

AVERAGE LONG-TERM OUTCOMES OF LAPAROSCOPIC INGUINAL HERNIA REPAIR

Mendybaev A.A.¹, Fursov A.B.¹, Ismagambetova B.A.¹, Volchkova I.S.¹,
Kovalenko T.F.¹, Dalenov N.Y.¹, Sagatov I.Y.²

¹Astana Medical University, Faculty of General Medicine, Department of
Surgical Diseases, Bariatric Surgery and Neurosurgery, Astana, Kazakhstan,
²A.N. Syzganov National Scientific center of surgery, Almaty, Kazakhstan

Abstract

Objective: to determine the long-term postoperative outcomes of inguinal hernias using the TAPP approach with the internal ring suturing.

Materials and methods. The design is a randomized multicentre clinical study. The study is based on a survey of 268 patients aged 18 to 84 years (mean age 59.2±10.6 years), including 46 (17.2%) women, 222 (82.8%) men with primary inguinal hernias. A total of 187 (69.8%) patients had a normal body mass index, 72 (26.9%) were overweight, 9 (3.3%) were obese. Interventions supposed the open techniques (Lichtenstein technique - 118 patients or Shouldice technique - 29 patients) and laparoscopic technique by TAPP approach (total 121), and specifically the modification with the internal ring suturing (12). The frequency and severity of chronic postoperative pain (up to 1 year) and the recurrence rate of inguinal hernia (up to 2 years) had been determined.

Results. The incidence and severity of chronic pain syndrome was moderate and in most cases were found to have no any intergroup significant differences. Single case showed the significant differences in incidence between open hernioplasty by Lichtenstein technique and TAPP ($\chi^2=4.241$, $p=0.040$). The recurrence rate of hernias over the 2-year follow-up period was 3.0%. There were no significant differences whichever surgical method to be used. There was not any single case of relapse in the TAPP-IRS target group. The age of patients related to the most crucial risk factor; the intervention technique ranked number two. Account must be taken of the TAPP-IRS subgroup, where any recurrence not reported. The type of intervention had a minimal effect on the risk of recurrence, in particular due to interventions techniques restricted by open operations only.

Conclusions. When performing open and laparoscopic hernioplasty for indirect inguinal hernia, the incidence and severity of postoperative pain after 1 month is lower with the laparoscopic method, and after 12 months it remits and has comparable characteristics. The TAPP-based internal ring suturing does not affect the postoperative pain syndrome.

The recurrence rate of inguinal hernia after open and laparoscopic hernioplasty found to have no significant differences. When using TAPP-IRS, no relapses were reported.

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Mendybaev A.A.
orcid.org/0000-0002-7854-9891
Fursov A.B.
orcid.org/0000-0002-6992-8646
Ismagambetova B.A.
orcid.org/0000-0003-2680-1319
Volchkova I.S.
orcid.org/0000-0001-7792-1084
Kovalenko T.F.
orcid.org/0000-0002-1782-4773
Dalenov N.Y.
orcid.org/0000-0001-9993-9672
Sagatov I.Y.
orcid.org/0000-0002-4668-1513

Author for correspondence:
Mendybaev A.A. - Astana Medical
University JSC, Assistant Professor
at the Department of Surgical
Diseases, Bariatric Surgery and
Neurosurgery, Astana, Kazakhstan,
e-mail: koshakan_888@mail.ru

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TAPP; internal ring suturing

Шап жарығын лапароскопиялық емдеудің орташа алшақмерзімді нәтижелері

Меңдібаев Ә.А., Фурсов А.Б., Исмағамбетова Б.А., Волчкова И.С.,
Коваленко Т.Ф., Дәленов Н.Е., Сағатов І.Е.

¹Астана медицина университеті, Жалпы медицина факультеті,
хирургиялық аурулар, бариатриялық хирургия және нейрохирургия
кафедрасы, Астана қ., Қазақстан,

²А.Н. Сызганов атындағы Ұлттық ғылыми орталығы Алматы қ.,
Қазақстан

Тұжырым

Зерттеу мақсаты. Ішкі шап сақинасын тігу арқылы TAPP әдісімен шап жарығын емдеудің орташа алшақмерзімді нәтижелерін анықтау.

