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Pulmonary artery banding: long-term telemetric adjustment ☆

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Abstract

Objective: Adjustment of pulmonary blood flow is difficult in pulmonary artery banding for complex congenital heart defects. A new wireless, battery free, telemetrically controlled, implantable device (FloWatch™, EndoArt, S.A., Lausanne, Switzerland) allowing for progressive occlusion/reopening of the device through a remote control at the wanted percentage of occlusion (adjustable pulmonary artery banding) underwent experimental evaluation. **Methods**: Eleven mini-pigs underwent FloWatch™ implantation around the main pulmonary artery through left thoracotomy. The first group ($n = 4$), mean age 18.2 ± 0.1 weeks, mean body weight 12.0 ± 0.1 kg, underwent FloWatch™ implantation as device tolerance test. The second group ($n = 7$), mean age 8.6 ± 3.4 weeks, mean body weight 5.1 ± 1.5 kg, underwent functional evaluation: at implantation, 1, 3, 5, 8 and 10 weeks after implantation, the device was progressively occluded and reopened, with Doppler evaluation of the developed pressure gradient. **Results**: The four mini-pigs of first group were sacrificed at mean age of 42.3 ± 0.1 weeks, mean body weight 25.1 ± 3.2 kg (mean interval of 24 weeks after implantation); the device was still functioning and histology revealed almost normal morphology of the pulmonary artery. In all seven mini-pigs of second group the possibility of narrowing/releasing the pulmonary artery was confirmed at implantation and during follow-up: at last control their mean age was 20.5 ± 2.8 weeks and the body weight 12.7 ± 3.7 kg. **Conclusions**: Complete adjustment of pulmonary blood flow is now possible with an implantable device allowing for pulmonary artery banding with early and late telemetric flow control.

Keywords: Adjustable device; Congenital heart defects; Congenital heart surgery; Palliative procedure; Pulmonary artery banding; Pulmonary hypertension

1. Introduction

Indication for pulmonary artery banding is currently limited by several factors:

(a) difficulty in determining the optimal perimeter of the band,
(b) influence of several clinical variables with mutual interference, including general anesthesia with positive pressure ventilation, chest opening particularly with thoracotomy [1], heart rate and contractility, arterial PO_2 and PCO_2, acid–base status, hematocrit, systemic and pulmonary vascular resistance [2]. Substantial changes occur to all these variables, particularly within the first few hours or days after the operation [2],
(c) variability of ventricular adaptive response, particularly in 'functionally' univentricular hearts [3], transposition of the great arteries where a left ventricular training is required in view of arterial switch operation [4], and where simultaneous associated surgical procedures are required,
(d) repeated operations frequently required to adjust the band perimeter,
(e) long periods with intensive respiratory or pharmacological interventions to control the pulmonary blood flow [4],
(f) frequent need for a reconstruction of the pulmonary artery at the moment of the conventional de-banding for surgical repair.

To overcome these difficulties, several attempts have been made to find an adjustable pulmonary artery banding, allowing for external regulation [5–19]. A MedLine research for 'adjustable pulmonary artery banding' revealed 16 different techniques reported within the last 10 years, the

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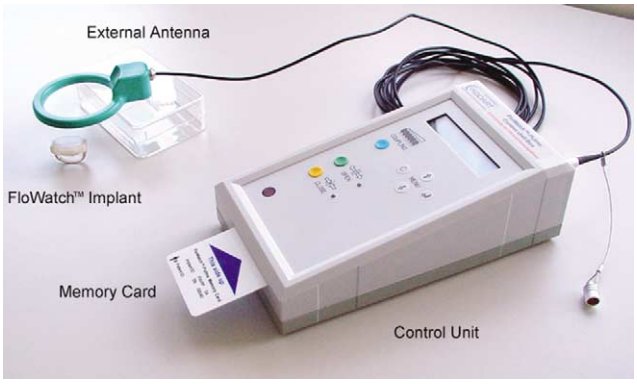

Fig. 1. The FloWatch™ system comprises the implant and the external control unit with an antenna.

majority of which, however, did not result in a device allowing for a precise, long-term, non-invasive, adjustment of pulmonary blood flow in both ways, with repeated narrowing and releasing of the pulmonary artery.

