Short Communications

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Radical Trachelectomy Using A Titanium-Nickelide Metal Tricotage Implant to Preserve Fertility in Cervical Cancer Patients

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Abstract

Objective: Among malignant neoplasms of the female reproductive system, cervical cancer traditionally occupies a leading position in terms of both morbidity and mortality. Traditional surgical treatment of early-stage cervical cancer leads to satisfactory oncological results, but irreversibly reduces the fertility in this category of patients. The aim of this work was to evaluate the applicability of a metal-ceramic implant with shape memory made of titanium nickelide for the purpose of forming uterine closure and strengthening the anastomosis zone. **Methods:** A total of 168 untreated patients with cervical cancer underwent radical trachelectomy with reinforcement of the utero-vaginal anastomosis using a titanium-nickelide shape memory implant. The fertility of women after organ-preserving treatment was evaluated. Thirty-nine pregnancies were registered**. Results:** Currently, 28 healthy children have been born. Two patients gave birth twice, one woman gave birth to twins. In addition, 2 miscarriages were registered at 7 and 19 weeks, 7 patients terminated pregnancy for social reasons at early stages, 2 patients are currently pregnant, at 24 and 32 weeks. The median follow-up for this category of patients is 89±9.6 months. Eight relapses were registered at various follow-up periods with the localization of the relapse mainly in the area of the anastomosis and iliac vessels. Analysis of menstrual function showed that the duration of the menstrual cycle after surgical treatment in the volume of radical trachelectomy was 29±4.7 days and did not differ significantly from the indicators before the operation. The duration of menstruation also did not differ significantly before and after surgical treatment. **Conclusion:** Improvement of the method of organ-preserving surgical treatment by radical trachelectomy with the formation of the uterine locking apparatus using titanium-nickelide metal tricotage contributes to the improvement of reproductive results without compromising oncological effectiveness.

Keywords: Cervical cancer- radical trachelectomy- titanium-nickelide metal tricotage implant- fertility

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Introduction

Malignant neoplasms of the organs of the female reproductive system have the largest share (more than 40%) in the structure of oncologic pathology in women [1, 2]. Cervical cancer traditionally occupies the leading position in terms of morbidity, second only to breast cancer and uterine body cancer [2, 3]. In 2023, 15986 new verified cases of cervical cancer were registered in the Russian Federation. The average age of cervical cancer patients is 52 years, however, in recent years there has been an increasing prevalence of this pathology among women under 35 years of age. This trend is characteristic not only for Russia, but also for the world [2, 3]. These circumstances explain not only the medical but also the social side of the problem, especially given the widespread use of delayed childbearing in the modern world. All these aspects dictate the need to develop new and improve existing techniques for organ-preserving treatment of invasive cervical cancer [4].

Wide cone cervical resection with cervical scraping is one of them. However, this method of organ-preserving treatment has a significant limitation, namely FIGO stage IA1. Thus, patients with deeper invasion of cervical cancer have long been forced to receive surgical treatment in the volume of uterine extirpation with appendages (or without appendages), which, along with the radicality of the treatment and satisfactory oncologic results, undoubtedly leads to irreversible loss of fertility [4, 5]. The rarity of ovarian lesions and tumor spread directly

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to the uterine body prompted the development of such a method of organ-preserving treatment of invasive cervical cancer as radical trachelectomy. The essence of radical trachelectomy is the complete removal of the cervix with perineal tissue, the upper third of the vagina and pelvic lymph nodes. In this case, the ovaries, fallopian tubes and uterine body with the internal pharynx remain surgically intact, which ensures the possibility of subsequent pregnancy and childbirth [6].

In 1994, D. Dargent et al. first described the results of treatment of a small group of patients who underwent radical vaginal trachelectomy with satisfactory oncologic results. Then A. L. Smith and L. Ungär proposed to perform radical trachelectomy using abdominal access, believing that this option is technically simpler [7]. At the same time, the first positive reproductive results were obtained - successful cases of pregnancy and delivery [8].

The first radical trachelectomy was performed in Russia in 2005 [9] and criteria for selection of patients for this intervention were formulated: reproductive age, desire to preserve fertility, stage 1A1 with invasion into the lymphovascular space, stages 1A2 and 1B1 less than 4 cm, histologic variant (squamous cell cancer or adenocarcinoma), intact upper third of the cervical canal, no signs of metastatic involvement of regional lymph nodes, no signs of infertility, possibility of dynamic follow-up [10].

Our group has quite a lot of experience in performing this type of surgical treatment (since 2010) for cervical cancer [6]. To improve oncologic and reproductive results of organ-preserving treatment of cervical cancer, we made a number of modifications described below.

