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RANDOMISED CONTROL TRIAL OF COUGH TEST VS NO-COUGH TEST DURING THE TENSION-FREE VAGINAL TAPE (TVT) PROCEDURE FOR STRESS URINARY INCONTINENCE

Hypothesis / aims of study

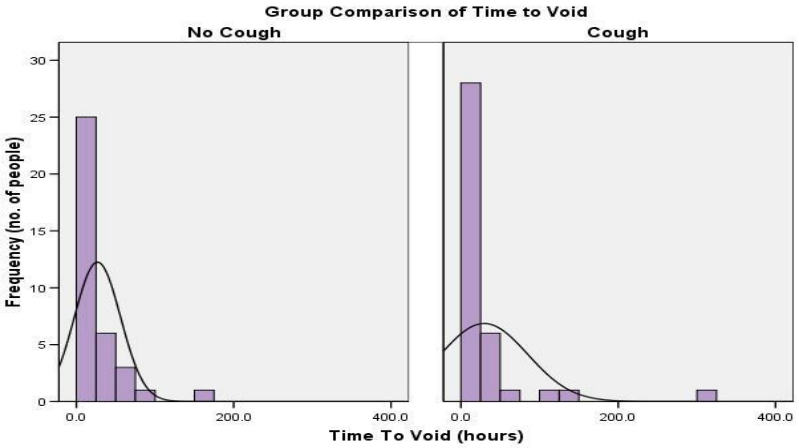
The TVT was originally described to include an intraoperative cough test(1), but many surgeons have discarded this, despite their being no RCT evidence to support its deletion. We conducted an RCT of the cough test vs no-cough test and hypothesised that subjects in the no-cough test group would have greater voiding dysfunction (our primary outcome) because of less precise definition of the "tension-free" tape position.

Study design, materials and methods

After blind randomisation, all our patients had anaesthesia for the TVT using a combination of intravenous sedation with local anaesthetic (100 mls of 0.2% Naropen with 1:200,000 adrenalin), injected retropubically, subpubically and suburethrally. The tape was initially placed loosely at the mid-urethra and IV sedation was discontinued after cystoscopy. In the cough group, the bladder was filled with 300 mls of fluid and the patient asked to cough. If no stress leak was seen the patient's bladder was filled to their maximum cystometric capacity (MCC). As the patient coughed, the tape was pulled up slowly until only a drop of urine was seen at the urethral opening. In the no-cough group tape position was determined by best estimate with loose interposition of Metzenbaum scissors .A sample size of 71 in each group was needed to detect a 15% difference in the primary outcome (defined as duration of time to achieve normal voiding), with 80% power based on a 5% alpha error. "Cure" of stress incontinence (our secondary outcome) was measured by 24-hour pad test and QOL questionnaires (UDI-6, IIQ-7, ICIQ) at 6 weeks, 6 months and 12 months. This abstract reports the result of our interim analysis carried out when half the sample size had reached six weeks. Interim analysis was indicated on ethical grounds, to ensure that any severe (clinically significant) increase in voiding dysfunction in the no cough group was detected. Data are described as median (interquartile range), unless normally distributed and significance testing by Wilcoxon rank sum.

Results

To date 73 women have been recruited to this trial [38 cough group, 36 in the no-cough group]. Demographic variables showed that randomisation was adequate at the interim for most variables. No statistically significant difference was found for age (p= 0.833), BMI (p=0.149), smoking, previous surgery or preoperative urodynamics diagnosis, however, there was a significant difference in parity, with the 'no cough' group having a higher parity (2.1 vs 2.7, p= 0.044).
Interim analysis of the primary outcome (time to void in hours, Fig 1) demonstrated no significant difference between the two groups (Wilcoxon *P* value = 0.247).



N=36
Median = 12.8 hours
Interquartile Range = 20.1
Mean = 29.5 hours
SD = 55.3

N=38
Median = 17.8 hours
Interquartile Range = 21.5
Mean = 26.8 hours
SD = 29.3

Significant improvements in incontinence severity were noted in all secondary outcome measures. However, interim analysis of these cure rates (including QOL questionnaires and 24-hour pad test), for 6 weeks (n=73) (see table 1) was similar and showed equivalency between the groups.

Table 1. Comparison of Secondary Outcome Measures between Groups (median and interquartile range)

Outcome Measures	Six-Week Post-operative		
	Cough	No Cough	*P* value
Pad Test	2.1 (1.1-15.4)	2.1 (1.0- 5.2)	0.320
UDI-6	6.0 (0-28)	3.0 (0-11.0)	0.140

IIQ-7	0 (0-9.5)	0 (0-0)	0.124
ICIQ-SF	3.0 (0-7.0)	0 (0- 4.0)	0.0413

As expected, the mean (± standard deviation) intra-operative time for the no cough group was shorter than the cough group, with 35.56 mins (± 13.194) and 40.32 mins (± 12.466) respectively (*P* value = 0.051).
At the time of surgery, 27 of the 38 participants (71.1%) in the cough group were sufficiently alert to produce a successful cough test at 300mls in theatre. After further time had elapsed plus filling to MCC, another 3 produced a good cough. Thus, 8 participants (21.1%) randomised to the cough group were not able to perform a successful intra-operative cough test. Nevertheless an intention-to-treat analysis was performed. Furthermore, only 10 out of the 30 participants who successfully coughed actually leaked in theatre. **(Thus, only 26.3%(10/38) of the total cough group demonstrated a stress leak in theatre)**.

Interpretation of results
Our interim analysis found no significant difference in either voiding dysfunction or subjective and objective cure rates between the cough and no cough groups.

Concluding message
Although these data indicate no ethical barrier to continuation of the randomised controlled trial, we were very surprised to find that only 26% of patients in the 'cough test' arm actually leaked with coughing intraoperatively. This observation has never been reported. Thus the wisdom of continuing this RCT will be open for discussion.

References

1. Int Urogynecol J 1996;7:81-5

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**The Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12608000597392**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**South Eastern Sydney and Illawarra Area Health Service Human Research Ethics Committee Southern Section. 05/95 Moore**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**