

THE SAFETY OF CARBON BEAD INJECTION FOR INCONTINENCE IN PATIENTS ON WARFARIN

Hypothesis / aims of study

To determine the safety of the use of Durasphere™ (Carbon Medical Technologies, Saint Paul, Minnesota) in patients on warfarin anticoagulation.

Study design, materials and methods

This retrospective study analyzed twenty patients (nineteen women and one man), all taking therapeutic doses of warfarin, who underwent carbon bead injections for the treatment of SUI between 1999 and 2005. All patients were diagnosed with either ISD or mixed urinary incontinence and had bladder outlets absent of hypermobility. A coagulation panel was not routinely drawn prior to the procedure in patients on stable warfarin regimens as managed by their primary physicians. Patients were not asked to hold any of their medications before or after the procedures.

For the nineteen women, the carbon bead injections were performed under local anesthesia in an out-patient urodynamic suite. (The single male patient had the injections performed transurethraly under general anesthesia in a day-surgery center.) For the nineteen women, local anesthesia and periurethral injection of the carbon bead bulking agent was accomplished by a technique previously described [1]. Under cystoscopic guidance, the 1.5-inch bent, 18-gauge needle was inserted periurethraly at either the 4 or 8 o'clock position to approximately 0.5 cm distal to the bladder neck and the carbon beads were injected. The material was injected until either the luminal appearance demonstrated coaptation of the mucosa or 6 ml of the product had been used. If good circumferential coaptation of the tissue could be achieved by injecting the carbon beads from just one injection site, the needle was not inserted on the other side. After removing the needle and cystoscope, direct pressure was held at the injection sites until hemostasis was achieved. Sequential injections were performed at one-month intervals until continence was achieved.

Results

Nineteen women and one man underwent carbon bead injection therapy on thirty-six different occasions. The patients required an average of 1.8 sessions to achieve the desired continence, or until it was determined that future injections would not be of significant benefit. One minor complication related to the anticoagulation occurred with a patient developing a small periurethral hematoma as determined by bruising in the region of the left periurethral space on physical exam. A serious adverse event was encountered in another patient who developed urinary retention and intravesical hemorrhage. She presented to the emergency department two days after the procedure with gross hematuria and urinary retention. She required a blood transfusion and bladder irrigation. On review of her case, during the periurethral needle placement the needle entered the bladder at the bladder neck, however bleeding was not acute.

Interpretation of results

One of the benefits of carbon bead injection therapy is that it is a minimally invasive treatment option that can be performed in the office setting under local anesthesia. The minimal morbidity associated with the procedure makes it especially good for patients with multiple medical problems, such as those who require long-term anticoagulation.

Prior to performing any surgical procedure in patients on warfarin therapy, the physician must determine whether or not the anticoagulation should be reversed, and if so the safest means of accomplishing this goal. This involves consideration of both the patient's risk of a thromboembolic event if anticoagulant therapy is interrupted and the risk of bleeding that is associated with the procedure. Obviously, an office-based procedure that can be performed safely without the reversal of the anticoagulation therapy is very attractive.

Our experience with the use of carbon bead injection therapy in these twenty patients therapeutic on warfarin demonstrates that the injection of carbon beads under local anesthesia can be safely performed. This obviates the need for reversal of the anticoagulation, a process that can be financially expensive as well as associated with an increased risk of thromboembolic events. Patients and physicians must be aware, however, that there is still a risk of hemorrhage (acute or delayed) with the procedure.

Concluding message

The periurethral injection of carbon beads under local anesthesia in patients requiring long-term warfarin anticoagulation can be safely performed without interruption or reversal of the warfarin therapy. There is, however, a risk of both acute and delayed hemorrhage associated with the procedure.

Reference

1. Beyond collagen: injectable therapies for the treatment of female stress urinary incontinence in the new millennium. Urol Clin N Am 29: 559-574, 2002.