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Buccal mucosal graft urethroplasty of the bulbomembranous part of urethra

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Introduction Urethral stricture is a partial or complete narrowing of the urethra, caused by damage to the urethral epithelium. This disease leads to a persistent urination dysfunction, the elimination of which is a difficult task. The aim of this study was to perform a comparative analysis of the immediate and long-term narrowing treatment results of the proximal part of the bulbar and membranous urethral parts using the developed magnifying and anastomotic methods.

Material and methods A total of 102 patients with a confirmed diagnosis of stricture of the bulbomembranous urethral part of the urethra who underwent treatment in the urological hospital in Irkutsk City Clinical Hospital No. 1 during the period 2012–2018 participated in this prospective study. Urethroplasty operations were performed in two ways, using the anastomotic and intra-urethral substitution techniques. Through the assessment of preoperative parameters, statistical homogeneity of comparison groups was established.

Results The final data analysis showed relapse for 4 patients from Group I and for 2 patients in Group II. The absence of relapse during the entire observation period was equal in both groups and after 2 years amounted to 83.0 ±7.9% in Group I and 92.5 ±5.1% in Group II.

Conclusions In both groups, the desired result was achieved – adequate independent urination was restored. The anastomotic method of urethroplasty should be used with caution in patients at risk groups, as well as with the presence of predictors of complications: previous transurethral surgeries on the urethra and prostate, anastomotic urethroplasty, radical prostatectomy. The developed minimally invasive substitution technique has a similar effectiveness with a lower risk of complications.

INTRODUCTION

Urethral stricture is a partial or complete narrowing of the urethra, caused by damage to the urethral epithelium. This condition leads to a persistent urination dysfunction, the elimination of which is a difficult task. Until the 20th century, two main types of urethral strictures were mostly discussed – infectious and traumatic. Currently, the main cause of urethral damage is considered to be iatrogenic trauma [1]. The problem of stricture disease treatment remains extremely relevant in the past and present.

Because of iatrogenic injuries, as well as distraction defects, first of all, the membranous part and the bulbomembranous junction are damaged [1, 2, 3]. To define the proximal part of the bulbar and membranous parts of the urethra, the authors use the term 'bulbomembranous urethra' (BMU).

Knowledge of the surgical anatomy of the BMU and the structures surrounding it helps to minimize intraoperative injuries. Inadvertent damage to the muscles of the perineum or the distal urinary sphincter can lead to urinary incontinence [4]. Devascularization and denervation of the urethra can lead to

erectile dysfunction [5, 6, 7]. Such negative outcomes significantly decrease the quality of life of patients. The overall effectiveness of direct vision internal urethrotomy (DVIU) in the treatment of lesions of the proximal part of the bulbar and membranous sections is from 20 to 75%, depending on the cause and the extent of urethral stricture [8–12]. The effectiveness of this procedure for lesions of the posterior urethra is doubtful, and complete obliteration of the lumen is critically low [13]. Repeated DVIU does not lead to recovery and complicates subsequent treatment, worsening the course of the disease, and can also cause damage to the sphincter mechanism, which can as a result, lead to urinary incontinence [12, 13, 14]. That is why in case of a relapse, a different treatment method should be chosen [15–18].

There are several options for vascular-preserving excision and primary anastomosis (EPA), which can help to avoid disturbances in the normal blood supply of the spongy body and successfully perform plastic surgery of distal urethral strictures [19, 20].

Performing membranous urethroplasty with a graft or flap transplants is an alternative anastomosing operation. However, the results of the use of currently existing methods of substitutional urethroplasty are worse in comparison with anastomotic operations [8, 21]. The main problem of the substitutional reconstruction of the membranous urethra is considered to be the poor adaptation of transplants on the pelvic muscle membrane.

The technique for forming the urethral tube from a revascularized radiation graft is technically very complex and time-consuming. An indication for such an operation is the impossibility of repeated anastomotic surgery or a urethral defect too long for a corresponding graft [22].

The most promising new method for the repair of the membranous urethra is regenerative (tissue-engineering) surgery. Using this method eliminates the traumatic graft excision from the patient and reduces the risk of infection while still attaining comparable results. However, the use of regenerative surgery in general clinical practice is currently difficult due to the need for expensive equipment and the simultaneous coordinated work of highly qualified specialists [23].

Existing surgical transplantation techniques lead to the same complications as anastomotic methods of urethroplasty. Moreover, their effectiveness is much lower [5].

Despite the long history of the problem, there is still a lot of conflicting information about the negative or positive consequences of BMU operations [6, 7, 24]. Although there is much awareness about the likelihood of the negative effects of urethroplasty, little attention is paid to the development of methods for their prevention. Researchers are focused on finding methods for subsequent treatment, rather than preventing the occurrence of negative conditions. Currently, patients at risk for postoperative incontinence, shortening of the penis or impotence are warned about the possible need for subsequent implantation of an artificial urinary sphincter, penile prosthesis or further complex surgical correction.

Based on the literature analysis of the results of the currently used BMU lesions treatment methods, a number of conclusions can be made. Firstly, DVIU is an ineffective and dangerous operation that can aggravate the course of the disease and worsen the results of subsequent treatment. Secondly, there is a significant group of patients for whom the anastomotic or replacement plastic surgery can lead to negative consequences due to damage to the anatomical structures of the perineum (perineal muscles, urethral sphincter mechanism, vessels and nerves of the urethra and penis). Thirdly, the methods of existing substitutional urethroplasty are inferior in efficiency to anastomotic operations or are not available in everyday urological practice due to technical reasons (regenerative surgery).

Damage in the proximal part of BMU is relatively rare, but this is a severe pathology that determines the subsequent development of a number of complications such as chronic urinary retention, urinary infection, uremia, and even death. The use of some existing methods of surgical treatment of this pathology can lead to a number of complications such as shortening of the penis, urinary incontinence, and erectile dysfunction.

Thus, there is an urgent need to improve existing methods and develop new more effective methods of treatment for patients with narrowing of the proximal part of the bulbar and membranous parts of the urethra. The authors have developed and implemented an alternative method of magnifying plastic surgery of the BMU, which has demonstrated comparable effectiveness with less risk of complications [25].

The aim of this study was a comparative analysis of the immediate and long-term results of the treatment of patients with narrowing of the proximal part of the bulbar and membranous parts of the urethra using the author's magnifying and anastomotic methods of plastic surgery.

MATERIAL AND METHODS

The clinical research was approved by the local ethics committees of The Ministry of Health of the Rus-

sian Federation "Irkutsk State Medical University" and the Regional State Autonomous Healthcare Institution "Irkutsk City Clinical Hospital No. 1". A prospective, blind, randomized, single-center study was performed in the urological hospital at Irkutsk City Clinical Hospital No. 1.

The clinical part of the study includes an analysis of the examination and treatment results of patients who underwent surgical procedures for strictures (narrowing) of the bulbomembranous urethral part from April 2012 to February 2018.

