



Randomised Controlled Trial

Postoperative outcomes of sigmoid colon vaginoplasty for vaginal agenesis: A randomized controlled trial[☆]

Salahedin Delshad^{a,*}, Balal Delshad^b, Parisa Mogheimi^c

^a General Surgeon and Pediatric Surgeon, Maryam Hospital, Karaj, Iran

^b General Surgeon and Breast Surgery Specialist, Maryam Hospital, Karaj, Iran

^c Maryam Hospital, Karaj, Iran



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ABSTRACT

Objective: Mayer-Rokitansky-Kuster-Hauser syndrome (MRKH) is a rare disorder in women that is associated with vaginal agenesis and hypoplasia or loss of uterus. In this study we aim to study the outcome of sigmoid colon vaginoplasty among MRKH patients with vaginal agenesis.

Methods: In this randomized clinical trial study, from 2017 to 2021, 39 patients were reported to our center with vaginal agenesis as a result of MRKH. Patients were treated with sigmoid colon vaginoplasty and postoperative outcomes such as Female sexual function index (FSFI), depth of vaginal cavity, and postoperative complications were evaluated.

Results: The mean age of the patients was 32.3 ± 2.3 years. 18 patients (46.2%) were diagnosed using MRI whereas 21 patients (53.8%) were diagnosed with exploratory laparoscopy. The mean vaginal depth before and after the surgery was 2.8 cm and 17.3 cm, respectively. One patient (2.6%) developed fistula, and peritonitis due to perforation of the vagina, 26 months after surgery, respectively. Of 10 patients who were sexually active after the surgery, all of these patients were sexually satisfied. The FSFI was 32 ± 3.9 .

Conclusion: The postoperative complications after sigmoid colon vaginoplasty were minimum and all the sexually active patients were sexually active. This method appears to be an effective for surgical treatment of vaginal agenesis.

1. Introduction

Vaginal agenesis in Mayer-Rokitansky-Kuster-Hauser syndrome (MRKH) is one of the rare diseases in women and its approximate prevalence has been reported in one case in 5000 women [1]. The first sign is amenorrhea at puberty, and in cases that involve closed uterus, there is a feeling of lower abdominal pain. Most patients with Rocky Tansky syndrome have no uterus and, in some cases, have a closed uterus, which causes abdominal pain with the accumulation of menstrual blood that feels abdominal mass [2].

This disease is the most common form of class 1 agenesis - Müllerian hypoplasia, which is identified by insufficient growth or congenital lack of uterus and vagina in females [2,3] This disease is the second cause of amenorrhea and may be associated with other congenital skeletal abnormalities accompanied by urological complications (type II MRKH) [4,5]. The phenotype of these women is female, and their genotype

(karyotype) is 46, XX. Surgical treatment of these patients is aimed at creating a genital tract (vagina) for sexual intimacy and in cases that contain the uterus to drain the menstrual blood periodically. McIndoe method is used in most medical centers around the world for the treatment. In this method, a cavity is created by creating a depression four to 5 cm deep in the perineal area, covering the walls inside it with the skin of the thigh or buttocks. These patients have Bougie (mold) for months to keep the cavity open and can develop fungal and staphylococcal infections, dry skin and narrowing of the urethra [6–8].

Such patients always need psychological support, patients who have previously had McIndoe surgery and whose condition has led to divorce need more psychological and social support than other patients [9]. Fortunately, in vaginoplasty using a sigmoid bowel flap, women go through a married life (normal sex) and none of the complications are seen.

In this study, we present the outcome of patients who underwent

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* Corresponding author. Iran University of Medical Sciences, Tehran, Iran.

E-mail address: drdelshad@gmail.com (S. Delshad).

sigmoid colon vaginoplasty at our center for vaginal agenesis.

2. Methods

In this randomized clinical trial study from June 2017 to January 2021, 39 female patients with vaginal agenesis due to Mayer-Rokitansky-Kuster-Hauser syndrome were referred to (XXX). Patients with previous history of vaginal and abdominal surgery, sensitivity to general anesthesia, pregnancy, and history of sexually transmitted diseases were excluded from the study. These patients underwent sigmoid vaginoplasty as their primary or secondary surgery. Written consent was obtained from all the patients before participation in the study. Female sexual function index (FSFI), sexual satisfaction (using sexual satisfaction scale), depth of vaginal cavity, method of diagnosis and post-operative complications were evaluated for the patients and recorded in patient-based checklist. A standard pelvic examination was performed by inserting 2 fingers and using dilators of 2–3.5 cm diameter.

