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COMPARATIVE ANALYSIS OF VARIOUS TYPES OF IMPLANTS FOR THE CORRECTION OF EXTENSIVE DIAPHRAGMATIC DEFECTS

ABSTRACT

The study reports the results of the comparative analysis of treatment of patients with congenital diaphragmatic hernia (CDH), performed between 2008 and 2015. The surgery was performed on 169 newborns at the Filatov Hospital in Moscow. Diaphragmatic plastic was performed mainly using thoracoscopy and in most cases the defects were corrected using the patient's own tissues. In cases where it proved impossible to fully correct a defect by the patient's own tissues, implant materials were utilized. Thoracoscopic diaphragmatic dome plastic procedure involving a use of the implant material was performed on 42 children. We conducted a comparative analysis across the surgeries using synthetic and biological implants. The research showed the benefits of the biological implant. Using that type of material allows the surgeon to achieve correction of CDH in aplasia of the dome of the diaphragm; the follow-up with patients confirmed that the results were maintained over the long term.

Keywords: congenital diaphragmatic hernia, implants, newborns, malformation, thoracoscopy.

INTRODUCTION

Congenital diaphragmatic hernia (CDH) belongs to a type of malformations in compatible with life in absence of surgical correction. Lately, we have been seeing the increase in promise of mini-invasive surgery in newborns, but at the same time, a number of questions in treatment of CDH remains unresolved. Thus, more research is required to significantly improve the outcomes of diagnosis and treatment of congenital malformations in children. However, the extant literature focuses on the description of individual cases of treatment of newborns with CDH by endoscopic approach, which limit our understanding of the way to properly select the method of surgical intervention, and the feasibility of performing endoscopic surgery for large diaphragm defects. To date, neither the indications, nor the technique of endoscopic treatment, nor the types of prosthetic materials for infants with large defects of dome have been fully discussed. Reliable conclusions can only be drawn on the basis of many years of observations of the outcomes of treatment of this pathology, while other variables (e.g., a specific medical facility) being held constant.

Objective - to examine the results of using different types of implants in the correction of congenital diaphragmatic hernia in newborns.

MATERIALS AND METHODS

Between 2008 and 2016169 newborns with CDH were admitted to the Filatov Hospital in Moscow. Thoracoscopic diaphragmatic dome plastic surgery was performed on 42 children, using implant materials. Two comparative groups were created according to the type of implant material. The first group was made up of 14 (33%) newborns with CDH who were operated using synthetic material Ecoflon. The second group included 28 (67%) newborns that were operated by using of biological material Permacol. All children were full-term with the average body weight more than 3 kg. In most cases included congenital heart diseases, genetic malformations and extra pulmonary sequestration in one case from the second group (table 1).

Ecoflon synthetic material in Russia was created based on polytetrafluoroethylene by specialists of the Scientific-production complex «Ecoflon». First it was applied in 2008 for thoracoscopic access. The thickness of the implant is 1 mm, and it has two functionally different surfaces: microporous surface prevents the formation of adhesions with abdominal viscera and macroporous surface which initiates growth and development of fibroblasts (Fig. 1). The patch was immersed to the pleural cavity through a slit in a spot fixing of one of the trocars; the patch was fixed along the perimeter of the defect by interrupted stitch.

The biological material «Permacol» (porcine dermal collagen; Tissue Science Laboratories, Great Britain), which was used for the defect closure for the patients in the second group. It is made of pig skin, and representsa pure cross-linked collagen and elastin devoid of cellular structures and adipose tissue. The implant was first used in clinic in 2012. The material thickness is 0.5 mm. According to the manufacturer, this material does not have any antigenic properties. The collagen fibers are the framework for vascularization and germination by recipient tissues (Fig. 2). The implant patch was immersed through the channel of the trocar, fixed by interrupted stitch to the diaphragm, the lateral part of the defect, in the absence of the muscular layer, was fixed with single through stiches to the chest wall.

In the postoperative period the variables measured included: the duration of artificial lung ventilation (ALV), the duration of the hydrothorax, cases of chylothorax, start time of enteral load, cases of gastro-esophageal reflux (GERD), cases of relapse of CDH and the number of fatalities (table 2).

RESEARCH RESULTS

Comparative analysis of the intraoperative data patterns during endoscopic surgeries shows the advantages of using Permacol implant in reducing time of the operation. This is explained by the fact that this type of implant is inserted into the chest through the trocar channel. Considering that Ecoflon is thicker and has a lower compressibility, one of the working trocars needs to be removed to place it into the pleural cavity. The other factor that affects the time of the operation is the process of fixing the implant. Ecoflon has to be installed with the macroporous surface facing the thorax and the microporous one facing the abdominal cavity. At the same time Permacol has uniform surfaces and therefore it does not matter which side is facing the thorax of the abdominal cavity. From technical perspective Ecoflon's ability to absorb light create certain difficulties in visualization during the fixation of the implant.

