SAFETY AND EFFICACY OF TRANSCATHETER VERSUS SURGICAL CLOSURE OF VENTRICULAR SEPTAL DEFECTS IN CHILDREN

By

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ABSTRACT

Background: *While surgical repair of VSDs has been successful over 60 years, operative and late complications still occur and there are inherent risks associated with sternotomy and exposure to cardiopulmonary bypass . A desire to avoid these risks as well as the successful application of catheter –based device closure has led to an interest in developing a less invasive means by which to close VSDs.* ***Objectives:*** *To evaluate the safety and efficacy of trans-catheter versus surgical approach to correct VSD in a prospective comparative study.* ***Patients and Methods:*** *we performed this 2 years prospective observational study of 30 patients with VSD who were referred to Pediatric Cardiology Division of Cairo University and Al-Azhar university Pediatric Hospital to do either surgical or transcatheter VSD closure between 01/07/2014 to 01/07/2016 . After clinical and TTE examination we revised the criteria of the case upon which the decision was taken to close the VSD (surgery is indicated in patients with uncontrolled congestive heart failure symptoms, evidence of increased pulmonary vascular resistance or the development of aortic valve insuffiency secondary to leaflet prolapse). Their age ranged from 6 months to 18 years, weights from 6 Kg to 60 Kg and heights ranged from 60 to 160 cm.* ***Results:*** *In our study, success rate of trans-catheter and surgical closure was 100 %, The mean age of our prospective study was 3.01± 2.9 and 4.1± 2 years in surgery and cathter groups repectively , their body surface area was 0.4 ± 0.18 m2 and 0.6 ± 0.2 m2 in surgery and catheter groups respectively, the most common clinical presentations were, recurrent chest infection in 15(100%) vs. 13(86.7%) cases in surgery and catheter groups respectively, there were statistically significant difference between surgery and catheter before closure regarding LA/AO ratio (1.43 ±0.423 vs 1.17± 0.212) ,LVEDD (3.82+.608 vs 3.17+.704 respectively) and LVEDD Z-Score (2.61+1.16 vs 1.5+1.39 respectively), no mortality , stroke nor neurological deficit was observed ,no major adverse events were occurred in the trans-catheter group, only 1major event was observed in the surgical group (complete AV block postoperative , that needed pacemaker) ,the average hospital stay in surgical group 5.40+1.12 days vs 1.13+.35 days in catheter*

group , all patients in surgery group (100%) needed blood transfusion, ventilation and inotropic support, no one needed in catheter group (0%), LVEDD Z-Score showed statistical significant differences between surgery and catheter groups immediately after (mean 3.41+0.924 vs 1.52+1.39 respectively),3 days after(mean 3.61+1.06 vs 1.45+1.39 respectively) and 1month after (mean 1.45+1.03 vs 0.768+1.44 respectively) .cardiac enzymes ,systolic and diastolic functions were affected immediately post- operative and on 3rd day follow up in surgery not in catheter group and returned to normal after one month follow up. ***Conclusion:*** *Trans-catheter device closure of VSD is more safe and efficient than surgical closure, trans-catheter device closure had fewer myocardial injuries, shorter hospital stays and faster recovery times, also trans-catheter device closure had no systolic nor diastolic dysfunction as in surgical closure on short term follow up.*

Keywords: *Safety; VSD; transcatheter closure; surgical closure.*

INTRODUCTION

Ventricular septal defects (VSDs) account for 20% of the congenital heart disease **(Carminati et al., 2007).** In Egypt, VSD accounts for 22.7 % of the congenital heart disease **(Zeze et al., 2014).** According to their location within the septum, defects can be classified as: muscular, perimembranous, and supracristal. The most common are the perimembranous VSD (around 70%), while muscular VSD may occur in around 15% of the cases. Rarely, multiple VSDs may be present in a single patient, so called swiss cheese VSDs (**Nygren et al., 2005)** Indications to VSD closure are symptoms of heart failure, signs of left heart chambers overload, and history of endocarditis. In patients with an overload of left heart chambers, closure is necessary in order to prevent pulmonary arterial hypertension, ventricular dysfunction, arrhythmias, aortic regurgitation, and development of double-chambered right ventricle (**Monro et al., 2003)**. While surgical repair of VSDs has been successful over 60 years, operative and late complications still occur and there are inherent risks associated with sternotomy and exposure to cardiopulmonary bypass **(Daniel et al .,2012).** A desire to avoid these risks as well as the successful application of catheter –based device closure has led to an interest in developing a less invasive means by which to close VSDs **(Daniel et al., 2012).**

Aim of the work

The purpose of this study was to evaluate the safety and efficacy of trans-catheter versus surgical

approach to correct VSD in a prospective comparative study.

