

# Comparative Analysis of Polyacrylamide Hydrogel Injections and Trans-obturator tape in the Treatment of Stress Urinary Incontinence in Women: Evaluation of Efficacy and Safety Outcomes

## Kadınlarda Stres İdrar Kaçırma Tedavisinde Poliakrilamid Hidrojel Enjeksiyonları ve Trans-obturator Bantların Karşılaştırmalı Analizi: Etkinlik ve Güvenlik Sonuçlarının Değerlendirilmesi)

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### Abstract

**Objective:** To compare the efficacy and safety of polyacrylamide hydrogel (PAHG) injections with trans-obturator tape (TOT) surgery for managing stress urinary incontinence (SUI) in women and to assess treatment outcomes.

**Materials and Methods:** This retrospective cohort study involved 61 women diagnosed with SUI from 2022 to 2024. The study divided the patients into two groups: one comprising 32 patients who underwent TOT surgery and another comprising 29 patients who received PAHG injections. The key variables analyzed included demographic data, operation time, hospital stay, and patient satisfaction measured using the visual analog scale (VAS). Complications were recorded using the Clavien-Dindo classification. Statistical analyses were performed to identify the factors influencing the outcomes, including independent sample t-tests and regression models.

**Results:** The TOT group showed a higher treatment success rate, with 93.75% of patients having a resolution of SUI symptoms than the PAHG group (82.76%). PAHG demonstrated advantages in shorter operation times (mean difference, 8.31 minutes,  $p<0.001$ ), absence of catheterization, and shorter hospital stays (mean difference of 20.24 hours,  $p<0.001$ ). TOT was associated with higher rates of complications such as vaginal discharge (43.75%) and groin pain (28.12%), whereas the PAHG group reported no such complications.

**Conclusion:** TOT surgery provides higher success rates for SUI treatment; however, PAHG injections offer a viable, minimally invasive alternative with a lower risk of complications. Future research needs to involve larger sample sizes and include long-term follow-up to validate and refine these findings.

**Keywords:** stress incontinence, polyacrylamide hydrogels, trans-obturator tape, mid-urethral slings, treatment outcome, patient satisfaction

### Özet

**Amaç:** Kadınlarda stres üriner inkontinansın (SUI) tedavisinde poliakrilamid hidrojel (PAHG) enjeksiyonları ile trans-obturator band cerrahisinin etkinliğini ve güvenilirliğini karşılaştırmak ve tedavi sonuçlarını değerlendirmek.

**Gereçler ve Yöntemler:** Bu retrospektif kohort çalışmasına 2022-2024 yılları arasında SUI tanısı alan 61 kadın dahil edildi. Çalışma hastaları iki gruba ayırdı: biri trans-obturator band ameliyatı geçiren 32 hasta, diğeri PAHG enjeksiyonu yapılan 29 hastadan oluşuyordu. Analiz edilen temel değişkenler arasında görsel analog ölçeği (VAS) kullanılarak ölçülen demografik veriler, operasyon süresi, hastanede kalış süresi ve hasta memnuniyeti yer aldı. Komplikasyonlar Clavien-Dindo sınıflaması kullanılarak kaydedildi. Sonuçları etkileyen faktörleri belirlemek için bağımsız örneklem t-testleri ve regresyon modelleri dahil olmak üzere istatistiksel analizler yapıldı.

**Bulgular:** Trans-obturator band grubu, PAHG grubuna göre (%82.76) hastaların %93.75'inde SUI semptomlarında düzelme ile daha yüksek bir tedavi başarı oranı gösterdi. PAHG, daha kısa ameliyat süreleri (ortalama fark, 8.31 dakika,  $p<0.001$ ), kateterizasyon olmaması ve daha kısa hastanede kalış süresi (ortalama fark 20.24 saat,  $p<0.001$ ) avantajlar göstermiştir. Trans-obturator band vajinal akıntı (%43.75) ve kasık ağrısı (%28.12) gibi komplikasyon oranları ile ilişkili iken, PAHG grubunda böyle bir komplikasyon bildirilmedi.

**Sonuç:** Trans-obturator band SUI tedavisi için daha yüksek başarı oranları sağlar; bununla birlikte, PAHG enjeksiyonları, daha düşük komplikasyon riski ile uygun, minimal invaziv bir alternatif sunar. Gelecekteki araştırmaların daha büyük örneklem boyutlarını içermesi ve bu bulguları doğrulamak ve iyileştirmek için uzun vadeli takibi içermesi gerekir.

