A randomised trial of conventional versus BAUS procedure-specific consent forms for transurethral resection of prostate

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ABSTRACT

INTRODUCTION Conventional consent forms often contain incomplete information regarding risks associated with invasive procedures. BAUS has introduced procedure-specific consent forms (PSCF) documenting the risks associated with urological procedures. We compared patients' understanding of the risks and benefits of TURP after the consenting process with either conventional documentation or PSCF.

PATIENTS AND METHODS One hundred patients were randomised to be consented with either a conventional or PSCF. After 3 h, their understanding was assessed with a questionnaire asking patients to document the indication and likelihood of symptomatic improvement, estimate frequency of complications and the risk of future re-operation. Data were compared by Mann–Whitney test.

RESULTS Fifty patients were randomised to each group. There was no significant difference in mean age, grade of doctor obtaining consent or time interval from consent to questionnaire. Both groups accurately predicted the chance of improved symptoms (median, 80%). There was no significant difference in patients' median estimation of risk of complications such as incontinence, erectile dysfunction, or retrograde ejaculation. Patients consented with the PSCF predicted the risk of re-operation more accurately (median answer, 10% versus 30%; $P = 0.007$, Mann–Whitney test).

CONCLUSIONS Recall of data was sub-optimal in both groups. For most data points there was no significant difference in estimation of risks between groups. Those consented with a procedure-specific consent form predicted risk of re-operation at 10 years more accurately. Procedure-specific consent forms offer an advantage over conventional consent in this study. We feel that the provision of a written structured framework allows better informed consent for TURP.

KEYWORDS

BPH – Informed consent – TURP

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Informed consent may be defined as the process by which a patient who has the capacity and competence to consent to a given procedure, having been given sufficient information which he has understood, voluntarily arrives at a reasoned decision as to whether or not to agree to the proposed procedure.¹ Despite its importance in everyday practise, it remains a non-standardised procedure, varying between and within hospitals.

In 1974–1975, UK NHS clinical negligence expenditure was £1 million.² In 2005, £502.9 million was paid out in connection with clinical negligence and it is estimated that its current total liabilities are in the region of £6.89 billion for clinical claims.³ An adverse outcome, as perceived by the patient, along with lack of adequately documented consent may lead to a successful clinical negligence claim.⁴

Enhanced patient autonomy, on the other hand, improves compliance and patient satisfaction.⁵

Currently, the UK Department of Health guidance states that informed consent should be confirmed by a written record such as their standard consent form (Appendix 1). There are no recommendations for the information that must be documented, this being left to the discretion of the physician obtaining consent. Conventional consent forms have been shown to contain incomplete information regarding risks associated with invasive procedures,⁶ and information sheets given prior to TURP have been shown to vary in quality and adequacy.⁷ Recently, procedure-specific consent forms (PSCFs) have been designed by the British Association of Urological Surgeons (BAUS) to aid surgeons and provide a degree of standardisation to the consent process for urological procedures.

We conducted a randomised trial to assess informed consent for TURP after consent with either a conventional consent form or PSCF. Patients with capacity and competence to consent were included in a questionnaire-based study to determine whether sufficient information had been imparted and if this had been understood.

Patients and Methods

One hundred consecutive men admitted electively to the Norfolk and Norwich University Hospital for TURP between February and July 2005, were randomised by computer to be consented with either the conventional Department of Health Type 1 consent form or with a BAUS procedure specific consent form (Appendix 2). Exclusion criteria included those for whom English was not their first language, or lack of capacity or competence to give consent. Written consent was obtained by the admitting team on the day of admission, the night before surgery. The time taken to consent a patient was the same for both groups and patients were consented in a similar fashion for both consent forms. Three hours later, participants were given a short, standardized questionnaire, to be completed unaided. Their understanding was assessed through questions on the indication and likelihood of symptomatic relief of urinary symptoms, estimating the frequency of complications and predicting the risk of future re-operation at 10 years' post-procedure. Data were collated and compared by Mann-Whitney U-test (GraphPad Prism v.4.0; GraphPad Software, CA, USA).

Results

Fifty patients were randomised to each group. Mean age was 72 years in the BAUS group versus 75 years in the conventional group. The mean time interval from consent to questionnaire was 180 min in both groups. There was no significant difference in time taken to obtain consent between groups. Indications for

Figure 1 Patients' understanding of the indication for their procedure.

