

**Urinary complications after penile inversion vaginoplasty in transgender women:
Systematic review and meta-analysis**

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ABSTRACT

Introduction: Penile inversion vaginoplasty (PIV) remains the gold standard technique for vaginoplasty, a gender-affirming feminizing surgery, but has been associated with urinary complications; however, there is little literature synthesizing urinary complications after PIV surgery, and there is a need to compile these complications to counsel patients pre- and postoperatively on managing surgical expectations. In this systematic review, we summarize the prevalence of urinary complications following PIV.

Methods: We searched the MEDLINE, EMBASE, CINAHL, and Scopus databases in July 2020. The primary outcome was the prevalence of urinary and surgical complications in patients after penile inversion vaginoplasty. Pooled prevalence was determined from extrapolated data. ROBINS-I tool was used to assess study quality. The study was prospectively registered on PROSPERO (CRD42020204139).

Results: Of 843 unique records, 27 articles were pooled for synthesis, with 3388 patients in total. Overall patient satisfaction ranged from 80–100%. The most common urological complications included poor/splayed stream (11.7%, 95% confidence interval [CI] 5.7–19.3), meatal stenosis (6.9%, 95% CI 2.7–12.7), and irritative symptoms (frequency, urgency, nocturia) (11.5%, 95%

CI 2.6–25.1). Other urinary complications included retention requiring catheterization (5.1%, 95% CI 0.3–13.8), incontinence (8.7%, 95% CI 3.4–15.6), urethral stricture (4.6%, 95% CI 1.2–9.8), and urinary tract infection (5.6%, 95% CI 2.7–9.4). Most pooled studies had moderate risk of bias.

Conclusions: The available evidence suggests that there is a low prevalence of urinary complications following PIV. Overall, there is a need for standardization of data in transgender surgical care to better understand surgical outcomes and improve postoperative management.

INTRODUCTION

Penile inversion vaginoplasty (PIV) is the gold standard and most common approach used among a spectrum of transition-related genital feminizing surgeries^{1,2}. In penile inversion vaginoplasty, the penis is disassembled and the corporal bodies are resected. A neo-clitoris is created from a portion of the glans and preserved neurovascular bundle, a vulva is created from penile and perineal skin, and the neovagina is created by dissecting into the perineal space which is then lined with penile and scrotal skin. The native urethra is shortened, spatulated and fixed to an anatomic position at the base of the vestibule between the clitoris and the vaginal introitus³. A urethral catheter is typically left in place for 3-7 days until the vaginal packing is removed; a suprapubic catheter may also be placed. Studies have demonstrated high satisfaction rates following penile inversion vaginoplasty^{4,5}.

The prevalence of urological post-operative complications in penile inversion vaginoplasties are low^{6,7}. Short-term urinary complications include urinary retention and urinary tract infections (UTI)^{7,8}. Patients may also experience complications such as meatal stenosis, urinary stream spraying, and recurrent urinary tract infections. There are several reasons why the rates of urinary complications are largely unknown. Patients often travel great distances to specialty centers for surgery and are therefore unreachable for follow up care⁹. Furthermore, some patients do not seek help for fear of experiencing transphobia when accessing care, and it is believed that many patients live with complications without seeking help^{10,11}. As transition-related surgeries become increasingly common, it is of timely importance for the general urologic community to recognize and be aware of the common urological complications so that they can manage them appropriately. While previous reviews have examined outcomes following vaginoplasty, large-scale meta-analyses focusing on urinary complications are lacking⁷. Current systematic reviews often excluded clinically relevant outcomes such as retention, sprayed stream, incontinence, need for revision surgery, and patient satisfaction^{12–14}. Herein, we present the largest systematic review and meta-analysis to-date focusing on the prevalence of urinary complications after penile inversion vaginoplasty.

METHODS

Search strategy

The following databases were searched from database inception through July 2020: MEDLINE, EMBASE, CINAHL, and Scopus. Search strategy included MESH terms and keywords such as “sex reassignment surgery”, “vaginoplasty”, “gender affirming surgery”, and “urinary complications”, as detailed in Table 1. The references of published studies and grey literature were manually searched to ensure articles were not missed. This systematic review and meta-analysis was reported in accordance with the Preferred Reporting items for Systematic Reviews and Meta-Analyses (PRISMA) ¹⁵.

