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Percuteneous Trans-Mitral Commissurotomy (PTMC); Procedural Success and Immediate Results, an Experience from Tertiary Care Hospital in Northern Division of Bangladesh

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Abstract:

Background: One of the ultimate grave consequences of rheumatic heart disease is mitral stenosis. Percutaneous trans-mitral commissurotomy (PTMC) has been practiced with good results in the world since Inoue introduced it in 1982. Objective: The aim of this study was to audit the procedural success, in- hospital outcome in patients undergoing PTMC in our set up. Study Design: Observational cross sectional study. Place and Duration: The study was conducted in northern division of Bangladesh with the collaboration of department of cardiology, Rangpur Medical College Hospital, Rangpur & Zia Heart Foundation, Dinazpur from February 2018 to November 2019. Materials and Methods: Total Thirty patients who fulfill the inclusion and exclusion criteria for PTMC was enrolled in this study. Among them the procedural success & immediate results were assessed. Results: Among 30 patients , 22(73.33%) were female and 8(26.66%) were male showing a female predominance. The mean age was 28.28±8.4.The procedure was successful in 29(96.66%) patients. In 1(3.3%) patient, we failed due to inability to puncture the septum for unfavourable anatomy. There was no mortality related to the procedure, no systemic embolization but one patient (3.33%) had significant MR(G II). Pre PTMC mean MVA (cm^2) was 0.801± 0.1325 and post PTMC it was 1.545± 0.292 cm^2. Mean MVPG pre PTMC was 27.108±5.94 mmHg and post PTMC , 6.61±5.008 mmHg with significant p value 0.0001. Mean LA pressure before procedure was 28.65±8.456 mmHg and post PTMC, 11.27±6.34 and p value was 0.0001. Most of the patients 25(83.3%) before PTMC were in severe pulmonary hypertension and after PTMC most of the patients 21(70%) were in mild pulmonary hypertension.We successfully done 7 special cases like pregnancy, re do cases, H/O CVD etc.Conclusions: We conclude that PTMC is a safe procedure in experienced hand with good success rate and optimal results even in patients with special problems like pregnancy, previous CVA and redo cases.

Key words: Mitral stenosis(MS), Percutaneous Transmitral Commissurotomy(PTMC), Immediate results.

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Introduction:

Rheumatic heart disease is still a common problem in Bangladesh and other developing countries, though its incidence is on decline in the western world. The prevalence of rheumatic fever in Bangladesh is 0.6/1000 population and that of rheumatic heart disease is 0.3/1000[1]. Most frequently affected valve in rheumatic heart disease is Mitral valve, in 40% cases other heart valves are also affected along with Mitral valve but in 25% patients, Mitral valve is solely affected.[3] Mitral stenosis is more common in female while in male mitral regurgitation is more common. Male are more prone to suffer from aortic valve disease than female[4] and it results in increased morbidity and mortality.[5] Mitral stenosis alone or in combination with other valvular lesions is almost always rheumatic in origin[6] while other valvular lesions may have etiologies other than rheumatic fever. An exceedingly rare form of mitral stenosis is congenital stenosis which is associated with high mortality in first few years of life.[7] In our subconinent, during pregnancy most common cardiac lesion detected is mitral stenosis, rheumatic in origin[8] and it is due to overcrowding and poor socioeconomic status of population. Late diagnosis and late referral for management to specialized cardiac centers are the main problems

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responsible for these complications and sometimes lack of resources are also responsible for it.

In 1982, Inoue K and colleagues were the first to perform Percutaneous Trans- Mitral Commissurotomy (PTMC) and since then PTMC is the treatment of choice for symptomatic patients with moderate to severe MS having suitable valves for PTMC. In pregnancy, medical treatment is the first line of treatment and PTMC is only indicated when patients do not respond to medical treatment and/or patients presented with repetitive or persistent heart failure. Due to high maternal (1.7% - 3.1%) and fetal (5% - 33%) mortality rate, surgical commissurotomy is not good option in pregnancy.[9] In literature, there is almost more than 10 years documented experience of PTMC for mitral stenosis in pregnancy.[10] We can delay mitral valve replacement surgery for ten or more years in patients who benefited from PTMC with additional option to redo PTMC later on in suitable cases.[11,12] Two main techniques of commissurotomy are in the world; the balloon and the Metallic Commissurotomy.

