DOI: https://doi.org/10.17816/JOWD61994

Bulking agents for minimally invasive correction of stress urinary incontinence in women

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BACKGROUND: The study is relevant due to the widespread prevalence of stress urinary incontinence in women and the search for minimally invasive and safe treatment methods.

AIM: The aim of this study was to present data based on modern evidence-based information on the effectiveness of urethral bulking agents and their safety in stress urinary incontinence treatment in women.

MATERIALS AND METHODS: A review of the literature (original articles, systematic reviews) on the use of urethral bulking agents for stress urinary incontinence treatment in women was carried out.

RESULTS: Urethral bulking agents for stress urinary incontinence treatment are effective due to the creation of additional bulk in the paraurethral area without fibrosis or because of inflammation followed by fibrous tissue formation. The efficacy and complications depend on the properties of the used urethral bulking agents. Since the performed studies are heterogeneous and the methods for evaluating the use of bulking fillers in stress urinary incontinence treatment vary, it is difficult to comparatively characterize urethral bulking agents to determine the most effective one. The search is being conducted for an ideal proper filler, which should be biocompatible and non-immunogenic and maintain a long-term therapeutic effect.

CONCLUSIONS: Urethral bulking injections are an alternative therapy for women with stress urinary incontinence who are informed about its short-term effect and are expecting to avoid the risk of possible complications after surgery. Promising is to be regarded as the use of new urethral bulking agents based on hyaluronic acid with an optimal choice of concentration, degree of crosslinking and type of crosslinking agent to ensure maximum duration of action and minimum side effects.

Keywords: stress urinary incontinence; bulking agents; hyaluronic acid; surgical treatment; complications.

To cite this article:
Rusina EI, Zhevlakova MM. Bulking agents for minimally invasive correction of stress urinary incontinence in women. *Journal of Obstetrics and Women's Diseases.* 2021;70(4):115–124. DOI: https://doi.org/10.17816/JOWD61994

Received: 26.02.2021 **Accepted:** 11.03.2021 **Published:** 31.08.2021

УДК 616.62-008.222-08
DOI: https://doi.org/10.17816/JOWD61994

Объемообразующие вещества при малоинвазивной коррекции стрессового недержания мочи у женщин

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Обоснование. Актуальность темы исследования обусловлена широкой распространенностью стрессового недержания мочи у женщин и поиском минимально инвазивных, безопасных методик лечения.

Цель — представление научных данных, основанных на современной доказательной информации об эффективности объемообразующих веществ и их безопасности при лечении стрессового недержания мочи у женщин.

Материалы и методы. Проведен обзор научной литературы (оригинальные статьи, систематические обзоры) по теме применения объемообразующих веществ для лечения стрессового недержания мочи у женщин.

Результаты. Объемообразующие вещества при лечении стрессового недержания мочи эффективны за счет создания дополнительного объема в парауретральной области без явления фиброза либо за счет воспаления с формированием фиброзной ткани. Эффективность и характер осложнений связаны со свойствами используемого объемообразующего вещества. Учитывая разнородность исследований, а также различные методы оценки результатов применения объемообразующих наполнителей в лечении стрессового недержания мочи, сложно проводить сравнительную характеристику для определения наиболее эффективного объемообразующего вещества. Продолжается поиск идеального наполнителя, который должен быть биосовместимым, неиммуногенным и оказывать длительный лечебный эффект.

Заключение. Инъекции объемообразующих веществ являются альтернативной методикой лечения женщин со стрессовым недержанием мочи, желающих избежать риска возможных осложнений оперативного лечения, проинформированных о недолгосрочном эффекте. Перспективным направлением является применение новых объемообразующих веществ на основе гиалуроновой кислоты с оптимальным выбором концентрации, степени «сшивания» и типа сшивающего агента для обеспечения максимальной длительности действия и минимальных побочных эффектов.

Ключевые слова: стрессовое недержание мочи; объемообразующие вещества; гиалуроновая кислота; хирургическое лечение; осложнения.

Как цитировать:
Русина Е.И., Жевлакова М.М. Объемообразующие вещества при малоинвазивной коррекции стрессового недержания мочи у женщин // Журнал акушерства и женских болезней. 2021. Т. 70. № 4. С. 115–124. DOI: https://doi.org/10.17816/JOWD61994

Рукопись получена: 26.02.2021 **Рукопись одобрена:** 11.03.2021 **Опубликована:** 31.08.2021

BACKGROUND

Stress urinary incontinence (SUI) is an involuntary loss of urine due to a rise in intra-abdominal pressure as a result of coughing, sneezing, and physical exertion. Urinary incontinence is one of the most common problems in urogynecology. According to a systematic review, the prevalence of urinary incontinence in women ranges from 1% to 42.2%, and the proportion of SUI ranges from 12.5% to 79% [1]. There is a general notion that incontinence affects parous women and elderly female patients. However, this disease is registered more and more in young, nulliparous women. The main risk factors for urinary incontinence for such patients include increased body mass index, increased physical training, and connective tissue dysplasia [1, 2]. The prevalence of this problem is 33.6%–36.8% among Russian women and 70% among women over 50 years of age [3]. Urinary incontinence impairs the quality of life and affects psychological well-being [4].

