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PROCEDURE SPECIFIC CONSENT FORMS IMPROVE THE PROCESS OF INFORMED CONSENT IN PATIENTS UNDERGOING CONTINENCE SURGERY BY UROLOGISTS.

Hypothesis / aims of study

The British Association of Urological Surgeons has introduced procedure specific consent forms for an array or urological procedures. This study examines whether their introduction has improved the process and documentation of informed consent in patients undergoing continence surgery by urologists.

Study design, materials and methods

This study is a retrospective audit study of all patients undergoing surgery for stress urinary incontinence by urologists in a defined geographical region in two separate time periods. Data was collected by the same two clinical audit data collectors on each occasion and the whole process of consent was examined from the time surgery was offered during a clinic appointment, to the time it was undertaken. Documentation from clinical notes, clinic letters, communications and information leaflets given to the patients were examined, along with the consent forms, for information relevant to undertaking informed consent for the procedures. The same data set was collected for surgery undertaken between January 2003 and December 2003 and compared to data collected for surgery undertaken between November 2006 and October 2007 (termed 2007 data). All procedures for stress urinary incontinence were included, except urethral bulking with injectable agents. Some operations required patients to be warned of specific potential complications, whilst all procedures require the risk of failure to be explained to them along with the risk of retention and development of frequency and urgency. Consent should also include a discussion of alternative surgical procedures (and non surgical treatments).

Results

145 procedures for stress incontinence were carried out by 25 surgeons at 15 centres In 2003, whilst 202 procedures were performed by 22 surgeons in those 15 units during 2007. The table below shows the reasons why consent was incomplete during the two audit periods. Obviously many patients had more than one relevant factor omitted from their consent documentation.

Reason for Incomplete documentation of consent	2003 (n = 145)		2007 (n = 202)	
	No	%	No.	%
Not warned of possible failure of procedure	7	4.8%	4	2.0%
No discussion of other options	58	40.0%	4	2.0%
Not warned about possible need to self catheterise	28	19.3%	10	5.0%
Not warned about increased frequency & / or urgency	50	34.5%	8	4.0%
Not warned about possible rectocoele (Colposuspension patients only)	48 (n= 76)	63.2%	21 (n= 38)	55.2%
At least one reason for incomplete consent	104	71.7%	33	16.3%

Ultimately only 41 of the 145 patients in 2003 (28.3%) had properly documented consent which improved in 2007 to 169 of 202 patients (83.7%).

Although the improvements in individual components of consent are not all statistically significant using the Chi square test the overall improvement in patients having informed consent is highly significant ($p < 0.001$)
None of the urology units were using the procedure specific consent forms during the 2003 data collection period, as the forms were only made available towards the end of that time. By 2007, the forms were being used by 12 of the 15 units, either as their consent form, or as a reference whilst taking consent and / or patient information resource.

Interpretation of results

For patients to have been deemed to have given informed consent they must have been told about their intended procedure and expectations of success, warned of possible complications and had alternative management options highlighted to them. Consent is regarded as a process and does not rely just on the written consent form which is often left to more junior staff. Most surgeons assume they can take informed consent for the procedures they perform, but our data suggests that in the absence of a procedure specific consent form only 28.3% were consented properly for their continence procedure in 2003. The initial audit itself may have raised the awareness and improved the practise of some surgeons between the first and second audit period. Otherwise the introduction of procedure specific consent forms was the only change in practise identified during the data collection or the subsequent discussion of the data at the audit meeting to explain the significant improvement with 83.7% of the patients having properly documented informed consent in 2007.

Concluding message

This retrospective audit has shown a vast improvement in informed consent for treating stress urinary incontinence, across all procedure types and across a large number of institutions and surgeons, following the introduction of procedure specific consent forms by BAUS. Many units used the forms (or local modifications of it) to take the formal written consent from patients. Other units used the BAUS forms as an aide memoir when taking consent or as a patient resource. Three of the fifteen units still did not use them at all.

We believe two factors have potentially contributed to the improvement. Firstly the initial audit has identified to surgeons how poorly consent was being documented and this awareness has led to some improvement in practise. Secondly the introduction of procedure specific forms has ensured no relevant complications are omitted from the discussion when consent is taken.

We suggest that all UK urologists should use the forms and further, that other surgeons performing continence surgery in the UK, along with urologists elsewhere, seek access to the standardised consent forms. We believe this study also has implications for other types of operation and indeed other surgical specialities, where similar types of procedure specific consent form should be developed.

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