PATIENTS AND METHODS

Thirty patients were referred to Pediatric Cardiology Division of the Cairo University and Al-Azhar university Pediatric Hospital to do either surgical or transcatheter VSD closure between 01/07/2014 to 01/07/2016 were included in the study. After clinical and TTE examination we revised the criteria of the case upon which the decision was taken to close the VSD (surgery is indicated in patients with uncontrolled congestive heart failure symptoms, evidence of increased pulmonary vascular resistance more than 12 wood units/m^2,very large lt to rt shunt more than 10 mm or the development of aortic valve insuffiency secondary to leaflet prolapse), (N.B. Cases already referred to the Hospital with a previous decision from the Governmental Medical Insurance system). At the end of the study we had two groups of patients each group contains 15 patient (surgery group I & catheter group II).

2. Inclusion criteria: All Patients in the targeted age group(6m-18y), were referred to Pediatric Cardiology department of Cairo and Al-Azhar Universities Hospitals with hemodynamically significant VSD during the study period were included A left-to-right shunt was considered to be significant when the following were found:

1) cardiomegaly on chest X-ray;
2) left atrial enlargement, defined as a left atrial to aortic ratio 1.5:1;
3) left ventricular enlargement (left ventricular volume overload), defined as a left ventricular end diastolic diameter 2 standard deviations (SD) above the mean for the patient's age by using (Z score).
4) symptoms including frequent respiratory infections and/or failure to thrive. Frequent respiratory infections were defined as more than 6 events/year,
5) history of endocarditis).

- All types of ventricular septal defects (perimemtanous VSDs, or muscular) were included in the study, Age: 6m-18 y

3. Exclusion criteria: Patients above 18 years or under the Age of 6m, Patients with VSD as part

of complex congenital heart diseases, Patients with VSD with severe pulmonary hypertension> 70 mmHg (suspected Pulmonary vascular disease)and Patients with VSDs that tends to close spontaneously(< 5mm).

All patients were subjected to full history taking, clinical examination, echocardiography, ECG and cardiac enzymes before, immediately after, 3 d, 1 month and 3 months after transcatheter and surgical closure. In addition to comparison between both procedures regardin timing, success rate and post procedure comlications as vascular or infectious complications or need to ventilation, inotropes or blood transfusion.

Ethical consideration:

- Written conscent was written and signed by parents before study
- approval by ethical committee in pediatric department ,faculty of medicine, Al Azhar university was obtained before the study .
- no conflict of interest regarding this study.

Statistical Analysis

The data were coded, entered and processed on computer using *SPSS* (version 18).The results were represented in tabular and diagrammatic forms then interpreted.

Mean, standard deviation, range, frequency, and percentage were use as descriptive statistics.

The following tests were done:

- **Chi-Square test X^2** was used to test the association variables for categorical data.
- **Student's t-test** was used to assess the statistical significance of the difference between two population means in a study involving independent samples.
- **The repeated measures ANOVA** was a member of the ANOVA family. ANOVA is short for ANalysis Of VAriance. All ANOVAs compare one or more mean scores with each other; they are tests for the difference in mean scores. The repeated measures ANOVA compares means across one or more variables that are based on repeated observations.

P value was considered significant as the following:

* $P > 0.05$: Non significant

* $P \leq 0.05$: Significant.

