

Karaganda Medical University

ANNOTATION

dissertation work for the degree of Doctor of Philosophy

Comprehensive evaluation of the results of inguinal canal autoplasty with a
displaced aponeurotic flap

6D110100 Medicine

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Relevance of the Research Topic

For men, the risk of developing an inguinal hernia during their lifetime is 27-43% [1]. About 20 million inguinal hernia surgeries are performed worldwide every year [2; p.1]. Thus, inguinal hernia removal is one of the most frequently performed operations in the world. Despite the fact that professional communities have developed guidelines for the treatment of inguinal hernia, there is no consensus on a standardized method.

To date, "tension-free" hernioplasty using a mesh endoprosthesis is used as the "gold standard". The introduction of a mesh implant has reduced the recurrence rate, as shown in the Cochrane review [3].

However, by reducing the number of recurrences by 4.3-15% [4-7], as well as infection by 1-12% [8,9], chronic pain turned out to be the most serious clinical problem in modern inguinal hernia surgery, reaching 10-56.1% [10-12]. Chronic postoperative pain is a serious clinical problem that can significantly affect the patient's quality of life. A review of the literature data showed that the main causes of this pain are the formation of scar tissue around the mesh implant, its displacement, wrinkling and infection [13-15], and the involvement of nerves in scar tissue [16].

Sharma R. et.al [17] indicate that more than 1/3 of the reasons for the removal of mesh endoprostheses were due to an inflammatory reaction to the implant. The occurrence of perimplantation inflammation and the subsequent formation of coarse scar tissue leads to compression of the tissues around, in particular, the arteries of the spermatic cord, which leads to a decrease in perfusion in the testicular parenchyma [18].

Most of the works in the field of herniology are devoted to the study of the effectiveness and reliability of a particular method of inguinal canal plastic surgery. At the same time, due attention is not always paid to the peculiarities of inflammatory changes at the site of surgery, as well as vascular blood flow of the testicles on the side of hernioplasty. Our own observations in this regard have shown that the qualitative and quantitative characteristics of changes in the "surgical intervention zone" in the postoperative period have not been determined.

According to the literature, the results of hernioplasty with own tissues are variable. The HerniaSurge 2023 article lists preferred autoplasty methods with the following recurrence rate: Desarda 0.8-5% [19], Shouldis 7.1-37.6% [20,21], Bassini up to 3.7-8.6% [22]. According to the updated recommendations, inguinal hernia repair without the use of a mesh endoprosthesis can be offered after careful selection of patients due to the fact that data on relapses and chronic pain are heterogeneous and of insufficient quality [2; p.4]. In this regard, the new international guidelines of the HerniaSurge group indicate that there is no single surgical technique that is optimally suited for all clinical situations [2; pp.1-3].

The current situation prompted the search for an optimal method that eliminates the problems associated with the implantation of a synthetic endoprosthesis in the groin area. This series of "tension-free" operations for inguinal hernia using a flap from the anterior vaginal wall aponeurosis of the rectus abdominis muscle was proposed as a new concept of the method. The modified

method of inguinal canal autoplasty has not been studied clinically and instrumentally before, which determines the relevance of this study.

The purpose of the study: a comprehensive assessment of the results of inguinal canal autoplasty with a displaced aponeurotic flap in comparison with the results of Lichtenstein hernioplasty.

Research objectives:

1. Based on ultrasound (In-mode), compression elastography and CT, to characterize the development of an inflammatory reaction and fibrous changes in the implantation zone in the postoperative period during inguinal canal autoplasty with a displaced aponeurotic flap in comparison with hernioplasty using a mesh endoprosthesis.

2. To compare the results of changes in the hemodynamics of ultrasound (based on Dopplerography) in the testicular, capsular and intra-testicular arteries of inguinal canal autoplasty with a displaced aponeurotic flap with the results of Lichtenstein prosthetic plastic surgery.

3. To investigate the systemic inflammatory response after autoplasty with a displaced aponeurotic flap and hernioplasty using a mesh implant.

