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Mitral balloon valvotomy using the Inoue balloon technique for selected patients with severe pliable rheumatic mitral valve stenosis: immediate and short-term results [74]

Paulo A. Ribeiro, MD *, Mohamed Eid Fawzy, FRCP *, Mohamed Arafah, MD **, Bruce Dunn, MD *, R. Sriram, MD *, A. Shaikh, MD *, Edward Mercer, FRCP(C) *, G. Vanhaleweyk, MD *, CMG Duran, MD, PhD.

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Introduction

Inoue[1] first described mitral balloon valvotomy in 1984 using a transvenous approach in five patients. The ingenious balloon devised by Inoue is now commercially available. Until recently, the double balloon mitral valvotomy technique initially described by Zaibag et al[3] prevailed. Several studies have confirmed the excellent immediate and long-term results using this technique in patients with severe rheumatic mitral valve stenosis[4, 5, 6, 7]. The double balloon technique and its variants are difficult to master as they require two transeptal punctures or optimal balloon alignment using two different balloons for successful valvotomy. We describe our initial experience with the Inoue balloon technique in a selected young population of patients with severe pliable rheumatic mitral valve stenosis.

Patients and methods

We selected 40 patients with severe pliable symptomatic rheumatic mitral valve stenosis for mitral valvotomy using the Inoue balloon. There were 24 females and 16 males with a mean age of 31 ± 14 years (range 12-58) years. Thirty-six patients were in Class II NYHA and 4 patients were in Class III-IV NYHA. Thirty-two were in sinus rhythm and 8 were in atrial fibrillation. The patients were selected according to the following echo and angiographic criteria:

1. Mitral valve area < 1.1 cm^2;
2. Mitral regurgitation < ¼ grade;
3. Absence of significant subvalvular mitral valve disease;
4. Absence of calcification of the mitral valve commissures.
5. Good pliability of the anterior leaflet of the mitral valve.
6. Absence of left atrial clot/thrombus on echocardiography.

All patients had a Block echo score <8, and were considered good candidates for balloon valvotomy. Three patients who did not fulfil this echocardiographic criteria were excluded from the analysis. Two patients had mitral calcification on fluoroscopy.

Technique

The technique was described by Inoue and colleagues[1, 2] and we selected the balloon size according to the patient's height as described by Inoue[1, 2]. Oral diazepam was given (10 mg), as premedication together with 750 mg of oral kephlex as prophylaxis for bacterial endocarditis. Patients underwent diagnostic right and left heart catheterization. The Inoue balloon is made of a double layer of latex rubber between which there is a nylon micromesh[2]. Approximately half of the nylon mesh is bound with thin rubber bands pulled tightly in the central region and more loosely at the two ends, so that the shape of the balloon changes in three stages depending on the extent of the inflation; inflation occurs firstly at the distal half and subsequently to the proximal half; the balloon constriction remains in the middle section until full inflation is achieved (Fig. 1, 2). The Inoue balloon was conceived so that adjusting injection volume would alter the balloon diameter. The balloon size is selected according to the patient's height; 24 mm for patients less than 140 cm; 26 mm for patients >147 cm in height; 28 mm for those who measure between 160 and 180 cm; 30 mm diameter size balloon for patients >180 cm. The initial inflated diameter is less

* King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia.
** King Khaled University Hospital, Riyadh, Saudi Arabia.

