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Thoracoscopic clipping of patent ductus arteriosus: position of surgery in the era of transcatheter procedures

A.N. ARKHIPOV, A.YU. OMELCHENKO, A.V. ZUBRITSKIY, T.S. KHAPAEV, I.A. SOYNOV, S.M. IVANTSOV, P.M. PAVLUSHIN, A.V. BOGACHEV-PROKOPHIEV, A.M. KARASKOV

Meshalkin National Medical Research Center of Healthcare Ministry of the Russian Federation, Novosibirsk, Russia

ABSTRACT

Aim — to describe single-center evolution of the procedure and to evaluate the results of thoracoscopic clipping of patent ductus arteriosus (PDA) with diameter over 3,0 mm in term infants weighting over 4,0 kg.

Material and methods. Thoracoscopic clipping of PDA has been performed in 140 patients for the period from March 2012 to March 2018 in Meshalkin National Medical Research Center. Mean age was 4.0 years (range 3 months — 13 years), mean body mass index — 15.4±2.2 кг/м^2. Inclusion criteria: PDA size 3.5—10 mm, Qp/Qs >1,3/1,0, weight 4.0—40 kg. Mean PDA size was 4.6±0.9 mm (range 3.5—8.0 mm), mean pulmonary artery pressure — 34.3±5.8 mm Hg, mean systemic/pulmonary flow Qp/Qs — 1.6±0.3. All patients underwent successful PDA closure through four-port technique under endotracheal general anesthesia and no need for pleural drainage.

Results. Mean procedure time was 24.5±15.5 min. In 29 (20,7%) cases we used titanium clips, in 11 (79.3%) — polymer locking ligating clips. There was 1 conversion to mini-thoracotomy. There were no deaths, bleeding or any other life-threatening complications. 94 (67.1%) patients were weaned from ventilator within operating theatre, in other 46 (32.9%) patients mean ventilation time in ICU was 1.3±1.0 hours. In-hospital postoperative complications: pneumothorax — 2 (1.4%) cases, recurrent laryngeal nerve dysfunction — 1 (0.7%), false croup — 1 (0.7%). There were 2 residual leakages in 2 (1.4%) patients in 10 and 6 months after titanium clip deployment. Both of them underwent transcatheter closure using the coil. Considering these cases all following patients underwent PDA closure by polymer locking ligating clips with no cases of residual leakage.

Conclusion. Thoracoscopic PDA closure by polymer locking ligating clip is safe and effective technique for surgical management of PDA with diameter over 3.0 mm in term infants weighting over 4.0 kg.

Keywords: congenital heart disease, patent ductus arteriosus, thoracoscopic clipping, minimally invasive surgery.

INFORMATION ABOUT THE AUTHOR

Arkhipov AN — https://orcid.org/0000-0003-3234-5436
Omelchenko AYu — https://orcid.org/0000-0001-9564-755X
Zubritskiy AV — https://orcid.org/0000-0003-4666-2571
Khapaev TS — https://orcid.org/0000-0002-9765-0282
Soynov IA — https://orcid.org/0000-0003-3691-2848
Ivantsov SM — https://orcid.org/0000-0002-8715-0778
Pavlushin PM — https://orcid.org/0000-0002-6684-5423
Bogachev-Prokophiev AV — https://orcid.org/0000-0003-4625-4631
Karaskov AM — https://orcid.org/0000-0001-8900-8524

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Patent ductus arteriosus (PDA) is one of the most common congenital heart defects with an incidence 0.87 per 1000 live newborns and observed in 30% of low-weight (<1500 g) premature babies [1]. Large-persistent PDA is followed by pulmonary circulation hypervolemia and left ventricular overload. The last ones result pulmonary hypertension, heart failure and systemic circulation hypovolemia.