We report on the experimental evaluation of a new wireless, battery free, implantable device (FloWatch™), developed by EndoArt, S.A. (Lausanne, Switzerland) [20] allowing for repeated progressive occlusion and reopening of the device through a remote control, at the wanted percentage of occlusion (adjustable pulmonary artery banding).

2. Materials and methods

2.1. Technical characteristics of the device

The FloWatch™ system comprises the implant and the external control unit with an antenna (Fig. 1). The device is placed with a surgical procedure around the main pulmonary artery, with a minimal surgical dissection, enough to allow for the passage of the clip of FloWatch™ around the pulmonary artery, in a fashion similar to the conventional pulmonary artery banding (Fig. 2). With the device in clipped position, the dimensions are: 26 mm (length) × 18 mm (width) × 18 mm (height), therefore due to the size there are no chances of unwanted migration of the device after implantation and pericardial closure. The change in the adjustable area is obtained by means of a piston driven by an incorporated electrical micro-motor. The concave form of the adjustable area has been chosen so that during compression the area changes but the perimeter of the pulmonary artery remains unchanged, which is optimal for long-term use (i.e. reopening after several weeks of pulmonary artery compression). The adjustable area in fully open position correspond to a pulmonary artery banding with a perimeter of 30 mm, and with fully closed position to a pulmonary artery banding with a perimeter of 23 mm (Fig. 3). According to the Trusler's rule [21], theoretically the device should theoretically be suitable for pulmonary artery banding in patients from 3 to 10 kg of body weight. The adjustment is done via an external control unit delivering to the implanted device, via the antenna, the energy as well as the commands to drive the micro-engine. The device does not contain any battery. The telemetric system is designed such that the implant sends back to the control unit information about its functioning, which allows for control of the regulation by the treating doctor.

2.2. Experimental studies

A feasibility test performed with acute ($n = 2$) and chronic ($n = 2$) experimental studies on mini-pigs (acute study: 18 and 24 weeks of age, 12 and 17 kg of body weight; chronic study: 8 and 10 weeks of age, 7 and 8 kg of body weight), confirmed: (a) the applicability of the device around the pulmonary artery; (b) the possibility of progressively narrowing and releasing the pulmonary artery with telemetric control after chest closure; (c) the functioning of the device up to 6 weeks after implantation, with repeated adjustments of pulmonary artery banding.

At this point a device tolerance test and a functional evaluation test were performed on eleven mini-pigs.

After induction of general anaesthesia, tracheal intubation and mechanical ventilation, trough a left lateral thoracotomy the pericardium has been longitudinally opened with an antephrenic incision, and a short segment of the main pulmonary artery has been dissected free.

The first group ($n = 4$), mean age 18.2 ± 0.1 weeks, mean body weight 12.0 ± 0.1 kg, underwent FloWatch™ implantation as device tolerance test, with a period of 24 weeks of observation. At the end of the 24 weeks the mini-pigs underwent general anaesthesia, tracheal intubation and mechanical ventilation. The chest has been reopened through median sternotomy, followed by longitudinal peri-

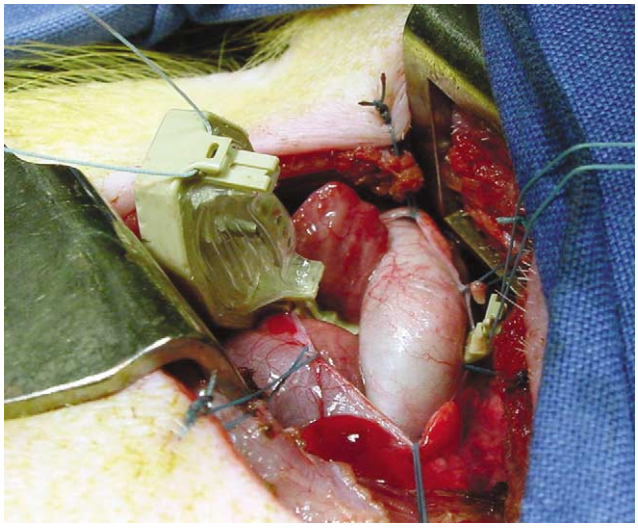

Fig. 2. The device is placed with a surgical procedure around the main pulmonary artery, in a fashion similar to the conventional pulmonary artery banding. The device is unclipped, with the clip already around the inferior aspect of the main pulmonary artery.