**Anahtar kelimeler:** stres inkontinans, poliakrilamid hidrojel, trans-obturator band, orta üretral askı, tedavi sonucu, hasta memnuniyeti

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## Introduction

Stress urinary incontinence (SUI) is a common health problem affecting millions of women worldwide and seriously impairing their quality of life. Defined by the International Continence Society (ICS) as “involuntary leakage of urine during exertion, exercise, sneezing, or coughing”, SUI is a condition that about half of women experience at some point in their lives [1]. SUI notably contributes to physical and psychological discomfort that negatively affects individuals’ social life and overall quality of life.

Recent complications in the surgical treatment of SUI have notably undermined confidence in traditional treatment methods. Mesh-based surgical approaches, such as trans-obturator tape (TOT), have been associated with serious complications including bladder injury and mesh erosion [2]. In this context, there is growing interest in alternative treatment modalities that are less invasive and reduce the risk of mesh-related complications.

Given the complications associated with traditional mesh-based surgeries, our study turns to emerging alternatives such as PAHG (polyacrylamide Hydrogel) injections, aiming to evaluate their efficacy and safety. Degradation-resistant PAHG was approved by the Food and Drug Administration (FDA). This polymer gel contains 2.5% cross-linked polyacrylamide and 97.5% water for injection and is considered a promising option for treating urinary incontinence [3]. However, available data on the long-term efficacy and safety of PAHG injections are limited, making it imperative to compare this treatment option with other surgical methods.

This study aimed to compare the efficacy and safety of PAHG injections with those of TOT surgery for the treatment of SUI, to reveal the differences between these two methods, and to determine which of these treatment options is more appropriate in clinical practice. By filling the knowledge gaps in the existing literature, we aimed to provide evidence-based recommendations to improve patient satisfaction and outcomes in SUI treatment.

## Materials and Methods

### Data Collection

This study included 61 patients who underwent surgery for SUI between October 2022 and March 2024. Data, including demographic details, medical history, preoperative examinations, and postoperative outcomes, were obtained from the patient records. Preoperative cough stress and Q-tip test results were also recorded. The classification of urethral mobility, critical for surgical decision-making, ranges from 0° (indicating no movement) to > 30°, which represents excessive mobility [4,5]. The post-treatment outcomes were evaluated using the Global Response Assessment Scale, while any complications were categorized based on the Clavien-Dindo system.

### Eligibility Criteria

Patients included in the study did not differentiate between mixed and pure urinary incontinence. Stress incontinence was sufficient. Therefore, the presence of intrinsic sphincteric deficiency (ISD) is not considered a valid criterion for

exclusion of any procedure. Patients with recurrent urinary tract infections, neurogenic bladder, neurological disorders with severe functional impairment, or mental health problems were excluded. Previous surgical interventions for stress urinary incontinence were considered exclusion criteria for participation in the study because they may confound the study results and, therefore, were not included in the analysis. Minimally invasive urodynamic studies were not conducted on uncomplicated patients and were, thus, beyond the scope of this study. A visual analog scale was used to evaluate patient satisfaction after the procedure.

### Treatment Decision Criteria

The decision to perform TOT or administer PAHG injections was based on a combination of clinical evaluations and patient-specific factors. Key considerations included:

**Urethral Mobility:** Patients with significant urethral hypermobility (as indicated by a Q-tip test angle >30°) were more likely to undergo TOT due to its higher efficacy in such cases.

**Patient Preferences:** Patients who desire a less invasive option with shorter recovery times were guided toward PAHG injections.

**Body mass index (BMI) and comorbidities:** TOT was preferred for patients with higher BMI (>35) or those who required greater structural support, while PAHG injections were recommended for patients with lower BMI or those unsuitable for surgical procedures due to comorbidities.

**Previous Treatment History:** Since no patients had prior treatments for SUI in this study, all interventions were considered first-line. Patients with contraindications for anesthesia or surgery were prioritized for PAHG injections.

**Physician Assessment:** The attending physician’s clinical judgment, based on the patient’s medical history, physical examination, and risk-benefit analysis, played a crucial role in the final decision.

### Ethical Considerations

Patients were apprised of the objective of the surgical operation and the potential risks and advantages associated with the procedures involved. Prior to and following the surgical intervention, the patients were informed that the obtained data could be used in a scientific study by safeguarding their personal information, and they provided written informed consent before the procedures commenced. This study adhered to the ethical guidelines of the Declaration of Helsinki and was approved by the Ethics Committee of Burhan Nalbantoğlu State Hospital (Number: YTK1.01, project code 29/24).

