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A Study of the Quality of Informed Consent of Anesthesia for Cesarean Deliveries: What and Whatnot was Discussed with Parturients

Muhammad Ajmal

Department of Anaesthesia, Coombe Women and Infants University Hospital, Dublin, Ireland

Abstract

Study objective: To examine whether the principle of informed consent was applied to practice of anesthesia for elective cesarean deliveries in our general hospital.

Design: Prospective observational cohort study.

Setting: Maternity ward of a general hospital.

Study subjects: Twenty-five parturients in their postoperative period after their first and elective cesarean deliveries and 25 anesthesiologists.

Interventions: Application of a questionnaire and an information pamphlet describing various forms of anesthesia for cesarean delivery.

Measurements/Observations: To assess patients' background knowledge about anesthesia, to determine the quality of informed-consent applied to the practice of anesthesia for elective cesarean deliveries i.e. explanation of proposed anesthesia procedure to parturients undergoing cesareans including explanation of advantages, disadvantages of proposed anesthesia procedure, alternative to proposed anesthesia procedure, explanation of its relative advantages and disadvantages and influence of adequate disclosure on patients' choice of anesthesia.

Results: In 19/25 parturients, trainees and in 6/25, consultants administered informed consent of anesthesia. All study patients (25/25) received spinal anesthesia. All those patients were given some information about spinal anesthesia but none of the patients (0/25) was informed about the availability of epidural or general anesthesia for their cesarean deliveries and benefits and risks associated with these techniques.

Conclusion: In this single institution study, patients reported that the risks/benefits of all possible anesthetic options for an elective cesarean delivery were not addressed during the informed consent process.

Keywords: Anesthesia-obstetric; Ethics; Informed-consent

Introduction

Responsibility of practitioners to obtain consent of their patients for treatment is not a new idea but its transition from consent to informed-consent occurred during 20th century as human civilization matured [1-4]. The term "consent" was limited to explain the nature of a treatment or stages of a procedure and its acceptance or rejection by the patients whereas the term "informed-consent" in addition includes explanation of benefits, drawbacks and alternative to a proposed treatment or a procedure. Society knew the concept of consent as early as the 18th century from an English case; Slater vs. Baker and Stapleton [1]. An American court acknowledged the necessity of informed-consent in early 20th century and term itself was used first by another American court in 1957 [2,3]. Currently there is no dispute about patients' right to know about their treatment or procedure but what and how much of it these patients should know is still open to question.

Informed consent of anesthesia is a basic component of good medical practice [4]. The goal of informed consent is to protect patients' rights whereas surgeons and anesthesiologists consider it a tool to protect them against medicolegal actions [5]. In the absence of appropriate code of procedure, anesthesiologists may start choosing anesthesia for their patients according to their personal preferences due to many motivational influences [6,7]. The objective of this study was to examine whether the principle of informed consent was applied to practice of anesthesia for elective cesarean deliveries (CD) in our general hospital.

Materials and Methods

After institutional ethical approval of Sligo General Hospital, Sligo, Ireland and verbal informed consent of participating patients, a prospective observational cohort study was performed. The objective of this study was to examine if the principle of informed consent was applied to the practice of anesthesia for elective CDs in our general hospital. Data collection was continuous for a six month period. A total of 25 parturients were recruited. Patients fit for regional (spinal and epidural) and general anesthesia (GA) for their first and elective CDs was eligible to participate. Women associated with healthcare professions or those who received both regional and GA due to any reason were excluded from the study. Data were collected through the application of a questionnaire. Questions were designed to assess patients' background knowledge about anesthesia (questions 1 and 2),

Corresponding author: Muhammad Ajmal, Department of Anaesthesia, Coombe Women and Infants University Hospital, Dublin 8, Ireland, Tel: 353 860231261; E-mail: Ajmal_c@hotmail.com

***Previous affiliation and data collection:** Department of Anaesthesia, Sligo General Hospital, Sligo, Ireland

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to assess quality of informed consent in practice of anesthesia (questions 3,4 and 5) and influence of adequate disclosure on patients' choice of anesthesia (question 6). The initial version of that questionnaire was piloted on five observations and was then modified to final version (Appendix 1). A simple description of regional anesthesia (spinal and epidural) and GA was also prepared in the form of a pamphlet (Appendix 2). That pamphlet was used to deliver information to patients about different types of anesthesia available for CD.

Operating room record of CDs was the primary source to indicate that a potentially eligible patient was available in the maternity ward for recruitment. Eligibility for recruitment was ascertained from her medical record. A dedicated investigator approached eligible patients within 12-24 hours in the postoperative period. After receiving formal verbal information, willing patients were recruited. Participants were asked to complete the questionnaire. They were instructed to read information pamphlet before answering the questions. Patients completed questionnaires according to their convenience during their hospital stay [8]. Completed questionnaires were checked for accuracy and unanswered questions at the time of collection. Patients were asked to complete and clarify the questionnaire if parts were left unanswered. During the period of data collection, anesthesiologists working in the hospital were blinded to the study. The number of anesthesiologists who worked in the hospital during the period of data collection was determined from the hospital record. The experience of anesthesiologists who performed pre-anesthetic assessment in study patients was determined from patients' records. Supposed informed consent for anesthesia was administered to these patients in the morning on the day of surgery during their pre-anesthetic assessment. Each patient was assessed in a separate room in complete privacy. None of these patients was given any anesthesia related information-pamphlet during their antenatal visits.

