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Use of periurethral injections of polyacrylamide hydrogel for treating post-vesicovaginal fistula closure urinary stress incontinence

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Abstract

Aims: Following successful closure of obstetric genitourinary fistula, stress urinary incontinence (SUI) is a common and challenging problem. Despite many decades of various treatment options, the effective management of post-fistula SUI remains unresolved. This study aims to assess the feasibility of periurethral injections of polyacrylamide hydrogel, commonly used for urinary stress incontinence in non-fistula women, in women with post-fistula closure SUI.

Material and Methods: Women with urinary incontinence following successful fistula closure were assessed to exclude detrusor overactivity and urinary residual volumes of more than 100 mL. The urethrovesical junction was identified and polyacrylamide hydrogel was injected through the periurethral skin and vaginal epithelium at three sites.

Results: Four women with post-fistula SUI were treated with polyacrylamide hydrogel injections. Three of the four women were dry post-operatively and remained continent at discharge.

Conclusion: In the short-term, periurethral injections of polyacrylamide hydrogel appears to be a promising method to treat post-obstetric fistula urinary stress incontinence.

Key words: bulking agent, obstetric fistula, urinary incontinence.

Introduction

Obstetric injury is the most common cause for genitourinary fistula with an estimated 2.6% of Ugandan women of reproductive age complaining of symptoms of fistulae.[1] Thus, the genital tract and lower urinary tract have often suffered marked tissue loss and scarring. It is therefore not surprising that these women are at significant risk of post-fistula closure bladder dysfunction. Stress urinary incontinence (SUI), overactive bladder symptoms and incomplete bladder emptying occur commonly following successful obstetric genitourinary fistula (VVF) repair. Persisting urinary incontinence has been reported in between 16% and 24% of women despite successful fistula closure.[2,3]

While treatment options for overactive bladder and incomplete bladder emptying in women with post-fistula bladder dysfunction, such as anticholinergic medications and catheter management, are not well documented in the literature, most fistula units do make use of these options if available with some success. The treatment of post-fistula SUI includes pelvic floor rehabilitation, urethral plugs and a number of continence surgery options.

Hilton *et al.*[4] first described the use of periurethral injection of autologous fat for the treatment of

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'sphincter insufficiency' following closure of obstetric urogenital fistula. Their series of six cases did demonstrate a 66% cure/improvement rate with short-term follow-up. A subsequent study of women with SUI with no history of fistula, by Lee *et al*.,[5] compared periurethral injection of fat with periurethral injection of saline (control) at 3 months' follow-up. These results did not show any benefit of fat injection compared to saline injection, with a success rate in both groups of around 20–22%. In addition, one death due to pulmonary fat embolism occurred out of a total of 189 procedures. There have been no documented studies or cases of the use of synthetic bulking agents in women with post-obstetric fistula repair SUI.

This series utilized periurethral injections of polyacrylamide hydrogel (Bulkamid, Ethicon, Johnson & Johnson Medical) as a periurethral bulking agent in a series of four women with SUI following successful closure of obstetric genitourinary fistula.

Methods

Ethics approval was obtained from the HEAL Africa Ethics Committee. Between 29 August 2011 and 9 September 2011, 65 women presented to the fistula clinic at HEAL Africa Hospital, Goma, Democratic Republic of Congo, for assessment of presumed fistula. Four of these women with a history of previous VVF repair were assessed to have an intact bladder (dye test negative) with SUI, and to be suitable for bulking agent continence surgery.

Bulkamid hydrogel is a transparent polyacrylamide gel consisting of 97.5% non-pyrogenic water and 2.5% cross-linked polyacrylamide (Ethicon, Johnson & Johnson).

Urodynamics assessment and cystoscopy were not available. Continence surgery was only considered after thorough clinical assessment of the bladder. A dye test was performed in all cases to exclude any residual fistula. The bladder was catheterized to measure residual urine volume. A Foley catheter was placed in the bladder and the bladder filled with saline to ≥300 mL. The catheter was held vertically approximately 15 cm above the pubic symphysis and the level of fluid in the catheter identified. If there was no elevation of the fluid and no urge symptoms, then the detrusor was considered to be stable. If there was no clinical assessment of detrusor overactivity and the residual urine volume was <100 mL with a positive cough test, then a bulking agent continence surgery was offered. The bulking agent surgery was performed under general anesthesia. Cystoscopy was not used as there was no cystoscopic equipment available. The urethral length and estimated location of the urethrovesical junction was established using a Foley catheter. The direction and path of the urethra was determined using a metal catheter. Bulkamid (1 mL per patient) was injected with a long 23G needle through the periurethral skin and vaginal epithelium, in three sites, at 3, 6 and 9 o'clock. The bladder was emptied at the conclusion of the procedure. The procedure was covered with prophylactic intravenous antibiotics.

