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A randomized controlled trial (PAMI trial) on our new trend periareolar minimally invasive (PAMI) technique versus inframammary approach for minimally invasive cardiac surgery

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Abstract

Background: A minimally invasive approach has become standard for mitral valve surgery. The periareolar approach has grown in popularity regarding the cosmesis for patients. We have adopted a new modification to the periareolar approach: the periareolar minimally invasive (PAMI) technique. The objectives of the current study are to test the hypothesis that the PAMI approach is more feasible and safer than the inframammary approach in addition to identify risk factors and assess outcomes of both periareolar and inframammary approach.

Methods: A randomized controlled trial of 3 months compared the PAMI technique to the inframammary approach for minimally invasive cardiac surgery.

Results: A total of 102 patients were enrolled and randomized into two groups: 53 received minimally invasive cardiac surgery through the periareolar approach, and 49 were the control group using the inframammary approach. Using intention-to-treat analysis, the periareolar approach was superior to the inframammary approach in surgical site infection (two cases in comparison to 8 with $P = 0.004$), and the number needed to treat for effectiveness was 8. No early deaths occurred, 97 cases (95.1%) needed no reoperation, and 5 cases (4.9%) were reopened for bleeding. The primary endpoints compared were the duration of procedure, duration of mechanical ventilation, amount of bleeding, ICU stay, and hospital stay. We found no statistically significant differences between the groups.

At 3 months, the secondary endpoints evaluated were the rate of surgical site infection, respiratory complications, groin complications, pericardial effusion, breast hematoma, and cosmesis using a Likert scale. We found no statistically significant difference between the groups, except for surgical site infection ($P = 0.004$) and cosmesis ($P < 0.001$).

Conclusions: The results of this PAMI trial are suggestive that the PAMI technique is most probably applicable for the right side of the heart, such as in atrial septal defect closure, tricuspid disease, and mitral valve surgery.

Trial registration: PAMI Trial [NCT04726488](https://clinicaltrials.gov/ct2/show/study/NCT04726488) Registered January 27, 2021

Keywords: Periareolar approach, Minimally invasive, PAMI technique, Mitral valve surgery, Atrial septal defect (ASD)

Background

The classic inframammary thoracotomy approach was first introduced by Carpentier in 1996. He performed the first video-assisted mitral valve repair through a minithoracotomy using ventricular fibrillation [1]. With more experience, video-assisted, two-dimensional

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endoscopes and robotics were introduced by Carpentier [1] and Chitwood [2, 3].

Poffo et al. adopted periareolar access for minimally invasive cardiac surgery in 2006 and published this technique in 2009 [4, 5]. Due to its safety and applicability to correction of mitral and tricuspid valve pathology, in addition to excellent aesthetic and functional results, Poffo et al. discussed in detail the patient selection, surgical technique, benefits, and drawbacks of their technique in 2018 [6]. This was followed by Durdu et al. [7], who highlighted the importance of the approach in female patients. Maruszewski et al. in Poland published a pilot study about the fully thoracoscopic periareolar approach in 2019, discussing the safety and feasibility of this approach [8].

The selection of patients for the Brazilian technique depends on the size of the areola, which should be more than 2.5 cm. The anesthesia is performed through a double-lumen endotracheal tube for selective pulmonary ventilation. In our new trend modification, the periareolar minimally invasive (PAMI) technique, the size of the areola is not important. Even in very small areolae, we extend the incision slightly medially for a few centimeters, and the anesthesia is still performed through conventional endotracheal intubation.

The periareolar incision in the Brazilian technique is performed at the lower edge of the areola, and the chest is entered through the 4th space. In contrast, in the PAMI technique, the incision is made along the upper edge of the areola, and the chest is entered through the 3rd space. The similarity is that in both techniques, the cannulation is femuro-femoral, and the surgery is video-assisted (Table 1).

The objectives of the current study are to test the hypothesis that the PAMI approach is more feasible and safer than the inframammary approach in addition to identify risk factors and assess outcomes of both periareolar and inframammary approach.

