Evaluation of Early Outcomes of Feminizing Genitoplasty in Virilized Female Children with Congenital Adrenal Hyperplasia

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ABSTRACT

***Background and Rationale**: Congenital adrenal hyperplasia in females leads to virilization of the external genitalia and an anomalous lower genitourinary tract. Hormonal therapy controls the endocrinopathy. Surgical repair of the anomaly is indicated to allow raising a female child with external genitalia matching her gender and to avoid psychological complications. Surgery at an earlier stage is believed to be easier and of better results than when deferred to adolescence. **Objectives**: To study the anatomical abnormalities of genotypic females with virilized atypical genitalia due to congenital adrenal hyperplasia and their impact on surgery and to review the surgical techniques of feminizing genitoplasty and their early short-term outcomes. We aim to highlight the multidisciplinary management for these complex cases and to discuss the difficulties and challenges met during this. **Patients & Methods**: Genotypic prepubertal females with virilized atypical genitalia due to congenital adrenal hyperplasia were included. Radiological studies in the form of sonography to visualize the uterus and gonads and genitography for delineation of the urogenital tract then followed. Endoscopic assessment (cystoscopy) was done at the time of surgery with catheter placement in both the vagina and urethra to guide the surgical procedure. Surgical genitoplasty aimed at a single-stage full correction for all cases preferring partial urogenital mobilization. **Outcome parameters**: Achievement of an acceptable female appearance of the external genitalia, achievement of adequately sized and positioned vaginal and urethral orifices, and occurrence of short term complications. **Conclusions:** Feminizing genitoplasty can be done safely between the age of 6 months and one year. Flap vaginoplasty and cut-back exteriorization are only suitable for low confluence. Partial urogenital mobilization is a safe and effective technique that is suitable to most cases.*

INTRODUCTION & BACKGROUND

Disorders of sexual differentiation (DSD), which used to be known as intersex disorders, are among the most challenging conditions facing the paediatric surgeon and paediatric endocrinologist. Ambiguous genitalia in newborns demand urgent and accurate diagnosis[1]. The incidence of female urogenital anomalies is relatively low. The commonest is persistent urogenital sinus and virilization due to congenital adrenal hyperplasia (CAH) accounting for about 70%. The incidence of CAH is 1 in 15,000 live births[2]. In these patients, the genetic sex is female and the internal gonads are ovaries, while the external genitalia are virilized to resemble male features. The current strategy for treatment is hormonal replacement and early feminizing surgery[3]. The external virilization manifests in the form of hypertrophy of the clitoris (clitoromegaly) that ranges from simple to a male-appearing phallus. The labia may be masculinized to form labioscrotal folds or, in severe cases, complete scrotal fusion[4,5].

In urogenital sinus anomalies (UGS), there is a persistent communication of the vagina with the lower urinary tract. In the majority of cases this connection occurs within the middle portion of the urethra. The two structures terminate into a common channel that exits on the perineum as a single opening[6]. The vagina is shortened and fails to descend to the perineum. The older descriptions classify this as either a “high” confluence if the connection is more proximal or a “low” confluence for more distal connections[7]. The recent descriptions regard the UGS anomaly to occur in a spectrum rather than simply high or low. Therefore evaluation and management must be tailored accordingly[6,7].

The ovaries, the uterus and fallopian tubes are all normal, the gonads are symmetrical and intra-abdominal and never descend into the labioscrotal folds[8].

Techniques and approaches for genitoplasty have evolved through years. The goals are to provide the external genitalia with a female appearance, to produce a functional vagina, and to retain sexually sensitive tissue[9]. Feminizing genitoplasty is divided into two components: clitoroplasty and vaginoplasty. Patients classified according to Prader's classification (from III to V degree) need reduction clitoroplasty[10,11]. Techniques for vaginoplasty are variable as no specific approach emerged as the perfect solution. The common surgical techniques for low confluence are cut back or posterior flap vaginoplasty[12,13]. To treat high confluence of the vagina and urethra, at least three surgical options exist: urogenital sinus mobilization; pull through vaginoplasty; and construction of a neovagina with skin grafts/flaps or a bowel segment[14,15]. The higher variants carry more risks and complications, and are noticeably more challenging[16,17]. The recent surgical techniques imply mobilization of the urogenital sinus, either partially or totally. For these techniques to be successful as regards the urinary continence and voiding function, the urethra should have an adequate length above the confluence[15,18].

