Consent process for elective total hip and knee arthroplasty

Nicolas Beresford-Cleary, Jane Halliday, Leela Biant, Steffen Breusch
Department of Orthopaedics, Edinburgh University, The Royal Infirmary of Edinburgh at Little France, Edinburgh, United Kingdom

ABSTRACT

Purpose. To assess the consent process for elective primary total hip replacement (THR) and total knee replacement (TKR) in our hospital.

Methods. Consent processes of 47 THR and 53 TKR patients performed by 11 surgeons were reviewed. Complications that were documented were recorded, as was the grade of surgeon (consultant or specialist trainee) performing consent, and the location at which this took place. Comparisons were made between rates of documented, clinically significant complications discussed during consent, and those listed in the British Orthopaedic Association (BOA), in the literature, and other joint registries.

Results. The consent processes of 37, 57, and 6 patients were conducted by consultants, specialist trainees, and both, respectively. 13% and 21% of THR patients had ‘revision’ and ‘heterotropic ossification’, respectively, documented as complications, neither of which were listed on the BOA consent form. In 23% of THR and 32% of TKR patients, none of the BOA-listed complications was documented. In 13% of THR and 15% of TKR patients, no complications were documented. In 13% of THR and 17% of TKR patients, only non-specific descriptions of complications (e.g. morbidity, mortality and medical complications) were used in their consent forms.

Conclusion. Documentation of complications for THR and TKR patients was often incomplete and variable. The use of structured, procedure-specific consent forms is recommended.

Key words: arthroplasty, replacement, hip; arthroplasty, replacement, knee; guideline; informed consent

INTRODUCTION

Informed consent for surgery is a process in which a patient is provided with clinically salient features of the procedure and alternative options and gives
authorisation to proceed. It aims to respect the individual’s autonomy and protect him/her from potential harm. It may be written, verbal or implied. Comprehensive documentation of the consent process helps protect the surgeon from subsequent complaints or litigation by keeping a record that the patient was informed of the potential complications of the surgery.

No English statute sets out the principles of consent. Nonetheless, case law has established that touching a patient without valid consent may constitute the civil or criminal offence of battery. There may be a claim of negligence if a health professional fails to obtain proper consent and the patient suffers harm as a result of treatment. The National Health Service faces an estimated £4.4 billion liability for negligence cases. Damage of tissues (vessels, nerves, and other underlying structures) are the commonest complications for which surgeons are sued, accounting for 38% of all claims settled by the Medical Defence Union between 1990 and 1999. Infection accounts for 12%. Complaints can also be filed through the National Health Service or professional bodies.

We assessed the consent process for elective primary total hip replacement (THR) and total knee replacement (TKR) in our hospital, and compared the documentation and rates of clinically significant complications with those listed in the British Orthopaedic Association (BOA), the United Kingdom

| Table 1 | Complication rates listed in the British Orthopaedic Association (BOA), joint registries, and the literature |
|---------|----------------------------------------------------------------------------------------------------------------------------------|
|         |                                                                                                                                |
| Complication                  | Rate (%)                                                                 | % of our patients informed of such complication |
| Total hip replacement          |                                                                                                                                |
| Bleeding necessitating transfusion* | 2-5 25.519 to 32.520                                                | 9 (including blood vessel damage)               |
| Blood vessel damage*           | <1 0.0311 to 0.0821, 22                                              | -                                               |
| Prosthesis wear*               | 2-5 Necessitating revision: 0.0223                                           | 36                                              |
| Loosening*                     | 2-5 Necessitating revision: 7 to 9.724                                   | 49                                              |
| Revision*                      | 1.49,11-15                                                               | -                                               |
| Heterotopic ossification*      | - 43; severe: 945                                                       | -                                               |
| Leg length discrepancy of ±1 cm* | 2-5 Uncemented: 5617; cemented: 2317                             | 47                                              |
| Dislocation*                   | 2-5 2.9 to 2.623 to 4.826                                              | 76                                              |
| Infection*                     | 0.77 to 1.37 to 1.624                                                   | 66                                              |
| Nerve damage*                  | <1 Femoral, sciatic, peroneal nerves: 0.09 to 3.728                   | 45                                              |
| Bone damage (fracture)*        | <1 1.129                                                                | 30                                              |
| Deep vein thrombosis*          | 2-5 Symptomatic: 2.710; asymptomatic: 13.210                            | 66                                              |
| Pulmonary embolism*            | <1 Non-fatal: 0.731 to 0.932; fatal: 0.2234                              | 57                                              |
| Myocardial infarction*         | 0.411                                                                  | -                                               |
| Death*                         | 0.511                                                                  | 34                                              |
| Pain                           | 2-5 Severe/very severe: 12.134                                       | 11                                              |
| Altered wound healing          | <1 -                                                                    | Scarring: 9                                      |
| Total knee replacement          |                                                                                                                                |
| Pain*                          | 2-5 1 month: 44.4; 3 months: 22.6; 6 months: 18.4; 12 months: 13.15       | 21                                              |
| Dissatisfaction*               | - 14.46 to 19.47                                                         | -                                               |
| Bleeding necessitating transfusion* | 2-5 15.136                                                          | 13                                              |
| Blood vessel damage*           | <1 0.0821 to 0.1722                                                     | 13                                              |
| Revision*                      | - 6.69,11-15                                                            | -                                               |
| Knee stiffness*                | 2-5 1.37 to 3.738 to 5.318; necessitating manipulation under anaesthesia: 2.39 | 40                                              |
| Prosthesis wear*               | 2-5 Necessitating revision: 7 to 15.10                                  | 21                                              |
| Infection*                     | 1.648                                                                  | 68                                              |
| Deep vein thrombosis*          | 2-5 Symptomatic: 1.810; asymptomatic: 38.110                            | 68                                              |
| Pulmonary embolism*            | <1 0.731 to 0.8146; fatal: 0.1531                                       | 62                                              |
| Myocardial infarction*         | 0.411                                                                  | -                                               |
| Death*                         | 0.511                                                                  | 21                                              |
| Nerve damage*                  | <1 Peroneal: 0.331; overall: 1.328                                     | 32                                              |
| Bone damage (fracture)*        | <1 Supracondylar fracture: 0.3 to 2.541; patellar fracture: 0.05 to 21.38; tibial fracture: rare | -                                               |
| Altered wound healing          | <1 -                                                                    | -                                               |
| Joint dislocation              | <1 -                                                                    | -                                               |
| Leg length discrepancy         | <1 -                                                                    | -                                               |

