## Midterm Results of Mitral Valve Replacement for Heart Disease in Females in Child Bearing Period - Mechanical Versus Tissue Valves

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#### Abstract

*Background:* Current guidelines limit mitral valve replacement to irrepairable valve pathology that will result in poor durability outcomes, especially in patients unlikely to tolerate future reinterventions. There are two basic types of prosthetic heart valves used in current clinical practice: Mechanical and bioprosthetic valves. Young women planning pregnancy are considered high risk patients who require careful selection of the optimal prosthetic heart valve. Some authors advocate that mechanical heart valve prostheses, which require lifelong anticoagulant therapy (warfarin), are not appropriate because of the teratogenic potential of anticoagulants. However, the main issue with bioprosthetic heart valves is their finite lifespan and high risk of reoperation in the future.

*Aim of Study:* To primary outcome: To compare midterm results of post-operative outcome between mechanical versus tissue valves in the terms of morbidity in females in the childbearing period. Hence guide future choice of prosthetic valves in females in childbearing period. Secondary outcome: To discuss the rate maternal complication for both types of valves during pregnancy.

*Patients and Methods:* This study was conducted at the Cardiothoracic Surgery Department, Souad Kafafi University Hospital and Ain Shams University Hospitals. The study period starting between 2013 to 2018.

*Results:* Our results showed that the pre-operative Left Ventricular End Diastolic Diameter (LVEDD), Left Ventricular End Systolic Diameter (LVESD) were significantly lower in the mechanical group and the Ejection Fraction (EF) was significantly lower in tissue group. The MVA was significantly lower and the pressure gradient was significantly higher in tissue group than mechanical group. Post-operatively, the LVEDD and LVESD remained significantly lower in mechanical group; however, the EF was comparable between both groups. Although, the post-operative pressure gradient was higher in tissue group, but it is not reflected on the durability of the valve at this age group regarding the midterm results of our study, and there were no statistically significant differences between both groups in terms of MVA, incidence of new regurge, or paravalvular leak. *Conclusion:* Tissue valves appear to be the preferred option for women in childbearing period with MVD with better mid-term results than mechanical valves. The present study demonstrated that women with mechanical valves had a high rate of pregnancy loss. The risk of cardiovascular complications is higher in mechanical valves, as the main risks are related to the need of anticoagulation therapy (hemorrhagic and thromboembolic complication) additional risks related to ventricular and valvular dysfunction as well. Furthermore the rate of reoperation is much higher in mechanical valves, it can be significant in the presence of bioprosthetic dysfunctions. So, large-scale, studies are still needed to confirm our findings.

Key Words: Left ventricular end diastolic diameter – Left ventricular end systolic diameter.

#### Introduction

**THE** Mitral Valve (MV) diseases are the secondmost common clinically significant form of valvular defect in adults [1].

Surgery performs a key role in order to treat the patients with valvular heart disease, which lead to less mortality and better quality-of-life [2].

Current guidelines limit mitral valve replacement to irrepairable valve pathology that will result in poor durability outcomes, especially in patients unlikely to tolerate future reinterventions. The presence of significant annular calcification; valvular dystrophic, inflammatory, or infective changes; subvalvular thickening or fusion; and progressive cardiomyopathy warrant primary mitral valve replacement to avoid the adverse operative outcomes associated with heroic attempts at repair that eventually result in replacement [3].

Mechanical valves are the commonest implanted valves, and thus, patients continue to take oral anticoagulants [4]. A mechanical prosthesis is recommended according to the desire of the informed

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patient if there are no contraindications for longterm anticoagulation [3]. Mechanical valves pose a special problem during pregnancy. Whoever warfarin is the most effective drug for preventing valve complications, is teratogenic and also increases fetal loss. Other anticoagulant regimens are less effective and therefore increase the risk of maternal and fetal complications. Chronic anticoagulation can also significantly affect young patient's quality of life [5].

