

# ETHICON eClinical Compendium – Article Summary

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<b>Title</b>	A Real-World Comparative Assessment of Complications Following Various Mid-Urethral Sling Procedures for the Treatment of Stress Urinary Incontinence
<b>Author(s)</b>	Magee G, Roy S, Hinoul P, Moretz C, Kozarev R, Waters H, Whitmore K
<b>Source</b>	<i>Journal of Long-Term Effects of Medical Implants</i> , 22(4), 329-340.

**The following product codes are currently unavailable in the United States**

810081	GYNECARE TVT OBTURATOR – SYSTEM
810081L	GYNECARE TVT OBTURATOR W LASR-CUT MESH
TVTOML	GYNECARE TVT-ABBREVO LASER CUT DISPOSABLE SYSTEM
TVTOML6	TVT-ABBREVO 6 PACK
TVTO6	TVTO6
TVTMI6	COMBINATION 6 PACK TVT-EXACT (3) AND TVT-ABBREVO (3)
TVTOML5	TVT ABBREVO 5-PACK PROMOTION

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<b>Key Takeaways</b>	<p>Stress urinary incontinence (SUI) affects a significant proportion of the adult female population in the US, with the prevalence increasing with age. Mid-urethral slings are among the surgical options offering important improvement in SUI. The most common surgical treatment for SUI today is a synthetic mid-urethral sling (MUS).</p> <p>This study evaluated surgical outcomes of patients treated with GYNECARE TVT™ Family of Products (ETHICON, US LLC) in comparison to other MUSs produced by other manufacturers when comparing both retropubic to each other as well as transobturator brands to each other.</p> <p><u>Transobturator vs. Retropubic Approach</u> Overall, fewer complications were noted with the transobturator procedures than the retropubic procedures.</p> <p><u>Retropubic Brands Compared</u> Patients in the retropubic category treated with GYNECARE TVT™ Tension-free Support for Incontinence (TVTR) had a significantly lower rate of urologic complications (6.6% versus 9.1%; <math>p = 0.002</math>), primarily driven by lower rates of urinary obstruction/retention (2.0% versus 3.7%; <math>p &lt; 0.001</math>) and urinary tract infection (4.7% versus 6.0%; <math>p = 0.049</math>) compared to patients treated with other retropubic slings (ORS). Even after statistical adjustments of the baseline the rates of urinary obstruction for TVTR remained significantly lower.</p> <p><u>Transobturator Brands Compared</u> In the transobturator group differences were noted in the rate of pelvic complications (6.5% versus 8.1%; <math>p = 0.007</math>). The difference appears to be driven by lower rates of dyspareunia, pelvic pain, and related symptoms (1.4% versus 2.0%; <math>p = 0.046</math>), as well as injury to blood vessels, nerves, or viscera (4.1% versus 5.2%; <math>p = 0.023</math>) in the TVTO subgroup. There were lower rates of dyspareunia, pelvic pain, and related symptoms and injury to blood vessels, nerves, or viscera with GYNECARE TVT™ Obturator System (TVTO) compared to the other transobturator slings (OTS). Even after adjusting for differences in demographic factors, rates of overall pelvic complications as well as urologic complications, were lower in the TVTO subgroup versus the OTS subgroup.</p> <p><u>Study Limitations</u> All utilization and complication rates relied on coding for each patient. Codes may be underestimated or missed altogether; therefore rates of complications shown in the study may be underestimated. There may be differences in coding between hospitals. Also, the outpatient information is limited to hospital outpatient facilities and did not capture treatment received in the physician's office. This study was limited to a one year post procedure follow up due to the low number of eligible patients with longer follow up.</p> <p><u>Summary</u> Complications associated with the use of GYNECARE TVT™ Family of Products may be lower due to the differences in the sling material, which offers greater flexibility for placement while still offering appropriate tensioning. It should also be noted that the findings of this report support recent meta-analysis reports that revealed "inside-out" method of placement with the GYNECARE TVT™ Obturator System is associated with fewer bladder injuries and voiding difficulties than transobturator tapes placed via the "outside-in" method.</p>
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## STUDY OBJECTIVE:

To evaluate the clinical outcomes of GYNECARE TVT™ Family of Product slings in comparison to other MUS products, including a comparison of perioperative and postoperative complications.