Материалдары мен әдістері. Жұмыс дизайны – рандомизацияланған көп орталықты клиникалық зерттеу. Жұмыс 18 бен 84 жас аралығындағы 268 пациентті (орташа жасы 59,2±10,6

Хат алысатын автор:
Меңдібаев Ә.А. - «Астана
медицина университеті»
АҚ, хирургиялық аурулар,
бариатриялық хирургия және
нейрохирургия кафедрасының
доценті, Астана қ., Қазақстан,
e-mail: koshakan_888@mail.ru

Мүдделер қақтығысы:
Авторлар мүдделер
қақтығысының жоқтығын
мәлімдейді

Түйінді сөздер:
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жас), оның ішінде 46 (17,2%) әйелді, 222 (82,8%) бастапқы шап жарығы бар еркектерді тексеруге негізделген. Дене салмағының қалыпты индексі 187 (69,8%) науқастарда, артық салмақ 72 (26,9%), семіздік 9 (3,3%) болды. Араласулар ашық тәсілдермен (Лихтенштейн бойынша – 118 немесе Шолдайс бойынша – 29 пациент) және Тарр әдістемесі бойынша лапароскопиялық тәсілмен (барлығы 121), оның ішінде ішкі шап сақинасын тігумен модификацияда (12) жүргізілді. Операциядан кейінгі созылмалы ауырсынудың жиілігі мен ауырлығы (1 жылға дейін) және шап жарығының қайталану жиілігі (2 жылға дейін) анықталды.

Нәтижелері. Созылмалы ауырсыну синдромының даму жиілігі мен ауырлығы орташа болды және көп жағдайда топтар арасында айтарлықтай айырмашылықтар болмады. Жиіліктегі маңызды айырмашылықтар тек бір жағдайда анықталды-Лихтенштейн бойынша ашық герниопластика мен TAPP арасында ($\beta=4,241$, $p=0,040$). 2 жылдық бақылау кезеңінде грыжаның қайталану жиілігі 3,0% құрады. Хирургиялық араласу әдісіне байланысты айтарлықтай айырмашылықтар болған жоқ. Мақсатты топта Tag-UVPC кезінде қайталанудың бірде-бір жағдайы болған жоқ. Ең күшті қауіп факторы пациенттердің жасы болды, екінші орында-араласу әдісі. Бұл жағдайда қайталанулар мүлдем анықталмаған TAPP-UVPC кіші тобының болуын ескеру қажет. Қайталану қаупіне ең аз әсер ету араласу нұсқасы болды, атап айтқанда, тек ашық операциялармен араласу әдістерін қолданудың шектеулеріне байланысты.

Қорытынды. Қиғаш шап грыжасы үшін ашық және лапароскопиялық герниопластикаларды жүргізу кезінде операциядан кейінгі ауырсынудың жиілігі мен ауырлығы лапароскопиялық әдіспен 1 айдан кейін төмен болады, ал 12 айдан кейін ол азаяды және салыстырмалы сипаттамаларға ие. TAPP араласқан кезде ішкі шап сақинасын тігу операциядан кейінгі ауырсыну синдромына әсер етпейді.

Ашық және лапароскопиялық герниопластикадан кейін шап жарығының қайталану жиілігінде айтарлықтай айырмашылықтар жоқ. TAPP-UVPC қолдану кезінде рецидивтер тіркелген жоқ.

Среднеотдаленные результаты лапароскопического лечения паховых грыж

Мендыбаев А.А., Фурсов А.Б., Исмагамбетова Б.А., Волчкова И.С.,
Коваленко Т.Ф., Даленов Н.Е., Сагатов И.Е.

