Detailed disclosure to Saudi Arabian patients on risks related to an invasive procedure

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ABSTRACT

الأهداف: قياس أثر إعطاء معلومات تفصيلية للمرضى السعوديين عن المضاعفات الممكنة لقسطرة شرايين القلب على الموافقة للخضوع للفحص.

الطريقة: أجريت دراسة عشوائية خلال الفترة من أغسطس 2006م إلى يونيو 2007م، في مستشفى الملك خالد الجامعي – الرياض – المملكة العربية السعودية. تم تقسيم المرضى بشكل عشوائي بناءً على ورقة تحتوي على معلومات مختصرة عن المضاعفات المتعلقة بقسطرة شرايين القلب، أو ورقة تحتوي على معلومات تفصيلية. أكملت كلتا المجموعتين الاستبيان المختصر بعد التعرض للورقتين. كان الهدف الأولي لهذا البحث هو عدم الموافقة على الخضوع للقسطرة، والأهداف الثانوية هي معرفة درجة القلق الناتجة من الورقة التي تحتوي على بيانات تفصيلية، ومدى مناسبة كمية المعلومات المتعلقة بالمضاعفات المصاحبة للقسطرة القلبية الشريانية.

النتائج: تم إدراج 106 مريض سعودي لهذه الدراسة، واستبعد 6 مرضى فيما بعد. كان متوسط العمر 58 عام، منهم 45 (45%) أمّيون. عرضت على 53 مريض ورقة المعلومات المختصرة، بينما عرضت على 47 مريض الورقة التفصيلية. رفض مريض واحد (1.8%) ممن عرضت عليهم الورقة المختصرة الخضوع للقسطرة، بينما رفض القسطرة 5 مريض (10.6%) عرضت عليهم الورقة التفصيلية (p=0.06, 95% CI 1.2-2.8). أجاب 94 مريض على الاستبيان وأشاروا بأن المعلومات التي أعطيت لهم كانت كافية، بما في ذلك كل المرضى الذين عرضت عليهم الورقة المختصرة. كما أشار 22 مريض (48.8%) من الذين عرضت عليهم الورقة التفصيلية بازدياد في درجة القلق بعد سماعهم للمضاعفات المتعلقة بالقسطرة القلبية.

خاتمة: لا يوجد أي دلالة إحصائية مختلفة في الموافقة للخضوع للقسطرة القلبية بين الورقة التي تحتوي على معلومات مختصرة، ومفصلة بين المجموعتين. لم يكن الكشف التفصيلي للمضاعفات المتعلقة بالقسطرة القلبية مطلوباً من غالبية المرضى.

Objectives: To measure the effect of providing a detailed description of coronary angiography risks on obtaining informed consent from Saudi Arabian patients.

Methods: This randomized controlled trial was conducted at King Khalid University Hospital, Riyadh, Saudi Arabia from August 2006 to June 2007. Patients were randomized to either an information sheet containing brief information on procedure-related risks (brief sheet), or full disclosure of risks (detailed sheet). Both groups completed a brief questionnaire following exposure to either sheet. Primary endpoint was refusal to consent to coronary angiography. Secondary endpoints were anxiety following exposure to the detailed sheet and appropriateness of the amount of risk disclosure contained in both information sheets.

Results: One hundred and six Saudi patients were enrolled, 6 patients were later excluded. Mean age was 58 years; 45 patients (45%) were illiterate. Fifty-three patients were randomized to the brief sheet, and 47 to the detailed sheet. Only one patient (1.8%) given the brief sheet refused consent, compared to 5 patients (10.6%) given the detailed sheet (p=0.06, 95% confidence interval 1.2 to 2.8). Ninety-four patients responding to the questionnaire felt that the information given was enough, including all of the patients randomized to the brief sheet. Twenty-two patients randomized to the detailed sheet indicated increased anxiety after hearing procedure-related risks.

Conclusion: We found no significant difference in consent status between the detailed and brief disclosure of procedure-related risk groups. Most patients did not require detailed risk disclosure.