RESULTS

Table (1): clinical characteristics of studied groups:

		Group I (n=15)		Group II (n=15)		P Value
		No.	%	No	%	
Sex	Female	2	13.3%	8	53.3 %	0.02
	Male	13	86.7%	7	46.7%	
Age(Year)	Mean +SD	3.01+2.90		4.14+2.03		0.22
Weight(Kg)		10.80+5.77		14.36+5.63		0.09
Hight(cm)		87.93+18.65		97.86+14.61		0.11
BSA		0.471+0.18		.602+.208		0.7

% of female was significantly lower among surgery than catheter (13.3%, 53.3% respectively) p =.020
Mean value of age was not significantly among surgery than catheter (3.01, 4.14 respectively) p=.227
There were no statistically significant difference between both groups regarding weight, length and BSA.

Table (2): Comparison between studied groups regarding Cardiac Enzymes before interference

		Group I (n=15)	Group II (n=15)	t. test	P. value
CKMP (u/L)	**Mean ±SD**	**16.73±5.04**	**22±2.90**	**3.50**	**.002**
Troponin (ng/ml)	**Mean ±SD**	**.018±.007**	**.018±.007**	**.000**	**1.00**

Mean value of CKMP was significantly lower among surgery than catheter (16.73, 22 respectively) p=.002 (but within normal range 15-30 u/l).
Mean value of Troponin was not significantly among surgery than catheter (.018, .018respectively) p=1.00 (normal range 0.01- 0.04 ng/ ml).

Table (3): Echocardiography finding in both groups before interference.

Echo findings		Group I (n=15)		Group II (n=15)		X^2	P. value
VSD TYPE	Inlet VSD	1	6.7%	0	.0%	6.34	.04
	Low muscular	0	.0%	1	6.7%		
	Outlet subpulmonic	1	6.7%	0	.0%		
	Perimemb subaortic	11	73.3%	14	93.3%		
size (mm)	Mean ±SD	8.13±1.53		5.98±2.38		2.91	.007
Number	One	13	86.7%	14	93.3%	1.03	.595
	Two	1	6.7%	1	6.7%		
	>Two	1	6.7%	0	.0%		
AR		1	6.7 %	0	0%	1.03	0.309
Aortic prolapse		4	26.7 %	1	6.7 %	2.00	.043
Aneurysm		5	33.3 %	6	40%	3.61	.495

There were statistically significant difference between surgery and catheter regarding VSD Type, VSD size and Aortic prolapse ($p<0.05$)
There were no statistically significant difference between surgery and catheter regarding number,AR and aneurysm($p>0.05$).

Table (4): Echo parameters in both groups before intervention.

		Group I (n=15)	Group II (n=15)	t. test	P. value
RVEDD1 (cm)	**Mean ±SD**	**1.12±.108**	**1.12±.217**	**.000**	**1.00**
RVEDD Z-SCORE	**Mean ±SD**	**.829±.610**	**.631±.861**	**.726**	**.474**
LA/AO	**Mean +SD**	**1.43+.423**	**1.17+.212**	**2.12**	**.043**
IVSD 1(cm)	**Mean ±SD**	**.530±.064**	**.546±.083**	**.611**	**.546**
IVSD Z-SCORE	**Mean ±SD**	**1.18±.398**	**.969±.779**	**.938**	**.356**
LVEDD (cm)	**Mean ±SD**	**3.82±.608**	**3.17±.704**	**2.730**	**0.01**
LVEDD Z-SCORE	**Mean ±SD**	**2.61±1.16**	**1.51±1.39**	**2.353**	**0.025**
LVESD1(cm)	**Mean ±SD**	**1.88±.390**	**2.15±.381**	**1.89**	**.069**
LVESD Z-SCORE	**Mean ±SD**	**.482±1.06**	**.800±1.30**	**.732**	**.470**
FS	**Mean ±SD**	**.394±.040**	**.405±.040**	**.769**	**.448**
ESPAP	**Mean ±SD**	**46.60±19.33**	**37.26±25.22**	**1.13**	**.265**

There were no statistically significant difference between surgery and catheter regarding RVEDD Z-Score, IVSD Z-Score, LVESD Z-Score, FS and ESPAP.

There were statistically significant difference between surgery and catheter regarding LA/AO ratio, LVEDD and LVEDD Z-Score.

Table (5): Comparison between group I and group II regarding Echocardiography 24 hr after intervention.