Surgical closure of PDA is indicated if medication is ineffective or contraindicated. Open intervention through mini-thoracotomy is preferred in low-weight premature babies [2]. There is a tendency to minimally invasive procedures for infants weighing over 4 kg. Favorable results of transcatheter closure are observed for PDA diameter up to 3 mm [3]. Endovascular occluder deployment or thoracoscopic clipping are advisable for large PDA. There are certain contraindications and disadvantages of occluder implantation associated with foreign body in bloodstream and transvascular access. Some centers continue to use thoracoscopic clipping of PDA.

The purpose of this work is to describe evolution of this technology in one center and evaluate early and long-term results of thoracoscopic clipping as an alternative method of open surgical closure of PDA over 3.0 mm in full-term newborns weighing over 4.0 kg.

Material and methods

Characteristics of patients

For the period from March 2012 to March 2018 thoracoscopic clipping of PDA was performed in 140 patients. The main clinical and demographic characteristics of patients are presented in **Table 1**. Mean age was 4.0 years (from 3 months to 13 years).

Indications for surgical treatment were determined according to significant arterio-venous drainage. Pulmonary circulation hypervolemia was the main diagnostic criterion (pulmonary-systemic flow ratio Qp/Qs >1.1/1.0). Inclusion/exclusion criteria for thoracoscopic clipping are presented in **Table 2**.

All patients underwent instrumental examination. According to chest X-ray, mean preoperative cardiopulmonary coefficient (Martin index) was 52.6±5.8%. Different grades of pulmonary circulation hypervolemia were observed in 126 (90%) patients. Mean diameter of PDA was 4.6±0.9 mm (from 3.5 to 8.0 mm), mean pulmonary artery pressure — 34.3±5.8 mm Hg, mean Qp/Qs ratio — 1.6±0.3.

Table 1. **Clinical and demographic characteristics of patients**

Variable	Value
Overall number of patients, n	140
Age, months	48.8±44.4
Patients younger 1 year, n	23 (16.4)
Gender (female), n (%)	119 (85)
Height, cm	99.5±27.6
Weight, kg	16.2±11.1
Body mass index (BMI), kg/m^2	15.4±2.2
Clinical manifestations, abs. (%)	128 (91.4)
Concomitant CHD without need for surgery, abs. (%)	42 (30)

Note: CHD — congenital heart disease.

Table 2. **Course of postoperative period**

Inclusion criteria	Exclusion criteria
PDA diameter 3.5—10 mm	Fenestrated type of the ductus, aneurysm, calcinosis
Qp/Qs >1.3/1,0	CHD requiring surgical repair
Weight 4 — 40 kg	Left pleural cavity adhesions

Anesthesia

Monitoring onset and peripheral vein catheterization were followed by inhalation of sevofluran 8 vol%, administration of pipecuronium bromide 0.015 mg/kg, suxametonium chloride 1.5—2 mg/kg and fentanyl 5 μg/kg for muscle relaxation and subsequent tracheal intubation. Therefore, central venous catheter was deployed central venous pressure monitoring and infusion therapy, artery (radial, femoral) was catheterized to monitor blood pressure and acid-base/gas analysis.

Fentanyl 3—5 μg/kg was additionally injected during trocar deployment. The whole operation was carried out under inhalation of sevoflurane 2.5—3 vol%. Carbon dioxide insufflation into pleural cavity followed by hypercapnia can require correction of ventilation (increase of breath rate, respiratory volume). Positive pressure in pleural cavity results hypotension that requires bolus administration or prolonged infusion of vasopressors (phenylephrine, norepinephrine). Need for vasopressors disappears as soon as pressure in pleural cavity is normalized. Flow of sevoflurane was stopped after completion of the main surgical stage and before skin closure. Propofol infusion 2—3 mg/kg/h was used to eliminate excitation stage for more comfortable waking up of the child. Advanced ventilation was applied after completion of surgical stage for quicker elimination of sevoflurane.

The child was weaned from mechanical ventilation after restoration of adequate spontaneous breathing, auscultation of the lungs and tracheobronchial tree sanitation. Next, the child was transferred to pediatric ICU, where propofol infusion was stopped. ECG, chest X-ray and echocardiography were postoperatively performed (to exclude PDA recanalization).

