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Tan J[1], Sherburn M[1]
1. *The University of Melbourne*

A VAGINAL TAMPON IN SITU REDUCES FEMALE STRESS INCONTINENCE LEAKAGE, PATIENT-REPORTED SYMPTOMS AND BLADDER NECK MOBILITY DURING PHYSICAL ACTIVITIES.

Hypothesis / aims of study

Vaginal tampons are often used in clinical management for women experiencing stress urinary incontinence (SUI). However, recent literature suggests that there is inconclusive evidence for the use of mechanical devices in urinary incontinence management (1). In addition, the mechanism for their effectiveness in patients has not been fully examined. To date, there have been no published studies on the effect of tampons on SUI symptoms and bladder neck mobility as assessed via transperineal ultrasound.

This study aimed to investigate the changes to SUI leakage during physical activities, self-reported urinary symptoms, and changes in bladder neck movement using transperineal ultrasound, with a vaginal tampon in situ. We hypothesised that women would experience a reduction in urinary leakage and self-reported urinary symptoms due to reduced bladder neck movement, with a vaginal tampon in situ.

Study design, materials and methods

In this cohort study, 40 women over 18 years of age with pure or predominant SUI were recruited from urogynaecology and continence clinics between February and September 2012. Power calculation using the pad weigh test indicated a total of 34 participants were required for an alpha of 0.05, with power set at 80%.

Exclusion criteria: predominantly urinary urgency or urge incontinence symptoms, stage II to IV pelvic organ prolapse, current pregnancy or breastfeeding, previous anti-incontinence surgery, active pelvic or vaginal infection, dyspareunia, chronic pelvic pain, or psychiatric conditions requiring current treatment, non-English speaking.

Primary outcome measures: Modified paper towel test, 24-hour pad weigh test (mean of three 24-hour measurements), three measurements of bladder neck movement imaged on transperineal ultrasound at rest and on valsalva, in lying and standing.

1. Gamma angle: between the urethral-vesical junction and central line of pubic symphysis
2. Retro-vesical angle (RVA): angle between proximal urethra and trigonal surface of bladder
3. Bladder neck descent (BND): distance between urethro-vesical junction and inferior pole of pubic symphysis

Secondary outcome measures: International Consultation on Incontinence Questionnaire – Female Lower Urinary Tract Symptoms (ICIQ_FLUTS), scoring the filling (F), voiding (V), and incontinence (I) scores separately, the Incontinence Impact Questionnaire (IIQ), and a 5-point Likert scale for participant acceptability of tampon use, dichotomised to represent low (categories 1, 2 and 3) and high acceptability (categories 4 and 5).

After informed consent was gained, participants attended two sessions; baseline, and three days later for assessment with a tampon in situ. For the three days prior to each session, participants wore pads and undertook their usual physical activities. For the second three days of pad usage, participants also wore a vaginal tampon. After daily removal, these pads were sealed in zip lock bags & brought to the assessment session. Two hours prior to each session, participants voided, then drank 250ml of water without voiding again before the assessment. Three hours prior to the second assessment session participants also inserted a tampon.

Each testing session comprised: completion of ICIQ-FLUTS and IIQ, modified paper towel test (cough, jump, then cough and jump, stopping at the first stressor causing a leak), and transperineal ultrasound imaging performed in supine and standing. In the second session, all measures were taken with a tampon in situ.

Statistical analysis: Paired t-tests were performed to assess change in each outcome with and without a vaginal tampon in situ. Data was assessed for normality prior to calculation.

Results

Thirty-four women (Mean age 46.9, SD 12.4, years) with predominantly SUI completed the study. All women reported leaking during physical activities. Six women declined to participate before the first assessment session. All women who attended the baseline assessment completed the study.

Table 1. Significant test results

Variable	Baseline without tampon in situ (Mean, SE)	Follow up with tampon in situ (Mean, SE)	t-score (p value)
Paper towel test (cm^2)	19.20 (4.68)	5.80 (1.40)	2.835 (0.008)*
Pad weigh test (gm)	15.93 (4.29)	5.85 (1.88)	2.651 (0.012)*
IIQ	35.29 (3.42)	29.68 (3.90)	1.948 (0.060)
FLUTS - I score (A /20)	8.47 (0.69)	6.88 (0.65)	2.700 (0.011)*
FLUTS - I score (B /50)	27.88 (2.09)	23.24 (2.15)	3.122 (0.004)*
Supine Rest – gamma angle (˚)	100.11 (3.58)	92.43 (2.59)	2.360 (0.025)*
Standing Rest – gamma angle (˚)	119.43 (3.09)	110.25 (3.30)	3.859 (0.001)*
Supine Valsalva – gamma angle (˚)	129.29 (4.81)	114.72 (4.15)	3.465 (0.002)*
Standing	145.84 (4.40)	131.39 (4.18)	2.806 (0.009)*

Valsalva – gamma angle (˚)			

* significant at 0.05 level
FLUTS – I score A = incontinence symptoms; FLUTS – I score B = incontinence symptom bother

There were no significant differences in the BND or RVA with and without a tampon in situ, nor in the filling or voiding components of the ICIQ-FLUTS.
High acceptability for tampon use was reported by 47.1% of participants.

Interpretation of results

A vaginal tampon in situ reduced the amount of urinary leakage and incontinence symptoms during physical activities in women with SUI. Transperineal ultrasound imaging showed that when women experienced a reduction in SUI with a tampon in situ, there was also a reduction in gamma angle i.e. reduced posterior rotational descent of the bladder neck. When examining how effective a mechanical device may be for women with predominant stress incontinence, the gamma angle may be more significant than measures such as retro-vesical angle or bladder neck descent. While retro-vesical angle and bladder neck descent have been used to define SUI (2), this study showed that the gamma angle was the most important measure in assessing effectiveness of a mechanical device. Less than 50% of participants reported that tampons were an acceptable form of management for their symptoms. Careful patient selection will therefore be an important consideration for effective use of tampons in clinical practice.

Concluding message

Vaginal tampons provide an effective and readily available support device to reduce urinary leakage during physical activity in women with stress urinary incontinence. A likely mechanism is that the tampon provides mid-urethral support reducing posterior rotation of the urethra.

References

1. 12. Lipp, A., Shaw, C., & Glavind, K. (2011). Mechanical devices for urinary incontinence in women. Cochrane Database Systematic Reviews, 6(7), CD001756.
2. 8. Pizzoferrato, A.C., Fauconnier, A. & Bader, G. (2011). Value of ultrasonographic measurement of bladder neck mobility in the management of female stress urinary incontinence. Gynaecology, Obstetrics and Fertility, 39(1), 42-48.

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