* Clinically significant complications that should be discussed during the consent process
Department of Health,7 the General Medical Council,8 other joint registries,9–15 and the literature.16–47

MATERIALS AND METHODS

Consent processes of 47 and 53 patients who underwent elective primary THR and TKR, respectively, between October 2009 and March 2010 in our hospital by 11 surgeons were randomly selected for review. The consent form was a universal form designed for any surgical or medical procedure. There was no space designated for listing surgical complications. Complications that were documented were recorded, as was the grade of surgeon (consultant or specialist trainee) performing consent, and the location at which this took place.

Comparisons were made between rates of clinically significant complications (e.g. bleeding necessitating transfusion, nerve damage, and leg length discrepancy of ≥1 cm) that were documented in the BOA form,6 joint registries,9–15 and the literature.16–47 Amended terms were used (e.g. ‘leg length discrepancy’ for ‘altered leg length’16–18) when not found in the BOA form. For each complication, the percentage of patients that had that complication discussed and documented was calculated.

RESULTS

The consent processes of 37, 57, and 6 patients were conducted by consultants, specialist trainees, and both, respectively. 23 THR and 21 TKR complications were documented in the joint registries and the literature, whereas 14 TKR and THR complications were documented in the BOA consent form6 (Table 1).

According to joint registries,9–15 the overall mean revision rates for THA and TKR were 11.4% and 6.6% per year, respectively.13 The rate of heterotopic ossification after THA was 43%, and in 9% it was severe.45 14% to 19%46 of TKR patients were dissatisfied with outcome in terms of pain and function. 13% and 21% of THR patients had ‘revision’ and ‘heterotopic ossification’, respectively, documented as complications, neither of which were listed on the BOA consent form. Similarly 4% and 11% of TKR patients had ‘revision’ and ‘dissatisfaction’, respectively, documented as complications, neither of which were listed on the BOA consent form.

In 23% of THR and 32% of TKR patients, none of the BOA-listed complications was documented. In 13% of THR and 15% of TKR patients, no complications were documented. In 13% of THR and 17% of TKR patients, only non-specific descriptions of complications (e.g. morbidity, mortality and medical complications) were used in their consent forms (Table 2). Non-specific description of complications may be insufficient to protect the surgeons against subsequent complaints or litigation. Discussion of the complications usually occurred in the outpatient clinics and pre-admission clinics (Table 2).

DISCUSSION

In 13 of 28 malpractice lawsuits against orthopaedic surgeons,3 the plaintiffs alleged that they had experienced a complication that had not been described preoperatively. Documentation of complications that are discussed during the consent process provides evidence to defend the breach of duty allegation.48 Nonetheless, such documentation is often incomplete and variable.49,50

There is a lack of consensus as to which complications are clinically significant enough to be discussed with patients.51–53 The guidelines of the Department of Health state that patients should be informed of any ‘material’ or ‘significant’ risks in the proposed treatment, any alternatives to it, and the risks incurred by doing ‘nothing’.7 The General Medical Council advises clinicians to inform patients of adverse outcomes that may result from the proposed treatment options (including taking no action).8 The use of structured, procedure-specific consent forms for documentation of complications is recommended.

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