

A Survey on Applying Ethics of Informed Consent Among Egyptian Surgeons

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ABSTRACT

KEYWORDS

*Surgical informed consent,
Invasive procedures,
Medical ethics,
Egypt.*

Surgical informed consent (SIC) is a fundamental part of safe clinical practice. SIC is an outcome of a proper informative process between surgeons and patients. The current study aimed to assess SIC-related practices among Egyptian surgeons. A self-administered questionnaire was formulated upon review of available literature and surgeons were invited to submit their responses electronically. 97 Egyptian surgeons participated in the study. Participants less than 40 years old represented 85.6% and 91.8% had less than 20 years' experience. Most surgeons (83.6%) had postgraduate qualifications, 38.1% were consultants. Upon analysis of responses, it was found that 73.2% of the surgeons didn't consider non-obtaining valid SIC an error. Regarding SIC practices, it was found that 82.5% of surgeons informed patients of all the possible risks, 75.3% of participants emphasized expected surgical outcomes and 70.1% ensured that patients understood the relevant information. 63.9% of surgeons explained the drawbacks of the procedure's refusal. Also, 63.9% of surgeons documented SIC elements. Alternative treatment strategies were provided by 62.9% of participants. Regarding scoring of these six SIC practices, the median score was 5. Male surgeons had significantly higher median scores compared to females ($p=0.003$). Higher scores were observed among those less than 40 years old, consultants and those with doctorate degrees. The study concluded that a high percentage of participating surgeons didn't appreciate the relationship between non-obtaining valid SIC and malpractice. However, the participants' practices of SIC elements were generally good. Current results highlighted need to raise surgeons' awareness of ideal SIC practices.

Introduction

Consent is one of the ethical and legal obligations of healthcare providers, particularly those engaged in invasive procedures. Without valid consent, performing surgery is considered a violation of human body rights (Bullock, 2012; Toulmin, 2020). Ethically, it ensures that medical care complies with the patient's best

interest and supports patient autonomy. Legally, it regulates the physician-patient relationship with subsequent protection of patients from being assaulted, and physicians from being accused of malpractice (Pallocci et al., 2023).

Autonomy is one of the essential pillars of medical ethics. Autonomy entails the right of the patient to make informed decisions regarding received medical care (Lewis, 2023). In this context, obtaining valid informed consent is a basic requirement in any healthcare procedure, particularly invasive interventions (Hariri et al., 2022).

For consent to be valid, three elements must be fulfilled which are disclosure, voluntariness, and capacity.

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Disclosure is the act of providing relevant information to the healthcare provider and ensuring its understanding by the patient (Glaser et al., 2020). Whereas voluntariness refers to the patient's right to make a free decision, without coercion or deception. Decision-making capacity means that the patient is competent to be responsible for his/her decisions regarding medical care (Millum and Bromwich, 2021).

Surgical informed consent (SIC) has become a critical element of surgical practice. It is not just a form to be signed, but a comprehensive process that ensures voluntary decisions by patients regarding the planned treatment procedures. Nowadays, the SIC process is considered a mainstay of standard surgical patient care (Caínzos and Gonzalez-Vinagre, 2019).

The SIC process begins with the assessment of the prerequisites of the consent which are mainly the competence and willingness of the patient. Afterwards, the surgeons do their best to provide the necessary information to the patients and ensure patients' understanding so that they can make the best decision according to their interests. The final step is the written consent form which is a legal document that authorizes the surgical team to operate (Skowron and Angelos, 2017).

In developed countries, the concept of informed consent has been treasured for decades (Mattick and Bligh, 2006). In developing countries, consent-related issues aroused attention recently due to increased unauthorized procedures applied to patients and increased malpractice claims against physicians (Grauberger et al., 2017; Joolae et al., 2017; Austin et al., 2021).