Plastic surgeries were performed by the method of urethral anastomosis after excision of the affected area (EPA) or by the developed method of magnification substitutional intraurethral grafting (BMG) with a buccal graft [16]. The proposed method relates to methods of replacement and magnifying urethroplasty using autotransplants [25].

Study participation criteria

The criteria for inclusion in the study were:
- The patient is scheduled for plastic surgery for urethral stricture;
- Urethral stricture is localized in the proximal part of the bulbar and / or membranous parts of the urethra;
- Patients are older than 18 years old;
- The patient signed a voluntary informed agreement to participate in the study;
- The patient is deliberately planning to perform urethroplasty using a method determined randomly until the day of operation

Exclusion Criteria:
- Strictures of the anterior urethra;
- The patient did not sign a voluntary informed agreement to participate in the study;
- The presence of benign prostatic hyperplasia (BPH), significantly affecting urodynamics;
- Complete distraction defect of the urethra;
- The patient refused to participate at any stage of the study;
- Due to any reason, the patient has not undergone a demanding operation or performed another operation that does not fit the criteria of the group.

Study groups characteristics

The selection of patients for the study who fit the inclusion criteria was carried out prospectively by the continuous sampling method until the desired quantity was achieved. Over the specified period of time, 272 patients were diagnosed with urethral stricture. Among them, 102 patients fit the crite-

ria for inclusion in the study. All included patients were randomly divided into two groups according to the approved study protocol. EPA was performed in patients of the first group, and BMG for the second group.

Of 102 patients initially included in both groups, 39 were subsequently excluded from the study. Out of the group of patients excluded from the study, 23 dropped out due to deviations from the study protocol, and 16 – due to personal reasons.

During the postoperative period, 10 patients from Group I (26.3%) and 6 patients from Group II (14.6%) refused to participate in the study. The completeness of clinical observation for Group I was 73.6%, and for Group II – 85.3%. The analysis of the effectiveness of postoperative observation demonstrated its comparability in both groups (p = 0.293). The clinical case was assessed as lost for observation when the patient missed the examination within three months from the time of operation – the first checkpoint. If the patient refused to continue the study after this checkpoint, he was considered to have completed the study.

Thus, 63 patients who fit all of the study criteria were included in the final clinical analysis. Two groups of patients were formed. Patients who underwent EPA were assigned to Group 1 (n = 28) and patients who underwent BMG were assigned to Group 2 (n = 35).

Table 1 presents the comparative data on the initial parameters of patients in the study groups.

Analysis / Diagnostic methods

During the examination, anamnestic (in order to establish a possible cause and duration of the disease), clinical, biochemical, radiological, ultrasound, magnetic resonance, and endoscopic research methods were used.

Evaluation of the quality of life, erectile function, the lower urinary tract symptoms and the severity of pain was carried out by patients independently using standard questionnaires and the visual analogue scale.

To clarify the nature and extent of pathological changes in the urethra, uroflowmetry, urethrography, urethrocystoscopy, or urethral calibration were performed for all patients. In doubtful cases, additional multislice computed tomography (MSCT) or magnetic resonance imaging (MRI) urethrography with 3D image reconstruction was performed for the final verification of the diagnosis.

In the three-month period after the operation, at least once every six months or once a year all patients passed the standard assessment established by the

Table 1. *The comparative characteristics before surgery*

Parameter	Group I (n = 28)	Group II (n = 35)	P
Urethral strictures, n (%)	19 (67.8)	25 (71.4)	0.897
Stenosis of anastomoses, n (%)	9 (32.1)	10 (28.5)	0.822
Age, years old	57.5 (45; 69.75)	54 (41; 63)	0.535
Etiological factor:			
Mechanical, n (%)	15 (53.5%)	30 (85.7%)	0.244
Chemical, n (%)	0 (0%)	2 (5.7%)	0.246
Physical, n (%)	7 (25%)	10 (28.5%)	0.809
Radiation therapy, n (%)	2 (7.1%)	1 (2.8%)	0.450
Chemotherapy, n (%)	1 (3.5%)	0 (0%)	0.268
TU operations, n (%)	7 (25%)	14 (40%)	0.371
OIU, n (%)	12 (42.8%)	19 (54.2%)	0.597
Bougienage, n (%)	14 (50%)	26 (74.2%)	0.341
Traumatic catheterization, n (%)	20 (71.4%)	29 (82.8%)	0.700
Anastomotic plastics, n (%)	9 (32.1%)	10 (28.5%)	0.822
General iatrogenic effects, n (%)	22 (78.5%)	32 (91.4%)	0.686
Pelvic injury, n (%)	7 (29.1%)	6 (17.1%)	0.385
Perineum trauma, n (%)	15 (53.5%)	10 (28.5%)	0.188
Sexual trauma, n (%)	0 (0%)	1 (2.8%)	0.374
General injury, n (%)	18 (64.2%)	12 (34.2%)	0.160
Prostatic hyperplasia, n (%)	12 (42.8%)	23 (65.7%)	0.326
Neurogenic urination disorders, n (%)	3 (10.7%)	8 (22.8%)	0.286
Urethritis, n (%)	16 (57.1%)	22 (62.8%)	0.818
Urinary tract infection, n (%)	20 (71.4%)	29 (82.8%)	0.700
Venous diseases, n (%)	6 (21.4%)	10 (28.5%)	0.616
Purulent process in urinary tract, n (%)	5 (17.8%)	9 (25.7%)	0.550
Diabetes, n (%)	1 (3.5%)	3 (8.5%)	0.446
Cystostomy, n (%)	19 (67.8%)	25 (71.4%)	0.897
Permanent urethral catheter, n (%)	2 (7.1%)	5 (14.2%)	0.420
Acute urinary retention, n (%)	15 (53.5%)	15 (42.8%)	0.615
Chronic urinary retention, n (%)	23 (82.1%)	30 (85.7%)	0.909
Urinary incontinence, n (%)	1 (3.5%)	7 (20%)	0.083
Bladder diverticula, n (%)	3 (10.7%)	6 (17.1%)	0.528
Shrunken bladder, n (%)	0 (0.0%)	3 (8.5%)	0.128
Urinary fistulas, n (%)	2 (7.1%)	2 (5.7%)	0.828
Bladder cancer, n (%)	0 (0.0%)	2 (5.7%)	0.211
Prostate cancer, n (%)	2 (7.1%)	5 (14.2%)	0.420
Varicocele, n (%)	4 (14.2%)	6 (17.1%)	0.792
Chronic hemorrhoids, n (%)	11 (39.2%)	17 (48.5%)	0.646
Chronic venous insufficiency, n (%)	6 (21.4%)	6 (17.1%)	0.723
Smoking, n (%)	13 (46.4%)	15 (42.8%)	0.860
Contact with harmful and toxic substances, n (%)	4 (14.2%)	5 (14.2%)	1.0
Allergy, n (%)	4 (14.2%)	4 (11.4%)	0.766
Acute cerebrovascular disorder, n (%)	0 (0.0%)	1 (2.8%)	0.374
Acute myocardial infarction, n (%)	2 (7.1%)	2 (5.7%)	0.828
Ischemic heart disease, n (%)	11 (39.2%)	20 (57.1%)	0.407
Asthma and chronic obstructive pulmonary disease, n (%)	3 (10.7%)	9 (25.7%)	0.210
TB, n (%)	1 (3.5%)	0 (0.0%)	0.268

