THE USE OF SYNTHETIC SLINGS IN SURGICAL TREATMENT OF EPISPADIAS IN BOYS

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The treatment of urinary incontinence in epispadias, which is malformation of the lower urinary tract, is a pressing problem due to the severity of congenital anatomic and functional pathology and the lack of a universal treatment to achieve urinary control. The aim of the study was to develop basic principles of surgical treatment of epispadias-related urinary incontinence. Additionally, we aimed to introduce into clinical practice the use of synthetic implants (synthetic slings) and evaluate treatment outcomes. The total of 20 boys aged 7–15 years received surgical treatment for subtotal and total epispadias. The first stage of surgical reconstruction was Cantwell's phallo-urethroplasty followed by the placement of synthetic slings TVT, TVT-O, and AdVance. The children began to accumulate up to 250–550 ml of urine in any position of the body at relative rest and on effort, and were able to hold urine for up to 3 hours and to empty the bladder completely with normal flow. The total loss of urine per day decreased 10-15 times and did not exceed 10–30 ml. The lower urinary tract was evaluated using urodynamic (uroflowmetry, urethral profilometry) and electrophysiological (electroneuromyography) methods. Restoration of urethral anatomy leads to improved accumulative ability of the detrusor, and use of synthetic slings is a low-invasive and highly effective surgical method for treating urinary incontinence.

Keywords: epispadias, boy, urethroplasty, sling, implant

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СИНТЕТИЧЕСКИЕ СЛИНГИ В КОМПЛЕКСЕ ХИРУРГИЧЕСКОГО ЛЕЧЕНИЯ ЭПИСПАДИИ У МАЛЬЧИКОВ

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Проблема лечения недержания мочи при эписпадии — пороке развития нижних мочевых путей — является наиболее сложной и актуальной в связи с тяжестью врожденных анатомо-функциональных нарушений и отсутствием универсального метода лечения, позволяющего в полной мере достичь управляемого акта мочеиспускания. Целью исследования была разработка основных принципов хирургического лечения недержания мочи при эписпадии и внедрение в клиническую практику имплантов (синтетических слингов) с последующей оценкой результатов лечения данного порока развития. Проведено оперативное лечение субтотальной и тотальной эписпадии у 20 мальчиков 7–15 лет. На первом этапе хирургической реконструкции выполнена фаллоуретропластика по методу Кантвелла (Cantwell), на втором — проведена имплантация синтетических слингов TVT, TVT-O, AdVance. Дети стали накапливать до 250–550 мл мочи в любых положениях тела, в состоянии относительного покоя и при напряжении удерживать мочу до 3 ч, полностью опорожнять мочевой пузырь по позыву нормальным потоком. Общие потери мочи в сутки уменьшились в 10–15 раз и не превышали 10–30 мл. Для оценки состояния нижних мочевых путей использовали уродинамические (урофлоуметрия, профилометрия уретры) и электрофизиологические (электронейромиография) методы исследования. Восстановление уретральной анатомии приводит к улучшению накопительной способности детрузора, использование синтетических слингов является малотравматичным и высокоэффективным хирургическим методом устранения недержания мочи.

Ключевые слова: эписпадия, мальчик, уретропластика, слинг, имплант

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Epispadias is a rare congenital malformation occurring in 1 in 100,000 births, with male : female ratio of 1 : 3.5 [1]

