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Ileal vaginoplasty as vaginal reconstruction in transgender women and patients with disorders of sex development: An international, multicenter, retrospective study on surgical characteristics and outcomes.

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ABSTRACT

OBJECTIVES. To describe surgical outcomes of ileal vaginoplasty in transgender women and patients with disorders of sex development (DSD).

PATIENTS AND METHODS. Transgender women and DSD patients, who underwent ileal vaginoplasty at the VU University Medical Center Amsterdam, University Hospital Trieste, University Hospital Essen and Belgrade University Hospital, were retrospectively identified. A chart review was performed, recording surgical technique, intraoperative characteristics, complications and reoperations.

RESULTS. We identified a total of 32 patients (27 transgender and 5 non-transgender), with a median age of 35 (range 6-63). Ileal vaginoplasty was performed as primary procedure in three, and as revision procedure in 29 patients. The mean operative time was 288 ± 103 minutes. The procedure was performed laparoscopically (n=7) or open (n=25). An ileal U-pouch was created in five, a single lumen in 27 patients. Intraoperative complications occurred in two patients (iatrogenic bladder damage (n=1) and intraoperative blood loss necessitating transfusion (n=1)). The median hospitalization was 12 (range 6-30) days. Successful neovaginal reconstruction was achieved in all. Mean achieved neovaginal depth was 13.2 ± 3.1 centimeters. Median clinical follow-up was 35 (3-

159) months. In one patient a rectoneovaginal fistula occurred, which lead to temporary ileostomy.

Introital stenosis occurred in four (12.5%).

CONCLUSION. Ileal vaginoplasty can be performed with few intra- and postoperative complications. It appears to have similar complication rates when compared to sigmoid vaginoplasty. It now seems to be used predominantly for revision procedures.

KEY WORDS: Gender Dysphoria; Reconstructive Surgical Procedures; Vaginoplasty; Sex Reassignment Procedures; Complications; Transgender Surgery.

INTRODUCTION

Surgical reconstruction of a functional vagina is indicated in non-transgender women with vaginal absence and transgender women. The most widespread surgical method for neovaginal (re)construction in transgender women is penile inversion vaginoplasty, with or without additional (scrotal) skin grafts or flaps.^{1,2} Intestinal vaginoplasty is a surgical option in women with congenital or acquired vaginal absence, in patients who underwent a previously failed vaginoplasty procedure and in transgender women with a shortage of penoscrotal skin. During this procedure, an intestinal segment, is isolated on its vascular pedicle and transferred to the neovaginal cavity, to form the neovaginal lining. For this procedure, mostly sigmoid or ileal segments are used, but sporadically also jejunum, cecum or rectum.³ Generally, sigmoid vaginoplasty is performed more frequently than ileal vaginoplasty. To date, it is not known if one method of intestinal vaginoplasty is superior. After sigmoid vaginoplasty, a good postoperative (sexual) quality of life is reported.⁴⁻⁸ Little is known on (surgical) outcomes of ileal vaginoplasty in transgender and patients with disorder of sex development (DSD). In this retrospective study, patients who underwent ileal vaginoplasty, in one of

four high-volume tertiary centers, were pooled to describe the surgical results of this scarcely performed procedure.

PATIENTS AND METHODS

Center and patient selection.

Multiple international healthcare centers, specialized in genital reconstructive surgery and/or transgender healthcare, were approached to participate in this study. A total of four centers indicated to have performed ileal vaginoplasty, and were willing to participate. Transgender women and DSD patients who underwent ileal vaginoplasty at the VU University Medical Center Amsterdam (The Netherlands), University Hospital Trieste (Italy), Belgrade University Hospital (Serbia) and University Hospital Essen (Germany) were retrospectively identified. All centers constitute tertiary referral hospitals with a high-volume of patients.

Chart review

Each center was requested to retrospectively identify patients who underwent ileal vaginoplasty from their hospital registry. A retrospective chart review was performed, recording: patient demographics (age at surgery, Body Mass Index (BMI), somatic and psychiatric comorbidity, history of smoking, alcohol and hard drugs, use of medication and operative indication), surgical technique (open versus laparoscopic, single lumen versus U-pouch, presence of gastroenterological surgeon, type of bowel anastomosis), intraoperative characteristics (operative duration, complications), postoperative complications and need of reoperations. A database was created containing all values mentioned above. Patient data was anonymized to ensure patient anonymity.

Ethical statement

This study was approved by the institutional medical ethical Committee of the VU University Medical Center (METC, reference number 2017.017). The study adhered to the STROBE guidelines for collecting and interpreting observational data. All patients gave permission for their data to be used in this publication.