Table 1. *Continued*

Parameter	Group I (n = 28)	Group II (n = 35)	P
Blood transfusion, n (%)	11 (39.2%)	18 (51.4%)	0.557
HIV, n (%)	0 (0.0%)	0 (0.0%)	0.000
Hepatitis, n (%)	2 (7.1%)	6 (17.1%)	0.294
Spine pathology, n (%)	8 (28.5%)	6 (17.1%)	0.389
Kidney stones, n (%)	4 (14.2%)	4 (11.4%)	0.766
Bladder stones, n (%)	3 (10.7%)	7 (20.0%)	0.390

TU – transurethral; OIU – optical internal urethrotomy; TB – tuberculosis; HIV – human immunodeficiency virus

Table 2. *Evaluation of treatment results using the multiple endpoint method*

Parameter	Good	Satisfactory	Poor
Absence of relapse	+	+	-
Qmax	>12 ml/sec	>12 ml/sec	<12 ml/sec
The volume of residual urine	Less than 50 ml	Less than 50 ml	More than 50 ml
Urethral lumen diameter in the reconstruction zone	>4 mm	>4 mm	<4 mm
Continence	+	-	+-
Erectile function (IIEF-5)	≥15 points	<15 points	Any
Penis shortening	-	+	+-
IPSS	≤19 points	>19 points	Any
QoL	>3 points	<3 points	Any

Qmax – maximum urine flow rate; IIEF-5 – international index of erectile functioning; IPSS – international prostate symptom score; QoL – the quality of life scale

protocol of the study: urological consultation, clinical blood and urine tests, urethrography, urethroscopy, uroflowmetry, and ultrasound. The patients' subjective conditions were also assessed using the international prostate symptom score (IPSS), quality of life (QoL), and international index of erectile function (IIEF-5) scales. Patient complaints were recorded.

The treatment effectiveness was evaluated according to several criteria: the maximum urine flow rate (by uroflowmetry), the diameter of the urethral lumen in the operating zone (urethrography), the volume of residual urine (ultrasound), and rating scale indicators (IPSS, QoL and IIEF-5).

The treatment results were evaluated based on a comprehensive analysis of the parameters of all primary and secondary endpoints. Absence of relapse and adequate urination do not give an accurate image of the patient's quality of life after surgery. Therefore, the interpretation of the results requires consideration of all factors. The treatment results were divided into three groups, the scheme is presented in Table 2.

Data analysis

The initial data and the results of surgical treatment were analyzed using the STATISTIKA software for Windows version 10.0 (Statsoft Inc, USA), SPSS Statistics version 23.0 (IBM, USA) and Stata version 14.2 (StataCorp, USA).

A comparative analysis of the examination results and surgical treatment was performed in two groups, conventionally designated: Group I (EPA) and Group II (BMG). The comparison was performed using the combined endpoint method.

Intraurethral plastic surgery technique

The intraoperative urethrocystoscopy or urethral catheter helped to determine the distal end of urethral narrowing. The spongious body and urethra were dissected in stages in the bulbomembranous physiological bend projection, but distal to the urethral lumen narrowing. The length of urethrotomic access was 2–3 cm (Figure 1).

The narrowed part of the urethra was dissected ventrally with little penetration beyond the urethra into the muscle thickness. Then, the scar-modified urethral tissue was excised in the ventral semicircle between five to seven o'clock (according to the standard dial). A graft site was formed within the excised scar tissue of the urethra. The proximal and distal borders of the formed site were 10 mm within the unchanged urethral tissues (Figure 2).

The adequacy of the urethral lumen was checked by inserting a 24 Fr catheter into the bladder.

An oral mucosa graft was used as replacement material, and was harvested according to the standard method. The shape and size of the graft correlates to the parameters of the bed formed for its transplantation.

The oral graft was fixed without tension in the urethra bed by successive sewing with separate nodal sutures (absorbable suture material 4\6-0).

After the proximal part graft fixation with triangular vertexes (the tab method), it was sewn through the center to the underlying structures, which allows the exclusion of the formation of a pathological cavity (Figure 3). The intraoperative urethroscopy and magnifying optics helped to control the quality of the surgical suture.

Then, a 16–18 Fr Foley urethral catheter was inserted into the bladder and its balloon inflated to 5–10 ml. In some cases, additional suprapubic drainage was used. The distal part of the graft was pierced and fixed with Onlay method (Figure 4).

To exclude the formation of a pathological cavity, separate nodal sutures with suturing of the sub-mucosal graft base closed the urethrotomic access (Figure 5) were performed.

Postoperative period

During the operation, in order to facilitate the subsequent mobilization of the urethra, urethrocystoscopy with a flexible conductor or urethral catheter was performed. To control the quality of the surgical suture during the transplant fixation, urethroscopy was used.

After the operation, patients remained in the intensive care unit for 3–6 hours. Infusion therapy was carried out during the first 24-48 hours. Antibacterial therapy, analgesia (non-steroidal or narcotic analgesics), prophylaxis of thromboembolic complications (low molecular weight heparins), protection against stress ulcers (proton pump inhibitors) was administered, and to eliminate the discomfort of urethral drainage, alpha-blockers were used ad-
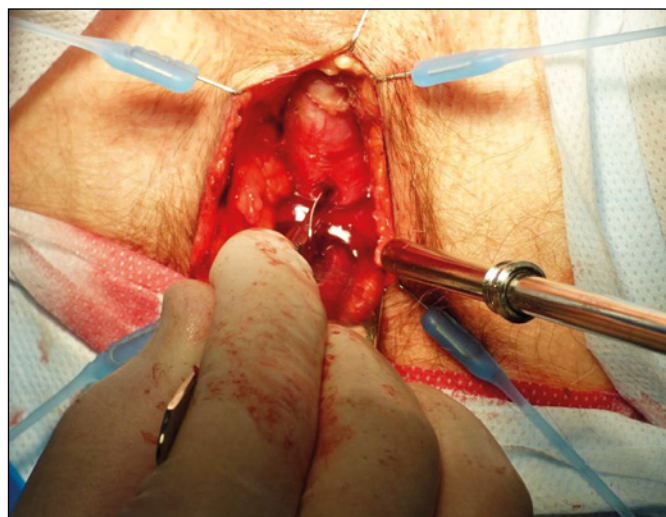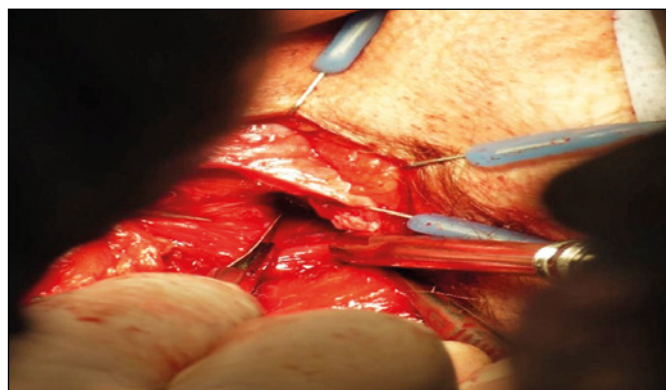