The most pronounced clinical symptoms of epispadias are urinary incontinence and absent urine output that force the child's parents to seek medical advice. Over the last 150 years, the efforts of the medical community have been focused on the search of effective surgical treatments to fully restore bladder function and stimulate its normal filling and emptying. The history of this search provides examples of incredible ingenuity [2–4]. Numerous publications demonstrated that most of the authors relied on isolated observations. Due to limited clinical experience and the use of a single surgical technique, the results of the intervention were unpredictable and often associated with poor outcome, so the problem remained unsolved. For a hundred years, the idea of surgical reconstruction and creation of an artificial sphincter mechanism using bladder tissues, autologous myofascial flaps or homografts did not materialize [2, 5]. It should be noted that in the middle of the XX century even time-proven variations of urethral sphincteroplasty were effective in no more than 50 % of cases. Half of the children received multiple surgeries. According to Derzhavin, who in 1962 proposed internal urinary sphincter reconstruction using the muscles of the urinary bladder trigone (the method is still used), 28 of 58 children with epispadias received revision surgeries. In N. E. Savchenko City Clinical Hospital, Derzhavin's and Young-Dees' methods were effective in 86.9 and 61.9 % of cases, respectively; however, 42 % of patients had revision surgeries [2].

Initially, the unsatisfactory results were attributed to failure to comply with the author's surgical technique. Another reason was discovered later. Epispadias is often accompanied by bladder hyperactivity and myelodysplasia associated with impaired innervation of the pelvic floor. It was found that an integral indicator of the severity of the structural and functional changes in the lower urinary tract of epispadias patients was the degree of pubic symphysis diastasis: a greater gap was associated with more severe bladder dysfunctions and innervation defects of the pelvic floor muscles and consequently with unsatisfactory results of traditional surgical treatment [6].

The doctors of the Department of Urology and Neurourology of the Scientific Research Institute of Pediatric Surgery have a 40-year experience in managing patients with epispadias. Throughout all these years, a need for fundamental changes in the traditional approaches to epispadias treatment has been gradually arising. It is believed that treatment should consist of several stages: urethral reconstruction followed by sphincterplasty and subsequent elimination of residual micturation disorders using minimally invasive techniques (paraurethral gel or collagen implantation); the final stage includes correction of cosmetic defects.

The aim of this study was to formulate the basic principles of a novel approach to surgical treatment of urinary incontinence in boys with epispadias based on the use of implants (synthetic slings) and to assess treatment outcomes.

METHODS

Since 2000, we have observed 20 boys of 7–15 years of age with epispadias (11 patients with subtotal form and 9 patients with total form). The main complaint was stress urinary incontinence, which appeared or increased as the abdominal pressure exceeded the intraurethral pressure.

The diagnosis of congenital malformation of the lower urinary tract was based on the clinical examination and standard and specialized test, such as intravenous urography, cystography, cystoscopy, uroflowmetry, and electrophysiological and urodynamic tests.

Clinical examination of boys left no doubts about the diagnosis of epispadias. Described in the literature in detail, the defect is obvious. A primary technique used to identify the defect is a standard physical examination sufficient to classify the disease as total or subtotal [2]. Further use of specialized techniques is necessary to detect concomitant renal and urinary tract defects and to assess the condition of the bladder and ureteral openings, pubic symphysis diastasis, sphincters and innervation of the pelvic floor muscles.

In the observed boys, the visible symptoms suggested a typical form of epispadias. In the supine and sitting positions, the children accumulated from 30 to 200 ml of urine in the bladder. The upright position led to increasing urinary incontinence aggravated by coughing and movement. The anterior wall of the urethra was cleft along the entire length; the external opening of the urethra had a funnel shape. Diastasis of pubic symphysis was 17.1–37.5 mm (compared to 7–8 mm in healthy individuals). In two cases during cystography bilateral grade II vesicoureteral reflux was detected; in one of them reflux was complicated by chronic pyelonephritis.

During cystometry, detrusor hyperreflexia was detected in 17 children. Electromyography revealed impairement of segmental somatic innervation in 11 children.

The severity of the pelvic floor dysfunction was evaluated by electroneuromyography and cough orthostatic profilometry, which helps to detect pelvic floor failure. Upon natural bladder filling possible with the child lying horizontally, uroflowmetry often registers a urodynamic dysfunction expressed as urgent urination.

After epispadias was diagnosed, Cantwell's phallourethroplasty was performed as the first stage of the treatment plan (Fig. 1).