Methods

Study design

This was a double-blinded, randomized, two-parallel-group trial. To allow for patient blinding, patient randomization was performed after the induction of anesthesia. Randomization used a computer program developed by the Division of Biomedical Statistics and Informatics. After the randomization results were displayed on a screen in the operating room, the surgical team performed the appropriate technique.

After the induction of anesthesia, the patient was prepped and draped in a sterile fashion.

To decrease variability, a dedicated surgical team with a single surgeon was established to perform the inframammary and PAMI procedures, and no code was broken before complete data analysis. The technical details for each approach are outlined in Fig. 1.

Patient selection

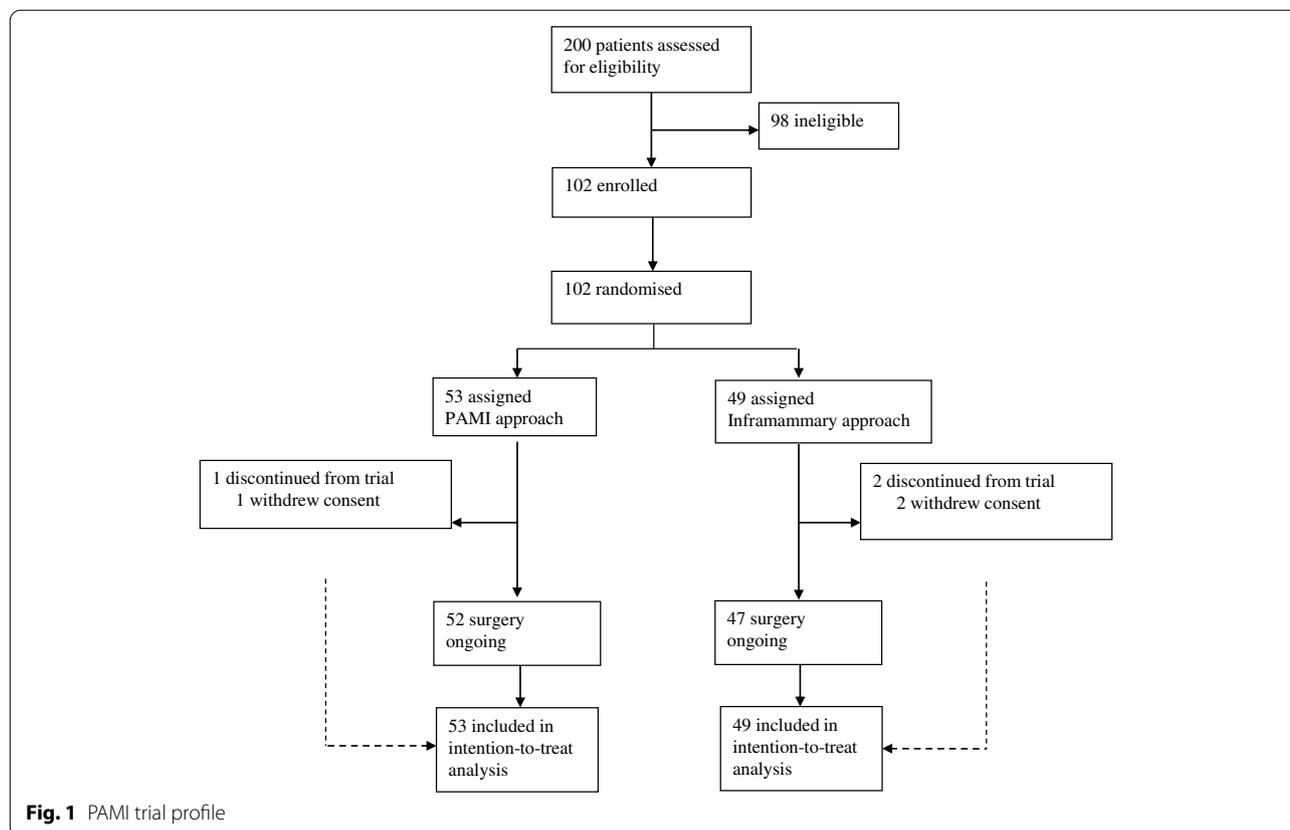
From March 2021 to January 2022, 102 patients were recruited for minimally invasive surgery in the study in our cardiothoracic surgery department and operated on by one surgeon. They comprised 22 patients with ASD; 79 with mitral valve disease, either regurgitation, stenosis, or combined; and one with tricuspid infective endocarditis.