There are various conservative and surgical methods of treatment. The most effective method of treating SUI with long-term preservation is surgical correction using synthetic slings (96.2% and 90.4% rates following a 1-year and 5-year period after treatment respectively) [5].

However, some patients refuse surgical treatment due to fear of surgery, birth planning, and other reasons. Therefore, specialists have to develop modifications of known methods and search for new alternative ones. Pelvic floor muscle training (PFMT) is a common conservative method of treatment. According to Zheleznyakova, the low efficiency of PFMT (20.8%) is associated with the need for training to perform the exercises correctly and poor motivation of patients for regular training. Biofeedback training is most effective (75%). However, about 38% of women with SUI are resistant to PFMT even after careful individual training [6].

Injections of bulking agents (BA) into paraurethral tissues represent a minimally invasive technique and are often performed along with the placement of urethral slings, although they differ from surgical treatment in their shorter duration of effect. The substances injected, due to the creation of additional volume in the paraurethral region, increase the resistance of the urethra, which contributes to the retention of urine [7]. Injections can be performed on an out-patient basis, without general anesthesia [8–11].

The persistence and complications of this technique are associated with the properties of the injected BA, the reaction of the surrounding tissues and the body as a whole. Ideally, BA should be biocompatible and non-immunogenic. In addition, it should not migrate, should be hypoallergenic and not subject to degradation. However, no ideal substance has been found that fully meet all these criteria till date.

Kirchin et al. note the heterogeneity of studies evaluating urethral BA injections. The authors believe that further research is required with an objective assessment of results [8].

We therefore aimed at presenting scientific data based on modern evidence-based information on the efficiency of BAs and their safety in the treatment of SUI in women.

Bulking agents in the treatment of urinary incontinence in women

BA injections are used to treat gastroesophageal reflux, epiglottis insufficiency, as well as eliminate wrinkles and increase soft tissue volume in cosmetology [12–14].

Injection treatments for urinary incontinence have been used for over a century. The first substances administered paraurethrally for the treatment of urinary incontinence caused a pronounced inflammatory response with further proliferation of connective tissue and hardening at the injection site, leading to compression of the urethra. In 1900, R. Gersuny described the effect of paraurethral injection of paraffin in the treatment of SUI [15]. In 1938, B. Murless injected sodium morrhuate into the anterior vaginal wall of 20 women, which helped to strengthen the urethrovesical segment due to the formation of fibrous tissue at the injection site [16].

Several other sclerosing agents have subsequently been described, but their use had complications such as excessive scarring, vaginal bleeding, and thromboembolic events. Later, in the 1970s, attempts were made involving urethral injections with polytetrafluorethylene. Polytetrafluorethylene consisted of a paste containing polytetrafluorethylene, glycerin, and polysorbate. Treatment was complicated by substance migration (regional lymph nodes, lungs, and brain) and a granulomatous reaction resulting in dysuria and urinary obstruction. Polytetrafluorethylene has ultimately been terminated to use as a BA [17].

In the 1990s, the use of autologous fat as BA was introduced and studied. Due to its low immunogenicity and availability, it has attracted great attention. However, its efficacy was questioned in a randomized controlled trial which showed no difference from placebo, along with a poor safety profile associated with fat embolism [18, 19].

In 1993, bovine collagen cross-linked with glutaraldehyde was used for urethral injections in USA. Socol et al. studied the results of polyacrylamide gel and bovine collagen injections in 345 women with SUI. After 12 months, 47.2% of patients after injections of polyacrylamide hydrogel and 50% of patients after injections of collagen gel recovered, while 77.1% and 70% of patients reported improvement or recovery, respectively [20]. Due to the local inflammatory response and subsequent collagen resorption, repeated injections were required. The long-term results of collagen injections were questioned by Gorton et al. who reported a subjective improvement in only 26% of women 5 years

after the treatment [21]. Complications included delayed skin reactions, arthralgias, public osteitis, pulmonary embolism, and periurethral infiltration. In 3% of patients, due to the local immune response and allergic reaction, allergy tests had to be performed [8]. Although collagen is currently not widely used, most research on this subject has been performed with it. Its efficiency is used as reference when developing new bulk-forming agents.