¹Медицинский университет Астана, факультет Общей медицины,
Кафедра хирургических болезней, бариатрической хирургии и
нейрохирургии, г. Астана, Казахстан,

²Национальный научный центр имени А.Н. Сызганова, г. Алматы,
Казахстан

Автор для корреспонденции:
Меңдібаев А.А. - АО
«Медицинский университет
Астана», доцент кафедры
хирургических болезней,
бариатрической хирургии и
нейрохирургии,
г. Астана, Казахстан,
e-mail: koshakan_888@mail.ru

Конфликт интересов:
Авторы заявляют об отсутствии
конфликта интересов

Аннотация

Цель исследования: определение среднеотдаленных результатов лечения паховых грыж по методике TAPP с ушиванием внутреннего пахового кольца.

Материалы и методы. Дизайн работы – рандомизированное многоцентровое клиническое исследование. Работа основана на обследовании 268 пациентов от 18 до 84 лет (средний возраст $59,2 \pm 10,6$ года), в том числе 46 (17,2%) женщин, 222 (82,8%) – мужчин с первичными паховыми грыжами. Нормальный индекс массы тела имели 187 (69,8%) больных, избыточный вес – 72 (26,9%), ожирение – 9 (3,3%). Вмешательства проводились открытыми способами (по Лихтенштейну – 118 или Шолдайсу – 29 пациентов) и лапароскопическим способом по методике TAPP (всего 121), в том числе в модификации с ушиванием внутреннего пахового кольца (12). Определялась частота и выраженность хронической послеоперационной боли (в срок до 1 года) и частота рецидивов паховой грыжи (в срок до 2 лет).

Результаты. Частота развития и выраженность хронического болевого синдрома была умеренной и в большинстве случаев не имела значимых различий между группами. Значимые различия по частоте были определены только в одном случае – между открытой герниопластикой по Лихтенштейну и TAPP ($\chi^2=4,241$, $p=0,040$). Частота рецидивов грыж за 2-летний период наблюдения составила 3,0%. Не было существенных различий в зависимости от способа оперативного вмешательства. В целевой группе, при проведении TAPP-УВПК, ни одного

случая рецидива не было. Наиболее мощным фактором риска оказался возраст пациентов, на втором месте – способ вмешательства. При этом следует учитывать наличие подгруппы TAPP-УВПК, в результате которого рецидивов не было определено вовсе. Минимальное влияние на риск рецидивирования оказывал вариант вмешательства, в частности по причине ограничений использования способов вмешательства только открытыми операциями.

Заключение. При проведении открытых и лапароскопических герниопластик по поводу косой паховой грыжи частота и выраженность послеоперационной боли через 1 месяц ниже при лапароскопическом способе, а через 12 месяцев уменьшается и имеет сравнимые характеристики. Проведение при вмешательстве TAPP ушивания внутреннего пахового кольца не влияет на послеоперационный болевой синдром.

Частота рецидивов паховой грыжи после открытых и лапароскопических герниопластик не имеет существенных различий. При применении TAPP-УВПК рецидивов не зарегистрировано.

Ключевые слова:
паховая грыжа; оперативное лечение; TAPP; ушивание внутреннего пахового кольца

Relevance

The inguinal hernias treatment for a long time is a “classic” task of the surgeon to be handled both in an emergency and in a planned manner. A long way has been come since the first experiments of hernia repair in the 19th century to modern endoscopic approaches to the operation and plastic surgery with synthetic materials. However, the problem does not appear to have been finally resolved, and hernia recurrences, especially at the later stages, remain a fairly common and unfavourable complication [1-3].

The main trend in the advanced treatment of hernias, as well as most other surgical pathologies in the late XX - early XXI became the development of endoscopic technologies [4,5]. It made it possible to achieve a rapid decline in the invasiveness degree of most interventions and, accordingly, a decrease of risk, a reduction in the duration of hospital and outpatient rehabilitation and disability [6].

Some authors consider a decrease in the individual focus of specific interventions, less radicalness and, as a result, a higher risk of recurrence of a treatable disease as the downside of the adoption of laparoscopic technologies [7,8].

To prevent this risk, approaches to endoscopic treatment of surgical diseases, including but not limited to inguinal hernias, are constantly being improved [9].

