

INCIDENCE OF PUBIC OSTEOMYELITIS AFTER BLADDER NECK SUSPENSION USING BONE ANCHORS

ROGER P. GOLDBERG, MARIE BLANCHE TCHETGEN, PETER K. SAND, SUMANA KODURI,
RAYMOND RACKLEY, RODNEY APPELL, AND PATRICK J. CULLIGAN

ABSTRACT

Objectives. To determine the incidence of pubic osteomyelitis after bladder neck suspension using suprapubic bone anchors.

Methods. The target population consisted of 290 consecutive women who underwent bladder neck suspension using suprapubic bone anchors between June 1994 and November 1999 at two referral centers. A structured telephone questionnaire was designed to elicit any history of clinical symptoms suspicious for pubic osteomyelitis. Positive responses were followed up by a detailed review of the medical records. Nonresponders were evaluated by chart review, with negative cases included only if the documented follow-up reached 1 year.

Results. The sample consisted of 225 women, representing 77.6% of the study population, with a mean age of 69.7 years (range 40 to 88) and a mean follow-up of 31.8 months (range 13.4 to 42.2). Of the 225 women, 179 (80%) completed the telephone survey; 46 patients (20%) were evaluated by long-term chart review. Three patients (1.3%) reported positive responses to the screening questionnaire and were confirmed to have developed pubic osteomyelitis. Each had undergone exploratory laparotomy, anchor removal, bony debridement, and prolonged parenteral antibiotics. The most common noninfectious complaints were irritative voiding symptoms and pubic or groin pain responding to "conservative" therapy (3.5%), including 1 case of osteitis pubis. One subject underwent repeated operation because of erosion of the sling sutures into the bladder.

Conclusions. The estimated incidence of osteomyelitis after bone-anchored bladder neck suspension was 1.3%. Although postoperative osteomyelitis is rare, each case incurs substantial morbidity and a complicated postoperative course. UROLOGY 63: 704–708, 2004. © 2004 Elsevier Inc.

Pubic bone anchors have been available as an adjunct in urinary incontinence surgery since 1992. Using a relatively small surgical dissection, bone anchors can provide a stable, fixed point for suture attachment. Advocates of this technology cite, in addition, the possibility of a reduced operative time compared with traditional anchoring techniques. Despite these technical attributes of bone anchors, others have criticized the lack of scientific evidence establishing their efficacy and safety.¹ More specifically, concern over postoperative pubic osteomyelitis has led some surgeons to

abandon their use. The morbidity associated with pubic osteomyelitis after bone anchoring has been well established^{2–5}; however, its incidence after pubic bone anchor placement during female pelvic reconstructive surgery has not been established. We undertook this retrospective study to determine the incidence of postoperative pubic osteomyelitis within a large cohort of women who underwent surgical repair for stress urinary incontinence using bone anchors.

MATERIAL AND METHODS

The study population included all 290 consecutive patients undergoing bladder neck suspension using suprapubic bone anchors, by one of four attending surgeons, between June 1994 and November 1999. Bone anchor procedures were identified through a manual review of the case lists encompassing the defined study period. Of the 290 patients, 171 women underwent surgery at the Cleveland Clinic and 119 women at the Evanston Continence Center.

From the Evanston Continence Center, Northwestern University Medical School, Evanston, Illinois; and Division of Urology, Cleveland Clinic Foundation, Cleveland, Ohio

Reprint requests: Roger P. Goldberg, M.D., M.P.H., Evanston Continence Center, Northwestern University Medical School, 1000 Central Avenue, Suite 730, Evanston, IL 60201

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TABLE I. Telephone questionnaire

1. Since your incontinence operation, have you had any problems or complications?
2. Have you been hospitalized, or treated at any medical facility, since the placement of your bone anchors?
3. Have you received antibiotics, or other medications, since the surgery?
4. Have you undergone any radiology testing, as a result of pelvic discomfort or fevers?
5. Do you have pain in your lower abdomen, groin, hip, thigh, or pelvis? Did you have this kind of pain at some point after your surgery?
6. Do you have difficulty walking?
7. Is there any drainage, redness, or tenderness in the area where the bone anchors were placed?