Surgical features

There was right decubitus position of patient on operating table with inclination forward up to 70° and small roller at the level of inferior angle of the scapula. Both arms are flexed under 90° in shoulder joint in horizontal plane, under 90° in elbow joint in sagittal plane, right shoulder under 90° and left shoulder under 100—120° to vertical axis.

The set of the tools (KARL STORZ SE & Co. KG, Tuttlingen, Germany): HOPKINS-II optics with anterolateral vision 30°, diameter of 3.3 mm, Metzenbaum scissors, various types of forceps for gripping and dissecting (Kelly, with right-angle branches, fenestrated) with a diameter of 3.3 or 5 mm, trocars 3.5; 3.9; 6 and 11 mm. KARL STORZ clip applicators with medium titanium clips (6 or 8 mm) and Weck Hem-o-lok clip applicators (Teleflex Inc., Wayne, Pa., USA) with polymeric clips sized ML, L and XL with lock mechanism were used for PDA clipping **(Fig. 1)**.

Trocar No. 1 (endoscope) 3.9 mm was deployed within V-VI intercostal space immediately below inferior angle of the scapula (posterior axillary line considering left scapula elevation after shoulder abduction), carbon dioxide insufflation was started through this trocar up to target pressure in pleural cavity 6—8 mm Hg. Endoscope was passed through the same trocar for preliminary examination of pleural cavity. Trocar No. 2 (instrumental) 3.9 mm was deployed within II—III intercostal space along middle axillary line, trocar No. 3 (instrumental) 6 mm or 11 mm — in VII—VIII intercostal space along paravertebral line, trocar No. 4 (instrumental) 3.5 mm — in IX-X intercostal space along scapular line **(Fig. 2)**.

Fenestrated clamp was passed through the trocar No. 4 under endoscopic assistance for anterior traction of the left lung. Lung abduction was followed by left vagus nerve exposure. Parietal pleura was dissected over descending thoracic aorta posterior to vagus nerve and inferior wall of the duct was visualized. An important aspect is identifying left recurrent laryngeal nerve. Then, superior wall of the duct was dissected. Surgical dissection of the duct was stopped here if titanium clips were applied. Trocar No. 3 (11 mm) was used for clip-applicator, the clip covered the duct from top to bottom. PDA was clipped by 2 titanium clips in 14 (10%) patients.

Complete circular dissection of the duct including posterior wall exposure was necessary if polymeric clips were deployed. For this purpose, Kelly dissector was passed under the duct and counter tissues were transected by scissors through the trocar No. 2. Trocar 6 mm was always deployed in the position of the trocar No. 3 if polymeric clips were used. If external diameter of the duct exceeded ML clip dimension (clip-applicator diameter 5 mm), dissection of the duct was followed by deployment of the trocar 11 mm. Clip-applicator 10 mm L or XL was passed through this trocar depending on dimension of the duct **(Fig. 3)**. Trocars were removed as soon as adequate hemostasis was achieved. The technology does not imply pleural drainage. Carbon dioxide is removed during advanced inspiration using vacuum-aspirator.

Results

The main intraoperative features, types and dimensions of clips are presented in **Table 3**. At the first time, the second titanium clip was superimposed in 11 (7.9%) patients if complete interruption of blood flow through the PDA was doubtful.

In our series, mini-thoracotomy was required in 1 child due to external diameter of the short duct was more than the diameter of the aorta. Duct intersection was followed by suturing aortic and pulmonary stumps. There were no deaths, bleeding and other life-threatening intra- and postoperative complications. Pleural drainage was applied in 3 (2.1%) patients due to excessive vascularization of para-aortic tissues.

Features of postoperative period are presented in **Table 4.** Ninety-four (67.1%) patients were weaned from ventilator in operating theatre, in the other 46 (32.9%) patients mean time of mechanical ventilation in ICU was 1.3±1.0 hours. At the initial stages 34 (24.2%) patients were stayed in ICU until the next morning, now all patients are transferred to the department after 2 hours. Early postoperative period was complicated by acute obstructive laryngotracheitis in 1 child aged 6 months that required 3-day follow-up in the ICU. The child was discharged in 9 days after operation.

