Written consent for laparoscopic tubal occlusion and medico-legal implications

Rasiah Bharathan, Rebecca Rawesh, Hasib Ahmed

Abstract

Objective To analyse the completeness of written consent for laparoscopic tubal occlusion and to consider the medico-legal implications of incomplete written consent.

Methods A retrospective review was undertaken of the medical records of all women who had laparoscopic tubal occlusion in 2006 in a district general hospital to elicit details of risks of the procedure as recorded on the consent form. The extent of documentation of risks and complications that were cited in the guidelines was analysed. In addition, the grade of doctor and the timing of obtaining written consent were studied.

Results A total of 267 women underwent laparoscopic tubal occlusion and 214 (80.1%) case notes were reviewed in the present study. The findings demonstrate wide variation in the description of risks by doctors of different grades. The majority of written consents (65.9%) were obtained on the day of surgery. Most cases (75.2%) trainees were responsible for obtaining written consent.

Conclusion Although the written consent form is a legally effective document, the process of documentation is inconsistent and this may leave the senior gynaecologist in a vulnerable position.

Keywords consent, laparoscopic tubal occlusion, medico-legal

Introduction

Obtaining valid informed consent is a process that is required by the principles of good medical practice. Guidelines regarding this process have been published by a number of organisations including the General Medical Council (GMC) and the British Medical Association (BMA). With certain exceptions (e.g. mental health, fertility treatment) there is no statutory requirement in the UK to obtain written consent prior to medical investigation or treatment. However, case law has established that touching a patient without valid consent may constitute the civil or criminal offence of battery. In the event of harm to the patient as a consequence of treatment, failure to obtain valid informed consent may be regarded as a factor in a claim of negligence against the health professional involved. A written consent form may be used in a court of law as evidence that bilateral discussion had taken place and consent obtained, but in itself is no proof of validity in obtaining that consent.

The GMC considers that “in exceptional circumstances the task of reaffirming consent can be delegated to a doctor who is suitably trained and qualified, is sufficiently familiar with the process and possesses the appropriate communication skills”. The BMA further clarifies this position by asserting that the responsibility of ensuring that valid informed consent has been obtained lies with the most senior clinician responsible for the investigation or treatment offered. The NHS Plan identified the need for change in consenting practice and subsequently the Department of Health issued a consent policy and model consent forms to be used throughout the National Health Service (NHS). This wave of changes underpinned a core principle of good practice: using a valid informed consent has been observed at our hospital and to consider the implications of incomplete written consent.

The Royal College of Obstetricians and Gynaecologists (RCOG) has published an advice document on consent for obstetrics and gynaecology. The inadequacy of this aspect in other clinical specialties has been highlighted in recent literature. Obstetrics and gynaecology is one of the most litigation-prone medical specialties in the UK. An important root cause of many clinical adverse events that lead to medico-legal issues is poor communication between the patient and the health care staff. Good communication regarding critical aspects of patient care should be reflected in the process of obtaining valid informed consent for diagnosis and treatment. The inadequacy of this aspect in other clinical specialties has been highlighted in recent literature.

The purpose of this retrospective study was to examine the extent to which the RCOG advice has been observed at our hospital and to consider the implications of incomplete written consent.

Methods

Patients who underwent laparoscopic tubal occlusion during a 12-month period were identified by clinical coding; by this method 267 patients were found. We retrospectively reviewed the consent forms of 233 patients. In the remaining 34 cases the consent forms could not be studied for one of the following reasons: patient records were not available (n = 21) or consent forms were not attached to the patient records (n = 13). In those 13 cases, the pre-operative checklist confirmed that they had a written consent form. A further 19 consent forms were not included in the study as these patients had been consented for concomitant procedures. Risks and complications identified in the RCOG consent advice were studied (Table 1). A suitable proforma was devised and the data were recorded by two of the authors (RB and RR).

Key message points

- Written consent for laparoscopic tubal occlusion is inconsistent.
- The current medico-legal climate indicates that the consenting process is exposed to legislative risk.
- We propose an entity-specific booklet to strengthen the consenting process.
Table 1 Complications as outlined by the Royal College of Obstetricians and Gynaecologists Laparoscopic Tubal Occlusion: Consent Advice recorded by doctors of differing grades

<table>
<thead>
<tr>
<th>Complication</th>
<th>Grade of doctor [n (%)]</th>
<th>p</th>
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<tbody>
<tr>
<td></td>
<td>Consultant (n = 53)</td>
<td>Registrar (n = 113)</td>
</tr>
<tr>
<td>Contraception failure</td>
<td>41 (77)</td>
<td>92 (81)</td>
</tr>
<tr>
<td>Ectopic pregnancy</td>
<td>29 (55)</td>
<td>77 (68)</td>
</tr>
<tr>
<td>Permanence</td>
<td>26 (49)</td>
<td>56 (50)</td>
</tr>
<tr>
<td>Bleeding</td>
<td>38 (72)</td>
<td>90 (80)</td>
</tr>
<tr>
<td>Organ injury</td>
<td>46 (87)</td>
<td>105 (93)</td>
</tr>
<tr>
<td>Uterine perforation</td>
<td>6 (11)</td>
<td>12 (11)</td>
</tr>
<tr>
<td>Conversion to laparotomy</td>
<td>30 (57)</td>
<td>94 (83)</td>
</tr>
<tr>
<td>Shoulder-tip pain</td>
<td>0 (0)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Death</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Results

In all cases ‘NHS Consent Form 1’ was used. The median age of the patients was 38 (range, 23–46) years. Nineteen (9%) patients were treated as inpatients for anaesthesia-related reasons. Seventy-three (34%) patients had completed written consent prior to the day of the procedure; in the remaining cases written consent was obtained on the day of the operation. Consultants were responsible for 53 (25%) instances, registrars obtained consent from 113 (53%) and senior house officers (SHOs) were responsible in the remaining 48 (22%) cases.

