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Outcomes of laparoscopic pyeloplasty and impact of an enhanced recovery protocol

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ABSTRACT

Purpose: The study aims to analyze the enhanced recovery protocol's (ERP) effectiveness in a comparative study of elective surgeries for ureteropelvic junction obstruction (UPJO).

Methods: The prospective study included 30 patients with UPJO who underwent laparoscopic pyeloplasty in 2018-2021.

Results: Postoperative complications developed rarely, and their frequency and severity were comparable. Independent predictors of UPJO recurrence were the spine osteochondrosis >II period (HR 13.97; 95% CI 1.26; 154.8; p=0.032), the concretions self-discharge (HR 28.49; 95% CI 1.78; 455.62; p=0.018), surgical operation duration > 110 minutes (HR 44.7; 95% CI 3.95; 505.4; p=0.002) and previous nephrostomy (HR 1.07; 95% CI 1.02; 1.13; p=0.002).

Conclusions: In the surgical treatment of UPJO, it is advisable to use ERPs, as this allows achieving a better treatment quality with comparable results.

Keywords: fast track surgery, ERAS, ureteropelvic junction stricture, ureteropelvic junction obstruction, UPJO, UPJO stricture, enhanced recovery, Anderson-Hynes dismembered pyeloplasty, minimally invasive surgery

INTRODUCTION

Enhanced recovery program is a special strategy of perioperative management aimed at reducing the treatment duration and preservation or improvement of postoperative outcomes. It affects all aspects: from optimizing preoperative examination and preparation, to changing surgical methods and materials, and to optimizing rehabilitation measures and general postoperative recommendations for lifestyle changes. Enhanced recovery program is the official name of the program, an analogue of ERAS in Russia, approved by the Russian Society of Surgeons in 2016.

The program includes a revision of the concept of preoperative and postoperative nutrition, bowel preparation, the introduction of the concept of multimodal anesthesia, which minimizes operational and postoperative stress in combination with early mobilization, maintenance of intraoperative normothermia, fluid control, postoperative pain, and nausea.

The ureteropelvic junction obstruction (UPJO) is the most common obstructive pathology of the upper urinary tract; the treatment still has many controversial aspects [1]. The occurrence frequency for a unilateral process according to various data is from 1:750 to 1:2,000 cases [2].

The urine abnormal outflow from the kidney with hydronephrosis is complicated by a chronic urinary infection, formation of concretions, and loss of renal function [3].

Etiologically, congenital strictures prevail. Strictures after urolithiasis, iatrogenic, infectious, ischemic, and false (due to polyps, malignant formations, or periureteral adhesions) are less common [4, 5]. The role of pyelovasal conflict remains unclear since the intersection of the ureter with vessels occurs in up to 30.0% of cases in the population, and up to 63.0% of cases among patients with established UPJO. Crossing the ureteral vessel can lead to direct compression, muscle hyperplasia, inflammation, or fibrous dysplasia [3, 6].

Despite the long-standing study of the problem, there are no treatment methods that claim to be the "gold standard".

Resection laparoscopic pyeloplasty is a popular urological operation for patients with an established diagnosis of congenital or acquired UPJO [7, 8]. The most common method is Anderson-Hynes dismembered pyeloplasty with an efficiency rate of about 90.0%. Previously, the operation was mainly an open surgical technique, now preference is given to endoscopic methods, for example, laparoscopic [9].

Performing pyeloplasty with significantly reduced renal function (from 15.0% to 30.0% differential renal function [DRF]) is also a matter of discussion. Obviously, a shrunken kidney with a DRF of less than 15.0% is not preservable. The meta-analysis results indicate the effectiveness of plastic surgery at DRF >15.0%. At the same time, there are no reliable predictors of treatment success. Overall, the expected DRF improvement is >5.0% [10].

According to the meta-analysis, the main factors of restenosis are the anastomosis tension (RR 3.86, 95% CI: 2.96 to 5.02; p<0.00001) and larger tissue dissections in the plastic surgery area (MD 303.97, 95% CI: 219.49 to 388.44; p<0.00001). Intraoperative blood loss, surgery duration, and additional renal vessels also proved to be significant [11].

Enhanced recovery protocols (ERPs) for pyeloplasty are at the initial stage of development, and publications on this problem are sporadic [12-14]. Thus, the development and implementation of protocols is a relevant task.

The relevance of the study is justified by the need to develop a protocol for accelerated recovery, which will improve the results of treatment without increasing the risks of complications by implementing elements of the ERAS program and other techniques, such as changing the technique of anastomosing, the use of adhesive applications, avoidance of stenting and others.

The aim of the study was to compare the post-operative status of patients using ERP for elective surgery for strictures of the ureteropelvic junction (UPJ).

Tasks of the study: to analyze the applicability of the ERAS protocol and some promising surgical technologies in laparoscopic pyeloplasty; to perform a prospective comparative clinical study of the application of the developed protocol; to evaluate the obtained results and formulate conclusions.

MATERIALS & METHODS

Research Design

There was a prospective, simple-blind, randomized study. The randomization method is a simple one based on a random number generator. One specialist performed all the surgical operations.

The study includes an analysis of the perioperative status and treatment outcomes of patients with UPJO after laparoscopic pyeloplasty (the Anderson-Hynes dismembered pyeloplasty) from January 2018 to October 2021 in Irkutsk, Russia.

Inclusion & Exclusion Criteria

Inclusion criteria

Planned UPJ surgery; indications for the operation meet the criteria of the approved protocol; the operation is planned according to the Anderson-Hynes dismembered pyeloplasty method through laparoscopic access by the surgical team established in the protocol; perioperative management is planned according to one of the approved protocols; patients are over 18 years old; the patient signed a consent to participate in the study.

Non-inclusion criteria

Absence of specified indications; refusal to participate in the study; initially low somatic status (decompensated diabetes mellitus, heart failure with an ejection fraction of less than 50.0%, gross neurological deficits, malignant diseases in the area of interest, etc.); inability to comply with ERP.