Calcine hydroxyapatite (Coaptite), zirconium oxide (Durapshere), and ethylene-vinyl alcohol copolymer (Tegress; Uryx) were also used as BA, which were later refused owing to many complications associated to their use [22, 23].

To date, several BAs have been used to treat urinary incontinence with varying advantages and disadvantages. The silicone polymer (Macroplastique) consists of an aqueous suspension of polyvinylpyrrolidone as a carrier and a polydimethylsiloxane firm elastomer (silicone particles). Most of its silicone particles are larger than 100 mm, which reduces the risk of migration from the injection site. However, the particle size ranges from less than 50 mm to more than 400 mm. In a meta-analysis, G. Ghoniem and C. Miller demonstrated improvement in SUI after administration of Macroplastique in 75% of cases after short-term follow-up (<6 months), in 73% of cases in the medium-term follow-up (6–18 months), and in 64% of cases in the long-term period (>18 months). Researchers concluded that silicone is a safe and durable injectable agent for the treatment of SUI [24]. This filler is widely used in the USA. Serrati et al. studied the long-term results of Macroplastique administration (more than 3 years) in 85 patients, where 49% declared themselves cured, and 47% objectively recovered. Multivariate analysis showed that a history of pelvic surgery and low qualification of the surgeon predicted subjective and objective treatment failure [25]. There were no clinically significant differences in the outcomes of the disease between cases of symmetric and asymmetric location of the BA according to ultrasound (US) results [26]. Despite the fact that silicone is considered inert, two female patients recently experienced injection failure due to immune rejection, and suburethral granuloma formation [27]. Rodriguez et al. conducted a retrospective study where erosion of the urethra or bladder neck was detected in 18 (2%) patients after treatment of SUI with the use of silicone polymer for 5 years. Patients complained of pelvic pain, hematuria, frequent recurrent urinary tract infections, stuttering urination, sensation of incomplete emptying of the bladder, and nocturia. The implant was removed [28]. G. Ghoniem and C. Miller conducted a meta-analysis of 24 articles published from 1990 to 2010, with the participation of 958 patients on whom Macroplastique were injected. The incidence of urinary tract infection was 3%, temporary urinary retention was 7%, urinary incontinence was 7%, and the incidence of temporary dysuria was 50% [24].

In 2011, new filler appeared, namely a silicone elastomer "cross-linked" with vinyl dimethylpolydimethylsiloxane (Urolastic). It polymerizes *in situ* into a homogeneous elastomer, remaining flexible and adapting to the environment, reducing the risk of migration [29]. De Vries et al. reported subjective improvement over 12–25 months in 76%–88% of patients. Among the complications, acute urinary retention, pelvic pain, and vaginal erosion were reported in 24%–33% of cases. This filler also caused vaginal erosion in 24.6% of women, which required excision of the implant in some patients [30].

Polyacrylamide gel (Bulkamid) consists of 2.5% cross-linked polyacrylamide and 97.5% water. The hydrogel is not biodegradable. Connective tissue cells penetrate into the hydrogel and form a firm network of thin fibers that anchor the gel at the injection site [31]. In Europe, Bulkamid has been used as BA since 2006. In a systematic review of 8 studies, including 767 patients, Kasi et al. demonstrated persistence of the effect of reducing incontinence one year after injection with polyacrylamide gel [32]. The largest randomized retrospective study involved 1200 female patients with SUI and stress-predominant mixed urinary incontinence treated with polyacrylamide gel injections. Furthermore, 388 patients were followed for 7 years. After the injection 1, 67.1% of patients noted recovery and improvement (recovery in 16.5% of cases, improvement in 50.6% of cases), 11.1% of women reported no changes, 2.3% noted worsening of urinary incontinence, and 19.5% of patients underwent further surgical treatment. On average, after 9 months, 127 patients underwent a repeated procedure of polyacrylamide hydrogel treatment, 15% of which recovered during a 7-year follow-up period, 46.5% of patients noted improvement, and 18.1% of patients underwent another surgical treatment due to lack of effect. After injections, 3.5% of patients had urinary tract infections, 15.3% noted an increase in the time of emptying the bladder, 8.6% had nocturia, 0.3% had acute urinary retention, 0.3% noted dysuria, and 9.6% had frequent urination [33].