Informed consent has been among the allocated Egyptian patient's rights since 2005 (Farrag and Harris, 2021). Egypt set specific

legal regulations regarding the informed consent practice. According to Egyptian Penalty law (Subject 240 and 241), failure to obtain valid informed consent may entail liability if the patient suffers some injury out of the professional's actions (National Legislative Authorities, Egypt, 1937).

In Egypt, several studies have focused on patient satisfaction with the surgical informed consent (SIC) process (Ghanem et al., 2015; Mohammed et al., 2018; Metwally et al., 2021; Elsehrawy et al., 2021), however, limited literature have investigated the informed consent practices of surgeons themselves (Mohamed et al., 2012). To address this gap, a study was conducted to explore the SIC practices of Egyptian physicians before performing invasive procedures.

Subjects and methods

Research design and setting

The current research is a cross-sectional descriptive study conducted on Egyptian physicians involved in invasive procedures. Non-probability convenience sampling method was used.

Data collection tool

An online self-administered questionnaire was formulated after a thorough review of SIC-related practices in published literature (Ashraf et al., 2014; Galal, 2016; Alsaihati et al., 2017; Skowron and Angelos, 2017; Chen and Das, 2022). Relevant questions were constructed and reviewed by three forensic medicine consultants to investigate the Egyptian surgeons' practices considering informed consent in invasive interventions. The questionnaire was anonymous and electronically distributed to participants who were personally invited and

encouraged to share their responses after full clarification of the aim of the study. Also, the questionnaire was available on different medical websites commonly accessed by Egyptian surgeons.

The questionnaire involved 15 questions that were divided into two sections. The first section comprised questions about the personal and professional data of the participants. The second section investigated the participating surgeons' practices of SIC and whether the surgeons considered the failure to obtain valid informed consent a malpractice error or not.

Sample size calculation

The sample size was calculated using the Epi Info-7 program by adjusting power at 80%, a confidence level of 95.0%, similar research showed that 94% of surgeons provide information to the patient before obtaining surgical informed consent. The minimum estimated sample size was 87 participants; it was increased to 97 participants to account for non-response and to increase the power of the study.

The following formula was used: $S = Z^2 \times P \times (1-P) / M^2$

Where:

- S = sample size for infinite population
- Z = Z score (1.96)
- P = population proportion (0.94)
- M = Margin of error (0.5)

Ethical considerations

Before the start of the study, ethical approval for the research protocol was obtained from the Research Ethics Committee of the Faculty of Medicine, Alexandria

University (IRB Number: 0012098, FWA Number: 0018699, Approval Serial Number: 0306241). All respondents' data was kept anonymous and confidential. Responding to the questionnaire and submission of responses was taken as implied consent for participation in the present study.

Statistical analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 25.0. Qualitative data were described using numbers and percentages. The Kolmogorov-Smirnov test was used to verify the normality of distribution, data was not normally distributed. Quantitative data was described using range (minimum and maximum), mean, standard deviation and median. The significance of the obtained results was judged at the 5% level. The Mann-Whitney test was used for abnormally distributed quantitative variables, to compare between two studied groups. The Kruskal-Wallis's test was applied for abnormally distributed quantitative variables, to compare between more than two studied groups.

Results

The current research comprised the responses of 97 Egyptian surgeons from nine governorates (Alexandria, Giza, Beheira, Monufia, Qalyubia, Dakahlia, Matrouh, Luxor, and Aswan).

Table (1) shows respondents' demographic and professional characteristics. A great majority (85.6%) of the respondents were aged less than 40 years old. More than three-quarters (77.3%) of the respondents were males. The great majority (91.8%) of the respondents had the experience of practising medicine for less than 20 years. Most surgeons (83.6%) had postgraduate

qualifications including fellowship, master’s, and doctorate degrees.

Considering the job level, 38.1% were consultants whereas specialists represented 35.1% of the respondents. Half (50.5%) of the responding surgeons worked for governmental healthcare institutions and 30.9% worked for both governmental and private sectors.

