure the impact of flat bed rest on the choice for a procedural access option.

APPENDIX IV EXPERIMENTAL DESIGN

TABLE 1 EXPERIMENTAL DESIGN GENERATED BY STATISTICAL SOFTWARE

VERSION	SET	ITEM 1	ITEM 2	ITEM 3	ITEM 4	ITEM 5	ITEM 6
1	1	1	8	5	12	7	15
1	2	9	10	3	4	6	13
1	3	7	5	9	10	15	2
1	4	5	6	2	9	11	14
1	5	11	7	4	3	9	15
1	6	4	11	13	1	8	7
1	7	3	12	14	8	4	6
1	8	6	14	10	5	1	8
2	1	2	4	11	7	14	8
2	2	15	2	8	6	10	5
2	3	10	9	7	14	4	1
2	4	12	14	7	5	3	9
2	5	8	15	3	7	5	10
2	6	13	7	12	9	2	4
2	7	8	4	6	1	12	13
2	8	6	13	8	11	5	3
3	1	14	3	5	9	7	12
3	2	9	1	4	14	6	12
3	3	5	9	15	2	12	6
3	4	4	3	6	15	8	11
3	5	7	8	2	13	10	4
3	6	11	1	9	6	13	5
3	7	4	6	1	15	9	11
3	8	2	5	12	8	13	7
4	1	3	15	12	4	6	8
4	2	5	11	13	2	7	9
4	3	8	10	1	6	14	5
4	4	6	5	10	13	9	3
4	5	7	2	4	11	8	14
4	6	14	4	9	10	2	6
4	7	15	8	11	7	5	1
4	8	10	9	7	4	1	15

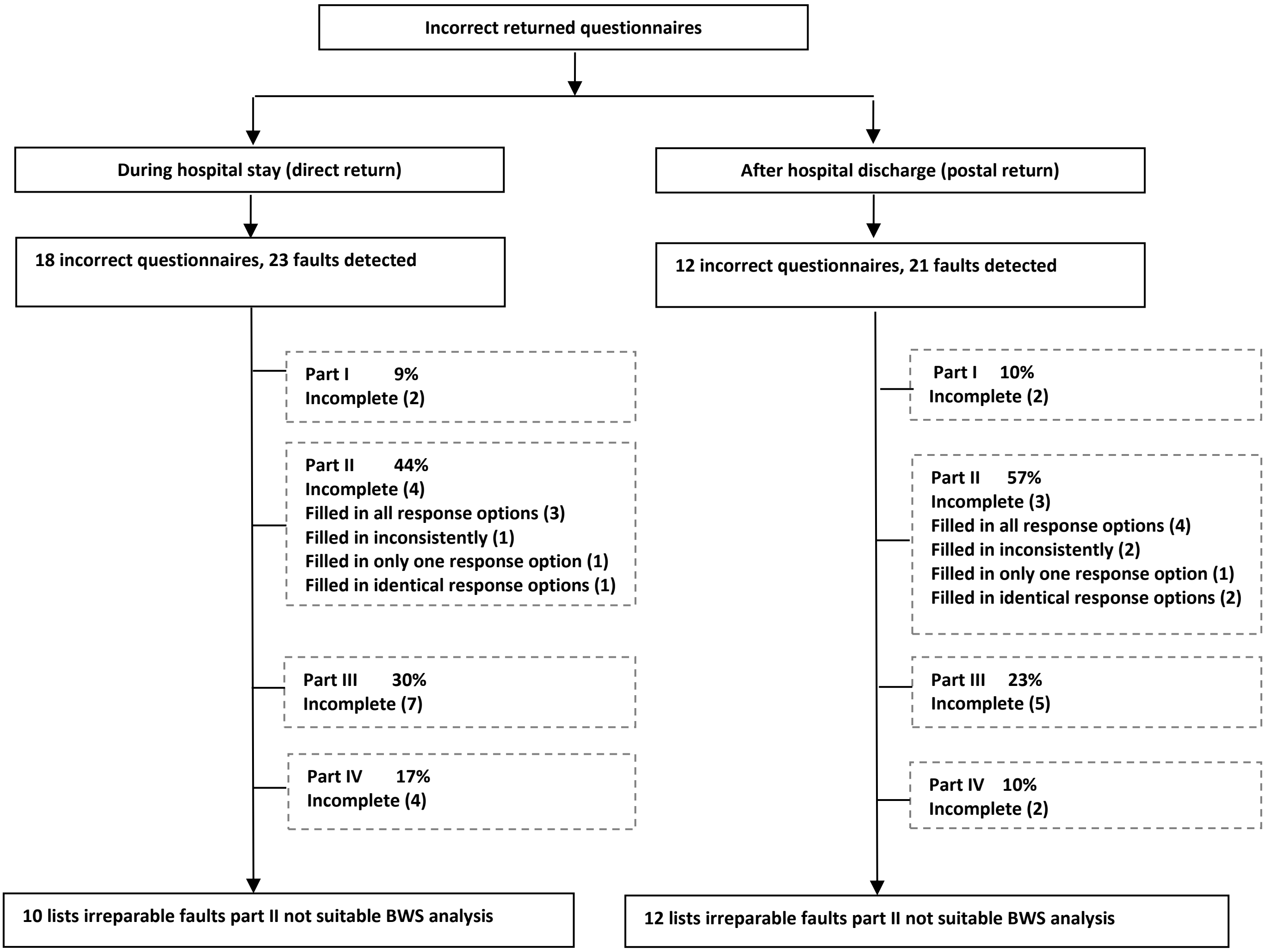
APPENDIX IV (CONTINUED)

TABLE 2 NUMBER OF ITEMS PER ATTRIBUTE, LEVEL AND VERSION

ATTRIBUTE	**LEVEL**	**V1**	**V2**	**V3**	**V4**	**TOTAL PER LEVEL**	**TOTAL PER ATTR**
1	**1**	3	2	3	3	11	**32**
	2	2	3	3	3	11	
	3	3	3	2	2	10	
2	**4**	4	4	4	4	16	**32**
	5	4	4	4	4	16	
3	**6**	4	3	5	4	16	**32**
	7	4	5	3	4	16	
4	**8**	4	5	3	4	16	**32**
	9	4	3	5	4	16	
5	**10**	3	3	1	4	11	**32**
	11	3	2	3	3	11	
	12	2	3	4	1	10	
6	**13**	2	3	3	2	10	**32**
	14	3	3	2	3	11	
	15	3	2	3	3	11	
TOTAL PER VERSION		**48**	**48**	**48**	**48**		**192**

APPENDIX V FLOWCHART INCORRECT RESPONSES PPQ

FLOWCHART SCRUTINIZATION INCORRECT RESPONSES



Note: The questionnaire consisted of four parts which were individually analysed on errors. Errors are scaled within five categories; incomplete, filled in all response options, filled in inconsistently, filled in only one response option, and filled in two identical response options.