The patients were surgically treated with ASD closure, mitral valve replacement, and tricuspid valve replacement, respectively, through a minimally invasive approach. Of all patients, 53 were treated through our new PAMI technique, and the remaining 49 cases were treated through the inframammary approach of minimally invasive surgery.

The patients were 31 males (30.39%) and 71 females (69.61%). Their ages ranged from 15 to 65 years, with a mean \pm SD of 36.13 ± 10.82 years old.

Table 1 Differences between Brazilian periareolar technique and new modification PAMI technique

	Brazilian technique (Poffo et al.)	PAMI technique
Anesthesia	Double-lumen endotracheal cannula for selective pulmonary ventilation	Conventional endotracheal intubation
Size of areola	> 2.5 cm	Not important; if < 2.5 cm, extend incision medially
Incision	Lower edge of areola	Upper edge of areola
Chest entry	4th space	3rd space
Video-assisted	Yes	Yes
Placement of telescope	Separate port in the 4th right intercostal space anterior axillary line	Separate port in the 3rd intercostal space between mid and anterior axillary line or can passed through the same the thoracotomy incision (i.e., uniportal PAMI technique).
Arterial cannulation	Femoral	Femoral
Venous cannulation	Femoral	Femoral



The inclusion criteria were patients undergoing mitral or tricuspid valve surgery and lesions of the right side of the heart. The exclusion criteria were patients undergoing aortic valve or CABG surgery, surgery on the left side of the heart, redo surgery, and any previous chemo- or radiotherapy to the breast.

The demographic and clinical profile of the 102 patients is shown in Table 2.

Informed consent was obtained from all patients. The research was approved by the ethical committees of our institution (IRB No. 17200554) and registered as a clinical trial (PAMI Trial NCT04726488).

The study enrolled 102 patients who fulfilled the inclusion criteria and continued to 3 months of follow-up. Those 102 patients were divided into two groups according to the minimally invasive incision approach.

Group I (periareola minimally invasive, i.e., PAMI)

Fifty-three patients who had minimally invasive surgery through the periareolar approach.

Group II (inframammary minimally invasive, i.e., IFMI)

Forty-nine patients who had minimally invasive surgery through the inframammary approach.

Table 2 Demographic details of our randomized controlled trial (PAMI trial)

Variables	PAMI (n = 53)	IFMI (n = 49)	P value
Age (years)	38.72 ± 8.89	33.33 ± 12.06	0.011**
Sex			
Male, n (%)	22 (41.51)	9 (18.37)	0.011*
Female, n (%)	31 (58.49)	40 (81.63)	
Weight (kg)	72.58 ± 15.06	73.71 ± 11.17	0.670
Height (cm)	165.4 ± 10.27	166 ± 6.5	0.726
BSA	1.82 ± 0.22	1.84 ± 0.16	0.576
DM	3 (5.66%)	7 (14.29%)	0.143
Diagnosis			
ASD	9 (16.98%)	13 (26.53%)	0.034*
MS	14 (26.42%)	12 (24.49%)	
MR	13 (24.53%)	20 (40.82%)	
MR + MS	16 (30.19%)	4 (8.16%)	
TV disease	1 (1.89%)	0	

PAMI periareolar minimally, IFMI inframammary minimally invasive, BSA body surface area, DM diabetes mellitus, ASD atrial septal defect, MS mitral stenosis, MR mitral regurgitation, TV tricuspid valve

Surgical technique

Anesthetic considerations

Anesthesia was conducted as in conventional open-heart

surgery, with some considerations.