Preparations based on hyaluronic acid (HA) are currently widely used as BA in cosmetology and in the treatment of urinary incontinence. HA is involved in the processes of regeneration, tissue repair, angiogenesis, and morphogenesis. When administered exogenously, HA inhibits the migration of lymphocytes, granulocytes, and macrophages in the peripheral blood without decreasing the activity of epithelial cells and fibroblasts [34]. For the treatment of SUI, drugs of high molecular weight HA stabilized by adjuvants (cross-linked) are used. HA can have different effects depending on the density, method, and degree of crosslinking. High-density HA is known to have an antifibrotic effect [35], is perfectly biocompatible, hypoallergenic, and non-toxic. HA-based preparations differ from other used BAs in their low immunogenicity, and their

ability to biodegrade to non-toxic substances. Their end products are water-soluble, which are either excreted from the body naturally, or undergo a further chain of chemical transformations up to carbon dioxide and water [36]. The severity and duration of the effect with the injection of HA depends on the substance concentration, the adjuvants in its composition and, accordingly, the rate of biodegradation of a particular preparation. Depending on the duration of biodegradation, different manufacturers guarantee certain duration of the effect of HA preparations.

HA cross-linked with a dextranomer (Zuidex) represent a complex of water-insoluble dextranomer microspheres suspended in a high-density HA gel of non-animal origin. Dextranomer microspheres are 80–250 μm in size and are not fragmented. The filler is biocompatible and does not migrate to various organs and tissues [8]. According to a prospective study evaluating the efficiency of treatment of female patients with SUI using Zuidex injections, the recovery rate was 60% and 62% after 12 weeks and 12 months, respectively. The efficiency of treatment was 78% after 12 weeks and 77% after 12 months [37]. Later, an intraurethral technique was developed for injection of a HA-based drug "cross-linked" with dextranomer microspheres, with the use of a patented device for insertion into the middle third of the urethra (Urodex). According to I.A. Apolikhina, after 6 weeks of the follow-up, 90.3% of patients noted clinical improvement, and after 3 months, efficiency decreased by 10%, and by 12 months, it decreased by another 30% [38].

Despite the effective action of Zuidex, problems associated with a high risk of pseudocyst formation in the urethra led to its rejection in several countries, including the USA. Thus, in a series of 35 patients with SUI who received intraurethral injections of dextarnomer-stabilized HA, Lightner et al. monitored four patients with the formation of pseudocysts of the urethra and its obstruction, due to which surgical treatment was performed [39]. In 2007, Elzayat et al. conducted a study on rats using HA with a dextranomer, in which the histological examination revealed fibrosis of the implant and the paraurethral region. These phenomena turned out to be due to the stimulating effect of dextranomer microspheres on the synthesis of new collagen fibers and the migration of fibroblasts [40], which may explain the formation of pseudocysts. The European Association of Urology also does not recommend HA preparations with dextranomer for the treatment of SUI due to the high risk of side effects such as the formation of pseudocysts with intraurethral HA injections [41].

The effects of high-density HA are undoubtedly influenced by a crosslinking agent (adjuvant). Therefore, further research on HA preparations stabilized by various substances is necessary. Cross-linked HA is widely used in cosmetology to correct wrinkles and enlarge soft tissues. In cosmetology, divinyl sulfone and butadiol diglycidyl ether are widely used as crosslinking agents [14]. During one year, Zakirova et al. monitored 35 female patients who underwent correction of face and neck wrinkles using fillers based on HA cross-linked with butadiol diglycidyl ether. The complications included ecchymosis, petechiae, itching, swelling, redness, and soreness, which disappeared within 7 days after injections. After 12 months, ultrasound of the soft tissues of the injection site was performed. According to the authors, HA cross-linked with butadiol diglycidyl ether, was effective and safe. Only one patient, according to ultrasound, had three foci of induration in the prolabium area. The researchers associated this reaction with the presence of an autoimmune pathology (autoimmune thyroiditis) and foci of chronic infection in the patient [42]. Additional substances (adjuvants) in preparations for crosslinking of HA can cause the development of autoimmune inflammatory syndrome (ASIA). The term ASIA was coined by the Israeli immunologist, Yehuda Schonfeld in 2011 to denote a suspected autoimmune disease caused by adjuvants. There is a risk of a cross-autoimmune reaction to the components of own products of connective tissue and especially HA, which can manifest itself as arthralgia of any anatomical region, myalgia, skin reactions such as vasculitis, erythema of the face and décolleté, unprovoked rise in body temperature above 36.9°C, lymphadenopathy, unprovoked fatigue, increased fragility of nails and hair [43]. Thus, the presence of autoimmune diseases is a contraindication to the use of adjuvant-modified HA preparations.