As is known, the cervix acts as a uterine locking apparatus during pregnancy and contributes to the favorable carrying and development of the fetus in the uterine cavity. Radical trachelectomy involves removal of the cervix and formation of utero-vaginal anastomosis. In the absence of a full-fledged uterine closure apparatus, the developing fetal bladder (amniotic sac) will inevitably prolapse into the vagina with subsequent traumatization of its membranes and infection, leading to miscarriage. To solve this problem, cervical serclage using various materials is used, but the effectiveness of this method is rather low, and the list of possible complications is very high: infection, ligature fistulas, threads cutting through, etc. [10]. Moreover, we developed a method of strengthening the formed uterine-vaginal anastomosis using a metal-tricotage implant made of titanium nickelide. In particular, immediately after suturing the uterine-vaginal anastomosis with a continuous thread, this area was strengthened from the outside with a mesh implant with the size of mesh cells from 3 to 5 mm, width 40-50 mm and length 70-80 mm, woven in the form of a stocking from superelastic nickelide-titanium threads with the diameter of 60-40 microns with the subsequent fixation with separate sutures along the perimeter (Figure 1, 2). It should be noted that the size of the metal knitted implant does not prevent its passage through trocars, which allows using this technique through laparoscopic access.

The aim of this work was to evaluate the applicability of a metal-ceramic implant with shape memory made of titanium nickelide for the purpose of forming the uterine closure and strengthening the anastomosis zone.

Materials and Methods

The use of this implant showed good tolerability and absence of perioperative complications. Our study on the evaluation of the anastomosis zone showed that epithelization of the utero-vaginal anastomosis zone was noted on average by 12 weeks, and full integration of the implant into the surrounding tissues occurs in 5-6 months. One of the positive features is that subsequently, the metal-tricotage implant does not interfere with ultrasound monitoring during dynamic follow-up of the patient, and the weak radiopaque contrast properties allow computed tomography and magnetic resonance imaging studies with minimal artifacts [11]. Thus, we can conclude that the use of metal-tricotage implant made of titanium nickelide in patients with cervical cancer of reproductive age is quite effective; its use allows a woman to bear a child independently until late term and subsequently give birth

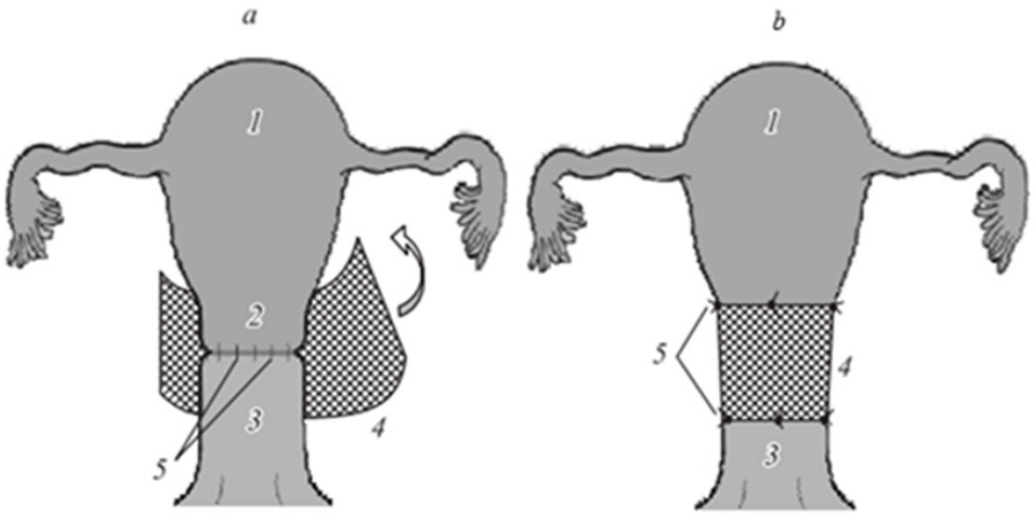

Figure 1. Schematic Representation of the Area of Implant Attachment and Fixation before (a) and after its reinforcement (b): 1- uterine body, 2- cervical canal, 3 - vagina, 4 - mesh implant, 5 - sutures. The cervix has been removed.

