TECHNOLOGY NOTE 2

Anesthesia For Transurethral Radiofrequency Energy Collagen Denaturation

Introduction

Transurethral radiofrequency energy (RF) collagen denaturation is a non-surgical, outpatient treatment for female stress urinary incontinence (SUI) secondary to hypermobility. Total treatment time, from perineal preparation and draping through completion of RF delivery, requires approximately 20 minutes. The transurethral treatment denatures collagen at microscopic sites circumferentially targeted within the bladder neck and proximal urethral submucosa. Transurethral RF collagen denaturation has demonstrated safety when performed with intravenous conscious sedation or a local anesthetic plus oral sedation.

Regardless of anesthetic approach, patients are administered a single dose of prophylactic oral antibiotic (such as a quinolone) at an appropriate time prior to treatment.

Conscious Sedation

Transurethral RF collagen denaturation using intravenous conscious sedation has demonstrated safety, efficacy, and patient comfort in clinical trials involving more than 160 women suffering from SUI.[1,2,3,4,5] Women received midazolam (Versed®) (typically 1mg to 4mg) and fentanyl (usually 25µg to 150µg). In addition, some women received propofol (Diprivan®) (typically no more than 200µg). All women underwent standard monitoring while receiving conscious sedation. While 1% or 2% lidocaine gel (not ointment) was utilized to lubricate the transurethral RF Probe, no other anesthesia or analgesia was administered.

At the time of discharge (when the conscious sedation had effectively worn off), 110 women in a U.S. clinical trial were asked to quantify their pain on a Visual Analog Scale (VAS). The scale ranged from "0 – no pain" to "10 – terrible pain." The mean VAS score was 1.3, and 51% of the women selected "0."

Local Anesthesia + Oral Sedation

Two clinical trials involving 49 women with SUI (16 in a foreign pilot trial, followed by 33 in a U.S. pivotal trial) have demonstrated the safety, feasibility, and patient comfort associated with transurethral RF collagen denaturation using local anesthesia plus oral sedation. None of the 49 trial subjects required premature termination of her treatment or conversion to conscious sedation for treatment completion (a 100% success rate for local anesthesia plus oral sedation).

In the U.S. clinical trial, 33 women with SUI were treated at three investigational sites. The physician investigators included one private practice urologist and two private practice gynecologists, and all treatments were performed in the physician's office. At the time of discharge, the 33 women were asked to quantify their pain on the same Visual Analog Scale (VAS). The scale ranged from "0 – no pain" to "10 – terrible pain." The mean VAS score was 1.4, and 42% of the women selected "0."

The local anesthetic plus oral sedation regimen utilized in the U.S. trial serves as the basis for the following guidelines. It is important to evaluate each patient's medical history individually to determine whether modifications to the following guidelines are indicated.

Oral Sedation

Diazepam (Valium®) 10mg is administered orally 30-90 minutes prior to treatment. Administration 45-60 minutes prior to treatment appears to best optimize the sedative effect. Reduction of this dose should be considered in elderly patients, in women with a known sensitivity to diazepam or related sedative agents, and in anyone with a pre-existing medical condition affecting the pharmacokinetics of the medication.

Local Anesthesia

The woman is placed in the lithotomy position and undergoes perineal preparation and draping according to each physician's routine practice.

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Either 1% or 2% lidocaine with epinephrine injectate is used for local anesthesia. A total of 10cc of lidocaine is utilized, delivered via 5cc bilateral injections. The anesthetic delivery target is the periurethral tissue (the tissue surrounding the urethra). **Specific use of a 25 gauge 1.25 inch needle is recommended** because, when passed fully into the periurethral tissue, the 1.25 inch needle delivers lidocaine to the tissue surrounding the bladder neck, the most proximal extent of the RF collagen denaturation treatment. Use of a longer needle may result in lidocaine delivery into or through the bladder neck wall. Use of a shorter needle may result in inadequate periurethral anesthetic delivery at the level of the bladder neck.

