Spring 2023

Comparison of Urethral Bulking Injection Therapy and Surgical Midurethral Sling Placement for Treatment of Stress Urinary Incontinence in Women

Ashley Black
University of North Dakota

Comparison of Urethral Bulking Injection Therapy and Surgical Midurethral Sling Placement for Treatment of Stress Urinary Incontinence in Women

Ashley Black, PA-S
Department of Physician Assistant Studies, University of North Dakota School of Medicine & Health Sciences
Grand Forks, ND 58202-9037

UND School of Medicine & Health Sciences
University of North Dakota

Abstract

This literature review aims to assess the comparative efficacy and safety of urethral bulking injection therapy and surgical midurethral sling intervention in the treatment of stress incontinence in women. A comprehensive search of the existing literature was conducted and includes studies from PubMed, an electronic search databases. The findings indicate that both urethral bulking injection therapy and surgical midurethral sling intervention are suitable interventions to be considered for the treatment of stress incontinence in women. Current research available regarding the efficacy of urethral bulking agents versus midurethral slings suggests that the placement of a miduerthral sling has the highest incidence of cure rates and symptom improvement. However, when evaluating the safety of these procedures, the literature suggests that urethral bulking agents offer a superior safety profile when compared with midurethral slings. Future studies with larger sample sizes, universal screening tools, and longer study durations would provide additional, reliable information regarding the long-term efficacy of these interventions and would aide in the decision-making process. The review concludes that both urethral bulking injection therapy and surgical midurethral sling intervention are effective in the treatment of stress incontinence in women, and the choice of treatment should be based on individual patient factors.

Keywords: stress urinary incontinence, injection therapy, bulking agents, midurethral sling, surgical sling

Introduction

- Stress urinary incontinence (SUS) is a common condition that affects 46% of women (Abufaraj et al., 2021).
- It is defined by the American Urological Association as the involuntary leakage of urine caused by an increase in intra-abdominal pressure during physical activities such as coughing, sneezing, or exercising (AUA, 2017).
- SUS is usually treated conservatively with pelvic floor exercises, weight loss, and other non-invasive interventions. However, when these treatments fail, more invasive options such as urethral bulking injection therapy and midurethral sling placement are considered.
- Urethral bulking injection therapy involves injecting bulking agents into the urethral sphincter to bulk and improve its control over urine flow.
- Midurethral sling placement is a surgical procedure where a sling is inserted below the urethra and anchored into surrounding tissue.

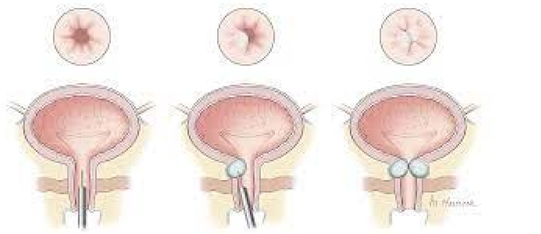
Statement of the Problem

Stress urinary incontinence treatment involves both non-invasive and invasive options, and women who do not improve with non-invasive treatments should consider more invasive treatments like urethral bulking injection therapy or midurethral sling placement. Midurethral sling is a common surgical treatment with high cure rates and low risk of complications. Urethral bulking injection therapy has improved outcomes due to advancements in materials and is being used more often as primary treatment for stress urinary incontinence. Clinicians should be knowledgeable about the safety and efficacy of these treatments to make an informed decision for individual patients based on their symptoms, severity, and therapy goals.

Research Question

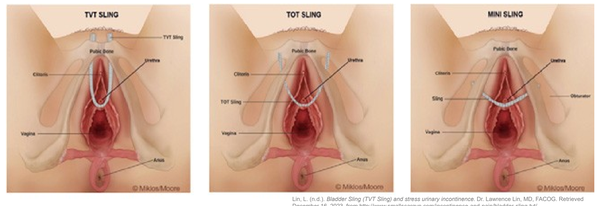
In women suffering from stress urinary incontinence, how does urethral bulking injection therapy compare with surgical midurethral sling intervention in terms of efficacy and safety in the treatment of stress incontinence?

