აპენდიციტის მეტად იშვიათი გართულების მაგალითია. 78 წლის ქალს მწვავე განგრენული აპენდიციტის გამო სასწრაფოდ გაუკეთდა ოპერაცია ლაპაროსკოპიულად. ნეკროზული ფასციიტი იმთავითვე დიაგნოსტირებული არ იყო. ნეკროზული ფასციიტი დიაგნოსტირდა ოპერაციიდან 10 საათის შემდეგ. პაციენტს ჩაუტარდა მარჯვენა ბარძაყის და ქვედა ფეხის ფლეგმონის გაკვეთა, მარჯვენა რეტროპერიტონეული სივრცის რევიზია. შემდგომ ჩატარდა ჩირქოვანი კერების სანაცია და ქირურგიული მკურნალობა. მიუხედავად ინტენსიური თერაპიის განყოფილებაში ჩატარებული კომპლექსური მკურნალობისა ფართო სპექტრის ანტიბიოტიკების გამოყენებით, დაავადება პროგრესირდა, განვითარდა მარჯვენა ქვედა კიდურის სველი განგრენა. პაციენტს ჩაუტარდა ამპუტაცია მარჯვენა ბარძაყის ზედა მესამედის დონეზე. დაავადება გართულდა სეფსისით, სეპტიური შოკით, ორმხრივი პნევმონიით, პოლიორგანული უკმარისობით და ცერებრული შეშუპებით. ჰოსპიტალიზაციიდან მე-8 დღეს დადგა ლეტალური შედეგი.

აღწერილი კლინიკური შემთხვევა ადასტურებს მწვავე ფასციიტის ადრეული დიაგნოსტიკის მნიშვნელობას მკურნალობის ოპტიმალური შედეგების მისაღწევად.

EVALUATION OF NOVEL PORCINE PERICARDIAL BIOMATERIAL FOR VENTRAL AND INGUINAL HERNIA REPAIR. THE RESULTS OF A NON-RANDOMIZED CLINICAL TRIAL

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More than 20 million hernias are estimated to be repaired every year around the world [1]. Per year, approximately 700,000 hernia repairs are carried out in the USA [2]. Currently, surgery possesses huge arsenal of various surgical methods of ventral and inguinal hernia repair. Recently, usage of meshes created from various synthetic and biological materials have become quite popular in the herniology.

There are many types of meshes and multiple methods of their placement during the hernia repair. Meshes vary by their origin (synthetic, biologic, composite), absorbability, pore size, weight (light- and heavyweight), elasticity and mesh durability [3-7].

The vast majority of synthetic meshes are made from polypropylene (PP), polytetrafluorethylene (PTFE), prolene dacron, orlon, mylar. There are different situations in which a surgeon must make a decision about what type of a mesh to use. For example, in a case of infected ventral hernia, generally, absorbable synthetic meshes are used, however, since they are absorbed, recurrence rate is very high and additional surgical intervention is needed to achieve permanent repair [5,8]. PTFE and PP are the most common meshes used to repair large ventral hernias [9,10]. However, when the macroporous meshes are placed so that they come in contact with abdominal viscera, they are associated with the development of bowel adhesions, obstructions, and enterocutaneous fistulae. Polytetrafluoroethylene (PTFE) meshes can lead to the development of encapsulation, collection of periprosthetic fluid, and excessive growth of bacteria [11].

Despite the fact, that there are vast number of synthetic and composite meshes from which you could pick an individual treatment method, complications are still a major problem. As it is reported in the manuscript, ventral hernia repair with prosthetic mesh has recurrence rates up to 54% and is contraindicated in the setting of infection [12].

The complications include post-operative pain and movement restriction, recurrence, adhesions, calcification, mesh migration and seroma. Chronic post-operative pain develops often in patients who underwent either open or laparoscopic ventral hernia repair, regardless of fixation type. Studies claim, that 26 to 34% of the patients reported chronic discomfort due to pain [13,14].

