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Results of Pulmonary Artery Debanding: Simple Band Removal Versus Pulmonary Artery Repair with Pericardial Patch

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ABSTRACT

Background: Among the complications noted after debanding is those related to residual pulmonary stenosis. Removal of band without repairing pulmonary artery could be enough. Others recommend patching pulmonary artery at the site of band during debanding because of possibility of residual gradient caused by a residual shelf or narrowing and distortion of the arterial wall. This may necessitate re-operation especially if it leads to pressure over-load on the right ventricle.

Objective: To compare between simple band removal and band removal with pulmonary artery repair using pericardial patch, at time of debanding; concerning early postoperative pressure gradients across the main pulmonary artery.

Patients and methods: This retrospective observational study included 40 patients who underwent pulmonary artery debanding in the period between January 2016 and January 2020 at the Cardiothoracic Surgery Department, Cairo University hospitals and Atfal Masr Hospital. Patients were divided into two groups; group A, which included 20 patients who underwent simple band removal and group B, which included 20 patients who underwent pulmonary artery debanding with pericardial patch repair.

Results: The median pressure gradient across the main pulmonary artery postoperatively was 15 mm Hg for group A (mean 22.58±18.0) and 10 mm Hg for group B (mean 11.3±8.0) with statistically significant value (p=0.020). 40.0% of cases in Group A had significant residual pressure gradient compared to only 10.0% of cases in Group B, and that difference was statistically significant (p=0.028). The median pressure gradient across the band immediate preoperatively was 60mmHg for group A (mean 62.0±9.8) and 70mmHg (mean 64.2±10.6) with statistically insignificant value (p=0.065).

Conclusion: Pulmonary artery repair with pericardial patch showed the advantage of reducing the risk of significant residual pressure gradient across the band site over simple band removal in pulmonary artery debanding.

Keywords: Ventricular septal defect, Atrio-ventricular canal, Pulmonary artery debanding, Pericardial Patch.

INTRODUCTION

Pulmonary artery banding was first suggested by Muller and Dammann[(1)] in 1952 as a palliative procedure for patients with large left-to-right (L-R) shunt who fail to thrive, to prevent further development of pulmonary vascular obstructive disease**.**

Current indications for pulmonary artery banding (PAB) include multiple ventricular septal defects (VSDs) (Swiss cheese ventricular septum), large apical VSD, VSD and complete atrioventricular canal defect (CAVC) complicated by other non-cardiac anomalies [(2)]**.**

Indications for pulmonary artery banding have been reduced in the last two decades, since early total repair has been proved to be superior to palliation and staged approaches. However, there is now an increasing support for pulmonary banding raised by new indications such as left ventricular training in delayed arterial switch operation. Debanding is usually performed several months after palliation during the total repair of the cardiac malformations. It can be done by simple band removal or by removal of the band and pulmonary artery repair with a pericardial patch [(3)]**.**

One of the complications noted after debanding is related to the right ventricular outflow tract obstruction occurring mainly at the band site [(4)]**.** Some Studies show that in most of patients, the removal of band without repairing Pulmonary artery could be enough [(5)]**.**

Nevertheless, other studies recommend patching of the pulmonary artery at the site of the band during the debanding procedure because of the possibility of a residual gradient caused by a residual shelf or narrowing and distortion of the arterial wall from extensive fibrosis. This may necessitate re-operation especially if it leads to pressure over-load on the right ventricle [(6)]**.**

The aim of the study was to compare between simple band removal and band removal with pulmonary artery repair using pericardial patch, at time of debanding; concerning early postoperative pressure gradients across the main pulmonary artery.

PATIENTS AND METHODS

Study place: This study was done at the Pediatric Cardiac Surgery Unit in Abo-elreesh hospital at Cairo University as well as Atfal Masr Hospital.

Study design: It is a retrospective observational study including 40 patients who underwent pulmonary artery debanding after passing the appropriate Hegar dilator through the pulmonary artery and its branches (no obvious pulmonary artery stenosis), either by simple band removal or band removal and pulmonary artery repair with a pericardial patch. The study cases were

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selected as a purposive/convenient nonprobability sample. Data collection was done using data compilation form as a research tool. The study was started after obtaining the approval of the local ethical committees and a written formal consent was obtained from all patients prior to surgeries.