A double-lumen endotracheal tube was not necessary except if severe pulmonary difficulty or adhesions were expected or in an emphysematous patient.

Transesophageal echocardiography (TEE) was placed with external defibrillator pads on the back of the patient.

Preparation and exposition (Fig. 2a)

The patient was placed in the supine position, elevated 30° on a towel roll using a sandbag below the right chest.

The arm was slightly abducted to clear the axilla for placement of the transthoracic aortic clamp and the 30° telescope.

We used a 30° 5-mm telescope, introduced in the 3rd intercostal space between the mid and anterior axillary lines.

Femuro-femoral cannulation (Fig. 2b)

A 2–3-cm oblique incision was made above and parallel to the inguinal crease. The subcutaneous tissue was dissected, and the deep fascia was opened to expose the femoral vessels. The common femoral artery was doubly encircled. A transverse arteriotomy was made in the artery, and the cannula was advanced; we preferred direct cannulation.

The distal clamping of the artery was proximal to the origin of the profunda artery to allow collateral circulation to the lower limb. The arterial jet was confirmed before connecting the pump lines to avoid femoral artery dissection, which could progress to catastrophic retrograde aortic dissection. A purse-string (5/0) polypropylene suture was placed in the femoral vein, and the femoral venous cannula (22–24 Multistage Edward femoral venous cannula) was advanced towards the right atrium with its tip in the SVC. The introduction of the femoral venous cannula was under echocardiographic guidance. Any resistance during insertion was not met by forceful insertion; reintroduction was guided by TEE.

Group I: PAMI technique (Fig. 2d,e)

A skin incision was made along the upper curvature of the areola. The incision could be extended slightly medially in the case of a small areola. This incision is directly over the 3rd intercostal space, which was advantageous in our opinion. The subcutaneous fat of the breast was cut sharply with electrocautery. The glandular tissue of the breast was retracted caudally to avoid lactiferous ducts as much as possible. The pectoral muscle was divided, and the chest was entered via the 3rd space, a favorable approach in minimally invasive surgery because it provides good access to the great vessels (the aorta and SVC). This allowed safe cannulation of the ascending aorta for the sake of antegrade cardioplegia, selective cannulation

of the SVC, and placement of caval tourniquets or bulldog closure of the SVC in mini-invasive ASD closure.

Group II: inframammary thoracotomy incision (Fig. 2f)

A right anterolateral thoracotomy incision was made in the inframammary crease (6–9 cm). The incision was made from just lateral to the midclavicular line to the anterior axillary line. Lateral incisions give better access and visualization of the mitral valve.

Access is usually through the intercostal spaces above the skin incision (3rd–4th) spaces.

A retraction suture of the diaphragm was applied. The pericardium was opened 2–4 cm anterior to the phrenic nerve over plastic suction in front of the aorta down to the diaphragm, and around 4 pericardial stay sutures were placed. After the institution of cardiopulmonary bypass and complete drainage of the heart, the purse-string suture of cardioplegia and cannula insertion was performed. The 30° 5-mm telescope was introduced in the 3rd intercostal space midaxillary line.

In both groups (I, II)

For mitral valve surgery, the mitral retractor was placed in the 3rd intercostal space in the parasternal line, and the left atrium was incised in Sondergaard's groove. Mitral valve replacement was performed with the conventional MICS technique. The left atrium was then sutured with a 4-0 polypropylene running suture. Intraoperative TEE was routinely performed to ensure the mitral valve leaflets remained away from the left ventricular outflow tract during systole and exclude systolic anterior motion (SAM) (Fig. 2c).

For ASD closure, a transverse incision through the right atrium was performed, and all ASD was corrected with an autologous pericardial patch sutured with a 4-0 or 5-0 polypropylene running suture. Then, the right atrium was closed with a 4-0 polypropylene running suture.

