Title: Randomized trial of laparoscopic cholecystectomy procedure specific consent form

Running head: A procedure specific consent trial

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Abstract

Introduction:

Prior to all surgical procedures possible risks are outlined to patients during an informed consent discussion and they are invited to ask questions. Written consent records this discussion and signals a patient's willingness to proceed with surgery. This study aims to improve documentation of complications discussed during laparoscopic cholecystectomy consent through the introduction of a procedure specific consent form.

Methods:

Phase 1 included a retrospective analysis of possible complications documented on standard consent forms for laparoscopic cholecystectomy. Phase 2 was a prospective randomized comparison of existing standard consent forms vs. procedure specific consent forms measuring the documentation of significant complications as identified from the Royal Australian College of Surgeons (RACS) brochure for laparoscopic cholecystectomy. These include bile duct injury, bile leak, bleeding, infection, conversion and damage to other organs. The proportion of participants in each cohort with documentation of specific complications was assessed using the two-sample test of differences in proportions.

Results:

Phase 1 of the study found that the possible risk of bleeding was documented in 82.1% of cases while damage to other organs was only documented in 7.7%.

Phase 2 of the study showed significant improvements in documentation of specific complications for both standard and procedure specific consent cohorts; 76.5% of participants in the procedure specific consent cohort had all complications documented while no participants in the phase 1 cohort had all complications documented.

Conclusion:

Introduction of a procedure specific consent form for laparoscopic cholecystectomy has improved documentation of a standard set of complications.

Keywords: documentation, cholecystectomy, laparoscopic, intraoperative complications, consent forms

Introduction

Informed consent is a central part of any surgical procedure. In the Australian public sector, consent for elective procedures typically occurs in the outpatient clinic. Informed consent requires a discussion between a competent patient or an appointed decision maker and a member of the clinical team. Issues concerning inadequate informed consent are a major source of medical negligence claims in Australia. An audit of nearly 10,000 Australian medico-legal cases between 2002 and 2008 found that one in 30 claims of medical negligence and one in 9 conciliated complaints included allegations of deficiencies in the consent process.¹ More than half of these cases were against surgeons and general surgeons were among the top four subspecialties targeted. The primary allegation in 71% of cases concerned a complication of treatment that had not been mentioned or fully understood, and then materialised. Other common

allegations reported included, exceeding the scope of consent, inadequate method of obtaining consent and use of incomprehensible language.

Failing to consider these frequent sources of medical negligence may expose clinicians to risk of litigation. Cholecystectomy is one of the most common elective and emergency general surgery procedures performed in Australian hospitals.² This study aimed to assess existing levels of consent documentation for laparoscopic cholecystectomy. Improvements in documentation would then be assessed following the introduction of a procedure specific consent form.

Methods

A procedure specific consent form was generated for laparoscopic cholecystectomy that included significant complications outlined in the Royal Australian College of Surgeons brochure (Fig 1). These included the risk of bile duct injury, bile leak, conversion, infection, bleeding and damage to other organs. In order to indicate that each specific complication had been discussed, surgeons marked a tick box associated with each complication. The consent form was reviewed by the legal department at Western Health and approved for use in the clinical setting. The procedure specific form was an exact copy of the standard consent form used at our institution except that the section titled "Risks and

complications discussed” was prepopulated with a list of possible complications associated with laparoscopic cholecystectomy.

The study had both prospective and retrospective arms. Baseline consent documentation was assessed by retrospective analysis of documentation on elective laparoscopic cholecystectomy consent forms. Clinicians were unaware that their documentation was being observed in this cohort. The prospective arm of the study randomized participants to either standard or procedure specific consent forms (Fig 2). The study was confined to a single surgical unit. A sample size calculation was performed for the prospective phase of the study. Baseline documentation prior to study was approximately 50% for each complication. It was hypothesised that documentation of all complications using the procedure specific consent form would increase to 90% . Accepting a Type I error of 5% and a power of 80%, 25 subjects per arm were calculated for a two-sided significant difference. All analyses were conducted with Stata 12.1 (StataCorp, College Station, TX, USA).