From Table 1 it is apparent that amongst the consultant staff no single complication or risk of surgery is consistently documented in the consent forms. Both the consultants and the registrars commonly documented the risks of contraception failure, ectopic pregnancy, bleeding, internal organ injury and conversion to laparotomy. Internal organ injury was consistently recorded by SHOs in all cases. In the majority of the cases of consent obtained by SHOs the risk of conversion to laparotomy, bleeding, contraception failure and ectopic pregnancy were recorded.

A notable feature is that in only approximately half the cases is the ‘permanence’ of the procedure explicitly written on the consent form by doctors of any grade. Uterine perforation was mentioned least frequently (in 11–13% of cases) on the consent forms. Both the consultants and the registrars mentioned more risks than did consultants. It is evident from our data that there is wide variation in the profile of risks and complications recorded on the consent forms. The ‘Bolam test’ has been used by the courts to assess whether a doctor is guilty of negligence in failing to provide an acceptable standard of care. If the provision of care is in line with the recommendations of a responsible body then the defendant is unlikely to be found guilty. The Bolam principle has been viewed as being excessively reliant on medical opinion supporting the defendant. However, since the case of Sidaway, several trials have shown that courts are willing to be critical of ‘responsible bodies’ of medical opinion. This case applied the Bolam principle to obtaining the consent of patients. It highlighted the need to obtain complete informed consent rather than merely ‘valid’ consent, which might omit certain serious rare complications. Therefore clinicians are advised to inform patients of any ‘material’ or ‘significant’ risks in the proposed treatment, any alternatives to it and the risks incurred by doing nothing.

The GMC has taken a further step in guiding the consent process in stating that it should take account of patients’ individual needs and priorities when providing information; this would be consistent with the principle of patient-centred processes.

The more recent case of Chester v Afshar reinforces the place of patient expectations as well as focusing on obtaining informed consent. Ms Chester was not informed of a 1–2% risk of cauda equina syndrome complicating a spinal procedure to which she had consented. Unfortunately the patient suffered this complication. The ruling was that the surgeon had breached his duty of care by not fully informing the patient. The critical medico-legal aspect of this ruling was that the claimant was not required to demonstrate a causal aspect of consenting in the adverse outcome she experienced. Technically the procedure was performed to a professional standard. The claimant successfully argued that the failure to inform her of this risk had influenced the timing and/or the choice of surgeon, which might in turn have affected her risk profile. In an earlier case in Australia, a court found an ophthalmic surgeon negligent for not warning a patient of a 1 in 14 000 risk of blindness. Incomplete consenting adds weight to a claim for negligence and therefore places senior gynaecologists and their employers in a vulnerable position. The issue of inconsistency in obtaining written consent has been highlighted in other specialties; this would suggest an underlying problem in obtaining consistent written evidence of consent.

Discussion

It is evident from our data that there is wide variation in the profile of risks and complications recorded on the consent form. Provision of information is an essential aspect of ensuring valid consent. The ‘Bolam test’ has been used by the courts to assess whether a doctor is guilty of negligence in failing to provide an acceptable standard of care. If the provision of care is in line with the recommendations of a responsible body then the defendant is unlikely to be found guilty. The Bolam principle has been viewed as being excessively reliant on medical opinion supporting the defendant. However, since the case of Sidaway, several
produced a number of patient leaflets on contraception.\(^{18,19}\) Our study only examined the risks communicated through the written consent form. It is likely that additional information may have been conveyed verbally (with documentation in the medical records) and supplemented through patient information leaflets.

We propose the use of a contraception-specific booklet that would include background information, treatment options with risks and benefits, consequences of not ‘managing’ contraception (i.e. risks of unwanted pregnancies) as well as a template to capture the woman’s risk profile. We believe that this approach would certainly advance the clinician’s position with regard to obtaining fully informed consent. Implementation of such a document across the country would confer consistency to the process of consenting. The verbal, written and psychological aspects that span the doctor–patient relationship cannot be captured and entirely quantified; the spirit in which consenting is conducted may be open to interpretation. Valid informed consent could be viewed as a compass guiding us towards the implementation of good medical practice. We believe that the medico-legal complexity of the written consent form is not accurately understood in clinical practice.

**Conclusions**

Written consent captured by the NHS model consent form is a legally effective adjunct in obtaining patients’ consent. Our study demonstrates that our current hospital practice for obtaining written evidence of valid informed consent for laparoscopic tubal occlusion is not optimal. It is evident from recent court rulings that unless all common and significant risks of a specific treatment or its alternatives are clearly communicated to the patient, as a claimant a patient would have the opportunity to mount a case of negligence in the care we provide. This study highlights the need to implement a consenting process that is both medico-legally and clinically coherent. Our recommendation is to implement the use of an entity-specific, patient-sensitive information booklet to strengthen that process.

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**References**


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