Surgery for fractured neck of femur – are patients adequately consented?

NICK PROBERT¹, ATIF A MALIK², MARTYN E LOVELL^{1,2}

¹University of Manchester, Manchester, UK

²Department of Orthopaedics and Trauma Surgery, Wythenshawe Hospital, Manchester, UK

ABSTRACT

INTRODUCTION Obtaining valid consent is a legal and ethical obligation when performing any procedure in clinical practice. This study was performed to identify the validity and effectiveness of the new consent form and any potential improvement that could be made when taking consent.

PATIENTS AND METHODS Case notes of 173 patients undergoing surgery for fractured neck of femur were retrospectively reviewed. Risks and complications of the surgery as listed on the consent form were noted. Sixty-five cases were excluded from the study as they had either old consent forms with no risks recorded or a consent form signed by a consultant due to patient inability to consent. Six of the consent forms could not be located in the notes. This left 102 consent forms to be analysed.

RESULTS The number of risks documented on each form ranged from 0–8 (mean, 3.92). No risks were recorded in 2 of these 102 forms. Most commonly recorded risks were infection (95.1%), DVT/PE (81.4%) and failure of procedure (59.8%). It was shown that many of the consent forms analysed did not have all the serious or frequently occurring risks recorded on them and that a large proportion of the forms had acronyms or phrases that may mean nothing to the patient. Comparison of documented risks for different hip surgery were made using Fisher's exact test showing no significant difference between the risks recorded on the forms for each type of procedure.

CONCLUSIONS Although documentation of risks has been improved compared to old consent forms, patients are not necessarily given the most appropriate information to ensure consent is valid. Further refining of consent forms may be necessary to ensure that all major risks are explained and understood by patients and that there is satisfactory recording of this information.

KEYWORDS

Consent forms – Fracture – Neck of femur – Hip surgery

CORRESPONDENCE TO

Atif A Malik, 14 William Jessop Court, Piccadilly Village, Manchester M1 2NE, UK
M: +44 (0)7970 899141; E: atif01@hotmail.com

The aims of this study were to assess the risks patients are informed of before providing 'informed consent' for corrective surgery of a fractured neck of femur. The effectiveness of the new consent form, which explained risks and allowed a copy of the form to be left with the patient, could therefore be judged.

Consent is an ethical and legal requirement that must be obtained before the start of any investigation, treatment or intervention of a patient. As a principle, consent allows patients to decide what happens to their own bodies based on balanced information provided to them. When informed consent is appropriately provided, it ultimately increases patient satisfaction in virtually all outcomes.

Seeking Patients' Consent: The Ethical Considerations was published by the GMC in 1998.¹ These legal guidelines outline the ethical considerations of good clinical practice.

Health professionals failing to obtain full consent risk litigation against themselves or the health body they represent. Since the introduction of the new consent forms, doctors are required to note serious and frequently occurring risks of the operation on the consent form as well as discussing them with the patient.

A patient with a fractured neck of femur is exposed to a variety of risks and a significant mortality with or without surgery. The complications encountered include hip joint infection, wound infection, pressure sores, pulmonary embolism (PE), deep vein thrombosis (DVT), myocardial infarction, urinary tract infection, pneumonia and failure of the procedure performed.²

These are obviously significant complications some of which are potentially fatal and, as such, to ensure consent

is valid, they need to be carefully explained to patients on whom such procedures are to be undertaken.

Patients and Methods

Case notes of patients undergoing surgery for fractured neck of femur were requested from the audit department at Wythenshawe Hospital. These procedures were carried out under the care of 6 different consultant orthopaedic and trauma surgeons. A total of 173 case notes were provided and retrospectively reviewed. These cases were taken from the study period of January 2003 to April 2004. Risks of surgery as listed on the consent form were studied and recorded. A record of the operation performed was also made. Any old style consent forms, with no set spaces for recording complications, were not included in the study. The new style consent form which is specifically for patients unable to consent and which also has no specific place to record risks of surgery were also excluded from the study. Results were analysed using confidence intervals and Fisher's exact test.