Control examination in 1 year after surgery included 107 (76.4%) patients. Residual bypass after titanium clip deployment was observed in 2 (1.4%) patients in 10 (patient A) and 6 months (patient B) after surgery **(Fig. 4)**. Both of them underwent transcatheter closure of PDA.

Considering 2 cases of recurrent PDA after titanium clips deployment, all subsequent procedures included polymeric clips. There were no cases of residual bypass in this group **(Fig. 5)**.

Table 3. **Surgical details**

Variable	Value
Mean time of surgery, min	24.5±15.5
Mean external diameter of PDA, mm	5.7±1.1
Titanium clips, abs. (%)	29 (20.7)
dimension 6 mm	9 (6.4)
dimension 8 mm	20 (14.3)
Hem-o-lok polymeric clip, abs. (%)	111 (79.3)
ML size	34 (24.3)
L size	70 (50)
XL size	7 (5)

Table 4. **Postoperative course**

Variable	Value
Postoperative data	
Ventilation weaning in operating theatre, %	94 (67.1)
Time of postoperative ventilation in ICU, h	1.3±1.0
Postoperative ICU-stay, h	9.1±8.5
Overall hospital-stay, days	6.1±3.0
Postoperative hospital-stay, days	4.0±2.2
Postoperative complications	
Recanalization of PDA (in-hospital period)	0
Pneumothorax (plural puncture in ICU), %	2 (1.4)
Conversion to thoracotomy (PDA >9 mm)	1 (0.7)
Injury of recurrent laryngeal nerve	1 (0.7)
Obstructive laryngotracheitis	1 (0.7)
Injury of vagus or phrenic nerve	0
Chylothorax	0
Bleeding	0

Discussion

PDA ultimately leads to high pulmonary hypertension and heart failure and in some cases may be followed by bacterial endocarditis, aneurysm of the duct, recurrent laryngeal nerve paresis [4]. In small preterm infants advanced drainage leads to the whole cascade of complications: prolonged mechanical ventilation, pneumonia, pulmonary hemorrhage, bronchopulmonary dysplasia, necrotizing enterocolitis, intraventricular hemorrhage, etc. [4]. Absolute indications for PDA closure are evident in children and adults with clinical manifestations and significant arterio-venous bypass. In asymptomatic patients with left heart overload and dilatation due to significant bypass through the duct, indications for closure are aimed at prevention of possible complications as a rule [5]. There are case reports of bacterial endarteritis in patients with clinically «silent» small ducts followed by with insignificant bypass which are diagnosed during echocardiogra-

phy, computed tomography or aortic angiography [6]. It is impossible to speak about absent risk of endarteritis despite the fact that the incidence of this complication has been minimized for recent years. Considering safety and efficacy of current methods of PDA closure, this strategy may be routinely applied for PDA in children and adults if Eisenmenger's syndrome is absent.

In premature newborns the first stage of isolated PDA closure can include heart failure management (adequate water balance, ventilation support with positive end-inspiratory pressure, vasopressors) followed by non-selective cyclooxygenase inhibitors administration (ibuprofen, indomethacin) [7]. Surgical ligation/clipping of the duct through the lateral mini-thoracotomy is performed if medication is ineffective [8].

Open surgical ligation of PDA has been considered as a preferable approach in full-term infants and older children for the last decades since the first successful operation performed by R. Gross [9] in 1938. For the first time, W. Portsmann [10] performed transcatheter closure of the duct using polyvinyl-formal sponge in 1967. This occluder like the later analogues (Rashkind, Sideris) was distinguished by high frequency of residual bypass, high price and advanced dimensions of delivery system that limited their application. In 1991, P. Cambier [11] reported transcatheter PDA occlusion in 4 patients using stainless steel helix. So, the era of endovascular surgery of PDA was began.