Study period: Cases were operated upon in the period between January 2016 and January 2020.

Study population: 40 Patients were included and were classified into two groups: **(1) Group A:** consisted of twenty patients who underwent pulmonary artery debanding through simple band removal. **(2) Group B:** consisted of twenty patients who underwent pulmonary artery debanding through band removal as well as pulmonary artery repair with a pericardial patch.

Inclusion criteria: Patients who underwent pulmonary artery debanding regardless their primary lesion and other surgical procedures associated with debanding (e.g. VSD closure, CAVC total repair).

Exclusion criteria: Patients who underwent pulmonary artery banding as a part of their permanent procedure, and they will not perform pulmonary artery debanding (e.g.: banding prior to Glenn Shunt as in cases of single ventricle with unprotected pulmonary circulation) were excluded. Also patients with obvious pulmonary artery stenosis as detected by not passing the appropriate Hegar dilator during debanding, were not included.

All patients were subjected to the following:

1- **History taking:** A thorough and detailed history was taken regarding age, sex, weight at the time of banding and debanding, history of other diseases like Down syndrome, prenatal risk factors, natal or post natal complications and reason of staged repair.

2- **Clinical examination:** A complete general and local cardiological examination was performed with special emphasis on weight and oxygen saturation, any neurological deficits, cardiac murmurs or chest wheezes or crepitations.

3- **Laboratory investigations:**
   - Full laboratory studies were done including:
     - Complete blood picture with differential analysis.
     - C Reactive protein.
     - Coagulation profile: PT, PC, INR.
     - Kidney function tests: Serum urea, Serum creatinine.
     - Liver function tests: AST, ALT, Albumin, Bilirubin (total, direct).
     - Serum electrolytes: Na, K.

4- **12 Lead Electrocardiogram (ECG):** A 12 leads ECG was done to detect any preoperative arrhythmias.

5- **Radiological examination:**
   The following were done:
   - **Plain chest X-ray (CXR):** Postero-anterior view (in erect position if possible) was obtained to evaluate cardiothoracic ratio, degree of lung congestion and to exclude any other diseases. Also, Lateral view was obtained to evaluate retrosternal adhesions and sternal wires in cases of previous median sternotomy.
   - **Transthoracic Echocardiography (ECHO):** was done routinely for all patients with special emphasis on the gradient across the pulmonary artery band immediately pre-operatively.

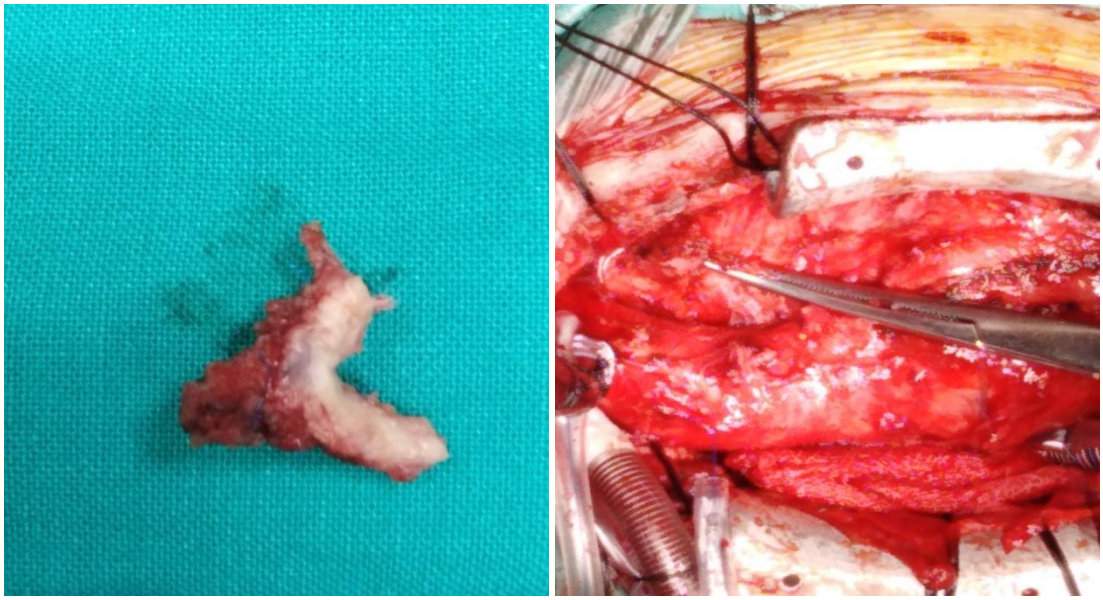
6- **Pre-operative Counseling:** Prior to surgery, a brief explanation of the steps of the operation, the post-operative events and the intensive care stay was discussed with the parents.