Recurrence of ventral hernia is still a major challenge in VH repair. Even though, the rate of recurrence has decreased from 50% to 10-23% after meshes were introduced, it still is quite frequent and traumatic experience for patients, since there is need for additional surgical interventions, which are performed in case of relapse of the disease [15-17]. Although, studies suggest, that VH recurrence can almost be eliminated by utilizing underlay technique, this method increases risk of adhesions, which are discussed below [17,18].

Adhesions are generally associated with intraperitoneal underlay technique, during which the mesh has direct contact with bowel. Increased risk of adhesions has been associated with macroporous structure of the mesh [19]. Incidence of unplanned surgical intervention done due to adhesions and enterocutaneous fistulas after ventral hernia is about 4% [20].

Calcification is a result of prolonged foreign body reaction, which may develop to certain meshes and, in the end, may result in generating chronic pain [21, 22].

Seroma are relatively minor complication of hernia and they typically develop with any type of a mesh. However, it is well known, that meshes with larger pores are less likely to lead to seroma. Overall incidence of seromas is 2% and they commonly resolve without any intervention after 6-8 weeks [23].

Migration is another severe complication, during which mesh may migrate into organs such as urinary bladder, sigmoid colon, hollow viscus, spleen, and it may cause respective discomfort, depending where mesh migrates into [24-27].

Also, in the cases when the wounds are heavily contaminated, prosthetic meshes are frequently considered to be contraindicated due to the high risk of infection. Additionally, prosthetic meshes are associated with the development of erosions adhesions, and chronic pain in the abdominal viscera. In the cases when the wounds are contaminated the mesh representing a biological tissue matrix (BTM) can be an alternative to synthetic mesh the use of which is related to the ability of the material to tolerate cutaneous exposure and withstand placement into a contaminated defect [28-35].

The aim of this study was to provide preliminary results of a non-randomized clinical trials evaluation of XI-S+® porcine pericardial biomaterial (Colorado Therapeutics LLC. USA) for ventral and inguinal hernia repair.

Material and methods. All patients signed written informed consent for the study, which was conducted according to the guidelines of the 1975 Declaration of Helsinki and approved by the Ethics Committee of the Tbilisi State Medical University, Tbilisi, Georgia.

Inclusion criteria were the following: M/F ≥ 21 years of age, negative for pregnancy, no known allergic reaction to porcine, IC signed, and candidates for open procedure. Exclusion criteria: lactating women, not available for follow-up, severe malnutrition, use of investigational agent, known malignancy, life expectancy ≤ two years, clinical symptoms of infected hernia site, or evidence of contaminated or clean contaminated fields, ascites, preexisting liver disease, immune compromised subjects, morbid obese, BMI ≥35, and diabetic subjects, insulin dependent.

Operative procedure. Ventral hernia repair in ten patients consisted of a midline laparotomy or through the old incision, which was removed. The fascial edges were trimmed to healthy tissue and the hernia sac excised. Hernia hilus was then closed by suturing the right and left side of the aponeurosis of external abdominal oblique muscle together. The sutures were done by 2-0 Prolene thread. Then, the onlay technique was performed with the XI-S+® mesh which was sutured by multiple simple interrupted sutures with 2-0 Prolene thread. One silicon surgical drain was placed above the mesh. The skin was sutured with 2-0 prolene thread.

Inguinal hernia repair in ten patients were done in the following fashion. After incising the skin, subcutaneous tissue, and external oblique aponeurosis, the hernial sac was identified, adhesions were removed and the sac excised according to standard Lichtenstein tension-free method. XI-S+® mesh (6 × 15 CM) was trimmed to fit individual patient inguinal canal floor. The mesh was then anchored to the conjoined tendon by simple interrupted sutures (Prolene 2–0). The skin was sutured with 2-0 prolene thread.