Recent studies proved that the upper urethra is the most innervated structure of the pelvis with completely circumferential innervations. The lateral and anterior aspects of the upper urethra and vagina are covered by sphincteric nerves. Hence, there are recommendations against routinely disrupting this proximal periurethral area. Dissection of the pubo-uretheral ligament during total urogenital mobilization (TUM) could endanger postoperative continence[19].

All patients with a urogenital sinus anomaly used to undergo a contrast genitography. The study is performed by insertion of the tip of a catheter into the single external opening. The retrograde instillation of radiopaque dye is used to define the anatomy[20]. Proper studies should identify the length of the common sinus, the depth (level) of the vaginal-urethral confluence, and the proximal urethra. Lateral and oblique views should be obtained. Some recent reports argue that genitography generally has limited usefulness in CAH[21].

Endoscopic evaluation of the anatomy is critical and should be performed on all cases. Generally, this is done under the same anesthetic as definitive surgical correction, particularly for lower and intermediate lesions. If the anatomy is complex on genitography, cystoscopy may be done initially alone in order to decipher the anatomy, prepare the patient and consent the family for a major and challenging reconstructive surgery[20].

Regarding the timing of surgery, feminizing genitoplasty done during infancy confers an early physical appearance consistent with sex of rearing and causes less psychological trauma than if delayed[3]. Recent consensus statements on the management of DSD suggest that cosmetic surgery in girls with significant virilization should be done in the first year of life, and when appropriate, in conjunction with common UGS repair[22].

PATIENTS & METHODS

This study is an experimental study (phase IV) aiming at assessment of the outcomes of the approved and commonly practiced approaches to feminizing reconstructive surgery of the anomalous urogenital tract in virilized females due to adrenogenital syndrome.

Thirty prepubertal females with virilized atypical genitalia due to congenital adrenal hyperplasia, presenting to the outpatient clinics of **Cairo University Specialized Paediatric Hospital** in the period from January 2011 to June 2013 were reviewed. The included cases were prepubertal females (46XX karyotype), with virilized external genitalia, controlled by hydrocortisone and fludrocortisone replacement therapy (if needed) and capable of tolerating radiological, endoscopic and surgical interventions. A voluntarily provided informed consent of the parents for the planned procedures, possible risks, and usage of the collected information for research was obtained in all cases. The excluded cases were post-pubertal females, male (46XY) DSD and debatable sex of rearing as mixed gonadal dysgenesis or ovotesticular DSD.

This work was done under guidance and supervision of the research ethics committee (REC) of the faculty of medicine, Cairo University.

For all cases an external genital examination and Prader staging were done. Serum electrolytes were measured at diagnosis and during follow-up. Karyotyping was done to confirm being 46XX. A hormonal profile in the form of cortisol, ACTH, 17OH progesterone, Dehydroepiandrosterone, Androstenedione, 11-deoxycortisol, Testosterone and Plasma Renin Activity were assayed initially and during follow up. An abdominal ultrasonography was done to visualize the uterus and ovaries.

Genitography under sedation was done for the delineation of the internal anatomy. It starts by positioning the patient in the exact lateral position. The tip of the urinary catheter is inserted into the external meatus. Contrast material was injected under fluoroscopic control. The injection continued under a moderate pressure until the confluence could be seen, followed by the bifurcation of the urethra anteriorly and the vagina posteriorly. The depth (level) of the confluence from the perineal floor was noted. The distance between the confluence and the bladder neck was determined to assess the urethral length proximal to the confluence. The caliber and length of the vagina proximal to the confluence were determined.