The following data were recorded for statistical analysis:
- Age, weight at time of Pulmonary Artery Banding.
- Age, weight at time of debanding.
- Gender.
- Associated Down syndrome.
- Type of congenital heart anomaly.
- Gradient across the band immediate pre-operatively.

The operation was continued as follows:

A- ***Group A*:** (The patients who underwent pulmonary artery debanding through simple band removal).
- After corrective operation and before weaning off bypass, the band was dissected freely from the aorta and surrounding pericardium. Then, the anterior part of the band was cut longitudinally to open the band. Using a combination of sharp and diathermy dissection, the band was carefully separated from pulmonary artery on both sides. When the anterior half of the band became well dissected, its free end was pulled and fully extracted as one part if possible (Figure **1**).

B- ***Group B*:** (The patients who underwent pulmonary artery debanding through pulmonary artery repair with pericardial patch).
- The same steps were undertaken as before then; the pulmonary artery was cut longitudinally proximal and distal to the band. A pericardial patch was sutured to the edges of the incision using 6/0 continuous running propylene sutures.



(A) **(B)**

Figure (1): (A) The band dissected freely from the aorta and surrounding adhesions, (B) The band after being pulled and removed.

Ethical consent:

An approval of the study was obtained from Cairo University Academic and Ethical Committee. Every patient signed an informed written consent for acceptance of participation in the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical Analysis

Data were coded and entered into the statistical package SPSS version 24. Data were then summarized using the mean, standard deviation, median, minimum and maximum for quantitative variables as well as frequencies (number of cases) and relative frequencies (percentages) for categorical variables. Comparisons between groups were done using unpaired t test in normally distributed quantitative variables while non-parametric Mann-Whitney test was used for non-normally distributed quantitative variables. For comparing categorical data, Chi square (χ^2) test was performed. Exact test was used instead when the expected frequency is less than 5. A P-value less than 0.05 was considered as statistically significant.

RESULTS

I. Pre-operative data:

A) Demographic data:

1. **Age & weight at the time of PAB:** The median age was 6 months for Group A (mean 6.1±2.1) and 5 months for Group B (mean 5.6±1.8) with no statistically significance difference between both groups (**P–value=0.419)**. The mean weight was 4.6±1.2 kilograms for Group A and 4.3±1.2 kilograms for Group B with also no statistically significance difference between both study groups (**P-value=0.368)** (Table 1).
2. **Age & weight at time at time of debanding:** On the other hand the median age at debanding was 24.5 months for Group A (mean 26.2±8.8) and 21.5 months for Group B (mean 29.7 ±9.7). Again there was no statistically significance difference between the two groups with a **P-value=0.248**. In addition the mean weight at debanding was 12.2±2.9 kilograms for Group A and 11.3± 2.1 kilograms for Group B with no statistically significance difference (**P-value =0.288)** (Table **1**).
3. **The time interval between banding and debanding:** There was no statistically significance difference between the two groups with a **P-value=0.354** (Table **1**).
4. **Gender:** There was no statistically significant difference between two groups regarding the distribution of male and female cases (**P-value = 0.632)** (Table **1**).
5. **Association with Down syndrome:** There was no statistically significant difference between both groups in concern the association with Down syndrome (**P-value=0.842**) with 12 cases in Group A (60%) and 13 cases in Group B (65%) (Table 1).