The mean hospital stay duration post-operatively was 2 days. The patients was followed up during the postoperative visits at the following time points: 1 week, 1 month, 3 months, 5 months, 12 months, 1 year, 2 years and 3 years. At each post-operative visit and at the initial preoperative evaluation and screening, to assess the quality of life changes related to the hernia and hernia repair procedure patients were given a copy of the Carolinas Comfort Scale (CCS). CCS itself allows us to evaluate quality of life in three areas: pain, sensation of mesh, movement limitations.

Results and discussion. The average age of the patients with ventral hernia was 54±1.4 years, and 30% of patients were female and 70% of patients were male. The average age of the patients with inguinal hernia was 62.5±9.4 years, and 10% of patients were female and 90% of patients were male. The average hospitalization length was 2 days. Table 1and 2 lists patient demographics and operative details. All patients that were enrolled into the study had primary hernias. Results of Carolina Comfort Scale survey for all the patients are depicted in Table 3 and 4.

Table 1. Ventral hernia repair patient characteristics and operative details

Ventral Hernia					
Variable	**Mean**	**SD**	**Median**	**Minimum**	**Maximum**
Age (years)	53.3	12.7	5.8	24	70
BMI (kg/m^2)	27.9	3.9	29.4	21.4	34.8
Fascial defect size (cm^2)	30.7	13.8	30	12	60
Mesh size (cm^2)	90	0	90	90	90
Incision length (cm)	14.2	4.8	12	10	20
Lengsh of stay (days)	2.6	0.5	3	2	3
Operative time (min)	75.4	27.3	70	40	135

Table 2. Inguinal hernia repair patient characteristics and operative details

Inguinal Hernia					
Variable	**Mean**	**SD**	**Median**	**Minimum**	**Maximum**
Age (years)	53.6	9	61	49	77
BMI (kg/m^2)	25.8	2.5	25.7	22.4	31.1
Fascial defect size (cm^2)	34.2	24.4	20	12	80
Mesh size (cm^2)	59.2	24.5	72	30	90
Incision length (cm)	5.9	0.9	6	5	8
Lengsh of stay (days)	2.1	0.3	2	2	3
Operative time (min)	51	4.6	50	45	55

Table 3. Mean Carolinas Comfort Scale Scores with Change (Ventral Hernia)

	Baseline	1 Week	1 Month	3 Months	5 Months	1 Year	2 Years	3 Years
N	10	10	10	10	10	10	10	10
Pain	1.27	0.84	0.09	0.06	0	0	0	0
Sensation of mesh	N/A	0.25	0.29	0.01	0.01	0	0	0
Movement limitation	1.60	0.85	0.10	0.03	0.02	0	0	0

Table 4. Mean Carolinas Comfort Scale Scores with Change (Inguinal Hernia)

	Baseline	1 Week	1 Month	3 Months	5 Months	1 Year	2 Years	3 Years
N	10	10	10	10	10	10	10	10
Pain	1.2	1.6	0.2	0	0	0	0	0
Sensation of mesh	N/A	0	0	0	0	0	0	0
Movement limitation	1.3	1.5	0.4	0	0	0	0	0

The XI-S+® mesh was used for all surgeries. It provided secure and adequate overlap in the periphery of each fascial defect; minimal mesh overlap was defined as not less than 3 cm by the study criteria.

Biologic mesh materials derived from human and animal donor source are based on a matrix of proteins, including collagen, elastin, glycoproteins and growth factors. They represent so-called ‘‘third-generation’’ mesh which provides ingrowth of host cells and generates “tissue-mesh” composite for replace the tissue in the hernia defect [36, 37].

The literature widely highlights issues of related to the use of such biologic mesh like human acellular dermis [38-40], porcine-derived acellular dermal matrix [41-43}, porcine small intestine submucosa [44-47], bovine pericardium [48-50].

The pivotal part of achieving permanent hernia repair is vascularization and remodelling, which, in contrast to synthetic materials, biologic materials can be subjected to [51].