The use of tissue valve prosthesis during childbearing period decreases the risk of thromboembolism and do not need maintenance of any kind of anticoagulation drugs during pregnancy, but it is associated with Structural Valve Deterioration (SVD), so requiring reintervention [4]. Practice guidelines are gradually moving toward recommending tissue valves in the majority of young women. There are emerging solutions for valve degeneration that will further tilt the balance in favor of these valves [5].

Lim et al., [6] developed a next-generation a-Gal-free tissue valve with GA-fixed cardiac xenografts, treated using a novel combined anticalcification protocol including immunological modification, with a-galactosidase, space filler, an organic solvent and detoxification. In addition, they extracted phospholipids with an ethanol/ octanol solution to reduce the calcification potential of the aldehyde groups. Furthermore, they proved the feasibility of the procedure by first using a mock circulation and then implanting the treated valves.

The GA fixation is commonly used to provide resistance to biodegradability and to reduce the antigenic host response [7].

### **Patients and Methods**

Study design: This is a retrospective study.

*Study setting:* This study was conducted at the Cardiothoracic Surgery Department, Souad Kafafi University Hospital and Ain Shams University Hospitals.

*Study period:* The study period starting between 2013 to 2018.

#### Study population:

*Inclusion criteria:* Female patients with mitral valve disease who has underwent MVR with mechanical or tissue valve. Age of the patients between 18-45 years at the time of surgery.

*Exclusion criteria:* Age of the patients below 18 or above 45 years at the time of surgery. Concomitant coronary artery bypass surgery. Concomitant other valve replacement surgery. Impaired renal and liver function. Obese patients (BMI >350). Valve implantation after 2016.

Sample size: This study included 240 female patients who underwent MVR divided into two groups. Group (A) 120 patients under went MVR with mechanical valve and Group (B) 120 patients under went MVR with tissue valve.

#### Study procedure:

#### All patients were subjected to the following:

*Pre-operative data:* Regarding age, presenting dyspnea class according to New York Heart Association (NYHA), and pre-operative medications. Echocardiographic data was recorded regarding left ventricular volumes, ejection fraction, left atrial size, mitral valve disease and pulmonary artery pressure.

Post-operative data; midterm results (3-5 years): Follow-up data collected at the patient's followup hospital or outpatient visit (with more than 3 years after valve implantation) were: NYHA class. Echocardiography data: Left ventricular volumes, ejection fraction, left atrial size, mitral prosthesis assessment (gradients, valve area, new regurgitation, paravalvular leaks endocarditis and valve thrombosis) and pulmonary artery pressure. Occurrence of pregnancy. Valve thrombosis and thromboembolic complication. Hemorrhage. Valve degeneration. Infective endocarditis. Significant hemolysis. Reoperations.

#### Ethical consideration:

*Delegation of investigator responsibilities:* The investigator was ensuring that all patients assisting the trial are adequately informed about the protocol, and their trial-related duties and functions.

Patient information and informed consent: Before being admitted to a clinical study, the patient must consent to participate after the nature, scope and possible consequences of the clinical study have been explained in a form understandable to her.

*Protocol approval:* Before the begging of the study and in accordance with the local regulation followed the protocol and all corresponding document were declared for ethical and research approval by the council of the Cardiothoracic Surgery Department.

#### Statistical analysis:

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 23. The quantitative data were presented as mean, standard deviations and ranges when parametric and median with Inter-Quartile Range (IQR) when non parametric and percentiles was used to assess the distribution of some parameters. Also qualitative variables were presented as number and percentages.

The comparison between groups regarding qualitative data was done by using Chi-square test and/or Fisher exact test when the expected count in any cell found less than 5.

The comparison between two independent groups with quantitative data and parametric distribution was done by using independent *t*-test.

The comparison between two independent groups with quantitative data and non-parametric distribution was done by using Mann-Whitney test.

The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the pvalue was considered significant as the following: *p*-value >0.05: Non Significant (NS). *p*-value <0.05: Significant (S). *p*-value <0.01: Highly Significant (HS).

