THE USE OF IMPLANTS FOR SURGICAL TREATMENT OF CONGENITAL DIAPHRAGMATIC HERNIA IN NEWBORNS

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Congenital diaphragmatic hernia (CDH) is an absolute indication for surgical treatment. In case of extensive defects of the diaphragm, such as diaphragmatic aplasia, the use of implants is required. So far, there is no unanimous opinion on the type of the implant. The article presents a comparative analysis of treatment of 40 newborns with left pseuso-CDH. All patients received thoracoscopic repair of the diaphragmatic cupula. The patients were divided into two groups according to the type of the implant: 16 newborns received Ecoflon synthetic implants (Ecoflon Scientific and Production Complex, Russia) and 24 newborns received Permacol biologic implants (Tissue Science Laboratories, UK). The study demonstrated the advantage of the biologic implant over the synthetic one: the surgery took less time (106 minutes compared to 144 minutes with Ecoflon, $p < 0.05$); relapses were also more rare (28 % and 54 %, respectively; however, p was >0.05); no implant rejection was observed (with Ecoflon, two patients responded with inflammation, $p < 0.05$).

Keywords: newborns, congenital diaphragmatic hernia, thoracoscopy, implant, implant materials, Ecoflon, Permacol

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ПРИМЕНЕНИЕ ИМПЛАНТОВ В КОРРЕКЦИИ ДИАФРАГМАЛЬНОЙ ГРЫЖИ У НОВОРОЖДЕННЫХ

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Врожденная диафрагмальная грыжа (ВДГ) — патология, которая требует обязательной хирургической коррекции. При значительных дефектах диафрагмы, например аплазии ее купола, зачастую возникает необходимость в использовании имплантационных материалов. До сих пор нет единой точки зрения по вопросу выбора импланта. В статье представлены результаты сравнительного анализа лечения новорожденных (n = 40) с левосторонней ложной ВДГ. Всем пациентам была выполнена торакоскопическая пластика купола дифрагмы. По типу использованного имплантационного материала детей разделили на две группы: для первой (n = 16) применяли синтетические импланты «Экофлон» («НПК "Экофлон"», Россия), для второй (n = 24) — биологические импланты Permacol (Tissue Science Laboratories, Великобритания). Результаты исследования показали преимущества биологического импланта: время операции при его использовании было меньше (106 мин против 144 мин при использовании «Экофлона», $p < 0,05$); число рецидивов — также меньше (28 % против 54 %, однако $p > 0,05$); случаев отторжения импланта не было (при использовании «Экофлона» у двух пациентов началось воспаление, $p < 0,05$).

Ключевые слова: новорожденные, врожденная диафрагмальная грыжа, торакоскопия, имплант, имплантационный материал, «Экофлон», Permacol

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Congenital diaphragmatic hernia (CDH) is a potentially fatal malformation that leads to death without surgical treatment. For effective diagnostics and management of various pathologies in newborns with low weight and narrow chest, advanced video equipment and tools for mini-invasive surgery have been introduced. However, many issues of CDH treatment are still a matter of discussion, such as criteria for selecting a particular surgical technique, indications for endoscopic surgery and a surgery type, especially in the case of extensive defects of the diaphragm, and the choice of patch type if a patient does not

have sufficient tissue for grafting. The vast clinical experience of the medical institution is often the key to an adequate solution.

Surgical treatment of CDH is aimed to close the diaphragmatic defect by bringing its edges together and fixing them with interrupted sutures. Difficulties may arise if the defect is large (e.g. diaphragmatic aplasia) and the edges cannot be brought together even after the posterior leaf has been mobilized. In this case, patch repair is indicated [1–8]. The research [9] showed that in infants with diaphragm aplasia the postoperative survival rate was 57 %, compared to the survival rate of 95 % in patients with smaller defects.