Table 1 Indication for TURP and grade of doctor obtaining consent

Indication for TURP	Consent form	
	Conventional	BAUS
Benign prostatic enlargement		
LUTS only	19	18
Retention + LTC	21	25
Carcinoma of prostate		
LUTS only	2	1
Retention + LTC	5	4
Re-do TURP	3	2
Grade of doctor		
	Conventional	BAUS
Pre-registration house officer	9	6
Senior house officer	33	35
Specialist registrar	2	2
Consultant	6	7

LUTS, lower urinary tract symptoms; LTC, long-term catheter.

TURP were similar in both groups (Table 1). Most patients were consented by senior house officers (three or more years post-graduation). All doctors obtaining consent had been instructed in this procedure at the beginning of their post. The grade of doctor obtaining consent varied in each group, but the overall distribution was similar (Table 2). Patients in both groups had a reasonable understanding of the indication for their procedure (Fig. 1), and there was no demonstrable difference in their understanding of the chance of an improvement of their symptoms (Fig. 2). When asked to estimate the frequency of potential complications, the spread of answers was wide, with only 40–50% correctly estimating each risk (Fig. 3). There was no significant difference in patients' median estimation of risk of

Figure 2 Patients' perception of the chance of improved symptoms after TURP (median $\pm$ interquartile range; $P > 0.05$).

Table 2 Risks documented in free-text box on conventional consent forms

Documented risk	Percentage of forms
Infection	100
Bleeding	100
Retrograde ejaculation	58.3
Erectile dysfunction	66.7
Incontinence	25.0
Re-do TURP	25.0
Failure to relieve symptoms	25.0
Pain	16.7
Bladder injury	16.7
Thrombo-embolic disease	8.3
TUR syndrome	16.7
Recurrence of 5% at 5 years	25.0

incontinence, erectile dysfunction, retrograde ejaculation, or UTI (Fig. 4). However, patients consented with the BAUS procedure-specific form were more likely to predict the risk of re-do accurately at 10 years (median answer, 10% versus 30%; $P = 0.007$, Mann-Whitney test; Fig. 5). Analysis of the documentation of risks on the conventional consent form showed a wide variation. All forms documented infection and bleeding (Table 2). The possibility of requiring a repeat procedure was referred to in 50% of forms, with the risk being quantified in 25%.

Discussion

The process of consent protects the physician from accusations of negligence or battery. An adverse outcome, as perceived by the patient, along with lack of adequately documented consent may lead to a successful clinical negligence claim.⁴ Adequate informed consent allows patients to make educated choices about their treatment. English law does not prescribe an invasiveness threshold above which consent should be documented for an intervention. As such, comparison with the practise of a 'reasonable physician' is used

Figure 4 Patients' median perception of risk for commonly described complications of TURP.

to determine this.⁸ Similarly, there is no common law requirement for a written consent document. However, for the purpose of defending claims, hospitals make this mandatory.⁹ Indeed, a signed consent form does not necessarily denote informed consent if the patient has no capacity to do so.¹⁰ Capacity requires comprehension, retention of information and an ability to arrive at a decision.¹¹ The General Medical Council (GMC) has outlined the information which it believes must be provided in informed consent: the purpose and details of the proposed treatment, details of diagnosis, treatment options (including no treatment), prognosis, benefits of the procedure, likelihood of success, and adverse effects.¹ With regard to the detail that should be imparted when obtaining informed consent, current English law is reflected by the Bolam principle. The surgeon should inform the patient of the facts which other surgeons in the same specialty think it is necessary for that patient to know.⁸ Imparting unbiased, comprehensive information to cover all points recommended by the GMC may be difficult, and the process can vary in its completeness according to the experience of the physician taking consent as well as the variation in patient education. Studies have shown variable completeness of risk documentation on consent forms.^{6,12,15} Our data confirm these findings for those consented with conventional documentation (Table 1). Patients' understanding of their procedure following informed consent has also been shown to be less than optimal.¹⁴⁻¹⁶

Deficiency in patient understanding may be a result of lack of knowledge on the part of the physician obtaining consent.¹⁷ This may theoretically be improved through education in the process of consent, or through consent being taken by the operating surgeon. According to the GMC, the practitioner who is performing the procedure should counsel the patient, obtain

informed consent, and complete consent forms. If this is not possible, that doctor should ensure that the delegated doctor knows about the procedure and its risks.¹ In a busy hospital setting, it is not always practical for the operating surgeon to obtain written consent, although during the pre-operative round, a responsible surgeon will check that the appropriate procedure is to be performed and that the patient has an adequate understanding of the risks and benefits. All junior doctors who obtain consent in this department undergo full instruction in the process at the beginning of their post including seeing the procedure as well as discussing the implications of complications. Only once a senior member of the department deems them competent are they then permitted to take consent from patients. Against this background of 'real-life' practise, tools that enable doctors who may be less familiar with procedures to cover all the essential points in obtaining consent for a procedure are welcome. Standardised consent forms obviate the need for handwritten entries and reduce variation in documented facts.⁶ They provide a useful *aide memoire* to accompany the consenting process.