Decellularized human dermal tissue was really popular and promising upon introduction, however, long-term follow-up studies showed very high rate of recurrent herniation, eventration and low long-term durability [52,53].

Porcine small intestinal submucosa tissue has widely been tested and studied and many authors suggest that it could cause tissue rejection [54]. While other studies claim, that severe tissue rejection decreased durability, it is frequently infected with B hemolytic Streptococcus [55, 56]. Authors also state, that it is durable, when it is not infected, however, it does not hold up well in contaminated areas [51,57].

Decellularized porcine dermal tissue was tested in animal and clinical trials, It has been proven that adhesions to intestinal segment is significantly lower than in synthetic materials, although, recurrences are at peak when it is bridged over hernia defect [51].

Studies claim, that decellularized bovine pericardium is a far superior biologic material, as it is as durable as synthetic material, has minimal adhesion rate, it is easy to suture and its structure remains consistent [58,59].

We have chosen XI-S+® for study because it is a novel mesh produced from porcine pericardial sac with a new method and similar to decellularized bovine pericardium shows tremendous promise since it has high durability, ability of remodeling and vascularization.

The clinical studies have shown that almost in all patients the post-operative pain was minimal and easily controlled by the use of single analgesics. In the immediate post-operative period we had 5 complications; 3 ventral and 1 inguinal hernia repair patient had seroma. 2 inguinal hernia repair patient had hematoma and testicular swelling occurred in 1 patients. We have not observed abscess formation or acute infection related to the presence of XI-S+® mesh.

We suppose that hematoma must have been linked to surgical procedure. In case of seroma, we think that it must be linked to the fixation of mesh, during which a closed environment (sac) between the mesh and the host tissue has been created and inflammatory cells were trapped, which led to the formation of seroma. With short-term and long-term (more than three years) observation, there were no recurrences of hernia.

Carolinas comfort scale surveys were successfully completed by all patients on 1st week, 1st, 3rd, 5th and 12th months, and 2nd and 3rd years of follow-up visits. In all patients, both with ventral and inguinal hernias, the feeling of relief was evident starting from the 1st week after surgery. After 1 month from surgery, the level of discomfort in patients has been significantly decreased, and after 3 months, it has been practically non-existent. As for the sensation of the mesh, in some patients it has been present up until 1 month after the surgery, but it fully disappeared by the end of the 3rd month.

In our opinion, it is very interesting to analyze the level of discomfort in patients depending on their type of activeness. Various conclusions can be made from the results. For example, one week after surgery, pain syndrome has been increased only in the cases of ventral hernias when the patient was lying down and bending over, it stayed the same when the patient was sitting up, and the pain syndrome has been deceased in all other cases. After 1 week from surgery, the biggest discomfort has been caused while the patient was coughing or deep breathing in ventral cases, and for the inguinal cases – while the patient was sitting up. After 1 month from surgery, pain syndrome has been still present while the patient was sitting up, performing activities of daily living and coughing or deep breathing, and for the ventral cases - additionally when the patient was bending over or walking. It has to be underlined that all pain sensations have been gone after 3 months from surgery.

Studies have shown that the XI-S+® mesh possesses homogenous (multidirectional) elasticity that causes minimal shrinkage after the implantation and its structure significantly increases hydrophilic features which provide a better adhesion and cell proliferation on its surface. Soft and elastic structure of XI-S+® mesh fully covers large surfaces in the cases of ventral post-

operative hernias, it ensures fast and quality formation of the "mesh-tissue" complex, which enables the creation of the thick layer of biological tissue on the basis of somewhat scaffold, which itself provides resilience of the anterior abdominal wall.

XI-S+® mesh possesses anti-adhesion features that prevent the formation of adhesions between the host tissue and the implanted mesh. Additionally, the mesh is extremely resistant to an infection that allows its use in patients with incarcerated hernias with infected wounds. XI-S+® mesh provides the favorable conditions for engraftment, early activity and rehabilitation of patient.