After atrial closure, the cardioplegia needle was connected to an aspiration line for deaeration, and the aortic clamp was released. After weaning from bypass, heparin was reversed, and cannulations were removed. The femoral artery and veins were reconstructed and sutured, and the femoral incision was closed in a standard fashion.

The periareolar incision was closed in layers with an absorbable suture.

Sample size calculation

The sample size to detect a significant difference in the mean length of incision between the two groups was calculated using G*power, version 3.1.9.2. A one-tailed test with a power of 80%, effect size of 0.5 (assumed based on the clinical experience of the surgeon), and α of 0.05, with

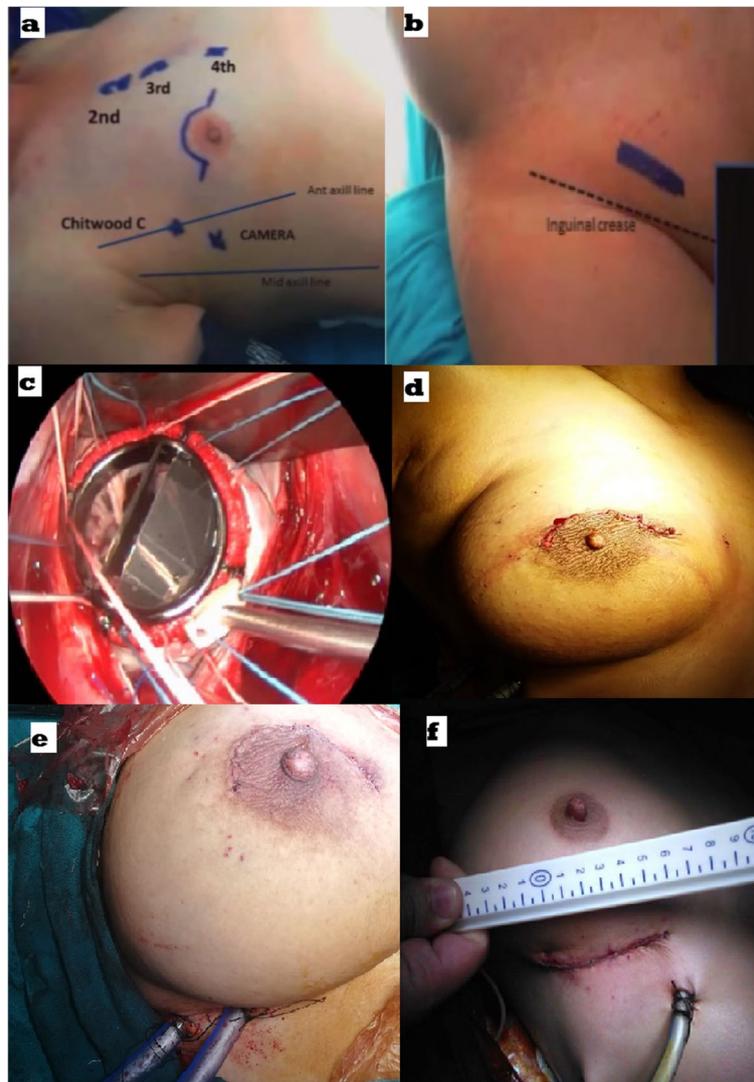


Fig. 2 **a** Skin demarcation for important landmark points during minimally invasive procedure. A point to the 4th intercostal space in the parasternal line for the left atrial retractor; a point in the anterior axillary line at the level of the 3rd space for Chitwood clamp; a point in the 4th intercostal space in the anterior axillary line for the 30° telescope. **b** Skin demarcation for groin cannulation. **c** Video-assisted mitral valve replacement (MVR) with tying the valve sutures using the knot pusher. **d** Incision for periareolar minimally invasive (PAMI) technique in a woman. **e** PAMI Incision in a woman with morbid obesity. **f** Incision for inframammary approach

a 1:1 allocation, yielded 51 patients in each group: a total of 102 required.