Apolikhina et al. presented the results of treatment of 19 patients with confirmed SUI, who underwent injections of platelet-rich HA. Within 3 months, all patients had clinical recovery. In 12 cases, a double injection was required with an interval of 6 months; and a pronounced clinical effect was noted in 6 patients within 12 months. As a result of an allergic reaction to anesthesia, one patient was excluded from the study. The rest had no complications for 12 months [44]. We previously reported on the effectiveness (91.7%) per one year paraurethral use of 2% stabilized HA in the treatment of SUI in 26 patients with a minimum number of complications [45].

The fillers currently used are characterized by a different mechanism of action, which determines the long-term effect. Depending on the mechanism of action, two types of BA can be distinguished. Substances of the type 1 contain solid microparticles in an absorbable liquid or gel carrier, capable of causing inflammation with the formation of fibrous tissue at the site of injection. These BAs include silicone polymer, calcium hydroxyapatite, carbon-coated zirconium oxide, polyacrylate, and polyalcohol copolymer. BA type 2 includes homogeneous gels without solid particles, among which the most famous are polyacrylamide hydrogel and cross-linked HA preparations. Their therapeutic effect is based on the creation of additional volume without the phenomena of

fibrosis [23]. Due to the heterogeneity of studies, different methods for assessing the efficiency of different fillers in the treatment of SUI, it is difficult to conduct a comparative characterization to determine the most effective BA.

According to a 2020 meta-analysis conducted by Capobianco et al., the frequency of improvements in female patients with SUI and mixed urinary incontinence using BA in studies with a follow-up of one year or less and more than one year was 46.0% and 57.0%, respectively. The recovery rate for women with follow-up for one year or less and more than one year was 26.0% and 21.0%, respectively. In the treatment with BAs, complications were revealed in 0.4% of cases, namely vaginal infections, irritation, worsening of urinary incontinence [11].

A meta-analysis by Maggiore et al. showed that the objective cure after sling surgeries is better, but subjectively, the results did not differ significantly from that on using BA injections [46]. According to a 2017 Cochrane Review, surgical treatments are the most effective and least safe compared to fillers, but treatment efficacy varies depending on the mechanism of SUI [8]. The pathogenesis of SUI is associated with insufficiency of the urethral sphincter and/or hypermobility of the urethra [47, 48]. Hypermobility of the urethra leads to a lack of equal transmission of pressure from the bladder to the urethra. Insufficiency of the sphincter of the urethra causes insufficient closure of the urethra due to weakness of the smooth, striated muscles of the sphincter and may result from damage to the innervation or sphincter structures [49], leading to a more pronounced form of SUI than its hypermobility [50, 51]. These two conditions can be combined, thereby complicating the choice of treatment approach. With hypermobility of the urethra and/or insufficiency of the urethra sphincter, synthetic slings are a well-proven choice. However, in case of an isolated urethral sphincter insufficiency, synthetic slings may be less effective, while treatment with BA is quite effective. Several studies have shown that fillers could be effective for hypermobility of the urethra [52–54].

The optimal injection technique is not yet standardized [11]. Intraurethral and paraurethral injections were equally effective, but cystoscopy was necessary for intraurethral administration. A higher incidence of early postoperative complications (acute urinary retention) was observed with paraurethral administration, possibly due to the larger volume of the substance injected [8].

According to the recommendations of the European Association of Urology in 2020, BAs are recommended for the treatment of SUI for women interested in treatment with a low risk of complications, and to those informed about the short-term effect and possible re-treatment of urinary incontinence [41]. The American Urological Association guidelines indicate that BAs can be used in female patients with SUI who want to avoid more invasive surgery, are concerned about a longer recovery period from surgery, or are not getting enough relief from previous treatment for urinary incontinence. However, paucity of information supports the recommendation of one injectable agent over others [55]. The Russian clinical guidelines also noted the absence of a persistent effect of paraurethral injections of BAs on SUI [56].

In case of ineffectiveness of urethral injections, subsequent surgical treatment can be used. In a retrospective study of 43 patients with SUI, Koski et al. revealed that prior urethral injections were not associated with success of subsequent surgery [57].

CONCLUSION

BA can be considered as the first-line therapy for SUI for patients who do not want to undergo surgical treatment due to the risks of complications and those informed about the short-term effect [11]. The duration of action and the possibility of complications in the treatment of SUI using BA injections are determined by the characteristics of the BA and its route of administration. Recently, new BAs have appeared, the effect of which continues to be studied. A promising direction is the use of new HA-based BAs with an optimal choice of concentration, degree of "crosslinking" and type of "crosslinking" agent to ensure maximum duration of action and minimal side effects.

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