Conclusion. The clinical studies of the patients that underwent ventral and inguinal hernia repair using XI-S+® mesh have shown that the post-operative pain was minimal and easily controlled by the use of analgesics. As for the sensation of the mesh, in some patients it has been present up until 1 month from surgery, but it fully disappeared by the end of the 3rd month.

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SUMMARY

EVALUATION OF NOVEL PORCINE PERICARDIAL BIOMATERIAL FOR VENTRAL AND INGUINAL HERNIA REPAIR. THE RESULTS OF A NON-RANDOMIZED CLINICAL TRIAL

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Using the mesh for hernia repair is the most common type of hernia surgery. There are many types of meshes made of various synthetic materials, but all of these meshes have their own respective disadvantages. The aim of this study was to provide preliminary results of a non-randomized clinical trial evaluation of novel porcine grafts XI-S+® (Colorado Therapeutics LLC. USA) for ventral and inguinal hernia repair.

All patients underwent a standardized surgical procedure. Onlay surgical repair technique has been performed in ten patients with ventral hernia and Lichtenstein tension-free method has been used for ten patients with inguinal hernia repair. The XI-S+® mesh fixation was performed with multiple simple interrupted sutures using prolene thread.

The average age of the patients with ventral hernia was 54±14 years, and 30% of patients were female and 70% of patients were male. The average age of the patients with inguinal hernia was 62.5±9.4 years, and 10% of patients were female and 90% of patients were male. The average hospitalization length was 2 days. During three years of observation, no recurrence of hernia

was observed in patients. The XI-S + ® mesh has anti-adhesive properties, is extremely resistant to infections, provides favorable conditions for engraftment, early activity and patient rehabilitation.

The clinical studies of the patients that underwent ventral and inguinal hernia repair using XI-S+® mesh have shown that the post-operative pain was minimal and easily controlled by the use of analgesics. As for the sensation of the mesh, in some patients it has been present up until 1 month from surgery, but it fully disappeared by the end of the 3rd month.

Keywords: ventral hernia repair; inguinal hernia repair; biological mesh.

РЕЗЮМЕ

ОЦЕНКА НОВОГО БИОМАТЕРИАЛА СВИНОГО ПЕРИКАРДА ДЛЯ ПЛАСТИКИ ВЕНТРАЛЬНОЙ И ПАХОВОЙ ГРЫЖ. РЕЗУЛЬТАТЫ НЕРАНДОМИЗИРОВАННОГО КЛИНИЧЕСКОГО ИССЛЕДОВАНИЯ

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В хирургии грыж часто используются сетчатые имплантаты, которые изготовлены из различных синтетических материалов. Однако, большинство из них вызывают различные послеоперационные осложнения.

Целью исследования явилось представить предварительные результаты нерандомизированного клинического исследования новых биологических имплантатов XI-S+® (Colorado Therapeutics LLC. США) для пластики вентральной и паховой грыж. Всем пациентам проведена стандартная хирургическая процедура. Техника хирургической пластики Onlay выполнена у десяти пациентов с вентральной грыжей, а метод без натяжения по Лихтенштейну использован у десяти пациентов с пластикой паховой грыжи. Фиксация имплантата выполнялась простыми узловыми швами с использованием проленовой нити.

Средний возраст пациентов с вентральной грыжей составил 54±14 лет, из них 30% пациентов составили женщины, 70% пациентов - мужчины. Средний возраст пациентов с паховой грыжей составил 62,5±9,4 года, из них 10% пациентов составляли женщины, а 90% пациентов - мужчины. Средняя продолжительность госпитализации составила 2 дня. Обследования по шкале комфорта Carolinas успешно завершены всеми пациентами спустя 1 неделю, 1, 3, 5, 12 месяцев, 2 и 3 года последующих посещений. Почти у всех пациентов, как с вентральными, так и с паховыми грыжами, чувство облегчения проявлялось уже спустя 1 неделю после операции. Спустя 1 месяц после операции уровень дискомфорта у пациентов значительно снизился, а спустя 3 месяца практически исчез. Сетка XI-S+® обладает антиадгезионными свойствами, чрезвычайно устойчива к инфекциям, обеспечивает благоприятные условия для приживления, ранней активности и реабилитации пациента. В течение трех лет наблюдения рецидивов грыжи у пациентов не наблюдалось.

