Male-to-Female Gender Reassignment Surgery: An Institutional Analysis of Outcomes, Short-term Complications, and Risk Factors for 240 Patients Undergoing Penile-Inversion Vaginoplasty

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OBJECTIVE To report outcomes, complications, and risk factors of a population cohort undergoing male-to-female gender affirmation surgery via penile-inversion vaginoplasty by a single surgeon at a large academic institution. As gender dysphoria awareness increases among the medical community, so does the population of patients seeking gender-affirmation surgery.

MATERIALS AND METHODS A prospectively maintained database of patients undergoing penile-inversion vaginoplasty was retrospectively queried for all available patients with at least 1 week of postoperative follow-up. Univariate and multivariate analyses were performed using Fisher's exact test and logistic regression, respectively, in order to evaluate relationship of risk factors to complications at 30, 60, and 90 days, as well as the likelihood of revision/reoperation.

RESULTS From November 2016 to April 2018, 240 penile-inversion vaginoplasties were performed. Median follow-up was 87 days. When accounting for competing risk factors, only noncompliance with postoperative dilation regimen and activity restriction was significantly associated with increased risk of complications or reoperation/revision. Overall incidence of reoperation/revision was 7.9% (n = 19). Reasons for reoperation included cosmesis (3.8%; n = 9), neovaginal stenosis (2.1%; n = 5), and wound dehiscence (0.8%; n = 2), with less than 0.5% (n = 1) reoperations for meatal stenosis, hematoma or rectovaginal fistula, respectively. Incidence of Clavien IIIa-b complications was 1.7% (n = 4). There were no Clavien IV-V complications.

CONCLUSION At short-term follow-up, gender-affirmation surgery is associated with low rates of reoperation and revision and few major complications when performed by an experienced, high-volume surgeon. Patient selection and compliance is imperative. Increased reporting among surgeons is necessary to continue to improve patient outcomes. UROLOGY 131: 228–233, 2019. © 2019 Elsevier Inc.

Gender dysphoria (GD) is recognized as a disorder of conflict between one's experienced gender and their sexual phenotype.[1] Management of patients presenting with GD is complex and requires multidisciplinary efforts among psychiatrists, endocrinologists, and surgeons.[2] Gender-affirmation surgery (GAS) is a heterogeneous group of transformational surgical procedures performed to allow one's sexual phenotype to match one's gender identity and is typically the final intervention sought by patients suffering from GD.[3] While some male-to-female (MtF) patient's will opt to undergo breast augmentation or orchiectomy and avoid genital reconstruction, others will undergo the total MtF gender affirmation surgery (MtF-GAS) at one surgical visit. The World Professional Association of Transgender Health has developed guidelines representing the standards of care with regards to treatment of the transgender population, which emphasize the life-altering nature of GAS and mandate that surgeons strictly adhere to the tenets of preoperative preparation to maintain patient safety and

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welfare. For genital reconstruction, these includes one year of living as the gender congruent with one's identity, as well as evaluation from 2 separate mental health professionals.[2] While regret is a common concern voiced among those less familiar with the transgender community, quality of life outcomes research demonstrates that patients undergoing these procedures rarely experience regret and are rather typically empowered by their surgical affirmation.[4,5]

Due to lack of standardization of GAS procedures, technique variations, short-term follow-up, and differing opinions on what constitutes a "complication," there is little transparency and great heterogeneity in available literature regarding objective outcomes and accurate rates of complications. The purpose of this study is to describe and evaluate the outcomes of a large, single-institution single-surgeon cohort of patients undergoing MtF GAS via penile-inversion vaginoplasty (PIV), as well as identify potential risk factors for complications in these patients.

MATERIALS AND METHODS

Patient Selection

A prospectively maintained database of patients undergoing MtF-GAS at a single institution by a single, high-volume surgeon was queried for all available patients who underwent PIV over the initial 18-month experience at this institution. Data were extracted from the outpatient and inpatient records. Patient follow-up was assessed based on the initial 1-week postoperative visit and then at 1 week, 6 weeks, 3months, 6 months, and if applicable 1-year postoperatively. Patients referred from outside of the Philadelphia region were followed remotely as they continued care with their home physicians.