Exclusion criteria

Deviation from the study protocol.

Design & Sampling

There was a simple-blind randomized prospective study. The randomization method is a simple one based on a random number generator. One specialist performed all the surgical operations.

The null hypothesis of the study was that there were no between-group differences on the primary point. When the null hypothesis was rejected, an alternative hypothesis of intergroup differences at the primary endpoint was accepted.

The required sample size was calculated using the application “STATISTICA for Windows version 12.0”. In the absence of early studies on enhanced recovery in laparoscopic UPJ reconstructions, sample size calculation in the study design was based on the results of analyses of the effectiveness of the accelerated recovery protocol in nephrectomy.

Accepting the results of the study, it was calculated that 13-15 (by t-test, ES=-1.136) patients in each comparison group would be sufficient to reproduce differences in success and postoperative status with probabilities of type 1 and type 2 error of 0.05 and 0.20, respectively. Study power >0.8. The sample size presented made it possible to demonstrate reliable differences in the main parameters being compared.

Patients were recruited continuously until the sample size was reached. In 2018-2021, there were 122 patients with UPJO, 56 cases were included in the study.

Deviations from Protocol

Of the 56 patients, 26 were excluded from the study (12 due to the deviation from the protocol, 14–refused to participate in the process). The final analysis included 30 cases (per-protocol): the first group (n=15, group I), standard treatment; the second group (n=15, group II), ERP.

Checkpoints

“Hard” checkpoints: absence of UPJO recurrence no sooner than six months; relapse detected at any stage of postoperative follow-up.

“Soft” checkpoints: postoperative minimum diameter of the anastomosis, pelvis dimensions, DRF data, postoperative complications according to Clavien-Dindo.

Study Groups Comparison

Table 1 shows the initial parameters of the patients.

A comparative analysis established the homogeneity of groups (p>0.05) for most of the initial parameters. An important difference is the prescription of the established disease until the hospitalization. In group II, it is significantly less due to the active reduction of the preoperative period according to ERP.

Table 1. Preoperative status of patients

Parameter	Group I (n=15)	Group II (n=15)	p-value
General parameters			
Age, years	47.2 (±16.0)	42.4 (±14.7)	0.401
Height, cm	173.8 (±8.8)	171.8 (±6.1)	0.490
Weight, kg	79.0 (±17.4)	74.0 (±13.2)	0.390
BMI, units	25.9 (±4.5)	25.0 (±4.2)	0.594
Female, n (%)	6 (40.0%)	8 (53.3%)	0.658
Anamnesis			
Established disease duration, days	93 (11.424)	14 (4.920)	**0.038**
Smoking, n (%)	7 (46.6%)	6 (40.0%)	0.816
Alcohol consumption, n (%)	9 (50.0%)	8 (53.3%)	0.846
Contact with harmful substances, n (%)	2 (13.3%)	1 (6.6%)	0.581
Allergoanamnesis, n (%)	0 (0.0%)	2 (13.3%)	0.170
Previous operations and manipulations			
Stenting, n (%)	7 (46.6%)	3 (20.0%)	0.664
Nephrostomy, n (%)	3 (20.0%)	4 (26.6%)	0.733
Dilation, n (%)	0 (0.0%)	1 (6.6%)	0.325
Laser incision, n (%)	1 (6.6%)	1 (6.6%)	1.000
Previous plastic surgery, n (%)	2 (13.3%)	0 (0.0%)	0.170
Probable cause of UPJO development			
Congenital, n (%)	5 (33.3%)	5 (33.3%)	1.000
Urolithiasis, n (%)	4 (26.6%)	5 (33.3%)	0.769
Iatrogenic, n (%)	5 (33.3%)	7 (46.6%)	0.625
Inflammatory, n (%)	6 (40.0%)	4 (26.6%)	0.583
Idiopathic, n (%)	1 (6.6%)	2 (13.3%)	0.581
UPJO complications			
Stone formation, n (%)	12 (80.0%)	11 (73.3%)	0.875
Secondary infection, n (%)	6 (40.0%)	4 (26.6%)	0.583
Chronic kidney disease >2, n (%)	5 (33.3%)	4 (26.6%)	0.769
Shrunken kidney, n (%)	4 (26.6%)	5 (33.3%)	0.769
Concomitant diseases			
Coronary heart disease, n (%)	8 (53.3%)	4 (26.6%)	0.326
Hypertension, n (%)	10 (66.6%)	5 (33.3%)	0.288
Diabetes mellitus, n (%)	0 (0.0%)	1 (6.6%)	0.325
Instrumental examination data			
Right kidney, n (%)	11 (73.3%)	10 (66.6%)	0.867
Stricture length, mm	4.4 (±3.0)	4.8 (±1.9)	0.670
Minimum diameter of segmented lumen, mm	0.56 (±0.2)	0.46 (±0.2)	0.195
Area of tub, mm^2	2,020 (±1,030)	1,805 (±1,124)	0.590
DRF, %	22.5 (±5.0)	22.9 (±6.9)	0.858
Initial creatinine, mmol/l	111 (±10.2)	110 (±10.2)	0.764

Note. BMI: Body mass index & DFR: Differential renal function

Diagnostic Methods

The examination incorporates anamnestic (to establish the prescription of the disease, concomitant diseases, etc.), clinical, biochemical, ultrasound, tomographic, X-ray, and endoscopic research methods. To reveal pathological changes in the kidneys and ureters there was MSCT with angiography and urography. Dynamic nephroscintigraphy helped to assess renal function (DRF is one of the parameters in the study). The postoperative status, the viability of the anastomosis, the urohematomas, etc. were evaluated by MSCT. The severity of postoperative pain was assessed by the visual analog scale (VAS). Postoperative dysuria and quality of life were recorded based on patient complaints and the ureteral stent symptom questionnaire (USSQ) a week after surgery (urination symptoms section U; 11 questions; from 11 to 56 points). Satisfactory quality of life was considered at U<20.