During the postoperative care, all children received artificial lung ventilation before normalizing the cardio-respiratory

Table 1

Comparative characteristics of children with CDH

	1-st group (n = 14)	2-nd group (n = 28)	p-value
Sex (male/female)	8/6	12/16	-
Gestational age (weeks)	38,1±2,44 (min 33-max 41)	38,8±0,83 (min 37 – max 41)	p>0,05
Birth weight (g)	2880±645 (min 1950 – max 4300)	3378,1±473 (min 2580 – max 4600 г)	p>0,05
Age at the time of the operation (days)	2,7±1,84 (min1 – max7)	4±1,37 (min1-max9)	p>0,05
Comorbidity	3 (19)	6 (25)	p>0,05
Antenatal diagnosis	13 (81)	20 (83)	p>0,05

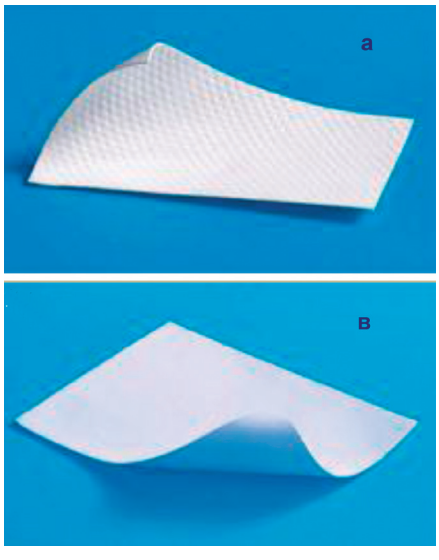

Figure 1 a, в Synthetic implant «Ecoflon», Russia (a – macroporous surface, b - microporous surface)

status and restoring independent breathing (Table 2). The average duration of the artificial lung ventilation in both groups had approximately the same duration. However, for the patients of the second group high-frequency artificial lung ventilation was more common, which indicates a more severe cardio-respiratory status.

One of the complications of the postoperative period is a chylothorax. One of the drivers of that complication could be a pressure increase in the system of the superior vena cava due to

Figure 2. Biological implant Permacol (Tissue science laboratories, UK)

high pulmonary hypertension. The other possibility is to view chylothorax as a response to the inflammatory process. In any case, the predecessor of chylothorax is hydrothorax, the duration of which depends on the degree of hypoplasia of the lung tissue. Comparative analysis (Table 2) revealed that in the early postoperative period chylothorax occurred in two groups with the same frequency. In all cases, chylothorx treatment was started with the conservative therapy. It should be noted that for patients of the second group in three cases (12%) the duration of the drug administration was more than 3 weeks, where as in the first group only one patient (6%) required a 3-week injection of sandostatin.

An important indicator of the postoperative treatment of patients with the congenital diaphragmatic hernia (CDH) is the onset of enteral load and the ability to feed a child with age-appropriate volumes. Data of the Table 2 testify that the patients of the second group started enteral feeding significantly earlier than patients of the first group. One of the possible explanations was lack of the inflammation markers in the laboratory results.

Gastroesophageal reflux (GERD) occurs as a result of stretching of the esophageal hiatus while performing the plastic dome. This complication occurs with the same frequency across both groups. Our study showed that GERD that happens after the plastic repair of the hiatus is tolerant and requires surgical correction, and patients undergo the laparoscopic Nissen fundoplication.

The technique of suturing when closing the defect of the diaphragm did not radically change in the transition to endoscopic methods of correcting the congenital diaphragmatic hernia, although certain difficulties may arise when there is a considerable tension or a pronounced deficit of the diaphragm's own tissue. In such cases a thorough dissection of the existing muscle rolls, due to which an additional mobility of the dome is created during the child growth, is necessary. The problem of diaphragm rupture at the place of suturing and the occurrence of replaces has not lost its relevance though. Another problem that can arise from the implanted material side is the infection in the area of the through-seams. Comparative results of

Table 2

Comparative results of treatment children with CDH using implants «Ecoflon» and «Permacol»