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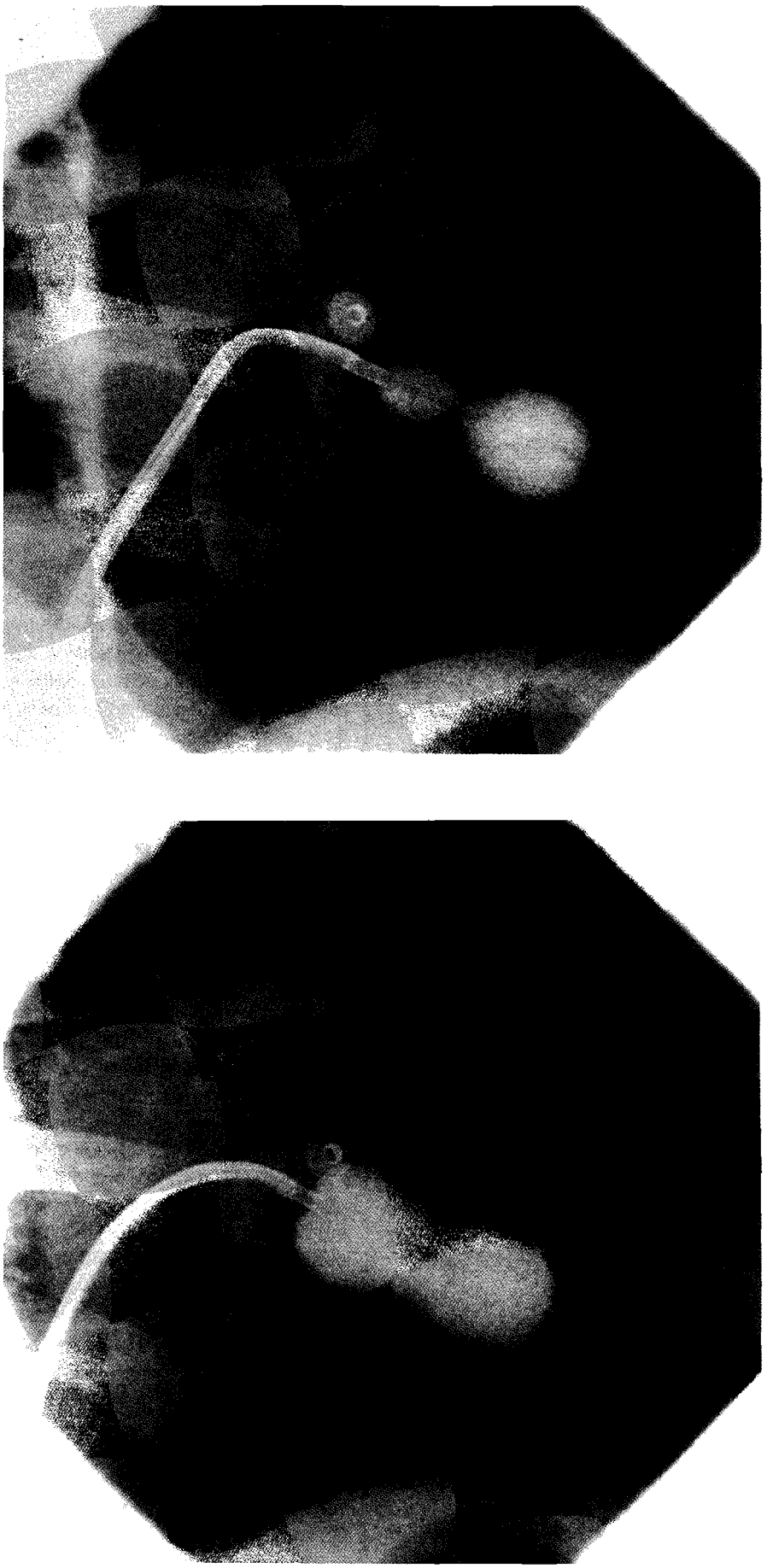

Fig. 1a, 1b Balloon valvotomy using the Inoue balloon. Note the balloon during early inflation (1a) and after successful valvotomy (1b).

than the predeterminated upper limit of the stepwise increase in balloon size and is implemented if the valve dilatation achieved is not considered adequate. The mitral valve area was measured by echo/Doppler using a Hewlett Packard phased array system with colour Doppler. Visual assessment of commissural splitting was corroborated by the hemodynamic decrease in the transmitral gradient. Pulmonary artery angiography will follow through to the left atrial cavity as was done to facilitate the transeptal puncture. Transeptal cardiac catheterization was done using an 8F Mullins transeptal, followed by the administration of 150 units of heparin per kg. A left ventriculogram was done before and after valvotomy. Mitral valve area (Gorlin) and transmitral gradient were measured before and after the procedure. Protamine was given at the end of the procedure to reverse the effect of heparin. The echo Doppler studies were done during the procedure and repeated at 6 week follow-up. Stepwise mitral valve dilatation was done according to Inoue's criteria, and echocardiography was repeated after each further dilatation to evaluate the degree of mitral valve regurgitation and calculation of mitral valve area using a Hewlett Packard phased array system. The Doppler mitral valve area was calculated using the method described by Hatle 48 hours after the procedure[9]. Patients were reviewed at a six-week follow-up study and the echo Doppler study was repeated. One patient was pregnant and the procedure was done with abdominal shielding and no angiography was done.

Statistics

Mean and standard deviation were calculated in the usual way. A Student t test were used to test the significance between the means.

Results

After mitral balloon valvotomy the mitral valve area increased from 0.8 ± 0.2 cm^2 to 1.7 ± 0.5 cm^2 ($P<0.001$) the mean mitral valve gradient decreased from 15 ± 5 to 6 ± 3 mmHg ($P<0.001$); the end diastolic mitral gradientdecreased from 9 ± 6 to 2 ± 3 mmHg ($P<0.001$). The mean left atrial pressure decreased from 21 ± 5 to 13 ± 5 mmHg $P<0.001$). There was a mild increase in cardiac output after balloon valvotomy from 3.9 ± 1.3 to 4.4 ± 1.2 l/m ($P<0.005$). After balloon mitral valvotomy mild mitral valve regurgitation developed in 5 patients and in one patient the degree of mitral regurgitation increased from mild to moderate. No patient developed severe mitral valve incompetence. There were no deaths or thromboembolic complications. There was one mild reaction to protamine, which was appropriately dealt with. We failed to cross the mitral value with the Inoue balloon in three patients. A further attempt was done with a transeptal puncture above the fossa ovalis in two cases, which was successful. All patients were discharged 48 hours after balloon valvotomy. The mean mitral valve area at hospital discharge was 1.9 ± 0.4 cm^2 (Doppler). There was one patient (2.5%) who exhibited residual mitral stenosis (MVA<1.5 cm^2).

