Improving consent in patients undergoing surgery for fractured neck of femur

ABSTRACT

Background

Neck of femur fractures and their subsequent operative fixation are associated with high rates of perioperative morbidity and mortality. Consenting in this setting is suboptimal with the Montgomery court ruling changing the perspective of consent. This quality improvement project assessed the adequacy of consenting against British Orthopaedic Association-endorsed guidance and implemented a series of changes to improve the documentation of risks associated with surgery for fractured neck of femur.

Methods

Seventy consecutive patients who underwent any operative fixation of a neck of femur fracture were included over a 6-month period at a single centre. Patients unable to consent or without electronic notes were excluded. Consent forms were analysed and the documented potential risks or complications associated with surgery were compared to British Orthopaedic Association-endorsed guidance. A series of changes (using the plan, do study, act (PDSA) approach) was implemented to improve the adequacy of consent.

Results

Documentation of four out of 12 potential risks or complications was recorded in <50% of cases for patients with intracapsular fractures (*n*=35), and documentation of seven out of 12 potential risks or complications was recorded in <50% of cases for patients with extracapsular fractures (*n*=35). Re-audit following raising awareness and attaching consent guidance showed 100% documentation of potential risks or complications in patients with intracapsular and extracapsular fractures (*n*=70). A neck of femur fracture-specific consent form has been implemented which will hopefully lead to sustained improvement.

Conclusions

Consenting patients with fractured neck of femur for surgery in the authors' unit was suboptimal when compared to British Orthopaedic Association-endorsed consent guidance. This project has shown that ensuring such guidance is readily available has improved the adequacy of consent. The authors hope that introduction of a neck of femur fracture-specific consent form within their unit will lead to sustained adequate documentation of risks associated with surgery.

Consent is an important aspect of both medical ethics and international human rights law. It is mandatory before undertaking any proposed patient investigation, treatment or intervention (Probert et al, 2007). *Consent: patients and doctors making decisions together* was published by the General Medical Council in 2008. This guidance highlights the need to inform patients of what their care and treatment entails as well as providing patients with the information they want or need in order to make decisions, including risk and understanding adverse outcomes associated with proposed treatment options (General Medical Council, 2008).

The law on informed consent has changed following a Supreme Court judgment in March 2015. Following the judgment in the case of Montgomery v Lanarkshire Health Board [2015], the law now requires a doctor to take 'reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments'. This is a significant development that requires a change in perspective to consent in comparison to the previous 'Bolam test'. This asked whether a doctor's conduct would be supported by a responsible body of medical opinion [Bolam v Friern Hospital Management Committee, 1957].

In relation to trauma and orthopaedic surgery, the British Orthopaedic Association (2016) issued advice and guidance on consent following the 2015 Montgomery case, and has also endorsed the website www.orthoconsent.com, which gives access to a variety of pre-written consent forms for a number of orthopaedic operations in both the trauma and elective setting (British Orthopaedic Association, 2016). The British Orthopaedic Association suggests that this guidance should be used as a 'benchmark' against which one's clinical practice should be compared (Atrey et al, 2008). Taking consent appropriately improves the information given to patients, allowing them to make more informed decisions in partnership with their doctor.

Neck of femur fractures are a challenge in current health-care practice. Such injuries,

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despite operative intervention, are associated with high rates of perioperative morbidity and mortality (Royal College of Physicians, 2017). Proficient documentation and record keeping are important pillars of good clinical practice. Consenting in this trauma setting is generally recognized as being suboptimal (Probert et al, 2007). Litigation rates in surgery are increasing in the UK and the aforementioned recent court rulings have changed the perspective of consenting in surgery (Fanous et al, 2017). Therefore, this project assessed the adequacy of consenting in a single trauma and orthopaedics unit against British Orthopaedic Association-endorsed guidance with the overall aim of improving the documentation of risks associated with surgery for fractured neck of femur.

Methods

Ethics

Ethical waiver was obtained by the trust's ethics and clinical governance departments. Reference numbers were assigned locally (DTT016045, DTT016046) as part of audit and quality improvement processes. The Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) were adhered to in an attempt to improve the quality, safety and value of health care (Ogrinc et al, 2015).

