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Use of titanium implants in the surgical treatment of complete uterine or vaginal prolapse in elderly and senile patients after hysterectomy

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ABSTRACT

BACKGROUND: With increasing life expectancy, the need to improve the quality of life in elderly and senile women has become more urgent. Pelvic organ prolapse is a significant concern, particularly because this pathology tends to progress in the postmenopausal period. Surgical treatment of pelvic organ prolapse using only the patient's own tissues often results in recurrence of the disease. This highlights the need for developing new surgical techniques that utilize durable and biologically inert materials, such as titanium implants.

AIM: The objective of this study is to analyze the effectiveness and reliability of surgical correction of complete uterine or vaginal prolapse after hysterectomy in elderly and senile women.

MATERIAL AND METHODS: A total of 65 women, aged between 65 and 86 years old, were examined and underwent surgery using two newly developed original surgical techniques. Group I (31 patients) underwent surgery with the use of a titanium mesh implant, while Group II (34 patients) underwent surgery with the use of a combination of the aforementioned mesh implant with two non-absorbable ligatures.

RESULTS: The outpatient follow-up was carried out on Months 1, 6, 12, 24, 36 and 48 after surgery. The comprehensive examination, comprising questionnaires, gynecological examination and transperineal post-surgery ultrasound, demonstrated that the surgical treatment was satisfactory, as evidenced by an improvement in the women's quality of life. During Month 1 after the surgery, 32 patients (49.2%) reported intermittent perineal pain and/or aches in the area of the inguinal folds, while 15 patients (65.0%) experienced frequent attempts to urinate. These symptoms abated with time. No recurrences of the disease or mesh-associated complications were recorded during the follow-up period.

CONCLUSION: The study demonstrates the efficacy and reliability of newly developed surgical techniques for treating complete uterine and vaginal prolapse after hysterectomy in elderly and senile women. The accumulated clinical experience attests to the fact that severe pelvic organ prolapse in elderly patients with concomitant somatic diseases can be successfully treated via surgical intervention. This has the potential to relieve women from the range of symptoms associated with the disease and normalize the functioning of pelvic organs. The introduction of such surgeries into clinical practice will improve the quality of life of elderly and senile patients.

Keywords: complete uterine prolapse; titanium mesh implants; surgical treatment of prolapse.

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Использование титановых эндопротезов в хирургическом лечении пациенток пожилого и старческого возраста с полным выпадением матки или купола влагалища после гистерэктомии

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АННОТАЦИЯ

Обоснование. С увеличением продолжительности жизни и возрастанием потребности в улучшении её качества у женщин пожилого и старческого возраста проблема пролапса тазовых органов приобретает всё большее значение, так как эта патология имеет тенденцию к прогрессированию в постменопаузальном периоде. Оперативное лечение пролапса органов малого таза с применением исключительно собственных тканей нередко влечёт за собой рецидивы заболевания, что обусловливает необходимость разработки новых хирургических методик с применением прочных и биологически инертных материалов, например, титановых имплантатов.

Цель. Анализ эффективности и надёжности хирургической коррекции полного выпадения матки или купола влагалища после гистерэктомии у женщин пожилого и старческого возраста.

Материал и методы. Обследованы и прооперированы 65 женщин 65–86 лет по двум новым разработанным оригинальным хирургическим методикам: I группа (31 пациентка) — с применением сетчатого титанового имплантата, II группа (34 пациентки) — комбинацией последнего с двумя нерассасывающимися лигатурами.

Результаты. Динамическое амбулаторное наблюдение проводили через 1, 6, 12, 24, 36 и 48 мес. после операции. Комплексное обследование, включающее анкетирование, гинекологический осмотр, трансперинеальную эхографию, в послеоперационном периоде показало удовлетворённость женщин результатами хирургического лечения, что отразилось на улучшении качества их жизни. В течение первого месяца 32 (49,2%) пациентки отмечали тянущие боли непостоянного характера в области промежности и/или пахово-бедренных складок, 15 (65,0%) — учащённые позывы к мочеиспусканию. В дальнейшем указанные симптомы нивелировались. Рецидивы заболевания и mesh-ассоциированные осложнения за время наблюдения не зарегистрированы.