The Inoue balloon is the most commonly used technique today worldwide and it was also used by the authors. Other balloon techniques are:

(a) Double balloon technique.

(b) Multitrack technique; it is the refinement of the double balloon technique that employ a monorail system first described by Bonhoeffer et al.[13]

Metallic commissurotomy was introduced by Cribier et al in 1990s.[14] It carries a high risk of haemopericardium due to stiff guide wire in LV cavity and now it is not commonly used. The potential advantage of this technique is its cost effectiveness.

Mitral regurgitation is a major complication of PTMC[15] and its incidence is 1.4% - 7.5% as documented in the literature.[16] Immediate results of PTMC are predicted from mitral valve anatomy as was evident in many studies. Regarding the procedural success and hemodynamic effects of PTMC very few studies have been done and data in Bangladesh is not sufficient. The objective of this study was to audit all my cases of PTMC, so far I have done from February 2018 to November 2019 at department of Cardiology, Rangpur Medical College Hospital, Rangpur & Zia Heart Foundation, Dinajpur, those are at northern division of Bangladesh.

Materials and Methods:

This was an observational cross sectional study conducted from February 2018 to November 2019 at department of Cardiology, Rangpur Medical College Hospital, Rangpur & Zia Heart Foundation, Dinajpur. Total 30 patients were enrolled.

Inclusion Criteria

Any patient (Male or Female) of age ≥10 years having symptomatic MS with NYHA functional class II or more with mitral valve area (MVA) ≤1.5 cm2 and mitral valve Echocardiographic score ≤11 according to scoring system described by Wilkins et al.

Exclusion Criteria

1) Patients with significant mitral regurgitation (MR ≥2).
2) Bilateral Commissural calcification.
3) Clot in LA and/or LAA.
4) Presence of other lesions which need open heart surgery.
5) Wilkin Score > 12.
6) Patients were excluded if valve area measurement was performed using other methods than area tracing technique (like mean transmitral diastolic pressure gradient technique or pressure-half-time technique) in a setting of associated mitral regurgitation.
7) End stage renal or liver disease.
8) Patients with severe COPD.

We prospectively included 30 consecutive patients with rheumatic mitral stenosis who fulfill the inclusion and exclusion criteria for PTMC and they were undergone PTMC using Inoue balloon technique during the period from February 2018 to November 2019 at department of Cardiology, Rangpur Medical College Hospital, Rangpur & Zia Heart Foundation, Dinajpur, those are at northern division of Bangladesh. Informed written consent from all the patients who participated in the study was taken. The demographic data regarding age, gender, occupation etc. were collected and a detailed physical examination especially relevant cardiovascular examination of all the patients were done. Symptoms regarding their referral for medical checkup were recorded. Height, weight and other anthropometric measurements of all the patients were taken at the hospital using standardized techniques. Previous record of each patient was scrutinized and noted.

Baseline routine investigations including complete blood count with ESR, electrolytes, CRP, LFT, RFT were done in each case. Any rheumatic activity was assessed by looking the ESR, CRP of the patient. To evaluate rate and arrhythmia like atrial fibrillation ECG was performed at the time of

examination and at morning on procedure day. To see signs of pulmonary oedema, pulmonary hypertension and other lung pathology like pulmonary infarction and infection, X-ray chest PA view was done. From clinical symptoms and signs functional status of the patients was graded according to the New York Heart Association (NYHA).

A baseline colour echocardiogram was performed in all patients. Examination was acquired by using a commercially available system (GE, vivid S-70N, USA) equipped with 2.5 and 3.5 MHz transducers .

Mitral stenosis was assessed with 2D, Spectral and Colour Doppler echocardiography. Mitral valve area was calculated by plannimetry using 2D Echo in parasternal short axis view and by pressure half time method, then finally valve area was determined by averaging the values. Every patient was subjected to Continuous Wave (CW) and Pulse Wave (PW) Doppler studies in apical 4 chambers view. Mitral valve gradient (Peak and Mean) observed in left ventricular inflow in each case. In apical 4 chamber view tricuspid pressure gradient was used to assess pulmonary artery pressure.

