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THE VALUE OF THE PREOPERATIVE PROLAPSE REDUCTION STRESS TEST IN WOMEN WITHOUT STRESS INCONTINENCE SYMPTOMS UNDERGOING VAGINAL PROLAPSE SURGERY WITH OR WITHOUT A TVT: RESULT FROM THE OPUS TRIAL.

Hypothesis / aims of study
To characterize the value of the preoperative prolapse reduction stress test (PRST) in a large clinical trial.

Study design, materials and methods
The Outcomes Following Vaginal Prolapse Repair and Midurethral Sling (OPUS) Trial is a multisite randomized clinical trial examining the efficacy of a prophylactic tension-free vaginal tape (TVT) versus sham in women without SUI symptoms undergoing vaginal prolapse surgery for > Stage II symptomatic anterior +/- apical prolapse. Preoperative PRST was performed by retrograde fill (300ml), removing the catheter and performing valsalva and cough testing: 1) in lithotomy postion without prolapse reduction, 2) in lithotomy with prolapse reduced with Proctoswab(s), 3) standing with prolapse reduced. Surgeons were masked to test results which played no role in treatment assignment. A positive stress test was defined as urine leakage in either position, with or without reduction, but no subjects had positive unreduced stress testing without positive reduced testing therefore results are all expressed as prolapse reduction stress test (PRST).
Surgical treatment failure was defined as one or more of: a positive cough stress test, bothersome UI symptoms ("moderately or quite a bit"), or treatment for UI (pharmacologic or surgical) at 3 and 12 months. The effect of PRST was assessed using tests for interaction in the conditional logistic model, controlling for surgeon and type of prolapse repair. If significant ($p<0.10$), separate subgroup analyses were performed for subjects with positive and negative PRST.

Results
337 women with a mean age of 63 years were randomized; 96% completed 1-year follow-up. Preoperative PRST was completed in 98% (331/337) of subjects and was positive in 33.5% (111/331). A cough was more likely to elicit a positive test than a valsalva maneuver. 33 subjects had a positive PRST only in the standing position. Consistent benefits of TVT were observed at both 3 and 12 months, regardless of whether subjects had a positive or negative PRST. There is modest evidence that those with a positive PRST had greater benefit with TVT than those with negative PST. At 3 months, 29.6% of TVT and 71.9% of SHAM subjects with a positive PRST had treatment failure (OR=7.77); 20.6% of TVT and 38.1% of SHAM subjects with a negative PST had treatment failure (OR=2.49; p-value for interaction = 0.06). At the 12-month endpoint, the test for interaction was not statistically significant (p=0.16), but the pattern of responses was similar to those at 3 months.
The Table below demonstrates the 3 month results. The number needed to treat to prevent an additional case of symptomatic SUI at 3 months was 2.4 with a positive PRST and 5.7 with a negative PRST.

Proportion of Subjects with Treatment Failure (Urinary Incontinence) at 3 Months

Prolapse Reduction Stress Test (PRST) (n=331)	Vaginal Prolapse Repair + TVT (n=165)	Vaginal Prolapse Repair + Sham (n=172)	Odds Ratio (95% CI)	NNT (95% CI)	p-value
Positive PRST (n=111)	29.6% (16/54)	71.9% (41/57)	7.77 (2.95, 20.44)	2.4 (1.6, 4.2)	<0.001
Negative PRST (n=220)	20.6% (22/107)	38.1% (43/113)	2.49 (1.33, 4.65)	5.7 (3.4,18.4)	0.004

Interpretation of results
Prophylactic TVT resulted in lower postoperative UI in patients with both a positive and negative PRST. Women with a positive PRST who do not receive a TVT are at highest risk of having UI at 3 months after vaginal prolapse surgery. Women with a negative stress test, who do not undergo a sling, have a lower, though still increased risk of UI at 3 months.

Concluding message
Stress continent women undergoing vaginal prolapse repair who have a postitive PRST and do not undergo concomintant TVT are at a nearly 8-fold increased risk of developing postoperative stress incontinence.

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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	**NCT00460434**
Is this a Randomised Controlled Trial (RCT)?	**Yes**

What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Institutional Review Board at 9 clinical sites, including Loyola**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**