Bone anchor operations included the Vesica,⁶ modified Pereyra with Mitek GII anchors, in situ sling, vaginal wall sling, and fascial patch sling procedures. Depending on the specific incontinence operation performed, either a single transverse midline incision or two separate suprapubic incisions (2.5 cm) to each side of the midline were used. Monofilament nonabsorbable sutures were used for the bone anchoring procedure in all cases. The suture ends were attached to the bone anchors and anchored into the pubic rami bilaterally, 1 cm lateral to the midline on each side, at the level of the pubic tubercle. One of several commercially available devices (Microvasive, Mitek, AMS) was used to either drill or press the anchor into the cortex of the pubic symphysis at its superior portion, with metallic "shoulders" preventing the anchor from penetrating too deeply into the bone. Suture arms were passed into the vagina, using Vesica suture passers or Pereyra needles. They were fastened to either autologous rectus fascia (fascial patch sling) or the vaginal wall (Vesica, Pereyra, vaginal wall sling). The free suture ends were then brought back into the retropubic space and through the suprapubic incision using one of these specialized needles.

In every case, the pubic area was shaved and prepared with povidone-iodine. The abdominal and vaginal operative areas were considered individual sterile fields. The patients received broad-spectrum intravenous antibiotics perioperatively, consisting of either a first-generation cephalosporin or multiagent therapy with gentamicin and clindamycin or vancomycin. Suprapubic incisions were irrigated with an antibiotic (Bacitracin) solution after bone anchor placement and again just before closure. Oral cephalosporin was continued for a period of at least 5 days postoperatively. To decrease the risk of contamination, care was taken to keep the sutures completely away from the vaginal field until the time of fixation to the vaginal epithelium or sling material.

The structured telephone questionnaire (Table I) used for long-term follow-up consisted of seven open-ended questions intended to elicit clinical evidence of possible pelvic infection. The questions were designed to maximize sensitivity and to detect all cases suspicious for previously treated or ongoing osteomyelitis. Urogynecology or female urology fellows, who had no direct participation in the initial surgical procedures, conducted the telephone interviews. Patients were instructed to report both immediate and delayed symptoms and any postoperative medical attention or treatment, regardless of where it was received. Any positive questions were followed up with additional patient interview and a review of the hospital and office records. For patients unreachable by telephone after multiple attempts, chart reviews were conducted. The chart

review data were retrieved from postoperative progress notes and visual analog symptom questionnaires quantifying pelvic and pubic pain symptoms, which had been completed by the patients at each office visit. Patients with a postoperative follow-up of less than 1 year were excluded from the final prevalence calculation, because although no cases suspicious for osteomyelitis were found, the possibility of delayed presentation could not be excluded.

RESULTS

The review of the operative records revealed 171 consecutive bone anchor procedures at the Cleveland Clinic from 1994 to 1999 and 119 cases at the Evanston Continence Center. The overall study population consisted of 290 subjects. The cohort was characterized by a mean age of 69.7 years (range 40 to 88) and a mean parity of 2.8 (range 0 to 9). Fifty-six percent were postmenopausal and 43% were using hormonal replacement therapy. A substantial number of previous reconstructive surgical procedures had been performed in these women, reflecting the referral practice settings at each institution. These included prior hysterectomy (33%), retropubic urethropexy (7.5%), needle suspension (2.5%), suburethral sling procedure (0.8%), and colporrhaphy (14%). At the time of the stress incontinence operation, concomitant procedures included vaginal hysterectomy (13%), anterior (51%) and posterior (46%) colporrhaphy, sacrospinous vault suspension (35%), enterocele repair (38%), and McCall culdoplasty (5%).

Of the 225 women in the final study sample, 179 (80%) completed the telephone survey; 46 patients (20%) were evaluated by long-term chart review only, with progress notes or visual analog questionnaires available for review at a mean interval of 19.5 months. Forty-five of these individuals were unreachable by telephone or had died. One patient declined interview; her chart review up to 18 months revealed no infectious complications.

The mean follow-up was 31.8 months (range 13.4 to 42.2). One or more positive survey responses were observed for 6.7% of the sample. Three patients (1.3%) reported positive responses to the screening questionnaire and were confirmed to have developed pubic osteomyelitis. Each of these individuals had undergone exploratory laparotomy, anchor removal, bony debridement, and prolonged parenteral antibiotics. Intraoperative cultures for all cases revealed polymicrobial, mixed aerobic, and anaerobic flora.

The first patient with pubic osteomyelitis had a history of renal transplant 6 years prior and was taking chronic immunosuppressive agents (cyclosporine, Imuran, and Florinef). Her medical history was also notable for insulin-dependent diabetes mellitus. Her pelvic reconstructive surgery included an in situ sling with drill-in pubic bone

anchors. Three weeks after surgery, the patient developed low-grade fevers accompanied by pain in her left pelvic area with radiation to the hip. Pubic bone tenderness was notable on examination. Nuclear bone scanning showed increased uptake suggestive of pubic osteomyelitis. Computed tomography revealed soft-tissue inflammation without other specific findings. The patient underwent surgical exploration 12 weeks after the initial surgery. Both bone anchors had dislodged, and extensive periosteal debridement was performed.

