Evaluation of Informed Consent Practice for Elective Surgeries in Zagazig University Hospitals: An Interventional Study

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Abstract:
Background: The informed consent is an important patient's right, has to be considered by physicians. The concept of consent arises from the ethical principle of patient autonomy and basic human rights. **Objectives:** To assess the informed consent practice for elective surgeries then design a training program to improve the practice and assess the effectiveness of the program. **Methods:** A randomized controlled trial was conducted by102 medical staffs that were responsible for informed consent practice, in ophthalmic department where cataract surgery is provided, in general surgery department, and in obstetric department where elective cesarean section is provided divided into two groups experimental and control groups in three stages, pre and post intervention over a period of 14 months from January 2015 to February 2016 by using a structured observation checklist. **Results:** Chi-square analysis to the following variables gender, job title, experience, timing of informed consent did not show significant relationship between the experimental and control groups. However, by comparing them in the dimensions of the informed consent practice there were statistically significant in test group after intervention ($p < 0.0001$). And also the percentage of those with s practical and legal problems decreased in test group in comparison to control group after intervention. **Conclusions**: Interventional program for health care providers has been improved the practice of informed consent.

Key words: Elective surgery, Informed consent, Zagazig University

Introduction: The concept of consent arises from the ethical principle of patient autonomy and basic human rights.[1,2] Patient has all the freedom to decide what should or should not happen to his/her body and to gather information before undergoing a test/procedure/surgery. No one has the right to force the patient to act in a certain manner. Even a doctor can only act as a facilitator in a patient's decision making.[3]

There is also a legal aspect to this concept. Any act done to a patient without permission is classified as “battery” - physical assault and is punishable. Hence, obtaining consent is a must for anything other than a routine physical examination.[4] In simple terms, consent can be defined as an instrument of mutual communication between doctor and patient with an expression of authorization/permission/choice by the latter for the doctor to act in a particular way.[3]

Informed consent must be preceded by disclosure of accurate, adequate and relevant information that must be provided truthfully in a form (using non-scientific terms) and language that the patient can understand. If

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adequate information has not been revealed to enable the patient to take a proper and knowledgeable decision, this will be considered a violation of patient autonomy. Consent cannot be a patient's signature on a dotted line obtained routinely by a staff member.[3]

Patient should be given a chance to ask questions and clarify all doubts. There must not be any kind of coercion. Consent must be completely voluntary and the patient should have the full freedom to cancel the consent. Consent given under fear of injury/intimidation, misconception or misrepresentation of facts can be held invalid.[5] Patient should be competent to give consent; must be an adult and of sound mind. Consent must be obtained from a parent in case of children and from the next of kin or legal guardians in case of incapacitated persons. Adequate information should be provided to a prudent patient during informed consent.[6]

Despite the many articles on the issue, widespread misunderstanding of what constitutes informed consent and how to provide it still exists. Although surgeons could agree about what informed consent is not, the optimal method for fully informing patients about the procedures they are about to undergo and the risks associated with them is not well defined [7]. So, this study was conducted to provide an example to the best practice of informed consent for elective surgeries.

The current study aimed at the following objectives; assessing the informed consent practice for elective surgeries in the teaching hospital at Zagazig University and designing and implementing a training program to improve the informed consent practice for elective surgeries. Also, it aimed to assess effectiveness of the program on the informed consent practice for elective surgeries.

Methods: This study is a randomized controlled trial. It was conducted in two experimental and control groups in three stages of before, pre and post intervention over a period of 14 months from January 2015 to February 2016. Study setting is the teaching hospital at Zagazig University where both elective surgeries and cataract surgery have been done. In general surgery department plastic surgery is conducted, and in obstetric department the elective cesarean section is conducted as well. These departments were chosen as they provide the most common types of elective surgeries.

The medical staff-members who are responsible for obtaining the informed consent were available pre intervention. The sample size was calculated through Epi-Info

(Epidemiological information package) software version 6.1, according to the following data; confidence interval 95%, power 80%, effect 25%, the effect size due to the interval 20% and the risk ratio 5%, so the calculated sample size was 120 subjects.