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Obtaining informed consent before performing invasive diagnostic, or therapeutic procedures is a standard of practice worldwide. Its primary purpose is to inform patients on the risks, and benefits of the planned procedure.[1-2] Furthermore, an informed consent serves as legal proof that patients are informed of known potential procedure related risks, should a patient litigate if a complication occurs.[2] Obtaining informed

consent reflects a recognition of patient autonomy, allows rational decisions regarding individual patient care to be made, and fosters trust between physicians, and their patients.[3-5] In addition, based on the universal declaration on bioethics, and human rights, obtaining informed consent is an essential requirement before patients are enrolled in medical research studies.[6] Receiving information prior to procedures that details potential adverse outcomes may increase some patients' level of anxiety.[2,7] In Eastern cultures, families very often instruct physicians to withhold information that might cause distress, or anxiety to the patient, and often decide on their behalf.[3,8] As a result, consent, often uninformed or based on abbreviated information, is obtained from these patients to please their families and to avoid refusal of consent. Based on the anecdotal evidence of many Middle Eastern physicians, full disclosure to their patients of the potential complications of an invasive procedure would lead to refusal to consent and would increase their anxiety. Accordingly, the objective of our randomized controlled trial was to investigate whether providing detailed information to Saudi patients on the potential complications of coronary angiography or angioplasty would lead to increased refusal of consent.

Methods.

Patient population. This study was conducted from August 2006 to June 2007. Patients eligible for this study were Saudi patients attending King Khalid University Hospital, Riyadh, Kingdom of Saudi Arabia, a government hospital that receives referrals from a wide geographical area, who were booked for elective diagnostic coronary angiography, and were able to consent to the procedure. Patients were excluded if: 1. Proper communication could not be established because of a hearing, visual, or mental impairment. 2. They had previously undergone a diagnostic, or therapeutic cardiac catheterization. 3. They had previously consented to a diagnostic, or therapeutic cardiac catheterization. 4. They had been previously exposed to information related to the risks of diagnostic, or therapeutic cardiac catheterization. To assess patients' knowledge on the procedure, patients were asked prior to enrolment if they had a friend, or relative who had undergone cardiac catheterization. Their knowledge of the procedure, and its related complications were then assessed; if they were well informed, they were excluded from the study.

Study design. This was a randomized controlled trial with an intention-to-treat analysis, and group allocation was concealed. Eligible patients were assigned via computer-generated randomization to one of 2 information sheets, "brief" or "detailed." Both information sheets were in Arabic, and were placed in sealed envelopes that were opened only after the patient was randomized. They were read by a physician dedicated to this study, and then given to patients.

The brief information sheet contained a full description of the procedure, including a brief general account of the procedure's risks, and complications. The detailed sheet provided the same description of the

Table 1 - The full text of the translated information sheets.

(1) **Brief information sheet**
Your physician has requested a coronary angiogram to check the arteries that supply your heart muscle with blood. This test is an accurate test to diagnose narrowing of the arteries supplying your heart, and is performed by physicians experienced in doing this test. You will be fully conscious during the exam, and the physician will inject the skin overlying the artery in your upper thigh or wrist with a local anesthetic so that you will not experience pain during the exam. He will then push a flexible plastic tube through the artery in the upper thigh or wrist. The tube will then be advanced until it reaches the arteries supplying the heart muscle with the guidance of an x-ray machine. Following that, a contrast material will be injected into the heart arteries, or the pumping chamber using the plastic tube. After pictures of your arteries are taken, the doctor will determine whether there is narrowing in one or more of the arteries supplying the heart muscle, and if suitable, will dilate the narrowing using a small balloon, then place a small metal tube to keep the artery open or to avoid repeated narrowing. Many patients undergo coronary angiography every day, without problems or complications. The complications that could result from the test are extremely rare, and if they occur, they are usually mild. I am prepared to answer any questions that you may have about this procedure.
(2) **Detailed information sheet**
Your physician has requested a coronary angiogram to check the arteries that supply your heart muscle with blood. This test is an accurate test to diagnose narrowing of the arteries supplying your heart, and is performed by physicians experienced in doing this test. You will be fully conscious during the exam, and the physician will inject the skin overlying the artery in your upper thigh or wrist with a local anesthetic so that you will not experience pain during the exam. He will then thread a flexible plastic tube through the artery in the upper thigh or wrist. The tube will then be advanced until it reaches the arteries supplying the heart muscle with the guidance of an x-ray machine. Following that, a contrast material will be injected into the heart arteries or the pumping chamber using the plastic tube. After pictures of your arteries are taken, the doctor will determine whether there is narrowing in one or more of the arteries supplying the heart muscle, and if suitable, will dilate the narrowing using a small balloon, then place a small metal tube to keep the artery open or to avoid repeated narrowing. Many patients undergo coronary angiography every day, without problems or complications. The complications that could result from the test are extremely rare, and if they occur, they are usually mild. Of the complications that could occur, one is a bruise at the plastic tube insertion site because of blood collection. This usually resolves within a few days; however, on some occasions, the blood collection is a result of continuous bleeding from the artery, which may require a blood transfusion. On occasion, electrical disturbances in the heart may necessitate giving you medications or possibly an electric shock to terminate the disturbance and bring your heart back to its normal condition. The contrast material injected into the heart arteries may cause allergy in the form of a skin rash, which can also be associated with shortness of breath or a drop in your blood pressure; this can be treated effectively with medications. In rare situations, the procedure may be associated with serious complications such as stroke, heart attack, the need for urgent cardiac surgery, or, very rarely, death, I am prepared to answer any questions that you may have about this procedure.