Described in 1894, this surgical technique was used to reconstruct the urethra in an epispadias boy [7]. It is quite effective and solves the main task of the first stage, namely, the restoration of urethral anatomy. In males with epispadias, this urethroplasty option should be considered the procedure of choice.

The second stage was the implantation of synthetic slings: TVT (Tension-free Vaginal Tape), TVT-O (Tension-free Vaginal



Fig. 1. Cantwell's phallourethroplasty: (A) penis before the surgery; (B) the final stage of the surgery, with Foley catheter Ch10 inserted

Tape Obturator) and AdVance performed as an independent minimally invasive technique.

Surgical technique. A semilunar incision was made across the perineum; the bulbous urethra was isolated down to the pelvic floor. Needles with a Prolene mesh tape were passed either side of the urethra through the obturator foramen to exit via skin incisions or guided through the retropubic space towards the anterior abdominal wall. The tape was positioned over the bulbous urethra and then pulled until urine leakage induced by an increase in abdominal pressure fully stopped. The following synthetic slings were used: GYNECARE TVT (Ethicon, Switzerland), GYNECARE TVT-O (Ethicon, Switzerland) and AdVance (AMS, USA). The Prolene tape ends were trimmed off and placed under the skin. The incisions were closed.

Postoperatively, the bladder was drained with a catheter for up to seven days. To prevent infectious complications, the antibiotic therapy was administered for 7 days.

We believe that in boys over the age of 10 with obvious pelvic floor prolapse, implantation of the AdVance sling is preferable, as it allows loop tensioning and creating a larger area of the controlled compression of the urethra.

Stages of the implantation of TVT-O (Fig. 2), TVT (Fig. 3) and AdVance (Fig. 4) slings are shown below.

RESULTS

Phallourethroplasty helped to restore the urethra completely in all the boys. However, in four children urethral fistulas were observed. In all cases, the fistula tract was suture ligated and fistulas were closed.

Thus, the reconstruction of urethra was successfully completed in 20 children with epispadias. The restoration of the urethral anatomy was accompanied by fundamental changes in the bladder function. The immediate and long-term (>5 years) result of the surgery was the crucial change in the urine transport through the lower urinary tract.

In all cases, the first phase of the micturation cycle (storage) was restored. Children began to accumulate up to 150–350 ml of urine in any positions of the body; as the bladder filled, the urge appeared; voluntary urination was characterized by normal flow and the absence of residual urine; the nature of urinary incontinence changed: it occurred when patients changed the position to vertical and after a sudden and sharp

increase in intra-abdominal pressure (induced by cough, brisk walking, etc.). The total loss of urine per day decreased more than 5 times and did not exceed 50–370 ml.

Indications to loop sphincteroplasty, which is the second stage of surgical correction, were considered individually. The main criteria were the physical development of a child and the condition of tissues at the potential surgical site. In our experience, sphincteroplasty can be performed 6–12 months after the first stage of surgical treatment.

The choice of the sling should be based on the results of clinical and instrumental test. Both the amount of urine passed in the vertical position of the body (such as on exertion) and the degree of innervation impairment reflected by urodynamic parameters should be considered. The most important here is intraurethral pressure gradient measured by orthostatic profilometry (Fig. 5, 6).

Urethral pressure profilometry was performed using Delphis B-94-R01-BT Urine Analyzer (LABORIE, Canada).

In the 2–15-year follow up of the sling surgery, bladder capacity in the vertical position varied from 150 to 550 ml in all children. The boys were able to hold urine in any position of the body at relative rest or on effort up to 3 hours and emptied the bladder completely after getting the urge; the flow was normal and no residual urine was present. In 5 boys, total urine loss did not exceed 5–10 ml per day; 15 other children were completely continent. Reliability of the results derived from the good clinical effect, which allowed us to skip statistical data processing.

DISCUSSION

Regardless of the severity of the urethral cleft, penis deformities and other manifestations of the disease, the primary complaint that forces parents to seek medical advice of the urologist is child's urinary incontinence, the most obvious and bothersome symptom that affects both the child and his/her environment, which in turn can aggravate the disorder. Children and teenagers are particularly vulnerable, especially in certain "critical" periods of life when they undergo psychological and physiological changes (enter a new social environment kindergarten, school, or adult society).