Before removing the urethral catheter, there was an ultrasound examination of the operated kidney to assess possible suture defects and to resolve the issue of prolonged urethral drainage. Drainage removal was performed in the absence of an increased drainage substance six-12 hours after removal of the urethral catheter. Upon reaching the six months, all patients underwent a standard examination at least once a year: urologist consultation, blood and urine tests, ultrasound or MSCT of kidneys, dynamic nephroscintigraphy.

Statistical Analysis

The initial data and surgical treatment results were analyzed using STATISTICA software for Windows version 10.0 (Statsoft, Inc, USA), SPSS statistics version 23.0 (IBM, USA), and Stata version 16.0 (StataCorp, USA). The significance level for all the methods is $p \leq 0.05$ (except multiple logistic regression). To determine the predictors of the development of postoperative complications and conditions, a logistic regression analysis was performed. To build a logistic model, the initial parameters of the patient were used (more than 100, partially presented in **Table 1**, and the parameters of the postoperative condition. The selection method is step-by-step. The logistic analysis was performed in the Stata program.

The hypothesis of normality of distribution was tested using the Shapiro-Wilk criterion. The condition of equality of dispersions of trait distributions was tested by calculating Levene's criterion.

For descriptive statistics of quantitative normally distributed signs with equality of dispersions parametric methods were used: calculation of mean values and standard deviations; for quantitative signs with distribution different from normal and qualitative ordinal signs non-parametric methods were used–calculation of medians and the corresponding interval between 25 and 75 percentiles (Q1; Q3); for qualitative nominal signs–relative frequencies in percent.

To determine the reliability of differences of pairwise comparisons was used: in groups of nominal data–nonparametric McNemar criterion; in groups of ordinal data–nonparametric Wilcoxon sign criterion; in groups of continuous data–paired t-criterion (in case of normal distribution of a sign), or nonparametric Wilcoxon sign criterion (in case of distribution different from normal). To determine reliability of differences of intergroup (independent) comparisons was used: in groups of nominal data–Chi-square test; in groups of ordinal data–nonparametric Mann-Whitney U-criterion; in groups of continuous data–student's criterion (in case of normal distribution of sign) or nonparametric Mann-Whitney U-criterion (in case of distribution different from normal).

When comparing three independent groups by one quantitative characteristic, the methods of nonparametric statistics (rank analysis of variances by Kraskel-Wallis) were used. When statistically significant differences in groups were identified, pairwise comparison of groups was performed using the nonparametric Mann-Whitney test with Bonferroni correction to overcome the problems of multiple comparisons.

Comparative analysis of freedom curves from reoperation was performed using the log-rank test, which was graphically expressed using the Kaplan-Meier method. Regression analysis of predictor variables was performed in the program "Stata version 16.0" (StataCorp LP). Simple and multiple logistic regression were used to identify predictor variables when the response variable was binary. Cox proportional hazards regression was used to assess the association between one or more continuous or categorical variables and time to occurrence of an adverse event. The significance level for all methods used was set as $p \leq 0.05$ (with the exception of multiple logistic regression).

Treatment Protocols

During the study, there were two treatment protocols: standard (group I), when the patient is prohibited from fluids intake and food on the day of surgery, prescribed bowel cleansing the night before and in the morning on the day of surgery, and sedated (diazepam). Intraoperatively, individual nodular sutures are made of absorbable suture material, including monopolar diathermocoagulation. The skin suture is nodular, standard bands. On the first day after the operation–only fluid intake, food was allowed from the second postoperative day. In the postoperative period, anesthesia with narcotic analgesics was performed on the first day after the operation, if necessary. The patient was mobilized on the second day after operation. Infusion therapy was performed during the day. Antibacterial therapy was carried out during the entire period of hospitalization. The recommended period of hospitalization after surgical treatment–is five days. The urethral catheter was removed two-seven days after surgery.

If the installation of the fourth port was refused, during ERP, the technique of sewing the pelvis to the abdominal wall or kidney was used to immobilize it and create a convenient working area. **Table 2** presents ERP scheme (group II).

The final treatment protocol was chosen in advance at the time of the initial treatment. Patients complied with ERP when at least 90.0% of the conditions were met.

All patients of both groups received the treatment for the prevention of thromboembolic complications (heparins) and protection against ulcers (proton pump blockers). The severity of postoperative pain was assessed by VAS on the first day. Dysuric complications of kidney stenting were assessed according to the first section of USSQ.

Platelet-rich plasma (the PRP method) and fibrin glue (i-PRF method and superfibrin) were obtained by centrifugation ("armed" centrifuge) in special test tubes from the peripheral venous blood of the patient. Glue sulfacrylate was ready-made. Glue and plasma were applied using a long thin needle.

Clinical Example of ERAS Protocol

In the preoperative period, detailed counselling on the possible treatment principles for strictures of the ureteropelvic junction, the causes of occurrence and the consequences of treatment failure is performed. An overview of the preoperative period, intraoperative nuances and a description of the expected condition in the postoperative period, possible complications as well as rehabilitation measures are presented.

Immediately after the initial consultation, the patient's consent to surgical treatment according to the principles of enhanced recovery is obtained. An examination plan was prescribed as part of the accelerated pathway: all investigations except dynamic scintigraphy were carried out on the next day within three hours. The indications and contraindications for surgery are reassessed on the basis of the results of the examination. A multidisciplinary team discussion was carried out: a urologist, anaesthetist, internist, radiologist, ultrasound technician, nurse and rehabilitator. Possibility of adhering to protocol on religious, ethical, social and other grounds assessed. Evaluated the need for prehabilitation: no need identified. Recommended table number 4 (low-slag diet) two-three days before surgery.

A surgery date has been set for the patient. Hospitalisation on the day of surgery, three hours before the planned surgical intervention. The preparation is done independently at home. No bowel cleansing has been carried out. No need for shaving of the operation area. Venous thromboembolism prophylaxis was provided by compression knitwear and subcutaneous injection of fraxiparin 0.3 ml.