Design and setting

This quality improvement project was undertaken retrospectively within the Department of Trauma and Orthopaedics at Ashford and St Peter's Hospitals NHS Foundation Trust over a 6-month period in 2016. Consecutive patients who underwent any operative fixation for neck of femur fracture were included. Patients unable to consent (i.e. patients who lacked capacity) or whose notes were not electronically available were excluded. Baseline audit was undertaken to assess the adequacy of the consent process against the British Orthopaedic Association-endorsed consent guidance contained on orthoconsent.com (Atrey et al, 2008). This website allows clinicians free access to a bank of procedural-specific, pre-written consent forms.

A series of changes were implemented using the Model for Improvement – plan, do study, act (PDSA) approach following baseline audit in an attempt to improve the adequacy of the consent process in patients undergoing surgery for fractured neck of femur (Langley et al, 2009).

> "Proficient documentation and record keeping are important pillars of good clinical practice."

Data collection and analysis

Data were collected from consent forms and neck of femur clerking proformas uploaded to the Trust's electronic database including type of neck of femur fracture (intracapsular or extracapsular), procedure performed, grade of doctor consenting patient, and the documented potential risks or complications on the consent form. Documented risks or complications were then compared to the suggested guidance contained within the British Orthopaedic Association-endorsed consent guidance contained within orthoconsent.

Table 1. Frequency of documentation of the potential risks or complications in intracapsular neck of femur fracture patients (*n*=35) – baseline audit

Potential risks or complications	Frequency, n (%)
Blood clots (deep vein thrombosis or pulmonary embolism)	34 (97)
Bleeding	34 (97)
Pain	18 (51)
Altered leg length	24 (69)
Dislocation	26 (74)
Infection	35 (100)
Catheterization	0 (0)
Altered wound healing	0 (0)
Nerve damage	30 (86)
Bone damage	5 (14)
Blood vessel damage	30 (86)
Death	5 (14)

Table 2. Frequency of documentation of the potential risks or complications in extracapsular neck of femur fracture patients (*n*=35) – baseline audit

Potential risks or complications	Frequency, n (%)
Blood clots (deep vein thrombosis or pulmonary embolism)	34 (97)
Bleeding	24 (79)
Pain	16 (46)
Infection	35 (100)
Catheterization	0 (0)
Altered leg length	1 (3)
Avascular necrosis	1 (3)
Hip stiffness	8 (23)
Nerve damage	34 (97)
Bone damage	12 (34)
Blood vessel damage	20 (57)
Death	0 (0)

Ashford and St. Peter's Hospitals NHS
NHS Foundation Trust

Department of Trauma and Orthopaedics

Consent Form 1

HIP FRACTURE (BROKEN HIP)

Patient Details (or pre-printed label)
Name:
DOB:
Hosp. No:
NHS Number:

Name of proposed procedure

Fracture inside the hip capsule:
Operative fixation with screws +/- plate, or half, or full hip replacement ☐

Fracture outside the hip capsule:
Operative fixation with plate and screws, or with a nail inside the bone ☐

Site:
LEFT ☐
RIGHT ☐

Statement of health professional

I have explained the procedure to the patient. In particular, I have explained:

The intended benefits: PAIN RELIEF ☐ RESTORE FUNCTION ☐ OTHER ☐
……

Significant unavoidable or frequently occurring risks:

Common: BLOOD CLOTS (DVT/PE) ☐ BLEEDING ☐ PAIN ☐
ALTERED LEG LENGTH ☐ JOINT DISLOCATION ☐ FAILURE ☐

Less common: INFECTION ☐

Rare: AVASCULAR NECROSIS (BONE DEATH FROM POOR BLOOD SUPPLY) ☐
WOUND PROBLEMS ☐ HIP STIFFNESS ☐ NERVE DAMAGE ☐
BONE DAMAGE (FRACTURE) ☐ BLOOD VESSEL DAMAGE ☐ DEATH ☐

Other potential medical complications: CHEST INFECTION ☐ HEART PROBLEMS ☐ CONFUSION ☐

Patient does not want to know significant unavoidable or frequently occurring risks ☐

Any extra procedures which may become necessary during the procedure. N/A ☐

Blood transfusion and/or other blood products ☐ Catheterisation ☐

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

The following leaflet/tape has been provided ☐ …… No leaflet/tape ☐

This procedure will involve:

General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation ☐

The precise nature of which will be discussed with you by the health professional administering the anaesthetic or sedation

Signed: (health professional) …….. Date: ……..

Name: (PRINT) …… Job title: ……

Name of Consultant in charge of patient care……..