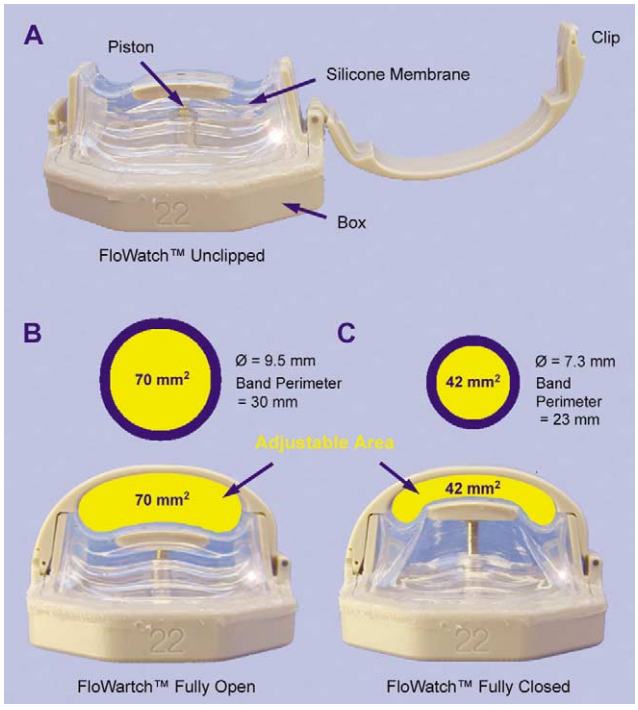

Fig. 3. Device in unclipped position (A) and in clipped position with the adjustable area fully open (B) and fully closed (C).

cardiotomy, as in any conventional surgical procedure for repair of a congenital heart defect with previous pulmonary artery banding. The device was progressively occluded and reopened, with Doppler evaluation of the developed pressure gradient, and with invasive pressure measurement by insertion of a pressure catheter into the right ventricle and another one into the distal pulmonary artery for simultaneous pressure monitoring. Then the device has been explanted, and the animal sacrificed. Both the main pulmonary artery and the tissues surrounding the device have been sent for histological evaluation.

The second group ($n = 7$), mean age 8.6 ± 3.4 weeks, mean body weight 5.1 ± 1.5 kg (range 3.4–6.9 kg), underwent functional evaluation test: at implantation, 1, 3, 5, 8 and 10 weeks after implantation, the device was progressively occluded and reopened, with Doppler evaluation of the developed pressure gradient. At the end of the observation period, the mini-pigs followed the same protocol of the device tolerance test, with invasive pressure measurements and device explantation through median sternotomy, followed by sacrifice and harvesting of main pulmonary artery and surrounding tissues for histological examination.

All animals received human care in compliance with the 'Principles of Laboratory Animals' formulated by the National Society of Medical Research and the 'Guide for the Care and Use of Laboratory Animals' prepared by the Institute of Laboratory Animal Resources and published by the National Institutes of Health (NIH publication 85 - 23, revised 1985). The protocol was approved by the institutional Committee on Animal Research.

3. Results

In all cases the device implantation was a fast track surgical procedure, with all animals extubated on at the end of the procedure, and sent back to the farm within few hours, without medications other than oral pain killers.

The four mini-pigs of the device tolerance test were sacrificed at mean age of 42.3 ± 0.1 weeks, mean body weight 25.1 ± 3.2 kg (mean interval of 24 weeks after implantation); in all of them the device was still functioning. Through median sternotomy and longitudinal pericardiotomy, the device has been easily identified in the same position of implantation, without any migration of the device. Macroscopic examination revealed a fibrous capsule surrounding the device, very similar to the tissue generally found around a pace-maker battery at the moment of battery replacement. Removal of the device has been very easily performed in all cases, without any lesion of the pulmonary artery, any bleeding or other hemodynamic deterioration as well. Macroscopic examination of the pulmonary artery after sacrifice revealed a very pliable vessel wall, without any sign of fibrosis externally as well as internally. Histology revealed in all animals almost normal morphology, with limited thickening of the intima and some sign of degeneration of the media of the pulmonary artery in correspondence with the narrowing induced by the device (Fig. 4).