On admission the patient was premedicated with celecoxib 100 mg, gabapentin 600 mg, omeprazole 20 mg once oral. An oral carbohydrate load of 200 ml of maltodextrose mixture was administered.

Antibacterial prophylaxis administered once 60 minutes before surgery as recommended. Preoperative urine culture was sterile and there was no need for preoperative sanitation.

Intraoperatively, the method of anesthesia was a combined endotracheal anesthesia in combination with epidural anesthesia and transverse abdominal plane block. The operation time was 70 minutes. A 14 Fr urinary catheter was installed. Intraoperative heating of the patient using an electric heating mattress. Heating of infusion solutions using a flow heater. Surgical access: one 12 mm port for placement of the endovideoscope and two five mm accesses for instruments.

Table 2. ERP of perioperative management of patients after pyeloplasty for UPJO (ERP: Laparoscopic pyeloplasty)

Preoperative period	Intraoperative period	Postoperative period
Patient information & education	Preferred method of anesthesia–local anesthesia/multimodal anesthesia	Early drink (two-three hours after surgery) & feeding (six hours after surgery)
Most of studies are same-day		
Rigorous evaluation of indications for surgical treatment: According to dynamic nephroscintigraphy & MSCT diagnosis with impaired renal function	Heating of patient	Early mobilization (six-eight hours after surgery)
Assessing feasibility of protocol compliance	Heating of infusion solutions & inhalation gases	Physical therapy (breathing exercises, walking, & other exercises)
Prophylaxis with antihistamines & antacids	Minimally invasive surgical approaches: three-port technology, if possible, 5Fr ports	Prevention of nausea & vomiting (dexamethasone +ondansetron)
Refusal of preoperative sedation	No monopolar energy	Early removal of urethral catheter after ultrasound guidance
Pre-rehabilitation on indications: age group, obesity, exhaustion, sarcopenia, impaired carbohydrate tolerance or diabetes mellitus	Bipolar or intellectual coagulation	Hyperbaric oxygenation therapy
Preoperative antibiotic therapy according to indications: latent or obvious infection of genitourinary system	Minimum tissue dissection/mesenteric accesses if possible/refusal of kidney mobilization	Regular postoperative checkups
Multidisciplinary examination of patients	Sealed double semicircular continuous anastomosing suture with monofilament thread 4-6/0	Continuation of prevention of thromboembolic complications
Preoperative planning with virtual models	Platelet-rich plasma injections into wall of pelvis and ureter	Multimodal analgesia for pain control (dexketoprofen +paracetomol)
Preoperative carbohydrate loading (200 ml of liquid 2.5 hours before surgery)	Fibrin glue/biodegradable sulfacrylate on anastomosing seam	Chewing gum on first & second day after surgery
Last meal no later than six hours before operation	Silicone urethral catheters 14-16 Ch	Monitoring of blood & urine parameters on first day after surgery
Antibiotic prophylaxis 60 minutes before surgery with 3rd generation cephalosporins with sterile urine culture	Rejection of drains	Strict glycemic control in case of impaired carbohydrate tolerance & diabetes mellitus
Shaving of surgical area subsequently applying skin antiseptics day before, if necessary	Sealed cosmetic skin seam with no loose ends or knots on skin	A detailed discussion of behavior of patient & rehabilitation plan before discharge
Preparation of intestine with laxatives or single microclysms	Adhesive bandage on skin	Detailed written instructions in discharge documents
Prevention of thromboembolic complications	Intraoperative euvolemia	Combination therapy to reduce dysuria: Mirabegron + alpha-adrenoblocker
Avoiding use of cleansing enemas	Working pressure within five-eight mmHg	Strict postoperative hygiene of genitals & postoperative wounds (with an adhesive bandage, patient is suggested to take a hygienic shower daily from second day)/refusal of daily bands
A slageless diet two-three days before surgery	Refusal to install drains	Early discharge
	Refusal of irrigation during operation	

Carboxyperitoneum with reduced working pressure of eight mmHg. Monopolar coagulation and irrigation were not used. Mobilization of the descending colon was partial, in the projection of the lower pole of the kidney. Transection of the splenic ligament was not performed. Dissection using the LigaSur machine. Partial mobilization of the pelvis and ureter within the operating window of about five cm was performed. After excision of the altered LMS, anastomosis of the ureter and pelvis without a stent was performed using the technique of two half-round continuous sutures with monocryl 5-0 thread.

Sealing of the suture with sulfacrylate glue. Control of hemostasis. Drainage was not performed. Closure of the peritoneal defect was done with Monocryl 4-0. Cosmetic skin sutures with an adhesive dressing using Sulfacrylate glue. Intraoperatively, prophylaxis for postoperative nausea and vomiting was performed–dexamethasone four mg and ondansetron four mg intravenously.

After the operation the patient was transferred to the post-operative observation room for three hours. Intraoperative pain management was continued in the postoperative period, according to “no pain” principle, i.e., performing prevention rather than elimination of pain. Prescribed–oral celecoxib 100 mg, drotaverine 20 mg and acetaminophen 250 mg every six-eight hours in the first postoperative day, combined with low doses of tramadol 50 mg intramuscularly in case of increased pain.

An additional postoperative transverse abdominal plane block under ultrasound guidance was performed. Immediately after transfer, breathing exercises were started with a balloon (inflate in multiples). Administration of maltodextrose mixture was suggested one hour after surgery. Postoperative consumption of solid food is allowed three hours after surgery. Chewing gum is recommended to reduce the risk of postoperative functional bowel disorders.

The patient is activated four hours after surgery. The urethral catheter was removed 20 hours postoperatively, after a control ultrasound scan to assess the possible leakage of the anastomosis. Glycaemic control on the first and second postoperative days, no correction was necessary. On the second postoperative day, a control clinical blood count was performed. Postoperative antibiotic therapy was not carried out. Wound treatment was not carried out. Independent daily hygiene–showering was recommended.