Figure 1. *Urethrotomic access.*

Figure 2. *The scar tissue excision, formation of a bed for buccal graft transplantation.*
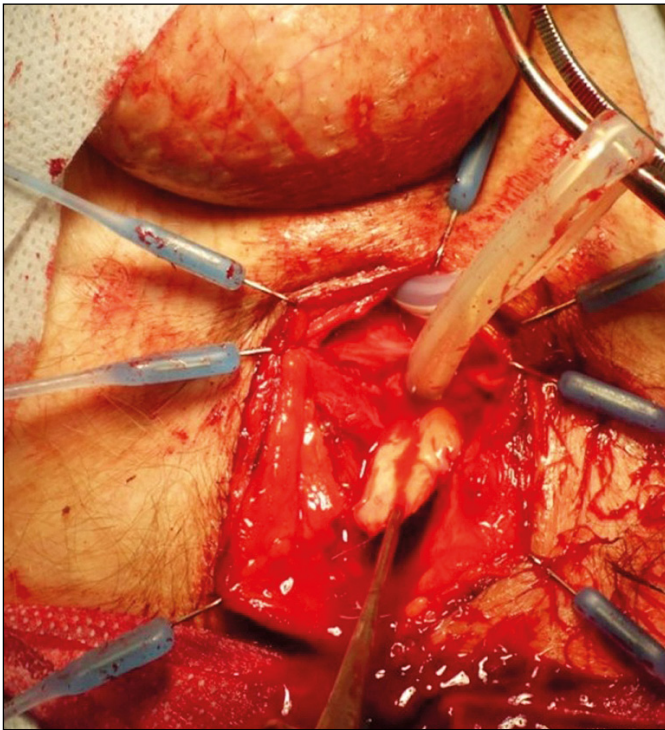
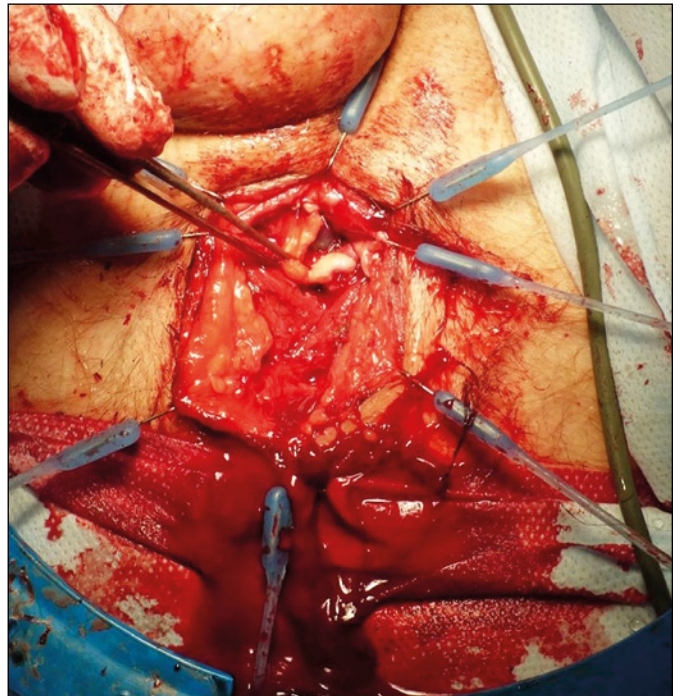**Figure 3.** *The intraurethral buccal graft fixation.*

Figure 4. *The final stage of the buccal graft fixation by the Onlay method.*

ditionally. On the first day after surgical treatment, the severity of postoperative pain was assessed according to the visual analogue scale (VAS).

During the postoperative period, in the absence of contraindications from the second or third day after the operation, 5–10 sessions of hyperbaric oxygenation were performed in a mode of 1–1.5 atmosphere for 40–45 minutes. Hyperbaric oxygenation helped to improve the probability of BMG engraftment and improve reparative processes. Drugs that improve microcirculation (Trental), wound healing (Solcoseryl), and also fibrinolytic therapy (Longidase) were prescribed.

Bladder drainage was performed with a 16–18 Fr silicone urethral catheter. The urethral catheter was removed 10–14 days after surgery for patients in Group II, and after 14–21 days – for patients in Group I.

Treatment results evaluation

There were several criteria to evaluate the treatment effectiveness: the maximum rate of urine flow (by uroflowmetry), the diameter of the urethral lumen in the operation zone (urethrography and urethral calibration), the volume of residual urine (ultrasound), evaluation scales indicators (IPSS, QoL and IIEF-5). After 3 months or more after surgery, the following treatment results were considered successful: Qmax
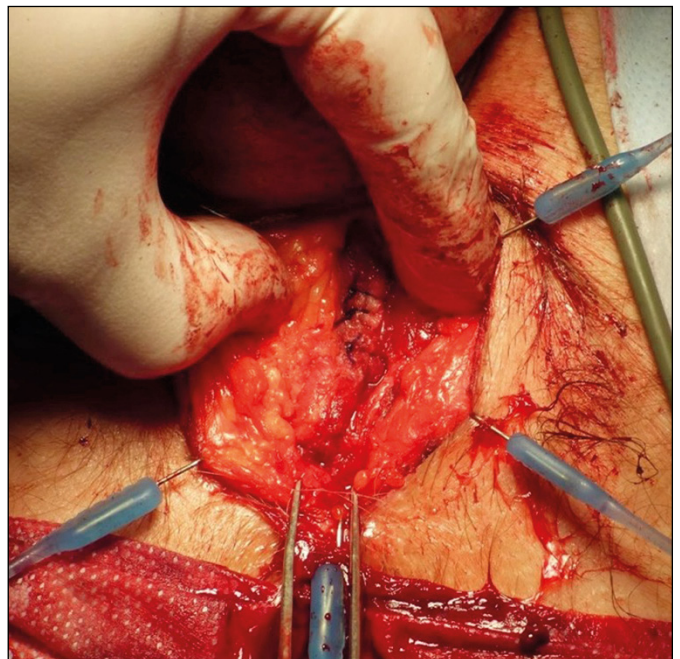

Figure 5. *The urethrotomic access closing.*

of more than 12 ml/sec; absence of residual urine or signs of relapse according to urethrography (the normal diameter of the urethral lumen 5 mm or more); absence of severe symptoms of the lower urinary tract, satisfactory quality of life.

