11

Hamoodi I[1], Tyagi V[1], Abdulrahman O[1], Guerrero K[1], Perera M[1]
1. *NHS Greater Glasgow and Clyde*

CONSENTING FOR TAPE PROCEDURES

Hypothesis / aims of study

Informed consent from patients is a widely discussed issue with different approaches taken between different countries, specialties and even within units. It has significant medico-legal implications but also results in patient and clinician dissatisfaction. Many countries and units have adopted operation specific consent forms for this purpose; however, this is not always standard practice with many clinicians declining to fill in yet another form and many hospitals still insisting on the use of hospital wide generic forms. The latter being the practice in our unit.
The aim was to review our consenting practice with regard to mid-urethral tapes for Stress Urinary Incontinence (SUI).

Study design, materials and methods

A retrospective audit was conducted in a busy Urogynaecology department, functioning in both a secondary and tertiary capacity. Eight consultant teams were identified who regularly performed tapes as part of their surgical practice. We aimed to sample a random selection of between 10-20 notes from each team thus avoiding unequal sampling between consultant teams. Case notes of women undergoing a tape procedure for SUI during 2010 from each team where reviewed. The aim was to look for what was felt by all clinicians performing these procedures to be a minimum standard of what should be documented. These are listed in Table 1 below. We reviewed medical correspondence, written notes and consent forms looking for evidence of the risks being discussed with the patient. We also looked at when consent was obtained and by whom.

Results

Eighty two case notes were reviewed. Forty-five patients (54%) where consented on the day of the procedure. Those remaining were consented 5 - 240 (mean = 59) days prior to surgery.
An information leaflet approved by our clinical governance department with all the risks detailed, was documented as having been given to only 10 patients (12%).
The frequency of documentation of the risks can be seen in Table 1. There was no complication that was documented in 100% of cases. In addition, only 16% of patients had all the complications documented (Table2).
Consultant documentation was compared to that of junior grades (table 3). Consultant documentation was (reassuringly) better than the junior grades in all key risks.

Table 1: Demonstrating frequency of risk documentation:

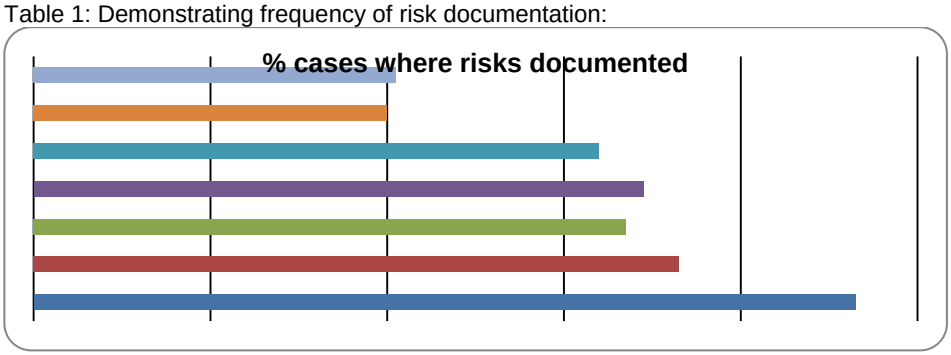

Table 2: The number and percentage of patients according to how many risks were documented:

No. of risks discussed	No. of patients
0	10 (12%)
1	9 (11%)
2	1 (1%)
3	4 (5%)
4	8 (10%)
5	13 (16%)
6	24 (29%)
7	13 (16%)

Table 3: Comparing documentation between medical grades:

Risk discussed	**Consultant (n=45)**	**Junior grades (n=37)**
Bleeding	36 (80%)	23 (60%)
Infection	36 (80%)	24 (63%)
Urinary tract injury	35 (78%)	20 (52%)
Erosion/Removal of tape	36 (80%)	22 (57%)
Retention/ catheter use	34 (75%)	19 (50%)
Pain and sexual discomfort	33 (73%)	0
Failure / Urgency symptoms	19 (42%)	10 (26%)

Interpretation of results

There was inconsistent documentation of what the patients were informed. Common risks such as bleeding and infection were the most documented risks, while procedure specific risks were less documented especially failure/urgency symptoms and pain/sexual discomfort.

Concluding message

It is often the case that we have explained the risks to patients, however, without accurate documentation, if complications do arise this can lead to dispute between parties.

Our results demonstrate the need to adopt a procedure specific consent form to improve the process of informed consent in patients undergoing tape procedures. This would benefit patients and medical staff as obtaining consent and counselling patients would be clearly structured, therefore minimising omissions. Of note, half of our patients were consented the day of surgery, which could be argued as too late to inform patients of potential risks. This process and documentation needs to be completed in beforehand.

Specify source of funding or grant	**No funding needed.**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Audit approved by local clinical governance department at the Southern General Hospital, Glasgow, UK.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**