The main disadvantage for spiral deployment was limited maximum diameter of PDA (up to 3.0 mm according to various authors) [12]. «Open» surgery remained the «gold standard» for large ducts. However, there were several disadvantages: cosmetic defect, possible chest deformity, risk of intra- and postoperative bleeding, pneumothorax, infectious complications, residual bypass, recurrent laryngeal nerve paresis. Some authors proposed closure of PDA over 3.0 mm using several occlusive spirals. However, this technology is associated with a greater risk of spiral migration, thromboembolic complications, residual bypass and hemolysis [13].

The first report of thoracoscopic clipping of PDA was published by F. Laborde et al. [14] in 1993. The technology was able to close PDA with a diameter up to 9 mm (limitation due clip size) and avoid complications of «open» surgery. Moreover, there were certain advantages of endoscopic surgery for patient (minimal surgical trauma followed by preserved chest framework and excellent cosmetic result, no blood loss, minimal pain, early activation of the child and short rehabilitation period) and for surgeon (better surgical exposure). The technology quickly became widespread due to numerous publications in the literature [15, 16]. According to various authors, absent mortality and mean hospital-stay of 3 days were associated with incidence of residual bypass near 2.1%, recurrent laryngeal nerve injury — 2.6%.

The largest samples were reported by E. Villa et al. [17] and M. Nezafati et al. [18]. In 2006 E. Villa reported 743 patients aged 2.9±3.7 years. Mean duration of surgery was 20 min, postoperative hospital-stay — 2 days. The incidence of conversions to thoracotomy, pneumothorax and chylothorax was 1.1, 1.2 and 0.5%, respectively. In long-term period residual bypass was observed in 0.9% of patients. M. Nezafati reported 2,000 patients (mean age 5.2 years). Ten (0.5%) patients required conversion due to PDA diameter over 9 mm. Long-term incidence of residual leakage was 0.2%.

Amplatzer Duct Occluder (ADO) has been used by interventional cardiologists since 1998 for PDA over 3.0 mm [19]. Currently, transcatheter closure is preferable for PDA over 3.0 mm in most centers. Technology is attractive due to minimal invasiveness, but some drawbacks should be considered. First, not all morphological types of PDA (according to A. Krichenko et al. [20] classification) may be closed by occluder. The most convenient are A1-A3 and E types with narrowed pulmonary end and wide aortic «ampoule». Short «fenestrated» ducts with narrow aortic end (B1-B3 types) and «tubular» ducts (type C) are anatomically «difficult» for occlude deployment [21].

The second feature of transcatheter closure of large ducts is delayed interruption of blood flow through the occluder. In Amplatzer multi-center trial including 25 US centers persistent residual blood flow through the occluder was observed in 24% immediately after implantation, in 11% after 1 day and only after 1 year this value decreased to 0.3% [22]. F. Godart et al. [23] reported complete interruption of blood flow through the Occlutech occluder in 45.3% on the first day, in 71% after 1 day, in 95% after 1 month and in 100% after 1 year. Residual blood flow through the occluder with ongoing thrombosis leads to high risk of infectious and thromboembolic complications, hemolysis and aneurysm of the duct [24, 25].

To date, there is no clear consensus about feasibility of transcatheter PDA closure in low-weight children. The national clinical trial included 14 centers in the UK and Ireland was published in 2017 and reported following incidence of complications in newborns weighing up to 6 kg: occluder dislocation — 5%, residual bypass in long-term period — 5%, vascular complications (including impaired blood flow through the femoral artery) — 6%, significant aortic and pulmonary artery stenosis at the level of occluder — 6.6% [26].

Advanced irradiation should be also considered because mean time of fluoroscopy during occluder deployment is 14.4±8.6 min [27].

Of course, there are some drawbacks of thoracoscopic clipping: need for intubation, risks of complications similar to those in «open» operations (pneumo- and chylothorax, recurrent laryngeal nerve injury). However, the technology is characterized by relatively low risks and high efficiency. We believe that the main advantages of thoracoscopic clipping are immediate result and no artificial object in bloodstream.