Statistical analysis

Statistical analyses were performed using SPSS version 26 (IBM Corporation; Endicott, New York, USA). The Shapiro–Wilk W test was used to test for normality. When the W statistical value proved significant, the hypothesis that the corresponding distribution was normal was rejected. Categorical variables were described with number and percent (N , %), whereas continuous variables were described with

mean and SD for normally distributed data and median and interquartile range (IQR) for non-normally distributed data. The chi-square test and Fisher's exact test were used to compare between categorical variables, and the t test was used to compare between continuous variables. A p value less than 0.05 ($P < 0.05$) was considered statistically significant.

Follow-up

Adverse events for both the active group (using our PAMI technique) and the control group (using the classic inframammary thoracotomy approach) were

reported, and their clinical significance was calculated using absolute risk reduction and the number needed to treat (NNT). The NNT for the effectiveness of the PAMI technique compared to the inframammary approach was approximately 8 for surgical site infection.

Results

Preoperative data

The preoperative data were nearly the same in the two groups (Table 2). The mean age was 38.72 ± 8.89 years in the PAMI group and 33.33 ± 12.06 years in the control group. The PAMI group had 22 men and 31 women, in contrast to 9 men and 40 women in the control group.

The surgery was uneventful in all patients, and no operative mortality occurred. A highly statistically significant difference was found in the length of incision in the periareolar approach compared to the inframammary approach (control group; $P < 0.001$). The durations of cardiopulmonary bypass and cross-clamp were comparable between the groups. The operative and intraoperative results of the 102 patients are shown in Table 3.

Postoperative data

No mortality occurred in either group, with freedom from reoperation in 97 cases (95.1%) and only 5 cases (4.9%) reopened for bleeding. The primary endpoints compared were the duration of procedure (from skin incision to cardiopulmonary bypass initiation), duration of mechanical ventilation in hours (first time to extubate), number of transfused packed RBC units, amount of bleeding, ICU stay, and hospital stay. We found no statistically significant differences between the groups (Table 4).

In the short-term 3-month results, the secondary endpoints evaluated were the rate of surgical site infection, respiratory complication, groin complication, pericardial effusion, breast hematoma, and Likert scale for cosmesis. We found no statistically significant difference in both groups except for surgical site infection ($p = 0.004$) and cosmesis using a Likert scale ($P < 0.001$) (Table 4).

A total of 5 cases were reopened for bleeding on either the same or the following day after surgery.

Among both groups, the complications were 10 cases of surgical site infection, 7 cases of groin complication, 2 cases of chest atelectasis, and 1 case of pericardial effusion. Three cases of breast hematoma in the PAMI approach resolved either conservatively or with surgical drainage (Table 4).

Echocardiographic control at hospital discharge revealed accurate mitral valve replacement and perfect ASD closure in all cases.

Discussion

All innovations in cardiac surgery aim to obtain smaller incisions with less invasive and better aesthetic results.

Navia and Cosgrove [9] and Cohn et al. [10] performed the first minimally invasive valve operations via the right parasternal and transsternal approaches. Remarkably, excellent exposure was achieved through smaller incisions, thereby making complex valve repair possible and safe. In 1996, Carpentier et al. [1] performed the first video-assisted mitral valve repair through a minithoracotomy using ventricular fibrillation. With more experience, video-assisted, two-dimensional endoscopes and robotics were introduced by Carpentier [1] and Chitwood [2, 3].

In 2009, Poffo et al. [4, 5] described a new technique of minimally invasive cardiac surgery. They adopted periareolar access for mitral valve surgery from 2006 and published this technique in 2009. Due to its feasibility and safety, it was soon incorporated as an ideal access for other cardiac pathologies such as tricuspid valve disease, ASD, atrial fibrillation, and pacemaker lead endocarditis. This led Poffo et al. to publish long-term results of the technique in 2018, supporting the use of periareolar access as a routine surgical technique for the correction of several cardiac pathologies, especially in women [6]. This was followed by Durdu et al. [7] highlighting the importance of the periareolar approach in women. Maruszewski et al. in Poland published a pilot study about the totally thoracoscopic periareolar approach in 2019, discussing the safety and feasibility of this approach [8].