In this study, there was no demonstrable difference in patients' understanding of complication rate when using conventional or standardised BAUS forms. Overall, there was poor retention of information at 3 h from consent. This may be dependent on memory or failure of initial imparting of information. Nevertheless, it is clear that there are limitations in assessing information transfer in this manner. Poor retention of information has been documented previously.¹⁶ Anxiety of hospital admission, consultations with admitting nursing staff, anaesthetists and surgical team, all imparting varied information within a short time-frame may explain, in part, the poor retention of facts. Certain aspects of the procedure or its complications may be perceived to be more relevant to individual patients, leading to a more focused recall of facts; for example, those who have an in-dwelling catheter may recall the chance of a successful procedure, but be unable to quote a risk for retrograde ejaculation. Within the confines of this study, it would appear that a written framework for consent did not positively influence recall of complication statistics at 3 h. However, PSCF-consented patients were better at predicting outcome in terms of estimating re-do TURP rate, perhaps reflecting the wider scope of information provided on the procedure-specific form compared to the conventional Department of Health paperwork, which often, although documenting risks well, may focus less on the discussion of benefits and long-term outcome, with only two lines of free-text space to cover this remit. Doctors obtaining consent were asked to consent both patient groups in a similar fashion. They were not asked to memorise the contents of the PSCF, as this may well have skewed the results. Perhaps if this had been the case, a more profound difference in results may have been teased out. This may be considered a methodological flaw.

A further methodological flaw may be that PRHO and SHO doctors performed the majority of consenting. We acknowledge

that it is not now deemed appropriate to use house officers or foundation-grade doctors to provide consent for operations of this magnitude. As a consequence, it could be argued that the difference in re-operation rates between the two groups may have been due to the ignorance of juniors. If specialist registrars or consultants had performed the majority of consenting, there may have been a different result and different conclusions to draw. However, it was the purpose of this study to assess whether the PSCF template alone enhanced patient understanding in the day-to-day setting. Artificially changing the profile of those obtaining consent would yield results that were not then applicable to our practice at that time. Senior clinicians may well consent patients with more depth of information and better continuity of recorded complications but, with information retention by patients demonstrably poor (40–50% at 3 h), arguably this would change the results little.

It has been stated elsewhere that additional written information does not improve a patient's understanding of risk and complications of a procedure;¹⁸ indeed, while the written consent form may provide an *aide memoire* to the physician, much of the consultation is, of course, verbal. This means that while the paperwork may have differed between groups, the verbal consent process may have been very similar, as such explaining the similar distribution of risk estimations. Closer questioning on the finer details of the procedure may have teased out larger differences between groups. It was, however, the purpose of this study to assess the impact of the PSCF as a tool for delivering consent. Any gains in patient understanding when using it, we feel, can be deduced as an advantage of the form and the consent method, despite a potentially similar verbal consent process for the two groups.

Informed consent is, of course, not merely obtained in a short pre-operative discussion. Our patients have a detailed discussion with their surgeon in the out-patient clinic, and are given a patient information leaflet on TURP to read at leisure before finally giving written consent by signing a document at the pre-assessment visit or on the ward. These data show that, even with this in-depth information-transfer process, the addition of a structured consent form can further enhance patient understanding.

The BAUS procedure-specific consent forms were introduced 3 years ago, initially to standardise and facilitate urological informed consent.¹⁹ The forms can be accessed via the BAUS website. During development, the information provided for each procedure was reviewed by BAUS and a working party of experts, and prior to implementation, the Clinical Negligence Scheme for Trusts (CNST) was consulted to ensure compliance with the implementation guide. A recent audit of their use in the UK¹⁹ demonstrated that only 29% of departments are currently using them in their practice. A further 26% are in the process of implementation. Of those questioned, 34% had met resistance from their NHS trust despite close involvement of the Department of Health in the design of the procedure-specific

forms. The PSCF may not have been adopted in a wide-spread fashion as established practitioners may feel that such paperwork is prescriptive and unnecessary if those obtaining consent have been adequately trained. This may certainly be the case for common procedures such as TURP; indeed, since this is a procedure with well-recognised complications such as erectile dysfunction, retrograde ejaculation and incontinence, it may be difficult to show an advantage of PSCF in enhancing information transfer. Further evaluation of the PSCF in a series of more complex major procedures with less well-known complications and possibly younger more motivated patients may prove the value of this documentation more clearly.