B) Preoperative echocardiographic data:

6. **Type of congenital heart anomaly** In Group A, 8 cases (40.0%) had complete AV canal and 12 cases (60.0%) had ventricular septal defect while in Group B 7 patients (35.0%) suffered from complete AVC defect and 13 patients (65.0%) suffered from VSD with no statistically significant difference **(P-value =0.744).**
7. **Pressure gradient across the band immediately pre-operative** There was no statistically significant difference between both groups (**P-value=0.065)** (Figure **2**).

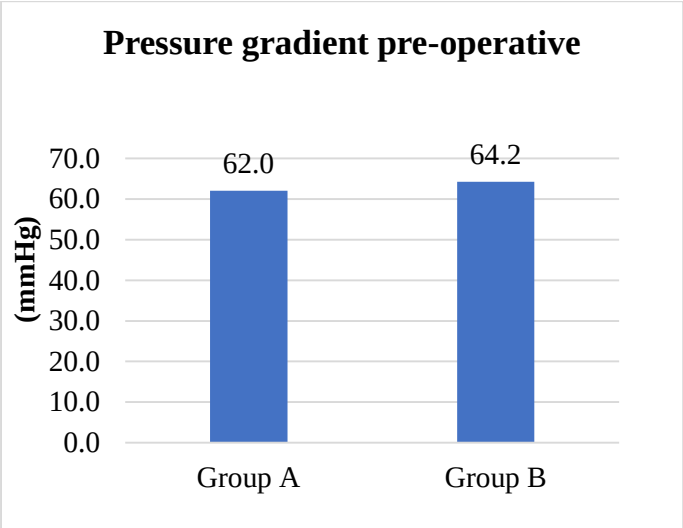


Figure (2): Pre-operative pressure gradients in both groups.

Table (1): Summary of pre-operative data.

Preoperative data	Group A N=20	Group B N=20	P-value
A. Demographic data. **Age at PAB (mean ±SD)**	6.1 ± 2.1 m	5.6 ± 1.8m	0.419
Weight at PAB	4.6± 1.2 Kg	4.3± 1.2Kg	0.368
Age at debanding (mean ±SD)	26.2 ± 8.8m	29.7 ± 9.7Kg	0.248
Weight at debanding **Time interval between PAB and debanding**	12.2± 2.9Kg 20.1 ± 8.4 m	11.3± 2.1Kg 21.6 ± 9.2 m	0.288 0.354
Gender Male Female	11 (55%) 9 (45%)	10 (50%) 10 (50%)	0.632
Down syndrome	12 (60%)	13 (65%)	0.842
B. Echocardiographic data **Type of anomaly** AVCD VSD	8 (40%) 12 (60%)	7 (35%) 13 (65%)	0.744
Pressure gradient across the band (mmHg)	62.0±9.8	64.2±10.6	0.065

PAB: pulmonary artery banding, Kg: kilogram, M: month, SD: standard deviation, CAVD: complete atrio-ventricular canal defect, VSD: ventricular septal defect

II. Operative data:

1. **Type of procedure:** As mentioned under the type of congenital anomaly, 8 cases in Group A (40%) received AVCD repair and 12 cases (60%) received VSD repair while in Group B, 7 patients (35%) underwent AVCD repair and 13 patients (65%) underwent VSD repair with no statistically significant difference.

2. **Intra-operative time parameters:**

The following table shows the different time parameters in the two groups. The mean aortic cross-clamp time was more or less the same in both groups (32 ± 10) minutes in Group A and (31 ± 8) minutes in Group B with no statistically significance difference (**P-value = 0.278)**.

On the other hand the mean total cardiopulmonary bypass time and total operative time were longer in Group B due to the time needed for patching of the pulmonary artery but with no statistically significant difference. The mean total bypass time was (50 ± 15) minutes for Group A and (56 ± 13) minutes for group B (**P-value = 0.236),** while the total operative time was (170 ± 30) minutes for Group A and (185 ± 25) minutes for Group B (**P-value = 0.215)** (Table **2**).

Table (2): Summary of operative time parameters.