#### **Results**

Table (1): Demographic data for age range, NYHA class and duration.

	Mechanical Valve No.=120	Tissue Valve No.=120	Test- value	<i>p</i> -value
Age at index: Mean ± SD Range	33.83±5.87 18-41	34.53±5.23 23-42	-0.976•	0.330
NYHA I:IV: I II III IV	0 (0.0%) 15 (12.5%) 35 (29.2%) 70 (58.3%)	3 (2.5%) 50 (41.7%) 66 (55.0%) 1 (0.8%)	98.417	0.000

p-value >0.05 : Non Significant (NS).

p-value <0.05 : Significant (S).

*p*-value <0.01 : Highly Significant (HS).

: Chi-square test.

Independent t-test.

‡ : Mann Whitney test.

Table (2): Pre-operative ECHO data.

	Mechanical Valve No.=120	Tissue Valve No.=120	Test- value•	<i>p</i> -value
LVESD (mm):				
Mean ± SD	48.93±7.51	57.14±6.26	-9.198	0.000
Range	28-61	44-74		
LVEDD (mm):				
Mean ± SD	30.41±5.53	38.49±6.07	-10.777	0.000
Range	23-42	26-64		
EF:				
Mean ± SD	64.81±6.97	56.52±7.31	8.994	0.000
Range	49-77	40-75		
LA dim:				
Mean ± SD	$52.28 \pm 11.64$	51.96±5.20	0.279	0.780
Range	40-78	44-66		
PASP:				
Mean ± SD	54.59±16.66	47.95±5.48	4.148	0.000
Range	35-95	35-65		

*p*-value >0.05: Non Significant (NS).

*p*-value <0.05: Significant (S).

*p*-value <0.01 : Highly Significant (HS).

• : Independent *t*-test.

Table (3): Pre-operative ECHO data.

	Mechanical Valve No.=120	Tissue Valve No.=120	Test- value	<i>p</i> - value
MV area:				
Severe	88 (73.3%)	115 (95.8%)		
Moderate	16 (13.3%)	4 (3.3%)		
Mild	16 (13.3%)	1 (0.8%)		
MR grade:				
0	7 (5.8%)	31 (25.8%)	34.601*	0.000
1	12 (10.0%)	8 (6.7%)		
2	37 (30.8%)	9 (7.5%)		
3	16 (13.3%)	24 (20.0%)		
4	48 (40.0%)	48 (40.0%)		
MV mean PG:				
Mean ± SD	$12.48 \pm 3.73$	$15.19 \pm 2.84$	-6.333•	0.000
Range	1-19	9-21		
Valve size #:				
Mean ± SD	28.15±2.41	27.38±1.58	2.909•	0.004
Range	25-33	25-31		

*p*-value >0.05 : Non Significant (NS). *p*-value <0.05 : Significant (S).

*p*-value <0.01 : Highly Significant (HS).

\* : Chi-square test.

• : Independent t-test.

	Mechanical Valve		Ti V	ssue alve	Test-	p-	Sig.
	No.	%	No.	%	value*	value	
Heat failure:							
No	117	97.5	118	98.3	0.204	0.651	NS
Yes	3	2.5	2	1.7			
Arrhythmias:							
No	119	99.2	119	99.2	0.000*	1.000	NS
Yes	1	0.8	1	0.8			
Hx of valve							
thrombosis:							
No	113	94.2	120	100.0	7.210	0.007	HS
Yes	7	5.8	0	0.0			
Hx of endocarditis:							
No	117	97.5	118	98.3	0.204	0.651	NS
Yes	3	2.5	2	1.7			
Hx of Hemorrhage:							
No	113	94.2	120	100	7.210	0.007	HS
Yes	7	5.8	0	0.0			
Valve degeneration:							
No	120	100	118	98.3	2.017	0.156	NS
Yes	0	0.0	2	1.7			

Table (5): Relationship between type of prosthetic valve and development of complications.

