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Original Research Article

An analysis of discrepancies in consent form for laparoscopic cholecystectomy in a tertiary care hospital: "FILTER" model

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ABSTRACT

Background: Informed consent is needed to be full-proof but many discrepancies arise as it is subjected to individualization for each patient depending on their IQ, personality etc. Considering all aspect, the study aims to identify the issues and seek for potential remedies through "FILTER" model.
Methods: This is a retrospective, Institution-based, observational study conducted in R.G. Kar Medical College over 3 years on 500 patients who underwent laparoscopic cholecystectomy.
Results: Most of the consents (79%) were taken by consultant surgeons and rest was by junior residents. Junior residents wrote the consent form on behalf of patients in most cases (67%). 78% of the forms were signed by the patient party, 23% by patient himself and 19% by the surgeons. 67% of the total consent forms were printed and rest were hand-written. 65% of the total consent forms were signed after the patient or the patient party was informed and rest were signed without informing them. CBD injury (72%), bleeding (55%), bile leak (46%) and post-op collection (37%) were the frequency of complications encountered by the patients not informed beforehand. As the patients were informed beforehand, the need for conversion to open operation (62%), retained stone (89%), cardio-respiratory (98% and 93% respectively) complications were common. Need for an open operation, cardio-respiratory complications were most commonly informed. Bleeding (10%), CBD injury (2%) and bile leak (12%) was less informed.
Conclusions: Proper and more standardized procedures and protocols should be followed for obtaining consent irrespective of the intervention required.

Keywords: Informed consent, Laparoscopic cholecystectomy, CBD injury, Bile leak, Therapeutic privilege, Full disclosure

INTRODUCTION

Laparoscopic cholecystectomy is one of the commonest operations practiced in modern day surgery indicated due to a symptomatic cholelithiasis. Though it is preferred over open cholecystectomy for a number of reasons e.g. fewer operative complications, improved cosmetics less duration of hospital stay and overall, since it bears less cost.[1-4] However, as thorn in the rose, laparoscopy is not without complications. Bleeding and bile duct injury is significant intra-operative complications.[5] Bile duct injury during laparoscopy can occur due to failure of visualization and identification of anatomy of gall-bladder bed or due to lack of experience according to Schol et al.[6] Huang et al also reported comparable data showing complications are more frequent during first 10-15 cases of laparoscopic cholecystectomy.[7] This is also supported by the study by Duca et al.[5] Post-operative complications can be early and late complications. Early complications according to Clavien's classification are port site infections (Grade I); bile leak and hemorrhage (Grade IIA); choleperitoneum, subhepatic abscess and retained stones (Grade IIB).[7] Late complications could be

presence of residual calculi and umbilical site incisional hernia.[5] All these complications are added with the anesthetic complications.

This necessitates informed consent from patients. Informed consent is the process, dialogue and invitation for the fully informed patient which dictates the willing participation of the patient in his/her choice to be involved in health-care and is memorialized by his/her signature.[8] The willing participation of patient comes from the knowledge disclosed during a formal and tangible discussion about the issue. This discussion should include the explanation why a surgery is warranted including the type of surgery with anticipated prognosis, expected and unexpected side-effects of proposed surgery, the remaining alternative with their individual outcomes and the consequences of "no treatment at all".[9]

The importance of informed consent is immense and partly the principle of informed consent depends on the expertise of the counsellor to make the patient understand the situation and take the consent in patient's fully competent mind after all queries being answered. Consent, as a whole, means voluntary agreement, compliance or participation and signifies acceptance by person of consequences of an act being carried out.[10] Informed consent protects a physician against negligence.[10] But the facts which a doctor should disclose depends on the normal practice in community, circumstances of the case and average IQ of the patient and/or relatives.[10] Ideally a patients should know "everything" and this is called "Full Disclosure" which is again subjected to exceptions known as "therapeutic privilege".[10] This can be described as not describing remote or "Theoretical Risks" which may frighten or emotionally disable a patient and may lead to refusal of treatment when actually there are minimal risks.[10] Thus, a doctor has to decide what facts should be disclosed considering the patient's and/or relatives' personality, IQ, physical and mental state etc. Not a many study has been performed on this issue and thus our study aims to find the discrepancies, the possible issues parenting the discrepancies and possible remedies in form of "FILTER" Model in consent form of a commonly performed elective procedure, laparoscopic cholecystectomy, in a tertiary care hospital of Kolkata, West Bengal, India.

