A Single-center Analysis on the Learning Curve of Male-to-Female Penoscrotal Vaginoplasty by Multiple Surgical Measures

A Single-center analysis on the learning curve of Male-to-Female penoscrotal vaginoplasty by multiple surgical measures

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ABSTRACT

OBJECTIVE

To asses and quantify the learning curve (LC) of the penoscrotal inversion flap vaginoplasty (PSV).

PATIENTS AND METHODS

We retrospectively reviewed clinical records of 69 patients who underwent PSV from January 2005 to January 2015. Two validated methods were used: a scatterplot representation and a splitting group. We selected as primary outcomes the operative time and vaginal depth. Surgical outcomes including blood losses, hospital stay, and postoperative complications such as vaginal stenosis or atresia or urethral meatus stenosis were also evaluated.

RESULTS

The overall median operative time was 245 minutes. Severe intraoperative complications were not reported. The overall incidence of postoperative major complications was 21.7 %, most of them being urethral issues. The splitting group analysis revealed a statistically remarkable difference between groups for the operative time ($P < .01$), the vaginal depth ($P = .01$), the hospital stay ($P < .01$), and the intraoperative complication rate ($P = .01$). On the contrary, no differences were evidenced between the cohorts for the amount of blood loss ($P = .08$). The scatterplot logarithmic analysis demonstrated a clear visible LC for most parameters. The operative time showed a sharp decrease within the first 20-30 cases, reaching a plateau after 40 cases. Considering the analysis of the vaginal depth, the logarithmic scatterplot curve evidenced a slight increase within the first 10 cases, reaching a clear stabilization after nearly 30-40 cases.

CONCLUSION

An evident LC for PSV is detectable, consisting of at least 40 cases needed to the surgical team to develop adequate skills to guarantee a safe and high-quality procedure.

Gender dysphoria (GD), as recently defined in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*, expresses the distress secondary to a marked incongruence between the experienced gender and the assigned one.[1] Initially described by Benjamin in 1967, this condition has progressively raised increasing interest in the scientific community[2] after the introduction of surgical solutions for the sex reassignment surgery (SRS). Following the initial description of penile skin inversion vaginoplasty by George Burou,[3] the surgical technique has been progressively improved over the years, thanks to the increase in the prevalence of GD in western countries,[4,5] with consequent increase in the number of procedures performed.[6,7] Despite its worldwide diffusion, however, SRS is still not universally codified, resulting in lack of evidence-based results in terms of outcomes.

Although it is widely accepted that the surgical steps needed in a male-to-female SRS are orchidectomy, subtotal penectomy, clitoroplasty, labioplasty, and finally the vaginoplasty,[7,8] the neovagina can be fashioned with skin graft, penoscrotal skin flap, or pedicled intestinal flap.[9,10] Based on recent scientific evidence, the penoscrotal inversion flap vaginoplasty (PSV) seems to be the preferred first-line approach by most gender surgeons.[7,11-18] It is widely recognized that to achieve good surgical outcomes, a meticulous and standardized technique is of utmost importance, and therefore adequate training and supervision during the learning curve (LC) of the surgeon is essential. By definition, the LC is the initial period of development of skills acquisition of an individual to a procedure, essential for both patients' safety and surgical training.[19]

As far as we know, no scientific reports are available on the LC for SRS, and in particular PSV. The aim of the present study is to assess which might be the optimal LC for PSV, analyzing in a retrospective fashion the outcomes of a single-surgeon series.

PATIENTS AND METHODS

Patient's Selection

The clinical records of 69 patients underwent PSV in our Urology department from January 2005 to January 2015 were retrospectively reviewed. Data on patients' characteristics, risk factors, duration of the procedure, neovaginal depth, intra- and postoperative complications, and surgical outcomes were collected. The operative time was calculated from the induction of the general anesthesia until the final dressing was completed. Vaginal depth was measured at the end of each surgical procedure by the use of a sized 21 Hegar-Mosquito dilator.

All patients completely fulfilled the requirements of both the legal and the Italian Department of Health. In all cases, a GD diagnosis according to the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* was confirmed by a psychiatrist included in our GD multidisciplinary group. According to the Italian legislation, patients are required to complete 1 year of real-life experience under hormonal treatment in the preferred gender to obtain the legal authorization to undergo the SRS. A complete

physical examination was carried out before surgery to exclude any possible surgical contraindication and to quantify the amount of skin disposable for the PSV. None of the patients had previously undergone circumcision. When a significant amount of pubic hair was present, patients
underwent sessions of laser hair removal prior to surgery. The procedures were all conducted by the same surgeon (LR) assisted by the same surgical team (MT and MF). The lead surgeon has gained a vast experience on penile surgery and urethral surgery with perineal approach before doing the PSV. These elements validate the LC exclusively for urologists.

