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A STUDY OF PATIENT MOTIVATION AND PREFERENCES REGARDING PARTICIPATION IN MEDICAL RESEARCH PRIOR TO CARDIAC SURGERY

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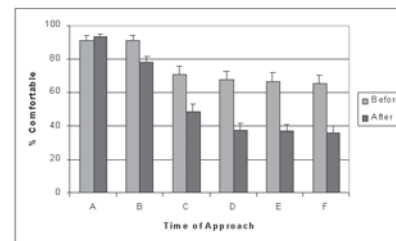
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Introduction: Little is known about patient's motivation and preferences regarding participation in medical research when they are faced with major surgical interventions such as heart surgery. Studies performed in a variety of different settings have previously uncovered some reasons such as altruism and perceived opportunity to receive better medical care for patient participation in clinical trials¹⁻³. Reasons for declining participation include a fear of risks involved with the study and anxiety about current illness or treatment^{1,4-6}. In addition, the time period when patients would prefer to be approached for participation in medical research is unknown. Therefore we designed a prospective clinical study to document these motivations and preferences in the cardiac surgery patient population.

Methods: Following IRB approval and informed consent, 241 adult patients presenting for cardiac surgery were enrolled. They were asked to complete a questionnaire designed specifically for this study comprising 12 questions (Q) including multiple choices and open ended items. A researcher was immediately available during survey completion to insure that the content and answers were properly interpreted as needed. Patients were approached either before surgery (group BEFORE, N=106) or after surgery (group AFTER, N=135) in an attempt to demonstrate whether a different attitude could be demonstrated as a result of the experience of the perioperative environment. A generalized estimating equation (GEE) was employed to compare both groups. Patient demographical information, health status and prior enrollment in research were recorded.

Results: The mean age of the population studied was 60.4 years old, male to female ratio was around 2:1, 82% were inpatients, and 71% presented for CABG surgery. Overall, 86% thought that medical research helps to improve the health of others (Q1). 71.6% of patients surveyed had previously been approached for another medical study (Q2), of which 57.6% had accepted to participate (Q3). For those patients who accepted the main reasons for accepting (Q4) were to improve the health others (88%) and to advance medical science (72%). Reasons most often given by those who had

previously refused participation to medical research (Q5) include anxiety related to cardiac surgery itself (17.1%), confusion about the nature or effect of the medical study (15.8%) or lack of interest towards the study (10.5%). Interestingly, 62.3% of patients surveyed did not think that the timing of the approach for consent in a study prior to surgery would influence their decision to participate (Q7). However, when given specific examples, they expressed a preference for being approached at the greatest possible interval prior to the surgical intervention (Q8). Furthermore, there was a significant difference ($P<0.001$) when comparing the BEFORE and AFTER groups (Figure 1). We found no other significant covariate that predicted answers in the comparison between BEFORE and AFTER groups. Finally, 20.2% of all patients surveyed would rather enroll in a non-surgical study, 21% would prefer a surgical study and 54% would be equally likely to enroll in both. The remaining 4.8% were not willing to participate in any medical study (Q12).



Discussion: This study demonstrates that patients faced to cardiac surgery are no different from other patient populations in their willingness to participate in medical research and in their motivations (mainly altruistic) in enrolling in such studies. However, this patient population manifests a decreasing degree of comfort towards possible participation as they get closer to surgery. Perhaps more importantly, this degree of discomfort is even greater for patients who have previously had the experience of cardiac surgery. The majority of patients in the AFTER group were not willing to consider participating in medical research on the same day of surgery if they were approached after they have left their hospital room.

References:

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