Figure 1. Proposed neck of femur fracture-specific consent form (subject to change).

com. Descriptive statistics were generated following data range and logic checks.

Results

Baseline audit

For intracapsular neck of femur fracture patients undergoing surgery (n=35), the documentation of four out of 12 potential risks or complications was recorded in <50% of cases (*Table 1*). Similarly, consenting in extracapsular neck of femur patients (n=35) showed that documentation of seven out of 12 potential risks or complications was recorded in <50% of cases (*Table 2*). The baseline audit revealed that the documentation of potential risks and complications in patients for surgery with fractured neck of femur within consent forms when compared to British Orthopaedic Association-endorsed guidance was inadequate.

PDSA cycle: raising awareness and attachment of consent guidance

As consenting in fractured neck of femur patients in the authors' unit was suboptimal when compared to British Orthopaedic Association-endorsed consent guidance, a series of changes was implemented. First, British Orthopaedic Association-endorsed guidance was attached to neck of femur fracture clerking documentation as an interventional change. Second, the baseline audit data were presented at the departmental clinical governance meeting as an educational change. Re-audit following these interventions showed 100% documentation of all potential risks or complications in patients with both intracapsular (n=35) and extracapsular (n=35) neck of femur fractures.

Given the significant improvement in documentation of all potential risks or complications in both intracapsular and extracapsular neck of femur fracture patients when using a standardized consent proforma, the authors decided to implement some further changes to sustain the improvement. A neck of femur fracture-specific consent form (adapted from but based on British Orthopaedic Association-endorsed guidance) and a patient information leaflet for patients undergoing surgery with a fractured neck of femur have been created. Both of these are in the process of trust-wide implementation but it is hoped that the introduction of both these documents will lead to sustained adequate documentation of risks associated with surgery.

Discussion

Neck of femur fractures are the most commonly reported serious injury occurring in the elderly population with a national incidence of >65 000 cases per year (Royal College of Physicians, 2017). This number is expected to rise to 100 000 by 2033 (White and Griffiths, 2011). Since 2010, following the introduction of the Best Practice Tariff by the Department of Health and National Hip Fracture Database, there has been a huge emphasis on improving neck of femur fracture care and individual NHS trusts are rewarded for meeting various targets and standards such as time to surgery, early comprehensive review by orthogeriatrician, falls assessment, risk stratification before surgery and bone protection (Audit Commission, 2012).

Despite these improvements in care and financial incentives the estimated costs to the NHS (including social care) are in the region of £1 billion per year (Royal College

of Physicians, 2017). Further these injuries and subsequent surgery are associated with high morbidity and mortality: the 30-day mortality rate is 6.7% rising to <30% at 1 year (Royal College of Physicians, 2017).

With regards to consent in surgical practice, a landmark Supreme Court ruling in March 2015 in the case of Montgomery v Lanarkshire Health Board [2015] has placed further emphasis and changed the perspective of the consent process. Further, the adequacy of consent in patients undergoing surgery for fractured neck of femur has previously been shown to have improved over time but is still suboptimal for fractured neck of femur (Probert et al, 2007). One suggestion was that consent forms may need to be further refined in an attempt to improve the process. Potential consequences of inadequate consent in this setting could have an adverse impact of patient care overall, resulting in a breakdown of the doctor–patient relationship and could have medicolegal implications. This was highlighted in a 10-year review of litigation costs associated with hip fractures in the NHS which estimated the cost of settling claims to be in the region of £5 million over this time (Fanous et al, 2017). In this study approximately 20% of claims were related to medical or surgical error which theoretically could directly involve the consent process itself.

Through conducting baseline audit the authors showed that the adequacy of consent with regards to the documentation of potential risks and complications associated with surgery for fractured neck of femur was inadequate which was consistent with previous literature (*Tables 1* and *2*). Therefore, using British Orthopaedic Association-endorsed consent guidance seemed a logical way of trying to improve the adequacy of consent in this setting. The authors set out to achieve this through the PDSA approach. By attaching the British Orthopaedic Association-endorsed guidance to the neck of femur clerking proforma, the authors demonstrated a vast improvement in the adequacy of consent in their unit with 100% documentation of all potential risks and complications associated with surgery in consent forms.

Limitations of this work include the retrospective nature of data collection, the relatively small number of patients considered, potential issues with sustainability of the improvement, and using the documentation of risks and complications associated with surgery as a surrogate for adequate consent. The authors aim to overcome these through the implementation of a neck of femur fracture-specific consent form for the trust (*Figure 1*). This will hopefully lead to sustained improvement in the documentation of risks and complications associated with surgery.