No.

120 100

120

0

120

0

118

2

0

Tissue

Valve

%

0.0

100.0

100.0

0.0

98.3

1.7

0.0

Test-

value\*

5.106

4.068

p-

value

0.024 S

0.044 S

9.643 0.002 HS

Sig.

Mechanical

Valve

%

95.8

4.2

3.3

100.0

0.0

88.3

11.7

No.

115

116 96.7

120

106

14

*p*-value >0.05 : Non Significant (NS).

0

4

5

Table (4): Relationship between type of prosthetic valve and development of complication.

Table (6): Post-operative echo data.

	Mechanical Valve No.=120	Tissue Valve No.=120	Test- value•	<i>p</i> -value	Sig.
<i>LVEDD:</i> Mean ± SD Range	48.93±6.48 31-58	57.11±6.04 44-70	-10.109	0.000	HS
LVESD: Mean ± SD Range	31.97±4.97 20-44	38.90±6.65 25-59	-9.154	0.000	HS
<i>EF:</i> Mean ± SD Range	55.84±5.22 45-65	55.68±6.19 31-74	0.214	0.831	NS
<i>LA dim.:</i> Mean ± SD Range	50.72±6.77 40-73	48.98±4.73 40-63	2.299	0.022	S
PASP: Mean ± SD Range	41.97±11.02 28-75	36.73±4.85 30-48	4.771	0.000	HS
p-value >0.05 : p-value <0.05 :	•: Indep	endent i	t-test.		

*p*-value <0.01 : Highly Significant (HS).

Table (7): Post-operative echo data.

	Mechanical Valve No.=120	Tissue Valve No.=120	Test- value	<i>p</i> -value	Sig.
MV mean PG					
grade:					
Mean ± SD	$3.47 \pm 1.91$	$4.88 \pm 1.65$	-6.113•	0.000	HS
Range	2-12	2-12			
MV area:					
Mean ± SD	$2.76 \pm 0.38$	$2.78 \pm 0.27$	-0.570•	0.570	NS
Range	2-4	0.7-3			
New regurge:					
No	117 (97.5%)	120 (100.0%)	3.038*	0.081	NS
Yes	3 (2.5%)	0(0.0%)			
Paravalvular					
leak:					
No	119 (99.2%)	120 (100.0%)	1.004*	0.316	NS
Yes	1 (0.8%)	0 (0.0%)			
<i>p</i> -value >0.05 :	Non Significa	nt (NS).	* : Chi-se	quare tes	st.
p-value <0.05 · Significant (S)			• : Indep	endent t	-test.
p-value < 0.01 :	Highly Signif	icant (HS).	. indep		

Table (8): Relationship between valve replacement and pregnancy.

	Mechanical Valve No.=120	Tissue Valve No.=120	Test- value	<i>p</i> -value	Sig.
Pregnancy: No Yes	104 (86.7%) 16 (13.3%)	100 (83.3%) 20 (16.7%)	0.523*	0.470	NS
	No.=16	No.=20			
Abortion	5 (31.2%)	0 (0.0%)	33.913	0.000	HS
<ul> <li>Intra uterine Fetal death</li> </ul>	3 (18.8%)	0 (0.0%)	20.000	0.000	HS

*p*-value >0.05 : Non Significant (NS).

*p*-value <0.05 : Significant (S).

\* : Chi-square test.

•: Independent t-test.

*p*-value <0.01 : Highly Significant (HS).

<i>p</i> -value < 0.05	: Significant (S).
p-value < 0.01	: Highly Significant (HS).

p-value <0.01 : Highly \* : Chi-square test.

*p*-value <0.05 : Significant (S). *p*-value <0.01 : Highly Significant (HS).

\* : Chi-square test.