RESULTS

Preoperative parameters

The average age of patients in groups I and II were 55.5 ±17.02 and 58.17 ±12.2 years, respectively (p = 0.329). All patients were male. The median index of disease duration in groups I and II were 2.0 (0.9; 8.25) and 5 (1.3; 13) years, respectively, and did not differ significantly (p = 0.154).

Among the concomitant diseases, the most common pathology was a urinary tract infection, noted in 71.4% and 82% of cases in groups I and II, respectively (p = 0.7). The frequency of other concomitant diseases occurrence, as well as other baseline indicators in both groups, did not differ statistically (p >0.05).

The subjective condition of patients and their functional status are presented in Table 3.

An analysis of anamnestic data revealed 13 possible etiological factors for the urethral stricture formation for 13 patients of the first group (46.4%) and 21 patients of the second group (60%) (p = 0.554). Previous surgical treatment of urethral stricture had 18 patients of the first group (64.2%) and 28 patients of the second group (80%) (p = 0.579).

According to the complaints analysis, medical records and uroflowmetry, all patients in the first and second groups had urination disorders (Qmax less than 12 ml/sec), and in some cases, there was no independent urination. In the first group, the absence of independent urination was reported by 4 patients (14.2%), in the second – by 7 (20%) patients (p = 0.617). In this case, symptoms of the lower urinary tract (LUTS) were evaluated with a maximum rate (35 points) to avoid confusion in the statistical analysis.

Table 4 presents the comparative data of the objective examination results in both groups.

Analysis of the obtained data showed that urethral stricture in patients of both comparison groups was characterized by extended, subtotal and total obliteration of the lumen with the development of a significant volume of residual postvoid urine, a critical decrease in the maximum urine flow rate and a mixed component of obstruction.

Thus, the comparability of the main characteristics of patients in both groups was established (p >0.05).

Treatment results

For a comparative assessment of the immediate results of urethral stricture disease surgical treatment after anastomotic operations (group I) and intra-urethral substitutional operations (group II), a comparative analysis of the postoperative parameters of the

Table 3. *Assessment of the subjective condition of patients*

Parameter	Group I (n = 28)	Group II (n = 35)	P
Erection-suppressing medications, n (%)	11 (39.2)	17 (38.3)	0.646
Treatment with a-blockers, n (%)	12 (42.8)	8 (22.8)	0.225
IPSS, points, Me (IR 25; 75)	28 (24; 30)	33 (24; 31)	0.564
QoL, points, Me (IR 25; 75)	5 (4; 5)	5 (4; 5)	0.658
IIEF-5, points, Me (IR 25; 75)	12 (7; 14)	14 (8; 16)	0.595

IPSS – international prostate symptom score; QoL – the quality of life scale; IIEF-5 – international index of erectile functioning; IR – interquartile range

Table 4. *The results of an objective examination of patients in comparison groups*

Indicator	Group I (n = 28)	Group II (n = 35)	P
BMU stricture length, mm	10 (10; 15)	15 (10; 15)	0.267
The smallest diameter of the lumen of the urethral stricture, mm	1 (0.75; 2)	1 (1; 2)	0.906
Complete obliteration of the urethral lumen, n (%)	7 (25%)	7 (20%)	0.705
Prostate volume, cm³	24.5 (20; 28.1)	25 (20; 30)	0.871
The volume of residual urine, ml	200 (80; 262)	300 (124; 545)	0.051
The volume of residual urine more than 100 ml, n (%)	20 (71.4%)	28 (80%)	0.769
Qmax, ml/sec	4 (2.9; 5)	3 (1.8; 4.9)	0.391
V average, ml/sec	2.85 (2; 4)	2 (1; 3)	0.108
Lack of urination, n (%)	4 (14.2%)	7 (20%)	0.617
Diverticula and false urethral passages, n (%)	2 (7.1%)	6 (17.1%)	0.294

BMU – the proximal part of the bulbar and membranous parts of urethra; Qmax – maximum urine flow rate; V – average flow rate

patients' condition and the final results of the study was performed.

An intergroup analysis of the surgical access sizes showed that its average linear sizes in Group I was 8.4 ±0.9 cm, which significantly (p <0.001) exceeds the measurement results (3.9 ±0.7 cm) in Group II. In the early and late postoperative period, there were no cases of mortality in both groups. Chronometric analysis of the operating period and the intensive care unit (ICU) period was performed. The average length of stay in the ICU was 3.3 ±0.8 and 3.0 ±0.0 hours for groups I and II, respectively (p = 0.017). The average duration of surgical intervention in groups I and II were 1.4 ±0.41 hours and 1.7 ±0.49 hours, respectively (p = 0.354).

In the early postoperative period, there were no complications from the anesthesiologic procedure or deterioration in general somatic status.

Table 5. *Comparative data of the immediate results in both groups*

Indicator	Group I (n = 28)	Group II (n = 35)	P
Stay in the intensive care unit, n (%)	1 (3.5%)	1 (2.8%)	0.876
Wound failure, n (%)	0	0	0
Hematoma in the area of operation, n (%)	0	0	0
Urethrorrhagia, n (%)	1 (3.5%)	0	0.268
Subfebrile condition in the early postoperative period, n (%)	21 (75%)	29 (82%)	0.794
Infectious complications, n (%)	0	0	0
Urethral suture failure, n (%)	2 (7.1%)	0	0.120
Severe pain syndrome (more than 7 points) in the first day after surgery, n (%)	13 (46.4%)	2 (5.7%)	0.0033
Average length of hospital stay, days	16.0 ±3,8	12.27 ±3.5	0.0002
Postoperative incontinence, n (%)	5 (17.8%)	0	0.016
Recovery of urine retention after surgery, n (%)	0	3 (8.5%)	0.128
Total continence patients after surgery, n (%)	21 (75%)	29 (82.8%)	0.794

Table 5 presents a comparative description of the postoperative condition factors.

Analysis of the study results showed that postoperative complications in the early and late postoperative periods developed extremely rarely.

To determine the predictors of postoperative complications, univariate and multivariate logistic regression analysis was performed. The selection of predictor variables was carried out according to the initial parameters. Data concerning predictor factors for the occurrence of postoperative complications (univariate and multivariate logistic regression analysis) is presented in Table 6.

The results were used to build a predictive model for significant pain syndrome in multivariate regression analysis (selection of predictor factors with significance level p <0.05). The anastomotic urethroplasty (BP 15.1; 95% CI 1.3–164.5; p = 0.026) became a significant predictor of severe pain syndrome, and the remaining factors were not significant (p >0.05). An odds ratio of less than one indicates a protective effect, and more than one indicates a provocative effect of the revealed predictor variables. Based on this correlation, the degree of influence of the predictor on the development of complications was calculated.