### Treatment and Follow-up Protocol

The trans-obturator type (out-in technique) procedure was applied to all patients. Polyacrylamide hydrogel injection was performed using a product-specific endoscope, endoscopy kit, and injection needle (23-gauge), and 2-3 cc was injected at 3-4 distinct locations at the junction of the bladder neck and urethra.

The primary objective was to eradicate stress urinary incontinence as a measure of success. The patients’ postoperative 6th-week stress incontinence was assessed via telephone. Bladder overactivity following the procedure is regarded as a complication

in patients diagnosed with pure stress incontinence. Postoperative satisfaction was assessed using a visual analog scale. The global evaluation scale indicated that the treatment success had a response rate exceeding 50%. During the evaluation, patients were questioned about their inclination to submit themselves to the procedure again and recommend it to their friends.

### Data Analysis

A power analysis was performed using G-power software to evaluate the validity of the study and dependability of the outcomes obtained. In the power analysis, the effect size (d) was determined to be 0.8, which indicates that there was a medium-high-level effect in our study. According to the power analysis results, the probability of a type I error ( $\alpha$ ) was 8.61%, the probability of a type II error ( $\beta$ ) was 8.61%, and the statistical power ( $1-\beta$ ) was 91.38. The categorical data encompassed the nature of the treatment, including TOT/PAHG, as well as the classification of urinary incontinence, such as mixed or pure. Moreover, it contains information on potential complications, including vaginal discharge and groin pain. The quantitative data examined in this study comprised several variables, such as patient age, body mass index (BMI), frequency of urinary incontinence episodes per day, operation time, hospital stay, and visual analogue scale (VAS) satisfaction score. These variables were analyzed using descriptive statistics, and an independent sample t-test was used to compare the results between the TOT and PAHG groups. The tables provide a summary of the descriptive statistics. Categorical data were expressed as numbers (n) and percentages, whereas quantitative data were presented as mean  $\pm$  standard deviation (SD). Regression and correlation tests were conducted to determine the factors influencing the treatment outcomes. Data analysis was performed using SPSS version 28.0 software.

### Results

This study included patients with a mean age of  $58 \pm 12.1$  years. A total of 29 patients underwent PAHG, while 32 underwent TOT. The mean BMI was calculated to be  $25.7 \pm 4.8$  kg/m<sup>2</sup>. The mean number of incontinences per day was  $3 \pm 1.1$  (range 2-7). None of the patients had undergone any prior surgical intervention or pharmacological treatment for SUI. A total of 48 patients were diagnosed with mixed-type stress incontinence, while 13 patients had pure SUI. Upon examination, all patients exhibited a hypermobile urethra, as determined by the Q-tip test, which had a result greater than 30°. Among the 17/58 patients with mixed-type stress incontinence, 17 received anticholinergic agents, local estrogen replacement, and medical treatment for constipation. Five patients in the TOT group and three patients in the PAHG group had a BMI > 35. The characteristics of the groups according to the surgical technique are shown in **Table 1**.

The treatment success rate was 30 (93.75%) in patients who underwent TOT. In 2 (6.25%) patients, no incontinence was observed with provocation in the lithotomy position; however, incontinence was detected while standing. Urinary incontinence in five (17.24%) patients in the PAHG group resolved completely a few days after the procedure but returned afterward. Three of the five patients with urinary incontinence after PAHG injection had a BMI > 35.

**Table 1.** Characteristic features of the surgical technique groups

Group (n)	TOT (32)	PAHG (29)	P-Value
Age (years)	55.6 $\pm$ 11.7	62.5 $\pm$ 11.8	0.58
BMI (kg/m <sup>2</sup> )	27.4 $\pm$ 5.7	23.9 $\pm$ 2.7	0.47
SUI type			0.91
- Mixed	25 (78.1%)	23 (79.3%)	
- Pure	7 (21.9%)	6 (20.7%)	
Urinary incontinence episodes	2.9 $\pm$ 1.1	3.1 $\pm$ 1.2	0.28
SUI duration (months)	33.3 $\pm$ 11.8	29.5 $\pm$ 11.7	0.31
Operation time (minutes)	20.3 $\pm$ 4.05	12 $\pm$ 2.7	<b>0.01</b>
Catheter duration (days)	22.5 $\pm$ 3.4	Nil	<b>0.01</b>
Hospitalization duration (hours)	25.3 $\pm$ 4.2	5.1 $\pm$ 1.4	<b>0.01</b>
Follow-up time (months)	14.75 $\pm$ 6.5	10.8 $\pm$ 4.3	0.17
Global response assessment	32 (100%)	24 (82.75%)	0.19
Return of urinary incontinence	2 (6.25%)	5 (17.24%)	<b>&lt;0.05</b>
VAS satisfaction score	7.81 $\pm$ 1.06	8.06 $\pm$ 1.36	0.12

