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Are we meeting the standards set for informed consent in spinal surgery?

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ABSTRACT

Introduction Informed consent empowers patients to exercise their autonomy and actively participate in their medical care. Guidance published by the British Association of Spine Surgeons (BASS) lists three components of consent: provision of information booklets, patient-centred dialogue and completion of appropriate consent forms. The aim of the study was to review the quality of the spinal surgery consent process against the BASS guidance in a single tertiary neurosurgery centre in London.

Methods Retrospective review of clinic letters and consent forms was performed for 100 consecutive cases of elective, non-instrumented spinal decompression surgeries performed in 2019. Documentation was graded for inclusion of the intended benefit (improvement of pain/prevention of neurological deterioration), alternative management options (including no treatment), surgical options and risks (infection, bleeding, paralysis, sphincter disturbances, dural tear and recurrence). Provision of supplementary information booklets was recorded. Two-tailed Fisher exact test was used to calculate statistical significance where appropriate.

Results Documentation of indications and risks of elective spinal surgery, specifically risk of recurrence (62%) and sphincter disturbance (85%), was suboptimal on the consent forms. Documentation of these risks was also poor in clinic letters (<50%). Alternative treatment options were explained in less than half of the clinic letters, and there was no documentation of information booklet provision prior to elective surgeries.

Conclusion Lack of informed consent plays a major role in medical malpractice claims in spinal surgery. Poor documentation puts the surgeon in a liable position. BASS guidance could be implemented to create a more standardised process of consent in spinal surgery.

KEYWORDS

Informed consent – Spinal surgery – Medicolegal claims – Three-legged stool – BASS

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Introduction

Informed consent is a crucial part of good surgical practice, and it goes far beyond signing a form. The process and ethical norm of informed consent have evolved over the years. Traditionally, the focus was on the physician's disclosure of information rather than on the patient's understanding of that information.[1] Standard of information provided during consent was judged using the Bolam Criteria: what a responsible body of doctors would regard as acceptable and adequate.[2] The impetus for reviewing the processes of consent has been driven for the most part by litigation and legal judgements. Most significantly, the Montgomery ruling in 2015 inculcated a step change in attitudes towards consent, shifting them from a doctor/procedure-focused process towards a patient-centric approach.[3] It is now accepted that informed consent is a shared decision-making process that respects, protects and promotes patient autonomy.

In the context of spinal surgery, a large proportion of litigation claims are related to poor consent process rather than technical errors.[4] Reviewing some of the landmark court cases demonstrates the evolving and dynamic approach to informed consent in spinal surgery. The case of Chester vs Afshar (2004) set the precedent that a surgeon must explain *and* document all potential risks of a surgical procedure during consent.[5] This case determined that the surgeon can be found negligent for not disclosing or documenting risks despite performing the surgery adequately.[5] More recently, in the case of Thefaut vs Johnston (2017), discussion of risk was further expanded to require discussion of both material risks *and* any other risk believed to be significant to a specific patient.[6] This meant that surgeons must not only describe objective risks but also explore whether there are subjective factors that may form relative contraindications for a specific patient. The case of Hassell vs Hillingdon (2018) proposed that to attain informed consent, information shared in the correspondence, the surgeon's personal website and in clinic discussions should also be complete and consistent.[7]

These cases highlighted inconsistencies and inadequacies in the consent process for spinal surgery. In an effort to standardise the process in the UK, the British Association of Spine Surgeons (BASS) proposed a model of consent referred to as a 'three-legged stool'. This model focuses on three equally important components:

use of information booklets, patient-centred dialogue and completion of appropriate consent forms (including procedure-specific ones).[8]

The aim of the study was to review the quality of spinal surgery consent process against the BASS guidance in a tertiary neurosurgery centre in London.

Methods

Electronic patient records of our trust were used to gather a list of adult patients (>18 years old) who underwent elective non-instrumented spinal decompression surgery in 2019. The first 100 consecutive patients that fit the criteria were included in the analysis (January 2019–June 2019). Lumbar decompressive surgeries and posterior cervical decompressive surgeries were included but anterior cervical spine operations and instrumented surgeries were excluded owing to their additional and specific risks.

