BIOELECTRIC STIMULATION OF THE ANTERIOR ABDOMINAL WALL IN EARLY PREVENTION OF POSTOPERATIVE ADHESIVE PROCESS IN THE ABDOMINAL CAVITY AND ITS INTRODUCTION INTO CLINICAL PRACTICE (DESIGN OF THE STUDY)

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Introduction: Adhesive disease and its complications remain in the focus of the medical interest. The incidence of intraabdominal adhesions varies from 67% to 93% after abdominal surgery and almost 97% after gynecological surgery [1-3].

Standart treatment algorithms commonly are related to the risk of the development of pathological adhesion during the postoperative period. Surgical adhesiolysis is the method of choice, but rate of the relapse is about 32-71%.

Development of new approaches can significantly improve results of abdominal surgeries in the postoperative period. Furthermore, it may benefit to health care system by reducing cost-related treatment, length of hospital stay, frequency of re-operations and mortality, as well as improving patients' quality of life. Medical and social rehabilitation is aimed to prevent visceroparietal adhesions showing a 4-fold reduction in postoperative complications, a 2-fold reduction in mortality and 4.5-fold reduction in poor results in the remote postoperative period [4-8].

The study is aimed at studying of the use of bioelectric stimulations of the anterior abdominal wall for the prevention of adhesions after abdominal surgery as an alternative treatment in clinical practice in patients in postoperative period. The proposed treatment approach is non-invasive. Additionally, bioelectric stimulations of the anterior abdominal wall in early abdominal adhesion prevention was studied in animals. It is expected to evaluate positive effect of the bioelectric stimulation on the prophylaxis of the formation of the postoperative adhesion.

Objectives

1. To determine morphologic characteristics of the postoperative adhesion formation in experimental study.
2. To develop anti-adhesion device (PSA-1) to study methods of its application in early adhesion prevention.

3. To assess morphologic and morphometric characteristics of the adhesion formation and its relapse frequency on the background of usage of the anti-adhesion device in experimental study.

4. To assess development of the postoperative adhesion process in abdominal cavity on the background of usage of the anti-adhesion device in clinical study.

5. To develop a methodology of early postoperative adhesion prevention in clinical practice.

**Materials and methods:** Design of the study will include 2 parts: experimental, pathomorphological and clinical part [8-17].

1. **Experimental and pathomorphological part:**

   90 rabbits aged from 24 to 36 months, weighing 4-5 kg are expected to be included into the experimental part. Rabbits will be housed in Vivarium of B. Atchabarov Research Institute. Animals will be fed following the standard laboratory diet in accordance to “Rules for Preclinical Research, Medical and Biological Experiments and Clinical Trials in the Republic of Kazakhstan” (July 25, 2007 No. 442). All manipulations on lab animals will be carried out in compliance of the Helsinki Declaration for the Protection of Vertebrates used for Experiments and Other Scientific Purposes (1975 and its revised version of 2008).

   Lab animals will be used for modeling of adhesive disease. Mid-laparotomy and deserializing of the cecum with a gauze cloth and thermal drying will be used to induce formation of the adhesion. Results will be assessed on 3, 7, 14, and 21 days after the adhesion modeling. Lab animals will be randomly divided into 3 groups:

   - 1st group - control (n = 10);
   - 2nd group - experimental №1 (n = 40);
   - 3rd group - experimental №2 (n = 40).

   The control group will be on a standard diet and maintenance. The experimental group №1 will be exposed to anti-adhesive device using the Almabayev method (Adhesive disease prevention method // Almabaev YI, et al., 2015 / 0395.1 // IPKA61N1 / 36, 2003). The 3rd group will be administered anti-adhesive drug «Mesogel» with Verbitskaya method and in accordance its protocol (Clinical testing of an anti-adhesive resorbable, sterile gel, OOO “Linteks”, St. Petersburg) [23].
The next methods will be used for evaluation of the effectiveness of the approaches:

- Laboratory assessments. Blood and urine analysis, electrolytes, biochemical compounds (total protein, blood glucose, alkaline phosphatase, urea, prothrombin). Blood sampling will be performed according to standard rules of venipuncture from the ear vein. The urine collection will be performed by bladder catheterization.

- Electrogastroenterography (EGEG) will be used to assess the functional status of the gastrointestinal tract. Sablin method was used for EGEG (O.A. Sablin, 2002; V.V. Balykina, 2000; J. Chen, R.W.M.D. McCallum, 1993).

- Dynamic observations will be carried out using diagnostic laparoscopy. “Endomedium”, Russia, was used as laparoscopic stand. Veress needle will be used for pneumoperitoneum (Certificate of Conformity No. POCC RU 0001.11IM18).

- Morphological assessments. Morphological type of each detected adhesion and adhesion formation level will be determined using Whang method\textsuperscript{[24]}. Standard methods for morphological studies were used. The sample dyeing will be carried out using the hematoxylin-eosin dyes. The histological assessment included protocols, animal autopsy with a detailed description of peritoneal cavity, microscopic examination of the intestine. Samples will be fixed in 10% formalin solution, and further go through paraffin to get sliced sections of tissues up to 8 microns, assessed with Digital Microscope Leica DM1000.

2. Clinical part.

Clinical part will be carried out at the #7 Almaty Clinical Hospital. The main inclusion criteria will be as follows: abdominal surgeries and informed consent. Participants will be divided into 2 groups \textsuperscript{[18-22]}:

- 1st group - cases (n = 120 participants);
- 2nd group - control (n = 60 participants).

Exclusion criteria will be as follows: Patients age under 18 and over 60 years; vulnerable population; absence of factors causing adhesion formation; no informed consent; pregnancy; heart pacemaker.

Each participant will be assigned a serial number on his/her medical record and then randomized. Standard clinical examination (main complaints, disease history, physical examination, lab assessment including the laboratory and instrumental methods such as ultrasound and radiography of the peritoneal cavity organs) will be used at the primary stage.

The case group will be exposed to anti-adhesion device after the surgery to prevent adhesion formation. Electric stimulation was conducted for the first 3 days after the surgery. 4 procedures a day were conducted on the first day, 3 procedures – on the 2nd, 2 procedures – on the 3rd (duration of the procedure was 3 hours, the procedure time and amount were justified by experimental research on lab animals).

Evaluation of the effectiveness of the anti-adhesive device will be determined by EGEG and the early intestinal movements, defication and gas signs. The control group had standard care and observation.

**Results:** The expected result of the project will be the invention of the anti-adhesion device for early adhesion prevention and its introduction into clinical trials to advance post-surgical results performed on peritoneal cavity organs. The novel device will reduce cost-related treatment by shortening the length of hospital stay. Furthermore, it improves patients’ quality of life by reducing the frequency of adhesion-related re-operations and complications.

Based on the research findings of the anti-adhesion device, we will submit an application for National Center for Expertise and Certification approval required for clinical application of medical devices in Kazakhstan (the Law of the Republic of Kazakhstan “On Licensing” with amendments and additions September 29, 2014).

**References:**


6. Филенко В.П., Землянков В.П., Борск И.Л., Иванов А.С. Спаечная болезнь: профилактика и лечение. Монография. Санкт-Петербург. 2013.– 171


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