Заключение. Результаты исследования показали эффективность и надёжность разработанных способов хирургической коррекции полного выпадения матки и купола влагалища после гистерэктомии у пациенток пожилого и старческого возраста. Накопленный клинический опыт свидетельствует о том, что пролапс органов малого таза тяжёлой степени у пациенток преклонного возраста с сопутствующей соматической патологией подвергается успешной хирургической коррекции, позволяющей избавить женщин от целого спектра жалоб, сопровождающих заболевание, и нормализовать функционирование органов малого таза. Внедрение подобных операций в клиническую практику позволит улучшить качество жизни пациенток пожилого и старческого возраста.

Ключевые слова: полное выпадение матки; сетчатые титановые имплантаты; хирургическая коррекция пролапса.

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使用钛质内植物治疗老年及高龄女性子宫脱垂或子宫切除术后阴道穹隆脱垂的手术方法

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摘要

背景。随着女性预期寿命的延长以及对生活质量要求的提高，老年及高龄女性中盆腔器官脱垂问题日益受到关注。这种病理在绝经后期具有持续进展的趋势。依靠自体组织进行的盆腔器官脱垂手术通常容易导致疾病复发，因此需要开发利用坚固且生物惰性材料（如钛质植入物）的新型手术技术。

研究目的。分析使用钛质内植物治疗老年及高龄女性子宫完全脱垂或子宫切除术后阴道穹隆脱垂的手术效果和可靠性。

材料与方法。对65名年龄在65至86岁的女性患者进行了检查，并实施了两种新开发的手术技术。第一组（31例患者）采用钛质网状植入物，第二组（34例患者）结合使用钛质植入物和两根不可吸收缝线。

结果。术后1、6、12、24、36和48个月进行了动态门诊随访。综合评估包括问卷调查、妇科检查及经会阴超声检查。术后结果显示，患者普遍对手术治疗效果满意，生活质量显著改善。在术后第一个月内，32例（49.2%）患者报告会阴部和/或腹股沟区的间歇性牵拉痛，15例（65%）患者报告排尿频率增加。然而，这些症状随后逐渐消失。在整个观察期间，未记录到疾病复发或与网状植入物相关的并发症。

结论。研究结果表明，新开发的手术方法在治疗老年及高龄女性子宫完全脱垂或子宫切除术后阴道穹隆脱垂方面具有显著的高效性和可靠性。累积的临床经验表明，这些手术方法可成功矫正严重盆腔器官脱垂，同时帮助患者摆脱相关症状并恢复盆腔器官功能。将该类手术广泛应用于临床实践将显著改善老年及高龄女性的生活质量。

关键词：子宫完全脱垂；钛质网状植入物；盆腔器官脱垂手术治疗。

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BACKGROUND

The gradual increase of the elderly population is one of the obvious trends in modern society. As of 1 January 2023, the Federal State Statistics Service reported that the share of people aged over 65 of years in Russia was 16.5%, and the share of women aged over 75 years was 9.6% [1]. Elderly age is known to be associated with various medical conditions, including gynecological conditions such as female genital prolapse or pelvic organ prolapse (POP). It is estimated that 50%–60% of elderly and senile women in Russia have POP of varying severity, which requires personalized diagnosis and treatment [2–4]. Special attention should be paid to elderly patients with severe prolapse, i.e. post-hysterectomy total uterine or vaginal vault prolapse, which significantly affects their quality of life. There are only few published studies that provide statistically reliable data on the prevalence of these conditions. The study by Milson et al. [5] showed that only about 4.1% of women aged 80 years and older have POP-related symptoms. Other authors reported POP rates ranging from 2.9% to 97.7%, and the number of surgical procedures for POP in women aged over 70 years may exceed 70% of all procedures in this group. Therefore, POP treatment in elderly and senile women is still relevant. Surgery is known to be the most effective treatment option for POP. Most surgeons use only the patient's own tissue for surgical treatment of this condition. However, the recurrence rate remains high, ranging from 30% to 60% [4, 6]. In some elderly female patients with no need for sexual life, organ-preserving Neugebauer–Le Fort surgery (midline colporrhaphy) is often performed, but it does not always prevent recurrence, so new surgical techniques using durable and biologically inert materials are needed to improve surgical outcomes [7–9].

