Title: Evaluation of Informed Consent for Anesthesia for Labor and Delivery

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Introduction: Our society has determined that all competent adults have the right to determine what medical treatment they receive. Consequently, there are legal and ethical requirements that patients give informed consent to medical procedures. However, the best way to fulfill this obligation is not clear.[1] A previous study documented only a 42% recall of informed consent topics despite a tape recorded pre-operative discussion.[2] Additionally, the mental and physical competence (a requirement for valid consent) of women during labor and delivery can be debated. The purpose of this study was to evaluate the ability of laboring women to recall a pre-anesthesia discussion, and to determine if verbal consent alone or verbal plus written consent provides superior recall.

Methods: Following approval by the Clinical Research Practices Committee, we studied one hundred and thirteen women who were admitted to the labor and delivery suite. Women were randomly assigned to one of two groups - verbal or verbal plus written. All pre-anesthetic interviews were performed by one of the investigators, and included a discussion of anesthetic options, procedures, and risks. A checklist was employed to ensure that certain topics were discussed with all women. Following the discussion, the verbal plus written group was given a written consent form that reiterated the topics previously discussed. Following a reading and signing of the form, the women were given a copy to keep. A telephone follow-up discussion to all women was attempted 5 to 7 months later. The investigator making the follow-up call was blinded to which group the women were in. Ten objective questions were asked regarding recall of the pre-anesthetic interview. Responses were scored: Correct = 10 points, incorrect = 0 points, not sure = 5 points. Subjectively, the women were asked whether or not they felt that they had been able to give valid informed consent for the anesthetic (if any) that they received. In addition, they were asked whether or not they considered a written consent form to be unnecessary (not informative) or frightening. Whether patients had private physicians or were on the teaching service was recorded. Statistical analysis included mean, standard error, and unpaired t-tests.

Results: Eighty two women (38 in the verbal group and 44 in the verbal and written group) were reached for follow-up. The verbal plus written group had significantly higher recall scores (90 ± 2) than the verbal group (80 ± 2). Only two women (both in the verbal group) felt that they were unable (due either to inadequate information or to situational stress) to give valid consent. Four women (3 in the verbal group and one in the verbal plus written group) felt that written forms were frightening and not informative. There was no significant difference between groups (eight in each group) in the number of patients on the teaching service.

Discussion: The concept of "valid" or "informed" consent is difficult to clearly measure or define. Informed, but uneducated, consent is of little value.[3] Recall of certain topics is not necessarily equivalent to understanding and comprehension of the topics. Due to a lack of suitable alternatives, however, recall scores are used as an indicator of understanding and comprehension and as a basis for comparing different consent protocols. Certain factors (presenter of information; amount, clarity, and type of information) can affect comprehension of informed consent. This study used a physician to present a limited amount of information in a structured manner. Information regarding risks was limited to those risks considered to be either quite common or the most severe. The risks presented were intended to represent a variety of possible complications, although the list was not intended to represent all possible complications. The discussion of risks was followed with reassurance. Aside from potential improved understanding and comprehension of anesthetic considerations by patients, there are other reasons to use a written consent form. A written consent form provides tangible evidence, obtained at a time when the discussion is not a focus of controversy, that certain topics were discussed. Ideally, a written consent form would be a non-threatening and educational document, as well as medico-legal evidence. This study found that, for laboring women, a verbal discussion plus a written consent form resulted in significantly higher recall scores than a verbal discussion alone. In addition, the high recall scores achieved by the women in both groups suggest that the majority of laboring women are at least as mentally and physically competent to give consent as pre-operative cardiac patients.[2]

References:

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