

The comparative outcome between TVTO and Altis® (Coloplast) in the Management of Urinary Stress Incontinence

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Hypothesis / aims of study

Stress urinary incontinence, prevalent in 13% to 46% of young women and peaking during menopausal ages, significantly impacts quality of life across various domains including sexuality, physical well-being, emotional, and social aspects (1,2). However, effective management options exist to improve patients' quality of life, with management strategies tailored based on symptom severity. Procedures like Transvaginal Tension-Free Vaginal Tape-Obturator (TVT-O) and Mini-sling have demonstrated efficacy both in the short and long term. This study aims to compare TVT-O and Altis® (Coloplast) procedures to identify an approach with high effectiveness and patient satisfaction, while also assessing the prevalence of short and longterm complications. Additionally, the study investigates the relationship between various factors such as age, body mass index (BMI), menopausal status, parity, vaginal delivery and chronic disease with the aforementioned outcomes.

Study design, materials and methods

This is a retrospective study, conducted at a specialized urogynecology department between February 2020 to 2024. The study included patients who underwent surgery for stress incontinence, either the Transvaginal Tension-Free Vaginal Tape-Obturator (TVT-O) procedure or the singleincision sling system Altis® (Coloplast). Patients who did not attend follow-up appointments after surgery were excluded from the study. Electronic health records of selected patients were reviewed to collect relevant data, including demographic details such as age, body mass index (BMI), menopausal status, parity, chronic illnesses, past surgeries, type of incontinence, complications, and follow-up information. The study was approved by the Institutional Review Boards, and adherence to good clinical practice guidelines was ensured throughout the study period.

Results

A total of **167 women** were included in this comparative study, with **36%** in the Altis® group and 64% in the TVT-O group. The age distribution was similar across both groups. In the Altis® group, 36.67% were aged 40-50 years, followed by 25% in the 50-60-year age range. Similarly, in the TVT-O group, 39.25% were aged 40-50 years, followed by 27.1% in the 50-60-year age group. Regarding **body mass index (BMI)**, obesity (BMI ≥ 30) was common in both groups: 51.67% in the Altis® group and 54.21% in the TVT-O group. The majority of patients in both groups were of Arab descent, comprising 96.7% in the Altis® group and 96.26% in the TVT-O group. Additionally, both groups consisted largely of non-smokers, with 100% nonsmokers in the Altis® group and 95.33% non-smokers in the TVT-O group.

In terms of menopausal status, the distribution was varied: in the Altis® **Demographics data**

Demographic data

group, 36.67% were pre-menopausal, 30% were post-menopausal, 26.67% were peri-menopausal, and 6.67% had undergone a hysterectomy. In the TVT-O group, 38.32% were pre-menopausal, 35.51% were peri-menopausal, 17.76% were post-menopausal, and 8.41% had undergone hysterectomy. With regard to parity, a significant number of patients in both groups reported having more than six children: 41.67% in the Altis® group and 57.94% in the

TVT-O group. **Chronic conditions** were reported as follows: in the Altis® group, 15.2% had asthma, 10% had constipation, 3.3% had hypertension, 28.8% had diabetes, and 23.33% reported no

Sample Size 60 patients 107 patients Age Distribution (40-50 years) 36.67% 39.25% Age Distribution (50-60 years) 25% 27.1% 51.67% 54.21% Obesity (%) Pre-menopausal (%) 36.67% 38.32% 30% 17.76% Post-menopausal (%) Peri-menopausal (%) 26.67% 35.51% 96.7% 96.26% **Ethnicity (Arab Descent)** 100% 95.33% Non-smokers (%) Parity (>6 children) (%) 41.67% 57.94% 15% 18% **Previous Surgical History (%)** 69.16% Type of Incontinence (Pure, 73.33%, 26.7% 30.84% Asthma (%) 15.2% 16.82% Constipation (%) 10% 22.43% Diabetes (%) 28.8% 29.91% No Comorbidities (%) 23.33% 30.84%

Coloplast Group

TVT-O Group

comorbidities. In the TVT-O group, 16.82% had asthma, 22.43% had constipation, 29.91% had diabetes, and 30.84% reported no comorbidities.

Short-Term Complications

Within **72 hours post-procedure**, short-term complications were reported by 8.33% of patients in the Altis® group and 2.80% of patients in the TVT-O group (p = 0.001). The Altis® group exhibited a significantly higher incidence of complications, including dysuria (20%), numbness (20%), and leg and back pain (60%). In contrast, the TVT-O group reported complications such as urinary tract infections (33.3%), numbness (33.3%), and leg/back pain (33.3%).

Long-Term Complications

Long-term complications, defined as those occurring within 12 months post-surgery or more, were reported by 13.33% of patients in the Altis® group and 17.76% of patients in the TVT-O group (p > 0.05). In the Altis® group, the most prevalent long-term complication was de novo voiding dysfunction, reported by **50%** of the patients who experienced complications, followed by de novo urgency (25%) and defective healing (25%). In the TVT-O group, de novo urgency was the most frequently reported complication, affecting 47.37% of those with long-term complications, followed by dysuria (15.79%), defective healing (10.53%), mesh erosion (5.26%), and voiding dysfunction (5.26%).