Table 6. *Predictors of postoperative complications*

Complications in the early postoperative period	Factor	Univariate analysis		Multivariate analysis	
		χ²	BP (95% CI)	P	BP (95% CI)	P
Severe postoperative pain syndrome Multivariate logit regression: χ² = 30.21; p <0.001	Age	4.38	0.9 (0.9–0.9)	0.042	0.9 (0.8–1.0)	0.182
	Disease duration	1.5	1.0 (0.9–1.1)	0.215	–	–
	Iatrogenic injury	1.91	0.4 (0.1–1.4)	0.164	–	–
	BPH	2.76	0.3 (0.06–1.3)	0.111	–	–
	Perineal injury	2.9	2.9 (0.8–10.7)	0.094	–	–
	Pelvic injury	9.34	8.1 (2.1–37.2)	0.003	62.2 (0.9–4153)	0.054
	Cystostomy drainage	5.57	7.8 (0.9–65.9)	0.058	–	–
	STI	3.72	3.75 (0.9–14.2)	0.052	–	–
	Atherosclerosis	5.12	0.2 (0.05–0.8)	0.035	6.4 (0.1–387.5)	0.371
	TU operations	2.87	0.2 (0.05–1.4)	0.123	–	–
	Significant residual urine volume	7.34	0.9 (0.9–0.9)	0.033	0.9 (0.9–1.0)	0.117
	Urethral stricture	0.03	0.9 (0.9–1.0)	0.864	–	–
	Operation duration	0.23	1.3 (0.3–4.4)	0.636	–	–
	EPA	13.76	14.2 (2.7–73.7)	0.002	15.1 (1.3–164.5)	0.026
	BMG	13.76	0.07 (0.01–0.36)	0.002	–	–
	Delayed urethroplasty	1.65	1.7 (0.7–4.1)	0.193		
Incontinence Multivariate logit regression : χ² = 11.96; p = 0.017	Age	1.24	1.0 (0.9–1.1)	0.312	–	–
	Severe LUTS	3.33	0.8 (0.7–1.0)	0.082	1.7 (0.9–3.2)	0.084
	ED before surgery	0.83	3.9 (0.2–67.5)	0.348	–	–
	Pelvic injury	1.73	4.2 (0.5–33.5)	0.176	–	–
	AMI	1.38	5.4 (0.4–69.4)	0.192	–	–
	CVI	2.02	4.7 (0.5–38.5)	0.142	0.4 (0.0–20.2)	0.680
	Pathology of the spine	1.68	4.1 (0.5–32.7)	0.183	–	–
	TU operations	4.36	1.3 (1.0–1.8)	0.034	1.6 (0.7–3.9)	0.229
	Prostate surgery	2.51	5.6 (0.5–58.4)	0.145	11.8 (0.3–412)	0.173
	Prostate volume	1.62	1.0 (0.9–1.0)	0.187	–	–

BP – the probability of risk; CI – confidence interval; STI – sexually transmitted infections; BPH – benign prostatic hyperplasia; TU – transurethral; EPA – anastomotic surgery; BMG – substitutional intraurethral plastic; LUTS – symptoms of the lower urinary tract; ED – erectile dysfunction; AMI – acute myocardial infarction; CVI – chronic venous insufficiency

Therefore, the anastomotic method increases the likelihood of severe pain in the postoperative period by 15.1 times.

After the analysis of incontinence predictors after the anastomotic operation, the significance of previously performed transurethral (TU) operations (BP 1.3; 95% CI 1.0–1.8; p = 0.034) was revealed.

Postoperative indicators of urodynamics and functional status (IPSS, QoL, IIEF-5) for both groups are presented in Table 7.

A comparative intergroup analysis of these indicators was performed. A significant (p = 0.013) intergroup difference in the state of erectile function was noted: in Group II, this parameter was better than in Group I. Deterioration of the state of erectile function in Group I was reported for 13 (46.4%) patients; in the second group, no such complications were recorded (p = 0.003) The Qmax intergroup analysis one month after the operation revealed no superiority of this urodynamic indicator in any of the groups [22.4 (19.8; 25.7) ml/sec for Group I; 22.1 (19.7; 24.3) ml/sec for Group II; p = 0.266].

The Qmax results demonstrate comparable effectiveness [18.9 (17.8; 22.6) ml/s for Group 1 versus 19.8 (18.3; 21.2) ml/s for Group 2] three months after the operation (p = 0.596). However, the final results [18.45 (15.5; 22.1) ml/s for Group I; 16.4 (13.7; 17.6) ml/s for Group II] showed superiority (p = 0.023) of this parameter (Qmax) in Group I.

The long-term results of stricture surgical treatment were evaluated according to the protocol checkpoints. The average clinical observation was from 736 days with a 95% CI of 613–860 days, to 1904 days maximum. The completeness of clinical observation of a total of 79 discharged patients (Group I and Group II) was 63 patients (79.7%).

For Group I patients, the average observation period was 686 days with 95% CI of 480–892 days (maximum period of 1850 days). For Group II patients – 778 days with 95% CI 621–935 days (maximum period 1904 days).

Figures 6 and 7 show a clinical example of retrograde urethrography in a patient before intraurethral urethroplasty and 2 years after surgery.

Remote results

In the distant postoperative period, a single episode of mortality in Group II was noted, however this was not connected with urethroplasty.

In the distant postoperative period, a number of significant complications were noted. In 5 (14.2%) cases from Group II and in 1 case (3.5%) from Group I, a severe inflammatory process of the urinary tract was observed in the period from 3 to 6 months, which required the administration of antibacterial therapy (p = 0.187). A logistic regression analysis of these complications did not reveal predictors of its occurrence.

Complaints about the shortening of the penis during an active survey 3 months after the operation were reported by 4 (14.2%) patients from Group I. In Group II, no such complaints were reported. It was surely estimated (p = 0.031) that there is a higher risk of shortening of the penis after anastomotic method (Group I), in comparison to the BMG method (Group II) with an initial length of urethral strictures of more than 2 cm.