Table 3. Postoperative status of patients

Parameter	Group I (n=15)	Group II (n=15)	p-value
Complications according to Clavien-Dindo			
I class, n (%)	14 (93.3%)	4 (26.6%)	0.056
II class, n (%)	7 (46.6%)	1 (6.6%)	0.056
IIIa class, n (%)	2 (13.3%)	0 (0.0%)	0.170
Subfebrility in early postoperative period, n (%)	15 (100%)	0 (0.0%)	**0.0008**
Nausea/intestinal dyskinesia, n (%)	14 (93.3%)	4 (26.6%)	0.056
Vomiting/diarrhea/intestinal paresis, n (%)	7 (46.6%)	1 (6.6%)	0.056
Anastomosis failure, n (%)	2 (13.3%)	0 (0.0%)	0.170
VAS more than five points, n (%)	14 (93.3%)	2 (13.3%)	**0.012**
Postoperative pain, points	7 (7; 8)	5 (4; 5)	**<0.001**
Narcotic anesthesia, n (%)	13 (86.6%)	1 (6.6%)	**0.005**
Duration of hospitalization, bed-day	12±4.3	4.4±3.5	**<0.001**
Catheterization time, days	5.4±1.8	1.2±0.4	**<0.001**
Stenting period, days	36.9±20.9	13.2±1.4	**<0.001**
Total treatment period, days	46.8±30.1	13.9±2.2	**<0.001**
Satisfaction with treatment, n (%)	10 (66.6%)	15 (100%)	0.458
USSQ, U-section, points	30.8±4.5	21.0±2.5	**<0.001**

Note. VAS: Visual analogue scale & USSQ: Ureteral stent symptom questionnaire

Prevention of venous thromboembolism was continued by wearing a compression stocking until 21 days postoperatively, plenty of fluids, and 0.3 ml of frauxiparin p/c injections until discharge.

The patient was discharged from the hospital to outpatient care on the third postoperative day. Daily contact with the attending physician via phone calls and messenger for the first 10 days, then once every two-three days for up to a month. Then monthly for one year. Check-ups and follow-up ultrasound on the 3rd, 7th, 10th, 20th, 30th day, then after three, six, and 12 months.

After 14 days after surgery, the use of the drug Longidase was recommended under the scheme of one suppository rectally once every two days, #20. Due to the refusal of stenting, prevention of symptoms associated with stenting was not performed.

There were no intraoperative and postoperative complications ≥II according to Clavien-Dindo classification in the patient. The patient was discharged in a satisfactory condition on the 3rd day after surgery.

One year after the operation no signs of hydronephrosis of the left kidney were detected. The diameter of the anastomosis was 3.5 mm. The quality of life indicators were in line with the population average.

RESULTS

Objective & Functional Results

In the intra- and postoperative period, there were no cases of lethality, complications of anesthesiological aid, critical deterioration of the state of health due to concomitant diseases in both groups. In the early and late postoperative periods, there were no complications of the anesthetic allowance or deterioration of the general somatic status.

Analysis of the size of surgical accesses (in total terms): the average linear dimensions of group I were 37±2.5 mm, which is more than of group II (29±3.3 mm, p<0.001). The duration of surgery in groups I and II averaged 85±15.9 and 77±10.8 minutes, respectively (p=0.100).

Table 3 shows the postoperative status of patients.

Postoperative complications of Clavien-Dindo classes I-III developed extremely rarely, their level was comparable in both groups (p>0.05). Overall, no significant difference in complications was obtained when group comparison was made by Clavien-Dindo grading, but subject analysis found better functional status and less likelihood of complications in patients in ER group, as presented below.

Two patients from group I had an anastomosing suture defect revealed during ultrasound control, confirmed by drainage separable and control MSCT urography, and therefore a decision was made on prolonged drainage, catheterization, and stenting. There were no anastomosis defects in group II (p=0.170).

The hospitalization period was significantly (p <0.001) longer for patients of group I (12±4.3 days) in comparison with group II (4.4±3.5 days). The timing of urethral drainage in group I was significantly higher than in group II (5.4±1.8 vs. 1.2±0.4; p<0.001). The total treatment period (from the moment of admission to the hospital and before recovery) was 46.8±30.1 days for group I, and 13.9±2.2 days for group II (p<0.001). Subjective satisfaction with the treatment (at the request of a critical analysis of all possible complaints) was comparable and amounted to 66.6% for group I and 100% for group II (p=0.458). However, USSQ questionnaire (section U) demonstrated the best functional and objective condition of group II seven days after surgery, in comparison with group I (30.8±4.5 vs. 21.0±2.5; p<0.001).

The average value of the index of postoperative pain in group I was equal to seven (7; 8) points, in group II–eight (4; 5) points (p<0.001). Anesthesia with narcotic analgesics on the first day after surgery was required in 13 (86.6%) patients of group I and one (6.6%) patient of group II (p=0.005). Thus, the severity of postoperative pain syndrome in group I was significantly higher than in group II.

Early postoperative complications from the gastrointestinal tract requiring correction (vomiting, diarrhea, and paresis) and not requiring (nausea and dyskinesia) in both groups were presented in statistically equal proportions (p>0.05). However, this conclusion is due to the small sample size. In direct analysis, the probability of these complications is significantly higher in group I.