Urethral bulking injection



Hoover, M., & Karram, M. (2020, October 15). *Urethral bulking agents for SUI: Rethinking their indications.* MDedge ObGyn. Retrieved December 16, 2023, from https://www.mdedge.com/obgyn/article/230038/urethral-bulking-agents-sui-rethinking-their-indications/page/0/2

Surgical midurethral sling



Lin, L. (n.d.). *Bladder Sling (TVT Sling) and stress urinary incontinence.* Dr. Lawrence Lin, MD, FACOG. Retrieved December 16, 2023, from http://www.smallscargyn.com/incontinence-and-pain/bladder-sling-tvt/

Literature Review

Safety and Efficacy of Urethral Bulking Injection

- Elmelund et al. (2019) performed a multivariate logistic regression analysis to predict relationships between dependent and independent variables and found that age 60 year or greater (p=0.007) and fewer than two and a half daily stress incontinence episodes at baseline (p=0.031) increased the odds of cure after urethral injection therapy.
- Giammò et al. (2020) found that when evaluating predictors of clinical outcomes, patients with higher severity of urinary incontinence were more likely to experience worse results in comparison to patients suffering from mild to moderate urinary incontinence (p=0.008).
- A lack of significant post-operative complications suggests that urethral bulking therapy with Bulkamid is a safe treatment choice for patients (Giammò et al., 2020).
- Leone et al., (2013) reported that at 1-year follow-up, subjective efficacy of urethral injection therapy was 74.4% (61 patients) with no patients reporting worsening of stress incontinence symptoms.
- Leone et al., (2013) reported objective efficacy with a decrease in the mean number of episodes of urine leakage within a 24-hour period (p<0.001) and a decrease in the mean amount of urine leakage within a 24-hour period (p<0.001).
- A larger percentage of patients reported higher rates of subjective success at their 1-month follow-up appointment compared to their 3-month (p<0.001), 6-month (p=0.010), and 12-month (p=0.026) follow-ups (Leone et al., 2013).
- Pia and Al-Singary (2015) reported objective data during 3-month follow-up showing a decrease in the number of incontinence episodes over a 24-hour period (p<0.0001), as well as a reduction of urine leakage with 24-hour pad testing (p<0.0001) following urethral bulking injection therapy.
- Seven patients (2.7%) experienced adverse effects from urethral injection therapy (Pia & Al-Singary, 2015).
- Responses to ICIQ and VAS quality of life questionnaires demonstrated maintained improvement/cure at 12-month follow-up and subsequent annual follow-up, up to 5 years (Pia & Al-Singary, 2015).
- Serati et al. (2019) found that previous history of radical pelvis surgery (p=0.04) and low surgeon skill level (p=0.03) were associated with higher risk of failure rate.
- At 3-month follow-up, only three patients (3.5%) reported experiencing adverse effects from their procedures (Serati et al., 2019).

Safety and Efficacy of Midurethral Sling Surgical Procedures

- Berger et al. (2019) reported an overall reoperation rate of 6% at nine years.
- A statistical significance of reoperation rates for recurrent stress incontinence in relation to sling type was found (p=0.03) (Berger et al., 2019).
- Brennand et al. (2015) reported that 95 (85.6%) women in the nonobese group were objectively cured by 1-hour pad test, compared to 40 (67.8%) in the obese group (p=0.006).
- Brennand et al. (2015) found that a higher presence of post operative urinary incontinence symptoms was present within obese women in comparison to non-obese women (p=0.003).
- Dejene et al. (2022).identified the 10-year and 15-year risk for sling revision to be 6.9% (95% CI 6.7–7.0) and 7.9% (95% CI 7.5–8.3), respectively.
- Women of ages 18-29 demonstrated an elevated risk for both surgical revision (hazardous ratio, 1.20; 95% CI 1.15–1.25) and recurrent stress urinary incontinence (hazardous ratio, 1.30; 95% CI 1.25–1.37) when compared to women 70 year of age or older (Dejene et al., 2022).
- Kim et al. (2021) found that patient characteristics that were found to affect symptoms of stress urinary incontinence following midurethral sling procedure included age (p=0.052) and body mass index (p=0.010).
- Kim et al. (2021) found that both TVT-O and TVT-A midurethral sling surgeries led to high surgical success rates, with few post-operative complications.
- Laterza et el. (2018) found that patients with higher age and body mass index at the time of surgery had a larger probability of a positive cough stress test at 5 years (p=0.05 and p= 0.01 respectively) and significant difference in age was associated with higher PGI-I scores at 5-year follow-up (p<0.0001).
- No statistically significant differences in objective or subjective cure rates associated with parity (p=0.50) (Laterza et el., 2018).