In Russia, the first clinical experience was published by L.A. Bockeria et al. [28] in 2002. The sample included 52 patients aged 3.3 years who underwent thoracoscopic

clipping of PDA by two titanium clips through 3 trocars. Conversion to mini-thoracotomy was required in 17 (32.7%) patients. Long-term follow-up included 44 (84.6%) patients nd revealed no residual leakage. Surgical technique was limited by PDA dimension up to 6 mm due to maximum available clip size (mini-thoracotomy was required for larger duct). The authors applied dissection of only inferior and superior walls of the duct considering the risk of injury by branches of titanium clip.

In 2017, A.Yu. Razumovsky et al. [29] reported own 15-year experience of thoracoscopic clipping of PDA in 74 children aged from 11 days to 13 years. In-hospital follow-up confirmed no residual leakage; long-term examination was not included in the study. Trocars deployment scheme proposed by A.Yu. Razumovsky was taken for our work.

Annual incidence of residual leakage after titanium clips deployment (n=2) in our sample was similar to that reported in the literature (2.1%) [14—18]. This fact made us think about advisability of using titanium clips. First, titanium clip dimension limits their application. Secondly, compression force of titanium clip is very subjective and depends on surgeon who is aware of the high risk of PDA rupture in case of excessive pressure. Thirdly, the technology does not imply dissection of posterior wall of PDA. Moreover, various authors insist on avoiding this measure due to high risk of damage of the wall [28, 29]. We consider that intact posterior wall can provoke false estimation of true diameter of the duct. On the one hand, retroductal tissue may be clamped between distal ends of the clip. There is less pressure in this area due to design of the clip-applicator that may be followed by advanced risk of residual blood flow. On the other hand, this leads to the risk of PDA injury by metal ends of the clip.

Weck Hem-o-lok polymeric clips are associated with better results compared with titanium clips for ducts over 5 mm [30]. The clip has a locking mechanism that ensures uniform compression force over the entire surface of the clip and eliminates the possibility of «insufficient» compression. However, application of polymeric clips implies complete dissection of posterior wall of the duct. In this regard, we have slightly changed deployment of trocars. Trocar No. 3 is placed 2—3 intercostal spaces below that facilitates dissection of posterior wall and subsequent clipping. There were no any difficulties during endoscopic exposure of posterior wall of the duct in all 111 patients. Control echocardiography immediately and 1 year after surgery revealed no residual leakage.

Our experience of polymer clips deployment allowed us to use thoracoscopic clipping for ducts 3.5—10 mm. At the same time, we do not oppose this technology to transcatheter procedure, perform both techniques in our center and certain approach is individually determined for each patient depending on dimensions and anatomical features of the duct. Endovascular closure using spiral is applied for PDA up to 3 mm. Ducts over 10 mm usually require open surgical closure through mini-thoracotomy with possible intersection in order to avoid aortic deformation.

Conclusion

Thoracoscopic clipping using polymeric clip with locking mechanism is safe and effective method of surgical treatment of PDA in full-term infants weighing over 4.0 kg and occupies logical place between «open» and transcatheter surgery. On the one hand, the technology is followed by high efficiency due to immediate interruption of blood flow through the duct with a minimum incidence of possible complications and excellent cosmetic result. On the other hand, it is a minimally invasive alternative to surgery in case of anatomical features followed by advanced risk of occluder implantation or in centers without interventional cardiology.