At our institution, from March 2021 to January 2022, we performed 53 surgeries using the new modification PAMI technique: 22 men (41.51%) and 31 women (58.49%). This study group included one case of isolated tricuspid valve pathology, 9 cases of secundum ASD, and 43 cases of mitral valve pathology, either stenosis or regurgitation. It did not include minimally invasive double valve procedures or aortic valve surgeries.

The patients' ages ranged from 20 to 65 years, with a mean of 38.72 ± 8.89 years. The median aortic cross-clamp and cardiopulmonary bypass times were 90 min

Table 3 Operative and intraoperative data of our PAMI trial

	PAMI (n = 53)	IFMI (n = 49)	p value
Length of incision (cm)	4.62 ± 0.53	7.96 ± 0.79	< 0.001**
Type of operation			
MV surgery	43 (81.13%)	36 (73.47%)	0.334
ASD closure	9 (16.98%)	13 (26.53%)	
TV surgery	1 (1.89%)	0	
Bypass time (min)	110 (90–120)	110 (70–120)	0.299
Cross-clamp time (min)	90 (75–100)	90 (50–90)	0.025*

PAMI periareolar minimally invasive, IFMI inframammary minimally invasive, ASD atrial septal defect, MV mitral valve, TV tricuspid valve

Table 4 Primary and secondary endpoints of our PAMI trial

	PAMI (n = 53)	IFMI (n = 49)	p value
Duration of procedure (min)	106.7 ± 12.32	107.2 ± 11.49	0.831
Duration of mechanical ventilation (hours)	3.09 ± 1.4	3.08 ± 1.35	0.963
Number of transfused packed RBC units	2 ± 0.88	1.88 ± 0.86	0.478
Reoperation for bleeding	1 (1.89%)	4 (8.16%)	0.142
Bleeding (cc)	271.88 ± 163.38	325.64 ± 192.24	0.162
ICU stay (hours)	36 (24–48)	48 (48–48)	< 0.001**
Hospital stay (days)	3 (2–3)	4 (3–4)	< 0.001**
Secondary endpoint			
Surgical site infection (SSI)			
Superficial	0	8 (16.3%)	0.004**
Seroma	2 (3.8%)	0	
Rate of SSI (weeks)	3.5 ± 0.71	5.88 ± 1.96	0.143
Breast hematoma	3 (5.66%)	0	0.091
Respiratory complications			
Pleural effusion	1 (1.89%)	2 (4.08%)	0.261
Atelectasis	0	2 (4.08%)	
Groin complication	2 (3.77%)	5 (10.2%)	
Femoral embolectomy	0	1 (2.04%)	0.499
Interposition vein graft for femoral artery	0	1 (2.04%)	
Right femoral cannulation was troublesome, and we shifted to left femoral cannulation	0 (0%)	1 (2.04%)	
Groin seroma	2 (3.77%)	2 (4.08%)	
Pericardial effusion	0	1 (2.04%)	0.296
Likert scale for cosmesis			
Disagree	0 (0%)	4 (8.16%)	< 0.001**
Neutral (neither agree nor disagree)	6 (11.32%)	14 (28.57%)	
Agree	19 (35.85%)	30 (61.22%)	
Strongly agree	28 (52.83%)	1 (2.04%)	

PAMI periareolar minimally invasive, IFMI inframammary minimally invasive

(interquartile range [IQR], 75–100 min) and 110 min (IQR, 90–120), respectively. The median length of hospital stay was 3 days (IQR, 2–3), and freedom from reoperation was 98%. Furthermore, no 30-day mortality occurred.