METHODS

Study design

Retrospective, institution-based, observational study.

Study location

Department of Surgery, R.G. Kar Medical College and Hospital

Study duration

January 2015-January 2018

Study population

500 patients undergoing laparoscopic cholecystectomy selected randomly out of all patients in Department of surgery, R.G. Kar Medical College and Hospital.

Inclusion criteria

Inclusion criteria were patients underwent laparoscopic cholecystectomy.

Exclusion criteria

Exclusion criteria were patients admitted for or undergone other surgical procedures including open cholecystectomy.

Study tools

- Pre-operatively signed and filled up patient's consent form.
- Clinical examination and investigations for identifying complications.

Study parameters

- Consent form parameters:
    - Signatures included in the form: Patient's signature, Patient party's signature, Surgeon's Signature
    - Forms signed after informing the patient's adequately
    - Personnel writing the consent
    - The mention of date, time, place of taking the consent.
    - Type of consent: Hand-written or printed.
- Surgical complications

Study technique

This is a retrospective observational study. The patients who underwent laparoscopic cholecystectomy were reviewed after operation along with their consent form signed pre-operatively. The study parameters were noted. The complications of the operations in individual patients were also noted and were asked if they were informed the complications beforehand. The data obtained were inserted in a MS Excel spreadsheet following which statistical analysis were done.

Statistical analysis

Inserting data in a MS Excel spreadsheet after which percentages were calculated.

RESULTS

Complications included in consent form

This concern is important since this holds a proof in support of the attending surgeon that he/she has taken care to include even the rarest adverse outcomes of the operation. As we only considered laparoscopic cholecystectomy, we considered conversion to open operation, common bile duct injury, bile leak hemorrhage, retained stone, wound infection etc. in the consent form. Complications included in consent form and the knowledge of the patients with or without knowing beforehand about the complication is demonstrated in Table 1. It showed that CBD injury, bleeding and bile leak occurred in patients without any prior knowledge about the complications.

Table 1: Comparison between the complications included in the consent form and the actual occurrence in patients with or without prior knowledge of the complication.

Complications	Included in consent form (%)	Patients informed beforehand (%)	Patients not informed beforehand (%)
Conversion to open	67	62	38
CBD injury	2	28	72
Bleeding	10	45	55
Bile leak	12	54	46
Respiratory complications	78	93	7
Retained stone	28	89	11
Wound infection	29	65	35
Pancreatitis	2	99	1
Urinary retention	1	0	0
Post-op collection	45	63	37
Cardiac complication	79	98	2
Recurrent symptoms	17	76	24

Taking, writing and signing the consent

Though ideally, the consent should be written and signed by the patients themselves, we found there is deviation from expected scenario. Ideally, the consent should be taken by senior surgeons since he/she is expected to be more experienced. However, there is also deviation from expectation. Figure 1-3 demonstrates the deviation. Figure 1 demonstrates most consents are taken by junior residents (79%). Figure 2 demonstrates most of the consents are written by the junior residents (67%) which is lower than those signed by the patient and/or relatives (28% in total) and consultant surgeons (5%). However, patient's relatives signed it most of the case (78%) according to Figure 3.

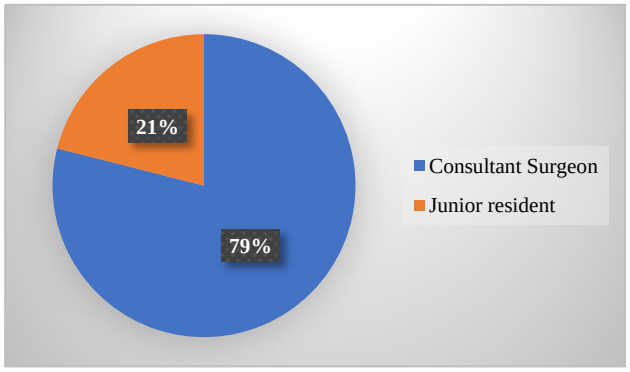

Figure 1: Proportion of consents taken by consultant and junior residents.