Surgical Technique

After an inverted U-shaped scrotal skin flap (4 × 12 cm) has been raised (Fig. 1A), a bilateral orchidectomy is performed. The bulbar urethra is then dissected off the bulbospongiosus muscle and the perineal central tendon is divided to develop a space in the prostatorectal with blunt dissection. At this stage, a Hegar-Mosquito dilator size 21 can be helpful to determine if the length of the cavity is adequate. Once the penile skin is then completely degloved through a subcoronal and a longitudinal ventral shaft incision, the neurovascular bundle is dissected from the corpora cavernosa together with a strip of albuginea, to minimize the trauma to the bundle and to facilitate the creation of the mons veneris, according to the technique of Soli et al.[20]

The bulbar urethra is then divided and spatulated ventrally and the crura of the corpora cavernosa are isolated and excised completely.

The glans is then incised in M-shape fashion, maintaining when possible a large amount of internal prepuce flap to create the neoclitoris according to Preecha's technique.[12] Two edges of the distal urethra are fixed circumferentially to the neoclitoris to achieve a more esthetically pleasing result.

At this stage, a combined penoscrotal flap is created and inverted to cover the walls of the neovagina. In contrast with some recent literature reports,[21] in the present series no anchoring stitches were applied to the vault of the neovagina to prevent prolapse. This is because we believe that scar tissue formation is enough to prevent any postoperative genital prolapse.

The major labia are finally configured, excising the excessive skin, and once a dedicated vaginal dilator is inserted in the neovagina, a compressive is applied to the external genitalia to minimize swelling and reduce the risk of hematoma formation.

Main Outcome Measures

Operative time and neovaginal depth represent the main outcomes analyzed in the present series, although blood losses, hospital stay, and postoperative complications such as vaginal stenosis or atresia or urethral meatus stenosis[19] were also evaluated.

LC Analysis

To statistically quantify the LC, 2 validated methods were used: a scatterplot representation and a splitting group. Concerning the first methodology, a standard curve and a logarithmic best-fit curve were drawn for each outcome measure. The LC was determined as the visual plateauing of the line of best fit. On the other hand, as expected by the group splitting method, we divided our series of patients in small consecutive cohorts, with an arbitrary cutoff point of 5 patients. Finally, the means between the group were statistically compared.[19]

Statistical Analysis

Data analysis was performed using IBM SPSS Statistics Software version 20. *P* value less than .05 was set as statistically significant. Nonparametric tests and analysis of variance were used to compare the groups.

RESULTS

Baseline patients' characteristics and surgical outcomes are reported in Table 1. The overall median operative time was 245 minutes. Severe intraoperative complications were not reported, except for a single case of rectal injury, which was managed with primary closure and with a temporary colostomy. Intraoperative blood loss was minimal, with only sporadic need of blood transfusions in the postoperative period. The overall incidence of postoperative major complications was 21.7%. Most of them (13%) were strictures of the neomeatus, which were managed successfully with a delayed meatoplasty. The most common neovaginal complications were stenosis (5.8%) and complete atresia (2.9%) of the introitus. All neovaginal complications required delayed revision surgery. Patients with vaginal stenosis were managed successfully with multiple relaxing incisions, whereas patients with complete atresia required a bowel vaginoplasty. All major complications were defined as IIIa according to the Clavien-Dindo classification.[22]

Cosmetic alterations requiring surgical correction, which were reported by 26% of our patients, were excluded from the present analysis. Overall, 80% of these patients requested a revision of the labia majora as they were asymmetrical, 10% a reduction of the clitoris, and the remaining 10% a repositioning of the clitoris.

The splitting group analysis revealed a statistically remarkable difference between groups with regard to operative time ($P < .01$), vaginal depth ($P = .01$), hospital stay ($P < .01$), and intraoperative complication rate ($P = .01$). On the contrary, no differences were evidenced between the cohorts for the amount of blood loss ($P = .08$).