Participants were randomized to either procedure specific consent or standard consent in the outpatient clinic. A series of numbered envelopes containing either the procedure specific or standard consent form were stored in the outpatient clinic. The forms were randomized to each envelope using the

Microsoft Excel © random number generator function. When medical staff booked laparoscopic cholecystectomy cases in the outpatient clinic, they selected the next numbered envelop in the stored pile. Following the consent process, clinicians affixed a patient label to the envelope, which allowed researchers to subsequently review the written consent documentation.

Before commencing the prospective phase of the study, researchers met with the surgical unit to explain the study. During the education session, researchers highlighted that they would be assessing documentation of the complications outlined in the RACS brochure.

The proportion of participants in each cohort with documentation of specific complications was assessed using the two-sample test of differences in proportions. This same test was applied to assess the proportion of patients who received the RACS brochure.

This study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616001373460) and was approved by the Western Health Low Risk Ethics Panel.

Results

Retrospective analysis showed documentation was poorest in the baseline cohort. The proportion of cases having complications documented ranged from 82.1% for bleeding to 7.7% for damage to other organs (Table 1).

The impact of the Hawthorne effect and education on documentation using the standard consent form is shown in Table 1. Significant improvements in documentation of conversion and damage to other organs occurred.

In the prospective phase of the study, a higher proportion of the cohort had documentation of each complication in the procedure specific consent cohort compared to the standard consent cohort (Table 2). This improvement in documentation only reached significance for documentation of bile leak and damage to other organs.

To assess how both education and the procedure specific consent improved documentation, we compared documentation between the randomized procedure specific consent form cohort and the baseline standard consent form cohort (Table 3). Documentation of complications improved across all areas and reached significance for all complications except bleeding and infection.

Following the introduction of the procedure specific consent form, 76.5% of participants had every complication documented. This compares to the baseline

cohort where none of 39 cases had every complication documented. The procedure specific consent cohort performed significantly better in documenting all complications than all other cohorts combined ($p < 0.05$ CI -0.87 to -0.57).

Documentation that the patient received a RACS information leaflet improved significantly from 23.1% of participants in the retrospective phase of the study to 60.9% in the prospective phase ($p < 0.05$ CI -0.56 to -0.20).

Discussion

Introduction of a procedure specific consent form for laparoscopic cholecystectomy has improved documentation of a standard set of complications. The risk of these complications is well studied. For example conversion occurs in 3.13% of cases, bile duct injury (0.6%), bile leak (3.98%), bowel injury (0.23%) and bleeding (2%).³⁻⁵ Documentation of these possible complications improve following educational sessions that establish standard expectations regarding complications that require discussion.

If complications do occur, the surgeon may not be negligent. To make a claim of negligence, the plaintiff must prove three elements. The plaintiff must show that the surgeon:

1. Owed them a duty of care

2. Breached the duty of care owed
3. Caused the specific harm or loss suffered as a result of the breach in the duty of care

In the setting of the informed consent process there are several laws governing what a surgeon is required to discuss. In Australia, each state has legislation governing the Standards of care required by professionals. In Victoria this is covered in the Wrongs Act 1958 s59. It states that “A professional is not negligent in providing a professional service if it is established that the professional acted in a manner that (at the time the service was provided) was widely accepted in Australia by a significant number of respected practitioners in the field (peer professional opinion) as competent professional practice in the circumstances.” If we consider this law in the context of laparoscopic cholecystectomy consent, a clinician would be practising to a reasonable standard if they discussed the same set of possible complications that their colleagues recognize as significant. Our procedure specific consent form outlines complications listed in the Royal Australian College of Surgeon patient information brochure. We would suggest that use of this consent then achieves an appropriate standard of care in line with existing medical judgment.

While the law recognizes medical opinion in establishing standards of care, it also considers material risk. In Australia, the concept of material risk was

highlighted in the case of *Rogers v. Whitaker* in 1993. The High Court of Australia found that “a doctor has a duty to warn a patient of any material risk involved in a proposed treatment”.⁶ A risk would be considered material if a reasonable person in similar circumstance would attach significance to the risk. This case law introduced a shift toward patient-centred expectations in establishing standards of care. Ms Whitaker had surgery to her right eye and subsequently developed sympathetic ophthalmia, a bilateral diffuse granulomatous intraocular inflammation that can result in blindness in both eyes. Prior to surgery Ms Whitaker expressed specific concerns that her contralateral eye be unharmed. While the risk of sympathetic ophthalmia was exceedingly small (1 in 14,000), Dr Rogers was found to be negligent because this qualified as a material risk that was not disclosed to Ms Whitaker. If we consider this case in the context of our procedure specific consent form, we must recognize that the risks discussed on the procedure specific consent form may not necessarily cover material risks. It is important therefore to always ask the patient whether they have any specific concerns beyond those discussed in the procedure specific consent form.