procedure; however, it contained a far more detailed description of the procedural risks. The risks cited were death, myocardial infarction, cerebrovascular accidents, bleeding, emergent cardiac surgery, and allergic reactions to the contrast agent. The risks were given as probabilities instead of percentage figures. Both information sheets stated that further inquires on the procedure, and its complications were welcome, and patients randomized to the brief sheet were allowed to cross over to the detailed sheet if further information on complications was requested. The full text of the translated information sheets is included in **Table 1**. Diagnostic coronary angiography, and percutaneous coronary interventions were performed in accordance with standard methods. Diagnostic catheters, and angioplasty guides were inserted via either the femoral, or radial arteries. Ethics approval was obtained from the King Khalid University Hospital institutional review board.

Data variables. Baseline demographics were obtained, including age, gender, marital status, area of residence, level of education, occupation, and indications for cardiac catheterization. Following exposure to either information sheet, all of the patients were asked to answer a short questionnaire. This included questions on whether enough information was provided on the procedure, and its complications, and whether the information on procedural complications helped the patient to decide whether or not to undergo the procedure. Patients randomized to the detailed information sheet were asked if knowledge on the procedural complications increased their anxiety level. Patients who refused to provide consent answered a standard questionnaire that investigated the cause of refusal; for example, being afraid of complications, needing the advice of family members, needing more time to think, and undecided on whether to undergo the procedure.

Study endpoints. The primary endpoint was initial refusal to consent to the planned procedure. Secondary endpoints were whether consenting patients preferred detailed, or brief information before undergoing the procedure, and anxiety following exposure to the detailed information sheet. An interim analysis was performed after 50 patients were enrolled, and the results were submitted to the ethics board. The individual, who performed the statistical analysis, was blinded regarding patient allocation to the information sheets.

Statistical analysis. With a power of 90% at a Type I error of 5% (two-sided), to detect a difference of 7.4 units in the anxiety level between the 2 groups assuming that the standard deviation of the response variable is 11.1, 98 patients were required for this parallel-design study. The analysis was carried out on an intention-to-treat basis. A secondary efficacy analysis was performed for those patients who crossed over to the detailed sheet arm. Categorical variables are summarized as mean ± standard deviation. Fisher's exact test, or chi-square test was used for categorical variables to assess group differences. All tests were two-sided, with a 5% level of significance. All analyses were performed using STATA version 9, (Stata Corp, Chicago, Illinois, USA).

Results. One hundred and six patients were enrolled from August 2006 to June 2007. Six patients were later excluded as they met an exclusion criterion. The mean age for the entire cohort was 58.4±11 years (range 23-85 years), and 69 (69%) were men. A large proportion of the patients was illiterate 45 (45%), and only 13% had a university degree or higher. Most of the patients came from urban areas 78 (78%). Of

Table 2 - Baseline characteristics of patients (N=100).