Objective: to determine the long-term postoperative outcomes of inguinal hernias using the TAPP approach with the internal ring suturing.

Materials and methods

The study design is a randomized multicentre clinical study. The period of study is from January, 2018 to September, 2021. The multidisciplinary clinics with surgical departments in Astana are the Clinical Trial Centre. Different surgeons operated while standardizing the methodological

and technical approaches to interventions in both the main and control cohorts.

The eligibility criteria were:

- age over 18 years;
- diagnosis of indirect inguinal hernia;
- open hernia repair by Liechtenstein, Shouldice techniques, or laparoscopic operation by TAPP method (Trans Abdominal Pre-Peritoneal Hernioplasty) [10], including TAPP with the internal ring suturing;

- a written informed consent of the patient to be enrolled into the study and a specific surgical intervention based on the randomization of the study group.

The exclusion criteria were:

- hernias of other localizations;
- inguinal hernia in case of recurrence;
- surgical interventions using other methods of plastic surgery;
- refusal of the patient to be enrolled into the study until the completion of the results processing.

The study is based on a survey of 268 patients aged 18 to 84 years (mean age 59.2±10.6 years), including 46 (17.2%) women, 222 (82.8%) men.

Distribution of subjects depending on body weight followed the up-to-date WHO classification, which allowed to determine the body mass index (BMI) in kg/m². In view of the predominant ethnic composition of patients, we used the boundary criteria for the Asian region, whereby the underweight was determined when BMI was <18.5; normal weight – with 18.5≤BMI<23; overweight - with 23≤BMI<25; obese - with BMI≥25 and severe obesity - with BMI≥30 kg/m².

Pursuant thereto a total of 187 (69.8%) subjects had a normal body mass index, 72 (26.9%) were overweight, 9 (3.3%) were obese. The subjects enrolled were distributed by age category and BMI (table 1).

Table 1.
Distribution of subjects by age
category and BMI

Age	Body weight						Total	
	Healthy		Overweight		Obesity			
	n	%	n	%	n	%	n	%
18-45 years	2	18.2	8	72.7	1	9.1	11	4.1
45-60 years	46	65.7	23	32.9	1	1.4	70	26.1
61-75 years	113	72.4	36	23.1	7	4.5	156	58.2
76 years and over	26	83.9	5	16.1	0	0.0	31	11.6
Total	187	69.8	72	26.9	9	3.4	268	100

The study included the fewest subjects in the age category from 18 to 44 years (11). Meanwhile, 9 of them were overweight and obese. There were also overweight and obesity in subjects of middle age - up to 60 years, in 34.3% of cases. On the contrary, a predominance of normal body weight was reported in those surveyed over the age of 60.

As often as not, the patients were subject to elective procedure (81.3%), in other cases, emergency interventions were performed in case of incarceration of inguinal hernias.

Right-sided localization of the hernia occurred in 153 (57.0%) patients, left-sided - in 115 (43.0%), and bilateral hernia developed in 17 (6.3%) patients.

The preoperative preparation in operated patients corresponded to the up-to-date protocols for diagnosis and treatment. The patients who were subject to elective procedure were mainly prepared on an outpatient basis; the emergency

operations were preceded by a set of measures aimed at correcting the impairment of the vital functions, being identified upon admission.

The anaesthetic support had been chosen against the patient's condition, on individual basis, age, body weight, overall health status, concomitant diseases and organs & systems dysfunctions, if any.

Interventions supposed the open techniques (Lichtenstein technique or Shouldice technique) and laparoscopic technique by TAPP approach, and specifically the modification with the internal ring suturing (TARR-IRS).

Laparoscopic hernioplasty had not been used in emergency surgical interventions. The Lichtenstein technique was refused in young people to prevent adverse effects on their generative function. Table 2 shows the number of examined patients who distributed by BMI level and type of intervention made.