A number of women had a history of previous 'urethral lengthening' to assist with urinary incontinence. This procedure involved using the skin of the labia minora to elongate the urethra, hence the new external meatus following the procedure is near the clitoris.

Results

The four cases of periurethral bulking surgeries are presented.

Case 1

A 33-year-old woman, para 2 (vaginal deliveries) with no live children, presented with urinary incontinence. She had undergone four VVF repairs over the previous 9 years. She initially was booked for an examination in the operating theatre as the initial assessment in the clinic was inconclusive. Her dye test was negative and the bladder was filled to 300 mL with no observed rise in detrusor pressure. Marked stress incontinence was demonstrated. She subsequently underwent injection of 1 mL bulking agent (Bulkamid). Day 1 postoperatively she developed urinary retention that required drainage with an in/out catheter. She subsequently was able to void well and at 12 days postoperatively, remained dry.

Case 2

A 48-year-old woman, para 7 (vaginal deliveries) with one live child, presented with urinary incontinence. She had a history of 10 VVF repairs, with her last repair 2 years ago. She also required an examination in the operating theatre for further assessment. She had a negative dye test, and marked SUI was demonstrated. The bladder was filled to 300 mL with no rise in detrusor pressure observed. The woman had a 5-cm elongated functionless urethra due to previous urethral lengthening. One milliliter of Bulkamid was injected at the bladder neck. On day 2 postoperatively she complained of symptoms of a urinary tract

infection, which was treated with further antibiotics and resolved rapidly. At 11 days postoperatively she remained continent.

Case 3

A 35-year-old woman, para 1 (stillbirth), presented with continuous urinary incontinence despite 11 previous attempts at VVF repair over the preceding 10 years. On examination, an elongated 5-cm urethra (from previous urethral lengthening) was evident, and the vagina was markedly stenosed. She underwent periurethral injection of 1 mL Bulkamid at the bladder neck. At 10 days postoperatively, she had only mild SUI.

Case 4

A 23-year-old woman, para 1 (cesarean section) stillbirth, presented with continuous urinary incontinence and a history of three previous VVF repairs, with her last repair 1 year ago. She had an elongated urethra from a history of urethral lengthening with marked leakage per urethra. A catheter was unable to be inserted in the outpatients department due to the unusual angulation of the urethra from the previous urethral lengthening surgery. She then underwent an examination under anesthesia where a catheter could be inserted and the dye test was negative. The bladder was filled to 300 mL with no detrusor overactivity observed. Pubococcygeal sling surgery was performed. Postoperatively she had some improvement in her incontinence with remaining dry in bed; however she leaked significantly while walking. She was then rescheduled for injection of Bulkamid, where 1 mL Bulkamid was injected. At final assessment, 5 days following her Bulkamid injection, she did not complain of any leakage of urine.

Discussion

Post-obstetric fistula SUI continues to be a challenging problem. Urethral plugs have been used widely in a few fistula centers with moderate success and complications;[6] however, effective surgery for SUI would be definitive management.