In all seven mini-pigs of the functional evaluation test the possibility of repeatedly narrowing and releasing the pulmonary artery was confirmed at implantation and during the entire follow-up: 1, 3, 5, 8 and 10 weeks after implantation. At last control before sacrifice their mean age was 20.5 ± 2.8 weeks and the body weight 12.7 ± 3.7 kg.

Results of all Doppler evaluations (mean ± SD), shown in Table 1, showed a very good correlation between percentage of occlusion and trans-banding pressure gradient, for the narrowing as well as for the releasing of the device, even weeks after the implantation of the device. In all cases

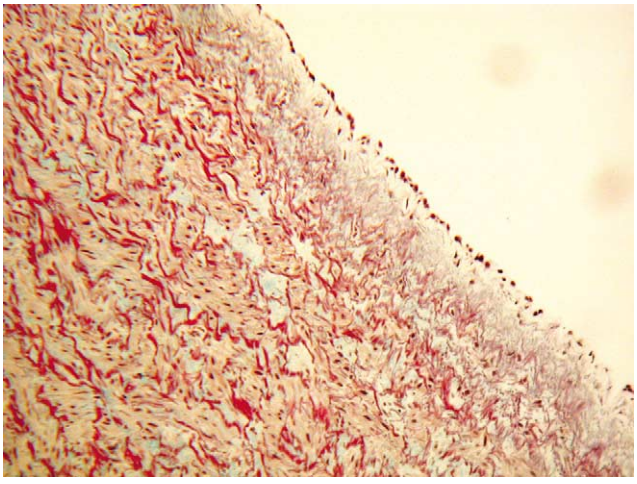

Fig. 4. Normal histology of the main pulmonary artery in correspondence of the narrowing induced by the device, 10 weeks after implantation.

Table 1
Correlation of second degree polynomial fit between % occlusion and Doppler gradient

	Implantation	1 week	3 weeks	5 weeks	8 weeks	10 weeks
mean ± SD	0.91 ± 0.11	0.89 ± 0.09	0.94 ± 0.04	0.97 ± 0.01	0.95 ± 0.03	0.97 ± 0.01

progressive occlusion of the device was followed by progressive increase of the pressure gradient, as well as progressive re-opening of the device has been immediately followed by reduction of the pressure gradient.

In all animals there was a great variability of the ventricular response to the same percentage of occlusion of the device (= narrowing of the pulmonary artery banding), with the pressure gradient generally increasing with the time elapsed from the day of implantation (example of a single animal is represented in Fig. 5).

Macroscopic and histological examination in this group of mini-pigs, after 10 weeks of implantation, showed the same results as in the previous group (device tolerance test) exposed to 6 months of device implantation.

4. Discussion

The clinical need for an adjustable pulmonary artery banding has been confirmed by several attempts in developing such a technique reported in the literature ([5–19]). A MedLine research confirmed the persistent unavailability of a reliable device, capable of repeated narrowing and releasing the pulmonary artery with effective remote control of the pulmonary blood flow. Mostly because of the known difficulties to control the pulmonary blood flow once the conventional pulmonary artery banding is in place, the indication to pulmonary artery banding is currently limited to the clinical situations without another suitable alternative surgical option.

With our experimental research we tested a wireless, battery free, telemetric controlled device (FloWatch™) for adjustable pulmonary artery banding [20]. Our experimental studies demonstrated that the device is easy to implant and to use, with proven evidence of repeated progressive occlusion and reopening of the device through a remote control, at the wanted percentage of occlusion. Furthermore, at the time of explantation the procedure was absolutely smooth and the pulmonary artery returned to the normal morphology, without the localised narrowing in correspondence of the banding and the fibrosis generally observed in the pulmonary arteries with the band in place for some time; therefore, another advantage of this device should be the possibility of avoiding the need for a plastic repair after a conventional banding.