Hx of Embolism:

Hx of significant hemolysis (hg

No

Yes

<9gm/dl):

No

Yes

Yes

Hx of reoperations Y or N:

No

Yes

Sternal wound complications: No

	Pregr	ancy			
Mechanical Valve	No No.=104	Yes No.=16	Test- value	<i>p</i> -value	Sig.
<ul> <li>Heart failure</li> <li>Arrhythmias</li> <li>Valve thrombosis</li> <li>Endocardiitis</li> <li>Hemorrhge</li> <li>Hx of embolism</li> <li>Re-operation</li> <li>New regurge</li> <li>Paravalvular leak</li> <li>Hx of significant hemolysis (hg &lt;9gm/dl)</li> <li>Post-operative mortality</li> </ul>	$ \begin{array}{c} 1 (1.0\%) \\ 0 (0.0\%) \\ 5 (4.8\%) \\ 3 (2.9\%) \\ 5 (4.8\%) \\ 5 (4.8\%) \\ 12 (11.5\%) \\ 3 (2.9\%) \\ 1 (1.0\%) \\ 4 (3.8\%) \\ \end{array} $	$\begin{array}{c} 2 \ (12.5\%) \\ 1 \ (6.2\%) \\ 2 \ (12.5\%) \\ 0 \ (0.0\%) \\ 2 \ (12.5\%) \\ 0 \ (0.0\%) \\ 2 \ (12.5\%) \\ 0 \ (0.0) \\ 2 \ (12.5\%) \\ 0 \ (0.0\%) \\ 0 \ (0.0\%) \\ 0 \ (0.0\%) \end{array}$	$\begin{array}{c} 7.574\\ 6.555\\ 1.494\\ 0.473\\ 1.494\\ 0.803\\ 0.012\\ 0.473\\ 0.155\\ 0.637\\ \end{array}$	0.006 0.010 0.222 0.491 0.222 0.370 0.911 0.491 0.694 0.425	HS S NS NS NS NS NS NS
<ul> <li>Age of the valve at the time of follow- up: Mean ± SD Range</li> <li>MV mean PG:</li> </ul>	4.73±1.73 2-9	4.94±1.91 2-10	-0.439	0.662	NS
Mean ± SD Range	3.92±2.48 2-15	3.44±1.67 2-8	0.756	0.451	NS

 Table (9): Relationship between pregnancy and maternal complication in mechanical valve.

 Table (10): Relationship between pregnancy and maternal complication in tissue valve.

	Pregi	nancy			
Tissue Valve	No No.=100	Yes No.=20	Test- value	<i>p</i> -value	Sig.
<ul> <li>Heart failure</li> <li>Arrhythmias</li> <li>Valve degeneration</li> <li>Endocardiitis</li> <li>Re-operation</li> </ul>	$\begin{array}{c} 0 \ (0.0\%) \\ 0 \ (0.0\%) \\ 0 \ (0.0\%) \\ 1 \ (1.0\%) \\ 0 \ (0.0\%) \end{array}$	2 (10.0%) 1 (5.0%) 2 (10.0%) 1 (5.0%) 2 (10.0%)	10.169 5.042 10.169 1.627 10.169	0.001 0.025 0.001 0.202 0.001	HS S HS NS HS
• Age of the valve at the time of follow- up: Mean ± SD Range	3.74±0.87 2-5	3.55±0.60 3-5	0.929	0.355	NS
• <i>MV mean PG:</i> Mean ± SD Range	4.90±1.64 2-12	5.03±2.00 2-10	-0.307	0.759	NS

#### Discussion

Heart valve replacement surgery significantly prolongs life expectancy and improves quality of life in patients with heart disease. Current guidelines limit mitral valve replacement to irreparable valve pathology that will result in poor durability outcomes, especially in patients unlikely to tolerate future reinterventions. There are two basic types of prosthetic heart valves used in current clinical practice: Mechanical and tissue (bioprosthetic) valves. Deciding which valve to use requires careful consideration of the specific advantages and disadvantages of the valve types and integration of this knowledge into the clinical characteristics and personal preferences of the individual patient [3].