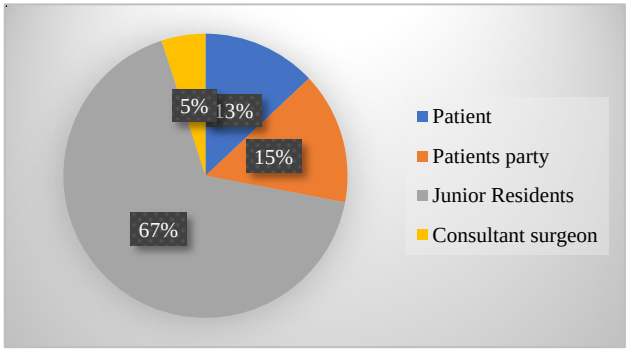

Figure 2: Proportions of the consent written by patient himself or their relatives, junior residents or consultant surgeon.

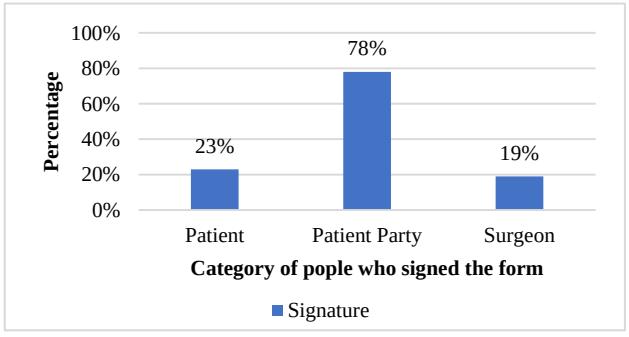

Figure 3: Proportion of the signature done by patient, patient party and the surgeon.

Types of consent form and consent forms signed after queries being answered

We observed 65% of the total consent forms were signed after the patient was informed about the complications and rest were signed before the patients were informed about the complications. Ideally, the consents should be signed before the procedure and here we see deviation from ideal practice.

Of the total consent forms 67% were printed and rest hand-written. This has future impacts since printed consents are comparatively more resistant to damage and probably will serve better in terms of condition of the evidence if required in the courts of law.

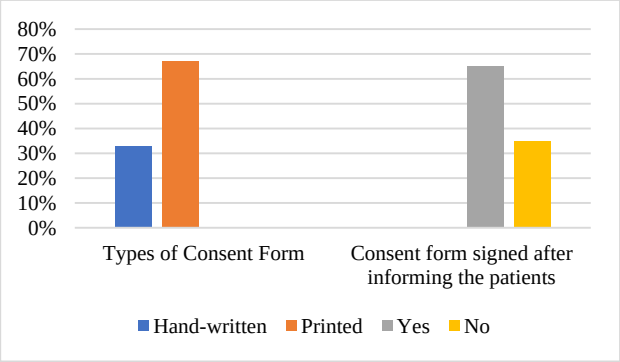

Figure 4: Types of consent form used and the proportion of consent forms signed after the patient was informed.

DISCUSSION

Informed consent plays a very important role in modern day medical practice. It saves the practitioner from being questioned in court of law regarding his/her options in conjugation with the patient's interest of own wellbeing for a particular scenario. In emergency practice, informed consent is of immense importance though elective procedures like a laparoscopic cholecystectomy can also bring life threatening hazards for a patient. Thus, from a medico-legal point of view, a practicing surgeon must explain all the possible complications, be it the least probable one, to the patient prior taking any decision of intervention. CBD injury, bleeding, bile leak are well documented complications following and during laparoscopic cholecystectomy. According to Clavien classification, bile leak and choleperitoneum is grade IIB and hemorrhage is grade IIA complication.[7] However, in this study we observed that CBD leak, hemorrhage and biliary leak was included in only few consent forms and patients developing the complications were comparable and even more (CBD injury and hemorrhage) in those who were not informed prior (Table 1). CBD injury, in future, can present with benign stricture and consequently obstructive jaundice later in the patient requiring endoscopic stenting, even an entire hepaticojejunostomy or choledochojejunostomy which will add significantly to the morbidity.[11] Thus, considering the fact that 80% of benign biliary strictures occur due to laparoscopic interventions during gall-bladder surgery, one should consider informing the patient regarding this. Hemorrhage and bile leak, similarly, on the same ground demands inclusion in consent forms due to potential early post-operative morbidity conferring to prolonged hospital stay.