We have analyzed a number of studies [3, 4, 6, 8] on primary repair of the diaphragm in infants with diaphragmatic aplasia and discovered that the most frequently used types of patches were synthetic non-absorbable patches; biological and composite non-absorbable materials were the second most frequent type. Generally, the highest relapse rate was seen in patients with biological implants (approximately 30 % of cases), however, with the other two types of materials it was almost the same (approximately 26 %). More significant differences were seen between the implants produced by different manufacturers [5, 9, 13].

The aim of our research was to compare the efficacy of the synthetic implant Ecoflon (Ecoflon Scientific and Production Complex, Russia) and the biological implant Permacol (Tissue Science Laboratories, UK) in the surgical treatment of congenital diaphragmatic hernia in newborns.

METHODS

The study included 40 neonates with left pseudo-CDH treated in N. F. Filatov Pediatric City Hospital No. 13, Moscow, Russia, from 2008 to 2015. All children received thoracoscopic repair of the diaphragmatic cupula with implants. Depending on the type of material, the neonates were divided into two groups: group 1 included 16 children who received the Ecoflon implant, and group 2 included 24 children who received the Permacol implant. All children were born full-term, with an average body weight of more than 3 kg. Further details are given in table 1. No statistically significant intergroup differences were revealed. Comorbidities were mainly congenital heart defects and genetic syndromes (Edwards syndrome in three cases and Patau syndrome in one case); extrapulmonary sequestration was observed in one patient from group 2.

All children received thoracoscopic repair of the diaphragmatic cupula with implants. The surgery was performed after stabilization of the general condition of the neonates.

The patient was placed in the right lateral decubitus postition on the operating table. The surgeon and the assistant stood at the patient's head, the monitor was located opposite. The reconstruction of the diaphragm was performed using three trocars (3 and 4 mm in diameter). CO_2 pressure in the pleural space was maintained at 3–7 mmHg, CO_2 flow rate was 1–2 l/min. The trocars were placed through the following portals: the endoscopic portal in the third intercostal space along the midaxillary line; the instrumentation portals in the third or fourth intercostal space along the posterior axillary line and in the third intercostal space along the anterior axillary line. After the examination of the pleural cavity, the abdominal organs were successively brought down into the abdominal cavity. The edges of the diaphragm were mobilized on the perimeter of the defect, thorough mobilization of the rear lip off the upper pole of the left kidney and the retroperitoneal space was conducted. After the retained muscular tissue of the diaphragm was brought together, interrupted suturing without tension was applied. A patch was formed from the implantation material corresponding to the size of the defect. Finally, drainage of the pleural space was performed. All children had postoperative prolonged mechanical ventilation (MV) until their cardio-respiratory function was normalized and spontaneous breathing was recovered.

The implant materials had to meet a number of specific requirements: they should be durable and flexible, have good modeling properties, be resistant to the liquid environments of the body and infections, non-responsive, hypoallergenic, and non-cancerogenic.

The synthetic material Ecoflon (Fig. 1) was first used in 2008 for thoracoscopic repair of extensive defects of the diaphragm. It is polytetrafluoroethylene-based and has a special nodular fibrillar structure with considerable porosity (up to 90 %). Ecoflon implants are flexible, elastic, and resistant to bending, twisting and external squeezing in unfavorable anatomical conditions. There are two functionally different surfaces: a microporous surface that prevents the formation of adhesions, and a macroporous surface that initiates the growth and development of fibroblasts. The disadvantages of the material include its relative susceptibility to infection, which is associated with multifilament and microporous components that cover bacterial agents. The Ecoflon implant is 1 mm thick. After an Ecoflon patch was formed, it was introduced through the wound and fixed along the perimeter of the defect with interrupted sutures with the microporous side facing the abdominal cavity. The surgical knots were tied extracorporeally.