Eligibility criteria and data collection

Observational studies with data on urinary complications following penile inversion vaginoplasty were included. Exclusion criteria included: narrative reviews, case reports/series including less than five patients, trauma-indicated or congenital surgery, studies not involving urinary complications, and supplement articles. Articles containing alternate vaginoplasty surgery techniques such as those involving bowel flaps or peritoneum were excluded as penile inversion vaginoplasty involving penile and scrotal skin is more commonly performed in gender affirming surgery, and these alternative techniques have unique complications. References from prior systematic reviews were included in the title and abstract screening.

Titles and abstracts were screened independently by two authors for full-text review. Any disagreements were resolved by a third author. The following data were included: number of patients, age at surgery, length of follow-up, and patient satisfaction. Urological complications captured in our review included: UTI, urethral stricture, meatal stenosis, urethral injury and other surgical complications, urinary retention, incontinence, poor or splayed stream, irritative symptoms, and revision surgeries for urinary complications. In the studies included, urological complications were either patient-reported outcomes or surgeon’s reports of outcomes. See Supplementary Table 3 for PICOTS criteria.

Statistical analysis

DerSimonian-Laird random effects models were used to pool the Freeman-Tukey double-arcsine-transformed urinary complication percentages for each complication. The 95% confidence intervals were calculated using Wilson's method. Summary statistics for the pooled cohort were estimated using weighted sampling based on the cohort size for each study. All statistical analyses were conducted using R version 4.1.1.

Risk of bias

In accordance with Cochrane recommendations ¹⁶, risk of bias for individual non-randomized studies was appraised using all domains of the ROBINS-I tool ¹⁷. Two authors independently assessed each study for risk of bias, and any discrepancies were resolved by consensus. Studies

with critical risk of bias were specified to be removed from quantitative synthesis. Funnel plots were generated to examine the risk of publication bias for all meta-analyses.

RESULTS

Search results and study characteristics

The PRISMA flow diagram for study selection is shown in Figure 1. A total of 843 unique records were screened after 776 duplicates were removed. After title and abstract screening, 133 articles moved onto full-text screening. The proportionate agreement was 86% in title and abstract screening. A third reviewer resolved any differences in title and abstract screening. Of these, 27 articles were pooled for quantitative synthesis comprising of 3388 patients.

Risk of bias

The risk of bias for each study based on the ROBINS-I tool is provided in Supplementary Table 2. Of the 27 articles, 2 were low risk, 21 were moderate risk, and 4 were severe risk of bias. The primary cause for at least moderate risk of bias was bias due to confounding factors and bias in measurement of outcomes.

Urinary complications

Mean age at the time of vaginoplasty was 36.2 ± 4.5 years (range 24-44 years). Mean follow-up was 2.6 ± 2.7 years (range 0.15-7.8 years). Overall patient satisfaction ranged from 80-100% (median satisfaction 96.1%). Urological complications following penile inversion vaginoplasty are summarized in Table 2. The three most common urological complications were poor/splayed stream, meatal stenosis, and irritative symptoms: frequency, urgency, nocturia.

Of the studies that reported urinary tract infection in penile inversion vaginoplasty (PIV), the rates ranged from 0%-32%, with 32% being an outlier (studies $n=10$). The remaining reported rates of UTI ranged from 0% to 15%. The median was 4.4%, and the pooled average of UTIs was 5.6% (95%CI: 2.7-9.4%).

Of the studies that reported urethral strictures ($n=11$), the complications rate ranged from 0% to 18.3%. The median was 7.1%, and the pooled average of urethral strictures was 4.6% (95%CI: 1.2-9.8%).

Meatal stenosis occurred from 1.1% up to 40% after PIV (studies $n=17$), with 40% as an outlier; the remaining reported rates of meatal stenosis occurring between 1.8% and 14.8%. The median rate of meatal stenosis was 4.4%, and the pooled average of meatal stenosis was 6.9% (95%CI: 2.7-12.7%).