Preoperative bowel preparation was achieved by 3-day semifluid diet. Enema was administered once every day for 3 days, which was cleared prior to the surgery. Prophylactic antibiotics were also given to all the patients. The procedure was performed under general anesthesia. For the surgery, the patients were placed in lithotomy position through which vulva and perineum can be accessed. Colon was immobilized with Pfannenstiel incision and 10–15 cm of sigmoid colon was separated for grafting. Bowel was sewn back with 3–0 silk sutures. H-shaped incision in perineum was made following by incision between urethra and rectum for neovaginal graft. Using urethral Hegar sounds, abdominoperineal tunnel was expanded and mobilized sigmoid colon was pulled downwards to reach vaginal epithelium followed by suturing with absorbable sutures. The proximal end of the neovagina was attached to the sacral promontory to prevent prolapse. Postoperatively, patients were taught self-dilation and irrigation of mucosa for 8 weeks, at minimum.

The data obtained was computerized and analyzed using SPSSv22 (IBM, Chicago, United States). Descriptive data was presented in terms of mean, standard deviation and frequency. Postoperative complications were accessed by surgical attendant who performed the procedure.

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The methods are stated in line with CONSORT statement for

randomized controlled trials [10].

3. Results

All patients were consented for having new vagina and none of the patients had coitus prior to the surgery. The mean age of the 39 patients included in the study was 32.3 ± 2.3 years. 18 patients (46.2%) were diagnosed using MRI whereas 21 patients (53.8%) were diagnosed using exploratory laparoscopy. The mean vaginal depth before the surgery was 2.8 cm and was 17.3 cm after the surgery (Fig. 1). Two patients had single kidney and one patient had horseshoe kidney. The mean follow up duration was 7.1 weeks. One patient (2.6%) developed fistula, which was alleviated by McIndoe's surgery for excision-induced fibrosis. One patient (2.6%) developed peritonitis due to perforation of the vagina, 26 months after surgery. Examination under anesthesia revealed that introital stenosis of 5 cm from the vulva opening due to a mucosal ulcer and the formation of fibrosis. After relieving the stenosis and suturing the intestinal flap and rinsing the abdominal cavity, treatment was performed. Out of 39 patients, 10 patients were sexually active after the surgery and all of these patients were sexually satisfied. The FSFI was 32 ± 3.9 .

4. Discussion

Vaginal agenesis in Mayer-Rokitansky-Kuster-Hauser syndrome requires special attention of obstetricians, surgeons and even pediatricians for prompt diagnosis and treatment. Delay in treatment can cause mental, psychological, and social problems for the patient. Treatment and modification of vaginal agenesis is a controversial issue and remain a significant challenge. At present, non-surgical techniques such as residual vaginal dilatation and finger bogie (Frank technique) and surgical techniques such as McIndoe, Davydov, Vecchiotti, and intestinal vaginoplasty have been reported for vaginoplasty [11]. The patient's history and background and the surgeon's ability an important role in choosing the right method [12,13].

Surgeon aims to create new vagina (neovagina) that can improve the quality of life of most of these patients if done timely and effectively [13]. The most commonly used method in this is modified McIndoe technique. In this procedure, various grafts, including skin or amniotic

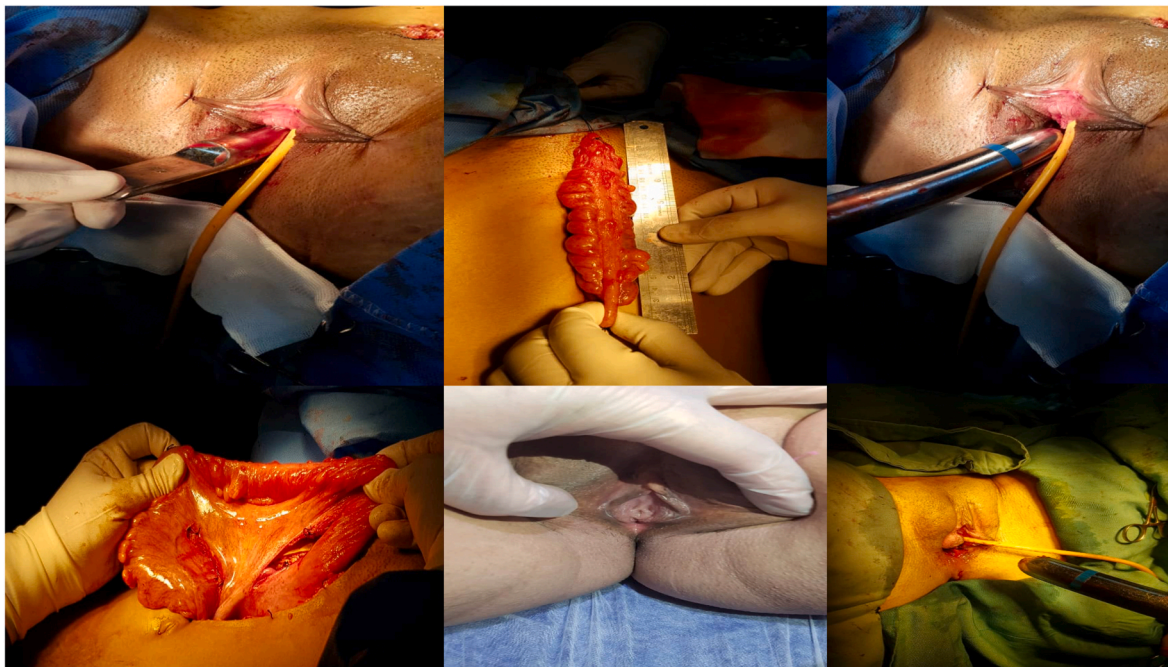


Fig. 1. The mean vaginal depth before the surgery was 3.8 cm and was 7.3 cm after the surgery.