Surgical Approach

The surgical procedure for MtF-GAS / PIV at this institution begins with bilateral orchiectomy and excision of the scrotal skin. The scrotal skin is epilated using bipolar electrocautery and defatted. Bilateral corpora cavernosa are divided from the spongiosum and discarded. The glans is reduced in size and used to create the neoclitoris, while the spongiosum forms the anterior neovaginal wall. The remaining portion of the bulbar and penile urethra is spatulated and sutured to the anterior neovaginal wall in an orthotopic female location. The penile shaft skin is then sutured to the epilated, tubularized scrotal skin, inverted, and placed into a plane developed between the rectum and prostate, thus forming the neovaginal canal. The neovaginal canal is kept in place using packing alone, which is sutured in place. The neolabia are formed utilizing the pubic mound and peri-penile tissue. Packing, Foley catheter, and drains remain in place until their 1-week postoperative appointment when they are removed. Figure 1 below demonstrates an individual's PIV at 1-year follow-up.

Postoperative care includes dilation of the neovagina that is taught in the office and the patient is subsequently watched for proper technique. For the first 4 weeks, dilation is twice daily for 20 minutes. Months 2 and 3 postoperatively include dilation 3 times daily for 20 minutes. Afterward it decreases to twice daily for 20 minutes until 6 months. Finally, from 6 months to 1 year it is daily for 20 minutes. Dilators for our population cohort are typically 9 inches in length and one and three-eighth inches in diameter.

Key steps taken by the surgeon at our institution in order to minimize complication rates in our population cohort include:

1. Injection of vasopressin into the space superior to the pelvic floor prior to dissection in order to assist with hemostasis.
2. A bolster is sewn over the spatulated urethral mucosa at the end of surgery.
3. Strict attention to preserving skin graft and pedicle flap in a cool, moist sponge throughout the procedure.
4. Meticulous fat scraping and hair follicle cauterization of the scrotal skin graft.
5. The neovagina is tightly packed with vaginal packing drenched in metrogel and Premarin to place in the neovaginal vault.
6. A compressive dressing is left in place for 24 hours after surgery.
7. Postoperatively patients must remain on strict bed rest for 3 days.

Patient Demographics and Risk Factors

Patient-specific factors included age, BMI, tobacco use, ethanol use, diabetes, hypertension (HTN), human immunodeficiency virus (HIV), neoadjuvant hormone therapy, simultaneous breast augmentation, prior vaginoplasty, and noncompliance with postoperative neovaginal dilation regimen and care. Noncompliance was determined based on patient reported variations in adherence to the specified dilation regimen or sexual activity restrictions.

Definition of Complications

Complications were indexed and included neovaginal necrosis, neovaginal stenosis, neovaginal prolapse, neolabial necrosis, wound dehiscence, hematoma, meatal stenosis, rectovaginal fistula, rectal injury, and deep vein thrombosis (DVT). Incidents of reoperation and revision were noted. Complications were assessed at the first date of presentation and revisions were assessed on the data of the procedure.

Statistical Analysis

Prevalence of demographic characteristics was summarized using frequencies of categorical data and medians for continuous data with interquartile ranges (IQR) reported. Patients were stratified by demographic variables and risk factors and compared using Fisher's exact test for categorical and the Mann-Whitney U test for continuous data. Logistic regression was performed in order to evaluate relationship of risk factors to likelihood of complications at 30, 60 and 90 days, as well as the likelihood of revision/reoperation. Case volume was divided into quintiles across the study period in order to assess whether patients in the initial study period had differing complication rates to those in the latter periods. Statistical analysis was performed using IBM SPSS statistics 24. Significance was defined at a 95% confidence interval (CI) with $P < .05$.