Of the studies that reported urinary retention requiring catheterization ($n=5$), the complications rate ranged from 0% to 13.9%. The median out of these studies was 6.8% and the pooled average was 5.1% (95%CI: 0.3-13.8%).

Urinary incontinence can occur in 1.1% to 27.3% of patients after PIV, with median reported incidence 9.1%, and pooled average of 8.7% (95%CI: 3.4-15.6%). Urinary incontinence was reported in 8 studies.

Poor or splayed stream occurs in 1.8% to 33.2%, with 33.2% being an outlier. The remaining reported rates of poor or splayed stream ranged from 0% to 22.5% (studies n=10). The median in the data set for poor or splayed stream was 10.2% and the pooled average was 11.7% (95%CI: 5.7-19.3%).

Surgical complications

Surgical complications are summarized in Supplementary Table 1. There was no standardized surgical complication grading system used in the publications. Of the reported surgical complications, the most common surgical complications were wound dehiscence (n= 9 studies, range 0.6% -33%, median 6.7%), vaginal stenosis (n=6 studies, range 2.1%-18%, median 3.05%), urethral injury (n=15 studies, range 0.6%- 10.9%, median 5%), and rectal injury (n=11 studies, range 1.1%-7.5%, median 2.3%). Of the studies that reported neovaginal fistulas (n=13), urethrovaginal fistulas ranged from 1.5% to 4.5% (median 2.55%) and rectovaginal fistulas ranged from 0.3% to 3.6% (median 1.15%). Many studies did not have any fistulas in their sample. The most common urinary revision surgeries were meatoplasty (n= 10 studies, 0.4%-15%, median 5.3%), and urethral revision (n=5 studies, 1.5%-27%, median 7.1%).

DISCUSSION

There is limited high-quality data available on the surgical risks and urinary complications of vaginoplasty which makes it difficult to counsel patients and educate physicians on the expected post-operative course. We performed the largest systematic review and meta-analysis to date examining urinary complications after penile inversion vaginoplasty. Twenty-seven studies regarding penile inversion vaginoplasty were examined and analyzed for urinary complications. Our systematic review, which included all studies reporting on the prevalence of urinary complications, suggests that the overall risk of complications is low and of minor severity. These complications could be managed by a general urologist in most cases. Of 3388 patients, the mean prevalence of reported urinary complications ranged between 5.0 and 11.9% in non-randomized studies with an overall intermediate risk of bias. The most common urological complications included poor/splayed stream (11.7% [95%CI 5.7-19.3%]), meatal stenosis (6.9% [95%CI: 2.7-12.7%]), and irritative symptoms (frequency, urgency, nocturia) (11.5% [95%CI: 2.6-25.1%]). Other urinary complications included retention requiring catheterization (5.1% [95%CI: 0.3-13.8%]), incontinence (8.7% [95%CI: 3.4-15.6%]), urethral stricture (4.6% [95%CI: 1.2-9.8%]), and UTI (5.6% [95%CI: 2.7-9.4%]). Further, many of these complications like UTI, splayed stream and meatal stenosis are of minimal morbidity and can be readily treated with antibiotics or meatal dilators.³ Urethral dilation is a short-term solution for an urgent situation of acute retention, and most patients with non-resolving meatal stenosis can be treated definitively with

meatoplasty (5.3%), and urethral revision surgery (7.1%). Majority of the pooled studies had moderate risk of bias.

There are multiple explanations of why there is a relatively low complication rate for this gender affirming surgery. Firstly, after PIV, the distance from the urethral meatus to the bladder is still longer than a cis-female urethra, which may be a preventative factor against UTIs¹⁸. Second, the urethra is spatulated widely during the surgery to decrease the rate of retention and stenosis. Furthermore, if strictures are present, they can be corrected at the time of gender affirming surgery. Finally, the prostate decreases in size from feminizing hormone therapy, which can lower the rates of retention and bladder outlet obstruction¹⁹.