TOT: tension-free obturator tape; PAHG: polyacrylamide hydrogel injection; BMI: body mass index, SUI: stress urinary incontinence; VAS: visual analog scale for satisfaction evaluation

Both methods were assessed in terms of operative time, postoperative urethral catheter duration, and length of hospital stay by using an independent t-test. The mean difference in operative times was 8.31 minutes. According to Levene's test, the p-value was 0.054, suggesting that the variances were equal. Therefore, the mean operative time was notably shorter in the PAHG group ( $p < 0.001$ ). The PAHG group did not experience catheterization, whereas the TOT group was catheterized for 22.53 hours. There was a statistically significant difference between the two groups regarding catheterization ( $p < 0.001$ ). In addition, there was a mean difference of 20.24 hours between postoperative hospitalization times, and the TOT group had a longer hospital stay ( $p < 0.001$ ). Statistical evidence revealed that the hospitalization requirements of the TOT group were more significant.

In a cross-tabulation analysis conducted using SPSS and employing the global response scale, 20 out of 32 patients in the TOT group were classified as "4," 10 as "5," and two as "2". For the PAHG group, 2 of 29 patients received a score of "0", 3 received a score of "2", 7 received a score of "4", and 17 received a score of "5". The results indicated a statistically significant difference between the two groups ( $p = 0.021$ ). The postoperative VAS satisfaction score for the TOT group was  $7.81 \pm 1.06$ , while that for the PAHG group was  $8.06 \pm 1.36$ . Since the postoperative VAS satisfaction scores did not follow a normal distribution, the Mann-Whitney U test was used to compare the two groups, and no significant difference was observed between them ( $p = 0.12$ ).

The results of the linear regression analysis were used to

determine the factors that influenced the VAS satisfaction score. The p-value for treatment method was 0.835, while the p-value for age was 0.019. As age increased, the VAS satisfaction scores also increased. The p-values for the number of urinary incontinence episodes and the duration of urinary incontinence were 0.213 and 0.630, respectively, indicating that these variables did not notably affect the VAS satisfaction score. The p-value for BMI was 0.675, suggesting that this variable had no significant impact on the VAS satisfaction score. The factors that influenced treatment success were analyzed using a logistic regression model. The results showed that the variables were collectively significant (Overall Statistics: p=0.003). Specifically, the Treatment Method (p=0.014), age (p=0.548), number of Urinary Incontinence episodes (p=0.094), duration of Urinary Incontinence (p=0.293), and BMI (p=0.014) were all found to be statistically significant.

None of the patients had urinary retention or required clean intermittent catheterization. Of the 32 patients who received TOT after 7 days, 14 (43.75%) were found to have vaginal discharge (Clavien-Dindo grade II). The patients were administered vaginal antibacterial suppositories. Of the 32 individuals who underwent TOT, 9 (28.12%) experienced pain in the groin area (Clavien-Dindo grade I). The patients were treated with nonsteroidal anti-inflammatory drugs (NSAIDs) without requiring physical therapy or additional medical or surgical intervention. Twenty-three patients with TOT experienced postoperative vaginal bleeding in the form of spotting that soiled the pads or underwear. No bladder injury or mesh erosion was detected in any of the patients in the TOT group during the follow-up period (Table 2).

## Discussion

This study was conducted to evaluate the efficacy and safety of PAHG injections and TOT surgery for the management of SUI in women. Our results indicate that both options are effective in treating SUI; however, there are notable variations between the two. In our study, we found that the TOT method demonstrated greater treatment success than PAHG injections. While 6.25% of TOT-treated patients experienced persistent urinary incontinence, 17.24% of those in the PAHG group experienced recurrence of urinary incontinence in a relatively short time. Our findings align with existing literature on this subject [6]. However, the minimally invasive nature of PAHG offers advantages, particularly, a short operative time and no catheter

requirement. These findings suggest that PAHG injections may be a potential treatment option for patients with a lower risk of complications, who wish to avoid invasive procedures.