RESULTS

Surgical technique

Preoperative psychological workup for transgender patients, including multiple counseling sessions by a psychologist with experience in the transgender field, was performed according to the Standards of Care for the Health of Transgender, and Gender-Nonconforming People.⁹ Patients with a history of inflammatory bowel disease were not deemed eligible for intestinal vaginoplasty. When intestinal vaginoplasty is performed as primary procedure, as in any vaginoplasty procedure, preoperative depilation of the genital region is desirable. Intravenous antibiotics are administered before surgery (Table 1). The patient is placed in supine lithotomy position. This provides both intra-abdominal and perineal exposure. When the procedure is performed laparoscopically, the first (umbilical) trocar is introduced and pneumoperitoneum is applied. A simultaneous abdominoperineal approach is possible. After intra-abdominal inspection, a right lateral trocar is positioned in the midclavicular line at umbilical height. A third trocar is placed in the right lower quadrant, lateral to the epigastric vessels. When the procedure is performed as open surgery, a Pfannenstiel incision or a median laparotomy incision is made (Figure 1). When the procedure is performed as primary surgery, surgical construction of the female external genitalia is performed as described before.^{10,11} A neovaginal cavity between rectum and bladder is created through blunt dissection. When the procedure is performed as revision surgery, remnants of the previous

neovagina are removed, which may be difficult due to excessive fibrosis. Residual skin grafts and cyst-like structures with sebaceous content may be found. Care must be taken not to damage adjacent structures, such as the rectum. An ileal segment of the desired length is isolated using a linear stapler. The ileal segment and its vascular pedicle are adequately mobilized to facilitate a tension-free transfer to the genital region. The distal end of the segment is transferred to the neovaginal cavity. The segment can be used as single-lumen to form the neovaginal lining. Alternatives can be a transversed retubularized single-lumen approach according to the Monti principle, or the formation of an U-pouch. An ileocutaneous anastomosis is performed through a perineal approach. Bowel continuity is restored in an end-to-end or side-to-side fashion using either an intracorporal approach, manual suturing or a linear stapler. To prevent neovaginal prolapse, the proximal end of the segment, the neovaginal top, can be fixed to the sacral promontory, uterosacral ligament, pelvic floor, connective tissue of the bladder, pelvic floor muscle fascia, or pelvic cavity posterior wall.^{12,13}

Intercenter variability between intra-operative and postoperative protocols

An overview of inter-center variability between intra-operative and postoperative protocols is presented in Table 1. Most centers used a cephalosporin and metronidazole as preoperative antibiotic prophylaxis. Differences exist regarding the presence of a gastrointestinal surgeon, urinary catheterization duration (range 2-7 days), hospitalization (range 4-8 days), postoperative dilation and outpatient visit schedules.

Demographics and surgical outcomes

A total of 32 patients (27 transgender and 5 non-transgender) were identified, with a median age of 35 (range 6-63). Some of these patients were previously described in literature.^{7,14-16} An overview of

patients and individual surgical outcome is presented in Table 2. Ileal vaginoplasty was performed as primary procedure in three patients and as revision procedure in 29 patients. The mean operative time was 288 ± 103 minutes. The procedure was performed laparoscopically (n=7) or open (n=25). An ileal U-pouch was created in five patients, a single lumen was used in 27 patients. Intra-operative complications occurred in two patients (iatrogenic bladder damage (n=1) and intraoperative blood loss necessitating transfusion (n=1)). The median hospitalization was 12 (range 6-30) days. The mean achieved neovaginal depth was 13.2 ± 3.1 centimeters. Median clinical follow-up was 35 (3-159) months. Introital stenosis occurred in four (12.5%) patients. Rectoneovaginal fistula formation occurred in one patient.

DISCUSSION

In this study, the operative characteristics and pooled surgical results of ileal vaginoplasty in transgender women and DSD patients performed in four specialized European centers were described. Ileal vaginoplasty can lead to successful neovaginal reconstruction with low morbidity. It appears to have similar complication rates when compared to sigmoid vaginoplasty. In this study, it was performed predominantly for revision procedures. Multiple surgical techniques are utilized when performing this surgery.

A great inter-center variability was observed in surgical technique utilized and postoperative protocols. Whether a laparoscopic or open approach was chosen or a single-lumen or pouch was created, was mostly surgeon- and center dependent. Because there are many variations in surgical technique, postoperative protocols and surgical indications, it is hard to draw generalizable conclusions from the presented data on ileal vaginoplasty as a whole. This retrospective case series, however, does provide an up-to-date overview of ileal vaginoplasty techniques, its current applications and surgical results.