There may be under-reported urinary complication rates, especially in studies from the earlier decades. Patients often travel for surgery and long-term consistent follow-up may therefore be limited⁹. Additionally, complications may be treated at local institutions and therefore are not captured in study follow-up. Furthermore, there are a small number of transgender patients who are post radiation or who have bladder outlet obstruction secondary to benign prostatic hyperplasia (BPH). They will not be captured in this review but will be at higher risk of complications and would need general urologic management.

Together, in our review, we summarized 27 studies and 3383 patients after penile inversion vaginoplasty; with robust data of urinary complications due to the large sample size. Moreover, we conducted the largest systematic review and meta-analysis of comprehensive urinary complications following female transgender surgery. Overall, these findings support the notion that penile inversion vaginoplasty is associated with low rates of urinary complications, and most patients are satisfied after surgery. However, our review suggests that patients should be advised that urinary complications can occur and may need conservative, medical or surgical management. Ultimately, our findings provide useful data summaries for patients and healthcare practitioners to aid in treatment decisions and managing realistic surgical expectations. General urologists can treat and manage most of these complications, and they should do so in a trans inclusive environment. This includes referring to the patient by their name which may be different than the legal name, avoiding questions around transition not relevant to their care, as well as including resources in the clinic where trans people are represented²⁰.

The findings in this study should be interpreted in the light of the following methodological limitations. First, in the studies included in this meta-analysis, the primary outcome of urinary complications was not reported in a standardized method. For example, urinary complication rates were reported from research questionnaires, patient-reported outcomes, which can introduce a risk of reporting bias and prohibits analysis of symptom severity. However, surgical correction rates had direct clinical indications, which was more objective than reported urinary symptoms. To account for this, we abstracted the surgical correction rate whenever possible. Future work should therefore implement standardized definitions and methods of reporting surgical and urinary complication, which would allow a

better understanding of outcomes after PIV and other gender affirming surgeries ²¹. Second, urinary complications were pooled based on the reported complication rate in the articles and zero-event studies were excluded if the outcome was not mentioned. Given a potential of a zero-complication rate for a specific outcome, the actual urinary complication rate may be lower than what is reported in this review. Finally, the overall study quality was medium (most studies had moderate risk of bias and 4 studies had a severe risk of bias). For this reason, randomized, large, or prospective studies are required for certainty with regards to these outcomes. Further studies are also needed to examine how to best manage the urinary complications.

CONCLUSIONS

PIV is the gold standard vaginoplasty technique with excellent patient outcomes. We have presented the largest meta-analysis on the urinary complications of PIV and have shown that complication rates are low. Complications that do arise are well within a general urologist's skillset. However, there remains a need for standardization of data collection in vaginoplasty surgery and by improving data, we will better understand the true prevalence of urinary complications. As such, urologists and other healthcare practitioners can use this systematic review to counsel patients pre- and post-operatively on managing surgical expectations.