Young women planning pregnancy are considered high risk patients who require careful selection of the optimal prosthetic heart valve, as it should be undertaken in consultation with a pregnancy heart team. Some authors advocate that mechanical heart valve prostheses, which require lifelong anticoagulant therapy (warfarin) are not appropriate because of its teratogenic potential. For example, the current American College of Cardiology/ American Heart Association (AHA) reported that the preferable valve choice for this patient group is bioprosthesis and the current European Society of Cardiology 2017 ESC/EACTS Guidelines for the management of valvular heart disease recommendation toward bioprosthetic valve (class IIa; a bioprosthesis should be considered in young women contemplating pregnancy) [8].

However, the main issue with bioprosthetic heart valves is their finite lifespan and high risk of reoperation in the future. The average lifespan of mechanical valves is 20 to 30 years, making these valves more suitable for younger patients. In contrast, bioprosthetic heart valves have 8 to 15 years' durability, depending on patient age, prosthesis type and position [9].

In the setting of mitral valve replacement, there is a scarcity in the available evidence which directly compares the benefits and harms of mechanical versus tissue valves replacement. Therefore, we conducted the present study in order to compare midterm results of post-operative outcome between mechanical versus tissue valves.

In the present retrospective study, a total of 240 young female patients with mitral valve disease who had underwent mitral valve replacement at the operating theatres of Souad Kafafi University Hospital and Ain Shams University Hospitals. The females were divided into the following groups according to type of valve:

- Mechanical group which included 120 women who received mechanical valve.
- Tissue group which included 120 women who received tissue valve.

In terms of demographic and clinical characteristics of the included patients, the mean age of both groups was around 34 years old, with no statistically significant difference. On the other hand, a greater proportion patient in mechanical group had New York Heart Association (NYHA) functional class IV than tissue group. The exact cause of such association between preoperative NYHA and type of valve in our cohort is unclear. Previous reports have shown that the decision to operate for a mechanical or bioprosthetic valve in patients with severe status should not be different than for patients with mild deterioration in cardiac functions [10]. Therefore, such association in our study may reflect availability of the valve type & surgeon's preference rather than an established guideline's policy.

In the terms of primary outcome of the present study, our results showed that the rate of reoperation (reflecting the durability of the valve) is significantly higher in mechanical valve group 11.7% and 1.7% in tissue valve group, as bioprosthetic heart valves are not associated with high incidence of severe bleeding and fatal complication such as valve thrombosis which is more common with mechanical valve.

In contrary, Sharma et al., [11] report that the incidence of reoperation is nearly similar in both types of heart valves, and there was no significant difference among two groups. Reoperation rate were 0.9% in mechanical valve replacement group and 1.2% in bioprosthetic valve replacement group. Chikwe and colleagues [12] found that the cumulative incidence of mitral valve reoperation at 15 years was significantly lower in the mechanical valve group (28 patients) compared with the bioprosthetic valve group (47 patients).

The exact causes of such heterogeneities between our findings and the above mentioned studies is that the follow-up period in our study is relatively short, when bioprosthesis start degenerating that reoperation and related morbidity become issues. A longer-term follow-up is required to conclusively comment on the superiority of one valve type over the other in this age group.

Regarding pregnant patients (16 patients in the mechanical valve group and 20 patients in the tissue valve group), our results showed that the incidence of abortion was significantly higher in mechanical valve group 31.2% than tissue valve group 0.0%. As well the incidence of intrauterine fetal death was significantly higher in mechanical valve group 18.8% and 0.0% in the tissue valve group.

In concordance with our findings, Mihaljevic and colleagues [13] performed a retrospective analysis of early and late outcome in 103 women of childbearing age who underwent mechanical (n=63) or biological (n=40) valve replacement between January 1982 and July 2002. The incidence of miscarriages and therapeutic abortion were greater in the group with mechanical valves than with bioprosthetic valves. On the other hand, no birth defects were observed in either group.