Table 2.
Distribution of subjects by the
hernioplasty technique used and
body weight level

Hernioplasty technique	Body weight						Total	
	Healthy		Overweight		Obesity			
	n	%	n	%	n	%	n	%
Shouldice	27	14.4	2	2.8	0	0	29	10.8
Lichtenstein	106	56.7	10	13.8	2	22.2	118	44.0
TAPP	49	26.2	55	76.4	5	55.6	109	40.7
TAPP-IRS	5	2.7	5	7.0	2	22.2	12	4.5
Total	187	100	72	100	9	100	268	40.7

When analysing the ratio of the body weight level and the hernioplasty technique, it should be noted that the use of the Shouldice method excluded the obese patients. Most of them were operated on using the TAPP technique.

The internal ring suturing became the main

approach to the prevention of recurrent hernias in laparoscopic hernioplasty. The suturing was intended for use when the diameter of the internal ring was greater than 3 cm, and this stage of the operation preceded the application and fixation of the mesh implant (Figure 1).

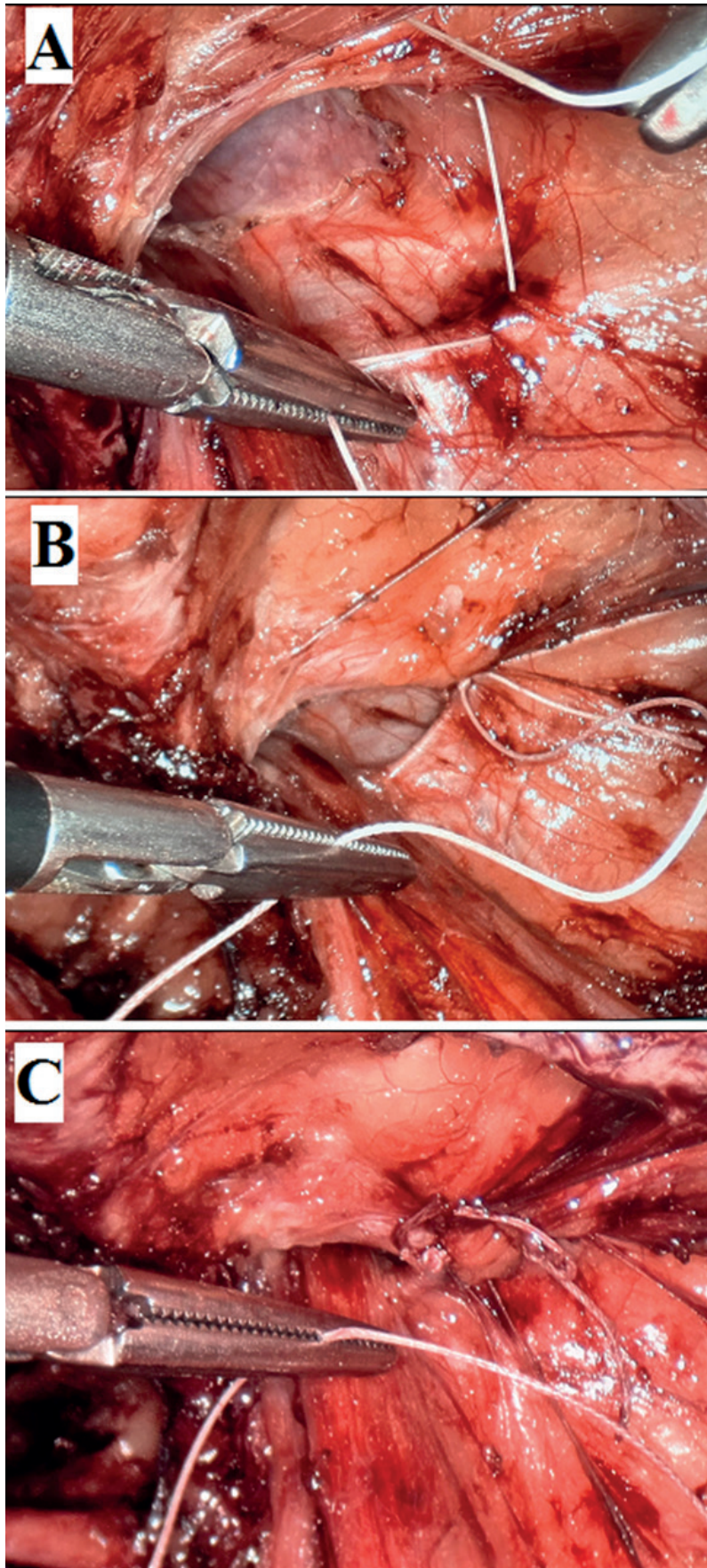


Figure 1.
Indirect inguinal hernia. The diameter of the internal inguinal canal is greater than 3 cm. The sequence of the main stage of the TAPP-IRS operation: A) Placement of the first intracorporeal suture; B) Knot tying; C) The internal ring is sutured

The sequence of the main stage of the TAPP-IRS operation

In the endoscopic hernioplasty technique, as in the Lichtenstein technique, preference was given to a low-density polypropylene mesh, which adapts well to the tissues of the inguinal region, fits easily with the TAPP technique and gives no discernible reaction of the surrounding tissues to a foreign body.

The clinical examination of patients prior to discharge from the hospital complied with the applicable Diagnosis and Treatment Protocols, as well as during outpatient follow-up.