The operative time decreased significantly from 350 minutes in the first group to 220 minutes after 35 cases, tending to a visible stabilization in the last cohorts. When analyzing neovaginal depth, apart from a solitary peak seen in the first group, it tended to be stable until 45 cases, whereas it had a slight progressive increase in the consequent cohorts, reaching plateau after 65 cases. The hospital stay was

characterized by a progressive decrease, excluding an isolated peak visible in the fifth group, and it stabilized after 55 cases. On the contrary, blood loss was stable in all the cohorts, reaching 2 isolated peaks after 40 and 55 cases.

The graphic representation of intraoperative complications showed an overall decrease, from 20% in the first to 0% in the last group. Few peaks were remarked, reaching 60% in the third and 40% in the fifth, sixth, and seventh groups.

The scatterplot logarithmic analysis demonstrated a clear visible LC for most parameters. The operative time showed a sharp decrease within the first 20-30 cases, reaching a plateau after 40 cases, even if a slight decrease was noticed in the last 10 cases. When analyzing vaginal depth, the logarithmic scatterplot curve evidenced a slight increase within the first 10 cases, reaching a clear stabilization after nearly 30-40 cases. The hospital stay, on the other hand, was characterized by a significant decrease within the first 10 cases, reaching a plateau after 40-50 cases. As for blood loss, a stable curve was evidenced for all groups.

DISCUSSION

Since the first SRS report in 1931,[3] many investigators have described their personal experience in male-to-female SRS. Nowadays, we are assisting to a widespread diffusion of the "transsexual phenomenon" both in the society and the scientific community. Recent epidemiological studies have reported a sharp increase in the prevalence of GD in male patients, assessing an overall presence of 1:12,900 in western countries.[5] Accordingly, a rise in SRS requests has been recently underlined.[7] Similarly, the scientific community has experienced a surprising boost in the volume of publications about transsexualism. Nevertheless, a specific nonprofit association devoted to professional's education, named WPATH, has been founded, aiming to promote academic research on GD and to increase the level of care of transgender patients.[23] Even if vaginoplasty is conducted mainly by plastic surgeons worldwide, it is no doubt true that the number of gender centers where this operation is performed by urologists is increasing. This fact is probably due to the familiarity of the urologists with perineal dissection, widely used for bulbar and membranous urethral surgery and genital demolitive surgery.

It is widely accepted that the SRS needs to go through few necessary surgical steps: orchidectomy, penectomy, clitoroplasty, labiaplasty, and finally the vaginoplasty.[7,24] However, different surgical approaches can be used: (1) nongenital skin grafts, (2) penoscrotal skin pedicled inversion flaps, or (3) pedicled intestinal flaps.[10,12,25]

1) Nongenital skin grafts have been widely employed in the first attempts of vaginoplasty. The well-known surgeon McIndoe used to apply split thickness skin graft in his technique.[26] However, considering the morbidity of the donor site and the high percentage of postoperative complications, this approach is nowadays strongly discouraged.[23]

2) Penoscrotal skin pedicled inversion flap, on the contrary, is currently the technique preferred by most authors in the scientific literature. It is essentially based on the combination of penile and scrotal skin to cover the wall of the created vagina.[7,12,14-18,23,27] Recently, Perovic et al[28] have proposed the interposition of a urethral flap to widen the diameter of the neovagina and to increase its lubrification.

3) Pedicled intestinal flap, including most rectosigmoid segments, is routinely used by a minority of surgeon.[10] As far as we are concerned, the additional need for an abdominal surgery and the related possible complications, the retention of mucus, and the persistent disturbing smell make this approach less attractive as a first choice. Nevertheless, it is undeniably our preferred choice in cases of salvage vaginoplasty after failed PSV.

In surgery, the LC is defined as the number of procedures that a surgeon needs to perform before reaching a safe and high-quality level of performance. This concept is raising a significant interest in the scientific community. It surely has a main role in surgical education, with the aim of improving the quality of the surgical care[8,19] A rigorous LC is essential especially when a standardized technique must be followed, as recently shown for robot assisted radical prostatectomy.[29] We strongly believe that the same concept should be applied to PSV, which among SRS procedures is the most codified and accepted.

The present analysis is based on a single-center series of 69 patients, which is currently placed among 1 of the largest PSV series reported. Even if retrospective, the present study reports intraoperative and surgical outcomes in a structured and reproducible fashion, raising the level of evidence in PSV literature, which currently is very poor. However, it is undeniable that 1 of the main limits, which need to be underlined, is the lack of a long follow-up, which is necessary to validate conclusions on long-term surgical outcomes. Consequently, in the present series, the focus has been placed on the intraoperative and short-term surgical outcomes.

