

Effectiveness of Periurethral Injection on Stress Urinary Incontinence

Stres Üriner İnkontinansta Periüretral Enjeksiyonun Etkinliği

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ABSTRACT Objective: To determine one-year subjective and objective evaluation results of periurethral injection (PUI) applied to women suffering from stress urinary incontinence (SUI). **Material and Methods:** Twenty five patients with complaints of SUI have participated in our study. Preoperative and postoperative results of urinalysis, stress and Q-tip tests, post voiding residual volumes (RV) and survey of incontinence quality of life (I-QOL) criteria were recorded. Later on, Urodex[®] (Cross-linked hyaluronic acid, detxranomere) was injected to them. The cases were monitored at regular intervals for a mean of 14 ± 5.84 months. **Results:** Eighteen (72%) out of all cases were encountered during menopausal period. Eight of the patients had previous gynecologic operations. Mean age was 53.97 ± 13.01 years. Mean application period of PUI was 6.95 ± 1.46 minutes. Differences between the preoperative and postoperative results of RV and I-QOL were not statistically significant. From subjective success point of view; 17 (68%) of the patients claimed no change on their incontinence problem, two (8%) of the patients claimed that their conditions were slightly improved, and six (24%) of the patients claimed that their conditions significantly improved. When objective success is considered, there was success in seven (28%) patients, and failure in 18 (72%) patients. **Conclusion:** PUI is a minimally invasive treatment method used in all types of SUI. PUI treatment might be preferred for the old, obese patients with additional health problems, having incontinence dependent on hypermobility at which the open surgery incurs a great risk. However, as the new techniques are not readily available, a periurethral injection technique may still be a valid choice in patients who have poor surgical risks, and to whom the low success rate has been adequately explained.

Key Words: Urinary incontinence, stress; urinary bladder neck obstruction

ÖZET Amaç: Stres üriner inkontinansı (SUI) kadınlarda uygulanan periüretral enjeksiyonun (PUI) sonuçlarının subjektif ve objektif olarak değerlendirilmesi. **Gereç ve Yöntemler:** SUI nedeniyle başvuran 25 hasta çalışmaya alındı. Preoperatif ve postoperatif olarak idrar tetkiki, stres ve Q-tip testleri, post-voiding rezidü volümleri (RV) ve inkontinans yaşam kalitesi anket (I-QOL) ölçümleri incelendi. Daha sonra bu hastalarda Urodex[®] (Cross-linked hyaluronic acid, dekstranomere) enjeksiyonu uygulandı. Hastalar ortalama 14 ± 5.84 ay süresince düzenli aralıklarla izlendi. **Bulgular:** Tüm olguların 18'i (%72) menopozal dönemde çalışmaya alınmıştı. Hastaların sekizi daha önceden jinekolojik operasyon geçirmişti. Yaş ortalaması 53.97 ± 13.01 idi. Ortalama PUI uygulama süresi 6.95 ± 1.46 dk. idi. Preoperatif ve postoperatif dönemdeki RV ve I-QOL arasında anlamlı farklılık gözlenmedi. Subjektif yarar açısından bakıldığında; 17 hasta (%68) inkontinans sorunlarında bir değişiklik olmadığını bildirdi, iki (%8) hasta durumun biraz daha iyi olduğunu bildirdi, ve altı (%24) hasta durumlarının belirgin düzeldiğini bildirdi. Objektif yönden başarı değerlendirildiğinde yedi (%28) hastada işlem başarılı bulunurken 18 (%72) hastada başarısız bulundu. **Sonuç:** PUI minimal invaziv bir yöntem olup SUI'nin tüm formlarında kullanılan bir metoddür. PUI tedavisi inkontinansı olan, cerrahi girişimin büyük risk oluşturduğu yaşlı ve ek sağlık sorunları olan, hipermobiliteye duyarlı hastalarda tercih edilebilir. Bununla birlikte yeni teknikler kullanılmaya henüz hazır olmadığından dolayı, PUI tekniği ameliyat olması sakıncalı olan, ve düşük başarı oranının kendilerine yeterince izah edildiği hastalarda hala geçerli bir seçenek olabilir.