Figure (1) reveals the different specialties of the respondents in the present research. 39.2% were general surgeons, 13.4% were orthopedic surgeons, 11.3% were plastic surgeons, and 10.3% were ophthalmologists. Each cardiothoracic surgeon and otolaryngologist were 6.2%. The rest of the surgeons included urology, neurology, colorectal, pediatric, maxillofacial, and vascular surgeons.

Table (1): Respondents’ demographic and professional characteristics (n=97)

Demographic and professional characteristics	n	%
Age (years)		
25- <40	83	85.6
≥ 40	14	14.4
Sex		
Female	22	22.7
Male	75	77.3
Experience (years)		
<10	41	42.3
10 - <20	48	49.5
≥20	8	8.2
Highest Scientific Degree		
Bachelor	16	16.5
Fellowship	18	18.6
Master’s degree	38	39.2
Doctorate	25	25.8
Job level		
Resident physician (GP)	26	26.8
Specialist	34	35.1
Consultant	37	38.1
Healthcare institute		
Governmental sector	49	50.5
Private Sector	18	18.6
Governmental sector and Private Sector (Both)	30	30.9

n: number, %: percentage

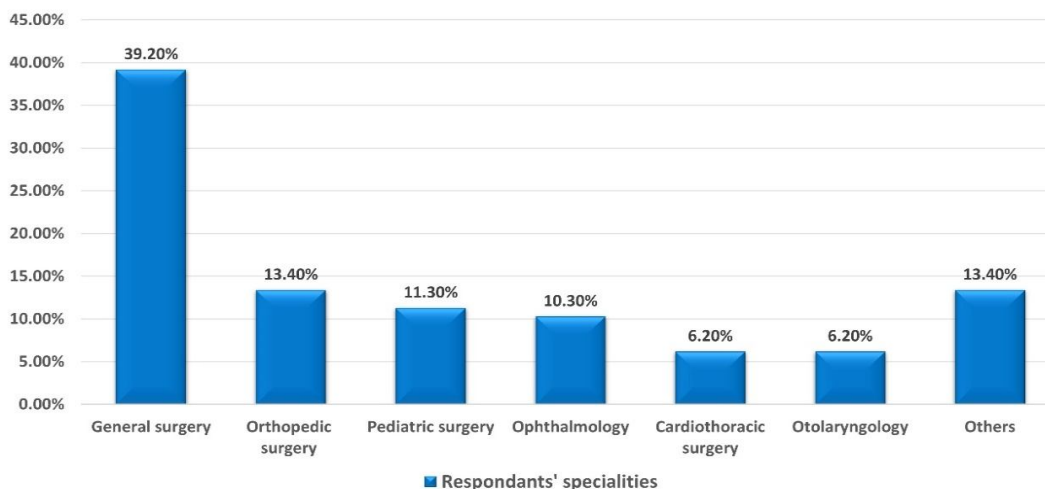


Fig. (1) Specialties of the responding surgeons (number=97)

Respondents’ informed consent-related practices

Figure (2) illustrates that 73.2% of the responding surgeons did not consider that non-obtaining valid SIC a sort of error.

Table (2) describes the frequency of six essential practices of SIC by the responding surgeons. A great majority (82.5%) of the surgeons inform the patient of all the possible risks. Three-quarters (75.3%) of the respondents inform the patient of the expected outcome and 70.1% confirm that the patient understands all details of the procedure. Nearly two-thirds (63.9%) of the surgeons inform the patient of the outcome of

refusing the intended procedure and document the elements of consent. 62.9% of the respondents provide all alternative strategies to the patient.

Table (3) illustrates that the respondents’ practices were quantified to give a total maximum score of 6. Practicing of only one item was scored by 1 and full practicing of the 6 items was scored by 6. The practitioner’s score ranged from one to six with a mean of 4.18 ± 1.95 and a median of 5. It was observed that 42.3% of the respondents achieved the maximum possible score (6) whereas 20.6% achieved the minimum possible score (1).