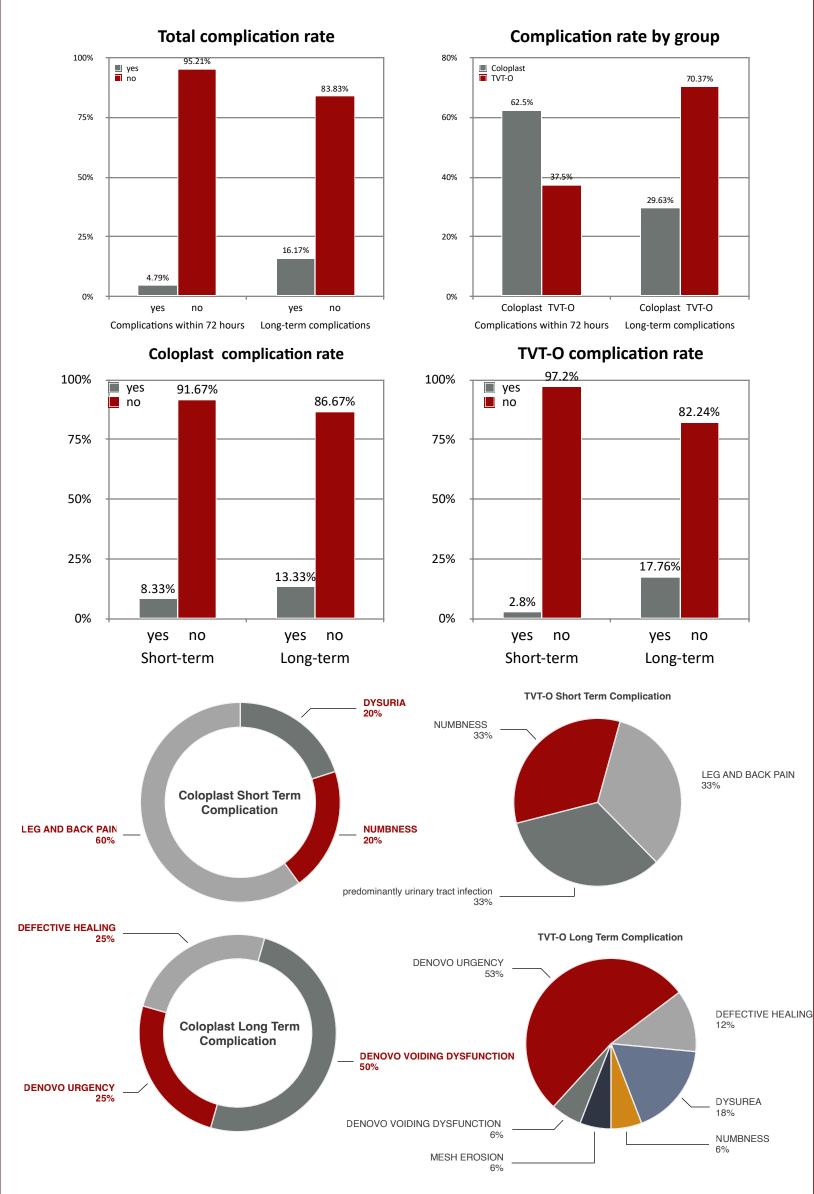
Patient Satisfaction

Patient satisfaction was high across both groups, with **2.7%** of patients in the Altis® group and 4.3% in the TVT-O group reporting dissatisfaction (p > 0.05).

Demographics and Associated Factors

The study examined the impact of various factors—age, body mass index (BMI), menopausal status, parity, history of vaginal delivery, and chronic disease on outcomes in both the Altis® and TVT-O groups. Notably, a higher BMI correlated with increased short-term complications, such as leg and back pain, seen in 60% of Altis® patients versus 33.3% in the TVT-O group (p < 0.05). Post-menopausal women showed a higher incidence of long-term complications, with 20% in the Altis® group compared to 18% in the TVT-O group (p > 0.05).

Additionally, higher parity was linked to an increased risk of long-term complications, particularly de novo urgency affecting 30% of high-parity women in both groups. A history of vaginal delivery was associated with short-term complications, reflected in an odds ratio of 2.5 (95% CI: 1.2–5.0, p < 0.01). Lastly, chronic diseases like diabetes contributed to a higher incidence of voiding dysfunction, impacting 30% of diabetic patients in the Altis® group compared to 10% in the TVT-O group (p < 0.05).



Interpretation of Results

The comparative analysis between the Altis® (Coloplast) and TVT-O procedures did not demonstrate any statistically significant superiority of one intervention over the other in terms of overall outcomes. Both techniques were found to be effective in managing stress urinary incontinence (SUI), with patient satisfaction remaining high across both groups.

This study identified several risk factors influencing outcomes, including BMI, menopausal status, parity, and chronic diseases. Obesity was a notable factor, with higher BMI correlating with an increased rate of short-term complications, particularly leg and back pain in the Altis® group. This finding is consistent with the understanding that elevated intra-abdominal pressure in obese patients can exacerbate SUI symptoms and complicate recovery(3). Additionally, post-menopausal status and higher parity were linked to greater incidences of long-term complications, particularly de novo urgency, which was more prevalent in the TVT-O group. Additionally, diabetic patients in the Altis® group were more susceptible to voiding dysfunction (30% vs. 10% in the TVT-O group).

Previous research aligns with these findings, suggesting that both TVT-O and mini-sling (Altis®) procedures provide comparable outcomes in terms of continence and quality of life improvements(2). Long-term complications such as de novo urgency and voiding dysfunction were more commonly reported in both groups, yet they did not significantly detract from the overall high patient satisfaction rates. This supports the view that both surgical approaches are equally viable options for SUI treatment, with no significant differences in symptom resolution or quality of life improvements between the two methods.

Conclusions

The comparative study of the **Altis**® (Coloplast) and **TVT-O** procedures for stress urinary incontinence (SUI) found no significant differences in overall outcomes, with both achieving high patient satisfaction and symptom resolution. BMI, menopausal status, and chronic diseases like diabetes influenced complication rates but did not favor one procedure over the other for long-term success. The Altis® group had more short-term complications, particularly in obese patients, while **TVT-O** showed higher rates of long-term complications, especially de novo urgency. Both procedures are effective, but patient-specific factors should guide the choice of intervention.

References

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