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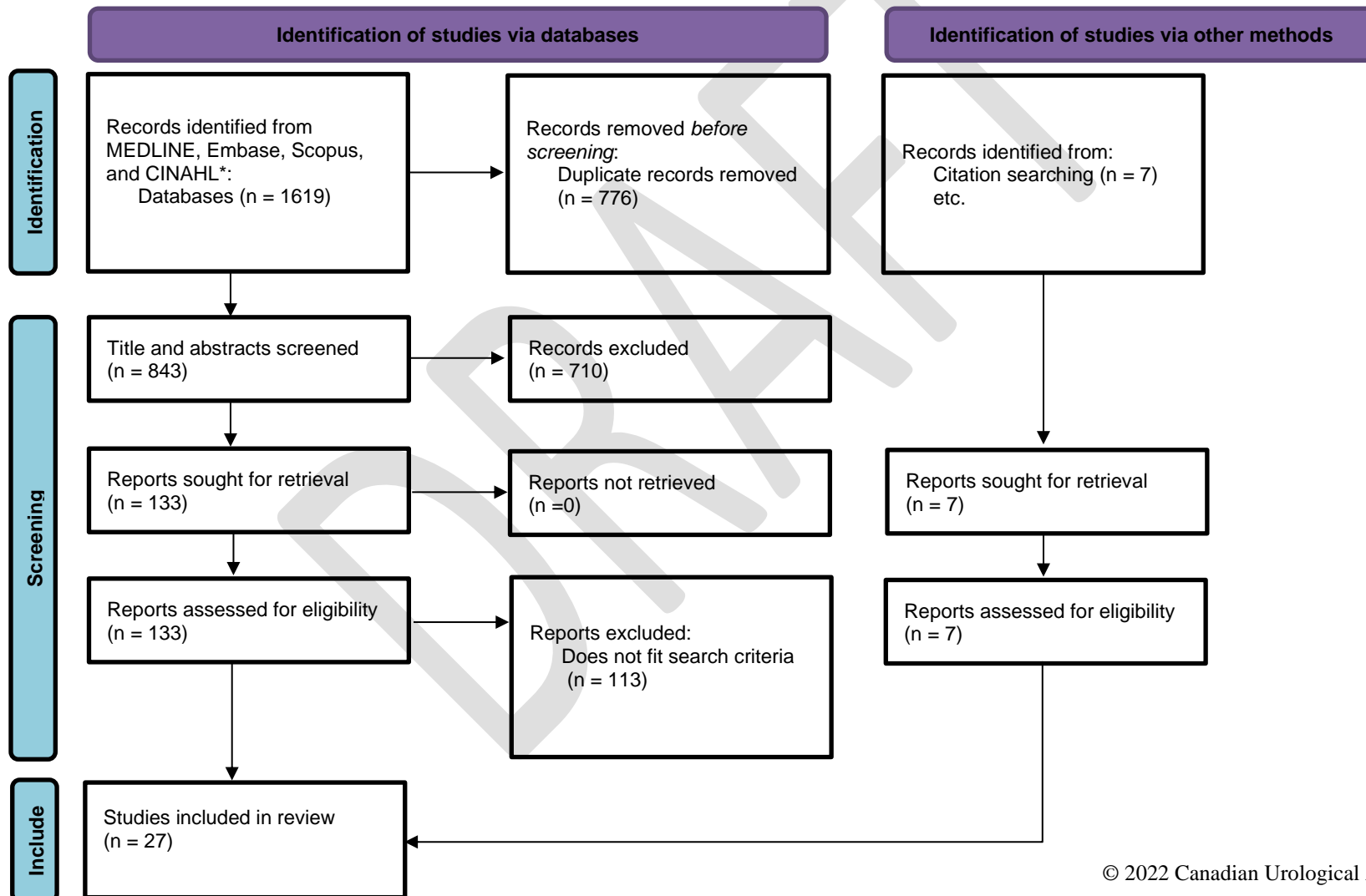
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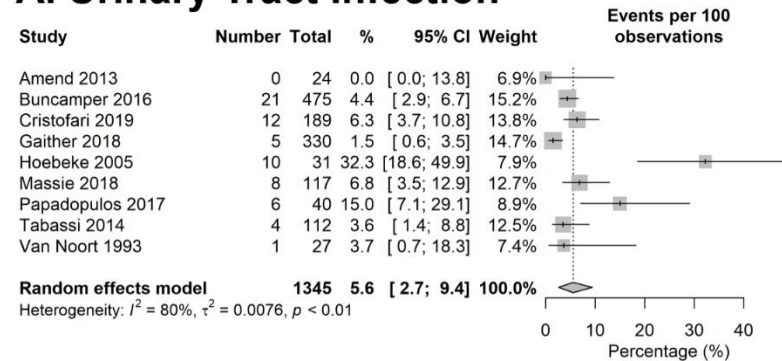
Figures and Tables

Figure 1. PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and other sources. Adapted from Page MJ, et al. BMJ 2021;372:n71. For more information, visit: <http://www.prisma-statement.org/>.