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Fig. 1. **Endoscopic devices.**

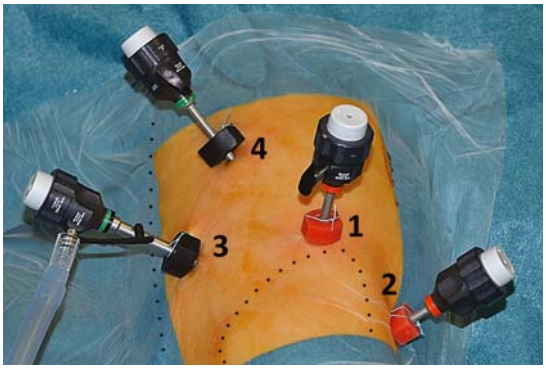


Fig. 2. **Placement of trocars (scapula and vertebral line are indicated by dotted line)**

a

b

c

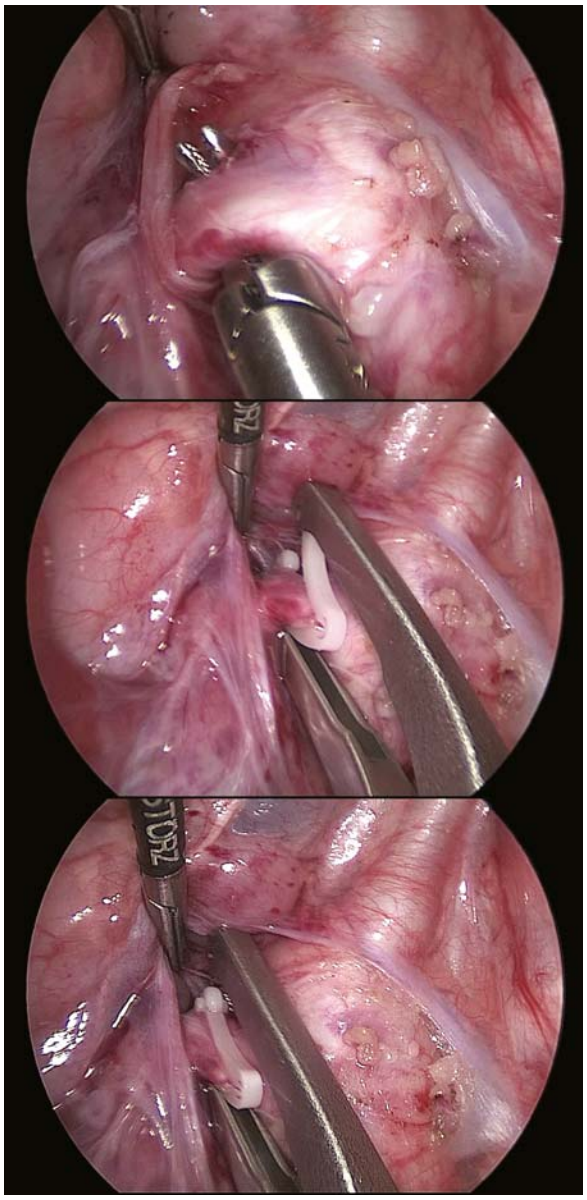
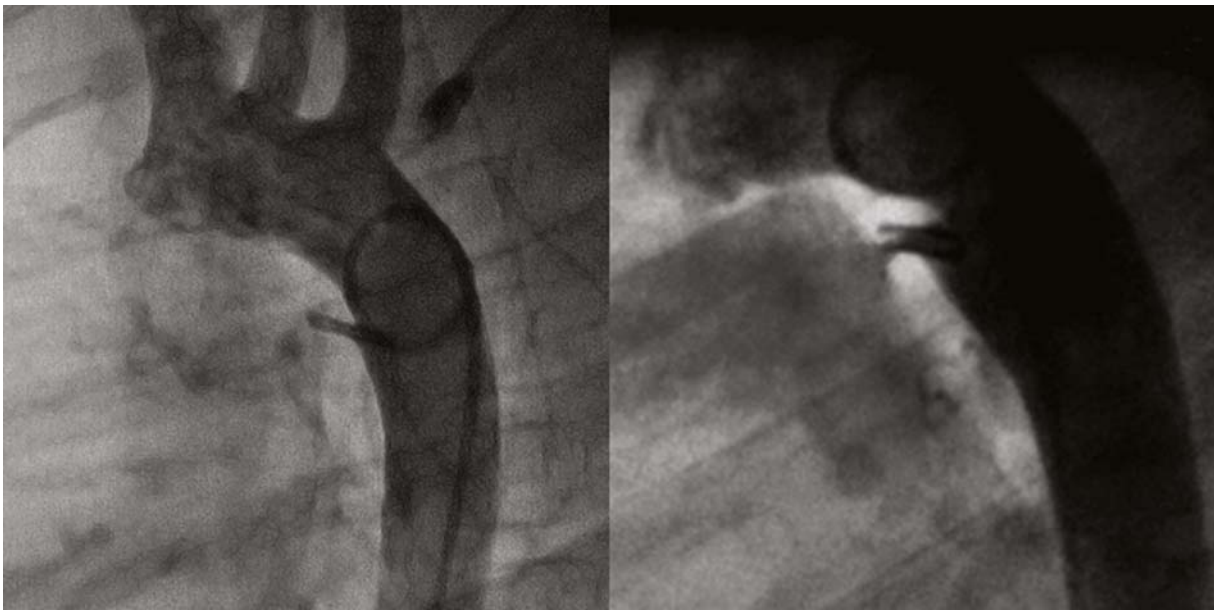