		Group I (n=15)	Group II (n=15)	t.test	P. value
LVEDd(cm)	Mean ±SD	4.59±.565	3.16±.704	6.17	0.000
LVEDD Z-SCORE	Mean ±SD	3.41±.924	1.52±1.39	4.391	0.000
LA/AO	Mean ±SD	1.50±.438	1.11±.266	1.86	.023
LVESd(cm)	Mean ±SD	2.36±.335	1.75±.381	4.694	0.000
LVESD Z-SCORE	Mean ±SD	2.73±1.10	.800±1.30	4.37	0.000
FS	Mean ±SD	.297±.053	.406±.038	6.46	0.000
EF	Mean ±SD	.579±.100	.719±.040	4.98	0.000
Residual flow	Moderate	1	0	3.71	.294
		6.7%	.0%		
	Small	5	3		
		33.3%	13.3%		
Patch or device in site		15	15	0	1
		100.0%	100.0%		

There were no statistically significant difference between surgery and catheter regarding residual flow, patch or device in site and inf. Endocarditis.

There were statistically significant difference between surgery and catheter regarding FS and EF, LVEDD, LVEDD Z-Score and LVESd Z-Score .

Table (6): Cardiac enzymes between both groups 24 hr post intervention.

		Group I (n=15)	Group II (n=15)	t. test	P. value
CK-MB (u/L)	Mean ±SD	114.53±34.34	23±3.18	10.27	.000
Troponin I(ng/ml)	Mean ±SD	8.78±1.55	.020±.006	21.78	.000

There were statistically significant difference between surgery and catheter regarding CK-MB and Troponin I (P=.000).

Table (7): Comparison between both groups regarding Echocardiography after 3 days follow up.

		Surgery NO. (15)	Catheter NO.(15)	t. test	P. value
LA/AO	Mean ±SD	1.51±.447	1.11±.266	1.86	.023
LVEDd(cm)	Mean ±SD	4.65 ±.564	3.06±.704	1.96	0.02
LVEDD Z-SCORE		3.61±1.06	1.45±1.39	4.78	0.00
LVESd(cm)	Mean ±SD	2.21±.352	1.65±.381	4.19	0.00
LVESD Z-SCORE		2±.975	.800±1.30	2.86	.008
FS	Mean ±SD	.331±.052	.404±.018	5.11	.000
EF	Mean ±SD	.629±.099	.709±.080	2.42	.022
residual flow	Small	5	1	3.84	.146
		29.7%	6.7%		

There were no statistically significant difference between surgery and catheter regarding residual flow and inf. Endocarditis.

There were statistically significant difference between surgery and catheter regarding LA /AO, LVEDD, LVEDD Z-Score , LVESd Z-Score , FS and E.

Table (8): Comparison between surgery group and trans catheter group regarding Echocardiography after one month.

		Group I (n=15)	Group II (n=15)	t. test	P. value
LA/AO	Mean ±SD	1.22±.330	1.01±.180	1.06	.154
LVEDd(cm)	Mean ±SD	3.22±.558	2.80±.625	1.962	0.04
LVEDD Z-SCORE	Mean ±SD	1.45±1.03	0.868±1.44	1.509	0.04
LVESd(cm)	Mean ±SD	1.95±.358	1.83±.385	1.17	.249
LVESD Z-SCORE	Mean ±SD	.327±.944	.187+1.22	.351	.728
FS	Mean ±SD	.372±.030	.407±.017	3.91	.001
EF	Mean ±SD	.686±.035	.724±.014	3.84	.001
Patch or device in site		15	15		
		100.0%	100.0%		
residual flow		13	14	1.03	.595
		86.7%	93.3%		
	Small	2	1		
		12.4%	6.7%		

There were no statistically significant difference between surgery and catheter regarding patch or device in site, residual flow and inf. Endocarditis.

There were statistically significant difference between surgery and catheter regarding LVEDD, LVEDD Z-Score , LVESD Z-Score, FS and EF (P=.001).