Results

A total of twenty-five anesthesiologists worked in the hospital during the period of data collection of which eleven were trainees and fourteen consultants (attending).

Characteristics of participating patients are summarized in Table 1.

All twenty-five patients were given spinal anesthesia. In 19/25 patients, supposed informed consent was obtained by trainees and in 6/25 patients by consultant anesthesiologists. From their background knowledge, all patients were aware of the existence of an alternate anesthesia (GA and epidural) technique for CDs but none of those patients (0/25) was informed by the anesthesiologist about the availability of an alternate option of anesthesia (epidural or GA) to her. Although all the patients were given information about the procedure of spinal anesthesia, 15/25 patients were not provided information about risks and benefits associated with it. Through their answers, seven of the twenty-five patients expressed a wish to choose alternate type of anesthesia (GA) in case they had to undergo CDs in future.

Age (mean) years	30.78
Education 3rd level/Degree/College O level/Secondary level/ Unknown*	 9/8/3 1/1 3
Profession Working women/House wives/ Student	 22/2/1
Anesthesia received Spinal/Epidural/General	 25/0/0
ASA** anesthesia risk grade ASA-I / ASA-II	 16/9
Indications for cesarean Unstable lie/Breach/CPD***	 9/10/6
Pre-anesthetic assessment performed by: Trainee/Consultant anesthetist	 19/6

*Patients not able to ascertain the level of their education.
**American society of anesthesiologists
***Cephalopelvic disproportion

Table 1: Patient characteristics.

Discussion

The results indicated that at the time of obtaining presumed informed-consent, patients were informed of the fact that they will receive spinal anesthesia for their CDs and that the procedure of spinal anesthesia was also described to them. They were not informed that epidural and GA was also available as alternate option to those who might not have been willing to accept spinal anesthesia or who might have required GA in case of a failed spinal anesthesia. They were also not alerted that they were being offered spinal anesthesia due to its advantages over epidural and GA for CDs. Sixty percent of the study patients were not given any information about the most common or most serious complications (although rare) which could have been associated with spinal anesthesia. In the setting described, although anesthesiologists were successful in applying the concept of consent their practice did not rise to the expectations of informed-consent. It appears that in choosing spinal anesthesia for their patients, anesthesiologists acted according to their medical knowledge rather than their ethical obligations. In this regard they seem to be motivated by their medical wisdom, available evidence and current trends in anesthesia practice for CDs. They presumed that they were offering a superior product in the form of spinal anesthesia to their customers and hence overlooked to address the advantages and disadvantages associated with it and its comparison with the alternate anesthesia technique. They probably felt that their plan A in the form of spinal anesthesia was invincible and completely forgot about GA as a plan B. In addition, that trend might have resulted due to heavy workload and concurrent shortage of anesthesia staff providing only briefer periods of communication with patients. Doctors are usually blamed for poor communication skills and patients feel that they were not informed [8]. Majority of anesthesia malpractice suits result from communication errors rather than inferior technical skills [9].

Obstetric patients present complex ethical challenges to anesthesiologists to obtain their informed-consent. Hoehner, in his review, concluded that one such challenge is an adequate disclosure of material information to those patients [10]. However, we elected to recruit patients undergoing elective CDs. Such patients would present few communication problems or time limitations for adequate disclosures. Waisel et al. in their professional actor based study, analyzed ethical, practical and relational problems faced by anaesthesiology trainees in obtaining informed-consent [11]. We undertook to explore the "real world" clinical practice of anaesthesiology trainees and experienced practitioners to explore the quality of informed-consents administered to patients during their daily practice. We agree with Hoehner and Waisel, et al. that in actual clinical scenarios, under the pressure of medical judgement, application of the principle of informed-consent has limitations. In this current study, patients, the actual beneficiaries of the informed-consent, personally assessed the quality of informed-consent administered to them. Blinding was ensured through anesthesiologists' unawareness during the period of

data collection about the conduct of this study.

This study has certain limitations. Actual sample size appears to be small but is representative of the quality of informed-consent administered to a cohort undergoing elective CDs during a six month period in the given set up. The validity of the questionnaire and information pamphlet was not established independently but those tools were piloted before the start of data collection. Risk of recall bias might have increased in an effort to obtain objective answers in the form of "Yes or No" instead of descriptive ones. To keep that recall bias minimum, patients were approached very early in postoperative period. Results are not representative of the practice of experienced anesthesiologists as majority (76%) of informed consents was administered by trainees. Patients' opinion to choose GA instead of spinal in their subsequent CDs might have resulted from a particular unpleasant experience with current spinal anesthesia.

Obstetric anesthesia is a high risk specialty [12-15]. It is not necessary to be negligent during a procedure such as spinal anesthesia for damage to occur [15]. Patients may reject well established treatments due to their religious or cultural believes [16]. Moreover the alternate form of anesthesia such as GA may be required emergently due to patially working spinal anesthesia during the procedure. Risks, benefits and alternative of a proposed anesthesia procedure should openly and clearly be discussed with patients. However it is still debatable which risk and how much of it should be mentioned to patients [17,18]. Results of this study justify conducting a comprehensive multicentre study. That large study can explore additionally the opinion of parturients about the type of anesthesia complications (i.e. death, permanent nerve damage, paraplegia) which they appear to be interested to know during informed-consent. In the setting described, necessity of informed-consent appears to be overpowered by medical judgement or general popularity of a given anesthesia technique. Until this alternate form of ethical discourse in practice of anaesthesia is acceptable to society, deviation from the standard model will be judged as professional negligence and malpractice.

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