Severity of mitral stenosis was graded as: very sever stenosis (valve area <1cm2), severe (valve area 1- 1.5 cm2) moderate (valve area 1.5- 2 cm2) and mild (valve area > 2.0 cm2). Transthoracic echocardiographic examinations were done within a week before intervention, during procedure and one day after the procedure. To assess the mitral valve morphology,Wilkins scoring systems were used. Presence of MR with its severity was noted. Color flow mapping was used to assess MR severity by expressing the ratio of maximal jet area to left atrial area in the same view and was graded from one to four according to Essop et al. In cases of uncertainty, PISA method was used to assess MR severity.

Presence of commissural calcification is another important factor to determine the suitability for PTMC and was assessed on 2D echocardiographic short-axis view. Commissural calcification (1 or both commissures) is an independent predictor of near-term success during the procedure, as well as long-term outcome.[17] In Cath. Lab pre and post PTMC invasive hemodynamics including LA, RA, RV, left ventricular end-diastolic pressure (LVEDP), and transmitral pressure gradient (PG) was calculated. The patient remained in the supine position during the procedure. There are two approaches to reach mitral valve, retrograde (Transarterial) and antergade (Transvenous) approach. The retrograde approach has a potential risk of arterial damage but eliminates risk of residual ASD after PTMC.[18]

Most commonly used approach in the world is antegrade through right femoral vein[19] and it was adopted by us. Interatrial septal puncture was done in lateral projection with Brockenbrough needle at 4^o clock to 6^o clock at fossa ovalis level. In supine position when we look from foot side of the patient atrial septum runs from 1^o clock to 7^o clock. Successful entry into the left atrium was confirmed by pressure tracing, by withdrawing oxygenated blood from LA and typical fluoroscopic picture during contrast injection. Those patients who have echo contrast on echocardiography were given 5000 IU heparin IV after septal puncture. As described in literature, standard protocol for PTMC was adopted.[14] Antibiotic prophylaxis was initiated in all patients thereafter. The procedure was performed under local anesthesia, if needed moderate sedation was given with midazolam. As a rule of thumb following equation was used to choose balloon size in

$$\text{PTMC: BALLOON SIZE} = \frac{\text{Patient height (cm)}}{10} + 10$$

In some special cases for septal puncture transthorasic echo was used. After each inflation, balloon was withdrawn in LA to measure LA pressure or to assess MR on color Doppler. Abrupt increased in LA or pulmonary artery pressure, suggests acute severe MR. The procedure was ended when either adequate increase in mitral valve area or increase in degree of MR or decrease in mitral valve gradient was observed. In Cath Lab. on the basis of hemodynamic criteria we can evaluate immediate results

For good immediate results frequently two definitions are used:

1) Valve area $\geq 1.5 cm^2$ without mitral regurgitation ≥ 2.
2) Valve area $\geq 1.5 cm^2$ with an increase in valve area of at least 50% of pre PTMC area.

At the end of procedure RA, RV, pulmonary artery pressure, LA pressure, LVEDP, was measured with multipurpose catheter. After 24-48 hours patient was discharged and before discharge transthorasic echo was done to measure all the parameters as pre PTMC along with any echo finding of pericardial effusion.

Statistical Analysis

Data was analyzed by SPSS (Statistical Package for Social Sciences). Significance testing of difference between proportions was conducted with a value corresponding to $p<0.05$ for significance.

Results:

Total 30 patients were studied, 22(73.33%) were female and 8(26.66%) were male showing a female predominance. The mean age was 28.28±8.4, ranged from 10 to 60 years. Most of the patients16 (53.28%) were in age group 21-30 years followed by in age group 10-20, 9(29.7%). (Table-II, Fig-1).

18(59.94%) patients were in atrial fibrillation and 12(39.96%) had sinus rythym. The procedure was successful in

29(96.66%) patients and PTMC was unsuccessful and was abandoned in 1(3.33%) patients (Table II). In one patient we failed to puncture the septum due to giant LA with aneurismal thick septum and the procedure was postponed..

Most of the patients 20(66.66%) were in NYHA class III and 10(33.3%) were in class II (Table II). After PTMC, iatrogenic ASD was present in 2(6.66%) patients. Before procedure 3(9.99%) patients had G-I MR. After PTMC, G-I MR was present in 2(6.66%) patients & G-II MR was seen in 1(3.33%) patient (Table III). The image (fig-2) below depicts tricuspid regurgitation & Mitral Valve Gradient before & after PTMC. The figure-3 below shows few steps of PTMC Most of the patients 25(83.3%) before PTMC were in severe pulmonary hypertension & 4(9.99%) had moderate pulmonary hypertension.