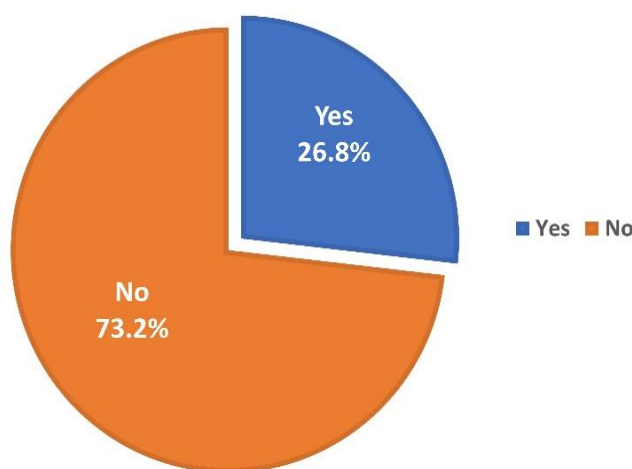


Fig. (2) Respondents’ perception of non-obtaining valid SIC as a sort of error (number =97).

Table (2): Surgical Informed Consent (SIC) practices among respondents (n=97)

Practices of Consent elements among the surgeons [†]	n	%
1 Inform the patient of all the possible risks	80	82.5
2 Inform the patient of the expected outcome	73	75.3
3 Confirm that the patient understands relevant information	68	70.1
4 Document the elements of consent	62	63.9
5 Inform the patient of the drawbacks of refusing the intended invasive procedure	62	63.9
6 Provide all alternative strategies to the patient	61	62.9

[†]: Categories are not mutually exclusive, n: number, %: percentage

Table (3): Respondents' Scores of the Surgical Informed Consent (SIC) practices (n=97)

SIC Practice score (1-6)	n	%
1	20	20.6
2	2	2.1
3	10	10.3
4	14	14.4
5	10	10.3
6	41	42.3
Mean± SD	4.18±1.95	
Median	5	
Min-max	1-6	

[†]: Categories are not mutually exclusive, n: number, %: percentage, min: minimum, max: maximum, SD: standard deviation

Relation between respondents' characteristics and their practices' scores

Table (4) reveals that sex was the only personal characteristic that shows a significant difference considering scores of SIC-related practices. The median score

achieved by males was significantly higher than that achieved by females (p=0.003).

Despite not reaching the level of significance, surgeons who were less than 40 years old, with 10 to 20 years of experience, holding doctorate degrees and those who were consultants achieved higher scores considering SIC-related practices.

Table (4): Relation between respondents' characteristics and their Surgical Informed Consent (SIC) Practice scores

	Practice Score			Significance
	Mean \pm SD	Median	Min-max	
Age (years)				
25-<40	4.25 \pm 1.93	5	1-6	p=0.429
\geq 40	3.78 \pm 2.11	4	1-6	U=507.5
Sex				
Female	3.09 \pm 1.99	3	1-6	p=0.003*
Male	4.50 \pm 1.84	5	1-6	U=1157.0
Years of practice				
<10	4.04 \pm 2.04	4	1-6	p=0.670
10<20	4.37 \pm 1.87	5	1-6	KW=0.802
\geq 20	3.75 \pm 2.12	3.5	1-6	
Qualifications				
Bachelor	3.81 \pm 2.25	4	1-6	p=0.253
Fellowship	4.5 \pm 1.75	5	1-6	KW=4.079
Master's degree	3.84 \pm 1.97	4	1-6	
Doctorate	4.72 \pm 1.81	6	1-6	
Job level				
Resident physician (GP)	3.76 \pm 2.17	4	1-6	p=0.183
Specialist	4.02 \pm 1.86	4	1-6	KW=3.397
Consultant	4.62 \pm 1.84	6	1-6	

min: minimum, max: maximum, SD: standard deviation, p*: p-value is significant at level <0.05, U: Mann Whitney test, KW: Kruskal Wallis test

Discussion

Surgical informed consent has gained much interest recently due to advancements in invasive procedures and escalating malpractice claims. In surgery, informed consent preserves the right of patients to decide freely regarding their management plan. In addition, consent safeguards healthcare providers against malpractice litigations. Proper counselling of patients and documentation is crucial in any valid informed consent (Cainzos and Gonzalez-Vinagre, 2019; Grant et al., 2020).