This retrospective case series has shown that ileal vaginoplasty is predominantly performed as revision procedure, for example when a previously performed vaginoplasty procedure provided too little depth. Revision vaginoplasty procedures are known for its increased risks of iatrogenic injuries and subsequent risks on rectoneovaginal fistula formation.^{16,17} In this retrospective study, rectoneovaginal fistula occurred in one patient, who underwent ileal vaginoplasty as revision procedure. Finally, temporary ileostomy surgery had to be performed without concomitant comorbidities. This underlines the necessity of performing this kind of surgery in specialized tertiary centers.

Performing ileal vaginoplasty as total laparoscopic procedure may have the classical advantages over an open approach. The use of a laparoscopic view enables the operating surgeon to prevent, check for, and control possible damage to adjacent structures. It provides an excellent overview of the surgical area and some claim that removal of the, sometimes totally obliterated, neovagina is easier when performed laparoscopically. However, to safely perform laparoscopic ileal vaginoplasty, an expert-team with the presence of a gastrointestinal surgeon with advanced laparoscopic skills is desirable.

An intestinal segment as neovaginal lining provides sufficient neovaginal depth, natural lubrication, and it has little tendency to shrink. Sigmoid and ileal segments are predominantly used for intestinal vaginoplasty. The choice for either one or the other depends predominantly on the surgeon's background.¹⁸ Each graft type has its own (dis)advantages. The sigmoid has a larger diameter and is anatomically closer to the neovaginal cavity. Disadvantages comprise the risk on neovaginal diversion colitis, and subsequent complaints of discharge and/or malodor, due to luminal nutrient deprivation.¹⁹ Sigmoid neovaginal inflammatory bowel disease and malignancies have been described. Urologists have more experience with the ileum, due to its use in bladder augmentation surgery. Most urologists consider the ileal conduit to be the technically least demanding technique. Future studies, comparing surgical outcomes, postoperative satisfaction, (sexual) quality of life,

(excessive) lubrication and malodour are needed to determine which graft type is more suited for neovaginal (re)construction.

Worldwide, ileal vaginoplasty is not frequently performed as vaginal (re)construction in transgender women. This is the first international research collaboration of gender surgeons, working in high-volume tertiary centers, worldwide, to investigate surgical outcomes of a scarcely performed procedure. The increasing activity of international (global) transgender health organizations, such as for example the European Association for Gender Surgeons, European Professional Association for Transgender Health (EPATH) and World Professional Association for Transgender Health (WPATH) organizations, allows for such research and offers great opportunities for the near future.²⁰ It also has a positive effect on global education collaborations.²¹ These factors may subsequently improve surgical healthcare for transgender and DSD patients worldwide.

CONCLUSIONS

In conclusion, though great surgical variability exists, it may be stated that ileal vaginoplasty can lead to successful neovaginal reconstruction with low morbidity. Currently it is predominantly used for revision vaginoplasty procedures.

CONFLICT OF INTEREST STATEMENT: The authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest, or non-financial interest in the subject matter or materials discussed in this manuscript.

FIGURE LEGENDS

Figure 1. An open approach to ileal vaginoplasty as revision procedure. A&B: After isolation, the ileal segment is brought to the neovaginal tunnel. C&D: A mucoepithelial junction is created by suturing the ileal segment to the remnants of the old neovagina. **E.** End result. **F.** Pfannenstiel incision at the end of surgery.

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Table 1. Interinstitutional differences regarding perioperative protocols.

	Amsterdam	Trieste	Belgrade	Essen
Vaginoplasty procedures per year	100	30	40	70
GE-surgeon present during surgery?	Always	No	No	Only if laparoscopic surgery is performed
Preoperative antibiotic regime	Cefuroxime/ metronidazole	Piperacillin / metronidazole	Ceftriaxone/ metronidazole	Cefuroxime/ metronidazole
Urinary catheter duration	5 days	5days	7 days	2-3 days
Minimal admission duration	5 days	7 days	4-5 days	8 days
Postoperative dilation protocol	Starts 14 days after surgery, daily 30 minutes introital dilation for a 6-month period	Starts 5 days after surgery	Starts 14 days after surgery, twice a day, for a 6-month period	During hospitalization very cautiously by a physician. After discharge, the patient starts using a vibrator
Postoperative outpatient visit protocol	2 weeks, 3,6 12 months and then annually.	1, 6 months and then annually	1,2,4 weeks, 3,6,12 months, and then annually	Visit at 4-6 weeks and 3 months