The long-term outcomes of treatment were determined in all patients for 1 year or more. The average period of prospective follow-up for the group was 2.1±0.4 years, for the Shouldice subgroup - 2.3±0.4 years, Lichtenstein - 2.1±0.3 years, TAPP - 2.0±0.2 years, TAPP-IRS - 1.9±0.3

years (p>0.05). Targeted examinations of patients at the attendance of the researcher or at the place of residence were carried out 4 times a year.

Statistical methods: Statistical processing of the study results was made by SPSS 20.0. To compare frequencies, Pearson's chi-square test and Fisher's two-tailed exact test were used; the contribution of various risk factors to the development of long-term complications was assessed by multiple factor analysis [11].

Results

Two main complications that characterize the late postoperative period after hernioplasty were assessed: the occurrence and severity of pain syndrome and the development of recurrent inguinal hernia. Table 3 shows the data reported for the pain syndrome.

Table 3.
The occurrence rate and severity of pain syndrome in patients in terms of the hernioplasty technique

Hernioplasty technique	Examination period					
	1 month			12 months		
	Number of patients with pain syndrome	%	Severity of the pain syndrome by VAS (if any)	Number of patients with pain syndrome	%	Severity of the pain syndrome by VAS (if any)
Shouldice, n=29	5	17.2	3.5 (2.5-4.5)	3	10.3	2.3 (2.0-3.0)
Lichtenstein, n=118	29	24.6	3.2 (2.3-3.7)	14	11.9	2.0 (1.5-2.5)
TAPP, n=109	15	13.8	2.4 (2.0-2.7)	6	5.5	2.2 (1.7-2.5)
TAPP-IRS, n=12	2	16.7	2.5 (2.0-3.0)	0	0.0	-
Total	49	18.3	-	23	8.6	-

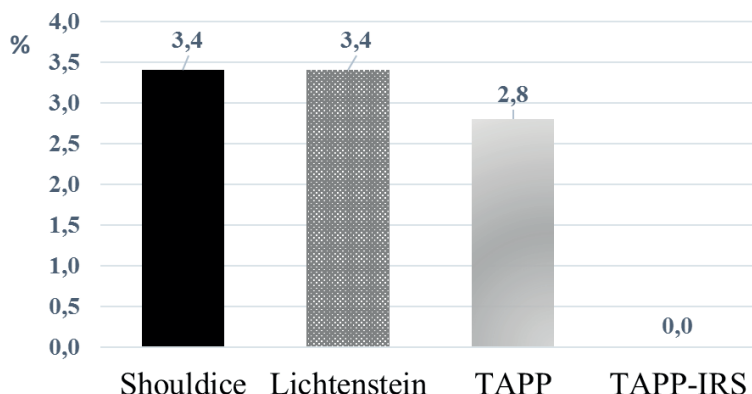
The incidence and severity of chronic pain syndrome was moderate and in most cases were found to have no any intergroup significant differences. After 1 month, the average incidence for the entire group was 18.3%, and after 12 months - 8.6%. The severity according to VAS in the first case was within 2-5, in the second - within 2-3.