To seek the potential explanation for this documented discrepancy in our study, we found that consent forms were very often gathered by the junior residents after they took the consent (Figure 1 and 2). This is a potential loophole since complications are well-acquainted by the consultant surgeons who is definitely more experienced than junior residents.

We also noted that most of the consent forms were signed by the patient parties rather than the patients (Figure 3). The consent of the patient party should be considered when the patient is a minor (less than 18 years age) or not mentally competent enough to give consent. In case of drunkenness, the patients should not be examined and blood, urine or breath should not be collected without his written consent. If he/she is unconscious with the consent of guardian examinations and treatment could be done.[10] Except for these mentioned scenarios, according to sec 87 IPC, a person above 18 years old age can give valid consent to suffer any harm, which may result from an act not intended or not known to cause death or grievous hurt.[10] Moreover, the signature of the surgeon should also be present in the consent form which denotes the surgeon's presence during the consent taking procedure. In the current era of medico-legal turmoil, informed consent is one of the tools to secure a doctor's interest in the court of law. Failing to take proper informed consent in context of a surgery, be it an elective or emergency one, may affect significantly in future. In our study, we saw there is significant discrepancies which could be addressed in a more sensible manner during day to day practice in order to avoid any possible unwanted malpractice which may contribute to the patient's ill-health. In order to avoid this, the possible issues that should be targeted in a larger scale are availability of standard informed consent form for commonly performed elective and emergency surgeries in a level of health-care based setting, awareness of the patients as well as the doctors regarding importance of informed consent form, shifting and ensuring the responsibility of the senior consultant surgeon to obtain the properly signed consent form after informing about the potential outcomes of the procedure to the patient rather than a junior resident.

As we discussed earlier, "full disclosure" and "therapeutic privilege" are something more subjective as this is subjected to individualize each and every patient. It is very difficult to provide a "Standard Informed Consent Form" for a particular procedure. Thus, there is always a "grey zone" where law does or doesn't allow patients to be "touched" without informing them. Simultaneously, a

surgeon can be held legally responsible for not obtaining consent as a "battery" or as a "negligence" as well as he/she can defend himself under the ground of "Paternalism".[9,10] Professional paternalism is the fact of abusing medical knowledge so as to distort the doctor patient relationship in such a way that the patient is deprived of his autonomy or of his abilities to make a rationale choice.[10] Paternalism stands in opposite to the Autonomy though both of them shares the same view of "well-being" of the patient.[12] Simply put, paternalism describes physician as someone "who knows better than the patients" and under certain circumstances the decision, be it harmful, made by the physician in the good faith of patients even after violating autonomy won't be considered as an offense provided the patients or his/her legal guardian is not able to give consent in that time.[10] However, this holds true for certain situations mainly during emergency. Before an elective procedure, especially like laparoscopy or other form of minimally invasive surgery, the patients should be explained the probability of converting it to open operations under the specific indications, be it even minimal; failure of which holds the surgeon responsible of negligence.