STUDY AIM

The aim of this study was to evaluate the efficacy and reliability of surgical treatment of total uterine or vaginal vault prolapse after hysterectomy in elderly and senile women using a titanium mesh implant or its combination with two non-resorbable sutures.

MATERIALS AND METHODS

The study included 65 patients aged 65–86 years with total uterine or vaginal vault prolapse after hysterectomy, who consulted at the National Medical Research Center "Treatment and Rehabilitation Center" and the Sechenov Center for Maternal and Child Health, which are clinical sites of the Department of Obstetrics and Gynecology No. 1 of the Sklifosovsky Institute of Clinical Medicine of the Sechenov First Moscow State Medical University. Of these, 21 (32.3%) were aged 65 to 70 years, 35 (53.8%) were aged 71 to 79 years, and 9 (13.9%) were aged 80 to 86 years.

The groups were comparable for clinical symptoms, medical and gynecological history, objective examination data, and diagnosis.

The women underwent a comprehensive clinical evaluation, surgical treatment with two proposed techniques, and outpatient follow-up in the early (1 month) and late (6, 12, 24, 36, and 48 months) postoperative periods.

Patients were evaluated according to standards of care for POP, including analysis of symptoms, medical history, physical examination, gynecologic and rectal examinations, imaging tests (transvaginal and transperitoneal ultrasound examinations, colposcopy) and laboratory tests (complete blood count and blood chemistry, coagulation test, urinalysis, bacterioscopy and bacteriology of vaginal and cervical smears, ecto- and endocervical cytology). Depending on individual clinical symptoms, medical history, and necessary preoperative examinations (ECG, chest x-ray, pulmonary function tests, Doppler ultrasound of lower extremity vessels, etc.), other examination modalities were used together with consultations with specialists (general practitioner, endocrinologist, pulmonologist, urologist, proctologist, etc.).

Type and time of onset of signs and symptoms, stages of underlying disease, heredity, extragenital diseases, menstrual and reproductive function parameters were determined based on medical history data. Previous gynecological diseases and surgeries were considered.

The clinical examination included evaluation of the external genitalia, perineum, vagina, and cervix, followed by the gynecological examination, which was used to diagnose POP.

Rectal examination clarified the severity of posterior vaginal wall prolapse and differentiated rectocele from enterocele.

The Pelvic Organ Prolapse Quantification System (POP-Q) was used to determine the severity of POP [10].

Carl Zeiss 170F (Germany) was used for extended colposcopy.

Voluson P8 (General Electric, USA) with transvaginal and convex transducers was used for transvaginal (before surgery) and transperineal (before and after surgery) ultrasound examinations.

Surgery for total uterine or vaginal vault prolapse after hysterectomy was performed using original techniques with a titanium mesh endoprosthesis (Group I) or a combination of the endoprosthesis with two non-absorbable sutures (Group II) using a transobturator access.

Clinical characteristics of patients

All 65 (100.0%) women reported discomfort and foreign body sensation inside and outside the vagina. Pulling and aching pain in the lower abdomen and lumbosacral region was reported by 57 patients (87.7%). Difficulty urinating was reported by 63 patients (96.9%), intermittent increased urgency by 14 patients (21.5%), and constipation by 60 patients (92.3%). All patients had no sexual needs.

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Mild vaginal discomfort first appeared 21–35 years ago in 9 patients, 10–20 years ago in 37 patients, and 5–9 years ago in 19 patients. Symptom severity increased with age.

Family history suggested the hereditary nature of POP, as mothers of one in five patients and maternal grandmothers of one in six patients had this condition.