DISCUSSION

VSD is considered the most common among congenital heart diseases, accounting for almost one-fifth of all defects. In developing countries, many children with congenital heart disease are waiting to be treated, There is an immediate need for an economical, effective and less-invasive technique **(Yang et al., 2014).**

In our study, success rate of trans-catheter and surgical closure was 100 % ,this is in agreement with **J Yang et al., (2014)** and **shang et al., (2016)** study who had same asuccess rate and **Zheng Q et al. (2009)** who had no difference between the device and surgical groups according to the success rates (99.8 vs. 100%) respectively.

The mean age of our comparative prospective study was 3.01± 2.9 and 4.1± 2 years in surgery and cathter groups repectively, their body surface area was 0.4 ± 0.18 m^2 and 0.6 ± 0.2 m^2 in surgery and catheter groups respectively, **Yang et al., (2014)** reported in his study that average age at closure was 5.8 ± 2.4 years and 5.5 ± 2.6 years in surgery and cathter groups repectively ,and body surface area was 0.5 ± 0.2 m^2 and 0.7 ± 0.2 m^2 in surgery and catheter group respectively.

In the present study, the most common clinical presentations were: recurrent chest infection in 15(100%) vs. 13(86.7%) cases, repeated hospital admission in 12 (80%) cases in both groups, failure to thrive in 14 (93.3%) vs.7(46.7%) cases, congestive heart failure in 9(60%)cases vs. 6(40%) cases and feeding difficulty in 5(33.3%) cases vs. 4(26.7%)cases in surgery and catheter groups respectively (16.7%).

This is in harmony with **yang et al. (2014)** study who found that 35(35%) cases in surgery group vs 28 (27.7%) cases in catheter group had symptoms such as refractory pneumonia, congestive heart failure, delayed growth, sweating with feeding and failure to thrive.

In our study mean size of defect was 8.13±1.53 mm and 5.98± 2.38 mm

In the surgical and transcatheter groups respectively (p=0.007), this is in agreement with **S Liue et al., (2012)** who demonstrated that the mean VSD diameter of patients with surgical closure was larger than that of those with percutaneous catheter closure (p=0.000).

In the current study There were statistically significant difference before closure regarding aortic prolapse 4cases (26.7%) vs 1 case (6.7%) in surgery and cateter groups respectively (p=0.04).

In our study there were statistically significant difference between surgery and catheter before closure regarding LA/AO ratio (1.43 ±0.423 vs 1.17± 0.212), LVEDD (3.82±.608 vs 3.17±.704 respectively) and LVEDD Z-Score

(2.61±1.16 vs 1.5±1.39 respectively) this is not agree with **Yang et al.,(2014)** who observed no statistical significant difference between surgery and catheter groups before closure regarding LA dimension (21.5 ± 4.3 mm vs 20.7 ± 3.8 mm respectively, (p=0.220) and LVEDD Z-Score (1.8±1.5 vs 1.7± 1.4 respectively), (p=0.493).

Our study had observed no difference between both groups regarding systolic function(EF & FS) before closure (p>0.05), this is in agreement with **Pawelec et al., (2005)**, **Yang et al., (2014)** and **Shang et al., (2016)** who observed no difference between both groups regarding systolic function before closure (p>0.05).

In our study there were no statistical significant difference regarding diastolic functions by TDI between surgery and catheter group on lat wall LV, septum and RV before closure (p> 0.05), this is in harmony with **Pawelec et al., (2005)** who observed no statistical significant difference regarding diastolic functions by TDI between both groups (p= 0.606).

In our cohort study, no mortality, stroke nor neurological deficit was observed ,no major adverse events were occurred in the trans-catheter group, only one minor (trivial residual flow in 2 cases), whereas 1major event was observed in the surgical group (complete AV block postoperative, that needed pacemaker) plus 3 minor events in 5 cases (sepsis in one case, pneumonia in one case and trivial residual flow in 3 cases).

This is in harmony with **K Dalton et al. (2014)** who did not observe mortality, stroke nor neurological deficit in their studies, no major adverse events in catheter group ,one major event in surgery group (bleeding requiring thoracic re-exploration)**,** also there were more than one –third fewer minor adverse events in the catheter group compared with the surgical group (7 vs 32, p<0.001).