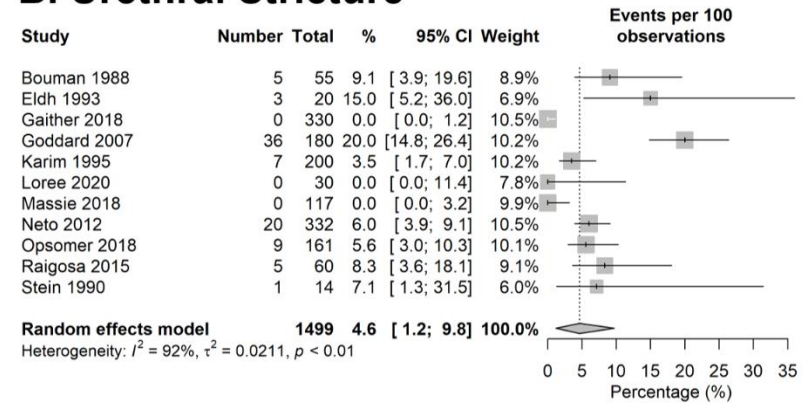


Figures 2a and 2b. Urinary complications of penile inversion vaginoplasty.

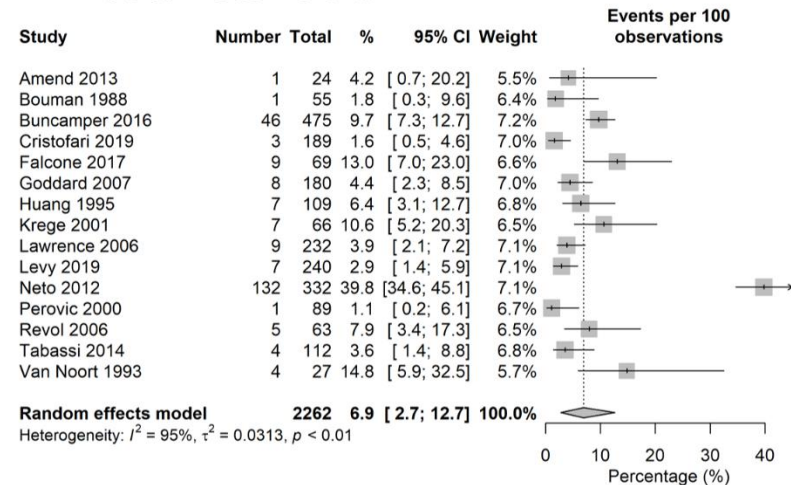
A. Urinary Tract Infection



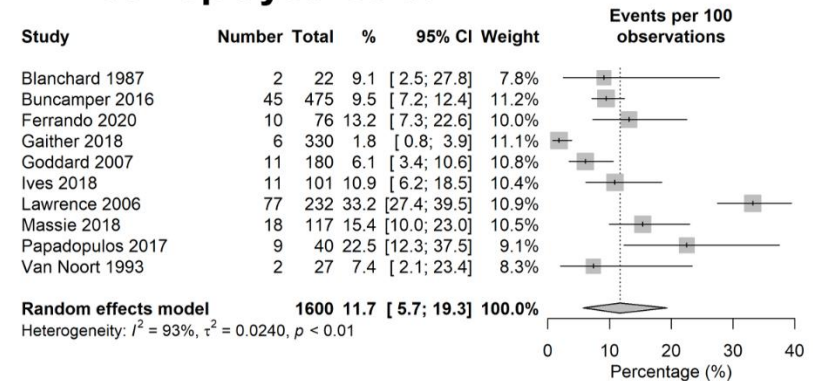
B. Urethral Stricture



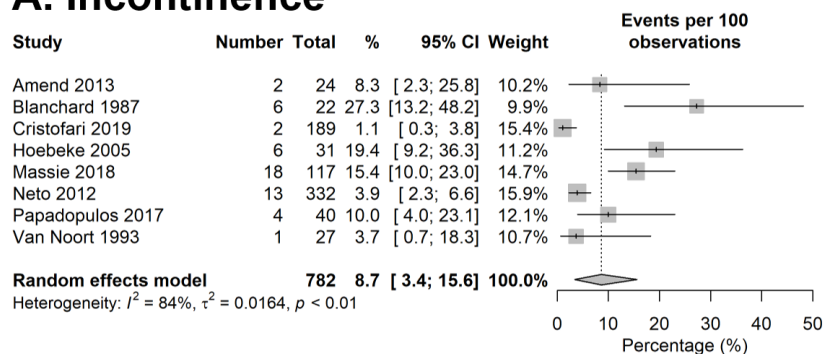
C. Meatal Stenosis



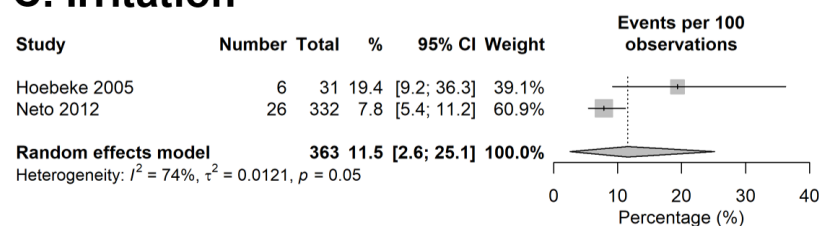
D. Poor/Splayed Stream



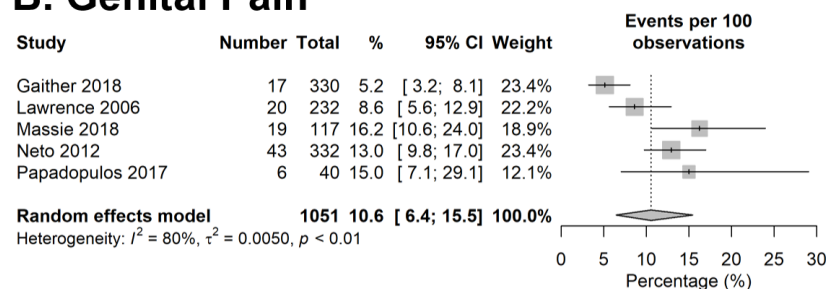
A. Incontinence



C. Irritation



B. Genital Pain



D. Retention

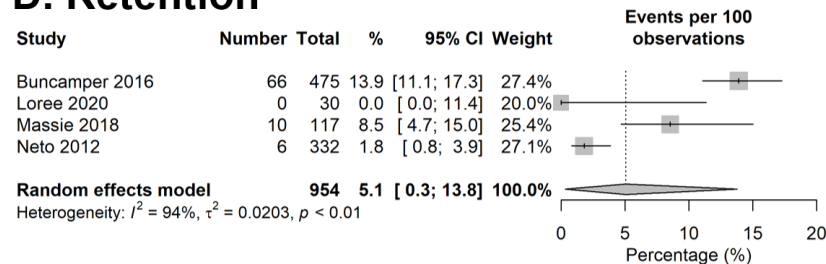


Table 1. Search strategy from Embase Classic + Embase 1947 to July 17, 2020	
Search line	Search terms
1	exp Sex reassignment procedures/
2	Transsexualism/su
3	(Gender affirm* adj3 surger*).tw,kw.
4	((transit* or gender*) adj3 (surg* or procedure* or operation*)).ti,kw.
5	Sex change*.tw,kw.
6	Gender reassignment*.tw,kw.
7	Transsex*.tw,kw.
8	Gender change*.tw,kw.
9	Transgender*.tw,kw.
10	Transvestism*.tw,kw.
11	Gender identity disorder*.tw,kw.
12	Genitoplast*.tw,kw.
13	Vaginoplast*.tw,kw.
14	Neovagina*.tw,kw.
15	Vagina/su
16	(Penile inversion* adj3 vaginoplast*).tw,kw.
17	Scrotal inversion vaginoplasty.tw,kw.
18	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
19	13 or 14 or 15
20	18 and 19
21	16 or 17 or 20

Table 2. Study characteristics on studies including the prevalence of urinary complications after penile inversion vaginoplasty