To complement the implementation of a neck of femur fracture-specific consent form, the authors have introduced and updated a patient information leaflet for those with a neck of femur fracture. This will ensure patients and their relatives will be better informed of the potential risks and complications associated with surgery and will help to overcome problems of retention of information. It has previously been shown that patients with a neck of femur fracture are less good at retaining information conveyed to them at the time of consent compared to patients undergoing elective total hip replacement despite being intellectually and physiologically matched (Khan et al, 2012).

Conclusions

Consenting in fractured neck of femur patients in the authors' unit was suboptimal when compared to British Orthopaedic Association-endorsed consent guidance. The documentation of potential risks or complications in patients for surgery with fractured neck of femur within consent forms was inadequate. The authors have shown that attaching British Orthopaedic Association-endorsed guidance to neck of femur clerking proformas has improved the consent process. The introduction of a neck of femur fracture-specific consent form within their unit will hopefully lead to sustained adequate documentation of risks associated with surgery. This will allow patients and relatives to be better informed of the potential risks and complications associated with surgery. **BJHM**

Conflict of interest: none.

KEY POINTS

- Consenting in fractured neck of femur patients in the authors' unit was suboptimal when compared to British Orthopaedic Association-endorsed consent guidance.
- Raising awareness and making such guidance available has improved the adequacy of consent.
- The introduction of a neck of femur fracture-specific consent form will hopefully lead to ongoing sustained adequacy of the documentation of risks associated with surgery.

Atrey A, Leslie I, Carvell J, Gupte C, Shepperd JAN, Powell J, Gibb PA; British Orthopaedic Association. Standardised consent forms on the website of the British Orthopaedic Association. J Bone Joint Surg Br. 2008 Apr;90-B(4):422–423. https://doi.org/10.1302/0301-620X.90B4.20497

Audit Commission. 2012. Best practice tariffs and their impact. (accessed 11 April 2018) https://www.bl.uk/collection-items/best-practice-tariffs-and-their-impact

Bolam v Friern Hospital Management Committee [1957] 1 WLR 582

British Orthopaedic Association. 2016. Guidance on Consent. (accessed 1 April 2018) https://www.boa.ac.uk/wp-content/uploads/2016/09/BOA-Consent-Guidance.pdf

Fanous R, Sabharwal S, Altaie A, Gupte CM, Reilly P. Hip fracture litigation: A 10-year review of NHS Litigation Authority data and the effect of national guidelines. Ann R Coll Surg Engl. 2017 Jan;99(1):17–21. https://doi.org/10.1308/rcsann.2016.0277

General Medical Council. 2008. Consent: patients and doctors making decisions together. (accessed 11 April 2018) https://www.gmc-uk.org/-/media/documents/consent---english-0617_pdf-48903482.pdf

Khan SK, Karuppaiah K, Bajwa AS. The influence of process and patient factors on the recall of consent information in mentally competent patients undergoing surgery for neck of femur fractures. Ann R Coll Surg Engl. 2012 May;94(5):308–312. https://doi.org/10.1308/003588412X13171221591970

Langley GL, Moen R, Nolan KM, Nolan TW, Norman CL, Provost LP. 2009. The Improvement Guide: A Practical Approach to Enhancing Organizational Performance. 2nd edition. San Francisco: Jossey-Bass Publishers

Montgomery v Lanarkshire Health Board [2015] SC 11

Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. Squire 2.0 (Standards for Quality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process. Am J Crit Care. 2015 Nov 01;24(6):466–473. https://doi.org/10.4037/ajcc2015455

Probert N, Malik AA, Lovell ME. Surgery for fractured neck of femur - are patients adequately consented? Ann R Coll Surg Engl. 2007 Jan;89(1):66–69. https://doi.org/10.1308/003588407X160846

Royal College of Physicians. 2017. National Hip Fracture Database (NHFD) annual report 2017. (accessed 11 April 2018) https://nhfd.co.uk/files/2017ReportFiles/NHFD-AnnualReport2017.pdf

White SM, Griffiths R. Projected incidence of proximal femoral fracture in England: A report from the NHS Hip Fracture Anaesthesia Network (HIPFAN). Injury. 2011 Nov;42(11):1230–1233. https://doi.org/10.1016/j.injury.2010.11.010