Should Progressive Perineal Dilation be Considered First Line Therapy for Vaginal Agenesis?

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Abbreviations and Acronyms

MRKH = Maver-Rokitansky-Küster-Hauser syndrome PPD = progressive perineal dilation

Study received institutional review board ap-

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Purpose: In women with vaginal agenesis progressive perineal dilation provides a minimally invasive method to create a functional vagina without the attendant risks or complications of traditional surgical options. We report our 12-year experience with this technique.

Materials and Methods: Patients with vaginal agenesis treated at our institution were analyzed retrospectively and followed prospectively using case report forms and semistructured interviews. Patients diagnosed with vaginal agenesis were counseled on vaginal reconstruction options. Those electing progressive perineal dilation were instructed on the proper use of vaginal dilators by one of us (MRL) and advised to dilate 2 or 3 times daily for 20 minutes. All patients received physician, nursing and social work education and counseling. Parameters reviewed included primary diagnosis, start and end of vaginal dilation, dilation frequency, dilator size, sexual activity and whether the patient experienced pain or bleeding with dilation or sexual activity. Functional success was defined as the ability to achieve sexual intercourse, vaginal acceptance of the largest dilator without discomfort or a vaginal length of 7 cm. Univariate and multivariate analysis was performed to identify factors associated with successful neovaginal creation.

Results: From 1996 to 2008 we enrolled 69 females with vaginal agenesis in a progressive perineal dilation program. The primary diagnosis was Mayer-Rokitansky-Küster-Hauser syndrome in 64 patients. Mean age at the start of vaginal dilation was 17.5 years (range 14 to 35) Mean followup was 19 months (range 0 to 100). Four patients (5.7%) were lost to followup. In 7 of the remaining 65 patients (12%) treatment failed due to noncompliance and 50 (88%) achieved functional success at a median of 18.7 months. Patients who dilated frequently (once daily or greater) achieved a functional neovagina at a mean \pm SD of 4.3 \pm 2.4 months. Functional success correlated positively with frequent (once daily or greater) dilation and the initiation of sexual activity. Complications were minor. Three patients reported infrequent pain and 2 reported a single episode of bleeding with dilation. A total of 18 sexually active patients reported satisfactory intercourse without dyspareunia.

Conclusions: Progressive perineal dilation for neovaginal creation is a valuable, minimally invasive therapy to create a functional vagina with a high success rate and a much lower complication rate than that in published surgical series. Given these findings, progressive perineal dilation should be offered as first line therapy in adolescents with a congenitally absent vagina.

Key Words: vagina, abnormalities, dilatation, coitus

Vaginal agenesis is an uncommon condition with an estimated incidence of 1/5,000 to 1/10,000 live female births. Implicated etiologies are MRKH, androgen insensitivity syndrome (including Morris syndrome) and certain intersex disorders. Regardless of cause, creating a functional neovagina in these patients remains a significant challenge and a controversial subject. While a number of techniques have been described and continue to be used, long-term outcomes and diagnosis related success rates remain indeterminate. Of the techniques used, including split-thickness skin grafts, bowel vaginoplasty, myocutaneous grafts and progressive dilation, pediatric urologists and pediatric surgeons prefer bowel vaginoplasty, as reflected in the urological literature. 1,2 While short-term results are favorable, bowel vaginoplasty remains a major surgical procedure that often requires postoperative dilation and carries significant long-term complications, including mucous production, vaginal stenosis, vaginal prolapse, diversion colitis, bowel obstruction and rarely carcinoma.

The primary end point in these patients should be creating a vagina that is satisfactory for sexual intercourse and provides adequate cosmesis of the external genitalia, while minimizing short-term and long-term patient morbidity. Progressive dilation is recommended by the American College of Obstetricians and Gynecologists as the first choice in neovaginal creation, particularly in patients with Mayer-Rokitansky syndrome.³ Successful neovaginal creation by PPD obviates the need for major surgery. We reviewed our 12-year experience with this technique.

MATERIALS AND METHODS

Patients with vaginal agenesis treated at our institution were analyzed retrospectively and followed prospectively using case report forms and semistructured interviews. Institutional review board approval was obtained. Initial patient evaluation was performed by a single practitioner (MRL), and included vaginal examination and structured interview with a nurse specialist (PT or VB). A review of all techniques available for neovaginal creation was discussed with each patient. Patients electing PPD received spoken and written instructions on the proper technique. During the initial visit the physician instructed the patient on the correct use of dilators with mirror. Syracuse vaginal dilators (Syracuse Medical Devices, Syracuse, New York) are used in our practice. The patient is shown the vulvar anatomy and how to place the tip of the smallest dilator at the introital dimple between the anus and the urethra.

When starting the home dilation regimen, patients were advised to take a warm bath for at least 10 minutes before dilator use and then assume a semireclining position with the knees flexed and apply gentle pressure to the vaginal dimple for 20 minutes 3 times daily. A small amount of water based lubricant, such as K-Y® Jelly or

Surgilube® Lubricating Jelly, could be used on the tip of the vaginal dilator as needed. Patients were seen at followup visits 4 to 8 weeks apart with the nurse and physician. Vaginal length and width were assessed by a single practitioner (MRL) in all patients. Patients were instructed to proceed to the next dilator length and width depending on progress. Emotional and psychological support from the team clinical psychologist, nurse specialist or social worker was made available as needed before, during and/or after treatment.

Parameters assessed were age, vaginal length and width at dilation start and end, total dilation time, dilation frequency, dilator size and any complications during or after dilation, such as bleeding or pain. Sexually active patients were asked whether they noticed bleeding or dyspareunia with intercourse. Functional success was defined as the ability to achieve satisfactory intercourse, vaginal acceptance of the largest dilator without discomfort or a 7 cm vaginal length. Patients who attained functional success but were not routinely sexually active were instructed to dilate on a maintenance regimen consisting of the largest dilator (Syracuse 3 or 4, measuring 15.2×3.2 and 15.2×3.5 cm) 2 or 3 times weekly.

Statistical analysis was performed using SPSS® 15.0. Statistical significance was determined with the independent sample t tests with equal variance not assumed and 1-way ANOVA with the Bonferroni post hoc test.

RESULTS

From 1996 to 2008 we enrolled 69 females with vaginal agenesis in a PPD program. The primary diagnosis was MRKH in 64 patients (93%), VATER in 2, androgen insensitivity syndrome in 1 and Goltz syndrome in 1. Mean \pm SD age at the start of vaginal dilation was 17.48 \pm 3.27 years (range 14 to 35). Mean followup was 18.89 \pm 21.86 months (range 0 to 100) (table 1). Four patients (5.7%) were lost to followup. Of the remaining 65 patients treatment failed in 7 (12.1%) due to noncompliance and 50 (88%) achieved functional success at a median of 18.7 months. Eight patients (11.6%) remained in the program (table 2). Of the 50 patients who achieved functional success 29 achieved a vaginal length of 7 cm or greater.

There was no statistically significant difference in starting age at dilation and mean dilating time in patients with vs without functional success (p=0.85 and 0.54, respectively, table 3). There was a statistically significant difference between these 2 groups in vaginal length at the start and end of PPD, and in

Table 1

Mean ± SD cm Vaginal Length (range)
0.75 ± 1.08 (0-5.0)
$5.98 \pm 2.15 (0-10.0)$
$5.10 \pm 2.27 (0-10.0)$

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