Table 4. Postoperative status six months after surgery

Parameter	Group I (n=15)	Group II (n=15)	p-value
Area of pelvis after surgery, mm^2	493 (±190)	413 (±136)	0.197
Change in area, mm^2	-1,526 (±1,125)	-1,392 (±1031)	0.735
DRF final, %	36.1 (±5.7)	39.33 (±6.1)	0.151
DRF change, %	+13.6 (±6.1)	+16.4 (±6.3)	0.228
Achieved diameter of ureteral lumen in area of surgery, mm	1.87 (±0.3)	2.07 (±0.4)	0.190
Change in diameter of ureteral lumen in area of surgery, mm	+1.31 (±0.36)	+1.61 (±0.52)	0.080
Final creatinine, mmol/l	85.5 (±12.6)	81.0 (±11.6)	0.322
Creatinine change, mmol/l	-25.6 (±14.1)	-29 (±15.5)	0.543

Note. DFR: Differential renal function

Table 5. Predictors of complications & satisfaction with treatment

Complications in early & late postoperative period	Predictor	Univariate analysis			Multivariate analysis	
		χ^2	Coefficient (95% CI)	p-value	Coefficient (95% CI)	p-value
Nausea/vomiting/paresis–Multivariate logit regression: χ^2=7.12 & p=0.0682	Standard protocol	6.72	2.5 (0.23; 4.77)	**0.030**	.42 (-2.65; 5.51)	0.493
	Congenital obstruction	4.02	.73 (-0.009; 3.470)	0.051	-	-
	Prior nephrostomy	3.98	1.84 (0.0009; 3.6900)	0.052	-	-
	Total access size, mm	5.62	0.22 (0.01; 0.43)	**0.040**	0.05 (-0.30; 0.40)	0.770
	VAS >5 points	5.66	2.31 (0.05; 4.57)	**0.045**	0.83 (-2.53; 4.21)	0.625
Postoperative pain syndrome, >5 points on VAS scale–Multivariate logit regression: χ^2=23.44 & p=0.0003	Standard protocol	22.33	4.51 (1.99; 7.02)	**<0.001**	Not used	-
	Arterial hypertension	4.96	1.70 (0.13; 3.27)	**0.033**	3.77 (0.25; 7.28)	**0.036**
	Atherosclerosis of blood vessels	3.90	1.55 (-0.06; 3.16)	0.060	-	-
	Surgical access size >30 mm	14.45	3.24 (1.28; 5.20)	**0.001**	3.65 (0.26; 7.04)	**0.035**
	Nausea/intestinal dyskinesia	6.69	2.05 (0.38; 3.71)	**0.016**	-0.98 (-4.00; 2.10)	0.533
	Vomiting/intestinal paresis/diarrhea	5.66	2.31 (0.05; 4.57)	**0.045**	4.18 (-0.50; 8.86)	**0.080**
	Urogematoma	4.53	1.79 (0.002; 3.580)	**0.049**	-0.11 (-3.50; 3.30)	0.948
Subjective satisfaction in patients after end of treatment–Multivariate logit regression: χ^2=7.78 & p<0.001 (0.0001)	Stenting period, days	11.33	-0.09 (-0.1800; 0.0001)	0.050	-	-
	Total duration of treatment, days	10.12	-0.073 (-0.140; 0.001)	0.053	-	-
	Total access dimensions, mm	5.53	-0.25 (-0.5100; 0.0002)	0.050	-	-
	Change in ureter diameter, mm	10.84	4.30 (0.97; 7.64)	**0.011**	5.55 (0.16; 10.94)	**0.044**
	Operation time>100, minutes	4.95	-2.39 (-4.55; -0.24)	**0.029**	-1.23 (-5.11; 2.60)	0.532
	Catheterization, days	5.30	-0.34 (-3.50; 1.02)	0.058	-	-
	VAS, points	9.29	-1.26 (-2.35; -0.17)	**0.023**	-1.76 (-3.70; 0.22)	**0.082**

Note. VAS: Visual analogue scale

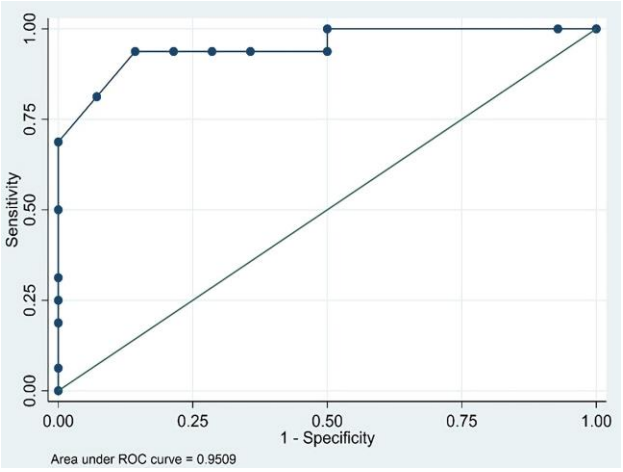

Figure 1. ROC curve for multivariate logit regression of predictors of postoperative pain >5 points on VAS (Source: Authors' own elaboration)

Table 4 presents the postoperative status six months after surgery. The comparability of the groups was established according to the results of the examination six months after the operation (p>0.05).

To determine the predictors of the postoperative complications and conditions development, there was a logistic regression analysis, the results of which are partially presented in **Table 5**. There were no reliable predictors of anastomosis failure.

A univariate logistic analysis of the prognosis of postoperative gastrointestinal dysfunction in the early postoperative period the following predictors established as reliable: standard treatment protocol (coefficient 2.5; 95% CI 0.23; 4.77; p=0.030; area under curve [AUC]=0.75), total access size in millimeters (coefficient 0.22; 95% CI 0.01; 0.43; p=0.040; AUC=0.75) and pain syndrome VAS >5 points (coefficient 2.31; 95% CI 0.05; 4.57; p=0.045; AUC=0.73). The sensitivity and specificity values (AUC) for the performed analysis correspond to a good (>0.7) quality of the model. Multivariate regression has not demonstrated reliable results.

Logistic regression analysis for postoperative pain syndrome >5 VAS points established a high prognostic significance of several factors, as reflected in **Table 5**. Based on the results, a multivariate regression analysis was performed (selection from predictor factors with a significance level of p<0.05, the statistical significance of the result p<0.1). Significant predictors of the occurrence of pain syndrome were arterial hypertension (coefficient 3.77; 95% CI 0.25; 7.28; p=0.036), postoperative intestinal complications of class II according to Clavien-Dindo (coefficient 4.18; 95% CI -0.50; 8.86; p=0.080), as well as the total size of surgical access more than 30 mm (coefficient 3.65; 95% CI 0.26; 7.04; p=0.035). **Figure 1** presents a model with excellent predictive value (AUC=0.95) as a ROC curve.