Table 2. Surgical outcomes of ileal vaginoplasty

Case #	Center	Primary or revision	Age at surgery	BMI	Somatic comorbidity	Open or laparoscopic	Lumen type	Neovaginal depth	Intraoperative complications	Postoperative complications and reoperations	Clinical FU
1	A	Revision	40	NR	-	Open	Single	12,0	-	+ 5.0y Meatal stenosis, meatotomy under general anesthesia and cosmetic labial reduction	5,4
2	A	Revision	20	22,0	Asthma	Laparoscopic	Single	12,0	Bladder injury	-	2,9
3	A	Revision	55	21,3	-	Laparoscopic	Single	NR	-	+9d Intestinal anastomotic stricture: successfully salvaged laparotomically +7m introital stenosis, for which double Z plasty +20m mucocutaneous junction stenosis, for which jumping man plasty	2,7
4	A	Revision	50	21,5	-	Laparoscopic	U-pouch	11,0	-	+5d urinary retention, for which a urinary catheter was placed for 5 days	2,3
5	A	Revision	45	29,0	CYP17 deficiency, hypertension	Open	Single	15,0	-	-	2,8
6	A	Primary	45	21,2	-	Laparoscopic	Single	15,0	-	+12d superficial wound infection of the inverted penile skin flap, for which surgical debridement and IV antibiotics +4m introital stenosis, for which banner flaps	0,9
7	A	Revision	28	24,2	-	Laparoscopic	U-pouch	14,0	-	-	0,4
8	B	Primary	28	20,7	-	Open	Single	26,0	-	+ 8.5y Revision: neovaginal length reduction	12,9
9	B	Revision	22	23,2	-	Open	Single	14,0	-	+7m Introital stenosis, for which introitoplasty	2,6
10	B	Revision	36	27,0	Hypertension	Open	Single	14,0	-	None	0,8
11	B	Revision	22	19,1	-	Open	Single	12,0	-	+19m Introital stenosis, for which introitoplasty and labioplasty	2,0

12	B	Primary	6	Child	Neurogenic bladder CIC	Open	U-pouch	6,5	-	Bladder stones	13,3
13	C	Revision	29	20,5	-	Laparoscopic	Single	12,0	-	-	13,1
14	C	Revision	29	21,7	-	Laparoscopic	Single	13,0	-	-	12,3
15	C	Revision	45	23,0	-	Open	Single	12,5	-	Cosmetic labial reconstruction	10,8
16	C	Revision	49	22,6	-	Laparoscopic	Single	12,0	Bleeding, for which transfusion	-	NR
17	C	Revision	25	19,3	-	Open	Single	10,0	-	-	10,3
18	C	Revision	37	19,5	-	Open	Single	15,0	-	Cosmetic labial reconstruction	7,5
19	C	Revision	35	22,3	-	Open	Single	12,0	-	-	NR
20	C	Revision	26	23,6	-	Open	Single	13,5	-	Superficial wound infection and pneumonia	10,3
21	C	Revision	53	NR	-	Open	Single	14,0	-	-	8,6
22	C	Revision	34	21,5	-	Open	Single	12,0	-	-	6,0
23	C	Revision	44	19,7	-	Open	Single	15,0	-	-	4,7
24	C	Revision	28	20,7	G6P-DH deficiency	Open	Single	10,0	-	-	2,2
25	C	Revision	63	NR	-	Open	Single	9,0	-	Superficial wound infection	NR
26	C	Revision	22	19,4	-	Open	Single	12,5	-	-	NR
27	C	Revision	30	18,9	-	Open	Single	13,5	-	-	0,8
28	C	Revision	42	22,2	Mediterranean anemia	Open	Single	14,0	-	-	NR
29	C	Revision	43	18,5	-	Open	Single	15,0	-	Rectal-noevaginal fistula, anastomosis leakage, peritonitis and colonic	3,0

											diversion	
30	C	Revision	43	22,7	Previous cervical cancer	Open	Single	15,0	-	-	-	0,4
31	D	Revision	32	NR	NR	Open	U-pouch	NR	-	-	Urge incontinence	9,0
32	D	Revision*	35	NR	-	Open	U-pouch	NR	-	-	+4m Reversal of the temporary ileostomy	NR

NR not reported. *At the first vaginoplasty procedure, a rectovaginal fistula occurred. An ileal vaginoplasty with temporary colostomy as performed as revision.