Comparison Between the Safety and Efficacy of Urethral Bulking Injection Therapy and Midurethral Sling Surgical Procedures

- Bach and Toozs-Hobson (2020) found that 59.2% of patients reported feeling “very much better” or “much better” following urethral bulking injection, compared to 91% within the retropubic tape group (p≤0.01).
- Bach and Toozs-Hobson (2020) found that only 0.8% of patients who underwent urethral bulking injection developed de novo overactive bladder symptoms as a post-operative complication, compared to a 3.8% occurrence rate within the retropubic tape group.
- There were no intraoperative complications recorded within the urethral bulking procedure group vs. a 4.19% occurrence rate of intraoperative complications recorded within the retropubic tape procedure group (Bach & Toozs-Hobson, 2020).
- Cadish et al. (2022) found that patients undergoing urethral bulking procedures were more likely to be suffering from several comorbidities in comparison to patients undergoing surgical treatment (p<0.001).
- The median time for repeat procedure was approximately 5 years in the sling group, as compared to 3.3 years in the bulking group (p<0.001) (Cadish et al., 2022).
- Itkonen et al. (2020) found that patient satisfaction outcome scores of 80 or greater at 1-year follow-up we higher within those who had a midurethral sling procedure compared to urethral bulking (p <0.001).
- 96 (95.0%) patients who underwent sling placement experienced a negative cough stress test, while only 71 (66.4%) were recorded withing the bulking group (95% CI 18.4-38.5%) (Itkonen et al., 2020).
- Nineteen post-operative complications were found within the sing group, while only three were noted within the bulking group (Itkonen et al., 2020).
- Itkonen et al. (2021) reported that at 1-year, total scores of UDI-6 and IIQ-7 indicated less urinary symptom-related distress among midurethral sling patients compared to bulking injection patients (p< 0.001).
- Health-related quality of life showed significant improvement in physical functioning and social functioning in both groups, with better outcome in the TVT group for physical functioning (p< 0.001) (Itkonen et al., 2021).

Discussion

- Current research available regarding the efficacy of urethral bulking agents versus midurethral slings suggests that the placement of a miduerthral sling has the highest incidence of cure rates and symptom improvement. However, when evaluating the safety of these procedures, the literature suggests that urethral bulking agents offer a superior safety profile when compared with midurethral slings.
- Treatment decisions should be patient dependent and made on an individualized basis. Available treatment options and associated risks/complications should be discussed, at length, with patients. Most studies analyzed were noted to have been conducted over a 1-year time frame, a relatively short length of time. Future studies with larger sample sizes, universal screening tools, and longer study durations would provide additional, reliable information to aide in the decision-making process.

Applicability to Clinical Practice

- Clinicians should make decisions on the use of invasive interventions for stress incontinence on an individual basis.
- Factors such as general health, level of incontinence severity, body habitus, and age should be considered.
- Patients should be informed about the outcomes and realistic expectations of invasive procedures.
- Midurethral sling placement offers better outcomes in terms of symptom improvement and cure rates than urethral bulking injections.
- Urethral bulking injections are a better option for patients avoiding more invasive surgery or those with less severe symptoms, larger body habitus, or at an advanced age.
- Patients should be counseled on the likelihood of needing reinjection of bulking materials to maintain results long-term.