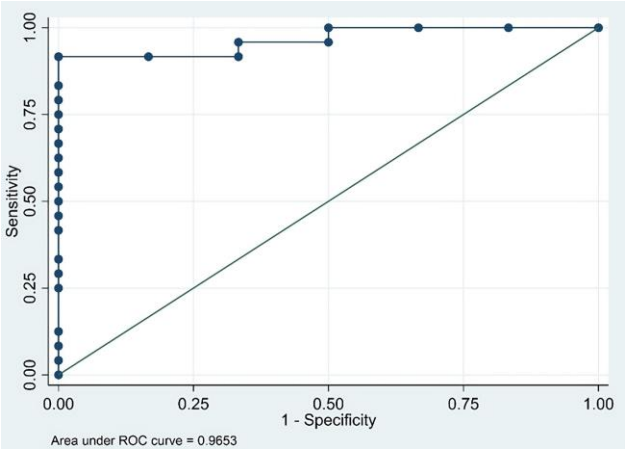

Figure 2. ROC curve for multivariate logit regression of predictors of satisfaction with treatment (Source: Authors' own elaboration)

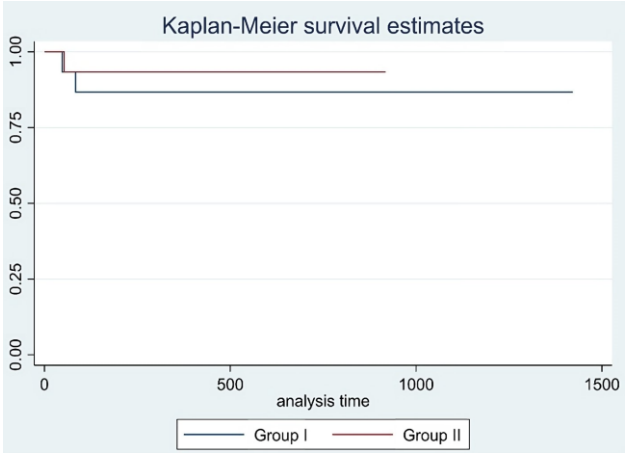

Figure 3. Freedom from relapse in the Kaplan-Meyer study groups (Source: Authors' own elaboration)

Table 6. Regression model of proportional Cox risks

Variable	Univariate Cox analysis		
	Valda: χ^2	HR (95% CI)	p-value
Spine osteochondrosis >II period	4.75	13.97 (1.26; 154.80)	0.032
Independent discharge of concretions in anamnesis	4.06	28.49 (1.78; 455.62)	0.018
Operation time >110 minutes	8.75	44.70 (3.95; 505.40)	0.002
Prior nephrostomy	8.75	1.07 (1.02; 1.13)	0.002

Note. DRF: Differential renal function

A logistic regression analysis for satisfaction with the treatment according to multivariate regression data found a change in the diameter of the ureteral lumen to be a significant predictor (for each +1 mm; coefficient 5.55; 95% CI 0.16; 10.94; p=0.044) and pain syndrome VAS (for each point of increase, coefficient -1.76; 95% CI -3.75; 0.22; p=0.082). A model with excellent predictive value (AUC=0.96) is presented as a ROC curve in **Figure 2**.

Evaluating Effectiveness & Predicting Outcomes

The average period of clinical observations was 559 (272; 843) days, the maximum period was 1,422 days. Group I–765 (434; 843) days (max 1,422 days). Group II–471 (256; 844) days (max 918 days). The follow-up period was comparable for both groups (p=0.091).

In the postoperative period, there were no cases of mortality or complications of Clavien-Dindo >3a. Accordingly, there is no statistical analysis of survival.

In group I of 15 operations, the success rate was 86.6% (n=13), and in group II–93.3% (n=14). The primary efficiency was comparable (p=0.888). Relapse was recorded after 48 and 84 days for patients of group I, and after 53 days–for a patient of group II.

The values of Kaplan-Meyer estimates of freedom from recurrence of UPJO in group I were 86.6±8.7% (95% CI 56.39-96.49%) during the entire follow-up period, and in group II–93.3 ±6.4% (95% CI 61.26-99.03%).

The log-rank criterion did not reveal statistically significant differences (p=0.550; χ^2=0.36) in the frequency of relapse over the entire follow-up period, which is graphically expressed by the Kaplan-Meyer method in **Figure 3**.

Table 6 presents a regression model of proportional Cox risks demonstrating the influence of variables on the risk of relapse. **Table 6** presents only those predictors that demonstrated a statistically significant effect on treatment outcomes (p<0.05).

Regression analysis of proportional Cox risks revealed independent predictors of recurrence: spinal osteochondrosis > period II (HR 13.97; 95% CI 1.26;154.8; p=0.032), independent discharge of concretions in the anamnesis (HR 28.49; 95% CI 1.78;455.62; p=0.018), operation time >110 minutes (HR 44.7; 95% CI 3.95;505.4; p=0.002) and previous nephrostomy (HR 1.07; 95% CI 1.02;1.13; p=0.002). Multivariate risk analysis has not demonstrated reliable results.

DISCUSSION

ERPs address all aspects of perioperative patient management. A literature search in the databases of Scopus, PubMed, and others did not reveal early works devoted to the development and implementation of ERPs for UPJO laparoscopic pyeloplasty. Only a few dozen comparative randomized studies have been found on the problem of treating UPJO with laparoscopic pyeloplasty, published in peer-reviewed journals over the past 10 years (search in PubMed, from 02/16/2022). The basic results of the study, such as the treatment success, the complications risks, and the surgery duration, are comparable with the works of other authors [15]. The alternative Y-V plastic surgery demonstrates worse results and can be used only after a preliminary discussion of treatment tactics with patients [4].