	1-st group (n = 14)	2-nd group (n = 28)	P-value
Operation time (min.)	144 ± 28 (min 100 - max180)	106±10 (min 95 – max 126)	p<0,05
Duration of mechanical ventilation (hours)	15,4±8,8 (min 4 – max46)	16 ± 7,4 (min 6 – max 42)	p>0,05
High-frequency oscillatory artificial ventilation (patients)	2 (4,7)	8 (19)	p>0,05
Duration of hydrothorax (hours)	14,6±2,8 (min 4 – max 27)	14,7±2,8 (min 4 – max 37)	p>0,05
Chylothorax (patients)	4 (9,5)	5 (11,9)	p>0,05
Enteral loading (days)	12,9 ± 2 (min 2 – max 15)	5,1 ± 2 (min 2 – max 11)	p<0,05
Gastroesophageal reflux (patients)	4 (9,5)	7 (16,6)	p>0,05
Recurrence (patients)	6 (14,2)	6 (14,2)	p>0,05
Implant rejection (patients)	2 (4,7)	0	p<0,05
Mortality	5 (11,9)	7 (16,6)	p>0,05

the condition of implanted materials of our patients are shown in Table 2. Clinically, the relapse of CDH was indicated by an increase in respiratory failure and symptoms of dysphagia. However, for the purpose of monitoring and detecting relapses that are not accompanied by clinical symptoms, all patients underwent chest X-ray examinations at 1, 3, 6, and 12 months. In doubtful cases, multispiral computer tomography of the abdominal and thoracic cavities was also performed. To confirm the diagnosis repeated surgery was performed. As can be seen from the table, there is no statistical difference in the incidence rate of relapse of the disease depending on the implant material. In the first group of patient infectious complications were revealed in 2 cases. A rejection reaction was noted after 2 and 3 months after the plastic repair of the diaphragm. Clinically, it was manifested by the appearance of granuloma on the lateral surface of the chest in the place of application of the through-seam. Both children had granuloma and ligature removed, but the inflammatory process persisted, which then became an indication for the surgery. During the examination through the incision in the thorax, it was revealed that the bottom of the fistula was an implant. The latter was removed without hindrance from the chest cavity. Macroscopically, no changes in the material were detected.

The main result of the treatment of patients with CDH is a discharge from the hospital. To date there is still no 100% survival rate with such pathology (Table 2).

Fatal outcome was observed in 15 newborns. As can be seen in Table 2, there is no statistical difference in the lethal case incidence between the types of the implanted materials. This once again shows that the postoperative lethality is caused by the presence of a defect in the diaphragm, and the severe cardio-respiratory status of these patients, not suppressed by pulmonary hypertension, as a result of lung hypoplasia and the onset of a general infection.

DISCUSSION

The situation where CDH is in the closure of the diaphragm defect presents a particular challenge for the surgeon. The greatest difficulty with the plastic procedure occurs with aplasia dome of the diaphragm [1]. Nowadays thoracoscopy is a preferred solution, but there are several issues in the treatment of children with aplasia of the dome of the diaphragm. Selection criteria for neonatal endoscopic surgery was proposed in the research of Okazaki T.: location of stomach and liver in the pleural cavity; absence ofhiatal hernia; assisted ALV with pressure of the breath not more than 24 mm Hg. St.; stable cardiopulmonary status for 10 minutes in sideways position [5]. According to other authors, despite the progress of minimally invasive surgery, the best surgical way for CDH remains laparotomy, considering the recurrence rate of CDH is higher with endoscopic procedures [5]. The paper by P. Szavay [6] reported a significant number of recurrences after thoracoscopic treatment (5 of 21; 23.8 per cent). According to other authors, relapse in the treatment of CDH in newborns remain at the level of 26,3%[4,12]. Research by K. Tsao discussed the data of 93 health centres, where the recurrence rate was 2.9% (126 out of 4390 patients) [7]. A high percentage of relapse was observed in the group of children who were operated by thoracoscopic access [2].

The problem of choice of method to close the defect of the diaphragm with a lack of its own tissues still remains [3]. The analysis application of implant materials in primary plastic aplasia dome of diaphragm in children [4] shows that synthetic absorbable materials was used in 62,1%cases, biological - 25,9%, not absorbable composite materials - 11,7%. Synthetic material GoreTex® implant and biological Surgisis® (68%) were applied most frequently. Using composite absorbable implants led to recurrence (relapse) in 100% of cases [4]. Biological materials caused recurrences in 30.9% of cases, Permacol™ material had the smallest number of relapses (11.1%) identified in the diaphragmatic plastic. But according to most authors, despite of the results of the experimental researches, the main complication in use of biological implants in practice is an infection, inflammation of the soft tissues in implantation area [4]. This is probably caused not only by material properties but also by characteristics of conservative therapy in the postoperative period.

CONCLUSIONS

1. Thus, several observed variables, such as survival, number of relapses and occurrence of gastro-esophageal reflux, have not revealed statistically significant differences in the use of synthetic or biological implants.

2. Analysis of data showed the advantages of a biological implant «Permacol» over synthetic material «Ecoflon» performing the surgery of large defects of the dome of the diaphragm such as reduced operating time, reduced time before enteral load and the lack of inflammatory changes by the implant.

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