Medical history revealed that 55 women (84.6%) had cardiovascular disorders, 18 (27.7%) had chronic bronchitis, 30 (46.2%) had chronic gastritis, 36 (55.4%) had chronic cholecystitis and cholelithiasis, 16 (24.6%) had hernia, 33 (50.8%) had varices, and 24 (36.9%) had hypermobile and dislocated joints, 60 (92.3%) had arthroses of major joints and osteochondrosis of various parts of the spine, indicating the potential for congenital connective tissue disorders in patients with POP, which was consistent with the findings of other researchers [11, 12].

Menstrual function and onset of menopause were normal. The mean age of menarche was 14.7 ± 1.5 years, and the mean age of menopause was 51.8 ± 3.6 years.

Fifty-four patients (83%) had 1–2 previous full-term vaginal deliveries, 8 (12.3%) had 3–4, and 1 (1.5%) had 5. Two patients (3.2%) had no history of childbirth. In 48 women (76.2%), delivery was complicated by cervical, perineal, and/or vaginal injuries. Artificial abortions were reported in 33 patients (50.8%), and spontaneous miscarriages were reported in 14 patients (21.5%).

Russian and foreign literature shows that connective tissue dysplasia and natural childbirth with/without birth trauma, as well as gynecological surgeries are triggering risk factors for POP [13].

As for gynecological conditions, 18 women (27.7%) had a history of benign cervical disease (cervical polyps, endometriosis, leukoplakia); 5 (7.7%) had salpingo-oophoritis, 18 (27.7%) had polyps and endometrial hyperplasia, 23 (35.4%) had uterine myoma, and 9 (13.8%) had benign ovarian tumors with uterine myoma.

Thirty-two patients (49.2%) in both groups had a history of total abdominal hysterectomy, 18 (27.2%) had a history of one to three therapeutic and diagnostic procedures (hysteroscopy, separate diagnostic curettage of the endocervix and endometrium), 18 (27.2%) had a history of electrodiathermocoagulation, laser vaporization, or cervical cryodestruction.

Gynecological and rectal examinations revealed signs of pelvic floor failure, as evidenced by a gaping pudendal cleft (the result of divergence of the muscles that lift the anus) and a thinned, hypotonic, and shortened perineum. Total uterine prolapse was reported in 33 patients (50.8%), and vaginal vault prolapse into the pudendal cleft after hysterectomy was reported in 32 patients (49.2%).

Transperineal echography showed typical signs of pelvic floor failure, including the decreased height of the perineal body, muscle diastasis in the area of the perineal body, and the decreased width of the bulbocavernosus muscle bundles.

The indication for surgical treatment was total uterine prolapse in 33 patients (50.8%) and vaginal vault prolapse after hysterectomy in 32 patients (49.2%), which caused severe discomfort and dysfunction of adjacent organs and consequently affected quality of life.

Study design

This was a multicenter, randomized, controlled, prospective study.

Eligibility criteria

Inclusion criteria:

- Elderly and senile women,
- Total uterine prolapse,
- Vaginal vault prolapse after hysterectomy,
- Consent to proposed scope of surgery,
- Consent to titanium mesh implant placement,
- Voluntarily signed consent form.

Non-inclusion criteria:

- Current indications for hysterectomy,
- Decubital cervical ulcers,
- Pelvic and/or abdominal inflammatory disease,
- Severe extragenital conditions that do not allow adequate anesthesia,
- Congenital or acquired pelvic and/or hip deformities contraindicating transvaginal surgery.

Exclusion criteria:

- Refusal to participate in the study,
- Gynecologic cancers.

Study setting

Federal State Autonomous Educational Institution of Higher Education Sechenov First Moscow State Medical University (Sechenov University), Ministry of Health of Russia, Moscow, Russia.

Treatment and Rehabilitation Center of the Ministry of Health of Russia, Moscow, Russia.

Study duration

The study was conducted from 2019 to 2024.

Intervention description

All patients underwent transvaginal surgery under spinal anesthesia.

In Group I (*n*=31), a modified Neugebauer–Le Fort surgery was performed using a rectangular titanium mesh implant fixed to the anterior vaginal wall wound (Figures 1–2), followed by union of the anterior and posterior walls. The titanium mesh implant strengthened the vaginal walls and improved the vaginal tissue regeneration [14].