An audit of claims for clinical negligence in the UK regarding laparoscopic cholecystectomy found the highest proportion of claims were related to bile duct injury (41%). Other claims included bile leak (12%), bowel injuries (9%), bleeding (9%), death (9%), port site hernia, postoperative pain, infection, DVT and retained stones.⁷ Common bile duct injury resulted in the highest

proportion of successful claims (86%) with an average compensation amount of 65,000 pounds.⁷ In Australia, in 71% of cases concerning inadequate informed consent the primary allegation is that a complication of treatment had not been mentioned or fully understood and then occurred.¹ Previous studies have shown that patient information leaflets improve patients knowledge, understanding and recall, especially when used with other modalities such as DVD or multimedia information.⁸ While we continue to support the use of patient information leaflets, documentation of receipt of the information leaflet is poor and cannot be relied upon to act as a substitute for appropriate written consent.⁹ Leaflets are also of limited value when treating a diverse community where many patients are non-English speaking.

It would appear that there is no single strategy that protects clinicians against possible claims of medical negligence. While written documentation provides evidence that complications are discussed, it may not guarantee patient comprehension, which is another significant cause of medical negligence claims.

¹ Positive patient-doctor relations increase patient perceptions of physician competence and reduce their intentions to file malpractice claims.¹⁰ Establishing good relationships may encourage open discussion of treatment options that better inform patients and thereby potentially protect surgeons from litigation relating to the consent process.

The main limitation of this study was the presence of the Hawthorne effect in the prospective phase of the study. The Hawthorne effect occurs when study participants are aware they're being observed and subsequently alter their behaviour. The study tried to measure this effect by assessing baseline documentation of complications prior to the prospective study phase. While the Hawthorne effect influenced both cohorts in the prospective phase of the study, the procedure specific consent form performed significantly better than the standard consent form. The initial goal of the study was to have 90% of cases document all significant complications. Further education regarding the consent process including providing the RACS brochure is required to achieve this goal.

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Legends for Figures

Fig. 1. Copy of laparoscopic cholecystectomy procedure specific consent form

Fig. 2. Consort flow diagram

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Table 1 Comparing randomized standard consent form cohort and baseline standard consent cohort

Complications documented (%)	Standard Consent. Baseline cohort. (n=39)	Standard consent. Prospective/Observed cohort. (n=35)	Proportion difference (%)	Exact p Value (95% ci)
Conversion	51.28	82.10	31.60	0.004 (0.10 to 0.50)*
Bleeding	82.05	91.40	9.38	0.24 (-0.07 to 0.26)
Infection	74.36	85.70	11.36	0.23 (-0.08 to 0.30)

Bile Leak	71.79	62.90	-8.94	0.41 (-0.30 to 0.12)
Bile duct injury	66.70	82.90	16.20	0.11 (-0.04 to 0.35)
Damage to other organs	7.70	48.60	40.90	0.001 (0.22 to 0.58) [*]

* Significant difference in proportion; 95% ci: 95% confidence interval

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Table 2 Comparing randomized procedure specific cohort and randomized standard consent cohort

Complications documented (%)	Standard consent (n=35)	Procedure Specific (n=29)	Proportion difference (%)	Exact p Value (95% ci)
Conversion	82.90	96.60	13.70	0.08 (-0.02 to 0.30)
Bleeding	91.40	96.60	5.10	0.39 (-0.10 to 0.20)
Infection	85.70	89.70	3.90	0.64 (-0.14 to 0.21)
Bile Leak	62.90	96.60	33.70	0.001 (0.15 to 0.51)*
Bile duct injury	82.90	96.60	13.70	0.08 (-0.02 to 0.30)
Damage to other organs	48.60	93.10	44.50	0.0001 (0.24 to 0.62)*