Retrospective review of clinical letters and scanned consent forms was performed. Letters from patients' last clinic visits were graded for inclusion of clinical history, examination findings, imaging findings, management options (alternative treatments, physiotherapy, medical analgesia and epidural injection), surgical options with intended benefit (improvement of pain, improvement in or prevention of neurological deterioration) and common risks of spinal surgery (infection, bleeding, paralysis, sphincter disturbances, dural tear and recurrence). The list of serious and common risks studied was based upon the documented risks included in previous studies[4] and was consistent with those listed in BASS's spinal surgery-specific consent form.[9] Written consent forms were available on electronic records for only 61 of the 100 patients. Consent forms, all signed by competent adult patients (Consent Form 1), were evaluated for inclusion of indication, intended benefits and risks. We also assessed whether the section confirming whether an information leaflet had been given was ticked. Scores for intended benefit were given only if the information was clear and complete (to relieve pain and to improve or prevent deterioration in mobility/neurological function).

Two-tailed Fisher exact test was used to calculate statistical significance (p-value <0.05) using Microsoft Excel software when comparison was made between different groups of data: consultants vs registrars/fellows and clinic letters vs consent forms.

Results

One hundred adult patients who underwent elective, non-instrumental spinal decompression in 2019 were identified (January 2019–June 2019). These included 29 posterior cervical decompressions and 71 lumbar decompressions.

Retrospective review of the clinic letters showed that 57% were written by registrars or fellows whereas 43% were written by consultants. Median time between the clinic visits and the day of surgery was 68 days (range 8–422 days). Clinical history, imaging findings and surgical options were generally well documented (>90%). Examination findings and alternative management options were less frequently documented at 69% and 49%, respectively (Figure 1). Documentation was not affected by seniority, except that registrars and fellows more frequently documented examination findings (82% vs 51%) (Figure 1). Documentation of risks varied: paralysis (82%), dural tear (65%), infection (63%) and bleeding (56%) were documented more frequently than sphincter disturbances (43%) and recurrence (20%) (Figure 2). Registrars and fellows were significantly more likely to document bleeding, dural tear and recurrence as risks compared with consultants (Figure 2).

Scanned consent forms were available on the electronic system for 61 of the 100 patients. These included 17 posterior cervical decompressions and 44 lumbar decompressions. All consent forms were Consent Form 1, signed by competent adult patients on the day of the surgery; none had witness signatures. The vast majority (97%) were completed by registrars or fellows (3% by consultants). The section related to providing patients with additional information (leaflets) was not ticked in any of the consent forms. Indication for the operation was documented appropriately in only 85% of the forms. Almost all the consent forms listed the risks of infection (100%), bleeding (98%), dural tear (92%) and paralysis (90%) but documentation of sphincter disturbances (85%) and recurrence (62%) was less frequent (Figure 3). Documentation of all the risks, except paralysis, was significantly better in the consent forms compared with the clinic letters (Figure 3).

Discussion

Informed consent enables patients to exercise their autonomy and actively participate in their medical care. Guidance published by BASS on spinal surgery highlights the components of informed consent that can be implemented in daily practice to create a more standardised approach to informed consent.

BASS suggests patient-centred dialogue should include discussion of the intended benefits, alternatives and risks of the proposed treatment at a reasonable level specific to each patient.[8] In practice, clinic letters act as the main documentation of this discussion and are the sole document patients receive prior to their surgeries. Our data show that half of the clinic letters failed to include discussion of the alternative treatments, and this was not affected by the seniority of the consenting surgeon. Risks of surgery were generally poorly documented on clinic letters (Figure 2); specifically, recurrence and sphincter dysfunction were listed as a risk in less than 50% of the letters.