Eight subjects were excluded due to their participation in the training course concerning informed consent practice during the study period and ten subjects were lost so the actual sample size is 102 subjects. This sample was randomly allocated equally into the two groups; an experimental group 51 subjects and the same number as the control group. Cluster sampling was used for the selection of subjects and throwing coin was used for dividing individuals into two groups.

All patients who are listed for elective surgeries were included regardless their age, gender, and type of surgery. Nobody can deny that timing of these surgeries is heavily reliant upon patient's demands, expectations and anxieties. They are not so urgent that they could interfere with the best practice of informed consent instead they need detailed explanation to help the patient to take his informed decision.

Tools of the study: Informed consent practice observation checklist: aimed to assess the performance of the studied subjects during informed consent practice. It was prepared by reading various books, recent articles, different researches, researcher's experiences and valuable comments of faculty supervisor and advisor. It encompassed the following sections:

- Section I: the characteristics of the studied subjects including; age, gender, job title, experience, and timing of informed consent.
- Section II: the information that should be disclosed during informed consent practice, 20 items (20 points)
- Section III: the patient counseling skills, 27 items (27 points)
- Section IV: the requirements of informed consent practice, 4 items (4 points) including; assessment of patient decision making capacity, use of additional media for illustration, documentation, and reading consent form by the patient.
- Section V: the consequences of improper informed consent practice, 2 items (2 points).

If the practice was correct, it was scored as one while if it was incorrect or not done, it was scored as zero. The total dimensions of the informed consent practice, had 53 points which were divided into four categories: weak (less than 13), medium (14- 26), good (27-40) and excellent (41-53). Subjects who scored

below 26 were placed in the control and experimental groups equally.

The field work passed through three phases:

- **1st phase:** pre-intervention (assessment phase): It took three months where performance of the studied subjects during the informed consent practice was assessed using a structured observation checklist. Data were collected, analyzed and used to guide designing the intervention.
- **2nd phase:** intervention (training program): Authors tried to design the training program proportionate to the needs of participants. The intervention stage was carried out just for the experimental group, and control group did not receive any intervention. The participants in the experimental group were divided into small groups; each group included five to facilitate training program application. The training was conducted by the researchers through direct personal communication in participants' workplace. All the groups received two 30 to 45 minutes sessions during a two-month period. The training methods included viewing videos, practicing in simulated cases and role plays, and open discussion and answering questions.

  The training program illustrated the best practice for the informed consent for elective surgery explaining the following; the value of proper informed consent, who should obtain the informed consent, timing of informed consent, the information that should be disclosed during informed consent practice, techniques of patient counseling and the requirements of informed consent practice.
- **3rd phase:** post-intervention (Evaluation phase): It was conducted six months after the intervention in the experimental group and in control group six months after the pre-intervention phase. This phase took three months and emphasized on estimating the effect of the training program through reassessing participants' performance during the informed consent practice by the same observation checklist used before intervention. The data obtained from the checklist was collected, analyzed and the effect of training program was calculated and compared in both groups.

Ethical considerations: The research protocol was approved by Ethics Committee of Faculty of Medicine, Zagazig University, Egypt. Before carrying out the study, the necessary official permission was taken from the head of Zagazig University Hospitals and the head of the Ophthalmology, General Surgical and Obstetrics and Gynecology departments. An informed written consent was obtained from the studied physicians. They were reassured about the confidentiality of any obtained information and that the results would be used for the purpose of research.

Data Management: The obtained data were coded, entered and processed using Statistical Package for Social Sciences (SPSS 20.0). The

appropriate statistical tests including paired-t test, independent t-test, McNemar test, and Chi-square test were used to measure the statistical difference between the pre and post intervention and between the experimental and control groups.

Results: In table (1), the mean and standard deviation of age in the experimental and control group were 26.9±0.75 and 27.1±1.0 respectively. Independent t-test did not show any significant difference between two groups in age. The highest percentage of the subjects in both groups was male and senior house-officer. 29.4% of experimental group and 37.2% of control group were capable of performing the procedure themselves. In the experimental and control group, respectively 39.2% and 56.8% perceived specialist training in advising the patients about procedure. In experimental and control groups respectively 82.4% and 74.6% of subjects took the consent on the day of surgery. Chi-square Statistical test for variables such as gender , job title, experience, timing of informed consent did not show any significant relationship between the experimental and control groups.