The average operative time in the present series is significantly shorter than what was recently reported by Amend et al.[13] On the contrary, it is evident that, in highvolume centers, as experienced in Thailand by Preecha's group (nearly 400 patients),[12] the average operative time decreased to 180 minutes, which is much less than in the present series.

According to the present series, 30-40 cases need to be performed to optimize the surgical time, reaching adequate levels, currently comparable to high-volume centers. Even if operative time is frequently considered as a valuable measure to assess a surgical LC, in reality it represents a measure of surgical efficiency. In fact, a direct effect on surgical or functional outcomes has never been demonstrated.

Considering the measurement of the intraoperative blood loss, no investigators, apart from us, have ever described the exact amount by a reproducible measure. However, focusing on the postoperative blood transfusion, the present series seem to agree with the majority of studies, affirming that they are rarely needed, if the operation is conducted in selected tertiary referral centers.[7,12,13]

The hospital stay, which is a measure frequently considered in surgical studies, is rarely addressed when focusing on PSV. In the present study, it appears that hospital stay is a measure strongly affected by the LC as nearly 40 cases are needed to reach an evident plateau. In the current series, the clear reduction of

the postoperative stay could be explained by both the shortening of the operative time, and consequently the anesthesia time, and the negligible blood losses. Last but not least, the progressive optimizing of the inpatients care and the pain control pathways surely added to this effect and it could potentially represent a confounding factor on the surgical LC, although no definitive conclusions can be supported.

An adequate vaginal depth is a major goal, which needs to be pursued by surgeons dealing with male-to-female SRS as it is one of the main factors influencing the patient's postoperative satisfaction.[9] Even on this notable aspect, the results of the present series are in line with recent international reports.[13,14] Moreover, this study has clearly shown that vaginal depth is strictly connected to the surgical skills of the operator and consequently is highly affected by the LC. It is widely accepted that when dissecting the prostaterectal space, the maximum length obtainable is partially limited by the bladder neck and the peritoneum, which are the farthest cranial points reachable. According to the present study, LC seems to play a determinant role in extending the length of the dissection, probably giving the operator sufficient confidence to completely dissect the space, reaching its maximum extension. At least 30-40 consecutive operations seem to be needed to develop the sufficient skill to dissect properly the prostate-rectal space, obtaining a stable value of 13-14 cm in length, which are comparable to high-volume centers.

Focusing on the intraoperative complications, which probably represent the most valuable parameter to assess a surgical LC, the present series shows an overall incidence that seems to be slightly higher when compared with other recent reports.[7,12,13] However, in many of these studies it is not clear if the first surgeries performed during the initial phase of the LC were included.[7,13] We strongly believe that the absence of a universally accepted technique forces each surgeon approaching PSV to develop his own approach, with tips and tricks based on personal experience. This fact explains how the incidence of complications in our study, being significant in our first cohorts, decreased to zero when our approach was well encoded. Taking all this into consideration, the present analysis clearly showed that PSV is a safe technique, which reaches an incidence of complications tending to zero after nearly 40 procedures.

The main limitation of this study is surely the low case number, which is, however, remarkable if we consider the rarity of GD. We strongly believe that the present study could have a role in helping scientific associations deal with transgender health care to outline validated guidelines to select the high-skilled center addressing SRS, with the aim of improving the quality of care in this field. Furthermore, we hope that our results can be used to determine systematic methods to train young surgeons in PSV.

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TABLES

Age, median, years [SD]	33,5 [10,2]		
Follow-up, median, months [SD]	5 [3,2]		
Diabetes	Yes (4 %)	No (96 %)	
Smoking	Yes (39 %)	No (61%)	
Operative time, median, minutes [SD]	245 [51]		
Intraoperative blood loss, median, Hb, g/dL [SD]	5.2 [1.2]		
Intraoperative complications	Yes (1.5 %)	No (98.5 %)	
	1 case rectal injury		
Postoperative red blood cells transfusions, median, units [SD]	0 [1]		
Hospital stay, median [range]	8 [2.6]		
Postoperative complications	Yes (21.7 %)	No (78.3%)	
	Vaginal atresia	Vaginal stenosis	Urethral stenosis
	2.9 %	5.8 %	13 %
Vaginal depth, median, cm [SD]	12 [1.6]		