Cystoscopy was done immediately prior to surgery and under the same anaesthetic. The procedure used size 9Fr. or 11Fr. scope with a working port. Water flow was used to distend the urethra; this allowed appreciation of the vaginal orifice in the back wall of the urethra. The vaginal orifice was looked for around the pseudo-verumontanum. Balloon catheters were introduced into both the vagina and the bladder over guide-wires.

Surgical Genitoplasty aimed at a single-stage full correction for all cases. Clitoral reduction, labioscrotal adjustment, and exteriorization of the vagina were done together to take advantage of any available tissue. Clitoral reduction started by identifying the glans and neurovascular bundle, along the dorsal aspect, and removal of most of the erectile tissue through a ventral approach. Labioplasty was done through labioscrotal tissue mobilization, trimming, and a V-Y plasty to create labia majora lateral to the vaginal orifice. The preputial skin was used to reconstruct the labia minora and sutured to the lateral wall of the vagina on either side. The mucosal layer of the prepuce was used to line the vestibule. The extent of vaginoplasty was mandated by the anatomy of the vagina. Our technique of choice was partial urogenital mobilization (PUM). This was escalated to a total urogenital mobilization (TUM) or a Passerini-Glazel flap in more difficult cases. However, each case was expected to need a combination or modification of various maneuvers [Figures 1 – 7].

Figure [1]: Posterior inverted U-flap incision

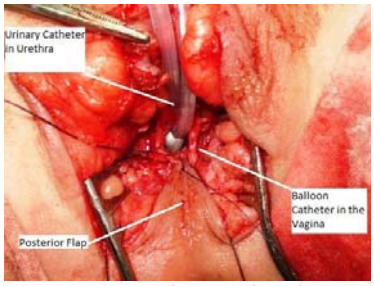

Figure [2]: Flap Vaginoplasty

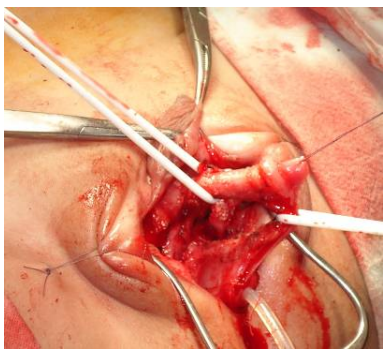

Figure [3]: Reduction Clitoroplasty; Preservation of the posterior neurovascular bundle

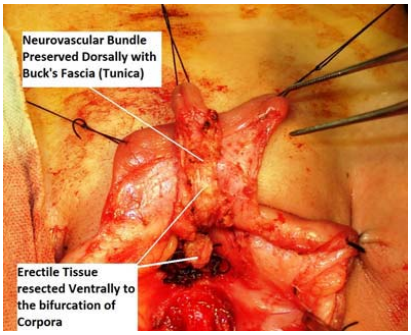

Figure [4]: Reduction Clitoroplasty; excision of erectile tissue

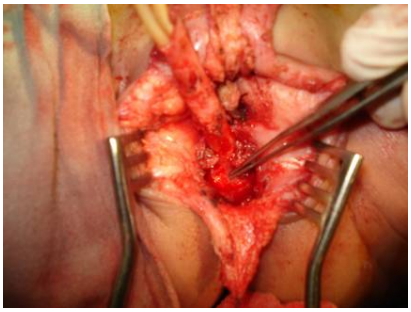

Figure [5]: Urogenital mobilization; forceps pointing to balloon of catheter in the vagina