Figure (1) shows that the highest percentage of subjects who achieved good and excellent scores during the informed consent practice was in the experimental group after intervention. The results of comparing experimental and control groups in the dimensions of the informed consent practice are listed in tables (2). The mean scores of the information that should be disclosed during the informed consent practice and the counseling skills were highly statistically significantly elevated in test group in comparison to control group after intervention ($p< 0.0001$).

The percent of subjects who used additional media for illustration and carried out documentation was statistically significantly in test group in comparison to control group after intervention while there was no statistically significant difference between the two groups in the dimensions of assessment of patient decision making capacity and asking the patient to read the consent form. The percent of subjects who faced practical and legal problems was statistically significant decreased in test group in comparison to control group after intervention.

Discussion: Undergoing surgery represents a threatening and often fear-provoking event even to adult patients. Medical practitioners are responsible for alleviating this fear though obtaining informed consent, which explains the reasons for surgery and its possible effects. In practice, a dilemma exists between the principles of respect for autonomy of the

patient, and the wish to do no harm. Little information is available about informed consent practice in Egypt. To our knowledge, it is the first study done in Egypt and also it is one of fewer studies done to assess informed consent situation aiming at improving this neglected vital practice.

A randomized controlled trial was conducted on 102 medical practitioners divided in two experimental and control groups as 1:1 (51 in each group) in the teaching hospital of Zagazig University over a period of 14 months from January 2015 to February 2016.The objectives of this study were to assess the informed consent practice for elective surgeries in the teaching hospital of Zagazig University to design and implement a training program to improve the informed consent practice for elective surgeries and to assess the effectiveness of this program on the informed consent practice for elective surgeries.

On comparing experimental and control groups pre- post intervention, there were statistically significant improvements in dimensions of the informed consent practice, using additional media for illustration and carried out documentation in experimental group after our intervention. On the other hand, no statistically significant difference between the two groups in the assessment of patient decision making capacity and asking the patient to read the consent form. The percent of subjects who faced practical and legal problems was statistically significantly decreased in test group in comparison to control group after intervention.

A study done to examine the extent to which patients have been shown to benefit or to be harmed by information about elective surgery. y reference to existing studies of surgical patients and to the author's data gathered, for interviews and observations on two samples of 131 and 80 women undergoing minor gynecological surgery suggested that most adult patients wish to be informed in detail about their surgery. Information about the complications is upsetting to some patients, but accurate information about the effects of surgery is welcomed, and may even promote faster recovery after the operation. However, much information presented to patients is not understood or is rapidly forgotten. Greater involvement by patients in discussions about their medical care may redress some of these problems and shift some of the responsibility towards the patient. [8]

Another prospective controlled intervention study of the WHO SSC in Norway[9] found that intervention had positive effects on two dimensions of patient safety

culture: a significant decrease in 'frequency of events reported' and significant improvement in perceptions of 'adequate staffing' in the Checklist intervention group.

The desire to be involved in decision-making about respondents' health is not related to educational status.[10] Some physicians consider that highly educated patients are not in a true need to get detailed information, others consider poorly educated are far away from understanding details of medical procedures.

Physicians consider informed consent as a routine practice to protect themselves from legal accountability from one side. Being a physician may make one look at medical data as default knowledge patients already have.

Different studies in Nigeria[11,12]) reported that only 20% of the doctors who participated regarded obtaining informed consent solely as respect for the patient's right to self-determination while the rest sought informed consent when dealing with an educated patient or when there is a high risk of complications or to avoid malpractice lawsuits.

The American Medical Association has over a period of 144 years moved drastically from overt physician paternalism to greater patient autonomy.[13] Some surgeons opt for partial disclosure of information believing that full disclosure of information may affect the patient adversely.[14] In an international survey of breast cancer patients, only 16% of the patients felt 'overwhelmed' by the amount of information available to them although 63% of the physicians thought that the patients were 'overwhelmed'.[15]

Study limitations: Non-availability of adequate funds and logistics limited the geographical coverage of the study.

Conclusion and recommendations: Interventional programs targeted to health care providers improved informed consent practice. The percent of subjects who faced practical and legal problems was decreased in test group. So, we recommend application of educational programs to medical practitioners and making them prerequisite for promotion.