In Group II (*n*=34), a titanium mesh endoprosthesis was placed on a rectangular anterior vaginal wall wound, as in Group I, followed by suspension of the cervix and vagina or vaginal vault after hysterectomy using two transobturator non-absorbable sutures (midline cervicorrhaphy and

Fig. 1. Preparation of the site for implantation of the titanium implant for vaginal prolapse after hysterectomy.

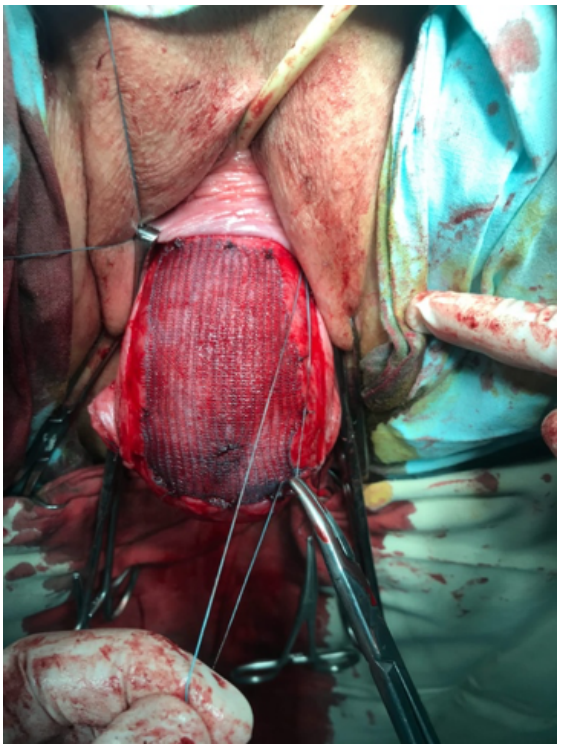

Fig. 2. Fixation of the titanium implant to the wound of the anterior vaginal wall. Suturing of the cervix and of the left anterior vaginal wall with the use of non-absorbable sutures.

colporrhaphy with transobturator suture suspension using TiMesh) [6–8, 15] (Figure 3).

Pelvic floor augmentation (colpoperineorrhaphy with levator plasty) was performed at the end of surgery in Groups I and II.

Main study outcome

Table 1 characterizes the postoperative course in both clinical groups.

In Group 1, 2 patients (6.5%) had a hematoma in the surgery area in the early postoperative period. They received conservative therapy. One month after surgery, a gynecological examination and transperineal echography showed no hematoma.

Thirty-five patients (53.8%) in both groups reported perineal pain and/or inguinal fold pain during the first month after surgery. The pain syndrome later resolved.

During their hospital stay, 8 patients (12.3%) had difficulty urinating spontaneously after Foley catheter removal and underwent intermittent catheterization. However, 6 patients (9.2%) reported frequent urinary urgency. These symptoms later resolved.

Outpatient follow-up continued for 48 months after surgery (at 1, 6, 12, 24, 36, and 48 months).

At 3 and 6 months, 2 patients (3.07%) in Group II reported the unilateral rupture of transobturator sutures in the inguinal folds due to a sudden fall from a ladder (n=1) or a fall from a height (n=1), resulting in a pain syndrome in these areas.

Methods for registration of outcomes

The efficacy of surgical treatment was comprehensively evaluated at 1, 6, 12, 24, and 48 months using a Prolapse Quality of Life questionnaire (P-QoL), a validated tool for assessing pelvic floor function and quality of life in patients with POP, as well as objective examination modalities