membrane, are used to cover the cavity inside the perineum (new vagina). This procedure is associated with complications such as partial or complete occlusion of the new vagina, vaginal dryness, wound risk, colloid formation, and external and staphylococcal infection in the graft [14,15]. The formation of squamous cell carcinoma of the new vagina has been reported in one case [16].

Performing this technique requires constant bougie and regular examination by the treating-physician [7], alternative approaches in this technique are the use of amniotic membrane instead of skin graft, which is highly welcomed by donors due to the reduced of viral infection such as hepatitis and HIV. These complications can have negative impact in personal lives of patients. Of the 10 married patients, 5 underwent McIndoe surgery leading to divorce [17]. In the approach of using a part of the small intestine or sigmoid to create a new vagina as well as using it to create a vagina with preservation of intestinal vessels has been proposed as a new method [18]. The advantages of this method include no need for continuous and long-term dilatation, no shortening, less chance of stenosis and obstruction, and less risk of fungal diseases. Therefore, intestinal graft is more acceptable, although abdominal surgery is required in this method [19]. Creating a new weight using sigmoid clone sections is an effective approach to treating these patients. One of the main advantages of using sigmoid colon compared to ileum is that its diameter is more suitable for proximity and due to the thickness of the wall, the possibility of rupture during proximity is minimized. In addition, due to the very low production of mucus, it can greatly improve the quality of sexual life of these patients [18,20]. Also, the inner mucosal wall of the new vagina becomes similar to normal vaginal mucosa over time. In this approach, satisfactory sexual function has been reported in 80% of women who have been sexually active after surgery and 2% patients reported dyspareunia [21,22]. Cai, Zhang [23] reported that among 26 women who underwent laparoscopic sigmoid colon vaginoplasty infection and blood transfusion were perioperative complications reported in 1 and 3 cases, respectively. Two cases reported introital stenosis and 91% women were had were satisfied with sexual intercourse. In a 7-year study on 29 patients, Karateke, Haliloglu [24] reported introital stenosis in 79% unmarried women and none in married women. One case of intraluminal abscess in neovagina and rudimentary uterine horn, hematometra was reported, respectively, in long-term follow-up.

In the present study, in one patient, stenosis of the end of the neovagina at a distance of 4 cm from the vulva was observed due to fibrous tissue from a previous operation performed by McIndoe method. In one case, a wound infection at the site of the abdominal incision with abscess was observed which was drained and treated. In one case, after 26 months of surgery, a new vaginal obstruction due to an infection due to proximal ulceration and subsequent perforation of the upper part of the graft (new vagina) leading to peritonitis was seen. The patient underwent laparotomy and after draining the pus and closing the perforation site, the stenosis inside the neovagina was removed. In one case, perforation of the wound containing accumulated blood was observed and repaired. In this study, 5 patients with a spouse and 3 patients who were married after surgery had complete satisfaction with their sexual function.

It is essential that obstructive vaginal abnormalities are correctly diagnosed before surgical treatment [22]. There are reports that several patients have undergone multiple surgeries as a result of misdiagnosis [4].

One of the significant challenges when conducting the study was to obtain data regarding sexual activity of women. We included women residents in our research team to facilitate participants, allowing them to communicate comfortably.

5. Conclusion

Intestinal vaginoplasty using part of the sigmoid can be a good option for vaginal replacement in patients without a vagina. In this

method, in addition to not observing the side effects of other methods, it provides sexual satisfaction for the patient and the spouse.

Human and animal rights

No animals were used in this research. All human research procedures followed were in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013. This study was approved by the Research Ethics Board of Alborz University of Medical Sciences.

Consent for publication

Informed consent was obtained from each participant.

Availability of data and materials

All relevant data and materials are provided with in manuscript.

FUNDING

None.

Contributors' statement page

Dr. Salahedin Delshad: conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript.

Dr. Balal Delshad: Designed the data collection instruments, collected data, carried out the initial analyses, and reviewed and revised the manuscript.

Dr. Parisa Mogheimi: Coordinated and supervised data collection, and critically reviewed the manuscript for important intellectual content.

Registration of research studies

Name of the registry: Tehran Islamic Azad University of Medical Sciences.

Unique Identifying number or registration ID:

Hyperlink to the registration (must be publicly accessible):

Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Guarantor

Dr. Salahedin Delshad.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Declaration of competing interest

The authors deny any conflict of interest in any terms or by any means during the study.

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