* Significant difference in proportions; 95% ci: 95% confidence interval

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Table 3 Comparing procedure specific consent form and baseline consent

Complications Documented (%)	Standard Consent. Baseline cohort. (n=39)	Procedure Specific Forms (n=29)	Proportion Difference (%)	Exact P value (95% ci)
Conversion	51.28	96.60	45.30	0.0001 (0.27 to 0.61)*
Bleeding	82.05	96.60	14.50	0.07 (-0.01 to 0.30)
Infection	74.36	89.70	15.30	0.11 (-0.04 to 0.33)
Bile Leak	71.79	96.60	24.80	0.008 (0.08 to 0.41)*
Bile duct injury	66.67	96.60	29.90	0.002 (0.12 to 0.46)*
Damage to other organs	7.70	93.10	85.40	0.0001 (0.67 to 0.94)*

* Significant difference in proportions; 95% ci: 95% confidence intervals

**REQUEST FOR ELECTIVE ADMISSION-
Laparoscopic Cholecystectomy***RACS Sticker to be placed here.*

PATIENT DETAILS OR IDENTIFICATION LABEL

☐ male☐ female

WH

UR: _____

SURNAME: _____

FIRST NAME: _____

DOB: _____ eg. 1/Feb/1975)

***Must be alphanumerical as shown above

Address: _____

Phone: _____

Medicare No: _____

Western Health Waiting List Referral and Consent for Procedure(s)

I, _____ given name _____ surname _____ understand that I will be referred for placement on the hospital's wait list and give my consent for the

following **LAPAROSCOPIC CHOLECYSTECTOMY**

specify operation(s) / procedure (s) _____

being performed on _____

myself or name and relationship to patient if completed by person other than patient _____

The nature and effect of the above procedure(s) have been explained to me by Dr/Mr/Ms _____**I have been advised and understand that:**

- a) I will receive written confirmation of waiting list placement from the hospital. I also understand I may receive my surgery at another Western Health campus by a different surgeon than the surgeon referring me to the waiting list.
- b) The medical practitioner who originally saw me or who placed my name on the waiting list may not be the person who performs the procedure(s).
- c) I understand that at times representatives of medical device and prosthetic suppliers may be present during my procedure.
- d) If I have further questions about my condition and/or the above procedure(s), I will have the opportunity to discuss them with doctors at the hospital.
- e) If I am concerned about any changes in my condition or health, that occurs whilst I am on the waiting list I should contact my General Practitioner for advice.
- f) If I have any further questions regarding placement on the waiting list, I should contact the Booking Office at the relevant hospital.
- g) I also consent to such further operative procedures as may be found necessary to be performed during the course of the operation(s) / procedure(s) stated above. In conjunction with the above stated operation(s), I consent to the administration of such anaesthetics as may be considered by the anaesthetist to be necessary or advisable.
- h) I understand that during the procedure photographs of the procedure or of operative findings may be obtained. I understand that such photos will be regarded as part of my medical record and used ethically for teaching and clinical meetings where appropriate.
- i) If I have elected to be a public patient I understand that a registrar may perform the procedure or give the anaesthetic under the supervision of the consultant specialist.
- j) I understand the proposed procedure and that in the case of significant delay in time from addition to the wait list and surgery, consent may need to be reobtained or confirmed.

The nature and effect of the above procedure(s) have been explained to me by Dr/Mr/Ms _____

Specific Risks and Complications discussed include:

Conversion	
Bleeding	
Infection	

Bile duct leak	
Bile leak	
Damage to other organs	

Other risks include: _____

Other options for treatment have been discussed with me ☐ No ☐ YesI have been given the consent information sheet for the surgery/procedure above ☐ No ☐ Yes

Signed: _____ Self or relationship to patient _____ Date: ____ / ____ / ____

Reason if consent given by person other than patient: _____

Name of Interpreter

Reason for the person other than qualified interpreter

Confirmation by Medical Officer

I, _____ have explained to the *patient / person responsible for the patient, the nature of the above operation(s) / procedure(s). In my opinion, **he / she understood the explanation.

Figure 1.tiff

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