The focus on clinic letter documentation may seem excessive. After all, signed consent forms act as the sole

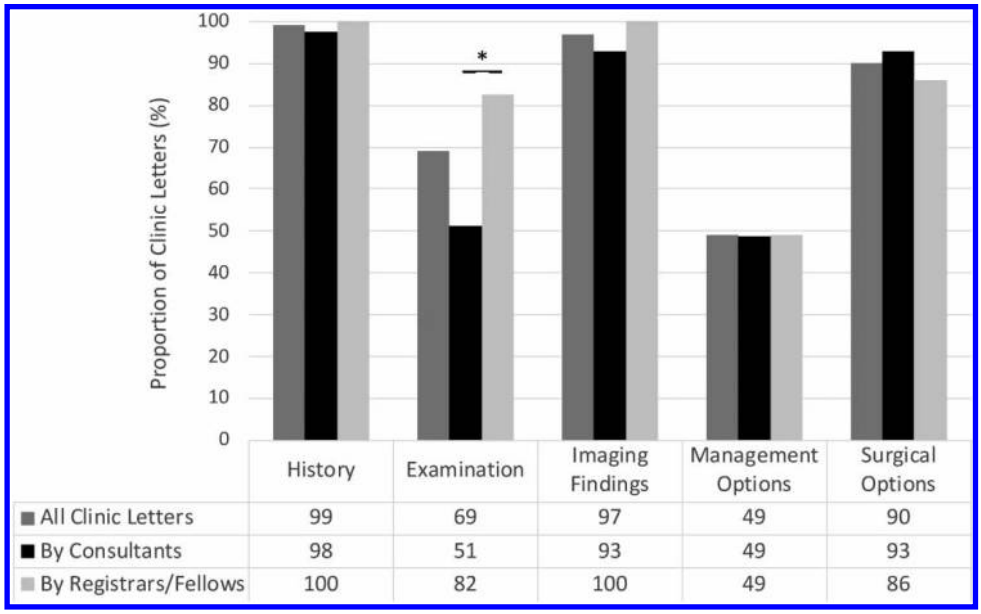

Figure 1 Documentation of relevant information on clinic letters ($N = 100$) by seniority. Statistically significant changes with $p < 0.005$ are marked with an asterisk (*).

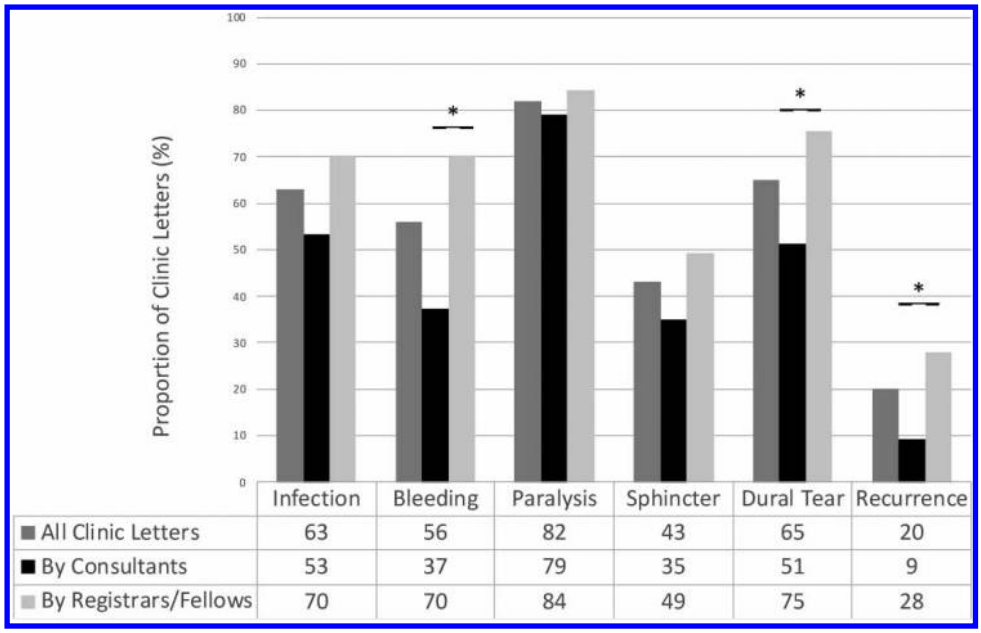

Figure 2 Documentation of relevant information on clinic letters by seniority ($N = 100$). Statistically significant changes with $p < 0.005$ are marked with an asterisk (*).