References

- Abufaraj, M., Xu, T., Cao, C., Siyam, A., Isleem, U., Massad, A., Soria, F., Shariat, S., Sutcliffe, S., & Yang, L. (2021). Prevalence and trends in urinary incontinence among women in the United States, 2005-2018. American journal of obstetrics and gynecology, 225(2), 166.e1–166.e12. https://doi.org/10.1016/j.ajog.2021.03.016
- Bach, F., & Toozs-Hobson, P. (2020). An analysis of 1386 periurethral bulking procedures with comparison to 18,763 retropubic tapes. Post reproductive health, 26(2), 71–78. https://doi-org.ezproxylr.med.und.edu/10.1177/2053369120924929
- Berger, A., Tan-Kim, J., & Menefee, S. (2019). Long-term Risk of Reoperation After Synthetic Mesh Midurethral Sling Surgery for Stress Urinary Incontinence. Obstetrics and Gynecology., 134(5), 1047–1055. https://doi.org/10.1097/AOG.0000000000003526
- Brennand, E., Tang, S., Williamson, T., Birch, C., Murphy, M., Robert, M., Ross, S., & Calgary Women's Pelvic Health Research Group (2015). Twelve-month outcomes following midurethral sling procedures for stress incontinence: impact of obesity. BJOG: an international journal of obstetrics and gynaecology, 122(12), 1705–1712. https://doi-org.ezproxylr.med.und.edu/10.1111/1471-0528.13132
- Cadish, L., Ford, C., Wu, J., & Anger, J. (2022). Mortality and Reoperation Following Midurethral Sling Versus Urethral Bulking in Older Women. Urology, 165, 144–149. https://doi-org.ezproxylr.med.und.edu/10.1016/j.urology.2022.03.033
- Dejene, S., Funk, M., Pate, V., & Wu, J. (2022). Long-Term Outcomes After Midurethral Mesh Sling Surgery for Stress Urinary Incontinence. Female Pelvic Medicine & Reconstructive Surgery., 28(4), 188–193. https://doi.org/10.1097/SPV.0000000000001094
- Elmelund, M., Sokol, E., Karram, M., Dmochowski, R., & Klarskov, N. (2019). Patient Characteristics that May Influence the Effect of Urethral Injection Therapy for Female Stress Urinary Incontinence. The Journal of urology, 202(1), 125–131. https://doi-org.ezproxylr.med.und.edu/10.1097/JU.0000000000000176
- Ford, A., Rogerson, L., Cody, J., Aluko, P., & Ogah, J. (2017). Mid-urethral sling operations for stress urinary incontinence in women. The Cochrane database of systematic reviews, 7(7), CD006375. https://doi.org/10.1002/14651858.CD006375.pub4
- Giammò, A., Geretto, P., Ammirati, E., Manassero, A., Squintone, L., Vercelli, D., & Carone, R. (2020). Urethral bulking with Bulkamid: An analysis of efficacy, safety profile, and predictors of functional outcomes in a single-center cohort. Neurourology and Urodynamics, 39(5), 1523–1528. https://doi.org/10.1002/nau.24388
- Guralnick, M., Fritel, X., Tarcan, T., Espuna-Pons, M., & Rosier, P. (2018). ICS Educational Module: Cough stress test in the evaluation of female urinary incontinence: Introducing the ICS-Uniform Cough Stress Test. Neurourology and urodynamics, 37(5), 1849–1855. https://doi-org.ezproxylr.med.und.edu/10.1002/nau.23519
- Hoover, M., & Karram, M. (2020, October 15). *Urethral bulking agents for SUI: Rethinking their indications.* MDedge ObGyn. Retrieved December 16, 2023, from https://www.mdedge.com/obgyn/article/230038/urethral-bulking-agents-sui-rethinking-their-indications/page/0/2
- Itkonen Freitas, A., Mentula, M., Rahkola-Soisalo, P., Tulokas, S., & Mikkola, T. (2020). Tension-Free Vaginal Tape Surgery versus Polyacrylamide Hydrogel Injection for Primary Stress Urinary Incontinence: A Randomized Clinical Trial. The Journal of Urology, 203(2), 372–378. https://doi-org.ezproxylr.med.und.edu/10.1097/JU.0000000000000517
- Itkonen Freitas, A., Mikkola, T., Rahkola-Soisalo, P., Tulokas, S., & Mentula, M. (2021). Quality of life and sexual function after TVT surgery versus Bulkamid injection for primary stress urinary incontinence: 1-year results from a randomized clinical trial. International urogynecology journal, 32(3), 595–601. https://doi-org.ezproxylr.med.und.edu/10.1007/s00192-020-04618-5