Single case showed the significant differences in incidence between open hernioplasty by

Lichtenstein technique and TAPP ($\chi^2=4.241$, $p=0.040$).

It should be noted the zero cases with pain syndrome after TAPP-IRS in the long-term period. Figure 2 shows the recurrence rate of inguinal hernia over the period of prospective follow-up, depending on the intervention technique, and Figure 3 further shows the rate, depending on the overweight and obesity.

Figure 2.
The total number of the recurrent inguinal hernias during the prospective follow-up, depending on the intervention



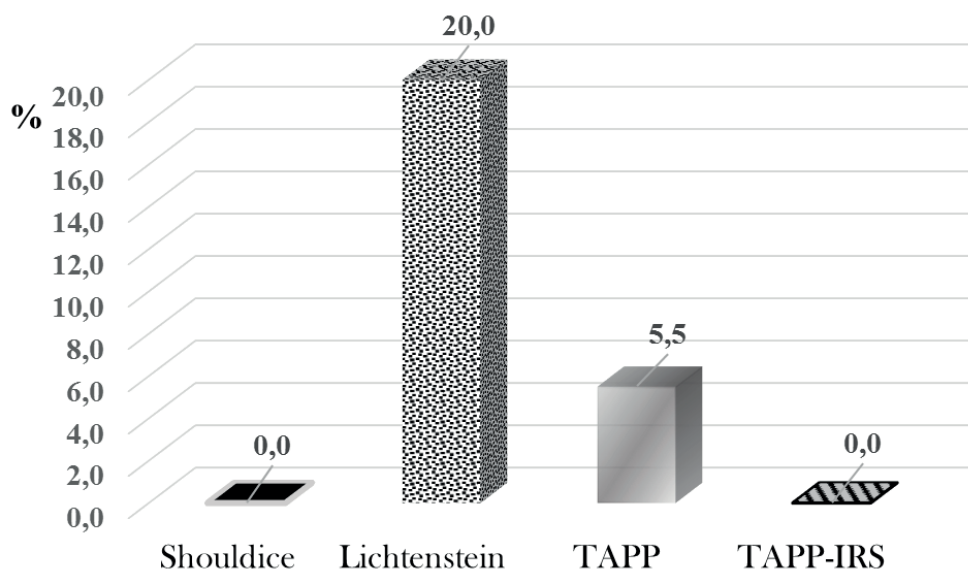


Figure 3. The total number of the recurrent inguinal hernias during the prospective follow-up in overweight and obese subjects, depending on the intervention

The percentage of recurrent hernia was low (in total, 8 recurrences occurred during follow-up). There were no significant differences in the recurrence rate depending on the intervention technique. During the TAPP-IRS, there was not a single case of recurrence in the target group.

A marked excess of the recurrence rate was found where overweight and obesity observed.

Since no Shouldice surgery had been performed for obesity, and no relapses at all with TAPP-IRS reported, the peak of excess fell on the Lichtenstein technique, where the rate reached 20.0%, also the recurrence rate in this category using TAPP without IRS was twice as high as the average for the group. Table 4 shows the timing of recurrence depending on the intervention and BMI.

Hernioplasty technique	Body weight		P
	Healthy	Overweight and Obesity	
Shouldice, n=29	12	-	-
Lichtenstein, n=118	16±2,0	9±1,5	0,025
TAPP, n=109	-	11±1,5	-
TAPP-IRS, n=12	-	-	-
Average	15±2,2	10±2,0	0,068

Table 4. The timing of the recurrent inguinal hernia, depending on the intervention and the level of body weight (months)

The average timing for the recurrent inguinal hernia was longer with healthy body weight only when hernioplasty by Liechtenstein technique

was used, but not on average for the analysed groups. Figure 4 shows the results of a factor analysis of the recurrence risk.