After PTMC, most of patients 21(70%) were in mild pulmonary hypertension.There was marked decrease in pulmonary hypertension after the procedure and p value was significant 0.0002 (Table III).

Pre PTMC mean MVA (cm^2) was 0.801± 0.1325 and post PTMC it was 1.545±0.292cm^2 with significant p value 0.0001 (Table III). Mean MVPG (mmHg) pre PTMC was 27.108±5.94 and post PTMC it was 6.61±5.008 with significant p value 0.0001 (Table III). Mean LA pressure before procedure was 28.65±8.456 mmHg and post PTMC it was 11.27±6.34. There was significant decrease in mean LA pressure and p value was 0.0001. 07 patients had special problems, 1 had previous H/O PTMC, 2 were pregnant lady, one has kyphoscoliosis, one had large IAS aneurysm, one had H/O CVA and one had developed hemopericardium during procedure which was managed by auto transfusion.

Table-I

Echocardiographic Wilkin's scoring system to predict PTMC outcome.

Grade	Mobility	Valvular Thickening	Calcification	Subvalvular Thickening
1	Only tips of leaflet restricted	Thickness of leaflet is near normal (4-5 mm)	Echo brightness increased at a single area	Just below the mitral valve there is minimal thickening.
2	Leaflets show reduced mobility in basal and middle portions	Margins of leaflet are markedly thickened	Leaflet margins show scattered areas of brightness	1/3rd of chordal length show thickening of chordal structures.
3	Mainly base of leaflet move forward in diastole	Entire leaflet show thickening (5-8 mm)	Up to mid portion of leaflet brightness extends	Thickening extends up to distal 1/3rd of chordate
4	In diastole leaflet show minimal forward movement	Whole leaflet tissue show marked thickening (>8-10 mm)	Most of the leaflet tissue show extensive brightness	Subvalvular apparatus shortened and extensively thickened up to papillary muscles.

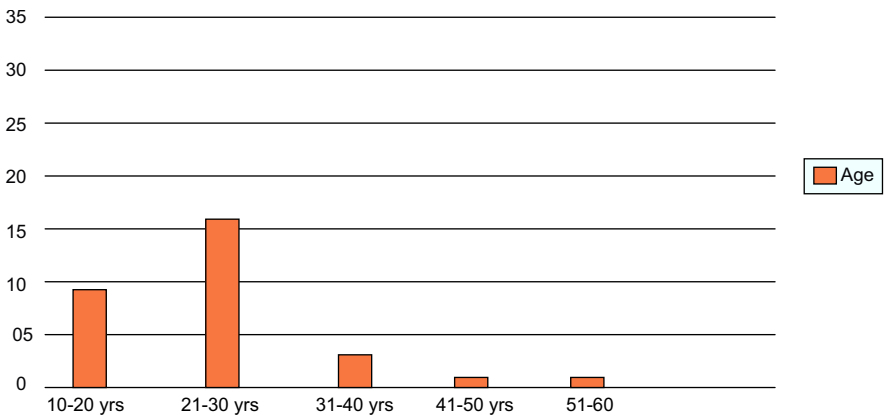

Fig.-1: *Age wise distribution of patients*

Table-II

Baseline characteristic of patients

Variables	Frequency	Percentage
Total number of PTMC	30	**100%**
Female	22	73.33%
Male	08	26.66%
Age		
10-20 Years	09	29.7%
21-30 Years	16	53.28%
31-40 Years	03	9.99%
41-50 Years	1	3.33%
51-60 Years	1	3.33%
Wilkin Score (Mean)	9.15 ± 0.776	
Rhythm		
Atrial Fibrillation	18	59.94%
Sinus Rhythm	12	39.96%
Other Associated Lesions		
Mild AR	03	9.99%
Successful PTMC	29	96.66%
PTMC Abandoned / Unsuccessful	01	3.33%
NYHA Class		
NYHA Class II	10	33.3%
NYHA Class III	20	66.66%
NYHA Class IV	Nil	Nil
Patients need Urgent MVR	00	00%
Mortality from PTMC	00	00%
Ischemic Stroke	Nil	
Iatrogenic ASD after PTMC	02	6.66%