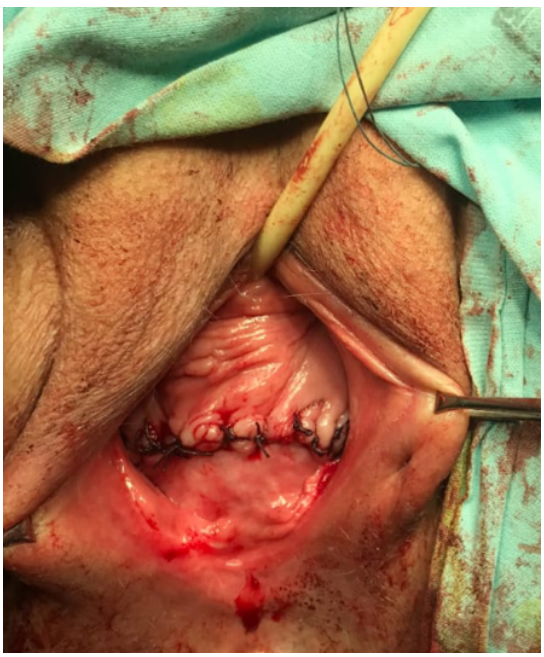

Fig. 3. Midline colporrhaphy with the use of titanium implant. Suture-based colposuspension.

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Table 1. Characteristics of early and delayed postoperative periods in patients of two clinical groups

Complication	Group I (*n*=31)	Group II (*n*=34)
Surgical wound hematoma	2 (6.5%)	—
Perineal pain	16 (51.6%)	19 (55.9%)
Urinary retention	4 (12.9%)	4 (11.8%)
Frequent urination	3 (9.7%)	3 (8.8%)
Detachment of the fixing suture	—	2 (5.9%)

(physical examination, gynecological examination with functional tests, transperineal echography).

Statistical analysis

Variation statistics software was used to process the study results. Student's t-test was used to analyze quantitative characteristics (a significance level of p <0.05).

RESULTS

Surgery duration ranged from 45 to 70 minutes. Intraoperative blood loss was 40–80 mL (mean: 50±15 mL).

The early postoperative period was characterized by rapid verticalization of patients who received a course of antibacterial, anti-inflammatory, analgesic, desensitizing, infusion and anticoagulant therapy.

The length of hospital stay ranged from 6 to 8 days. Sutures healed by primary intention.

During the first month of follow-up, 35 patients (53.8%) in Groups I and II reported perineal pain and/or inguinal folds pain, 8 (12.3%) reported difficulty urinating, and 6 (9.2%) reported frequent urination.

In the late postoperative period (at 3–6 months), 2 patients (5.9%) in Group II reported symptoms of unilateral rupture of transobturator non-absorbable sutures due to a fall from a ladder (*n*=1) or a fall from a height (*n*=1), leading to a pain syndrome and surgical removal of the titanium suture stopper due to its migration.

No evidence of disease recurrence and/or mesh-related or general surgical complications were observed during the follow-up period.

DISCUSSION

Management of elderly and senile women with total uterine or vaginal vault prolapse after hysterectomy has been an important issue for many decades. Surgical treatment under local anesthesia was described as early as the 19th century, e.g. the Neugebauer–Le Fort surgery, with results rarely reported in the world literature. After reviewing publications from 2000 to 2006, Menard et al. concluded that the most commonly used surgical technique for POP was vaginal removal of the uterus with colpoperineorrhaphy or sacrospinous fixation [16].

However, conventional surgical techniques for genital prolapse aimed at repairing the pelvic floor and restoring the anatomical and topographical relationships of the pelvis, or radical surgery (hysterectomy), are not always suitable for elderly and senile patients due to their traumatic nature, the need for prolonged and deep anesthesia, and the high risk of postoperative complications and recurrence.

In addition, some papers describe Neugebauer–Le Fort surgery as an effective and reliable surgical treatment option for genital prolapse in elderly women without sexual needs. The authors emphasize that this option demonstrated good results but was overlooked.

Our study showed that women with total uterine or vaginal vault prolapse after hysterectomy presented with a range of different complaints associated both directly with the internal genital prolapse and with concomitant descent and dysfunction of adjacent organs, which significantly affected the patients' quality of life and caused them considerable suffering.