Results

From the 173 case notes analysed, 33 of the consent forms gave consultant consent (patient unable to give consent), 32 of the case notes contained the older consent forms, and 6 sets of notes had no consent forms. This left 102 cases for

study. Of these, 17 patients underwent internal fixation using dynamic hip screws, 2 patients underwent AO screws and 83 patients had a hemi-arthroplasty performed.

The most commonly recorded risks were infection (95.1% CI 89.0–97.9), pulmonary embolus/deep vein thrombosis (81.4%, CI 72.0–87.0), failure of operation/non-union (59.8%, CI 50.1–68.7), risks of general anaesthetic (58.8%, CI 47.1–66.1) and bleeding (46.1%, CI 36.7–55.7). Twelve other risks were recorded but only appeared in less than 10% of the consent forms. Table 1 shows the risks as stated on the form and their relevant frequency.

Two consent forms had no risks recorded. All consent forms with chest infection also had the word 'infection' recorded implying that these patients were informed of different types of infection.

There was a range of 0–8 risks recorded on each form. The mean number of risks recorded was 3.92 and the mode 4.

Sixty forms had 'complications of GA' recorded but of these only 2 actually used the words 'general anaesthetic'. Similarly, 83 forms recorded 'DVT/PE' as a complication with only 3 recording the words 'deep vein thrombosis' and 'pulmonary embolism'.

Results were cross-tabulated and Fisher's exact test showed no significant difference ($P < 0.05$) between different types of hip surgery and the recording of the risks for each particular procedure on consent forms. DVT/PE ($P = 0.496$), failure of operation/non union ($P = 0.158$), infection ($P = 1.0$), bleeding ($P = 0.274$), neurovascular damage ($P = 0.294$),

Table 1 Risks and their frequency with 95% confidence intervals

Risk	Frequency	Percentage	95% CI
Infection	97	95.1	89.0–97.9
PE/DVT	83	81.4	72.0–87.0
Non-/mal-union/failure/dislocation/loosening of prosthesis	61	59.8	50.1–68.7
Risks of general anaesthetic	60	58.8	47.1–66.1
Bleeding	47	46.1	36.7–55.7
Neurovascular damage	40	39.2	30.7–48.9
Significant mortality/death	6	5.9	2.7–12.2
Chest infection	11	10.8	6.1–18.3
Scar	5	4.9	2.1–11.0
Avascular necrosis	4	3.9	1.5–9.7
MI	4	3.9	1.5–9.7
Leg shortening	2	2.0	0.5–6.9
Shaft fracture	2	2.0	0.5–6.9
None recorded	2	2.0	0.5–6.9
Damage to synovial structures	1	1.0	0.7–5.3
Stiffness	1	1.0	0.7–5.3
Pain	1	1.0	0.7–5.3
Difficulty in mobilisation	1	1.0	0.7–5.3

risks of general anaesthetic ($P = 0.325$) and chest infection ($P = 0.506$).

Discussion

Our results show great variability between the number of risks being recorded on consent forms. The fact that 1.96% of the consent forms showed no risks recorded has huge legal implications for the health body. It is unknown as to whether complications and risks of surgery were actually explained to the patient in these 2 cases and whether it was simply a matter of failure of adequate recording on the consent form. In either case, if there is no clear recording of consent in patient notes, there may be difficulty if litigation is pursued, in proving that valid informed consent was satisfactorily obtained with the patient understanding any potential complications of the procedure undertaken. Fixation using dynamic hip screws was under-represented in this study.