4. To compare the quality of life of patients using the questionnaire "Carolinus Comfort Scale" after autoplasty with a displaced aponeurotic flap and prosthetic plastic surgery according to Lichtenstein.

Scientific novelty

- For the first time, based on the analysis of ultrasound and tomographic patterns, the nature of the inflammatory reaction, the formation of scar tissue in the postoperative area with qualitative and quantitative characteristics was assessed (Patent No 9768, 05/12/2020; 07/18/2024 No. 48461);

- For the first time, a comparative analysis of the results of hemodynamic changes in the testicular, capsular and intra-testicular arteries of inguinal canal autoplasty with the results of hernioplasty using a mesh implant was carried out (Patent No 48461, 07/18/2024).

The main provisions submitted for protection

- The use of inguinal canal autoplasty with a displaced aponeurotic flap is characterized by the formation of weakly expressed scar tissue in the postoperative area from 6 to 12 months, which does not violate the hemodynamics of the testicular and capsular arteries.

- Assessment of the systemic inflammatory response by ELISA showed that in the group of patients who underwent prosthetic inguinal canal surgery according to Lichtenstein, there was a statistically significant increase in the level of C-reactive protein compared with the group of autoplasty with a displaced aponeurotic flap.

- Inguinal canal autoplasty with a displaced aponeurotic flap is characterized by a significant improvement in the quality of life of patients 12 months after surgery in 3 domains (pain, implant sensation and movement restriction).

Practical significance

A method for the comprehensive assessment of the inflammatory reaction after hernioplasty has been developed and implemented in the activities of medical organizations (acts of implementation of the PUE "Multidisciplinary Hospital No. 1

of Karaganda city", Clinic of the Medical University of the Non-profit Joint-stock Company "KMU";

A technique of compression elastography of the postoperative zone after inguinal hernia repair has been developed for ultrasound diagnostics and surgeons and introduced into the activities of the medical organization Clinic of the Medical University Non-profit Joint-stock Company "KMU".

Approbation of the work

The main provisions of the dissertation were reported and discussed:

- at the International MED Congress "Man and Health. Multidisciplinary approach in Medicine" (Semey, Kazakhstan, 2022),
- at the Congress of Scientists of Kazakhstan "Global Science and Innovation 2022: Central Asia" (Astana, Kazakhstan, 2022);
- at the III Congress of Surgeons of Kazakhstan with international participation "Topical issues of surgery and transplantation" (Almaty, Kazakhstan, 2022);
- at the International Congress "Nevsky Radiological Forum-2024" (St. Petersburg, Russia);
- at a meeting of the Department of Surgery and the Department Oncology and Radiation Diagnostics of the NAO "Medical University of Karaganda" of the Medical University Non-profit Joint-stock Company "KMU".

Publications

Based on the materials of the dissertation, 13 scientific papers were published, including:

- 3 articles in scientific publications recommended by the Committee for Control in the field of Education and Science of the Ministry of Education and Science of the Republic of Kazakhstan;
- 2 certificates of entry of information into the State Register of Rights to Objects Protected by Copyright;
- 6 abstracts in the materials of international conferences;
- 1 publication in the international scientific publication "Asian Journal of Surgery", indexed in the Scopus information database (percentile 74%)
<https://doi.org/10.1016/j.asjsur.2024.06.055>

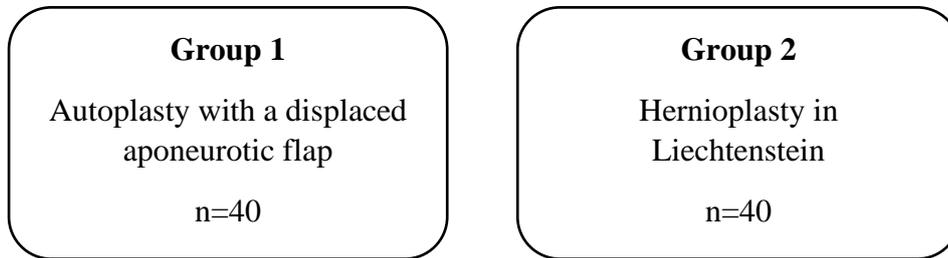
Methodological foundations of the study. The design of the study.