## METHODS:

This retrospective study utilized data from the Premier Perspective Database for mid-urethral sling procedures between January 1, 2005 and December 31, 2009. Patients were grouped into retropubic or transobturator cohorts, and these cohorts were further divided by the brand of sling utilized during the procedure. A total of 6361 patients were identified as having retropubic sling procedures, of whom 5007 were in the GYNECARE™ brand subgroup, and 1354 were in the

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other retropubic slings (ORS) subgroup. A total of 9754 patients were identified in the transobturator sling cohort, with 2895 in the GYNECARE™ brand subgroup and 6859 in the other transobturator slings (OTS) subgroup. Surgical outcomes and 12-month complication rates were assessed.

## OUTCOMES MEASURED:

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- Sling failure / SUI reoperation within 1 year surgery
- Revision or removal of sling
- Urologic complications (including urgency incontinence, urinary obstruction/retention, i.e., diagnosis or intervention, and urinary tract infections)
- Pelvic complications (including dyspareunia, pelvic pain and related symptoms, fistula diagnosis or interventions, wound-related complications, injury to blood vessels, nerves, or viscera, i.e., diagnosis or intervention, other abdominal complications' diagnosis or intervention, other complications attributable to procedure, device, graft, or implant, pelvic organ prolapse diagnosis or intervention)
- Urologic investigations (including cystoscopy, imaging studies, and urodynamics)

## RESULTS:

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### RETROPUBIC SLINGS:

- Both subgroups of patients treated with retropubic slings demonstrated a low rate of failure/SUI reoperation within one year post surgery (less than 2% in each subgroup).
- Patients treated with a retropubic GYNECARE™ brand product had a significantly lower rate of urologic complications (6.6% versus 9.1%) compared with patients treated with other brands.
  - Driven by lower rates of urinary obstruction/retention (2.0% versus 3.7) and urinary tract infection (4.7% versus 6.0%) among the TVTR subgroup compared to the ORS subgroup.
- There were no significant differences in the categories of pelvic complications or urologic investigations between the subgroups.
- Multivariate analysis in the retropubic cohort was conducted for urinary complications and pelvic complications
  - This subcategory of urinary obstruction demonstrated a significant difference in the odds ratio with TVTR patients having about half the odds of experiencing urinary obstruction compared to the ORS group.

### TRANSOBTURATOR SLINGS:

- Both transobturator treatment groups demonstrated a low rate of failure/SUI reoperation within one year post surgery (less than 1% in each subgroup).
- The TVTO subgroup had fewer urologic complications than the OTS subgroup (4.9% versus 7.6%).
  - The difference appears to be driven by lower urinary tract infection rates (3.7% versus 5.5%) and lower incontinence rates (0.2 % versus 1.2 %) in the TVTO subgroup.
  - No differences in urinary obstruction/retention were observed between the groups.
- The TVTO subgroup had significantly lower rates of pelvic complications than the OTS subgroup (6.5% versus 8.1%).
  - The difference is driven by lower rates of dyspareunia, pelvic pain, and related symptoms (1.4% versus 2.0%) as well as injury to blood vessels, nerves, or viscera (4.1% versus 5.2%)
- The TVTO subgroup demonstrated lower likelihood for urologic and pelvic complications compared to the OTS subgroup.
  - The odds ratio of urgency incontinence and urinary tract infection were also significantly lower.

## STUDY LIMITATIONS:

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The retrospective design of this study, which lacked baseline evaluations, may pose an inherent limitation to the study. All utilization and complication rates relied on coding for each patient. Codes may be underestimated or missed altogether; therefore rates of complications shown in the study may be underestimated. There may be differences in coding between hospitals. Also, the outpatient information is limited to hospital outpatient facilities

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