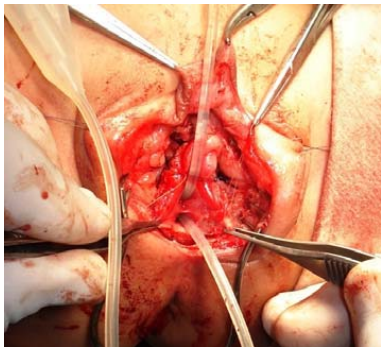

Figure [6]: Urogenital mobilization; vagina and urethra orifices exteriorized

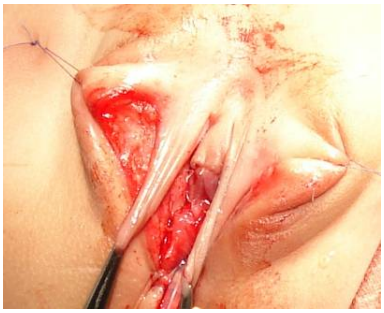

Figure [7]: Byars' (preputial) flaps used to reconstruct the labia minora

The urinary catheter was removed at the 3rd day postoperatively and the vaginal stent at the 5th day. The patients were usually discharged at the 6th or 7th day after surgery. Six weeks after the operation the patients were reassessed under general anesthesia, calibration of the vagina was done and recorded. Complications were searched for in the regular follow-up visits, during which examination under a sedative was done, if needed. Evaluation of postoperative complications and cosmetic outcome via a questionnaire for parents and professionals was carried out six months after surgery.

Counseling and informed consent of the parents included the postoperative difficulties of the need for further dilatation sessions, the possibility of urinary difficulties, clitoral re-growth in case of medical non-compliance and the possible need for surgical readjustment at the time of puberty or afterwards.

RESULTS

The mean age at which surgery was performed was 22 months. Nine cases (30%) were operated upon at an age less than 1 year old. The last 6 cases (20%) in this series were operated upon at an age ranging from 6 to 9 months. A significant proportion of our cases (77%) ranged between Prader's III and IV degrees [table 1].

Table [1]: Description of virilization according to von Prader's Score.

Virilization (Prader's Score)	*Value*
I	1 (3.3%)
II	5 (16.7%)
III	14 (46.7%)
IV	9 (30 %)
V	1 (3.3%)

The reduction clitoroplasty was needed in 29 cases (96.6%). In one case trimming of the skin hood (prepuce) was done with no removal of erectile tissue, due to minimal clitoral hypertrophy (Prader I). The V-Y reconstruction of the labioscrotal folds into labia majora was achieved effectively in 28 cases (93.3%). It was needed minimally in 2 cases (6.7%, Prader I & II), where the labioscrotal folds were minimally hypertrophied.

In 4 cases (13.3%) it was sufficient to superficialise the vagina by a posterior-based U-flap and preputial anterolateral flaps, due to a "low" vaginal-urethral confluence. Partial urogenital mobilization was used in 23 cases (76.7%); the mobilization was extensive beyond a depth of 2 cm in 43% (13 cases), but in 10 cases (33.3%) it was a limited mobilization. In two cases a Passerini-Glazel flap was used, and in one case a TUM was done [table 2].

Table [2]: Surgical procedures done for high confluence

	PUM	*TUM*	*Passerini-Glazel*	*Total*
Number	23/30	1/30	2/30	26/30
Percentage	76.7%	3.3%	6.7%	86.7%

For the purpose of simplicity and due to the large amount of operative details in each case, we allocated each case postoperatively according to its difficulty, operating time and the procedure performed into one of four levels; namely 1 to 4. Level (4) represents cases of TUM and Passerini-Glazel flap. Level (3) represents difficult cases of PUM, where the dissection was extensive but still partial (laterally and posteriorly, but not anteriorly); these were cases that needed an operative time of 3 hours or more. Level (2) represents easier cases of PUM, where a less extensive dissection and mobilization were needed; these were cases that needed an operative time of less than 3 hours. Level (1) represents cut back vaginal exteriorization and flap vaginoplasties [table 3].