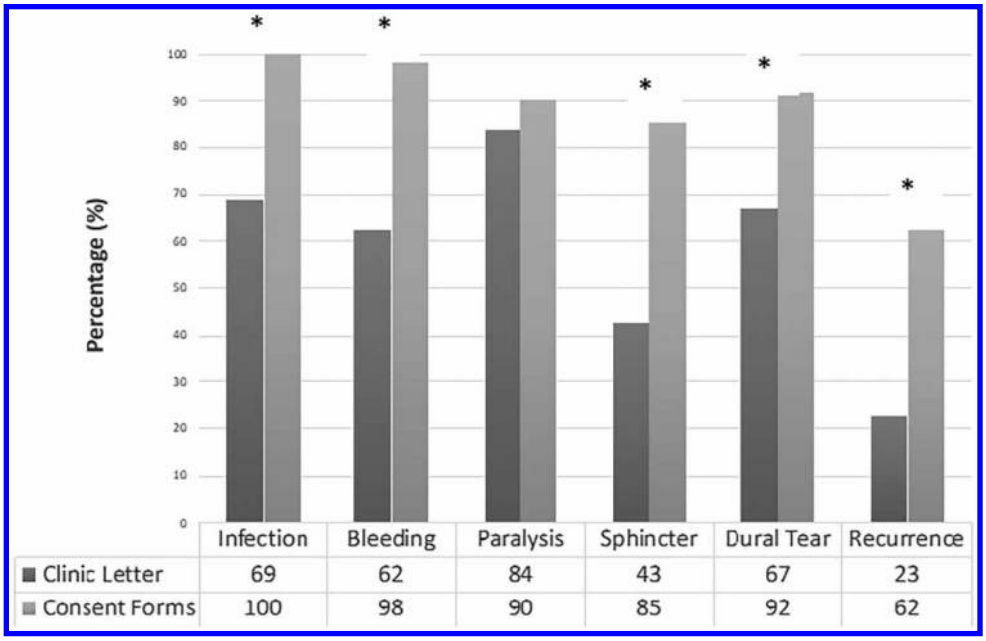

Figure 3 Comparison of documentation of surgical risks on clinic letters and on written consent forms ($N = 61$). Statistical significance with $p < 0.005$ marked with an asterisk (*).

proof of consent in everyday clinical practice. Surprisingly, the recent legal cases suggest their legal value may be debatable. In the case of Thefaut vs Johnston, the clinic letter sent to the Claimant was reviewed as the 'key evidence' in assessing the consent process.[6] The letter, recommending discectomy, made material overstatements of the chance of resolving back pain and failed to mention the option of having no surgery. Based on this information, the verdict was reached that the Claimant was not sufficiently consented and that had she been properly informed about her options, she would not have chosen an operation. Maybe more surprisingly, the signed consent form stating the relevant risks was not counted as real evidence.[6] Similarly, in the case of Hassell vs Hillingdon, the verdict was based on the inadequate clinic letter documentation.[7] In this case where Mrs Hassell suffered a spinal cord injury during a cervical spine operation, the clinic letters failed to outline the risk of paralysis or state conservative management options. She claimed that had she been informed about the risk of paralysis, she would not have chosen to undergo an operation. The consent form, clearly stating the risk of paralysis, was discarded because she felt rushed in signing the form on the day of the operation.[7]

Consenting the patient on the day of the surgery is not accepted as best practice because the stress of an expected imminent operation brings into question the state of mind and competence of a patient to make an informed decision.[8] Same day consent could also lead to last minute cancellation, waste of resources and patient anxiety. Additionally, Lo *et al* demonstrated that patients are significantly more likely to recall risks of spinal surgery, especially risks of paralysis and recurrence, if consented >14 days compared with <2 days before the surgery.[4]

Although their legal power may be debatable, consent forms provide proof that discussed terms have been acknowledged by the patient. BASS suggests use of procedure-specific consent forms; however, this is not standard practice in all UK neurosurgery units. In our institution, generic hospital consent forms are used where the intended benefits and risks are hand-written by the surgeon. Although this permits flexibility, it carries the risk of forgetting to discuss or document crucial information. In fact, our study demonstrated that description of the intended benefits and indication of the procedure was vague and/or incomplete in 15% of the forms. Risk of recurrence (62%) was especially poorly documented. Ten per cent of the patients in our study were not consented for the risk of paralysis and 15% were not informed about risk of sphincter disturbance. Our findings are similar to previous studies where documentation of risks, especially paralysis, sphincter disturbances and recurrence, for elective lumbar decompressive surgeries was poor on the consent forms.[4] Paralysis and incontinence have life-changing implications, and therefore they should be discussed and documented without exception.