The biological material Permacol (Fig. 2) has been successfully used since 2012. This implant is made of pig skin and is basically a pure cross-linked collagen and elastin free of cellular structures and fatty tissue. This material does not have any antigenic properties and induces minimal inflammatory response that is no different from the normal reparative process. The collagen fibers form the framework for the reparative tissues and vascularization. Due to its cross-linked structure, it is resistant to tissue and bacterial enzymes,

Table 1. Comparative characteristics of newborns with congenital diaphragmatic hernia

Index	Group 1 (n = 16)	Group 2 (n = 24)	P-value
Sex, m/f	10/6	10/14	–
Gestational age, weeks (min; max)	38.1 ± 2.4 (33.0; 41.0)	38.8 ± 0.8 (37.0; 41.0)	p >0.05
Birth weight, g	2880.0 ± 645.0 (1950.0; 4300.0)	3378.1 ± 473.0 (2580.0; 4600.0)	p >0.05
Age at the time of surgery, days	2.7 ± 1.8 (1.0; 7.0)	4.0 ± 1.4 (1.0; 9.0)	p >0.05
Comorbidities	3 (19 %)	6 (25 %)	p >0.05
Antenatal diagnosis	13 (81 %)	20 (83 %)	p >0.05

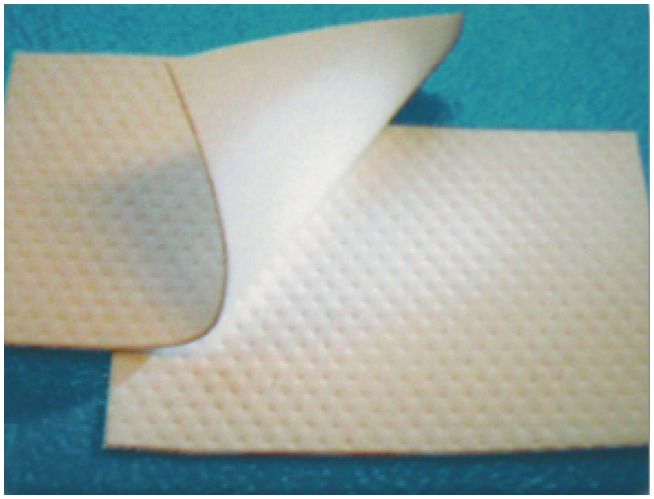

Fig. 1. Synthetic implant material Ecoflon (Ecoflon Scientific and Production Complex, Russia)

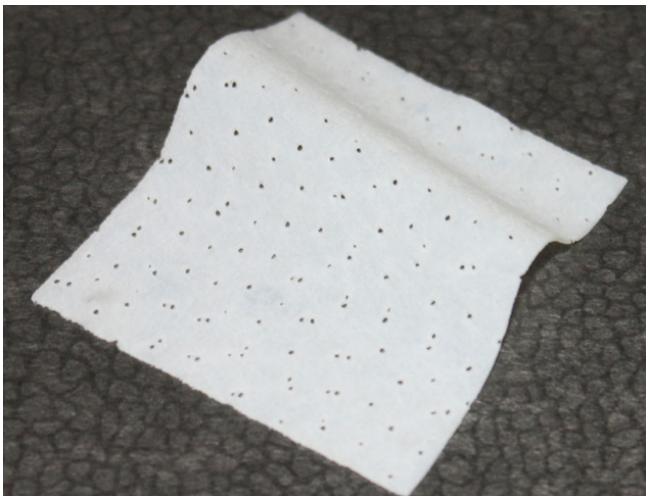

Fig. 2. Biological implant material Permacol (Tissue Science Laboratories, UK)

therefore, it is non-resorbable, non-deformable, and ensures the continuous strengthening of soft tissues without causing adhesions. Permacol does not stimulate suppuration and can be used in patients with controlled infections or at high risk of surgical site infections. The material thickness is 0.5 mm. The implant was introduced through the right trocar portal. Then its edges were sutured to the retained muscular rims, the anterior, medial and posterior regions of the diaphragmatic cupula with interrupted sutures. In the absence of a muscular layer, the lateral part of the defect was sutured to the chest wall with full-thickness sutures.

The following parameters were analyzed: surgery duration, location of the liver in the pleural space, MV duration and the number of cases when high-frequency MV (HF MV) was used, hydrothorax duration and the number of chylothoraces, the onset of enteral feeding and the number of cases of gastroesophageal reflux (GER), the frequency of relapses and implant rejection, and also the number of deaths.