The treatment results depend on many factors, both from the patient himself and from the medical organization. Thus, the significance of using 3D modeling based on the results of MSCT has been established, which makes it possible to better plan the course of the operation and, as a result, achieve superior results (reduction of the operation time, blood loss, etc.) [16, 17]. It should be noted that among the patients

included in the study, all underwent preliminary MSCT with angiography, urography, and 3D reconstruction during the intervention planning.

The role of intraoperative techniques has yet to be evaluated. For example, the influence of the anastomosis technique on the treatment outcomes remains controversial, since there are works refuting such a connection [18]. Preoperative planning, the creation of strict step-by-step surgical protocols, in turn, avoids several negative factors that can affect the outcome of treatment. For example, it reduces the probability of anastomosis tension [19]. It is also impractical to reduce (resect) the pelvis during pyeloplasty because it does not affect the outcome of the operation [20]. One author presents two similar works demonstrating the effectiveness of fibrin glue during pyeloplasty according to the tubeless protocol, which reduces urine leakage and improves treatment outcomes [21]. We consider it expedient to reduce surgical trauma further by using mini laparoscopic techniques, which is confirmed by some early works [22].

Traditionally, it is advisable to remove the stent four-six weeks after pyeloplasty. In our study, we allowed early removal 10-14 days after surgery. The results of the study demonstrated the safety of such early disposal of the stent, which corresponds to the results of the works of other authors. In two comparative studies, the authors demonstrated the safety and effectiveness of stent removal one week after surgery [23-26].

ERP demonstrates superiority in many aspects of the perioperative period. There is a reduction in the preoperative waiting period ($p=0.038$). Several important parameters of the postoperative status, such as the severity of pain, body temperature, the severity of dysuric phenomena according to USSQ, the duration of stenting and catheterization, the total treatment period, showed significant superiority of ERP over the standard treatment protocol ($p<0.05$). The logistic analysis of satisfaction with the treatment demonstrates the primary importance for the perception of the quality of the achieved result (the consistency of plastic surgery, reflected in the achieved diameter of the lumen) and the unsatisfactory postoperative condition (first of all, pain).

The analysis of predictors of severe pain demonstrated the fundamental role of the scale of surgical trauma (expressed in terms of the total size of accesses), postoperative dysfunction of the gastrointestinal tract (more pronounced with standard laparoscopy and probably caused by drainage, higher cardioperitoneum pressure, and the internal trauma) and arterial hypertension. Consequently, all these factors correlate in achieving a satisfactory postoperative condition. Moreover, as the analysis demonstrated, they all can synergistically strengthen each other and worsen the patient's status.

It is also important to note the predictors of UPJO recurrence established in the study, such as a relatively long operating time, previous nephrostomy, spontaneous discharge of concretions in the anamnesis, and spinal pathology. As part of the discussion of ERPs, it is important to note the expediency of reducing the duration of surgery to achieve better treatment outcomes. An important practical implication of this analysis is the negative prognostic role of nephrostomy, which should be avoided if surgery is planned, if possible. Patients with a history of urolithiasis and spinal abnormalities also deserve increased attention. Increased operative time is probably more related to increasing surgeon experience or intraoperative conflicts but may be adversely affected by increasing operative stress.

Overall, the univariate and multivariate logistic models demonstrate the complex interplay of a cascade of adverse factors, all of which are minimized by the use of protocols as part of an enhanced recovery program. Logistic analyses will establish the relationship between the individual elements of the program and the outcome.

These results allow us to draw an extremely important conclusion–the quality of surgical care depends not only on outcomes, but also on the patient's condition during treatment. This explains the relevance and feasibility of developing and implementing ERPs that can improve perioperative perception and improve postoperative status without significantly affecting treatment outcomes.

Research limitations

Limitations of the study: small sample size, the average postoperative follow-up period of fewer than five years.

Advantages of the study: one operating surgeon, prospective randomized blind set of patients, strict consideration of inclusion, non-inclusion and exclusion criteria, strict postoperative control, homogeneity of groups, in-depth analysis of initial and postoperative data.

CONCLUSIONS

Both treatment protocols are safe and effective. Both protocols lead to freedom from UPJO (86.6% vs. 93.3%; $p=0.888$), demonstrate similar duration ($p>0.05$), frequency and severity of complications ($p>0.05$). ERP demonstrates superiority in many aspects of treatment; reduction of the preoperative waiting period; less postoperative pain (according to VAS) and dysuric manifestations (according to USSQ), duration of stenting and catheterization, total treatment period ($p<0.05$).

The results have high practical and scientific significance. The prospective randomized blind study conducted according to the established protocol allowed to achieve high statistical reliability of the results without adjustments for the nature of inclusion or the structure of the groups. Thus, in the surgical treatment of UPJO, it is advisable to use ERPs, since it allows for a better quality of treatment with comparable outcomes. Protocols need to be optimized based on the principle of feedback from the results, statistical and logical analysis data.

Implementation of these protocols will require training of all health care providers in the basics of ERAS care. We recommend a step-by-step implementation of individual elements of the program over two-three years.

Each of the program elements, especially innovative solutions not included in the ERAS framework, require further study for applicability and relevance. Further research and analysis of the importance of each of the elements is warranted.

Author contributions: VB, AK, & SS: study conception & design; **VB & VV**: revision & proofreading; **IS, MF, & DL**: material preparation, data collection, & data analysis; & **MF & DL**: writing first draft of manuscript. All authors have sufficiently contributed to the study and agreed with the results and conclusions.

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Ethical statement: The research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. The research was approved by the local ethics committees of Irkutsk State Medical University (protocol no. 497 dated from 12/12/2017).

Declaration of interest: No conflict of interest is declared by authors.
Data sharing statement: Data supporting the findings and conclusions are available upon request from the corresponding author.

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