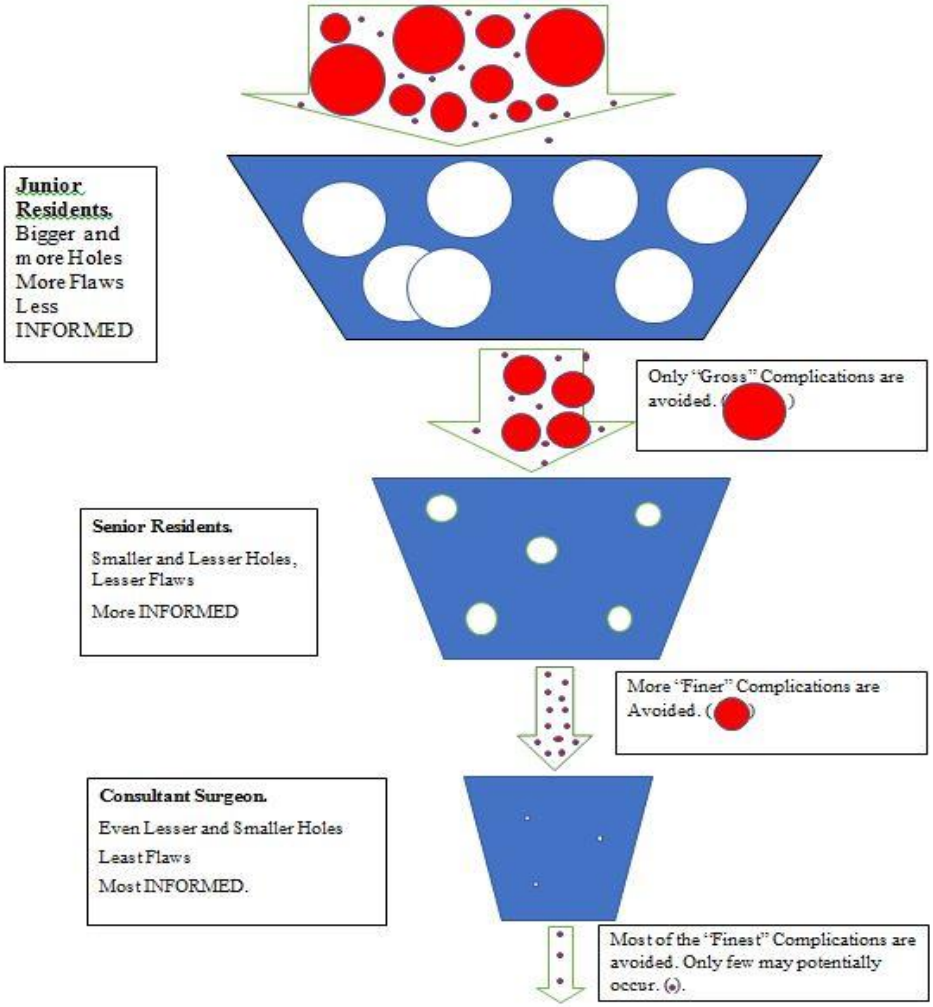

Figure 5: The FILTER model.

Apparently, in courts of law, printed evidences have no superior qualitative value over handwritten evidences provided both were taken maintaining the courtesies of consent taking. But printed evidences may sustain longer shelf-life than hand-written evidences and when required may be found in a better condition. In Figure 4, we find 65% of the consent forms are printed and we can assume these have longer shelf-life than rest of the handwritten consents. This may harbor a medico-legal importance though currently no legislation demonstrates the compulsory need for printed consent forms over handwritten forms.

Patient safety is a very important issue in medical profession and is described in different approaches. Heinrich safety pyramid, developed in 1931, describes that the amount of "near misses" ultimately progress through "minor injuries" to "major injuries".[13] Thus minimizing "near misses" by being vigilant about minor factors may prevent "major injuries". But it is almost impossible to make sure every single "hole" being covered while providing care which is described by "Swiss Cheese Model" by Reason.[13] Consent is one of those "hole" which could possibly be sealed though not completely.

Here we propose an analogy regarding the issues in consent taking. The model we are going to describe is "FILTER" model (Figure 5). According to this model, we are describing that the person who is taking consent can influence the outcome. There are three series of "Filters" with different sized "Holes". The surface area of the holes denotes the degree of flaws during consent taking. Consequently, the rest of the filter paper (BLUE in figure) represents how much "informed" the consent will be. Here, the junior residents have larger "Holes" due to their lack of knowledge, experience and technique and the consent taken by them are less "informed". On contrary, the consultants have smaller and lesser holes due to their experience, knowledge and technique and thus their consents are more "informed". Senior residents are midway between them. This is a potential area where we should look for to minimize the consent related issues in case of elective procedures from the physician's side.

Since consent in each patient should be individualized as mentioned above, a standard consent form is difficult to suggest. But common complications and risks of a particular procedure must be well informed to the patients. Similarly, better answers and suggestions for established discrepancies could be found if we could include other different types of operations both in elective and emergency setting.

CONCLUSION

Informed consent, a simple yet important tool to protect the doctor's interest should be given more importance. Proper and more standardized procedures and protocols should be followed for obtaining consent irrespective of the intervention required.

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