In our study, the concentrations of cardiac enzymes (CK-MB and cTnI) before intervention were normal in both groups, in surgery group CK-MB (average 114.53± 34.3 u/l) and cardiac troponin i, cTnI(average 8.78±1.55 ng/ml) elevated 1st day post –operative ,still high on 3rd day (average 85.73± 14.46 u/l vs 2.82± 2.11 ng/ml respectively) and returned to normal after 1 month (average 22± 2.90 u/l vs 0.018± 0.007 ng/ml respectively) ,on the other hand, in trans-catheter group, both CK-MB and cTnI levels remained

unelevated in 1st (average 23± 3.18 u/l vs 0.02±0.006 ng/ml respectively and 3rd day (average 19± 2.20 u/l vs 0.01± 0.006 respectively) after deployment of the device (p =0.000 in 1st and 3 rd day between both groups).

This is in harmony with **Yang et al.,(2014)**, who observed that the concentrations of CK-MB and cTnI before intervention were normal in both groups, In the surgery group, CK-MB levels peaked after 24 h, whereas cTnI levels began to rise after aortic clamping and peaked 12 h later. The levels of cTnI did not return to normal even 72 h after de-clamping, In the trans-catheter group, both the CK-MB and cTnI levels remained unchanged after the deployment of the device (p< 0.001 in 72 hr post procedure between both groups).

In our comparative study regarding TTE post procedure follow up, we observed that there is statistically significant difference between surgery and catheter groups regarding systolic function in 1st day (FS 0.29±0.05 vs 0.40± 0.03, p=0.00, and EF 0.57±0.10 vs 0.71±0.04 , p= 0.00, respectively), 3rd day (FS 0.33± 0.052 vs 0.40± 0.018, p=0.00, and EF 0.62± 0.099 vs 0.70± 0.080, p=0.022, respectively) and 1st month (FS 0.37±0.03 vs 0.40±0.01, p=0.001, and EF 0.68± 0.3 vs 0.72±0.01 , p= 0.001 respectively), no statistical difference between both groups at 3rd month follow up(p> 0.05), this is in agreement with **Pawelec et al. (2005)** who observed that left ventricular EF was significantly (p=0.004) lower after surgery than in children treated with the occluder.

In our cohort, LVEDD Z-Score showed statistical significant differences between surgery and catheter groups immediately after (mean 3.41±0.924 vs 1.52±1.39 respectively),3 days after(mean 3.61±1.06 vs 1.45±1.39 respectively) and 1month after (mean 1.45±1.03 vs 0.768±1.44 respectively) p<0.05, this is can be explained by the effect of cardioplegia, direct surgical trauma and CPB in surgical group.

Our results in agreement with **Pacileo et al., (1998**) who observed that surgical closure, even for a moderate sized VSD deleteriously affects post-operative left ventricular geometry and shape, since prolonged volume overload may be detrimental to myocardial function ,Our results are in agreement with **El-Sisi et al. (2017)** who observed that LVEDD Z-Score decreased after device closure from 1.1 to 0.63,0.35 and 0.23 at 1,3 months

and last follow up respectively.

In our cohort study, we found that there were statistically significant difference between surgery and catheter group regarding MPI immediately post procedure (mean 0.607 ± 0.026 vs 0.500± 0.038 respectively on LV lateral wall, 0.619 ± 0.031 vs 0.496± 0.019 respectively on septal wall and 0.419± 0.021 vs 0.363± 0.025 respectively on RV wall, p=0.000) and also on 3rd day post procedure (mean 0.561±0.022 vs 0.356± 0.019 respectively on LV lateral wall, 0.574±0.030 vs 0.345± 0.021 respectively on septal wall and 0.431± 0.018 vs 0.248± 0.019 respectively on RV wall, p=0.000). on 1 and 3 months we found no more statistical significance between both groups regarding LV, septum and RV MPI (p>0.05).

This is in agreement with **Baghdady et al, (2010)** who observed that, in children operated on for VSD ,on the 2nd day after surgery a significant elevation of both RV MPI and LV MPI was observed, in his study (which was conducted on 30 patient for VSD surgery and 30 healthy control), values of RV MPI and LV MPI were significantly higher in the patient group than in the control group, especially on the 2nd and 7th post-operative days (p= 0.000), this difference disappears at 1 month (p=0.3) between control and patients for both LV MPI and RV MPI(ANOVA p= 0.000).