Patients with chylothorax received the antisecretory drug Sandostatin (Novartis Pharma, Switzerland) intravenously. The starting dose was 80 mg/kg a day; the maximum dose was 120 mg/kg a day. Treatment duration was determined individually for each patient.

In patients with GER laparoscopic Nissen fundoplication was performed.

Recurrent congenital diaphragmatic hernia is clinically manifested through progressing respiratory distress and dysphagia. However, in order to detect asymptomatic relapses, control chest X-rays were performed in all patients 1, 3, 6 and 12 months after surgery. In doubtful cases, multislice helical computed tomography of the abdominal and thoracic cavities was performed. Once the diagnosis was confirmed, revision surgery was performed.

The C-reactive protein and white blood cell count were used as inflammation markers.

Parents gave written informed consent.

RESULTS

The surgical treatment results are presented in table 2.

Fixation of synthetic implants took longer than preparation of a biologic patch: mean time was 144 and 106 min, respectively ($p < 0.05$). The presence of the left lobe of the liver in the left hemithorax indicates the severity of the diaphragmatic defect corresponding to subtotal or total aplasia. Severe defects were more frequent in group 2 than in group 1, but differences were not statistically significant.

The mean duration of MV in both groups was almost the same. However, patients in group 2 required HF MV more often compared to group 1, which indicated a more severe cardio-respiratory dysfunction. However, the intergroup difference in this parameter was not statistically significant — perhaps, due to a moderate sample size.

One of the postoperative complications is chylothorax. In patients with congenital diaphragmatic hernia, chylothorax is thought to be the result of increased superior vena cava pressure in the presence of concomitant pulmonary hypertension. Another hypothesis is that chylothorax is a response to inflammation. In any case, chylothorax is preceded by hydrothorax, whose duration depends on the degree of pulmonary hypoplasia. The average duration of hydrothorax and the number of chylothoraces were similar in both groups. However, only one patient from Group 1 required Sandostatin therapy for over 3 weeks, while in group 2 there were 3 such patients.

An important indicator of a normal postoperative period was the start of enteral feeding and baby's ability to consume the amount of food normal for his/her age. As shown in table 2, enteral feeding started much earlier for the patients in group 2 compared to the patients in group 1: in average, on day 6 and 12, respectively ($p < 0.05$). One of the possible causes here was the absence of inflammation revealed by the blood test.

Gastroesophageal reflux is caused by the dilation of the esophageal hiatus after the reconstruction of the diaphragmatic cupula. This complication was seen in both groups with almost equal frequency: 4 and 5 cases in group 1 and group 2, respectively ($p < 0.05$). Our study showed that GER occurring after diaphragm repair is resistant to standard treatment and requires surgical correction.

Relapses were observed in 6 cases (54 %) in group 1 and in 5 cases (29 %) in group 2, but the difference was not statistically significant. In group 1 an infectious complication was detected in 2 patients: patch rejection was observed 2 and 3 months after surgery. The rejection manifested clinically as granuloma formation on the lateral surface of the chest in the site of the full-thickness suturing. Removal of granulomas and ligatures was performed for both patients, but the inflammatory process persisted, which determined the necessity of surgical intervention. Through the incision on the chest it was revealed that the bottom of the fistula channel was the implant.

Table 2. Results of thoracoscopic repair of congenital diaphragmatic hernia in newborns using Ecoflon and Permacol implants