Intra-operative time parameters (minutes)	Group A N=20	Group B N=20	P-value
Aortic cross-clamp time **Cardiopulmonary bypass time**	32 ± 10 50 ± 15	31 ± 8 56 ± 13	0.278 0.236
Total operative time	170 ± 30	185 ± 25	0.215

III. Post-operative data:

All the patients were transferred to the cardiothoracic ICU mechanically ventilated. Patients were carefully monitored and discharged from the ICU when hemodynamically stable with no inotropic support or chest drains, and with satisfactory postoperative laboratory profile.

1. **Duration of postoperative mechanical ventilation.** The mean duration of postoperative mechanical ventilation was almost the same for both groups, namely 12 ± 8 hours for Group A and 11 ± 9 hours for Group B with no statistically significant difference **(P-value=0.685)** (Table **3**).

2. **Duration of inotropic support:** Inotropic support was required in all patients. The median duration of inotropic support (hours) was the similar for both groups, namely 78 ± 36 for Group A and 72 ± 24 for Group B, with no statistically significant difference between two groups (**P-value= 0.539)** (Table **3**).

3. **Duration of ICU stay:** The mean duration of ICU stay (hours) was 84 ± 12 hours for Group A and 78 ± 12hours for Group B which shows no statistically significance difference with a **P-value of 0.368** (Table **3**).

4. **Postoperative blood loss:** There was no significant difference between both groups regarding the amount of blood loss in the chest drains postoperatively **(P-value=0.246)**. The mean amount of blood loss was 130 ± 50 milliliters for Group A and 120 ± 60 milliliters for Group B (Table **3**).

5. **Postoperative complications**

Three patients needed re-exploration for bleeding in both groups (15%) with no significant difference between both groups regarding the need for re-exploration (**P-value = 0.142).** Five patients had superficial wound infection, 2 in Group A (10%) and 3 in Group B (15%) with also no statistically significant difference between two groups (**P-value = 0.759).** All these patients were managed by repeated dressings and antibiotics according to culture and sensitivity.

In addition, seven patients developed severe chest infection, 3 in Group A (15%) and 4 in Group B (20%) with again no statistically significant difference between two groups (**P-value = 0.847).** Cases complicated with chest infection were successfully treated by proper antibiotics with only one patient died due to respiratory failure in group A. ECG changes were detected in both groups. Most of the changes were reversible arrhythmias including, paroxysmal supraventricular tachycardia and premature ventricular contractions. Irreversible complete heart block requiring permanent pacemaker was recorded in 3 cases, 1 case in Group A (5%) and 2 cases in Group B (10%) with no statistically significant difference between the two groups (**P-value = 0.853)** (Table **3**)**.**

6. **Duration of hospital stay:** The mean duration of hospital stay (days) was 9 ± 3 days for Group A and 8 ± 2 days for Group B which shows no statistically significance difference with a **P-value of 0.746** (Table **3**).

7. **In-hospital mortality:** There was only one mortality in Group A (5%) due to respiratory failure complicating sever chest infection with no statistically significant difference between both study groups (**P-value**=632) (Table **3**).

Table (3): Summary of postoperative data

Postoperative data	Group A N=20	Group B N=20	P-value
Mechanical ventilation (hours)	12±8	11 ± 9	0.685
Duration of ICU stay (hours)	84 ± 12	78 ± 12	0.368
Inotropic support (hours)	78 ± 36	72 ± 24	0.539
Amount of blood loss (ml)	130 ± 50	120 ± 60	0.246
Postoperative complications			
Superficial wound infection	2	3	0.759
Re-exploration for bleeding	3	3	0.142
Chest infection	2	3	0.847
Irreversible heart block	1	2	0.853
Duration of hospital stay (days)	9 ± 3	8 ± 2	0.746
In-hospital mortality	1	0	0.632

IV. Postoperative echocardiographic data

1. **Pressure gradient across the pulmonary artery post-operative.**

Table (**4**) show the mean values of pressure gradients across the pulmonary trunk in the two groups immediately post-operatively in the ICU, just before discharge from the hospital and 1 month post-operatively in the outpatient clinic. As it is shown in the table statistically significant differences were present between both groups with a higher-pressure gradient in Group A. In addition significant pressure gradient (defined as residual pressure gradient above 35 mm Hg at discharge) was detected in 8 cases (40%) of Group A and only 2 cases (10%) in Group B. This difference was statistically significant (**P-value=0.028)** (Table **4**).