Most studies in this context discussed informed consent from the patient's perspective rather than that of healthcare providers (Jawaid et al., 2012; Ghanem et al., 2015; Mohammed et al., 2018; Agozzino et

al., 2019; Lemmu et al., 2020; Elsehrawy et al., 2021; Metwally et al., 2021). Surgical Informed Consent (SIC) is not just a signed approval from the patient to an invasive intervention but rather is the result of a satisfactory trustful patient-surgeon relationship. Accordingly, some other studies were concerned with the surgeons' participation in the consent process (Bean et al., 2010; Bhanot et al., 2019; Hagopian et al., 2020; Chen and Das, 2022).

In this context, in an Egyptian study conducted (Galal, 2016), patients' perspectives were compared to those of physicians while in another study, Egyptian residents in Alexandria University Hospitals were invited to share their knowledge and attitudes towards informed consent and medical ethics (Mohamed et al., 2012).

The current study assessed SIC practices among surgeons in Egypt. Therefore, a self-administered questionnaire was formulated after careful reviewing of relevant literature and distributed online (Ashraf et al., 2014; Galal, 2016; Alsaihati et al., 2017; Skowron and Angelos, 2017; Chen and Das, 2022). Responses were received from 97 surgeons from nine Egyptian governorates, a relatively limited number of participants could be attributed to a tendency of non-disclosure of work-related data or non-interest in the research topic (Zaki and Sobh, 2021; Sobh et al., 2022).

Regarding the personal data of the respondents, the great majority of them were males, aged less than 40 years old, practicing medicine for less than 20 years and holding postgraduate qualifications. Similar personal characteristics were observed by Galal (2016) who investigated informed consent among Egyptian physicians. These personal and professional characteristics of participants pointed to the high concern of highly qualified young physicians regarding informed consent and its relevant malpractice issues.

In the current study, residents constituted only 26.8% of the participating surgeons whereas the rest were specialists and consultants. On the other hand, almost half of the participants in a study conducted by Alsaihati et al. (2017) were residents. The inclusion of surgeons with higher job levels might enhance the reliability of the results of the current study. A great majority of participating surgeons work for governmental healthcare institutions which represent the greatest healthcare sector in Egypt.

The surgeons in the present research were of different specialties. General surgeons were the most common respondents followed by orthopedic surgeons, plastic surgeons, ophthalmologists, and otolaryngologists, in

addition to many other surgical subspecialties. The same specialties were involved in investigating SIC-related practices in Saudi Arabia (Alsaihati et al., 2017) and Pakistan (Ashraf et al., 2014).

It is worth mentioning that these surgical areas were the most litigations specialties due to defective informed consent practices as mentioned by Pallocci et al. (2023) among malpractice allegations in Italy.

In the current study, nearly three-quarters (73.2%) of the respondents did not consider that non-obtaining valid SIC an error that may lead to malpractice. Similarly, Ashraf et al. (2014) reported that all Pakistani physicians in their studies believed that SIC did not affect patients' well-being,

Defects in applied ethics were observed even in developed countries such as Germany (Moehring et al., 2011) and the United States (Mattick and Bligh, 2006). In Arab countries, Alsaihati et al. (2017) investigated the attitude of Saudi Surgeons toward SIC and declared that their participants consider SIC as a medicolegal ritual.

The current study investigated the six main elements of valid informed consent including disclosure of the possible risks, disclosure of the expected outcome, provision of alternative treatment, explanation of the sequelae of non-conduction of the operation, confirmation of the patient's understanding and finally proper consent documentation.