The use of specific equipment for PAHG applications makes this method easy and standardized [7]. The use of PAHG may be considered for patients with hip issues who are placed in a restricted lithotomy position during mid-urethral sling procedures as it has demonstrated comparable treatment outcomes. In our case series, three patients were referred to the PAHG by their surgeons for this specific purpose.

When evaluated in terms of patient satisfaction, there was no statistically significant difference between the two methods; however, the satisfaction rates in the PAHG group tended to increase with age. In the literature, satisfaction rates with PAHG injections have been reported to range between 64% and 90% [4], which is consistent with our findings [4,8,9]. Despite the high success rates of the TOT method, the low complication rates and minimally invasive nature of PAHG injections may support the preference for this method in certain patient groups. However, in contrast to more invasive methods such as TOT and tension-free vaginal tape (TVT), no disparity in satisfaction rates has been detected in most studies [4].

Remarkably, patients with high BMI benefited less from PAHG injections, suggesting that the efficacy of this method may be related to BMI. However, the fact that patients with similar BMI benefited notably from TOT suggests that TOT may be more effective in this patient group. Although the sample size of our study was small, this finding suggests that BMI may be an important factor in treatment selection, and this issue should be examined in greater depth in studies with larger sample sizes.

The effect of surgical experience on treatment outcomes was an important finding of our study. The surgeons' long years of experience with the TOT method may explain the high success rates of this method, whereas less experience with PAHG injections may have led to lower success rates. This suggests that surgical experience and skill can notably influence treatment outcomes, especially with new or less commonly used methods [10,11].

With regard to complications, higher rates of vaginal discharge and groin pain were observed in the TOT group. These complications may be related to the invasive nature of TOT, and surgical techniques should be revised to reduce such complications [10,11]. The absence of such complications in the PAHG group suggests that the PAHG injections have an advantageous safety profile. Nevertheless, it is reasonable to anticipate low complication rates by carefully selecting the patients in the PAHG group [6,12]. Unfortunately, this study did not include long-term follow-up data. Long follow-up periods of up to 7 years have been documented in previous studies for PAHG patients with PAHG and are consistent with our observations [13].

This study has some limitations. First, the relatively small sample size limited the generalizability of our findings. Furthermore, the inhomogeneity of the patients and lack of separation between mixed-type and pure SUI cases may have affected the accuracy of the results. Furthermore, the absence of long-term follow-up data in this study introduces uncertainty, particularly concerning the long-term efficacy and safety of PAHG injections. Moreover, the fact that a single surgeon

**Table 2.** Postoperative complications

Complication Type	TOT Group (32)	PAHG Group (29)	P-value
Vaginal discharge	14 (43.75%)	0 (0%)	<b>0.001</b>
Groin pain	9 (28.12%)	0 (0%)	<b>0.001</b>
Urinary retention	0 (0%)	0 (0%)	-
Bladder injury	0 (0%)	0 (0%)	-
Mesh erosion	0 (0%)	0 (0%)	-
Urethral erosion	0 (0%)	0 (0%)	-
Vaginal bleeding*	23(71.8%)	0 (0%)	<b>0.001</b>

\*Staining on pads or underwear

performed all the surgical procedures could have influenced the outcomes. Notably, while the surgeon had 17 years of experience in the TOT group, they had only two years of experience in the PAHG group. This disparity in experience may have affected the results and should be considered when interpreting the findings. Considering these limitations, randomized controlled trials with larger sample sizes and long-term outcomes should be conducted in the future [6].

## Conclusion

In conclusion, although the TOT method offers higher success rates, the minimally invasive nature and low complication rates of PAHG injections make this method an effective alternative in certain patient groups. Future studies should examine the cost-effectiveness of these treatment methods and their impact on patient satisfaction by evaluating the long-term outcomes of both methods, using larger sample groups. Furthermore, multicenter studies conducted by different surgeons are recommended to better understand the impact of surgical experience and skills on treatment outcomes.

**Ethics Committee Approval:** This study was performed according to the Helsinki Declaration and with permission from the local ethics committee of Burhan Nalbantoğlu State Hospital (Number: YTK1.01, project code 29/24).

**Informed Consent:** An informed consent was obtained from all the patients.

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