GENERAL GYNECOLOGY

Vaginal dilation treatment in women with vaginal hypoplasia: a prospective one-year follow-up study

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OBJECTIVE: Vaginal dilation treatment has been shown to be a (cost) effective first-line alternative to surgery in normalizing vaginal length and improving sexual function in women with vaginal hypoplasia. There remains, however, a need for prospective studies, with long-term assessment of multiple outcomes.

STUDY DESIGN: This was a prospective, single-centre observational study of 16 women with Mayer-Rokitansky-Küster-Hauser syndrome (n = 12) or 46,XY disorders of sex development (n = 4). All women underwent an outpatient vaginal dilation program supervised by a psychologist and physiotherapist. At baseline (T0), stop of treatment (T1) and 1 year follow-up (T2), semistructured interviews, and validated questionnaires assessed sexual function and distress, self-esteem, vaginal perceptions, and health-related quality of life. Gynecological examinations evaluated vaginal dimensions.

RESULTS: Ten women completed the program, 3 are still in the program, and dilation failed in 3 and chose vaginoplasty. Sixty-nine percent reached a normal vaginal length ($\geq$6.5 cm) in 5.8 $\pm$ 3.3 months. Seventy percent were sexually active with pleasurable experiences at T1, 57% at T2. The significant decrease in sexual distress at T1 ($P < .05$) was followed by a nonsignificant increase at T2. Depressive mood symptomatology remained high at T1 and T2, related to loss of bodily integrity and fertility. The majority refused further psychological counseling.

CONCLUSION: Vaginal dilation treatment should remain the cornerstone of treatment in women with vaginal hypoplasia. However, the diagnosis remains to have a negative impact on emotional well-being in the long term. The role of psychological intervention as both a primary and adjuvant treatment needs clear evaluation.

Key words: complete androgen insensitivity syndrome, Mayer-Rokitansky-Küster-Hauser syndrome, psychosexual functioning, vaginal dilation, vaginal reconstruction

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Congenital vaginal hypoplasia is most commonly seen in Mayer-Rokitansky-Küster-Hauser syndrome (MRKH) and complete androgen insensitivity syndrome (CAIS) (1:5000 female births for MRKH[1]; 1:13,000 to 40,000 for CAIS[2]). In addition, in girls with ambiguous genitalia at birth, or other rarer complex conditions affecting the urinary and gastrointestinal tracts, there may be associated vaginal hypoplasia.[3]

One of the key focuses of clinical management is to increase vaginal dimensions to permit penetrative sexual intercourse.[4] Vaginal enlargement may be achieved by nonsurgical vaginal dilation and by surgical reconstructive techniques.[5,6] These conditions present often in adolescence, which means the patient can be fully involved in decisions about the type and timing of treatment, based on psychological readiness. In instances in which presentation is earlier (in childhood or early adolescence), it is generally advised that all methods are best deferred until adolescence or even adulthood when the patient has reached physical and psychological maturity.[7] This allows for proper decision making and possibly also increases compliance with vaginal dilation therapy whether used as primary treatment or as a postoperative adjuvant treatment to prevent vaginal stenosis.[3,8]

Progressive pressure to the vaginal dimple with vaginal molds of gradually increasing length and width (Figure 1) has been used for more than 70 years.[9] Because it has been shown to be a (cost)-effective technique, with few complications and no anesthetic and surgical risks,[1,4,10-12] it is proposed as first-line technique.[13] However, it is time

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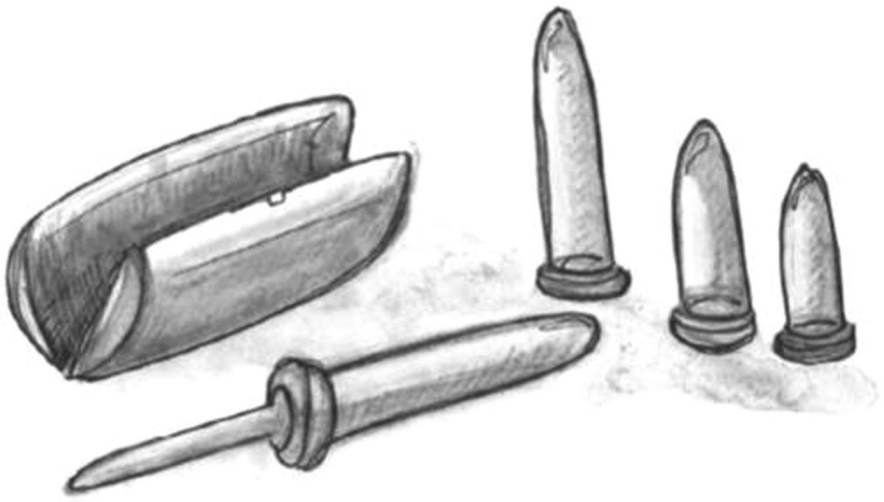
FIGURE 1
Dilators