RESULTS

From November 2016 to April 2018 240 patients underwent PIV and were found to meet inclusion criteria. Of the 240 patients, 3 were lost to follow-up. One patient was incarcerated, one switched providers/surgeons, the third was entered into a rehabilitation facility after relapsing secondary to previous substance abuse. Median follow-up was 87 days (IQR 42-142), median age was 33 years (IQR 27-44), and median BMI was

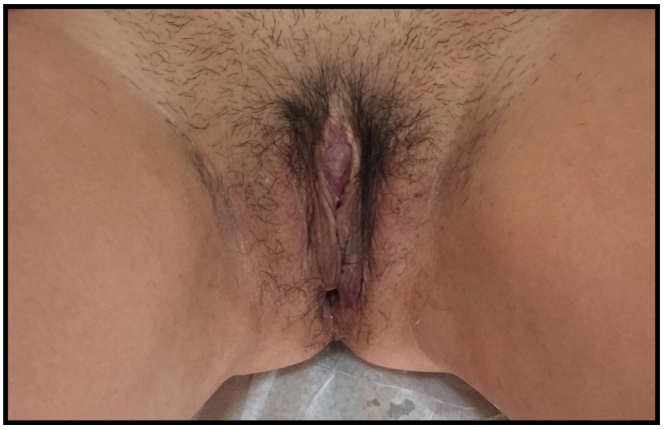

Figure 1. As shown above demonstrate a 1-year postoperative visit of a patient undergoing penile-inversion vaginoplasty (PIV). (Color version available online.)

25.1 kg/m^2 (IQR 22.0-28.8). Patients undergoing concurrent breast augmentation included 17.9% of the population cohort (n = 43). More than 98.3% of patients (n = 236) had been treated with hormonal therapy prior to undergoing their surgical procedure. A total of 2.5% of patients had prior vaginoplasties (n = 6).

Overall complication rate was 23.8%, 31.8%, and 32.1% at 30, 60, and 90 days postoperatively, respectively. Thirty-day complications were noted to be more likely in patients in the second quintile of volume (patients 41-90), such that the incidence in these patients was 36% (odds ratio [OR] 5.1; $P = .007$) compared to the first (10%; $P = .088$), third (24%; $P = .093$), fourth (26%; $P = .062$), and fifth (20%; $P = .188$) quintiles. No statistically significant differences in 60-day or 90-day complications was noted among quintiles (all $P > .05$) Among patients in the second quintile, no differences were noted in prevalence of risk factors except for noncompliance. The prevalence in noncompliance in patients in the second quintile was 18% (OR 13.7; $P < .001$) while prevalence ranged from 0% to 2% in the other quintiles.

Complications were typically minor Clavien I wound healing aberrancies and required no interventions. The only Clavien II complication was a DVT in a single patient (0.4%; n = 1). The incidence of Clavien IIIa-b complications was 1.7% (n = 4) and included 1 rectoneovaginal fistula, 1 neolabial hematoma requiring evacuation, and 2 incidents of wound dehiscence requiring closure. There were no Clavien IV-V complications. Total rates of complications as experienced per risk factor are listed in Table 1, along with the univariate and multivariate analyses examining likelihood of complications at 30 and 90 days by risk factor.

Overall rate of revision and reoperation was 7.9% (n = 19). Aside from the above complications, reasons for reoperation were aesthetics (3.8%) including granulation tissue at the introitus (2.5%; n = 6) and perceived labial asymmetry (0.4%; n = 1), as

Table 1. Rates of 30- and 90-day complications by risk factor along with univariate and multivariate analyses