The highest percentage (82.5%) of surgeons informed the patient of all the possible risks of any procedure that agreed with Alsaihati et al. (2017) who reported that 76% of surgeons in Saudi Arabia told the patients about possible operation-related hazards. Nevertheless, Ashraf et al. (2014) found that only 40 % of surgeons in Pakistan disclosed possible complications before

surgery. In addition, three-quarters (75.3%) of surgeons informed the patient of the expected outcome which coincides with Alsaihati et al. (2017) who found that 69% of surgeons told patients the predictable advantages of surgical intervention.

It was found that 70.1% of participants confirmed that the patient understood the relevant information which is relatively better than the results of Ashraf et al. (2014) study which stated that nearly none of the participating surgeons ensured their patients' understanding. The physicians should appreciate that a considerable portion of patients in developing countries including Egypt and Pakistan have low educational levels that might influence their perception of health-related information.

In the current study, nearly two-thirds (63.9%) of the surgeons sincerely explained the drawbacks of refusing the intended procedure. Whereas Alsaihati et al. (2017) stated that only 38% of surgeons tried to persuade patients who refused a needed intervention. It was found that 63.9% of participating surgeons were concerned with proper documentation of consent elements. It is important to consider medicolegal documents including consent protect the rights of patients and physicians, particularly in malpractice claims (Austin et al., 2021)

Alternative treatment strategies were provided by 62.9% of the participants. However, better results were reported in Galal (2016) study where 89.5% of physicians explained alternative lines of treatment to their patients. Non-providing treatment alternatives are considered sort of paternalism that deprives patients of choosing management strategies in their best interests (Bullock, 2012).

The current study scored participants' practices regarding SIC's six elements. It was found that the median score was five. The

maximum possible score (6) was achieved by 42.3% of the participants, yet 20.6% achieved the minimum possible score (1). The current results pointed to the reasonable implementation of SIC elements, however, there is a need for further improvement.

By analysis of personal and professional characteristics of surgeons with their scores, it was observed that the median score achieved by males was significantly higher than that achieved by females which could be explained by the engagement of male surgeons in more risky surgeries that entail more comprehensive practice regarding SIC to safeguard themselves against malpractice claims. On the other hand, Mohamed et al. (2012) found that female physicians were more compliant with ethical practices in general.

Despite the relatively young age and short duration of experience, surgeons participating in this study achieved higher scores in addition to those holding doctorate degrees and those who are consultants. The observed high scores among younger generations of highly qualified surgeons could be explained by the enhancement of medical ethics in undergraduate and postgraduate curricula in Egyptian universities. In contrast, Ashraf et al. (2014) found that juniors, less experienced surgeons in Pakistan had poorer SIC practices compared to the seniors.

Conclusions and Recommendations

The current study investigated the applied ethics of informed consent practices among Egyptian surgeons. SIC practices were represented by the six elements of valid informed consent. The more frequently applied practices included disclosure of the possible risks, informing the patient of the expected outcomes, and confirmation of the patient's understanding. Whereas, less

frequent practices were explaining the sequelae of non-conduction of the operation, proper consent documentation and providing alternative treatment.

It is worth mentioning that the median score of SIC practices among participants was five out of six, reflecting the adherence of participants to the appropriate ethical practice. Higher median scores were especially observed among younger, highly qualified surgeons and scores of male surgeons were significantly higher than females.

On the other hand, there was a noticeable defect in the legal knowledge among study participants. Nearly three-quarters of the surgeons did not appreciate that non-obtaining valid informed consent is considered an error that might end in malpractice, indicating a need for improving the knowledge of surgeons about medical laws and ethics.

Therefore, it is recommended to increase the awareness of surgeons about SIC standards. In addition, there is a necessity for more rigorous supervision to ensure the validity of the consent process.