Although there are numerous publications on this problem, many controversial issues are yet to be discussed. One of them is the classification of the pathology. Classification of epispadias



Fig. 2. Implantation of the TVT-O synthetic sling: (A) placement of the sling: the Prolene tape is placed under the bulbous urethra, the ends are brought out through the obturator foramen; (B) final appearance after the surgery: perineal skin sutures and tape exit sites

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Fig. 3. Implantation of the TVT synthetic sling performed on a boy with epispadias: TVT tape exit sites on the anterior abdominal wall





Fig. 4. Implantation of the AdVance synthetic sling. (A) the bulbous urethra is isolated; (B) preparing to fix the synthetic tape over the urethra. The sling is placed over the bulbous urethra and pulled until urine leakage induced

by an increase in intra-abdominal pressure fully stops

by Savchenko and Derzhavin published in 1976 is considered to be the most comprehensive [2]. However, its practical value with regard to the choice of treatment is minimal.

The most prominent results were obtained by Derzhavin who in 1962 proposed the internal sphincter plasty using the muscles of the urinary bladder trigone [8]. It is still considered one of the most effective methods of surgical correction of urinary incontinence in epispadias.

The choice of surgical techniques for urinary incontinence treatment in epispadias patients should be based on the detailed analysis of the anatomical and functional properties of the defect [9, 10].

Before the surgery, the surgeon faces a difficult task the choice of surgical technique, and they have to decide whether to start with urethroplasty or sphincteroplasty. In our experience, it is reasonable to restore the integrity of the lower urinary tract first, i.e. to perform urethroplasty. There are a lot of surgical techniques for urethroplasty that can be performed on males and females with various malformations of the external genitalia.

The Cantwell technique for treating epispadias in men has been proved to be one of the most effective [7]. It was successfully applied during the surgery on an 11-year-old boy with epispadias and described in May, 1894. In addition to restoring the anatomy of the urethra, the surgery restored voluntary urination. From our observations a firm conclusion can be made that not only the sphincter apparatus of the bladder, but also the urethra is involved in the complex mechanism of continence.

The surgical correction of incontinence in the "sphincterspelvic floor" system is based on the use of the so-called loop surgeries. In the second half of the 20th century, loop (sling) surgeries were introduced into pediatric practice based on the use of autologous tissue: free muscle, fascial, skin or vaginal flaps, vascularized muscular, aponeurotic or muscularaponeurotic segments of the rectum, pyramidal or oblique muscles of the anterior abdominal wall, the tensor fasciae latae muscle, and gluteal muscles [11, 12].

Since 1989, we have been using various autologous tissues, mainly vascularized muscular-aponeurotic flaps of the rectum and pyramidal muscles of the anterior abdominal wall. However, the lack of efficacy in long-term periods (over 2-3 years) forced us to continue the search for materials that could be used for surgical treatment of urinary incontinence [13]. At some point, we used velour vascular grafts. Then, a new method for treating stress urinary incontinence in women was suggested: implantation of the free synthetic loop (TVT); the tape was passed through the retropubic space and brought up to the abdominal skin incision. The technique was suggested by Ulmsten and Petros in 1990 and was based on the idea of urethral occlusion on exertion resulting from the contraction of the anterior abdominal wall muscles [14-19]. In 2000 our clinic pioneered the use of a new implant type, synthetic slings, in children. Later in 2002 and 2003, modifications were proposed to the technique: the Prolene tape was passed through the obturator foramen (TOT and TVT-O surgeries) [3, 20-22]. In 2006, a new sling technology, AdVance, was introduced into clinical practice. Our clinic was the first in the Russian Federation to suggest the use of Prolene tapes (TVT, TOT, TVT-O; AdVance) for surgical treatment of stress urine incontinence in children of both sexes with malformations and pelvic floor innervation impairments.