Fig. 3. **Surgical stages (intraoperative images).**
a — dissection of posterior wall of the duct; b — Hem-o-lok clip (size L) is under the duct, locking mechanism is over superior wall; c — clip is lockeg.



a b

Fig. 4. **X-ray scans of 2 cases of residual bypass in long-term period.**
a — patient aged 2 year and 9 months, shunt 1 mm, b — patient aged 5 years, shunt 2 mm.

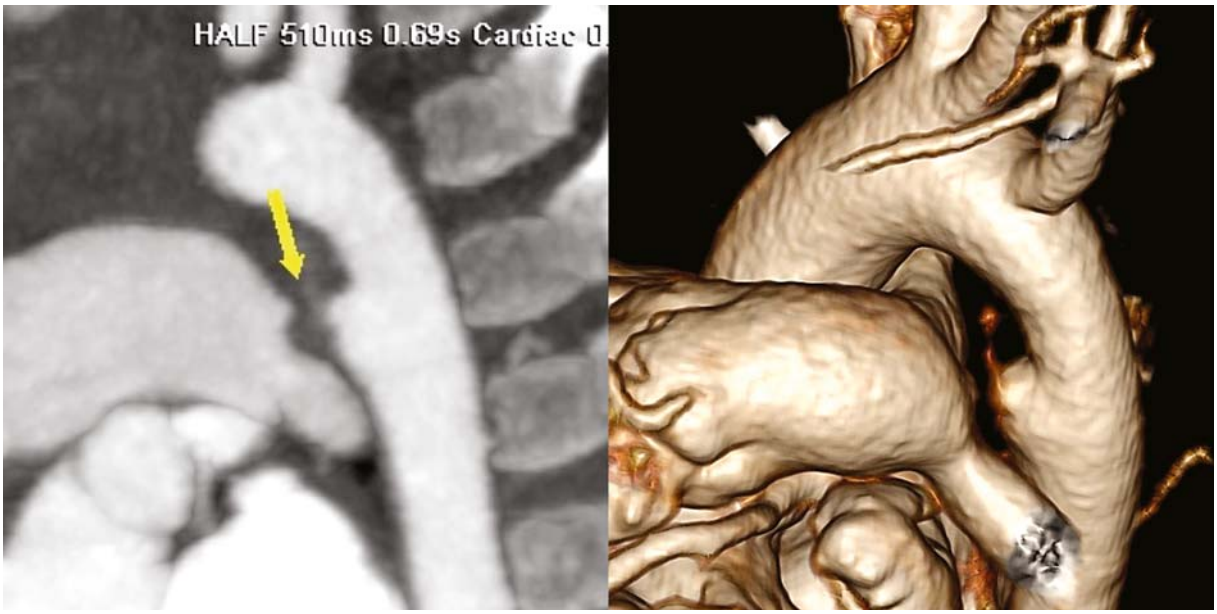


Fig. 5. **CT-scan after OAD clipping by Hem-o-lok clip.**