Ahahtar Kelimeler: Üriner inkontinans, stres; mesane boynu tıkanıklığı

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Urinary incontinence is usually neglected, although it is encountered frequently. It impairs the quality of life by limiting routine daily activities. In addition, treatment cost is substantially high.¹ In a study on 22430 cases, urinary incontinence rate was found as 8.5% for women aged between 15-64 years, while it was found as 11.6% for the ones over 65 years of age.² Real stress urinary incontinence (SUI) constitutes 46% of all cases with urinary incontinence. The rate of stress urinary incontinence varies between 16-51% among women.³ Its treatment varies from simple physical exercises to the artificial sphincter implantation. Despite the presence of numerous different types of surgical approaches, colposuspension operation is the gold standard for treatment.⁴⁻⁶ Periurethral injection (PUI) is a method applied in stress urinary incontinence treatment. With this treatment method complication rates are low and the complaints of the patients resolve in a short time while their quality of lives improve. Patients with internal sphincter insufficiency, low grade urethral hypermobility, and normal detrusor function form the suitable patient group for this treatment. Periurethral substance injection is not a new method. In 1938, Murless described injection of a sclerosine agent to anterior wall of vagina. Following this, teflon, collagen, and more recently silicon have been used for the same purpose. The goal in PUI is to provide continence and closure of urethral lumen via increasing submucosal volume without changing the position of bladder neck or urethral support. There are some studies reporting healing rates of 70-90%, and cure rates of 10.3-50% with periurethral "bulking" agents in real SUI cases.⁷⁻¹⁰ Urethral injection treatment is preferred for old patients along with the patients for whom surgical treatment options may not be utilized. The most important advantage of this method is that morbidity and complications are low and it can be applied under local anesthesia.¹¹ Especially in selected cases, in spite of high costs, it can be preferred as the first choice. Disadvantages of the procedure are high costs, requirement of repeated treatment, and the risk of displacement of the injected material.

MATERIAL AND METHODS

The study was carried out with the approval of Mustafa Kemal University Medical Faculty Ethical Committee. Each patient was informed about the procedure and content of the study, and their oral and written consents were obtained. Twenty five patients who applied to our polyclinics with the complaints of urinary incontinence under stress conditions between June 2007 and June 2008 were included in our study. Two (8%) of the patients had a previous unsuccessful incontinence surgery. Before operation, demographic characteristics, urogynecological and neurological inspections and urinalysis of the patients were recorded. Stress and Q-tip tests were applied. Post voiding residual volumes were examined. Survey of incontinence quality of life (I-QOL) criteria was conducted and then scored according to the results. Later on, Urodex® (Cross-linked hyaluronic acid, detxranomere) was injected. The cases were monitored at regular intervals for 14 ±5, 84 months. Patients were questioned about their incontinence condition in terms of subjective success and stress tests were performed for objective assessment. Patients with negative stress tests were regarded as having successful results. After operation, urinalysis and postvoiding residual volumes were reexamined and survey of quality of life (I-QOL) was reconducted. Complications were recorded. Results were statistically evaluated.

RESULTS

Eighteen (72%) cases were in their menopausal period. Eight of the patients previously underwent gynecologic operations: Four had total abdominal hysterectomy and salphingo-oophorectomy, two had caesarean sections and the remaining two had incontinence operations. Mean parity was 5.31 ± 2.76 , mean body mass index was 31.06 ± 4.87 kg/m². Mean age of the patients was 53.97 ± 13.01 years. SUI was detected in 14 (56%) and mixed urinary incontinence (MUI) in 11 (44%) patients. Pre-operative RV average was measured as 18.20 ± 21.97 cc, and postoperative average RV, calculated at the 6th hour, was measured as 24.60 ± 26.97 cc. Increase in postoperative RV was not statistically