Although the current study included a relatively limited number of participants, it acts as a valuable reference that denotes SIC practices in Egypt. Thus, it is advisable to conduct future Egyptian studies on a larger sample size that includes other personnel in surgical teams.

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Conflict of interest

The authors declare no conflict of interest in this research.

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مسح ميدانى عن تطبيق أخلاقيات الموافقة المستنيرة بين الجراحين المصريين

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تعد الموافقة المستنيرة أحد أساسيات الممارسة الطبية السليمة. فبدونها يمكن للمريض أن يرفع دعوى قضائية ضد الجراح بسبب سوء الممارسة. ويجدر بالذكر أن الموافقة الجراحية المستنيرة ليست مجرد وثيقة يتم توقيعها من قبل المريض، بل هي نتاج التواصل الجيد بين الجراح والمريض. هدفت الدراسة الحالية إلى تقييم الممارسات المتعلقة بالموافقة المستنيرة قبل الإجراءات الجراحية بين الأطباء المصريين. تضمنت الدراسة صياغة استبيان بعد إطلاع شامل على الأبحاث المنشورة في هذا السياق، ومن ثم تمت دعوة الجراحين في مصر للمشاركة والاستجابة للاستبيان الكترونياً. شارك في هذه الدراسة سبعة وتسعون جراحاً مصرياً من تسع محافظات. وقد كان ٨٥,٦% من المشاركين أقل من ٤٠ عاماً بالإضافة إلى أن الغالبية العظمى (٩١,٨%) كانت خبرتهم المهنية أقل من ٢٠ عاماً. وكان معظم الجراحين المشاركين (٨٣,٦%) حاصلين على الزمالة أو الماجستير أو الدكتوراة. مثل الاستشاريون ٣٨,١% من المشاركين. وتحليل استجابات المشاركين تبين أن ما يقرب من ثلاثة أرباعهم (٧٣,٢%) لم يعتبروا عدم الحصول على موافقة مستنيرة صحيحة في الإجراءات الجراحية يعد خطأ. وفيما يتعلق بممارسات الموافقة المستنيرة قبل الجراحة، وجد أن الغالبية العظمى (٨٢,٥%) من المشاركين أفصحوا للمرضى عن جميع المخاطر المحتملة، وحرص ٧٥,٣% من المشاركين على إبلاغ المرضى بالنتيجة الجراحية المتوقعة، وأيضاً تأكد ٧٠,١% منهم أن المريض استوعب المعلومات ذات الصلة. كما وجد أن ٦٣,٩% من الجراحين بيّن للمريض تبعات رفض التدخل الجراحي. كما وجد أيضاً أن ٦٣,٩% من المشاركين وثّق عناصر الموافقة المستنيرة قبل الجراحة، في حين قام ٦٢,٩% من المشاركين بتقديم استراتيجيات العلاج البديلة للمرضى. قامت الدراسة بتصنيف الممارسات الستة الرئيسية السابقة من خلال درجات تراوحت من ١ إلى ٦ وقد وجد أن متوسط الدرجات خمسة. ولوحظ أن الجراحين الذكور قد حققوا متوسط درجات أعلى من الإناث حيث كان الفارق ذو دلالة إحصائية، بالإضافة إلى أن متوسط الدرجات كان أعلى لدى الأعمار الأصغر سناً (أقل من ٤٠ عاماً)، والاستشاريين، والحاصلين على درجة الدكتوراه. أظهرت الدراسة أن نسبة عالية من الجراحين المشاركين لم يدرك العلاقة بين عدم الحصول على الموافقة المستنيرة الصحيحة والتعرض للمساءلة الطبية. ومع ذلك، كانت الممارسات المتعلقة بالموافقة المستنيرة في الإجراءات الجراحية بين الأطباء المصريين جيدة بشكل عام وقد أبرز هذا البحث الحاجة إلى رفع مستوى الوعي بالممارسات المثلى بين الجراحين في هذا السياق.