CONCLUSION

Based on the results of the current study it can be concluded that:

- Trans-catheter device closure of VSD is more safe and efficient than surgical closure .
- Trans-catheter device closure had fewer myocardial injuries, fewer complications, trans-fusions, shorter hospital stays and faster recovery times.
- Trans-catheter device closure had no systolic nor diastolic dysfunction as in surgical closure on short term follow up.

RECOMMENDATION

- Trans-catheter device closure is recommended for suitable patients of VSD than surgical closure .
- Studies on large number and long term follow up needed to strengthen our data .
- Trans-catheter VSD closure provides less invasive alternative that may become the

first choice in selected VSD patients.

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مقارنة أمان وكفاءة علاج عيب الحاجز البطينى فى الأطفال باستخدام قسطرة القلب العلاجية والجراحة

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المقدمة يمثل عيب الحاجز البطينى حوالى 20% من عيوب القلب الخلقية , حوالى 70% منهم يقع فى المنطقة المحيطة بالحاجز الغشائى و 15 % فى الحاجز العضلى كما أن مؤشرات غلق العيب تشتمل على تضخم غرف القلب فى الجانب الأيسر ,علامات فشل القلب وكذلك حدوث التهاب الشغاف المعدية.

في حين أن الإصلاح الجراحي لعيب الحاجز البطينى كان ناجحا أكثر من 60 عاما، لا تزال تحدث مضاعفات خاصة بشق القص والتفاف القلب الرئوى وقد أدت الرغبة في تجنب هذه المخاطر وكذلك التطبيق الناجح لإغلاق الجهاز القائم على القسطرة إلى مصلحة في تطوير وسائل أقل خطورة لإغلاق العيب, المزيد من الخبرة والمتابعة على المدى الطويل إلزامية لتقييم سلامة وفعالية الإجراء عبر القسطرة كبديل للجراحة التقليدية.

الهدف من البحث: الغرض من هذه الدراسة هو تقييم سلامة وفعالية مقاربة القسطرة مقابل النهج الجراحي لتصحيح عيب الحاجز البطينى في دراسة مقارنة المحتملين.

طرق البحث: قمنا بتصميم هذه التجربة العشوائية والمراقبة كمقارنة مستقبلية للعلاجين للأطفال المصابين بعيب بالحاجز البطينى، 30 حالة من العيوب تم إحالتها إلى قسم أمراض القلب للأطفال في القاهرة ومستشفيات جامعة الأزهر إما لإغلاق الجراحي أو القسطرة ، في نهاية الدراسة كان لدينا مجموعتين من المرضى تحتوي كل مجموعة على 15 طفلا، وجميعهم تعرضوا لأخذ التاريخ المرضى، والفحص السريري، و تم عمل الإنزيمات القلبية ، اشعة اكس على الصدر، رسم قلب كهربائى,موجات صوتية ثنائية الأبعاد على القلب وتصوير دوبلر لأنسجة عضلة القلب فى الأوقات التالية:

قبل، مباشرة بعد، 3 أيام بعد، 1 شهر بعد و 3 أشهر بعد إجراء الغلق . وقد تم تدوين المعلومات التى توفرت من المشاهدات أثناء القسطرة والجراحة للمرضى الذين تم دخولهم لمحاولة غلق العيب لهم و كل المعلومات تم تجميعها وحللت إحصائياً وتم ترتيبها فى جداول.

النتائج : تمت الدراسة خلال سنتين فى الفترة من يوليو 2014 حتى يوليو 2016 واشتملت الدراسة على 30 حالة ,15 حالة لكل من القسطرة والجراحة تتراوح أعمارهم بين 6 شهور إلى 18 سنة وأوزانهم ما بين 6 إلى 60 كيلو جرام وقد أجريت عملية غلق عيب الحاجز البطينى بواسطة القسطرة أو الجراحة وقد نجح الغلق فى جميع حالات القسطرة والجراحة, بنسبة 100% .