Table [3]: Operative difficulty levels

Difficulty	*Level 4*	*Level 3*	*Level 2*	*Level 1*
Number	3	13	10	4
Percentage	10%	43.3%	33.3%	13.3%

We encountered a strong correlation between the operative difficulty and either the vaginal depth or the urethral length [figure 8 & 9]. The operative difficulty is directly proportionate to the vaginal depth and inversely proportionate to the urethral length; the deeper the vagina, the shorter the urethra, the more difficult and lengthy the operation is. The correlation coefficient (*r*) for this relationship was 0.756 (calculated by Spearman rank correlation equation), and the *(p)* value was 0.001. On the contrary there is weak correlation between the operative difficulty and Prader's degree of virilization, this is shown by the more horizontal slope in (figure 10) compared to (figure 8 & 9). The correlation coefficient (*r*) was 0.203 and the *(p)* value was 0.282.

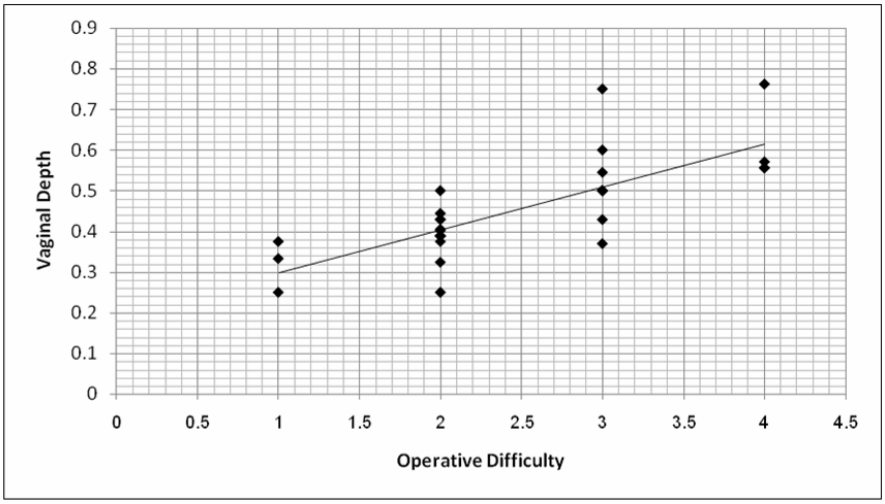

Fig. [8]: Correlation between operative difficulty and vaginal depth

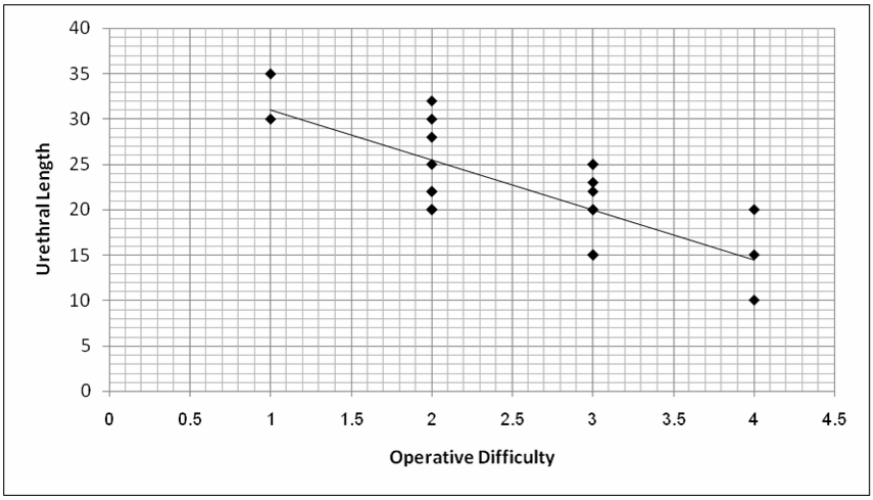

Fig. [9]: Correlation between operative difficulty and urethral length

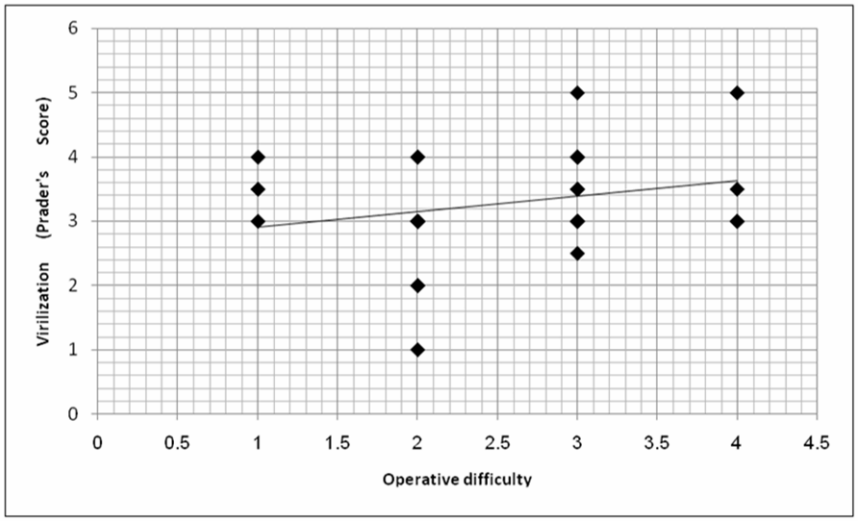

Figure [10]: Weak correlation between operative difficulty score and Prader's virilization

The early complications of feminizing genitoplasty could be analyzed into two categories. The first of which is the anatomical outcome of the vagina i.e. the diameter of the introitus (ideally ≥ 1cm) and the introitus depth (ideally ≤ 1cm i.e. the vaginal and urethral orifices should be visible together). Seven cases (23.3%) had imperfections in this anatomical outcome. Three of them (10%, Prader III, IV & V) are expected to need a further corrective surgery, either during childhood or at puberty. The other 4 cases (13.3 %) showed a dilatable vaginal introitus, which encouraged a closer follow-up of examination under sedation. [Figure 11]

Figure [11]: Postoperative vaginal Calibration