Conclusions

Data included on a conventional consent form are frequently incomplete. Standardised BAUS procedure-specific consent forms have been developed to cover the information which reasonable professional colleagues would expect a prudent patient to know in order to give informed consent. Patients consented with a standardised BAUS consent form showed a significant improvement in predicting long-term outcome. We suggest that these procedure-specific consent forms provide a better framework for giving informed consent and that patients should be consented with a standardised form for TURP.

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Appendix 1

Conventional NHS/Department of Health Consent Form¹

Patient identifier/label

Name of proposed procedure or course of treatment (include brief explanation if medical term not clear)

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

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

The intended benefits

Serious or frequently occurring risks

Any extra procedures which may become necessary during the procedure

blood transfusion.....

other procedure (please specify)

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

This procedure will involve:

general and/or regional anaesthesia

local anaesthesia

sedation

Signed:.....

Date

Name (PRINT)

Job title

Contact details (if patient wishes to discuss options later)

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed

Date

Name (PRINT)

Top copy accepted by patient: yes/no (please ring)

Appendix 2

BAUS procedure-specific consent form for TURP

Patient identifier/label	
Name of proposed procedure (Include brief explanation if medical term not clear)	ANAESTHETIC
TRANSURETHRAL INCISION OR RESECTION OF THE PROSTATE THIS OPERATION INVOLVES THE TELESCOPIC REMOVAL OF OBSTRUCTING PARTS OF THE PROSTATE WITH A HEAT DIATHERMY OR LASER. TEMPORARY INSERTION OF A CATHETER FOR BLADDER IRRIGATION	☐ - GENERAL/REGIONAL ☐ - LOCAL ☐ - SEDATION

Statement of health professional (To be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy) I have explained the procedure to the patient. In particular, I have explained:

The intended benefits RELIEF OF URINARY OBSTRUCTION AND IMPROVEMENT IN URINARY FLOW

Serious or frequently occurring risks including any extra procedures, which may become necessary during the procedure. 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. Please tick the box once explained to patient

COMMON

☐ TEMPORARY MILD BURNING, BLEEDING AND FREQUENCY OF URINATION AFTER PROCEDURE

☐ NO SEMEN IS PRODUCED DURING AN ORGASM IN APPROX: 20% if INCISION or 75% if RESECTION

☐ MAY NOT RELIEVE ALL PROSTATIC SYMPTOMS

OCCASIONAL

☐ POOR ERECTIONS POSSIBLE (IMPOTENCE IN APPROX 5-10%)

☐ INFECTION OF BLADDER OR KIDNEY REQUIRING ANTIBIOTICS

☐ BLEEDING REQUIRING RETURN TO THEATRE AND/OR BLOOD TRANSFUSION.

☐ POSSIBLE NEED TO REPEAT TREATMENT LATER DUE TO REOBSTRUCTION (APPROX 10%)

☐ MAY NEED SELF CATHETERISATION TO EMPTY BLADDER FULLY IF BLADDER WEAK

☐ FAILURE TO PASS URINE AFTER SURGERY REQUIRING A NEW CATHETER

RARE

☐ FINDING UNSUSPECTED CANCER IN THE REMOVED TISSUE AND THIS MAY NEED FURTHER TREATMENT

☐ INJURY TO URETHRA CAUSING DELAYED SCAR FORMATION

☐ LOSS OF URINARY CONTROL (INCONTINENCE), TEMPORARY OR PERMANENT

☐ ABSORPTION OF IRRIGATING FLUIDS CAUSING CONFUSION, HEART FAILURE (TUR SYNDROME)

☐ VERY RARELY, PERFORATION OF THE BLADDER REQUIRING A TEMPORARY URINARY CATHETER OR OPEN SURGICAL REPAIR

ALTERNATIVE THERAPY: DRUGS, USE OF A CATHETER OR STENT, OBSERVATION OR OPEN OPERATION

A blood transfusion may be necessary during procedure and patient agrees YES or NO (Ring)

Signature of Health Professional	Job Title
Printed Name	Date

The following leaflet/tape has been provided

Contact details (if patient wishes to discuss options later)

Statement of interpreter (where appropriate) I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signature of interpreter: _____ Print name: _____ Date: _____

Copy (i.e. page 3) accepted by patient: yes/no (please ring)