Conflict of interest: There is no conflict of interest to be declared

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Table (1): Characteristics of experimental and control groups

Characteristics	Test No=51(%)	Control No=51(%)	P value
Age in years (*Mean* ±SD)	26.9±0.75	27.1±1.0	0.2559
Gender			
▪ Males	33(64.7)	39(76.4)	0.192
▪ Females	18(35.3)	12(23.6)	
Job title			
▪ Pre-registration house-officer	19(37.2)	11(21.5)	0.0821
▪ Senior house-officer	32(62.8)	40(78.5)	
Experience			
▪ Capable of performing the procedure themselves	15(29.4)	19(37.2)	0.4007
▪ Perceived specialist training in advising the patients about procedure	20(39.2)	29(56.8)	0.074
Timing of informed consent			
▪ During pre-assessment clinics	9(17.6)	13(25.4)	0.335
▪ On the day of surgery	42(82.4)	38(74.6)	

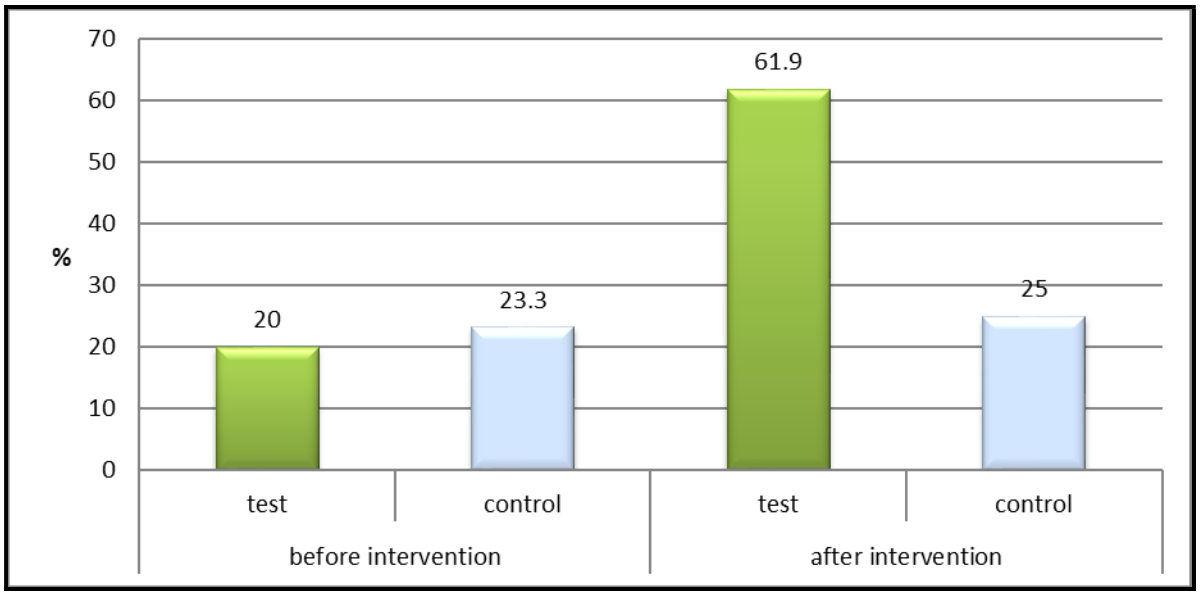

Fig (1): the percent of the studied subjects with good and excellent scores in experimental and control groups

Table (2) : Dimensions of informed consent in experimental and control groups

Stages→ Dimensions and Groups ↓	Before		After		Paired t -test
	Mean	SD	Mean	SD	
Disclosed information	**Test**	9.6	2.5	17.0	2.0	p< 0.0001
	Control	10.5	2.4	10.6	2.5	p= 0.83
	Independent t-test	p= 0.066		p< 0.0001		
Counseling skills	**Test**	13.2	4.4	20.1	3.4	p< 0.0001
	Control	13.8	3.5	13.5	3.5	p=0.598
	Independent t-test	p=0.447		p< 0.0001		

Table (2): Dimensions of informed consent in experimental and control groups (cont.)