Index	Group 1 (n = 16)	Group 2 (n = 24)	P-value
Intraoperative characteristics			
Duration of surgery, min (min; max)	**144 ± 28 (100; 180)**	**106 ± 10 (95; 126)**	p <0.05
Location of the liver in the pleural cavity	4 (25 %)	8 (33 %)	p >0.05
Characteristics of respiratory intensive care			
Duration of MV, days (min; max)	15.4 ± 8.8 (4.0; 46.0)	16.0 ± 7.4 (6.0; 42.0)	p >0.05
Number of cases of HF MV	2 (12 %)	8 (33 %)	p >0.05
Characteristics of hydro- and chylothorax			
Duration of hydrothorax, days (min; max)	14.6 ± 2.8 (4.0; 27.0)	14.7 ± 2.8 (4.0; 37.0)	p >0.05
Number of cases of chylothorax	4 (25 %)	5 (21 %)	p >0.05
Characteristics of enteral status			
Onset of enteral feeding, days after surgery (min; max)	**12.9 ± 2.0 (2.0; 15.0)**	**5.1 ± 2 (2.0; 11.0)**	p <0.05
Number of cases of gastroesophageal reflux	4 (25 %)	5 (21 %)	p >0.05
Characteristics of implant condition			
Number of relapses	6 (54 %)	5 (29 %)	p >0.05
Number of cases of implant rejection	2 (12 %)	0	p <0.05
Survival rate			
Number of deaths	5 (31 %)	7 (29 %)	p >0.05

The latter was freely removed from the chest cavity. No changes in the implant material were identified macroscopically.

Death occurred in 13 cases: 5 (31 %) patients in group 1 and 7 (29 %) patients in group 2 (p >0.05). The lack of statistically significant differences demonstrates that postoperative lethality was not caused by the diaphragmatic defect, but resulted from severe cardio-respiratory dysfunctions and intractable pulmonary hypertension, i. e. was a consequence of pulmonary hypoplasia and the severe cardio-respiratory pathology resistant to any therapy.

DISCUSSION

The Permacol implant allows for shorter surgery time since it can be introduced into the thorax through the trocar channel without removing the trocar. Given that Ecoflon is thicker and has less compressibility, one of the operation trocars must be removed to extend the incision at the site of the trocar placement; next, the implant must be placed into the pleural cavity and after that the trocar can be re-introduced. Another factor influencing the duration of the surgery is the process of the implant fixation. Specifically, Ecoflon must be positioned with the macroporous surface facing the chest and the microporous surface facing the abdominal cavity, while both Permacol surfaces are identical and their position is irrelevant for fixation. Another technical difficulty in fixing Ecoflon is its ability to absorb light making it hard to determine how accurate the implant is fixed to the edges of the diaphragmatic defect.

Nowadays, various types of implant materials are used for correction of major defects of the diaphragm [11, 13, 14]. However, the survival rate of newborns with this pathology is low, so it is very difficult to compare the results of treatment by the type of the implant. Nevertheless, scientific research in this field yields important results. Thus, the guide of Molloy [11] presents the scientific analysis of the use of implant materials of various types and the experimental data. Also, the advantages of biologic implants have been shown: they ensure better tissue regeneration than synthetic implants and do not cause inflammation. Some publications report recurrent congenital diaphragmatic hernia when prostheses are used for its repair. Riehle et al. [8] conducted a number of studies using the Gore-Tex/Marlex implant and observed a relapse in only one of 28 patients, i. e. in 3.6 % cases. At the same time, Mitchell et al. [10] conducted a comparative analysis of efficacy of repair with Gore-Tex and Permacol implants and reported relapses in 8 of 29 patients (28 %) who had received the implanted Gore-Tex, and zero relapses in all 8 patients with the implanted Permacol. Grethel et al. [4] also conducted a comparative analysis of efficacy of repair with synthetic and biologic implants. Their study showed that after Gore-Tex implantation, relapses occurred in 17 of 57 patients, while after Surgisis (a bioactive material) repair, relapses occurred in 12 of 27 patients.

Thus, currently there is no consensus on the use of implant materials. However, most authors believe that the use of biological materials is more promising because the latter are better integrated into the patient's own tissues and do not cause inflammatory response, which depends not only on the properties of the material, but also on the specific aspects of conservative therapy in the postoperative period.

CONCLUSIONS

Our study has found no statistically significant differences between the synthetic implant material Ecoflon and the biological implant material Permacol with regard to the survival rate, the number of relapses and the occurrence of gastro-esophageal reflux. However, Permacol is more beneficial for patients with extensive defects of the diaphragmatic cupula: it allows for shorter surgery time and earlier enteral feeding and causes no inflammatory response.

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