The second group of outcomes is related to the cosmetic aspects as residual clitoral abnormalities and labial inaccuracies. We had no cases of inadequate positioning of the clitoris. Two cases had a residual clitoromegaly; 12 mm and 13 mm (6.7%) and only one case that had an undersized clitoris of less than 5 mm. Five of our cases (16.7%) had labial inaccuracies; 2 cases of which had residual scrotal-like rugae of the labia, and 3 cases showed redundant labia. Collectively these minor complications were found in eight of our cases (26.7 %). None of these cases is expected to need any revision operation due to the cosmetic outcome. All of them have steadily improved over the six months period following the surgery. To conclude 90% of our cases had a normal appearance of the clitoris and 83.3% had a normal appearance of the labial folds.

The third group of outcomes is urinary complications, as regards the voiding function and continence, which is a long term outcome. Intermittent urinary difficulties, frequency and dysuria were noticed in 2 cases (6.7%), their uroflowmetry and ascending cystourethrography showed a detrusor instability and hyperactive bladder. One case had dribbling and urinary incontinence and is currently being investigated for further management. Collectively this group represents only 10% of our cases.

In this study the follow up ranged from 9 months to 30 months, with a mean of 20.5 months and a median of 21 months.

Table [4]: Percentage of overall outcomes

	Number of cases (out of 30)	*Percentage*
(A) Excellent Outcome	**19**	**63.3%**
(B) Acceptable Outcome	**8**	**27.7%**
(C) May Need Revision	**3**	**10%**

Table [5]: Overall outcomes contrasted to operative difficulty

		Operative Difficulty			
		LEVEL 4	**LEVEL 3**	**LEVEL 2**	**LEVEL 1**
Outcome	**Excellent**	**3**	**6**	**6**	**4**
	Acceptable	**0**	**4**	**4**	**0**
	Poor	**0**	**3**	**0**	**0**

Preoperative

Figure 12

Postoperative

Figure 13

Figure 14

Figure 15

Figure 16

Figure 17

DISCUSSION

The mean age at surgery (22 months) in this series is comparable to recent reports of similar cohorts that achieved a mean age of 15 to 19 months[23,24,25].