وكانت أكثر الأعراض حدوثا هى عدوى الصدر المتكررة فى 30 حالة بنسبة 100% وأقلها حدوثا هى التهاب الشغف المعدية بنسبة 0%, وكان عيب الحاجز البطينى الغشائى هو أكثر الأنواع

استخداما فى الدراسة بنسبة 93% فى حالات القسطرة و73% فى حالات الجراحة , وكان متوسط حجم العيب حوالى 8 مليميتر و 6 مليميتر فى الجراحة والقسطرة على الترتيب.

وقد أظهرت الدراسة أنه يوجد اختلاف إحصائى هام بين مجموعتى القسطرة والجراحة قبل الغلق بخصوص القطر الانبساطى للبطين الأيسر ونسبة قطر الأذين الأيسر للأورطى حيث كانت أعلى فى حالات الجراحة عن حالات القسطرة, بينما لا يوجد اختلاف بين المجموعتين بخصوص كفاءة عضلة القلب الانقباضية والانبساطية قبل الغلق , كما أن نسبة إنزيمات القلب طبيعية قبل الغلق فى المجموعتين.

وقد أوضحت النتائج أنه لا توجد وفيات , سكتات دماغية أو عجز عصبى لأى من حالات القسطرة أو الجراحة غير أنه قد حدث مضاعفات رئيسية ,خاصة برسم القلب الكهربائى وهى انسداد كامل أذينى بطينى لحالة واحدة بعد الجراحة مباشرة استدعت تركيب جهاز تنظيم ضربات القلب المستمر.

وقد أوضحت الدراسة أيضا أن جميع حالات القسطرة دون الجراحة قد استدعت الانتقال لعناية مركزة وإعطاء دم ووضع الحالات على جهاز تنفس صناعى وإعطاء مقويات تقلص عضلى للقلب وبالتالى فترة إقامة أطول.

وبمقارنة المتابعة الطبية لكل من حالات الجراحة والقسطرة بعد الغلق تبين الأتى :

- ارتفاع إنزيمات القلب مباشرة وبعد 3 أيام من الجراحة دون القسطرة ثم رجوعها للمستوى الطبيعى بعد شهر من الجراحة.
- ارتفاع متوسط قيمة القطر الانبساطى للبطين الأيسر ونسبة قطر الأذين الأيسر للأورطى مباشرة ,بعد 3 أيام وبعد شهر من الجراحة دون القسطرة مما أدى إلى انخفاض متوسط نسبة القوة الانقباضية لعضلة القلب بعد الجراحة دون القسطرة ورجوعها للطبيعى بعد 3 أشهر من المتابعة.
- انخفاض متوسط قيمة الوظيفة الانبساطية لعضلة القلب مباشرة بعد وبعد 3 أيام من الغلق الجراحى دون القسطرة وذلك باستخدام تصوير الدوبلر لأنسجة عضلة القلب وحساب مؤشر أداء عضلة القلب ثم الرجوع للمتوسط الطبيعى بعد شهر من الغلق.

الاستنتاجات: خلصت الدراسة إلى أن غلق عيب الحاجز البطينى أكثر أمانا وكفاءة بجهاز القسطرة عن الجراحة حيث أن القسطرة أقل فى حدوث المضاعفات وإصابات عضلة القلب التى تؤثر على الوظيفة الانقباضية والانبساطية لعضلة القلب كما أن القسطرة أسرع فى وقت الإقامة بالمستشفى والشفاء التام فى مرحلة المتابعة قصيرة المدى.

التوصيات تنصح الدراسة باستخدام جهاز القسطرة العلاجية لغلق عيوب الحاجز البطينى التى تصلح للقسطرة وخاصة عيوب الحاجز الغشائى البطينى حيث أنه أكثر كفاءة وأمانا من الجراحة ويعتبر الاختيار الأول للغلق فى وجود أطباء قلب أطفال مدربين ومركز جيد للقسطرة التشخيصية والعلاجية كما تنصح الدراسة باجرا دراسة أخرى للمقارنة على عدد أكبر من المرضى ولفترة متابعة أطول.