Variable	Brief sheet (n=53)	Detailed sheet (n=47)
Age (mean)	57.5±11	59.4±12
Gender		
Males	34	35
Females	19	12
Education		
Illiterate	25	20
≤Secondary school	19	21
≥Secondary school	9	6
Residence		
Rural	12	10
Urban	41	37
Marital status		
Married*	39	43
Widowed*	9	1
Divorced	5	3
Indication for catheterization		
Acute coronary syndrome	33	31
Heart failure	6	4
Valvular dysfunction	2	2
Others	12	10
Employment		
Employed	28	28
Self employed	4	5
Unemployed	3	3
House wife	18	11

*p=0.02

Table 3 - Patients stratified by consent status.

Consent status	Brief sheet (n=53)	Detailed sheet (n=47)
Consented	52	42
Refused to consent n(%)*	1 (1.8)	5 (10.6)
Reasons for consent refusal		
Need family help	0	4
More time to think	1	4
Afraid	1	5
Unsure	1	4

*p=0.06 (NS - not significant)

the 100 patients enrolled, 53 were randomized to the brief information sheet, and 47 to the detailed sheet. **Table 2** depicts patient baseline demographics of the 2 groups. There were no differences between the 2 groups with respect to baseline characteristics, except for a significantly higher rate of marriage in the group assigned to the detailed sheet, and a significantly higher rate of widowers in the group assigned to the brief sheet (p=0.02). A total of 6 patients (6%) refused to consent to coronary angiography; one patient (1.8%) was in the brief information group, and 5 (10.6%) were in the detailed information sheet group (p=0.06, 95% confidence interval 1.2-2.8). All 6 patients refusing to consent were illiterate. Four patients assigned to the brief information sheet required more details, and therefore, crossed over to the detailed sheet. None of the patients who crossed over refused consent, after detailed risk disclosure. All 6 patients who initially refused consent, eventually consented after receiving counseling from their physicians, or families. When asked on the reasons for refusing to consent, all 6 patients listed fear of procedure-related complications, and the need for further family consultation (**Table 3**). Ninety-four patients responded to the question of whether the information provided was sufficient. All 94 patients thought that the provided information was sufficient; including all of the patients randomized to the brief information sheet. Ninety-six patients responded to the question of whether they felt that the information helped with their decision to undergo the procedure. Of these, 91 patients (94.7%) felt that it did not help them with their decision to undergo the procedure. Twenty-two (48.8%) patients randomized to the detailed information sheet felt that information on risk increased their anxiety level. Four out of the 5 patients refusing to consent, who were randomized to the detailed sheet indicated that there anxiety level increased.

Discussion. Our study revealed that detailed disclosure of complications related to coronary angiography increased anxiety, and led to an approximately 5 fold increase in the rate of refusal to consent to the procedure. Although none of the treating physicians refused to involve his patients in this study, and all of the patients deemed to be suitable for the study were randomized, most treating physicians were worried that full disclosure of risk would cause anxiety or distress to the enrolled patients and their families, leading to refusal to consent. Our brief questionnaire did show increased anxiety in a large proportion of patients randomized to the detailed information sheet, and fear of undergoing the procedure was the most common reason given for refusal to consent. However, refusal to consent following exposure to the detailed sheet was not statistically different than refusal to consent following exposure to the brief sheet. Moreover, all of the patients eventually, consented shortly after receiving counseling from their families, or treating physicians. Goldberger et al,[2] previously showed that detailed knowledge of the risks of a cardiac electrophysiology study led to a significant increase in anxiety, as assessed by the Spielberger State-Trait Inventory. In another study,[7] detailed risk disclosure prior to receiving intravenous contrast for computed tomography was associated with increased anxiety levels. Our study confirmed these findings; furthermore, it explored the potential adverse outcomes of excessive anxiety, such as the acceptance, or refusal of a necessary medical procedure. Despite the crossover of 4 patients to the detailed consent group, all of the patients eventually, agreed to undergo the procedure; thus, there was no statistical trend for refusing consent.