None of our cases were subjected to clitoral recession or clitoridectomy. During reduction clitoroplasty care was taken not to place the glans too high on the pubis, and to direct it in a posterior feminine direction, rather than a protruding masculine appearance. Subtotal de-epithelialization and partial concealment of the glans clitoris was performed in less virilized cases of this series (23.3%). Resection of a wedge of the glans was done in the more virilized cases (73.3%). These maneuvers and modifications were described by previous reports, but we re-assembled them to suit every individual case[12,26,27,28].

We support the current views that the use of skin flaps alone when the confluence is high is inappropriate because it leaves the urethral meatus on the anterior vaginal wall, resulting in vaginal voiding and recurrent urinary infection[29,30]. In as much as 87% of our studied cases, the flap vaginoplasty were not sufficient.

Rink et al (2006) reported that PUM was sufficient in 68% for their cases, and that TUM was needed in the remaining 32%[23]. This contrasts to the results presented here that PUM was sufficient in 77% of the cases, and 10% needed a TUM or Passerini-Glazel. The surgical team favored PUM to avoid dissection anterior to the urethra in TUM or separation of the vagina from the urethra in Passerini-Glazel. In a series by **Braga et al (2006)** with a comparable sample size (24 cases) and age group to our series, the degree of virilization was Prader III and IV in 79 %. This is similar to our findings that about 77% of the cases are between Prader III and IV. In their series PUM was done in 70% of cases. Their outcome analysis reported that the genital appearance was considered good in 21 cases (87.5%) and satisfactory in 3 (12.5%)[31]. Our results are also very comparable to **Gupta et al.**[32] [table 6].

Table [6]: Overall cosmetic outcomes among various studies

	Our Results	*Braga et al*[31]	*Gupta et al*[32]
Good	**73.3 %**	**87.5%**	**74%**
Satisfactory	**20 %**	**12.5%**	**20%**
Poor	**6.6 %**	**0**	**6%**

Recent reports considered post-operative calibration of the vagina to Hegar #10 to be acceptable[10,32]. In the present study, vaginal calibration took place easily in 27 cases (90%). Hegar dilatation ranged from 8 to 16 mm with a mean of dilatation to Hegar # 12.

Observation of late outcomes following feminizing genitoplasty is a must to allow pursuit or abandonment of individual procedures. Such a long-term follow-up is beyond the scope of this report; however, the surgical team has performed the procedures reported to provide the best sensory outcomes for the clitoral innervation, and favored to resort to the less invasive partial urogenital sinus mobilization.

Egyptian parents desire the surgery to be performed at the earliest possible age. Seventy percent of the parents of the patients of this study believed that the timing of surgery was suitable. 30% believed that an earlier surgery would have been better. Multidisciplinary management including the different related specialties is a necessity to provide the proper services and avoid the complications and consequences of the disease and its repair. This team should include paediatric surgeons with interest in DSD, paediatric endocrinologists, radiologists, paediatric psychiatrists, social workers and legal consultants. There still exists a deficiency in the social support and psychiatric care for the children with these disorders and their families.

CONCLUSIONS & RECOMMENDATIONS

Most cases of virilized females with congenital adrenal hyperplasia present in the first month. The virilization degree is mostly Prader II, III and IV. Persistent UGS occurs in a spectrum rather than either high or low. The degree of virilization does not accurately reflect

the depth of the confluence or the operative difficulty. Feminizing genitoplasty is safe to be done between the age of 6 months and one year, in the hands of an experienced surgical team. The majority of cases (87%) could not be corrected by a simple flap vaginoplasty and need a degree of mobilization of the urogenital sinus. Partial urogenital mobilization is a safe and satisfactory procedure that is suitable to most cases. The surgeon should only proceed to more extensive dissection if it is deemed necessary.

Assessment of the success of these complex procedures is difficult. However, we found the overall outcome of feminizing surgery to be excellent in 63%, acceptable in 27% but 10% of the cases had an unsatisfactory outcome that might need a further surgical correction.

Acknowledgment

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