			Univariate			Multivariate		
	n (%)	30-d Complication Rate by Risk Factor (%)	OR	CI	*P*	OR	CI	*P*
Total cohort	240 (100%)	57 (23.8%)	-	-	-	-	-	-
Breast augmentation	43 (17.9)	12 (27.9)	1.30	0.62-2.75	.553	0.77	0.34-1.73	.529
Hormone therapy	236 (98.3)	55 (23.3)	0.15	0.01-1.71	.142	7.33	0.62-87.19	.115
Prior vaginoplasty	6 (2.5)	1 (16.7)	0.64	0.07-5.63	1.000	1.08	0.12-10.22	.945
HIV	35 (14.6)	9 (25.7)	1.12	0.59-2.01	.831	1.53	0.54-4.28	.422
HTN	20 (8.3)	7 (35.0)	1.82	0.69-4.81	.271	0.66	0.19-2.28	.512
Diabetes	10 (4.2)	3 (30.0)	1.39	0.35-5.56	.706	1.16	0.18-7.63	.876
Smoking	80 (33.3)	22 (27.5)	1.34	0.73-2.49	.421	0.70	0.36-1.36	.293
Noncompliant	12 (5.0)	6 (50.0)	3.45	1.07-11.16	**.040**	4.83	1.17-20.00	**.029**
		90-d Complication Rate by Risk Factor (%)	OR	CI	*P*	OR	CI	*P*
Total cohort		77 (32.1)	-	-	-	-	-	-
Breast augmentation		18 (41.9)	1.68	0.85-3.31	.150	0.55	0.26-1.15	.110
Hormone therapy		75 (31.8)	0.23	0.02-2.59	.242	4.81	0.41-56.23	.211
Prior vaginoplasty		1 (16.7)	0.42	0.05-3.67	.668	1.55	0.17-14.47	.701
HIV		11 (31.4)	0.96	0.44-2.07	1.000	2.47	0.89-6.82	.081
HTN		8 (40.0)	1.46	0.57-3.73	.458	0.72	0.22-2.32	.578
Diabetes		3 (30.0)	0.90	0.23-3.59	1.000	1.63	0.25-10.73	.609
Smoking		29 (36.3)	1.29	0.73-2.27	.384	0.76	0.41-1.41	.388
Noncompliant		7 (58.3)	3.16	0.97-10.30	.059	6.99	1.56-31.25	**.011**

Bolded p-values demonstrating statistical significance.

Table 2. Rates of reoperation/revision by risk factor along with univariate and multivariate analyses

			Univariate			Multivariate		
	n (%)	Revision/Reoperation by Risk Factor(%)	OR	CI	*P*	OR	CI	*P*
Total cohort	240 (100%)	19 (7.9)	-	-	-	-	-	-
Breast augmentation	43 (17.9)	5 (11.6)	1.67	0.57-4.92	.356	0.63	0.19-2.14	.461
Hormone therapy	236 (98.3)	18 (7.6)	0.17	0.01-1.92	.222	8.59	0.61-120.82	.111
Prior vaginoplasty	6 (2.5)	0 (0)	-	-	1.000	-	-	1.000
HIV	35 (14.6)	5 (14.3)	2.24	0.75-6.67	.171	1.21	0.26-5.64	.805
HTN	20 (8.3)	1 (5.0)	0.59	0.07-4.63	1.000	2.02	0.21-19.17	.540
Diabetes	10 (4.2)	0 (0)	-	-	1.000	-	-	1.000
Smoking	80 (33.3)	8 (10.0)	1.46	0.56-3.77	.456	0.75	0.26-2.17	.595
Noncompliant	12 (5.0)	4 (33.3)	7.03	1.90-26.05	**.010**	10.53	1.75-62.5	**.010**

HTN, hypertension; HIV, human immunodeficiency virus.
Bolded p-values demonstrating statistical significance.

well as functionality (2.5%) including repair of neomeatal stenosis (0.4%; n = 1) and neovaginal revisions for stenosis (2.1%; n = 5). Total rates of reoperation by risk factor can be found in Table 2, along with the univariate and multivariate analyses examining likelihood of reoperation by risk factor. Table 3 demonstrates the incidence of reoperations by complication.

Follow-up, age, and BMI did not differ significantly among patients who did and did not experience complications at 30, 60, and 90 days, respectively (all $P > .05$). When controlling for age and BMI, only noncompliance with postoperative wound care (dilation and activity restrictions) was significantly associated with increased likelihood of 30-day complications (OR 3.45; CI 1.07-11.16) on univariate analysis, and 30-day (OR 4.83; CI 1.17-20.00), 60-day (OR 7.14; CI 1.59-32.26), and 90-day (OR 6.69; CI 1.56-31.25) complications on multivariate analysis. Simultaneous breast augmentation, neoadjuvant hormone therapy, prior vaginoplasty, HIV status, HTN, diabetes, and tobacco usage revealed no significant relationship (all $P > .05$).