Stages→ Dimensions and Groups ↓	Before no=51(%)	After no=51(%)	Mc-Nemar test
Use of illustration media	**Test** 8(15.6)	22(43.1)	p=0.002
	Control 15(29.4)	9(17.6)	p=0.148
	Chi-square test p= 0.09	p=0.002	
Assessing patients decision making capacity	**Test** 14(27.4)	26(50.9)	p= 0.001
	Control 19(37.2)	20(39.2)	p=1.00
	Chi-square Test p=0.289	p=0.232	
Documentation	**Test** 8(15.6)	23(45.0)	p=0.0003
	Control 11(21.5)	9(17.6)	p=0.4795
	Chi-square Test p=0.445	p=0.0028	
Reading the consent form by the patient	**Test** 7(13.7)	23(45.0)	p= 0.0002
	Control 12(23.5)	15(29.4)	p= 0.2482
	Chi-square Test p= 0.203	p= 0.101	
Faced practical problems	**Test** 24(47.0)	10(19.6)	p= 0.0176
	Control 19(37.2)	20(39.2)	p= 1.0
	Chi-square Test p=0.316	p=0.029	
Faced legal problems	**Test** 8(15.6)	1(1.9)	p=0.023
	Control 6(11.7)	9(17.6)	p=0.248
	Chi-square Test p= 0.565	p=0.007	

الملخص العربي
تقييم ممارسة الموافقة المستنيرة للعمليات الجراحية الاختيارية بمستشفيات جامعة الزقازيق

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الخلفية: تعتبر الموافقة المستنيرة واحدة من أهم حقوق المريض والتي يجب أن يحترمها الأطباء. وقد نشأ مفهوم الموافقة من المبدأ الأخلاقي لاستقلالية المريض وحقوق الإنسان الأساسية.**الأهداف:** تهدف الدراسة لتقييم ممارسة الموافقة المستنيرة للعمليات الجراحية الاختيارية ومن ثم تصميم وتنفيذ برنامج تدريبي لتحسين هذه الممارسة وتقييم أثر هذا البرنامج. **المنهجية وطرق البحث:** أجريت دراسة عشوائية مضبوطة لعدد مائة واثنين من الطاقم الطبي المسئول عن ممارسة الموافقة المستنيرة في كلا من: قسم طب العيون حيث تجرى جراحة المياه البيضاء و قسم الجراحة العامة حيث تتوافر الجراحة التجميلية وأيضا قسم التوليد حيث تتوافر العملية القيصرية الاختيارية. وقد تم تقسيمهم إلى مجموعتين؛ المجموعة التجريبية و المجموعة الضابطة في ثلاث مراحل؛ قبل وأثناء وبعد التدخل خلال فترة أربعة عشر شهرًا من يناير 2015 إلى فبراير 2016 باستخدام قائمة مرجعية للملاحظة المنظمة لممارسة الموافقة المستنيرة. **النتائج: :** لم تظهر النتائج أي علاقة ذات دلالة إحصائية بين المجموعتين من حيث الجنس والمسمى الوظيفي والخبرة وتوقيت الموافقة المستنيرة ($P \geq 0.05$) . ولكن بالمقارنة في أبعاد ممارسة الموافقة المستنيرة كان هناك ارتفاع ذو دلالة إحصائية كبيرة ($P \leq 0.0001$) في المجموعة التجريبية بعد التدخل حيث ارتفعت من ٢,٥± ٩,٦ الى ٢±١٧. وكذلك فإن النسبة المئوية للأشخاص الذين واجهوا مشاكل عملية وقانونية انخفضت بشكل ذو دلالة إحصائية ($P < 0.05$) في المجموعة التجريبية (من ٤٧% الى ١٩,٦% ومن ١٥,٦% الى ١,٩% على التوالي) مقارنة بالمجموعة الضابطة (من ٣٧,٢% الى ٣٩,٢% ومن ١١,٧% الى ١٧,٦% على التوالي) بعد التدخل. **الخلاصة:** خلصت الدراسة إلى أن البرامج التدخلية والتي تستهدف مقدمي الرعاية الصحية قد حسنت بصورة ذو دلالة إحصائية من ممارسات الموافقة المستنيرة.