Local Anesthetic Delivery Specifics

The external urethral meatus (orifice) lies within a slightly protruding tissue mound. Surrounding this protruding tissue mound is a sulcus (tissue depression) which identifies the border between the outer urethral wall and the surrounding periurethral tissue.

1. The 25 gauge 1.25 inch needle is advanced at either the 9 o'clock (patient's right lateral) or 3 o'clock (patient's left lateral) position through the skin within the sulcus adjacent to the protruding external urethral meatus tissue mound. **The needle is passed parallel to the adjacent urethra until the plastic needle hub abuts the skin and the needle lies completely within the periurethral tissue** (Figure 1).

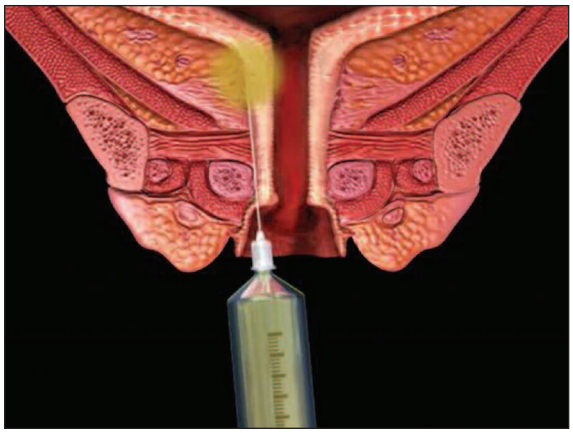

Figure 1. Needle positioned to deliver local anesthetic to periurethral tissue at the level of the bladder neck.

2. The syringe plunger is gently withdrawn to confirm that the needle tip is not positioned within a vascular structure.
3. Without withdrawing the needle from the tissue, 1-2cc of lidocaine is delivered into the periurethal tissue adjacent to the bladder neck.
4. Next, as the needle is slowly withdrawn approximately 1cm, 3-4cc is delivered (for a total of 5cc), infiltrating the periurethral tissue adjacent to the proximal urethra (Figure 2).

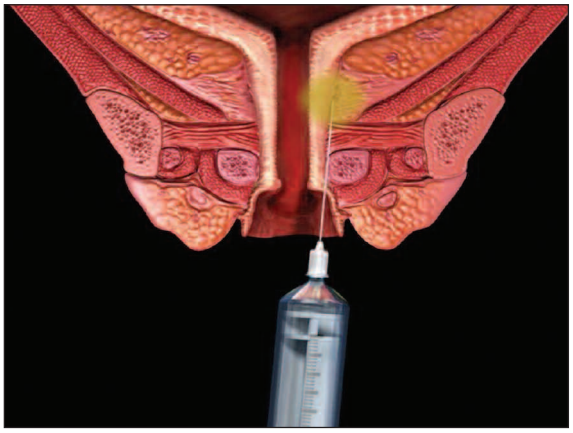

Figure 2. Needle positioned to deliver local anesthetic to periurethral tissue at the level of the proximal urethra.

5. The needle is then completely withdrawn, **with no local anesthetic being delivered to the periurethral tissue adjacent to the mid or distal urethra.**
6. The process is then repeated identically on the contralateral side (at the 9 o'clock or 3 o'clock position).

The result of this process is the bilateral administration of 5cc lidocaine (a total of 10cc) into the left lateral and right lateral periurethral tissue adjacent to the bladder neck and proximal urethra.

Note that following lidocaine administration, it is important to allow at least five minutes to pass prior to initiating the RF collagen denaturation treatment. This allows the lidocaine to further dissipate into the periurethral tissue surrounding the bladder neck and proximal urethra, as well as for an adequate anesthetic tissue response. During this waiting period, the bladder catheterization required prior to RF treatment may be performed.

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Summary

Non-surgical transurethral RF collagen denaturation has demonstrated safety and efficacy in the outpatient treatment of women suffering from SUI secondary to hypermobility. Clinical trials have also demonstrated that the treatment can be safely and comfortably performed using either intravenous conscious sedation or local anesthesia plus oral sedation. Thus, physicians are provided two options when recommending an anesthetic approach for their SUI patients undergoing non-surgical transurethral RF collagen denaturation.

References

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