The study was conducted on the basis of the Clinic of the Medical University, which is based on a prospective clinical study. Based on the macroscopic intraoperative assessment of aponeurosis, patients were divided into group I and group II, in the number of 80 people (40 subjects in each group) with uncomplicated inguinal hernias aged 20-75 years. The developed method of autoplasty and hernioplasty according to Lichtenstein are comparable and at the same time correspond to the new principles of herniology "without tension" of tissues.

Group 1 – inguinal canal plastic surgery with a displaced aponeurotic flap of the anterior vaginal wall of the rectus abdominis muscle.

Group 2 – Lichtenstein inguinal canal plastic surgery using an Ultrapro mesh implant (Ethicon).

Research design



| | | |
|----------------------|-----------------------|--|
| After surgery | Before surgery | <ul style="list-style-type: none"> • Ultrasound |
| | 1 day | <ul style="list-style-type: none"> • ELISA |
| | 7 days | <ul style="list-style-type: none"> • Computed tomography(n=40) • Ultrasound |
| | 1 months | <ul style="list-style-type: none"> • ELISA • Ultrasound • Survey |
| | 3 months | <ul style="list-style-type: none"> • ELISA • Ultrasound • Survey |
| | 6 months | <ul style="list-style-type: none"> • Computed tomography (n=40) • Ultrasound • Compression elastography • Survey |
| | 12 months | <ul style="list-style-type: none"> • Ultrasound • Compression elastography • Survey |

Inclusion criteria: the presence of a herniated defect in the inguinal region, age from 20 to 75 years, written consent to participate in the study and initially a high willingness to follow the instructions of the researcher's doctor (compliance).

Criteria for non-inclusion: women, recurrent inguinal hernia, complicated variants of the course of the disease - pinched inguinal hernias, phlegmon of the hernial sac, cardiovascular diseases in the decompensation stage, chronic liver

failure, chronic renal failure, diabetes mellitus in the decompensation stage, mental and oncological diseases, exacerbation of concomitant chronic diseases.

Exclusion criteria: withdrawal from the study: the subject may be excluded from the study at the discretion of the researcher if he believes that the continuation of the study is harmful to the health of the volunteer; the presence of medical indications or the occurrence of adverse events that can be regarded as related to the use of one of the methods of hernioplasty; exceeding the permissible annual radiation load (more than 10 mSv) for CT scan of the abdominal cavity.

Research methods

- The Toshiba Aquilion 64 CT scanner was used to perform CT scans of the abdominal cavity and retroperitoneal space in order to assess the severity of inflammation and fibrous changes in the postoperative area.

- Ultrasound scanning device "MySonoU6" (Samsung Medison) and "LOGIC P9" for the diagnosis of inguinal hernia; dopplerography of vessels of the spermatic cord and testicle with measurement of blood flow velocity; diameter of the testicular artery. Compression elastography ("LOGIC P9")- measurement of the index of elasticity and stiffness of soft tissues of the postoperative area.

- As part of the study of inflammatory reactions in response to an autoimplant and mesh endoprosthesis, immunological markers of inflammatory process activity were evaluated by solid-phase enzyme immunoassay (determination of C-reactive protein, tumor necrosis factor) and markers of activation of specific cellular immunity (determination of interleukin-2). The ELISA was carried out in the Laboratory of collective use of the Scientific Research Center NAO "MUK".

- Assessment of the quality of life of the subjects after hernioplasty was carried out using the questionnaire "Carolinas Comfort Scale".

Statistical data processing

All statistical procedures were performed using the software "Statistica for Windows v. 13.0" (StatSoft Inc, USA) and "IBM SPSS Statistics 29.0.2.0" (IBM, USA). The results were analyzed using descriptive statistics methods. For all variables, the nature of the distribution was evaluated using the Shapiro-Wilk test, the kurtosis coefficient and the Kolmogorov-Smirnov criterion. At a critical significance level of $p < 0.05$, the null hypothesis of the normality of the distribution was rejected.