Table 7. *Postoperative indicators of urodynamics and functional status (IPSS, QoL, IIEF-5)*

Parameter	Group I (n = 28)	Group II (n = 35)	P
IPSS, points	7.5 (5; 12)	10 (8; 14)	0.080
IIEF-5, points	10.5 (6.5; 14)	16 (12; 18)	0.013
QoL, points	1 (1; 3)	1 (1; 2)	0.970
Qmax, ml/sec	18.45 (15.5; 22.1)	16,4 (13.7; 17.6)	0.023
Residual urine volume, ml	0 (0; 0)	0 (0; 0)	0.852
The achieved diameter of the lumen of the urethra in the area of operation, mm	7 (6; 8)	6 (5; 7)	0.064

IPSS – international prostate symptom score; IIEF-5 – international index of erectile functioning; QoL – the quality of life scale; Qmax – maximum urine flow rate

Table 8. *Predictors of postoperative complications*

Complications in the early postoperative period	Factor	Univariate analysis			Multivariate analysis	
		χ^2	BP (95% CI)	P	BP (95% CI)	P
Penis shortening	Age	0.52	0.9 (0.9–1.0)	0.464	–	–
	Disease duration	2.03	1.0 (0.9–1.1)	0.142	–	–
Multivariate logit regression $\chi2$ = 10.25; p = 0.0059	Pelvic injury	3.04	8.6 (0.7–104)	0.091	–	–
	Fistula of the US	1.94	8.3 (0.5–120)	0.119	–	–
	EPA	4.63	3.9 (1.1–13.8)	0.031	36.4 (1.1–1116)	0.039
	Failed EPA	5.26	19.2 (1.4–251.1)	0.024	5.36 (1.1–25.9)	0.037

BP– the probability of risk; CI – confidence interval; US – urinary system; EPA – anastomotic surgery

Figure 6. *Patient T, 68 years old, before intraurethral urethroplasty.*
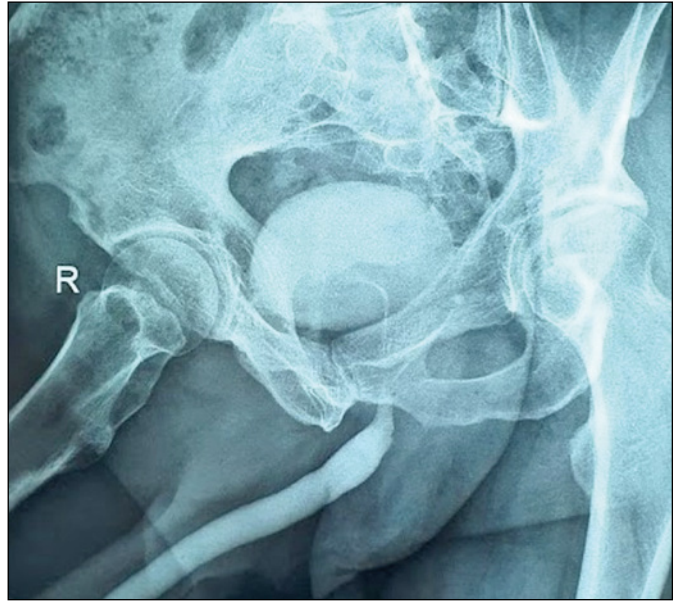

Figure 7. *Patient T, 2 years after intraurethral urethroplasty.*

To determine the predictors of the complication's development, a univariate and multivariate logistic regression analysis was performed. The selection of predictor variables was carried out according to the initial parameters. Data concerning predictor factors for the occurrence of postoperative complications (univariate and multivariate logistic regression analysis) is presented in Table 8.

The results were used to build a predictive model for penile shortening in multivariate regression analysis (choice of factors p <0.05). Significant predictors of the occurrence of this complication were anastomotic plastic surgery (BP 36.4; 95% CI 1.1–1116; p = 0.039) and anastomotic insufficiency after EPA (BP 5.36; 95% CI 1.1–25.9; p = 0.037).

Table 9. *The long-term comparative data on the success of urethroplasty*

Indicator	Group I (n = 28)	Group II (n = 35)	P
Successful primary, n (%)	24 (85.7%)	33 (94.2)	0.796
Relapse, n (%)	4 (14.2%)	2 (5.5%)	0.297

Table 10. *Cox proportional risk regression model*

Variable	Cox Univariate Analysis			Cox Multivariate Analysis, $\chi^2 = 1.65$; p = 0.033	
	Wald test χ^2	BP (95% CI)	P	BP (95% CI)	P
Age	0.21	1.0 (0.9–1.0)	0.647	–	–
Urethritis	0.38	2.1 (0.1–25.5)	0.535	–	–
Neurogenic disorders of urination	4.27	6.3 (0.8–46.9)	0.038	1.6 (0.6–4.3)	0.293
Pelvic injury	1.96	4.9 (0.4–59)	0.161	–	–
Permanent urethral catheter	1.99	6.2 (0.3–113)	0.158	–	–
Purulent process of the US	1.69	3.6 (0.4–28.4)	0.193	–	–
Prostate cancer	2.06	6.2 (0.3–108)	0.151	–	–
Contact with harmful substances	5.04	9.3 (0.8–101)	0.024	1.1 (0.4–3.1)	0.718
Pathology of the spine	6.19	11.9 (0.9–143)	0.012	1.0 (0.5–2.3)	0.819
Hyperbaric oxygenation	2.67	0.2 (0.03–1.5)	0.102	–	–
Late complications	5.5	6.9 (1.0–45.1)	0.019	0.5 (0.1–1.6)	0.257

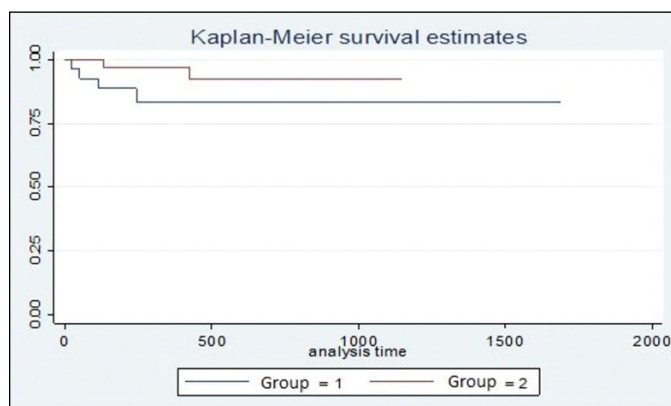US – urinary system; BP – the probability of risk; CI – confidence interval

Figure 8. *Absence of relapse in study groups according to the Kaplan-Meyer method.*

Therefore, when performing EPA and / or insolvency anastomosis, the risk of penile shortening increases.

Comparative information on the success of surgical treatment of patients in the comparison groups is presented in Table 9.

The Kaplan-Meyer rates of absence from recurrence of urethral stricture in Group I during the first three months turned out to be 92.5 ±5.0% (95% CI 73.5–98.0%), after a year – 83.0 ±7.9% (95% CI 60.1–93.4%) and two years later – 83.0 ±7.9% (95% CI 60.1–93.4%). These indicators in Group II during the first three months were 100%, after a year – 96.9 ±2.9% (95% CI 80.3–99.5%) and after two years – 92.5 ±5.1 % (95% CI 72.7–98.1%).

The log-rank test did not reveal statistically significant differences (p = 0.190; χ^2 = 1.9) in the recurrence rate over the entire observation period, which is graphically expressed by the Kaplan-Meier graphic (Figure 8).

The selection of predictor variables was carried out according to the initial parameters, as well as according to the control parameters in the postoperative period. The Cox regression proportional risk model, demonstrating the effect of variables on relapse risk, is presented in Table 10.