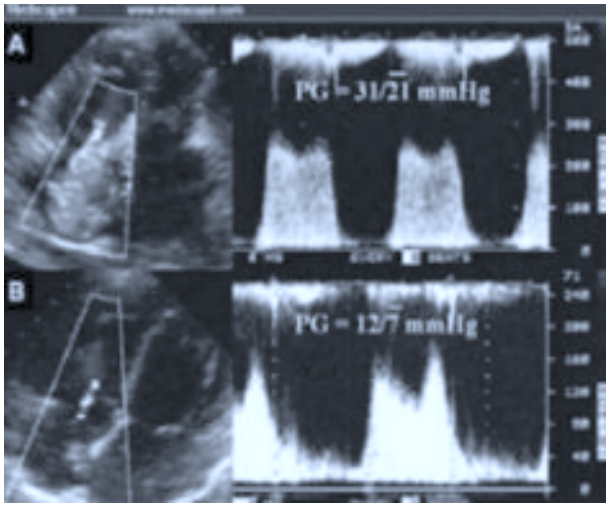

Fig.-2: *Echocardiographic pressure gradient across mitral valve*

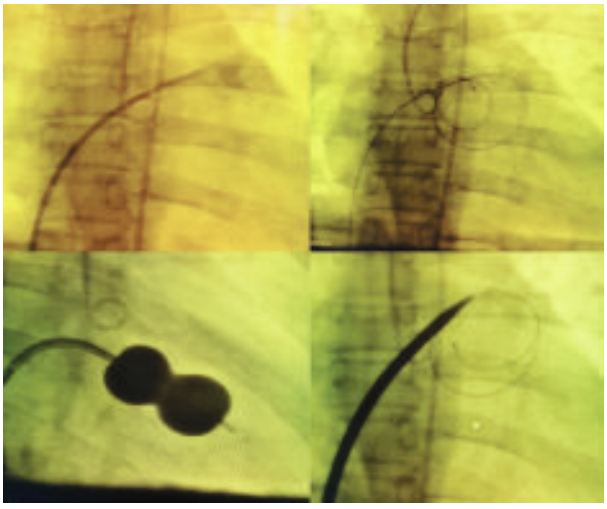

Fig.-3: *Steps of PTMC*

Table-III

Pre & Post PTMC Echo Doppler data

Parameters	Pre PTMC	Post PTMC	P value
MVA (cm2) Mean ±SD	0.801 ±0.1325	1.545 ±0.292	0.0001
Mean MVPG (mmHg) (Mean ± SD)	27.108 ±5.94	7.61 ±5.008	0.0001
Pulmonary Hypertension(mmHg)			
Mild	01(3.33%)	21(70%)	
Moderate	04(13.32%)	07(23.31%)	0.0002
Severe	25(83.3%)	02(6.66%)	
Mitral Regurgitation			
G-I	03(9.99%)	02(6.66%)	
G-II	Nil	01(3.33%)	
G-II+	Nil	Nil	

Table-IV

Pre & post PTMC hemodynamic and procedural data

Parameters	Pre PTMC	Post PTMC	P value
LA Pressure (mmHg) (Mean ±SD)	28.65 ±8.456	11.27 ±6.34	0.0001
RV Pressure (mmHg) (Mean ±SD)	65.2 ±9.55	42.90 ±8.67	0.0001
LVEDP (mmHg) (Mean ±SD)	3.3±2.0	6.4±2.4	0.0003
Transmitral PG(mmHg) (Mean ±SD)	26.208±5.12	6.3±3.8	0.0001

Discussion:

Rheumatic heart disease is the most frequent cause of abnormal valvular function. In the United States the prevalence of rheumatic fever is less than 1/100000 people and in India and other developing countries prevalence is 100–150 cases per 100,000 people. Due to aggressive initial attack, rheumatic heart disease may develop as early as in teenage.