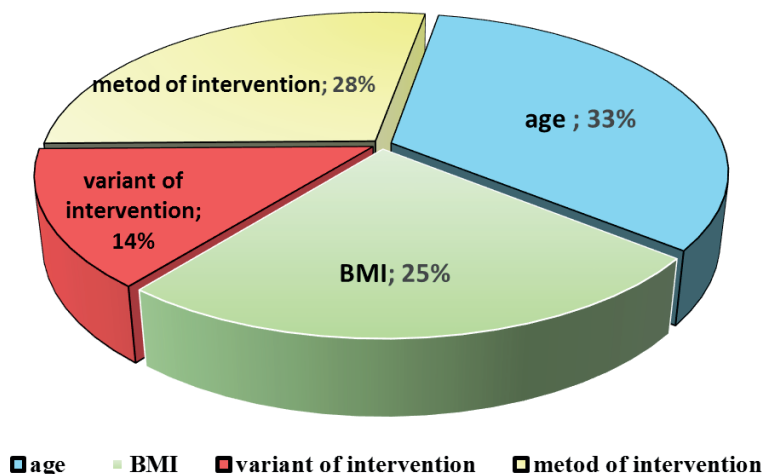


Figure 4. Results of factor analysis of the recurrent inguinal hernias risk

The following factors were considered as significant ones in the development of hernia recurrence: the age of the patient (up to 60 years and after 60 years); BMI (normal or excess); variant of intervention (elective, emergency) and method of intervention (open, laparoscopic).

The age of patients related to the most crucial risk factor; the intervention technique ranked number two. Account must be taken of the TAPP-IRS subgroup, where any recurrence not reported. The type of intervention had a minimal effect on the risk of recurrence, in particular due to interventions techniques restricted by open operations only.

Discussion

Inguinal hernias are among the most common surgical pathology in men [12]. To date, in most cases it treats in a planned manner [13].

The laparoscopic variant of operative access in abdominal surgery is predominant for most common diseases, and specifically for inguinal hernias [14,15]. It attracts with a minimal invasiveness while maintaining radicality, the possibility of the quickest possible postoperative rehabilitation and short periods of in-patient care [6,16].

Meanwhile, the ratio of the late postoperative complications rate after hernioplasty, primarily relapses, does not appear to have been finally resolved [17,18]. One of the key aspects in the relapse prevention is the possibility of suturing an overly expanded internal ring, which is the problem of our study.

Postoperative pain syndrome as a complication of the long-term period can also be of some importance in terms of the achievement of the quality of patients' life [19], although some researchers reject its significance [20].

When determining the risk of developing the above complications, the main role is given to

the quality of the surgical intervention, the strict adherence to the methodology of the surgical support both in open and laparoscopic operations [21,22]. At the same time, the role of common factors independent of the surgical technique is recognized, primarily the age of the patient and the concomitant pathological conditions, including obesity [23-26]. The question of the preference for one or another approach to hernioplasty, if available, doesn't appear to have been finally resolved in the meantime.

The development of techniques aimed at improving the immediate and long-term outcomes of inguinal hernia treatment, in particular in laparoscopic surgery, continues to be hot topic. In our study, we suggest the indications for use and TAPP-IRS technique, which turned out to be the most preferable in terms of preventing postoperative complications when evaluating the outcomes. Unfortunately, in this publication, we were able to include in the analysis only a limited number of operated patients who were followed up for quite a long time. In the course of extension study, the outcomes of a larger number of interventions performed will be reported.

Conclusions

When performing open and laparoscopic hernioplasty for indirect inguinal hernia, the incidence and severity of postoperative pain after 1 month is lower with the laparoscopic method, and after 12 months it remits and has comparable characteristics. The TAPP-based internal ring suturing does not affect the postoperative pain syndrome.

The recurrence rate of inguinal hernia after open and laparoscopic hernioplasty found to have no significant differences. When using TAPP-IRS, no relapses were reported.

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