With regards to reoperation and revision, noncompliance was again the only risk factor that demonstrated a statistically significant relationship on univariate (OR 7.03; CI 1.90-26.05) and multivariate (OR 10.53; CI 1.75-62.5) analyses. Simultaneous breast augmentation, neoadjuvant hormone therapy, prior vaginoplasty, HIV status, HTN, diabetes, and tobacco usage revealed no significant relationship (all $P > .05$).

DISCUSSION

Though there is limited outcomes research surrounding GAS, several studies reporting complication rates exist.

Table 3. Rates of reoperation/revision by complication

	n (%)	Revision/Reoperation by Complication (%)
Total cohort	240 (100%)	19 (7.9)
Neovaginal necrosis	36 (15.0)	0 (0)
Neolabial necrosis	20 (8.3)	0 (0)
Neovaginal stenosis	9 (3.8)	5 (55.6)
Neovaginal prolapse	1 (0.4)	0 (0)
Wound dehiscience	23 (9.6)	2 (8.7%)
Neolabial hematoma	19 (7.9)	1 (5.3)
Meatal stenosis	7 (2.9)	1 (14.3)
Rectovaginal fistula	4 (1.7)	1 (25)
DVT	1 (0.4)	0 (0)
Cosmesis*	9 (3.8)	9 (100)

HTN, hypertension; HIV, human immunodeficiency virus.

Based on available literature, our series of patients represents one of the largest cohorts reported on to date and over a relatively short time frame of 18 months. While there are variations in technique for genital reassignment, most contemporary centers utilize PIV; consequently, most available data regards this approach.[5-9] Gaither et al recently reported data of 330 individuals from 2011 to 2015 undergoing primary PIV with 28.7% of patients experiencing postoperative complications. Approximately 9.0% of their cohort required subsequent reoperation.[6] Reoperation rates have been reported to be from 4.8% to 9.0%.[6,7] This is consistent with the reoperation rate as demonstrated in our cohort of 7.9% of individuals requiring reoperation. Additionally, our incidence of recto-neovaginal fistula of 1.7% among patients undergoing surgery with a subsequent reoperation rate of 0.4% of patients is similar to reported complication rates in the literature of ~1.0%.[6-8] Overall, risk of serious complications are low and include deep vein thrombosis in 0.4% of patients and rectal injury resulting in recto-neovaginal fistula in 0.4% of patients.

In discordance with prior rates of meatal stenosis reported in the literature of up to 40%, the incidence in our series was 2.9% (n = 7), with only one patient requiring revision.[8] It is felt that sufficient spatulation of the urethra is necessary to prevent stenosis, but this may not be commonplace among reconstructive gender-affirmation surgeons. Additionally, our incidence of neovaginal stenosis (6.4%; n = 9) was much less than previously reported in the literature, mentioned to occur in up to 15% of patients. It is unclear if this is secondary to patient selection or compliance factors. One surgical technique variation that may contributed to improved stenosis rates is the utilization of tubularized scrotal skin for the neovaginal canal. Surgeries which only use the inverted penile skin and discard the scrotal skin may predispose the patient to stenosis. Similarly, the incidence of rectal injury (1.7%; n = 4) in our patients was significantly lower than the commonly reported rate of 3%.[7,8] Congruent with previous reports, however, is the notion that most complication are minor and resolve with conservative management with no overall impact on patient's surgical outcomes or overall quality of life.[6] A prior meta-analysis of all available retrospective studies of GAS complications found a total reoperation

rate of 21.7%, with an incidence of reoperation of 4.5% for neovaginal stenosis, 15.5% for meatal stenosis, and 0.7% for rectovaginal fistula.[9] Overall, the complication rates reported in this cohort of patients seem to suggest equivalent, if not better, outcomes. It is uncertain if this represents patient selection bias, surgical technique or volume effects, or heterogeneous reporting standards. Recently, in June 2018 a study involving 117 patients undergoing PIV by Massie et al reported patient complications in accordance with patient satisfaction. Approximately 94% of patients ultimately would do the same operation again even though reported complication rates for their population cohort was approximately 70% (n = 82).[10]