After a comprehensive clinical evaluation, a decision was made regarding the scope and approach of surgery for total uterine or vaginal vault prolapse after hysterectomy in elderly and senile patients with a burdened medical and obstetric/gynecologic history. The lack of sexual needs determined the choice of an organ-preserving procedure (modified Neugebauer–Le Fort surgery) using a titanium mesh implant (31 patients in Group I) or a combination of the implant with two non-resorbable sutures and titanium stoppers (34 patients in Group II). Titanium is used due to its high biological inertness, plasticity, low fuse effect and high strength, the absence of factors triggering aseptic (serous) inflammation and structural changes in the implant during long-term follow-up, which is very important in elderly patients. In addition, deposition of type I collagen onto titanium helps form a strong thin scar. The use of a titanium endoprosthesis between the wound surfaces strengthens the vaginal walls in elderly patients with weakened microcirculation, hypoestrogenism, and consequently low tissue repair capacity.

Transobturator suture suspension of the cervix and vagina or vaginal vault after hysterectomy using non-absorbable monofilament sutures secured with stoppers provides additional fixation of prolapsed organs.

Additional surgical interventions slightly increased the duration of surgery without increasing blood loss, which,

together with spinal anesthesia, improved the effectiveness of the procedure.

Many publications demonstrated that elderly women often have multiple comorbidities with a tendency to their decompensation and complications. Therefore, we consider it extremely important to reduce the duration of surgery for total uterine or vaginal vault prolapse after hysterectomy and to avoid intubation anesthesia in order to minimize the burden on vital organs and to ensure rapid rehabilitation of patients after surgery.

Unfortunately, there are virtually no published papers that provide a detailed and comprehensive analysis of the long-term results of the Neugebauer–Le Fort surgery. One of the possible reasons is the age of the patients, which at the time of surgery was close to or exceeded the life expectancy of women, making it extremely difficult or even impossible to evaluate the results of the surgery after several years.

At 3–6 months after surgery, 2 patients (5.9%) in Group II were diagnosed with unilateral rupture of a non-absorbable suture due to a sudden fall from a ladder (*n*=1) or a fall from a height (*n*=1), that led to migration of the suture fixing element (a 10 mm×10 mm titanium implant) into the perineal subcutaneous tissue, causing a pain syndrome that required minor surgery such as removal of the suture fixing element. No further recurrence of POP was reported.

Later, these findings led to the replacement of non-absorbable sutures with narrow (4 mm) titanium mesh tape implants, which are characterized by significant strength. The proximal ends of the titanium endoprostheses were bilaterally fixed to the distal lateral parts of the rectangular titanium mesh implant, the cervix and vagina or the vaginal vault after hysterectomy with separate non-resorbable sutures, the peripheral ends were placed transobturatorically and brought out into the inguinal folds on the right and left, pulled up, fixed, and the excess parts were cut off above the skin level.

The examination and long-term postoperative follow-up concluded that the proposed treatment options for total uterine or vaginal vault prolapse after hysterectomy in elderly and senile patients are highly reliable, making it possible to minimize or even eliminate the risk of disease recurrence.

CONCLUSION

Our results demonstrated the efficacy and reliability of the proposed surgical treatment options for total uterine and vaginal vault prolapse after hysterectomy in elderly and senile patients. Our clinical experience shows that severe POP in elderly patients with medical comorbidities can be successfully treated with surgery, relieving women of a variety of symptoms associated with the disease and normalizing pelvic organ function. The clinical implementation of such surgeries will improve the quality of life of elderly and senile patients.

ADDITIONAL INFO

Authors' contribution. A.I. Ishchenko invented and implemented new surgical treatment methods; Yu.V. Chushkov designed the work, wrote the manuscript; A.A. Ishchenko implemented surgical treatment methods; I.D. Khokhlova edited the manuscript; T.A. Dzhibladze edited the manuscript; E.G. Tevlina implemented surgical treatment methods; A.D. Komarova collected and reviewed literature data; A.P. Moskvicheva collected and reviewed literature data; A.D. Koryagina collected and reviewed literature data, D.V. Baburin — article editing. All authors confirm that their authorship meets the international ICMJE criteria (all authors have made a significant contribution to the development of the concept, research and preparation of the article, read and approved the final version before publication).

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