2. **Degree of pulmonary regurgitation:**

In the pre-discharge echocardiography, 45% in Group A, had no pulmonary regurgitation (PR), 40% had mild degree of PR and 15% had moderate degree. While in Group B, 55% had no regurgitation, 35% had mild degree and only 10% had moderate degree. These differences were not statistically significant **p=0.792** (Table **4**).

Table (4): Summary of postoperative echocardiographic data

Postoperative echocardiography	Group A	Group B	P-value
1.Pressure gradient (mmHg)			
Immediately postoperatively	22.8 ±18	11.3 ±8	**0.020**
Before discharge	23.4 ±16	11 ±7.5	**0.018**
One month follow up	24.3 ±16	10.8 ±7	**0.016**
Significant pressure gradient (PG ≥ 35 mm/Hg)	8 (40%)	2 (10%)	**0.028**
2. Pulmonary regurgitation			
No regurge	45%	55%	
Mild regurge	40%	35%	0.792
Moderate regurge	15%	10%	

DISCUSSION

I. Pre-operative assessment:

The preoperative profile of both groups was similar with no statistically significant difference. These two matched groups allowed us to compare adequately our postoperative results and outcomes to achieve a conclusion regarding the debanding procedure.

As regards to age and weight at the time of PAB the median age (months) was 6 months for Group A (mean 6.1 ± 2.1) and 5 months for Group B (mean 5.6 ± 1.8). The mean weight (Kilograms) was 4.6 ± 1.2 for Group A and 4.3 ± 1.2 for Group B. Recent studies conducted in Egypt and included PAB cases like the one done by **Elkhadragi *et al.*** [7] showed a mean age of 4.7 ± 1.78 months and a mean weight of 4.1 ± 0.83Kg which were similar to our study.

In general, there is an international trend toward performing PAB at a younger age before the development of pathological changes and irreversible pulmonary hypertension in the pulmonary vasculature.

Masaki *et al.* [3] discussed reverse remodeling after PAB and optimal timing of PAB. Their study showed that the reversibility of increased pulmonary vascular resistance was found to be most pronounced when PAB was performed before the age of 6 months. This was evidenced by significant pulmonary artery medial thinning and improvement in intimal lesions.

Sandrio *et al.* [8] reported cases with intraluminal PAB with a median age of 2 months (range: 5 days to 4 years) and a median body weight of 3.7 Kg (range: 2.6-13.0 kg). While **Hoseinikhah *et al.*** [9] reported 50 PAB patients with a mean age of 4.6 ± 1.3 months and a mean weight of 5.3 ± 1.7Kg.

In addition, regarding the age and weight at the time of debanding the median age (months) was 24.5 for Group A (mean 26.2 ± 8.8) and 28 for Group B (mean 29.7 ± 9.7). The mean weight (Kilograms) was (12.2 ± 2.9) for Group A and (11.3± 2.1) for Group B. There are variations in the timing of debanding and full repair among studies according to the pathologies included in each study and the mean initial PAP at the time of debanding. For example the study conducted by **Dehaki *et al.*** [5] showed a similar mean age (30.48 ± 11months) and mean weight (11 ± 2.6Kg) at the time of debanding to our study. This study included 175 cases of VSD compared to 63 cases of CAVC.

On the other hand the study reported by **Brooks *et al.*** [10] showed a higher mean age of 36.4 ± 24.9 months and mean weight of 11.8 ± 4Kg compared to our study. This study included 69 cases of CAVC (55%) compared to only 56 cases of VSD (45%).

Similarly, regarding the time interval between banding and debanding the median time interval (months) was 20 months for Group A (mean 20.1 ± 8.4) and 22.0 months for Group B (mean 21.6 ± 9.2). **Dehaki *et al.*** [5] showed comparable results to our study with a mean time interval between PAB and debanding of 21.7 ± 11 months.

While **Brooks *et al.*** [10] showed a higher mean time interval between PAB and debanding of 26.8 ± 9 months.