Study	Patient characteristics			Urinary complications							Patient satisfaction
	n	Mean patient age at surgery (range)	Mean followup length in years (range)	UTI	Urethral stricture	Meatal stenosis	Retention	Incontinence	Poor or splayed stream	Irritative symptoms (frequency, urgency, nocturia)	
Pooled Statistics				5.0% 0–15%	5.7% (0–18.3%)	10.8% (1.1–40%)	8.6% (0–13.9%)	6.6% (1.1–27.3%)	11.9% (1.8–33.2%)	8.8% (7.8%, 19.3%)	
Amend 2013 ²²	24	39.1 (20–54)	3.3 (1.6–5.8)	0%	–	4.2%	–	8.3%	–	–	100%
Blanchard 1987 ²³	22	32.3 (22.8–59.5)	4.4 (0.5–11.8)	–	–	–	–	27.3%	9.1%	–	90.4%
Bouman 1988 ²⁴	55	28** (10–60)	2.33 (0.16–6.25)	–	9.1%	1.8%	–	–	–	–	98.2%
Buncamper 2016 ²⁵	475	38.6 [†] (18.1–70.8)	7.8 [†] (1.0–15.9)	4.4%	–	9.7%	13.9%	-	9.5%		-
Cristofari	189	36.8 (19.9–	1.4 (12–59)	6.3%	–	1.6%	-	1.1%	-	-	98.4%

2019 ²⁶		64.7)									
Eldh 1993 ²⁷	20	34 (20–67)	5.8 (0.5–30.0)	–	15%	–	–	–	–	–	–
Falcone 2017 ²⁸	69	33.5 [†] (SD 10.2)	5 [†] (SD 3.2)	–	–	13.0%	–	–	–	–	–
Gaither 2018 ²⁹	330	35 [†] (18–76)	0.25 [†] (0.3–6.1)	1.5%	0%	–	–	–	1.8%	–	–
Goddard 2007 ³⁰	180	41 [†] (19–76)	0.15 [†] (0.02–0.96)	–	18.3%*	4.4%*	–	–	5.6%*	–	80%
Hoebeke 2005 ³¹	31	–	–	32.3%	–	–	–	19.3%	–	19.3%	–
Huang 1995 ³²	109	32.3 (18–71)	–	–	–	7.4%*	–	–	–	–	–
Ives 2019 ³³	101	42	0.25 (0.25–0.50)	–	–	–	–	–	10.9%	–	–
Karim 1995 ³⁴	200	(18–71)	–	–	3.5%	–	–	–	–	–	–
Krege 2001 ³⁵	66	36.8 [†] (20–57)	–	–	–	10.6%	–	–	–	–	–

Lawrence 2006 ⁶	232	44 (18–70)	3 (1–7)	–	–	3.9%	–	–	33.2%		
Levy 2019 ³⁶	240	33 (SD 23)	0.24 (SD 0.37)	–	–	2.9%	–	–	–		
Loree 2020 ³⁷	30	37 (SD 5.4)	1.27 (SD 9.9)	–	0%	–	0%	–	–	–	92.0%
Massie 2018 ³⁸	117	38 (16–78)	1.75 (1.1–2.8)	6.8%	0%	–	8.5%	15.4%			94%
Neto 2012 ³⁹	332	36.7 (19–68)	–	–	6.0%	40.0%	5.0%	4%	–	7.8%	
Opsomer 2018 ⁴⁰	161	38.2 (18–69)	2.4 (0.9–3.9)	–	5.6%	–	–	–	–	–	–
Papadopoulos 2017 ⁴¹	40	38.6 (26–50)	0.5	15.0%	–	–	–	10.0%	22.5%	–	–
Perovic 2000 ⁴²	89	28 (18–56)	3.6 (0.3–6.0)	–	–	1.1%	–	–	–	–	–
Raigosa 2015 ⁴³	60	28 (19–50)	2.0 (1.2–3.8)	–	8.3%	–	–	–	–	–	

Revol 2006 ⁴⁴	63	33 (22–56)	1.3 (0.2–6.6)			7.9%					
Stein 1990 ⁴⁵	14	31.4 (23–49)	1.8 (0.4–4)		7.1%						100%
Tavakkoli-Tabassi 2014 ⁴⁶	112	25.8 (SD 3.3)	1.1 (0.5–2.0)	3.6%		3.6%					85.7%
Van Noort 1993 ⁴⁷	27	24 (21–57)	2.58 ^{**} (0.1–8.6)	3.7%		14.8%		3.7%	7.4%		100%

*The full study population was not assessed for the outcome, and the population event rate is assumed from the sample event rate. **Estimated based on data given. †Median value provided if mean was unavailable. SD: standard deviation.