Among the advantages of this medical technology over other pediatric surgeries, such as myofascial loop surgery, are minimal invasiveness (it is less traumatic, faster and allows for

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Fig. 5. Patient Ch., 8 years. Cough urethral pressure profile prior to sling surgery Reduction of urethral pressure gradient to 40 cm water (normal values are 70–100 cm water), significant pressure reduction on exertion.

a shorter postoperative rehabilitation period), higher efficacy and simplicity.

Multiple causes and the exceptional complexity of pathogenic mechanisms and clinical symptoms in epispadias demand sufficient rationale for surgical exposure in patients with incontinence. Full control over urination in children with epispadias is hard or sometimes impossible to achieve [23–26]. This proves once again that surgical correction of the defect should be performed in the following sequence: urethroplasty \rightarrow sphincteroplasty \rightarrow elimination of residual urination disorders \rightarrow improvement of cosmetic defects.

One should always be aware of surgical failures when urinary incontinence is formally retained [6]. Classification of this pathology is also an issue. Currently, we differentiate between imperative, stress, combined and overflow urinary incontinence. All these forms of incontinence are found in epispadias and can be used as a criterion when deciding on treatment strategies. In some of our observations, we saw that imperative incontinence, which was erroneously attributed to the failure of the reconstruction of the sphincter apparatus, was easily eliminated with medication therapy. Thus, revision surgery was no longer necessary in those cases. Before deciding on revision surgery, the clinical form of the pathology and causes of incontinence must be identified.

After detrusor function has been restored, we can proceed to the next treatment stage. In cases of isolated lesions of the sphincter apparatus and weak pelvic floor (sphincter deficiency) the abdominal pressure is higher than the pressire inside the urethra, which results in stress incontinence [27]. The typical symptom here is loss of urine on effort or exertion (such as coughing, laughing, changing body position, lifting objects, etc.); it helps to assess indications for sling surgeries.

Based on our experience, the following indications for sling surgeries were formulated:

- intractable urinary incontinence on exertion;

- sufficient bladder capacity (at least 150 ml);

 low pressure inside the bladder in the storage phase (under 20 cm water);

- low profile of intraurethral pressure;

- negative cough test;

- positive external compression test of the urethra;





Urethral pressure gradient is 100 cm water, with high gradient of pressure profile on exertion.

- minimal changes in the urodynamics of the upper urinary tract.

It is possible that in some cases minimally invasive technologies (paraurethral administration of bulking agents) or pharmacotherapy may determine treatment outcome.

To assess the effectiveness of surgical treatment of urinary incontinence in children, we used the following criteria: urine continence for 1.5 h or longer at different body positions and on exertion; restored voluntary urination (if possible) characterized by sufficient urine flow in the absence of residual urine.

No complications, such as sling displacement, were observed for any type of synthetic slings (TVT, TOT, TVT-O; AdVance) used in this study [28].

CONCLUSIONS

For surgical treatment of urinary incontinence in boys with epispadias, a stage-by-stage approach should be applied, the first stage being phallourethroplasty followed by the sling surgery after the detrusor has restored its capacity and the ability to adapt to changing urine volume. For the second stage, the use of synthetic slings is recommended.

The main urodynamic indicator of the weakened pelvic floor is urethral profilometry data.

High pressure inside the bladder and the urodynamic disorders of the upper urinary tract are contraindications to sling surgery.

To summarize, we have carried out surgical treatment of boys with anatomical defects and urinary incontinence resulting from sphincter deficiency upon restoration of bladder storage function involving implantation of different sling types (we recommend synthetic materials). Complex and reliable evidence required for deciding on treatment strategies ensured positive outcomes including control over urination in most patients with epispadias and helped to minimize the number of revision surgeries. Coupled with improvement of cosmetic defects, this allowed the patients to successfully socialize and achieve a high quality of life.

Surgical treatment of such rare malformations as epispadias should be carried out in specialized surgical centers.

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