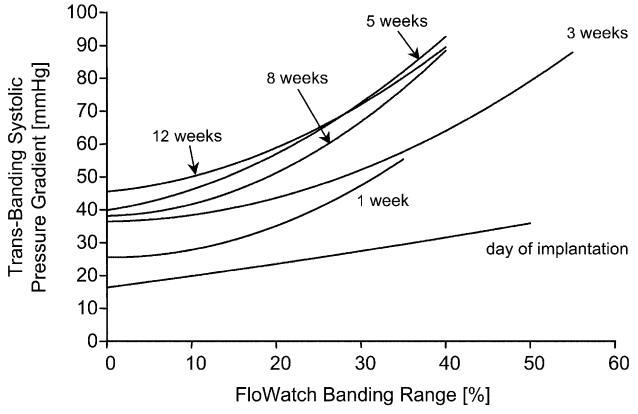

Fig. 5. Graphic showing the progression with the time from the day of implantation of the trans-banding pressure gradient for the same percentage of occlusion of the device.

In conclusion, our experimental studies demonstrated that the FloWatch™ allows for unlimited external telemetric adjustments of pulmonary blood flow, as expected and required from a really adjustable pulmonary artery banding.

The potential clinical benefits of this device allowing for unlimited external telemetric adjustments of pulmonary artery banding are the following:

- fast track surgical procedure,
- effective control of pulmonary blood flow,
- no need for banding-related re-operations,
- simplified post-operative course,
- reduction of mortality and morbidity.

If the clinical studies with FloWatch™ implantation will confirm our experimental results, and the potential clinical benefits will be demonstrated, this device will represent a major change in the management of children requiring for a pulmonary artery banding, particularly for the most complex pathophysiological situations, like univentricular hearts or transposition of the great arteries requiring for a left ventricular retraining because of a late referral. The size of the currently available device will limit the clinical application to children up to 15–20 kg of body weight, and therefore a larger size will need to be developed it be utilised in older children and adolescents.

Finally, the indications for pulmonary artery banding could be expanded in order to adapt the therapeutic strategies to this promising technology.

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Appendix A. Conference discussion

Dr G. Stellin (*Padova, Italy*): It is a very nice device and its implantation looks very appealing. However, I must say that most of the pulmonary artery banding that we need to place usually are in the neonatal period or in early infancy. I wonder, how can you get around the problem of compressing the coronary arteries or compressing the pulmonary artery branches with such a rigid body inside the chest?

Dr Corno: First of all, the size of the device is 26 mm length by 18 mm by 18 mm. Of course, it has to be rigid to sustain the increased pulmonary artery pressure when we do a banding. The size of the clip is exactly 4 mm, as the band that we used before having this device available. And I can tell you that in the experimental study, the smallest piglet with device implantation was 3.2 kilos. And we had never encountered a problem of compression of coronary arteries, of pulmonary artery distortion, or left bronchial compression in the observed period. And I can even add that after this experimental study, we started a multicenter clinical trial, and the device has been already implanted down to 3.5 kilos in human beings without negative consequences.

Dr R. DiDonato (*Rome, Italy*): I don't know all the methods of telemetric banding of the pulmonary artery, but I think this is the best one I have ever seen. And I would like to suggest one application in particular, namely for the cases of retraining of the left ventricle in corrected transposition that we were discussing earlier. Interestingly, for these cases the concept is coming out that the retraining has to be a gradual process, often with a need to be adjusted on a daily basis, maybe even an hourly basis, like the athlete that needs to train and build up muscle mass. So I think this is an ideal tool for this kind of application, i.e. for gradual banding and for retraining of the left ventricle.

Dr Corno: You are absolutely right. The main reason why we started this study is because, I'm sure you know, we had a complex group of patients who came with simple TGA, very late referral, up to 25 months of age, and we had to perform the left ventricular retraining. So we went for banding, shunt, plus/minus ASD and so forth. And I can tell you that it was a nightmare. We were successful, but in 50% of the patients we had to go back with a reoperation to adjust the banding, to further narrow the banding or to reopen the banding. And in one patient we had to go back three times. That's why we started this study. So it is a perfect indication for left ventricular retraining.

For the left ventricular retraining after failing Mustard or Senning or in congenitally corrected transposition, the problem at the moment is the size, because generally these are patients who are later on in life, with a body weight of 30, 40, 50 kilos. And at the moment this available device is too small. But we are already starting to develop a larger size device. I'm very pleased with your comment, because this will stimulate the company to accelerate their study with a larger size device.