Our PAMI technique and the Brazilian technique are described in the introduction and summarized in

Table 1. The adoption of the 3rd space in our PAMI technique has clinical implications. We preferred the 3rd space to the 4th space because it gives good access to the great vessels (aorta and SVC). For example, if displacement of the aorta occurs and we need the minimally invasive clamp, we can handle it by easily placing gauze behind the aorta to pull it in front, which could

Table 5 Pros and cons of 3rd and 4th space according to our surgical experience

	4th space	3rd space
Termed in relation to our experience	Space of practicability	Space of safety or Sense of security
Access to aorta	Limited access	Good access
Access to SVC	Limited access	Good access
Displacement of aorta	Cannot handle	Can handle by putting gauze behind it to pull it in front
Mitral valve	Directly in front	Must stand in a tilted position (30°)

be difficult if we entered the chest through the 4th space as other surgeons do. For that reason, we term the 3rd space “the space of safety.” In the 4th space, the mitral valve is in front but without good access to the aorta, so we term it “the space of practicability”.

We recommend starting with the space of safety, then using the space of practicability with more experience. The differences between the 3rd and 4th spaces in our experience are summarized in Table 5.

The learning curve for the periareolar technique is still growing. However, after an accurate learning curve and good experience, the approach seems to be promising for complex pathologies in the mitral valve, and the procedure is considered as safe as the conventional approach [3, 11–13].

Extension of the incision in the periareolar approach is preferred not to be over 180° around the areola. This helps in preserving the neurovascular supply of the nipple–areola complex and guarding against necrosis or sensitivity loss [14].

Patients who have received breast irradiation, surgery for breast cancer, or reconstructive surgery (mastopexy) are not good candidates for our technique. Due to unknown previous vascular compromise, both areola and nipple could be at risk of necrosis [15].

Modification to our present PAMI technique is ongoing. Firstly, we performed mitral valve replacement and ASD closure using the 3D-vision, totally endoscopic PAMI technique. Camera support toward the assistant makes the surgeon more comfortable, especially when the surgeon is going through a higher space.

Secondly, we are using the Cosgrove clamp instead of the Chitwood clamp, and the 30° 5-mm telescopic camera introduced through the same periareolar incision (i.e., uniportal PAMI technique).

Several limitations to our study need to be acknowledged. The study was conducted from a single center, so limited patients were operated on using our new modified technique. Various types of surgeries that would have an influence of the results. Additionally, the team’s learning curve may not be a factor in other circumstances.

Conclusions

The results of this PAMI trial are suggestive that the PAMI technique is most probably safe, effective, and reproducible approach for all video-assisted mitral valve surgery, tricuspid disease, and surgery of the right side of the heart such as ASD closure.

Abbreviations

PAMI: Periareolar minimally invasive; IFMI: Inframammary minimally invasive; SVC: Superior venae cava; IVC: Inferior venae cava; BSA: Body surface area; DM: Diabetes mellitus; ASD: Atrial septal defect; MS: Mitral stenosis; MR: Mitral regurgitation; TV: Tricuspid valve; MV: Mitral valve; MVR: Mitral valve replacement.

Acknowledgements

I would like to acknowledge Professor Farag Moftah, Professor of statistics and public health, Assiut University and Prof. Faten Rabea, Professor of Epidemiology and Public Health, Assiut University, for their support and encouragement for creation of this endeavor.

Authors’ contributions

All authors (ME, MAN, AA, MK) have contributed significantly to the content of the article. All authors analyzed and interpreted the patient data and help in writing the manuscript. All authors have read and approved the final manuscript.

Funding

The research has no funding.

Availability of data and materials

All data generated or analyzed for our modified technique during this study are included in this published article.

Declarations

Ethics approval and consent to participate

The Research approved by the Ethical Committees of Faculty of Medicine, Assiut University, Egypt IRB NO. 17200554 in March 2021. Informed written consent obtained from all patients. All methods were performed in accordance with the Declaration of Helsinki.

Consent for publication

Informed written consent obtained from all patients.

Competing interests

The authors declare that they have no competing interests.

Received: 17 November 2022 Accepted: 22 December 2022

Published online: 29 December 2022

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