The set is available through the hospital pharmacy and with discrete packaging.

Callens. Follow-up after vaginal dilation treatment. Am J Obstet Gynecol 2014.

consuming and anatomical success seems to be directly related to compliance,[1] which is said to be low.[14]

Factors associated with nonadherence include predicted or actual pain upon dilating, fear of damaging the vagina, or insufficient information about dilator use.[15,16] The regimen has been described as distasteful[16] and because of the intimate nature of the treatment carries emotional implications.[15-17] The usually young, adolescent women have to find a way to accommodate the device.[17] Moreover, the loss of bodily integrity and fertility can be surmised to have an impact on identity and body image.[18,19] These factors may also compromise relationship outcomes and sexual function. Therefore, vaginal length measurements cannot be used as the single parameter on which to quantify treatment success.[18]

Given the emotional sequelae of the diagnosis and the potential drawbacks of vaginal dilation, professional psychological support must be an integral part of medical care. With such an approach, barriers to dilation treatment adherence are more likely to be avoided, rendering it viable as first-line approach.[10] However, the effectiveness of dilator treatment, like any other intervention, should be thoroughly evaluated, ideally in a prospective study of multiple outcomes (eg, sexuality, quality of life, and emotional well-being), including long-term treatment gains.

Our aim was to report the preliminary short term and 1 year follow-up results of first-line dilation treatment using the original Frank technique[9] and delivered by a multidisciplinary team.

Materials and Methods

Study design, outcome variables, and population

This was a prospective, longitudinal, single-center study of all women with vaginal hypoplasia and without a previous history of vaginal surgery, who were prescribed vaginal dilation treatment, between March 2010 and April 2013. Participants followed the treatment protocol outlined in Figure 2. The outpatient program was designed based on previous experiences and careful exploration of the literature, especially motivational and behavioral psychology.[10,15]

At baseline (T0), at the stop of treatment (T1), and at 1 year follow-up (T2), validated standardized questionnaires on emotional and sexual well-being were completed (Table 1), and gynecological examinations were performed to measure vaginal length. Semistructured interviews included questions about the participant's reaction toward the diagnosis and experience of dilator treatment (advantages and disadvantages), information provision, and compliance with dilation treatment. The study was approved by the local ethics committee (EC 2010/030), and a written informed consent had been obtained at T0 from all participants.

Statistical analysis

Statistical analyses were performed using SPSS version 20.0 (SPSS Inc, Chicago, IL). Nonparametric Wilcoxon signed-rank tests were conducted with a Bonferroni correction for comparing mean rank scores for emotional and sexual well-being at T0, T1, and T2. Nonparametric effect size (ES) estimates and 95% confidence intervals were calculated.[20] Mann-Whitney U tests assessed differences in anatomical success when controlling for the frequency of dilation ($\leq$4 or $>$4 times a week), sexual activity during dilation program (yes or no), and karyotype (46, XY or 46, XX). Associations between variables were sought using Spearman correlation coefficients. A value of $P < .05$ was considered statistically significant. Two-tailed statistical tests were chosen to reduce the risk of type I errors.

Results

Of the 18 women approached, 16 agreed to participate (Figure 3). Two women were reluctant to discuss this sensitive issue, but both did start with the dilation program. The characteristics of the participants are displayed in Table 2.

Attitudes toward vaginal dilator use before and after dilation treatment

Table 3 summarizes the benefits and disadvantages of dilation treatment as mentioned by the participants. Before the start, they demonstrated good knowledge on the purpose of using vaginal dilators (ie, to have normal/pain-free intercourse) and to possibly avoid surgery and scars (ie, implying visibility of the condition). After treatment, women included also advantages of connectedness to the body and feeling better as a woman, but the majority

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