significant ($p= 0.087$). Mean application time of PUI was 6.95 ± 1.46 minutes. Postoperative complications developed in three (12%) patients. Two of them had urinary tract infection on postoperative first week, one of them had urinary retention and by application of catheterization intermittently, and urinary retention regressed on postoperative third day. Mean preoperative value was 63.92 ± 21.73 for incontinence quality of life scale (I-QOL), exploring the negative effects of incontinence on daily life and influence on mental condition, and mean postoperative 6th month value was 60.40 ± 19.87 while mean postoperative 12th month value was 55.44 ± 18.59 . In accordance with preoperative data, no significant improvement was statistically monitored on quality of life of the patients in postoperative 12th month ($p= 0.432$). The percentile change between the preoperative and postoperative 12th month value of quality of life scale was 3.64 ± 24.86 . From the subjective success point of view; 17 (68%) of the patients claimed no change on their incontinence problem, two (8%) of the patients claimed that their conditions slightly improved, and six (24%) of the patients claimed that their conditions significantly improved. When objective success is considered, there was success in seven (28%) of the patients, and failure in 18 (72%) of them.

DISCUSSION

PUI has been used for a long time as an alternative method to surgery in old patients suffering from UI in whom open surgery incurs a great risk. However, the best injection material has not been produced yet and research still continues. In a study were GAX-collagen was used as injection material, mean age of 131 cases was 67 years, and 29% of them had underwent surgical treatment previously. The patients were monitored approximately 12 months. As a result, while 13% of the patients had total cure, the symptoms improved in 27% of them.¹² In another study, in which collagen was utilized again, negative stress test was detected only in 10, 3% (19 patients) of the patients out of 184 cases that were monitored along 3 years.¹³ Furthermore, collagen may cause delayed type hypersensitivity reaction and arthralgia.¹⁴ Dextranomer microsp-

heres are found as average 80-250 micrometer particles in hyaluronic acid gel. Injection is performed by an instrument named Implacer, at the direction of 2, 4, 8, 10 o'clock under local anesthesia at outpatient settings.¹⁵ No distant organ migrations have been encountered in the experimental study with particles marked by radioactive iodine on rabbits.¹⁶ In MR studies, which were practiced with NASHA/Dx gel, after 12 months, existence of copolymer particles was identified with a ratio of 87.5%. This microcapsules start to shrink on the first 12th week and then fibroblasts migrate where they are injected and collagen synthesis is stimulated.¹⁷ Under local anesthesia, 42 patients received NASHA/Dx injection with implacer without requirement of cystoscopy, later on 18 patients received 2nd injection, and in the first three months 75%, at 6th month 63%, and at 12th month 58% of the patients were completely cured or their symptoms were improved.¹⁵ The ideal agent that will be used for PUI must have the following properties: non-allergic, minimal local inflammatory, non-migratory, repeatable in case of inadequacy, easily applicable, inexpensive, compatible with the tissue, minimally fibrotizing, non-toxic, absorbable (must preserve the injected volume), no further treatments, immunologically non-responsive, decomposable to sub-components, strong against deformation. No substance with these qualities have been found yet.¹⁸ Some studies reported improvement in 73% and total cure in 24-36% of the cases.^{19,20} Long term efficiency can be provided with reinjections. Duration of the efficiency depends on the quality of injection material, age of the patient, degree of urethral hypermobility, and severity of incontinence. In our study performed between 2007 and 2008, total cure was achieved in seven (28%) of the patients and we suggested that this rate was related to single dose of application and long term monitoring of the patients. It is a fact that SUI has many alternative treatment modalities and success rates are variable. But, usage area of urethral bulking agents is spreading out in most cases where the complaints are repeated. On the other hand it has to be taken into account that reapplication of these agents might cause inconvenience. As far as we are concerned, the most important question is what

kind of patients had better receive this treatment. We applied this procedure. to the patients who had intrinsic sphincter insufficiency, are very old, had unsuccessful previous incontinence surgery are overweight and ineligible to have general anesthesia because of co morbidities such as chronic obstructive pulmonary disease or heart problems.

CONCLUSION

PUI is a minimally invasive treatment method used in all types of SUI. Especially type III incon-

tinence (intrinsic sphincter insufficiency) is the primary indication of PUI. Besides, PUI treatment might be preferred for the old, obese patients with additional health problems, having incontinence dependent on hypermobility at which the open surgery incurs a great risk. However, as the new techniques are not readily available, a periurethral injection technique may still be a valid choice in patients who have poor surgical risks, and to whom the low success rate has been adequately explained.

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