This study found infection to be the most frequent risk recorded on consent forms for fractured neck of femurs. However, in previous studies, infection rates have been shown to vary from 1% for deep infection to 11% for urinary tract infection.² In cases where 'infection' is recorded, it cannot be assumed that patients were made aware of the types of potential infections possible. Other established complications of orthopaedic hip surgery for trauma include the formation of a thrombo-embolus and revision surgery due to failure of the original operation. This study showed that these risks were recorded on 81.4% and 59.8% of consent forms, respectively. The failure rates for traumatic hip surgery can be as high as 6% and this may involve further surgical management.² This obviously has great implications for the patient and certainly is something that needs to be mentioned at the time of taking consent.

It was further noted that risks recorded on consent forms often contained acronyms such as 'DVT/PE' or 'risks of GA'. In only a minority of cases were these phrases actually noted in full. Unless these words are explained carefully to a patient, they may not understand their meaning when they sign a consent form. It may be prudent to record these terms in their entirety to ensure an accurate record of explanation of these risks on consent forms.

In the East Anglia audit, 22% of patients developed pressure sores following fractured neck of femur surgery. Surprisingly, this study showed that not a single patient was informed about the risks of developing pressure sores and their resultant complications.² Pressure sores may, however, develop even if neck of femur fractures are treated conservatively and with the prolonged bed rest involved in conservative management may even be more likely to occur. However, it is probably good practice to inform patients of possible complications whilst explaining that they may not be directly as a result of the surgery itself.

Hospital mortality after admission for fractured neck of femur has been shown to be between 13–35%; for patients managed conservatively who are over 65 years, this can be as high as 28%.^{3–5} The reason for death can be due to a variety of reasons, but ultimately any severely ill elderly patient who needs surgery is certainly at risk of dying either on the operating table or shortly after. Clearly, mortality is significantly high in hip surgery but as it seems lower or similar to conservative treatment it is difficult to know exactly how patients should be counselled. We note that this was touched on in 60% of cases when patients were informed of the risks associated with this type of surgery.

Medical staff taking consent need to have an understanding of the procedure and the common complications encountered. Unfortunately, it is often junior staff that take consent from patients. The experience of junior staff is often variable and thus they may not be completely aware of all the risks the patient may be exposed to and so place themselves in a position where they are unable to explain fully the procedure and its potential complications to patients whilst obtaining consent.

The current system relies on many different variables as discussed above; however, on closer examination, the majority of risks that need to be explained to a patient to ensure that consent is valid are the general risks that apply to all operations for fractured neck of femurs. This raises the possibility that a separate consent could be used where these risks are pre-printed and explained in vocabulary easily understood by patients. The added advantages of this form would be less confusion for the patient and there would be written evidence that patients had understood each of the major risks involved with the proposed procedure. When litigation is involved, the recording of patient understanding and consent may prove to be vital. This proposed consent form would also reduce the chance that important risks and complications are omitted when consent is being taken, as well as tackling the issue of variability of experience or lack of knowledge by the person obtaining consent. Any additional risks specific to a particular patient could be added onto the consent form. An example is given in Appendix 1.

This could also be supplemented by providing written information to patients prior or at the time of consent to increase patient understanding and satisfaction, both of which are the most important factors in preventing litigation. Provision of a booklet has been found to enhance patient knowledge in previous studies.^{6,7}

Conclusions

Health professionals have an ethical and moral obligation to inform patients of the best health advice and treatment they can provide when obtaining informed consent for surgical

procedures. Although the new consent form has gone some way in improving this, further changes may be needed to refine this process.

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APPENDIX 1

Consent for procedure: fractured neck of femur

General orthopaedic surgery/post-surgery risks

Clots in lower legs (deep vein thrombosis)
Clots in lungs (pulmonary embolism)
Anaesthetic complications
Infection
 Wound infection
 Chest infection
 Hip infection
 Urinary tract infection
Nerve/blood vessel damage
May require blood transfusion
Bed sores

Consent

Y N
Y N
Y N
Y N
Y N
Y N
Y N
Y N
Y N
Y N

Risk specific to the operation

Failure, loosening of metal work

Y N

Additional risks specific to the patient : - - - - -

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