Does the seniority of the surgeon affect the documentation of the relevant risks? In our study, the risk of bleeding, dural tear and recurrence were

significantly more frequently listed in the clinic letters written by registrars/fellows compared with consultants. Lo *et al* demonstrated a similar trend where risk of bleeding was better documented by registrars compared with consultants.[4] This may be due to increased awareness of medicolegal implications of consent among junior staff or perhaps due to improved training on consent. Alternatively, junior neurosurgeons in training may be more careful to document such complications because of more reflective practice. Interestingly, these findings contradict previous studies where junior orthopaedic surgeons were found to lack competence and confidence in obtaining informed consent.[10] Multicentre studies on orthopaedic consent suggested that implementing formal training can improve surgical residents' confidence in obtaining informed consent.[10]

Increasing litigation claims on informed consent have placed a tremendous importance on medical documentation. Medical records are now treated as 'proof' for potential future medicolegal cases. It is possible that the pressure of creating these detailed and accurate records may be taking away the time that could be spent with patients. One could argue that spending time with patients to build rapport, understand their expectations and discuss the procedure should take priority over spelling out every single risk of the operation on the clinic letters. In our study we assumed that the risks not documented have not been discussed with the patient. This is a legal approach and may not represent the true quality of the patient–surgeon discussion.

Open and honest reflection on the consent process facilitates a positive change in neurosurgical practice. Our study highlights the imperfections of the consent process in elective spinal surgery for our institution and proposes several interventions that are likely applicable to other neurosurgical centres with similar deficiencies in the consent process. These include use of procedure-specific consent forms, provision of information leaflets or BASS online resources, and education of surgeons at all levels of seniority regarding the medicolegal importance of writing clinic letters to include all aspects of consent discussion (indication, examination, management options, risks).

One potential intervention that is worth discussing in detail would be implementing a surgeon-led consent clinic for elective operations. This could improve the patient-centred dialogue and allow designated time to discuss components necessary for informed consent. Holding this clinic 2–4 weeks prior to the operation date could give patients time to reflect as suggested by previous studies and improve recall of risks.[4] This practice has been adopted by some members of our department since the time of our audit. Future re-audit will help identify its effects on the consent process.

Another approach to implement BASS guidance is using electronic consent (eConsent) platforms such as consentapatient.org. These platforms could potentially unify consent in one document and minimise misunderstandings. They allow use of multimedia adjuncts during the consent process and enable patients time to process information prior to their surgery. Studies suggest that even after proper verbal dialogue, patients still have poor recall of the crucial information, especially on information related to risks and alternative treatments.[11] Use of multiple modalities of information videos in addition to verbal dialogue increases the recall of information.[12] These platforms using procedure-specific, adaptable information enabling efficient documentation could be the future of spinal consent. In fact, some members of our department have already implemented the addition of eConsent as part of their standard practice since the time of our audit.

We believe that given the evolving nature of the consent process driven by medicolegal precedents, institutions conducting spinal surgery should undertake regular consent audits against current best practice to appraise and improve the consent process on a continual basis. The shortcomings highlighted in this study are unlikely to be unique to our institution. We propose that a key goal of further studies should be to establish a baseline for the current standard of practice across spinal surgical centres nationally. This will help to identify the scale and sources of suboptimal consent across the country and facilitate the development of national-level collaborative approaches to improve consent in spinal surgery.

Conclusion

Guidance published by BASS on spinal surgery highlights the components of informed consent as use of information booklets, patient-centred dialogue and completion of appropriate consent forms.[8] Lack of informed consent plays a major role in medical malpractice claims in spinal surgery.[13] Poor documentation puts the surgeon in a liable position and compromises the patient–surgeon relationship. Our study identifies and proposes improvements to specific areas and causes of poorly documented consent in elective spinal decompressive surgery.

Authors' contribution

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Yagmur Esemen, Abteen Mostofi and Daniel Richardson. The first draft of the manuscript was written by Yagmur Esemen and all authors especially Erlick Pereira commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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