Клинические исследования пациентов, перенесших пластику вентральной и паховой грыжи с использованием сетки XI-S + ®, показали, что послеоперационная боль была минимальной и легко контролировалась с помощью анальгетиков. Что касается ощущения сетки, то у некоторых пациентов она сохранялась до 1 месяца после операции, но полностью исчезла к концу 3 месяца.

რეზიუმე

ღორის პერიკარდიუმისგან მიღებული ახალი ბიომასალის შეფასება ვენტრალური და საზარდულის თიაქრების დროს. არარანდომიზებული კლინიკური კვლევის შედეგები

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თბილისის სახელმწიფო სამედიცინო უნივერსიტეტი, საქართველო

თიაქრების სამკურნალოდ ქირურგიული ბადეები საკმაოდ ხშირად გამოიყენება. არსებობს უამრავი სინთეტიკური ბადეების ნაირსახეობა, რომელთაც აქვთ სხვადასხვა გართულებები.

კვლევის მიზანს წარმოადგენდა ღორის პერიკარდიუმისგან მიღებული ახალი მასალის XI-S+® (Colorado Therapeutics LLC. USA) შეფასება ვენტრალური და საზარდულის თიაქრების დროს არარანდომიზირებული კლინიკური კვლევის წინასწარი შედეგების სახით.

ათივე ვენტრალური თიაქრის მქონე პაციენტს ჩაუტარდა სტანდარტული ქირურგიული პროცედურა Onlay ტექნიკის გამოყენებით, ხოლო 10 პაციენტს საზარდულის თიაქრით ჩაუტარდა ოპერაცია Lichtenstein tension-free მეთოდის გამოყენებით. XI-S+® ბადე დაფიქსირდა რამოდენიმე პროლენის უწყვეტი ნაკერის საშუალებით.

ვენტრალური თიაქრების მქონე პაციენტების საშუალო ასაკი იყო 62.5±9.4 წ. ამ პაციენტების 10% იყო მდედრობითი და 90% მამრობითი სქესის. საზარდულის თიაქრის მქონე პაციენტების საშუალო ასაკი წარმოადგენდა 54±14 წელს. ამ პაციენტების 30% იყო მდედრობითი და 70% მამრობითი სქესის. ჰოსპიტალიზაციის საშუალო ხანგრძლივობა შეადგენდა 2 დღეს. 3 წლიანი დაკვირვების შედეგად არცერთ პაციენტში თიაქრის რეციდივი არ აღინიშნა. XI-S+® ბადეს გააჩნია ანტიადჰეზიური თვისებები, არის ინფექციებისადმი რეზისტენტული, ქმნის ხელსაყრელ პირობებს შეხორცებისათვის, ადრეული აქტივობის დაწყებისა და პაციენტის სრული რეაბილიტაციისთვის.

ვენტრალური და საზარდულის თიაქრებით პაციენტებში ჩატარებულ კლინიკურ კვლევაში, მკურნალობის მიზნით გამოყენებულმა XI-S+® ბადემ აჩვენა, რომ პოსტოპერაციული ტკივილი იყო მინიმალური და მარტივად ექვემდებარებოდა ანალგეტიკებს. ბადის მგრძნობელობა ერთი თვის განმავლობაში შენარჩუნებული იყო რამოდენიმე პაციენტში, ხოლო მესამე თვის ბოლოს აღარ აღინიშნებოდა არცერთ პაციენტში.