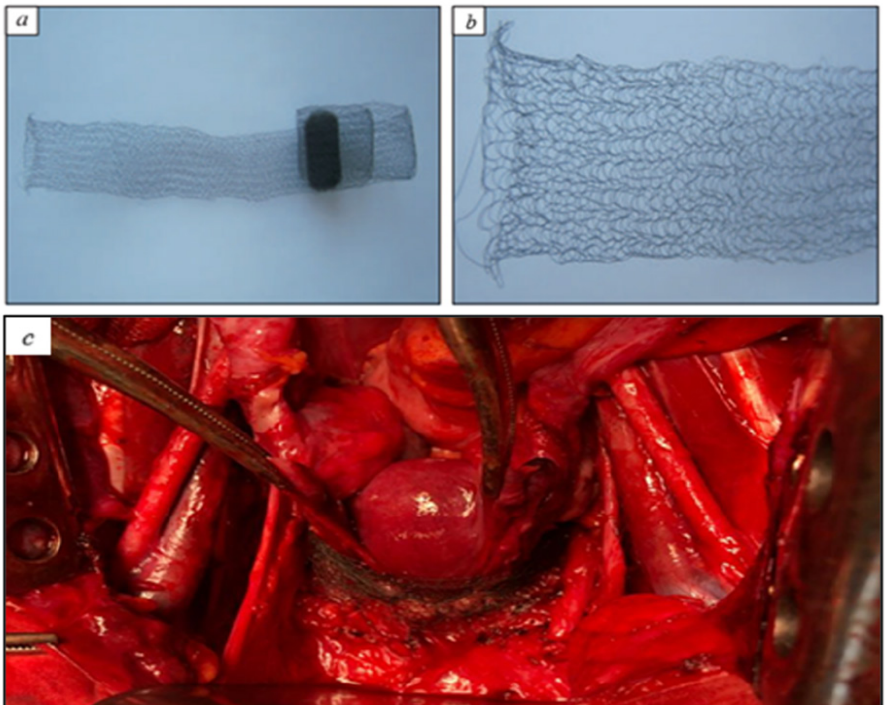

Figure 2. Metal Knitted Titanium Nickelide Implant: Diameter of the Stocking Thread 60-40 μm, Cell Size 6-7 mm(a), diameter of the stocking thread 20 μm, cell size 4-5 mm (b), intraoperative view of utero-vaginal anastomosis reinforced with a titanium nickelide metal-tricotage implant (c).

to a child by cesarean section.

Results

We performed 168 operations, 72 of which were performed by transabdominal access and 96 by laparoscopic access. Initially 81 cervical cancer patients (48%) did not have children before treatment, more than half of the patients had a history of abortions and spontaneous miscarriages, in 9 cases there was an ectopic pregnancy. Of the total number of patients treated, 102 (61%) retained their reproductive intentions. Among the reasons for abandoning further plans to have children were fear for their own and their child's health after treatment, lack of a sexual partner, and social factors. Thirty-nine pregnancies were registered, of which 4 were achieved through assisted reproductive technology procedures (3 due to male factor infertility and 1 due to infertility of unclear genesis), the rest were natural. At present, 28 healthy children have been born. Two patients gave birth twice, one woman gave birth to twins. In addition, 2 miscarriages were registered at 7 and 19 weeks, 7 patients terminated pregnancy for social reasons at low term, 2 patients are currently pregnant at 24 and 32 weeks.

The study of oncological effectiveness showed that the median observation period for this category of patients was 89±9.6 months. Eight relapses were registered at different observation periods, localized mainly in the area of anastomoses and iliac vessels. These indicators are consistent with the results of a number of studies and do not differ from survival rates in radical organ-preserving surgeries [12-14].

Discussion

It is known that the percentage of miscarriages after radical trachelectomy is up to 40% due to the absence of the cervix [15, 16]. In our work, miscarriages were recorded only in 2 cases in women against the background of high stress. Such encouraging results are probably associated with the fairly high efficiency of the implant with shape memory. Another serious complication of radical trachelectomy is stenosis of the internal os. According to literary data, this complication occurs in 18-32% [15, 16], however, in this study, such a complication was not recorded.

Thus, the data obtained show great prospects for improving organ-preserving treatment in gynecologic oncology, and the relevance of practical application of the technique of uterine closure formation using a metal-tricotage implant made of titanium nickelide is unconditional. Summarizing the results, we can unequivocally conclude that this category of patients should be managed in close consolidation of obstetrician-gynecologists, oncologists, psychologists and reproductologists in order to solve the issues of how to achieve and carry a pregnancy in each individual case.

Author Contribution Statement

Conceptualization, A. Ch; methodology, M.K., A.C, J.T. and E.M.; investigation, M.K., J.T., E.M.; data curation, A.Ch.; writing-original draft preparation, A.Ch.; writing-review and editing, A.Ch. and S.T.; supervision, A. Ch. All authors have read and agreed to the published version of the manuscript.

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Approval

The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Local Ethics Committee of the Cancer Research Institute of Tomsk National Research Medical Center (protocol N4 from 12 July 2010). Informed consent was obtained from all subjects involved in the study.

Conflict of Interest

The authors declare no conflicts of interest.

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