The second osteomyelitis case involved a 70-year-old woman undergoing vaginal wall sling using drill-in pubic bone anchors, performed for the indication of four-degree cystocele and potential genuine stress incontinence. She had no known underlying medical conditions increasing her baseline risk of infection. Three weeks after surgery, she developed right groin pain, without associated fever, erythema, or constitutional symptoms. Four weeks postoperatively, nontender warmth and erythema was appreciable in the suprapubic region. Plain radiography revealed marked irregularity with fragmentation of the inferior pubic ramus. Computed tomography revealed no specific findings suggestive of osteomyelitis. Radiolabeled leukocyte scanning showed increased leukocyte accumulation near the midline, but no definite bony involvement. Surgical exploration was notable for detached bone anchors; foreign body removal and debridement was performed.

The third case was notable for delayed presentation of pubic bone tenderness, at 4 months after modified Pereyra bladder neck suspension using drill-in bone anchors. The patient's medical history was notable for chronic corticosteroid use for osteoarthritis. Physical examination revealed a large, tender suprapubic mass, with overlying erythema. Computed tomography and nuclear bone scans were both suggestive of bony involvement. Her surgical treatment included drainage of the suprapubic abscess and wide debridement of the pubic periosteum. The right-sided bone anchor was found floating in the abscess cavity.

Other postoperative symptoms were encountered during the survey process. The most common clinical complaints elicited by the survey were irritative voiding symptoms and persistence of chronic symptoms unrelated to the pelvic operation (osteoarthritis, low back pain, hip discomfort). Pubic or groin pain resolving without surgical intervention and responding to "conservative" therapy was reported by 8 women (3.5% of the study sample), with the most significant as follows. One patient had persistent difficulty with bending. Another patient reported pain with walking. The third patient underwent repeated operation be-

cause of erosion of the sling sutures into the bladder, diagnosed 12 months after the initial surgery. The fourth patient was diagnosed with osteitis pubis, 6 weeks postoperatively. Her treatment had included oral cephalosporin and a nonsteroidal anti-inflammatory medication for 2 weeks, and she reported no residual pain symptoms at the time of her study participation. The inclusion of the first, second, and fourth patients resulted in a 1.3% rate of adverse postoperative symptoms not consistent with osteomyelitis. The remaining individuals reported self-limited pain that appeared consistent with a normal postoperative recovery, resolving within 3 to 6 months.

COMMENT

Concern over osteomyelitis after the use of pubic bone anchors stems from several theoretical risk factors for infection. Trauma and ischemia are incurred as the anchor is drilled or pressed into the bony cortex and the surgical area is devascularized. The presence of a foreign body presents another risk, because titanium and monofilament suture materials are placed into and around the bone. Finally, the possibility of transvaginal bacterial migration along the suture into its bony insertion—particularly when the anterior vaginal wall is traversed by suture material—creates an opportunity for vaginal flora to infect the retropubic space. In 1977, Osborne and Wright⁷ reported that the use of sterile scrubbing fails to sterilize the vagina fully, resulting in a clean, but not sterile, retropubic field during these procedures.

Several case series have been reported on bone anchors, reporting no or very few cases of osteomyelitis. None, however, were designed to determine specifically the incidence of osteomyelitis or infectious complications. Benderev⁸ reported no complications using Mitek anchors in 53 women. Rare cases of suprapubic infections occurred among 150 subjects in the initial series using the Vesica procedure⁹; however, these cases were reported to have resolved with oral antibiotic therapy alone, arguing against bony involvement. Between 1994 and 1999, numerous case series have been published on the Vesica^{10–12} and In-Tac¹³ anchors, accompanying both needle suspension and suburethral sling procedures. Appell¹⁴ reported 2 cases of osteomyelitis among 71 subjects in 1997 and none among 118 women who underwent bone-anchored suburethral sling procedures. Schultheiss *et al.*¹⁵ recorded 1 case among 37 procedures in 1998. Larger case series involving press-in bone anchoring systems have reported no cases of osteomyelitis in several case series, with varying lengths of follow-up and no systematic evaluation.^{16–20} Rackley *et al.*²¹ estimated an osteo-

myelitis rate on the basis of the case series published from 1990 to 2000. After suprapubic bone anchor placement, as determined by pooled statistics, this estimated rate was 0.6%, and no statistically significant difference was found between the transvaginal and suprapubic routes. None of these previous studies incorporated a uniform survey tool to screen for osteomyelitis systematically.