- Kim, M., Kim, J., Chae, H., Chung, J., Kim, H., Lee, S., & Kim, S. (2021). Surgical outcomes of tension-free vaginal tape (TVT)- Abbrevo® and TVT-obturator® for the treatment of stress urinary incontinence: a retrospective study. Obstetrics & Gynecology Science, 64(6), 540–546. https://doi.org/10.5468/ogs.21178
- Kirchin, V., Page, T., Keegan, P., Atiemo, K., Cody, J., McClinton, S., & Aluko, P. (2017). Urethral injection therapy for urinary incontinence in women. The Cochrane database of systematic reviews, 7(7), CD003881. https://doi.org/10.1002/14651858.CD003881.pub4
- Kobashi, K., Albo, M., Dmochowski, R., Ginsberg, D., Goldman, H., Gomelsky, A., Kraus, S., Sandhu, J., Shepler, T., Treadwell, J., Vasavada, S., Lemack, G. Surgical Treatment of Female Stress Urinary Incontinence: AUA/SUFU Guideline. J Urol. 2017 Oct;198(4):875-883. doi: 10.1016/j.juro.2017.06.061. Epub 2017 Jun 15. PMID: 28625508.
- Laterza, R., Halpern, K., Ulrich, D., Graf, A., Tamussino, K., Umek, W., & Austrian TVT vs. TVT-O Study Group (2018). Influence of age, BMI, and parity on the success rate of midurethral slings for stress urinary incontinence. PloS one, 13(8), e0201167. https://doi-org.ezproxylr.med.und.edu/10.1371/journal.pone.0201167
- Leone Roberti Maggiore, U., Alessandri, F., Medica, M., Gabelli, M., Venturini, P., & Ferrero, S. (2013). Outpatient periurethral injections of polyacrylamide hydrogel for the treatment of female stress urinary incontinence: effectiveness and safety. Archives of gynecology and obstetrics, 288(1), 131–137. https://doi-org.ezproxylr.med.und.edu/10.1007/s00404-013-2718-y
- Lin, L. (n.d.). *Bladder Sling (TVT Sling) and stress urinary incontinence.* Dr. Lawrence Lin, MD, FACOG. Retrieved December 16, 2023, from http://www.smallscargyn.com/incontinence-and-pain/bladder-sling-tvt/
- Pai, A., & Al-Singary, W. (2015). Durability, safety, and efficacy of polyacrylamide hydrogel (Bulkamid (®)) in the management of stress and mixed urinary incontinence: three year follow up outcomes. Central European Journal of Urology., 68(4), 428–433. https://doi.org/10.5173/ceju.2015.647
- Serati, M., Soligo, M., Braga, A., Cantaluppi, S., Coluccia, A., Di Dedda, M., Salvatore, S., Cetin, I., Ghezzi, F., & Publication Committee of the Italian Society of Urodynamics (2019). Efficacy and safety of polydimethylsiloxane injection (Macroplastique®) for the treatment of female stress urinary incontinence: results of a series of 85 patients with ≥3 years of follow-up. BJU international, 123(2), 353–359. https://doi-org.ezproxylr.med.und.edu/10.1111/bju.14550
- Skorupska, K., Grzybowska, M., Kubik-Komar, A. et al. Identification of the Urogenital Distress Inventory-6 and the Incontinence Impact Questionnaire-7 cutoff scores in urinary incontinent women. Health Qual Life Outcomes 19, 87 (2021). https://doi.org/10.1186/s12955-021-01721-z
- Utomo, E., Korfage, I., Wildhagen, M., Steensma, A., Bangma, C., Blok, B. Validation of the Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7) in a Dutch population. Neurourol Urodyn. 2015 Jan;34(1):24-31. doi: 10.1002/nau.22496. Epub 2013 Oct 26. PMID: 24167010.

Acknowledgements

I would like to thank the UND PA faculty for their continued support and dedication throughout the program. I would like to thank my advisor, Julie Solberg, PA-C, for her insight and direction throughout my PA education. I thank all of my preceptors who have helped guide my education and learning experiences. Further gratitude is extended to Dr. Marilyn Klug (statistician) and Agatha Ottem Lill (PA-C) for their input into this final project. Lastly, a sincere thank you to my husband, family and friends for their love and support through this challenging but rewarding endeavor.