HIV status has previously been described as noncontributory to the development of complications.[11] Our data correlate with this as our analysis demonstrated that individuals with HIV do not appear to have an increased likelihood of complications postoperatively and should not be a barrier to GAS. Additionally, hormone therapy has been associated with increased risk of cardiac mortality in the transgender population as well as up to 20-fold increase in risk of DVT.[4,12] While over 98% of the included patients had been treated with hormone therapy, only one patient developed DVT. Considering the increased risk of DVT, it has been recommended to discontinue estrogen supplementation in the perioperative period, 2-4 weeks both pre- and postoperatively.[12] Of the patient cohort examined, 2.5% were revision vaginoplasties, similar to previously reported rates of up to 2.9%.[7] Prior large series have demonstrated that patients undergoing revision vaginoplasties have significantly increased likelihood of developed rectovaginal fistulas, up to 8.6-fold.[13] However, in our current series none of the 6 patients undergoing revision vaginoplasties developed rectovaginal fistula. Noncompliance with postoperative care conferred the greatest risk of complications overall when controlling for other risk factors, highlighting the importance of patients to understand the personal commitment such life-altering procedures demand. Considering that GD may be associated with multiple comorbid mental health conditions, integrating a multidisciplinary team to provide support and encouragement to patients is of the utmost necessity.[2]

LIMITATIONS

Our population cohort is not without limitations including those patients who experience complications and are subsequently loss to follow. Unfortunately, there is no way to accurately quantify patients who present to outside hospitals with complications following surgery. Thus, our reported complication rates and those in the literature may end up falsely low. Finally, as we present short-term complication rates, it is likely such rates will increase as patients have longer follow-up. While rates of stenosis in our population cohort are low, long-term follow-up will help delineate if our population maintains such rates or if as time progresses, they approach stenosis rates similar to those in the literature.

CONCLUSION

The current study supports previously published literature and affirms that MtF-GAS is a relatively safe surgical procedure, particular in terms of short-term complications when performed by an experienced high-volume surgeon. Considering that noncompliance is associated with increased likelihood of complications, a multidisciplinary approach with primary care providers, infectious disease specialists, and gender reassignment surgeons working together may ultimately provide a setting to best reduce complications and encourage compliance with postoperative care.

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EDITORIAL COMMENT

This is a well presented manuscript describing a series of 240 patients undergoing male to female gender affirming surgery with penile inversion vaginoplasty by a single surgeon over an 18 month period of time in the United States. The authors are

to be congratulated for maintaining a prospective database of these patients and beginning to report some of their findings and patient outcomes. The manuscript mainly focuses on short-term outcomes with 30, 60 and 90 day complication rates outlined as well as risk factors among patients who did and did not experience complications, reoperations and revision surgery. Overall, the short-term complications were fairly infrequent and typically minor with no significant differences noted among the 4 quintiles of patients in the surgeon's experience. When looking at various patient related factors, only patient noncompliance with postoperative wound care was significantly associated with an increased likelihood of short-term complications and the need for reoperation and revision surgery. In this series, simultaneous breast augmentation, neoadjuvant hormonal therapy, prior vaginoplasty, HIV status, hypertension, diabetes and usage of tobacco had no significant relationship with reoperation and revision surgery. The follow-up is extremely short for some patients, as stated to be a minimum of 1 week. That being said, the limitations of follow-up in this population of patients is aptly discussed by the authors. It is likely that the short-term complications noted in the series will increase over time. Whether the moderate and longer-term complications of this prospectively maintained patient series become comparable to other series in the published literature remains to be seen. Inclusion of appropriate patient reported measures, as they become available, will be another necessary facet to the follow-up for these patients.

The authors briefly describe the general surgical technique, postoperative care plan and follow-up regimen. Seven key steps undertaken by the surgeon in order to minimize complication rates are listed. This number of penile inversion vaginoplasties performed over 18 months is undoubtedly high volume for this type of procedure and the fact that they are done by a single surgeon renders consistency with regards to surgical technique compared to some of the other contemporary literature with patient series spanning many years with the inherent possibility of more variability. The manuscript herein adds valuable data to the contemporary literature on penile inversion vaginoplasty for male to female gender reassignment surgery. This information is essential to surgeons as part of the multidisciplinary team taking care of patients considering and undergoing male to female gender affirming surgery.

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