For quantitative features with a normal distribution, the mean value and standard deviation were calculated. If the distribution deviated from normal, median and quartile intervals (25% and 75%) were used.

Frequency tables were built for qualitative indicators to determine the frequency of occurrence of values. Categorical data is presented in the form of absolute numbers and percentages relative to the entire group. To compare the frequency of distribution of patients by qualitative characteristics between groups, the Pearson's χ^2 criterion was used. At $p < 0.05$, the null hypothesis of the absence of frequency differences between the groups was rejected.

The Mann-Whitney criterion was used to find differences between groups in quantitative parameters. Pearson's χ^2 -criterion was used to compare qualitative

variables. The Wilcoxon criterion was used to analyze the differences in related (dependent) groups.

The internal consistency of the survey was assessed using the Cronbach's α coefficient, which summarizes the internal correlations of all points on the scale. The higher the coefficient (range 0-1), the more consistent the scale is and the more likely it is that it affects the basic single variable in the questionnaire. A value of ≥ 0.7 indicates high reliability; 0.5 to < 0.7 indicates moderate reliability; > 0.2 to < 0.5 indicates satisfactory reliability; and < 0.2 indicates low reliability.

The reliability of the retest test was assessed by the interclass correlation coefficient r (ICC) (determination of the absolute agreement of the two-factor random effect model) of two assessments performed with an interval of 3-4 weeks. Reproducibility was considered "excellent" ($r > 0.75$), "good" ($0.75 < r < 0.40$) or "bad" ($r < 0.40$).

To determine the linear relationships between quantitative indicators, a correlation analysis was performed using the Spearman correlation coefficient. In order to identify the dependencies of the outcome (quality of life scores) on the index of elasticity, a linear regression analysis was used with the calculation of the regression coefficient B and the p -value. At $p < 0.05$, the null hypothesis of the absence of a relationship between the predictor and the outcome was rejected.

Conclusions

1. The results of the study show that in the group with Lichtenstein hernioplasty, according to CT data, the formation of pronounced fibrous tissue of the postoperative area 6 months after surgery (Me1=69.5, Q25;Q75 55.0;77.0 HU; Me2=90.0, Q25;Q75 81.0;104.0 HU; $p=0.00$). This is confirmed by the results of compression elastography, characterized by a statistically significant increase in EI at 6 months (Me1=2.3, Q25; Q75 1.6;3.85; Me2=3.7, Q25;Q75 3.0;4.65; $p=0.00$), equally 12 months after surgery (Me1=3.65, Q25;Q75 2.4;4.5; Me2=5.1, Q25;Q75 3.8;5.7; $p=0.00$).

2. The obtained data from the study of blood flow in the vessels of the spermatic cord in patients after autoplasty with a displaced flap prove that the vessels of the spermatic cord do not suffer from compression - the PSC of the YAA increased by 4.9% within 1 year. In the group with the use of a mesh endoprosthesis, PSSC YAA decreased by 2.7% within 1 year, but remained within the normal range.

3. The results of the CRP level in the hernioplasty group using a mesh implant were statistically significantly higher from 1 day: (Me1=2.5, Q25;Q75 1.2;14.6 mg/ml; Me2=18.9, Q25;Q75 12.1;46.2 mg/ml; $p=0.00$) to 3 months after surgery (Me1 =1.45, Q25;Q75 0.78;1.95 mg/ml; Me2=9.9, Q25;Q75 5.3;11.4 mg/ml; $p=0.00$), which reflects the prolonged course of the inflammatory process in this group. TNF and IL-2 levels did not exceed the standard values in both groups.

4. There was a significant improvement in the quality of life after autoplasty with a displaced flap compared with Lichtenstein hernioplasty by domains: pain by 12.6% ($p=0.00$) and implant sensation by 21% ($p=0.00$) in all study periods after hernioplasty; restriction of movements for 12 months by 6.6% ($p=0.00$). The index of elasticity of the soft tissues of the postoperative area has a statistically significant

effect on the sum of quality of life scores ($p=0.00$) for a period of 6 months ($r=0.661$) and 12 months after surgery ($r=0.769$).

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