The surgical procedures documented in the literature include abdominal sling procedures using fascia lata, rectus fascia, or synthetics, and vaginal pubococcygeal or fibro-muscular slings. Ascher-Walsh *et al*.[7] reviewed 140 women who were treated with a sling procedure for SUI following successful fistula closure. Outcome was assessed clinically with a median follow-up time of just over 2 months, with 24.4% being identified as dry. In the group of women undergoing a polypropylene mesh sling, the mesh erosion rate was 20%.[7] Carey *et al*.[8] used urodynamic assessment to identify a group of nine women with urodynamic stress incontinence only following fistula closure. Abdominal retropubic urethrolysis, and insertion of a rectus sheath fascial sling and retropubic omental graft was performed. This resulted in a 78% success rate (subjective) at 4 weeks' follow-up and 67% success (subjective and objective with repeat urodynamic studies) at 16 months' follow-up. Abdominal urethrolysis with rectus sheath fascial sling, while resulting in a moderate success rate, does require an abdominal approach with often complicated dissections as the space of Retzius is usually obliterated and therefore does risk significant complications. Local muscle sling procedures were first described in 1958[9] for the treatment of post-fistula SUI. A similar technique was reintroduced in 2004[10] and did result in a success rate of 67% immediately postoperatively.[11] Unfortunately this technique is not possible in many women who have suffered serious injury with loss of tissue, resulting in insufficient pubococcygeal/fibro-muscular tissue to create an adequate sling. Long-term follow-up of this technique is not yet available and the benefit of the local tissue sling would be expected to decline over time. Urinary diversion is also used where continence surgery is not successful.

Periurethral injections of bulking agents have been used in the treatment of SUI for over a century,[12] with significant improvements in safety and success rates with the development of material technologies. Several bulking agents are currently in use, including bovine collagen, porcine collagen, carbon-coated zirconium beads, silicon particles, calcium hydroxylapatite, and polyacrylamide hydrogel. Kirchin *et al*.[13] reviewed 14 trials, which included 2004 women. They concluded that the evidence available was insufficient to guide clinical practice. Recent studies assessing polyacrylamide hydrogel[14] have demonstrated a good safety profile and useful success rates in women with symptomatic SUI. A potential benefit of periurethral bulking agents is that it is minimally invasive surgery. Lose *et al*.[15] determined a 66% subjective response rate in 135 women with symptomatic stress or mixed urinary incontinence at 12 months' follow-up, with no injection site or product-specific adverse events identified. Maggiore *et al*.[16] studied 82 women with a 12-month follow-up, quoting a subjective success rate of over 74%. These women were discharged on the same day and no intraoperative complications were

noted. A 24-month follow-up of periurethral injection of polyacrylamide hydrogel for women with stress and stress-predominant mixed urinary incontinence demonstrated a subjective responder rate of 64%.[17] Mohr *et al*.[18] published a 12-month follow-up of elderly women with SUI treated with one of four types of injection therapy, including 44 women receiving polyacrylamide hydrogel. Pad tests were negative in over 73% of women after bulking therapy. The overall complication rate was low for all agents, with no complications at all documented for the group who received polyacrylamide hydrogel.

While the overall success of periurethral injection of polyacrylamide hydrogel ranges from 64 to 74%, depending on outcome measures,[14–18] it would be expected that the success rates in women with serious anatomical dysfunction/loss of tissue secondary to obstetric fistula trauma would be lower. Polyacrylamide hydrogel is injected near the bladder neck, which is reliably identified with a Foley catheter balloon in women with previous obstetric fistulae. In comparison, the placement of a sling in the midurethral position can be difficult due to anatomical distortions of the urethra in this population of post-obstetric fistula repair. Dissection to create a tunnel for the placement of a sling can be hazardous due to scarring and poor tissue, resulting in iatrogenic injuries.

This case series is limited, with only four cases performed and very short-term follow-up achieved; however, it does demonstrate the use of a synthetic bulking agent without the availability of cystoscopy, and initial satisfactory outcomes, with three out of four women dry, and the remaining woman improved. While urodynamics equipment is not available in most fistula centers, assessment of the bladder with Foley catheter/bladder filling to identify detrusor overactivity and bladder capacity, cough test for stress incontinence, and residual urine volume to assess voiding function, do give a useful clinical overview of bladder dysfunction. The cost of the agent may also limit its use in developing countries.

Follow-up is often difficult in such regions where fistula is prevalent due to costs required for travel, concerns regarding personal safety and political instability. In addition, these women often do not have access to a postal service or telephone services to allow for further communication.

This series demonstrates that the use of periurethral injection of polyacrylamide hydrogel in women with post-fistula closure SUI may be a promising option. Larger studies are required, preferably with the availability of urodynamics assessment, to determine outcomes and success rates for this form of treatment. However, one of the main issues that may limit this treatment option in post-fistula closure women is the expense of synthetic bulking agents.

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Disclosure

None declared.

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