Dr V. Alexi-Meskishuili (*Berlin, Germany*): I just want to share with you a very limited experience of stage banding method, which we used in German Heart Institute. 3 years ago, I operated 2 patients sent to us for evaluation as inoperable with mitral atresia, restrictive foramen ovale and systolic pulmonary artery pressure of 80 mm Hg. In both patients I resected the atrial septum and tried to put a pulmonary artery band, but the patients cannot tolerate that. So I left the sternum open and tightened gradually the band during 4 days after the operation with the titan-clips, until mean pulmonary artery pressure fell to 18 mmHg. Now, 3 years after gradual banding both patients underwent very successful extracardiac Fontan operation. I think that in some cases such as ours it is a cheap and effective method of staged banding. This method may be useful also in older children and some adult patients for left ventricular retraining. In small children, we do banding very seldom, only in complex cases, it's a very safe operation nowadays.

Dr Corno: I fully agree with you. I was trained in a research lab at UCLA where I was able to use adjustable banding very cheap with 2-0 polypropylene and a rubber tourniquet. The only problem is that with this kind of adjustable device you are almost sure then you can go back and narrow the pulmonary artery furthermore, but you still have to reopen the skin for 2-3 cm. But then, if you have few weeks after the banding, you are almost never able to release the pulmonary artery. So when you have a grown up child and you need to release the pulmonary artery, with our device you can do it. With the other one, we have never been able to do it.

Dr J. Amato (*Chicago, Illinois*): Very, very ingenious device. And being an old-timer, I still think there's need for bands. Two complications that I can foresee, and I wonder how you can possibly prevent them. One is

erosion. As you know, even the common pulmonary band will erode posteriorly. I don't know how soft this silastic material is and secondly is the possibility of clot formation. I noticed that as you compress the pulmonary artery, it's not a circular compression but rather an elliptical compression, and I wonder whether you might anticoagulate, or do you anticoagulate these piglets and then children? May I also suggest that it might be safer to elevate the main pulmonary artery with a cord tape or vessel loop prior to inserting the device. It seems that the edges of the device are blunt and may injure the pulmonary artery tissues by inserting the device directly?

Dr Corno: Well, ingenious was the engineer who invented the device. Anyway, for your questions, we didn't see any lesion in the pulmonary artery in the experimental study and that's why at the moment of explantation we harvested the entire block of the pulmonary artery. And the histology showed in all the cases almost normal pulmonary artery with very pliable tissue. And this is most probably due, but is a speculation, to the shape of the pulmonary artery, which doesn't have a circular narrowing. With the conventional banding you always found a fibrosis. And if you go back after a few months, you have to reopen the pulmonary artery with a plasty. In all these animals, I can tell you, we explanted the last one 2 weeks ago, after 14 months, and we did need to reopen the pulmonary artery: simply amazing, the pulmonary artery opens up spontaneously.

We never gave any antiplatelets or anticoagulant. All the piglets were free of medication and we had no thrombus.

Dr K. Samir (*Marseille, France*): Firstly, I would like to thank you for the comments we had on line when we discussed the article before.

Secondly, when I calculated the effective diameters of your apparatus, I found it making bands between 28 and 32 to 33 cm. I think it is too loose bands to be applied for neonates. What do you think?

Dr Corno: First of all, the given circumference is 23 to 30 millimeters, not centimeters.

Before this device was available, I have done the banding following the Trusler rule. And the Trusler rule, you know better than I do probably, says that you should have a perimeter of the band of 20 mm plus 1 mm/kg. If you consider a neonate of 3 kilos, 23 mm should be the perfect size.

So far we have a relatively small group of patients, but we were never able to completely narrow the device even in a 3.5 kilogram patient. That means we never needed to reach the 100 percent occlusion, and therefore I speculate that this size should be enough even in neonates.

Now we have started to run a clinical trial, and we are not allowed to use the device in any child less than 3.5 kilos.

Dr A. Urban (*Augustin, Germany*): Which incision would you use to put in your device, median sternotomy or lateral thoracotomy, or what would you do in a human patient?

Dr Corno: In the experimental study all the devices have been implanted through a left thoracotomy and explanted through median sternotomy, like in a normal repair. But in the multicenter clinical trial we are performing, both in Switzerland and Paris, I can tell you the device has been implanted through both thoracotomy and median sternotomy, with associated procedure or without associated procedure, and even with procedure on cardiopulmonary bypass.