In Bangladesh and other developing countries Mitral stenosis is mostly rheumatic in origin. Due to overcrowding and low socioeconomic background, it is more common in young female. Percutaneous Trans Mitral Commissurotomy (PTMC) is treatment of choice for symptomatic mitral stenosis patients[12] since 1982, after the first mitral valvuloplasty by Inoue et al.[20]

Prediction of procedural success and immediate results is multifactorial. Independent predictors for procedural success and immediate results are; severity of mitral stenosis, presence of MR before PTMC, annular or commissural calcification, pulmonary artery pressure, severity of TR, history of previous commissurotomy, age of patient , NYHA functional class and morphologic factors.[18]

In the study, procedure was successful in 29(96.66%) patients. These results coincide with the results of international studies conducted by M S Alkhalife et al[21] and Syed Dawood Md et al 22 in which procedural success was 94.5% and 95% respectively. One subcontinental study conducted at Peshawar, Pakistan by Sher Bahader Khan et al[23] showed procedural success in 96% patients which coincides with our results. In 1% to 17% patients, PTMC may be unsuccessful and this failure result due to unfavorable anatomy i.e giant LA, thick septum, during initial portion of learning curve of the operator, subvalvular disease or heavy calcification or special problem like hiatus hernia, kyphoscoliosis and in our study PTMC was unsuccessful or/ and abandoned in 1(3.33%) patient and this result coincide with other international studies.The PTMC was considered unsuccessful if we could not succeed to puncture the septum, failure to cross the balloon through septum, or cannot cross MV or both commissures remained fused after balloon inflation.

Most commonly documented complication of PTMC is mitral regurgitation and frequency of severe MR varies from 2% to 19%.[24] Significant MR is defined as MR of ≥2/4 grade. Our results showed that 2(6.66%) got G-I MR & 1(3.33%) had MR grade II and these results coincide with other studies.Factors predicting severe MR during PTMC are not fully understood and rather controversial.[25] This complication is related to tear of the posterior or

anterior leaflet. Sometimes due to asymmetrical significant commissural calcification, severe MR can occur due to the non-calcified commissural tear.

After balloon valvuloplasty, the frequency of atrial septal defects in different studies ranges from 10% to 90% and these shunts are very small and left to right restrictive shunt. Sometimes, though rare due to very sever pulmonary hypertension these shunts are right-to-left. In this study, frequency of iatrogenic ASD was observed in 2(6.66%) patients and it coincides with other studies results. In this study, we could not perform PTMC for one patient1(3.33%) due to failure of septal puncture due to giant LA & aneurismal thick septum. There was no mortality (00%) regarding his study. One patient was resuscitated during procedure for haemopericardium due to free wall puncture. Blood from pericardium was aspirated and auto transfusion was done and patient was survived. Incidence of procedural mortality is documented 0-3% in other studies which coincide with our results. Poor general health and free wall perforation are the main causes of mortality. 0.5% to 12.0% patients may develop hemopericardium and this is due to free wall perforation by guide wires or balloon or during septal puncture. If haemopericardium occurs emergency pericardiocentesis should be done and patient should be transfer immediately to cardiac surgery after stabilization. During PTMC incidence of embolic events ranges 0.5% to 5.0% and sometimes but rarely this embolic event can cause death or permanent disability and in our study no patient got ischemic / embolic event. To avoid this complication TEE is must especially in patients having atrial fibrillation or previous history of TIA or stroke and high risk patients having lot of echo contrast in LA/ LAA must be given heparin after septal puncture.

1.5% patients may develop complete heart block during PTMC and it is mostly transient and very rarely may require a permanent pacemaker. In our study no patient (00%) patient got this complication.

The frequency of restenosis in different studies at 3-10 years interval after percutaneous mitral valvuloplasty is 2% to 40%. It is defined as loss of more than 50% of area gained during PTMC with a valve area less than 1.5 cm^2. Re do balloon valvuloplasty or surgical mitral valve replacement are options for restenosis after PTMC.[18,26,27] In our study, we performed one re do PTMC.

Conclusion:

Percutaneous transmitral valvuloplasty (PTMC) is a safe and effective intervention for patients with severe MS and suitable valve in expert hand and even during special situations like pregnancy and re do cases.

Limitations

This study has number of limitations. First, we could not perform transoesophageal echo because of lac and unavailability of such super-specialised investigation in such a peripheral part of the country.Second,

This is a hospital based study. There is possibility that only patients with advanced disease and significantly symptomatic cases were referred to us, representing the proverbial tip of a very great iceberg. The patients included in the study, are not likely to be the representative of the disease burden in our community.

Recommendations

In our population, large definitive studies to be executed. A screening program on echocardiography-based is the need of time to determine the true prevalence of rheumatic valvular diseases especially in our childhood population and to strengthen the commitment to primary and secondary prevention programs.

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