The present study design involved interviewing patients using a structured questionnaire designed to capture any postoperative complications regardless of where or when they were treated. This method was intended to minimize the potential for bias resulting from patients seeking care at other facilities—a factor that may result in underestimation of the true incidence of postoperative complications. The population was derived from two training centers for these procedures to increase the sample size and to reduce the confounding effect of operator inexperience. Potential limitations of our study design should be considered, including 22% of the target population who were unreachable and without adequate data for review—introducing the potential for response or “healthy volunteer” bias and underestimation of symptom prevalence. Our use of chart reviews might have reduced, but could not fully eliminate, this effect. Patients declining participation in the survey might have been cared for at other institutions. Furthermore, the retrospective study design might theoretically have introduced recall bias, although the typical severity of osteomyelitis-related symptoms should have served to increase the accuracy of event recall.

The pubic osteomyelitis cases occurring within this cohort illustrate, foremost, the potential for delayed presentation and also the difficulty of establishing the diagnosis on the basis of nonspecific early symptoms. The presence of these overlapping and nonspecific symptoms can lead to a delayed diagnosis of early osteomyelitis because pain, fever, and inflammatory signs may be attributed to soft-tissue infection or surgical healing. Both osteitis pubis and osteomyelitis may be characterized by the absence of fever, symmetric bony destruction of the symphysis, pelvic pain and gait disturbances, a delayed onset of symptoms, and failure to improve with antibiotics alone. Although osteitis pubis results in bony destruction of the margins of the symphysis, in contrast to osteomyelitis, it is treated with rest, physical therapy, and nonsteroidal anti-inflammatory medications. Some investigators have suggested that early cases of osteomyelitis may be misdiagnosed as osteitis pubis, leading to an underestimation of infectious risk. An indolent infection may only become apparent weeks later, when a sinus tract develops or a surgical wound breaks down. Chronic infection may

lead to ischemic necrosis of bone and lysis owing to phagocyte activity. As pus spreads into the vascular channels, intraosseous pressure may increase, leading to further impairment of blood flow and more ischemic changes. Histologically, with chronic osteomyelitis, osteocytes are replaced by necrotic bone, and organisms are absent.

Early diagnosis and the initiation of antibiotic therapy are important to prevent necrosis; in most cases, this will require a combination of diagnostic modalities. Gram stain or culture of the abscess may help to establish pathogenicity but cannot differentiate between soft-tissue and bony involvement. Most cases of osteomyelitis associated with the female genital tract are polymicrobial, mixed aerobic, and anaerobic. The erythrocyte sedimentation rate and C-reactive protein levels should be elevated with active disease, even in the absence of leukocytosis or constitutional symptoms. Because plain radiographs are not sensitive, advanced radiologic techniques may be required. Technetium radionuclide scans are typically positive within 24 hours of symptom onset; as a mirror of osteoblast activity, this test provides adequate sensitivity, but poor specificity, for diagnosing osteomyelitis. Gallium-citrate and indium-labeled leukocyte or immunoglobulin scans can help differentiate osteomyelitis from fractures, tumors, or infarction. Ultrasonography may reveal occasional periosteal fluid collections, periosteal thickening, or abscesses in soft tissue near bone. Computed tomography will reveal soft-tissue involvement more reliably than bony involvement. Computed tomography-guided needle aspiration or biopsy may play a useful role for establishing the diagnosis. Magnetic resonance imaging has equal sensitivity to bone scanning. In general, the role of diagnostic imaging in chronic osteomyelitis is to confirm the presence of active infection and to delineate the extent of debridement necessary to remove necrotic bone and abnormal soft tissue completely.

Even when promptly diagnosed, the treatment of osteomyelitis centers on surgical exploration, removal of all foreign bodies, and debridement, followed by parenteral antibiotic therapy for 4 to 6 weeks. The prolonged intravenous antibiotic therapy is necessitated, in part, by the tendency of bacteria to escape host defenses by adhering tightly to damaged bone and coating themselves and underlying surfaces with a protective polysaccharide-rich biofilm. Few data support the use of oral antibiotics.

CONCLUSIONS

On the basis of this retrospective evaluation of a large surgical cohort, the estimated incidence of osteomyelitis after bone-anchored bladder neck

suspension is 1.3%. An additional 1.3% of women reported adverse postoperative symptoms that were not consistent with osteomyelitis. Although postoperative osteomyelitis is rare, each case incurs substantial morbidity and a complicated postoperative course. Early recognition of retropubic abscesses, wound hematomas, unexplained constitutional symptoms, or atypical pain, tenderness, or gait disturbance should trigger an aggressive diagnostic approach.

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