An interesting finding of our study was that all of the patients felt that enough information on procedure-related risks was contained in both information sheets, including all of those exposed to the brief information sheet, which contained no individual risks, but a general statement indicating that complications may occur, and then provided an opportunity to ask questions if desired. This may indicate that full disclosure of risk was not preferred, or at least that it was not expected. There is evidence to suggest that many patients and/or their families have an implicit, or sometimes explicit wish that information pertaining to life-threatening conditions, or risks, and complications caused by invasive interventions be withheld; the patient's ethnicity is one determinant of how much or what information is expected.[8,9] A British study,[10] that interviewed patients following consent for coronary artery bypass surgery showed that 42% of patients did not want to know any of the procedural risks, and only 46% wished to know the risk of death. This is in contrast to a Swedish study,[11] which showed that the majority of patients preparing to undergo cardiac surgery wanted detailed information on complications, and that those who were given more details were not more anxious than patients receiving fewer details. A substantial majority of our study cohort felt that any information on risk would not have altered their decision to undergo the procedure. This may indicate a high level of patient-doctor trust, or, alternatively, full delegation of medical decision-making to their physician, or perhaps to their family. This could not be verified based on the questionnaire used in our study. Regardless of the cause, these findings suggest that our study participants follow the family-centered or physician-centered model of medical decision-making commonly seen in traditional cultures, as opposed to the Western patient-autonomy model.[3,9]

The perception of individual autonomy and the right to be informed is subject to change over time, and often reflects cultural evolution. This is evident by the fact that in 1961, 90% of physicians in the United States did not inform their patients of the diagnosis of cancer. This dramatically changed over the subsequent 19 years, after which a survey showed that 98% of physicians made it their policy to inform patients of their cancer diagnosis.[3,4] Education is often thought of as a means for developing individual autonomy.[12] Given that 45% of our study participants were illiterate, this may have influenced their perception of what constitutes sufficient information on risk; however, this assessment was not an aim of our study. Although there are differences between consenting to a medically mandated procedure, and consenting to research-based procedure, there are also some similarities. The results of our study are particularly important at this point in time, given the increasing cost of conducting randomized clinical trials in Western countries, and the increasing trend toward outsourcing clinical research to developing countries, including centers in the Middle East. Exploring ethical issues pertaining to obtaining informed consent in Middle Eastern cultures paves the road for conducting clinical research in this part of the world.

Our study has several limitations. Although the study venue was a large referral center that received patients from a wide geographical area, this was a single-center study, raising questions on the generalizability of the findings. Therefore, multicenter studies in Saudi Arabia need to be conducted to confirm our findings. To avoid contamination bias, our patients' knowledge on the planned procedure was investigated by asking them a simple question. The response to the question could have been influenced by recall bias. In addition, patients did not read the consent form or fill out the attached questionnaire on their own, raising the possibility of bias. Due to the large percentage of illiteracy, or functional illiteracy in this cohort, the only available approach was to train a physician to read the contents of the information sheets, and the brief questionnaire aloud in a standardized fashion. Moreover, anxiety was not assessed using a standard assessment tool, and therefore the assessment may not have been rigorous. There are no available validated Arabic language anxiety assessment questionnaires that can be used in an interview format rather than being self-filled. Although there was a statistical trend towards refusal to consent among patients randomized to the detailed sheet, potentially raising concerns on the adequacy of the sample size, this trend was abolished once more patients crossed over to the detailed sheet. When we made the sample size calculation, we used studies that assessed the effect of detailed risk disclosure on anxiety levels; an endpoint that we felt is a surrogate for refusal to consent. Although it is our belief that all patients should be informed on important potential procedure related risks, future research should focus on identifying types of risks that patients want to know, and consequently designing methods to separate those patients who do not want detailed risk disclosure in order to fulfill patient's wishes and decrease procedure-related anxiety. In addition, the use of multimedia in information presentation, a method that has been shown to improve patients' comprehension, recall, and on some occasions alleviate anxiety, should be considered in future studies addressing an endpoint similar to ours.

In conclusion, we found no significant difference in consent status between the detailed and brief disclosure of procedure-related risk groups. Patients did not require detailed information on risk, and those exposed to detailed information suffered from more anxiety. Physicians should continue to fulfill their ethical and legal obligation of fully informing their patients, while also counseling them on the importance of the therapeutic or diagnostic merits of the intended procedure.

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