Similarly, Sadler and colleagues [12] compared the pregnancy outcomes and cardiac complications in women with either mechanical or bioprosthetic valves at the mitral site in a historical cohort study. Young women (n=255) who had valve replacements between 1972 and 1992 were included pregnancy loss occurred more frequently with mitral mechanical than with mitral bioprosthetic valves.

Additionally, van Hagen and colleagues [13] retrieved the data from the prospective, observational, contemporary, worldwide Registry of Pregnancy and Cardiac disease (ROPAC). The pregnancy outcome of 212 patients with mechanical heart valve was compared with 134 patients with a tissue heart valve. The results showed that the incidence of pregnancy loss and threatened abortions were higher in mechanical valve group.

To sum up, Lawley and colleagues [14] performed a systematic review to assess risk of adverse pregnancy outcomes among women with a prosthetic heart valve(s) over the last 20 years. Electronic literature search of Medline, The Cochrane Library, Cumulative Index to Nursing and Allied Health Literature and Embase to find recent studies. Eleven studies capturing 499 pregnancies among women with heart valve prostheses, including 256 mechanical and 59 bioprosthetic, were eligible for inclusion. Pooled estimate of overall pregnancy loss was significantly higher among women received mechanical valve.

The significant association between mechanical valve and high pregnancy loss rate is postulated to stem from the use of anticoagulants in early pregnancy, with their teratogenic effects. For example, it was reported that high fetal loss rate in women with mechanical valves appeared to be related to the type of anticoagulation. Warfarin treatment throughout pregnancy was associated with a very high fetal loss rate and that lower dose warfarin may be associated with better pregnancy outcomes [12]. However further investigations are required to confirm this hypothesis.

Regarding the cardiac complications after valve replacement, the present study showed that there were statistically significant higher incidences of valve thrombosis, hemorrhage and history of embolic manifestation in the mechanical group than tissue group. In contrary, there are no significant differences between both groups in terms of incidence of heart failure, arrhythmia, endocarditis and valve degeneration.

In concordance with our findings, North and colleagues [15] reviewed outcomes in 232 females aged 12-35 years who underwent valve replacement between 1972 and 1992 in Auckland, New Zealand. The 10 year survival of patients with mechanical (n=178), bioprosthetic (n=73), and homograft (n=72) valves was 70%, 84%, and 96%, respectively. Thromboembolism occurred significantly more commonly in patients with mechanical prosthesis, with 45% having had a thromboembolic event by five years compared with 13% for bioprosthetic valves.

Similarly, van Hagen and colleagues [13] showed that the incidence of cardiac thromboembolic complications was higher in mechanical valve group. Lawley and colleagues [14] also reported that women with bioprostheses had significantly fewer thromboembolic events compared to women with mechanical valves.

In contrary, Mihaljevic and colleagues [13] reported no statistically significant differences between both groups in terms of bleeding complications or thrombosis. Similarly, Sadler and colleagues [12] demonstrated no association between the incidence of thromboembolic cardiac complications and type of valves.

The exact causes of such heterogeneities between our findings and the above mentioned studies are unclear. However, these heterogeneities can be attributed to the difference of population characteristics, sample size, type of mechanical or tissue valves, and the employed anti-coagulants regimen.

Alongside the parameters that reflect ventricular function, there are other important prognostic parameters playing an integral part of the assessment of patients with mitral valve diseases such as Mitral Valve Area (MVA) and mean gradient across the mitral valve [16]. More importantly, it was found that those parameters, especially MVA, are strongly associated with maternal complications [17].

Therefore, the effectiveness of valve replacement in women of child bearing period can be, partly, reflected by postoperative echocardiographic assessment. Our results showed that the preoperative Left Ventricular End Diastolic Diameter (LVEDD) & Left Ventricular End Systolic Diameter (LVESD) were significantly lower in the mechanical valve group and the Ejection Fraction (EF) was significantly lower in the tissue group. The MVA was significantly lower and the pressure gradient was significantly higher in tissue valve group than mechanical valve group.