Regression analysis of Cox's proportional risks revealed independent predictors of relapse in the long-term postoperative period: neurogenic disorders of urination [probability of relapse (BP) – 6.3; 95% CI 0.8–46.9; p = 0.038], contacts with harmful substances (BP – 9.3; 95% CI 0.8–101; p = 0.024), spinal pathology (BP – 11.9; 95% CI 0.9-143; p = 0.012) and late complications (BP – 6, 9; 95% CI 1.0–45.1; p = 0.019).

A multivariate regression analysis of Cox's proportional risks (sample from p <0.05) did not reveal reliable predictors.

DISCUSSION

The analysis of the effectiveness of existing treatment methods showed the feasibility of developing and introducing an alternative minimally invasive method of substitutional plastic surgery in case of narrowing the proximal part of the bulbar and membranous parts of the urethra. The new method should be comparable in effectiveness, have a lower risk of developing postoperative complications and fit several important criteria. Firstly, to minimize the risk of damage to the anatomical structures of the perineum, which are responsible for erectile function, the length of the erect penis and retention of urine. Secondly, to achieve comparable effectiveness in comparison to anastomotic methods, the technique of transplantation of autologous transplants should be optimized.

The prototypes for creating the BMG technique were the methods of urethral replacement with autologous grafts [26, 27], intraurethral methods of replacement of the bulbar urethra [28]. In addition, the experience of using other existing surgical methods was taken into account. As a result, it was possible to develop a new method for treating narrowing of BMU.

Other things being equal, such as group homogeneity and a single operation correction algorithm, restoration of normal urethral patency was achieved in both study groups. This result was evaluated on a number of parameters.

Analyzing the comparative intergroup effectiveness of the treatment based on the criteria established in the study, good treatment results were obtained in 6 (21.4%) patients from Group I and in 21 (60%) patients from Group II (p = 0.046). Satisfactory results were obtained in 18 (64.2%) patients from Group I and in 12 (34.2%) patients from Group II (p = 0.160). Unsatisfactory results were recorded in 4 (14.2%) patients of group I and in 2 (5.7%) patients of group II (p = 0.297).

It should be noted that the use of the developed method of BMG allows you to get better treatment results than the use of anastomotic methods. Both methods of urethroplasty are characterized by zero operating and hospital mortality and a low incidence of postoperative general and urinary system (US) related complications. Both methods are highly effective and safe when performing urethroplasty for strictures of the proximal part of the bulbar and membranous sections. However, the performance of anastomotic operations is associated with a risk of deterioration in the quality of life and sexual function.

The revealed statistical difference in the Qmax indicators analysis is due to the methodology of the op-

eration and does not affect the effectiveness of surgical treatment since the achieved result meets the most stringent assessment criteria (Qmax> 15 ml/s; achieved urethral lumen diameter of more than 5 mm) in both groups. According to subjective parameters (IPSS, QoL) and the volume of residual urine, no significant intergroup difference was found (p <0.05). According to the final data analysis, 4 patients from Group I (14.2%) and 2 patients from Group II (5.7%) had a relapse (p = 0.297). The lack of statistical significance can be explained by the low recurrence rate and the relatively small sample size. The absence of relapse was equal in both groups (p = 0.190) during the entire observation period and after 2 years was 83.0 ±7.9% (95% CI 60.1–93.4%) in Group I and 92.5 ±5.1% (95% CI 72.7–98.1%) – in Group II. Based on complications analysis in the early postoperative period, a more pronounced pain syndrome was noted on the first day after the anastomotic operation (p = 0.0033). Multivariate regression analysis confirmed the data on the effect of the anastomotic method on the occurrence of significant pain syndrome (BP 15.1; 95% CI 1.3–164.5; p = 0.026). The theoretical justification for the difference may be greater operational injuries (larger wound size, mobilization, and dissection of perineal structures). Analysis of incontinence cases in Group I (n = 5; 17.8%) proved the provocative effect of previously performed TU operations (BP 1.3; 95% CI 1.0–1.8) (p = 0.034). These results are consistent with the findings of other researchers about the risks of urinary incontinence after previous transurethral operations and interventions on the prostate gland with the destruction of one or more elements of the sphincter.

Performing anastomotic plastic surgery with a length of narrowing of more than 3 cm resulted in a shortening of the penis in 4 (14.2%) cases in Group I. In Group II, no such complaints were noted. Consequently, a negative effect of anastomosing urethroplasty on the postoperative parameters of the length of the penis was established reliably (p = 0.031) in comparison to those after BMG. Significant predictors of such a complication based on multivariate regression analysis are anastomotic plastic surgery (OS 36.4; 95% CI 1.1–1116; p = 0.039) and anastomotic insufficiency after EPA (BP 5.36; 95% CI 1.1; 25.9; p = 0.037), which confirms the conclusion.

The decrease in erectile function is moderate – none of the patients in Group I noted the development of impotence. However, erectile dysfunction (ED) reduces the quality of life and serves as an important marker of impaired blood supply to the spongy body of the urethra, which is important to consider in subsequent interventions on the urethra.

A comparative analysis of our results with previously published studies [6, 29–36] was carried out. It revealed that the work of these authors have several limitations: retrospective analysis (level 2b) or case-control studies (level 3b); lack of randomization; small sample size; lack of presentation of long-term clinical outcomes; lack of regular monitoring through the entire necessary set of studies (ultrasound, urethrography, urethroscopy). In almost all of these studies, an assessment of a decrease in erectile function was not performed, but only its persistent disappearance was recorded.

The largest studies [5, 6] indicate a significant risk of ED and urinary incontinence after urethroplasty. In this case, no statistically significant difference in the risk of ED development was demonstrated between EPA methods and BMG substitutional surgery in general. Our findings are consistent with the literature, confirming the negative impact of common surgical techniques for performing urethroplasty on erectile function and urinary retention.

Distinctive features of our study are: a prospective set of patients, the distribution into groups by randomization; a relatively large sample size for this pathology (102 patients included, and 63 patients completed the study in groups I and II) calculated when planning the study; homogeneity of groups according to initial characteristics, similar functional characteristics of patients; obligatory diagnostic algorithm before surgery and postoperative control for all patients; unified algorithm of surgical correction; presentation of immediate and distant clinical outcomes.

This study has a limitation - the average follow-up is less than 5 years. With continued observation, the results will be presented separately. Recruitment of patients for the study is ongoing. Currently, it includes 112 patients.

CONCLUSIONS

In both groups, the desired result was achieved – adequate independent urination was restored. The anastomotic method of urethroplasty should be used with caution in patients from risk groups, as well as with the presence of predictors of complications: previous transurethral surgeries on the urethra and prostate, anastomotic urethroplasty, radical prostatectomy. The developed minimally invasive substitution technique has a similar effectiveness with a lower risk of complications.

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