All cases in Group A and B had well-placed bands with adequate pressure gradient mean across the band (**62.0±9.8) mmHg in Group A** and (**64.2±10.6) in** Group B. The study performed by **Dehaki *et al.*** [5] showed similar results to our study with a mean preoperative pressure gradient across the band of 56 ± 18 mm Hg.

II. Intra-operative assessment:

There was no statistically significant difference between two groups regarding the mean aortic cross-clamp time. The mean was 32 ± 10 minutes in Group A and 31 ± 8 minutes in Group B with no statistically significance difference (**P-value = 0.278)**. On the other hand the mean total cardiopulmonary bypass time and total operative time were longer in Group B due to the time needed for patching of the pulmonary artery but with no statistically significant difference. The mean total bypass time was 50 ± 15 minutes for Group A and 56 ± 13 minutes for group B (**P-value = 0.236),** while the total operative time was 170 ± 30 minutes for Group A and 185 ± 25 minutes for Group B (**P-value = 0.215).**

III. Postoperative assessment:

Postoperative surgical outcome was satisfactory in both study groups with few encountered complications and mortality. Three patients needed re-exploration for bleeding in both groups (15%), five patients had superficial wound infection (2 in Group A and 3 in Group B), seven patients developed severe chest infection (3 in Group A and 4 in Group B) and irreversible complete heart block requiring permanent pacemaker was recorded in 3 cases (1 case in Group A and 2 cases in Group B. Only one mortality occurred in Group A (5%) due to respiratory failure complicating sever chest infection.

Baharestani *et al.* [11] reported in their study addressing debanding one patient (1.5%) with surgical hemorrhage requiring re-exploration and five patients (7.8%) with complete heart block requiring permanent pacemaker.

In the study reported by **Brooks *et al.*** [10]**,** only 1 patient out of 62 (0.02%) died after full correction and debanding was achieved.

Regarding the Echo-assessment done immediately post-operatively in the ICU, just before discharge from the hospital and 1 month post-operatively in the outpatient clinic, P-values were found to be 0.020, 0.018 and 0.016 respectively. Statistically significant differences were found between both groups regarding pressure gradients across the pulmonary artery postoperatively**.** Group A had a higher-pressure gradients mean than Group B**.** However, the pressure gradient was considered significant if only measured above 35 mm Hg, where it can cause pressure overload on the right ventricle. In Group A, eight patients had significant pressure gradient **(40%)**, where group B had

only 2 patients with significant gradient **(10%).** These results were statistically significant **(p = 0.028).**

There are only few studies including debanding cases that compared simple band removal with band removal and pulmonary artery patching. Most centers adopt only one technique and may add pulmonary artery reconstruction if residual stenosis of the main trunk is obvious.

In the study conducted by **Dehaki *et al.*** [5] only 20% of patients underwent pulmonary artery repair with pericardial patch and 80% underwent simple band removal without any repair. However the study compared both groups regarding residual PS after debanding either with or without pericardial patch and showed no significant differences. In this study only 2% of cases had significant residual PS, which is considered much lower than our study.

In the study reported by **Brooks *et al.*** [10]**,** only 3 patients out of 62 (5%) required patching of the pulmonary artery. There was no comparative data between patients who underwent pulmonary artery patching and those who did not. Similarly **Pinho *et al.*** [12] reported debanding cases with band-related RVOT or PA complications occurring in 8 patients (13.3%) and reconstruction of the pulmonary artery by a patch.

Finally the degree of pulmonary regurgitation was assessed postoperatively in our study to elicit the possibility of affection of pulmonary valve caused by pulmonary artery patching.

There was no significant PR (> moderate) encountered in our cases and there was no statistically significant difference between two groups **(p = 0.792).** The results reported by **Dehaki *et al.*** [5] showed an incidence of 0.3% of pulmonary valve injury and associated pulmonary regurgitation. **Baharestani *et al.*** [11] reported only one patient (1.5%) who had pulmonary valve regurgitation necessitating pulmonary valve replacement.

CONCLUSION

Pulmonary artery repair with pericardial patch showed the advantage of reducing the risk of significant residual pressure gradient across the band site over simple band removal in pulmonary artery debanding.

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Conflict of interest: Nil.

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