Post-operatively, the LVEDD & LVESD remained significantly lower in mechanical valve group; however, the EF was comparable between both groups. Although, the post-operative pressure gradient was higher in tissue valve group, but it is not reflected on the durability of the valve at this age group regarding the midterm results of our study, and there were no statistically significant differences between mechanical and tissue groups in terms of MVA, incidence of new regurge, or paravalvular leak.

Such findings reflect comparable impact of mechanical and tissue valve on post-operative, clinically-oriented, cardiac functions.

These findings were in contrary with the study held by Mourad and colleagues [18] in Minia governorate in Upper Egypt. They enrolled 60 patients with rheumatic mitral valve diseases (stenosis, regurgitation or both) admitted to Cardiothoracic Surgery Unit, Minia University Hospital, and underwent mitral valve replacement over the period of 12 months January 2013 and January 2014. Included patients were classified into two groups; group A underwent mechanical valves and group B underwent tissue valve. There was no statistically significant difference between both groups with regards to echocardiographic parameters (LVEDD, LVESD, LVEF and LA diameter).

*Study's limitations:* We acknowledge that the present study has some limitations. The study was a double-center experience and therefore the results cannot be generalized to the general population. In addition, the sample size in the present study was relatively small compared to other related trials. The retrospective nature of the present study precludes our ability to improve the precision of our evidence. The significant differences in the preoperative characteristics between the studied groups may also introduce potential confounders.

#### Conclusion:

Tissue valves appear to be the preferred option for women in childbearing period with MVD with better mid-term results than mechanical valves. The present study demonstrated that women with mechanical valves had a high rate of pregnancy loss. The risk of cardiovascular complications is higher in mechanical valves, as the main risks are related to the need of anticoagulation therapy (hemorrhagic and thromboembolic complication) additional risks related to ventricular and valvular dysfunction as well. Furthermore the rate of reoperation is much higher in mechanical valves. However the risk of complications is lower in tissue valves, it can be significant in the presence of bioprosthetic dysfunctions. So, large-scale, studies are still needed to confirm our findings.

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# نتائج منتصف المدة لإستبدال الصمام الميترالى لمرضى القلب من الإناث في فترة الإنجاب الصمامات الميكانيكية مقابل الصمامات النسيجية

توجه التوصيات الدولية الحالية لأمراض صمامات القلب إلى إستبدال الصمام المترالى الذى لا يمكن إصلاحه. هناك نوعان أساسيان من صمامات القلب المستخدمة (الصمامات الميكانيكية والصمامات النسيجية).

تعد السيدات فى سن الإنجاب من المرضى ذوى الخطورة العالية حيث آنهم يحتاجون إلى الإختبار الآمثل لصمام القلب الصناعى. حيث تتطلب الصمامات الميكانيكية علاجاً مضاداً للتخثر مدى الحياة على عكس الصمامات النسيجية التى عمرها الإفتراضى محدود.

لذا آجريت هذه الدراسة بآثر رجعى من آجل مقارنة نتائج منتصف المدة لإستبدال الصمام المترالى لمرضى القلب من الإناث فى سن الإنجاب (الصمامات الميكانيكية مقابل الصمامات النسيجية)، وتتضمن ٢٤٠ سيدة خضعن لإستبدال الصمام فى مستشفى سعاد كفافى الجامعى ومستشفيات جامعة عين شمس.

الظهرت النتائج الآولية للدراسة أن النساء ذوات الصمامات الميكانيكية كانت لديهم نسبة عالية من حدوث الإجهاض وعرضه أكثر لحدوث التخثر والنزيف وإنحلال الدم فى المقابل لا توجد فروق كبيرة من حيث قصور فى عضلة القلب آو عدم إنتظام فى ضربات القلب آو الإلتهاب البكتيرى على الصمام علاوة على ذلك لا تزال هناك حاجة إلى دراسات واسعة النطاق لتأكيد نتائجنا .