Follow-up

At the six-week follow-up study all patients were asymptomatic with the exception of two; one in Class II and one in Class III NYHA. Doppler mean mitral valve area was 1.9 ± 0.5 cm^2 and one patient exhibited persistent stenosis (mitral valve area<1.5 cm^2).

Discussion

With a large experience over the last 5 years with the double balloon technique we acknowledge that the Inoue balloon thechnique is simpler and a less demanding technique for mitral valvotomy. The mitral valve area results achieved are excellent and comparable to those obtained with the double balloon technique[5]. The Inoue technique exhibits several advantages of the double balloon technique; it requires one single transeptal puncture; the balloon catheter crosses the mitral valve independently; it permits sequential stepwise mitral valve dilatation; the balloon catheter does not slip from the mitral valve during balloon inflation. The main drawback is the difficulty in crossing the mitral valve in the minority of cases and the high price of the device. Experience has taught us that the transeptal puncture should be done at or above the fossa ovalis in those cases with a small left atrium and a low puncture in gigantic left atria. We have demonstrated that the mitral valve area results achieved are similar to those obtained with the double balloon technique. The long term results of this technique needs to be evaluated. The mechanism of the Inoue balloon dilatation is similar to that for the double balloon technique, i. e. commissural splitting[10]. Conceivably, the long term results will be comparable to those achieved with the double balloon technique[6]. Niyoboshi[2] reported the largest series of patients who underwent balloon valvotomy with the Inoue technique. The incidence of atrial septal defect was hemodynamically insignificant and occurred in only 5% of patients and therefore does not constitute a problem for this technique. In contrast to Niyo-

boshi's[2] patient population, our patients were younger with a difference of 20 years in the mean age. We selected patients with pliable mitral valves and without significant mitral subvalvular disease. Our selection criteria of suitable valves for the intervention may explain the better mitral valve areas achieved and the low incidence of iatrogenic mitral valve regurgitation compared to the Niyboshisi[2] series. For selection of patients, this study demonstrates that patients with a Block echo score <8 and absence of calcium at the mitral commissural sites are suitable candidates for balloon valvotomy. Using this selection criteria, the incidence of residual mitral stenosis is indeed very small.

We conclude that the Inoue balloon valvotomy[10] is a simple and effective technique for the treatment of rheumatic valve stenosis in selected young patients with severe pliable rheumatic mitral valve stenosis. The selection of suitable valves for the intervention achieve good mitral valve areas with a low incidence of residual stenosis and iatrogenic mitral regurgitation. The longer term results of this technique need to be evaluated.

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Resumo

Seleccionámos 40 doentes com estenose mitral reumática grave, sintomática, para valvulotomia por balão usando a técnica de Inoue. A idade média dos doentes era de 31±14 anos, sendo 24 do sexo feminino e 16 do sexo masculino. Os doentes foram seleccionados de acordo com os seguintes critérios, baseados na técnica de Eco-Doppler: 1. estenose mitral grave, isto é, com área valvular mitral<1,1 cm^2; 2. folheto anterior da válvula mitral flexível; 3. ausência de calcificações das comissuras mitrais; e 4. ausência de doença subvalvular mitral significativa (*score* de Eco de Block<8). Não conseguimos atravessar a válvula mitral em três casos, e tentativas repetidas com punção transeptal alta foram bem sucedidas em dois doentes. Houve sucesso técnico em 39 procedimentos (98%). Não houve complicações. Usamos o balão de Inoue de tamanho 24-30 mm com a dilatação mitral guiada por Eco-Doppler. Depois da valvulotomia mitral por balão, a área valvular mitral aumentou de 0,8±0,2 para 1,7±0,5 cm^2 (p<0,001). Cinco doentes desenvolveram regurgitação mitral ligeira, e em um doente o grau de regurgitação mitral aumentou de ligeiro para moderado. A média da área da válvula mitral 48 horas após o precedimento era de 1,9±0,4 cm^2 (Eco-Doppler); um doente (2,5%) ficou com estenose mitral residual(<1,5 cm^2). Às seis semanas, a média da área valvular mitral era de 1,9±0,5 cm^2 (Eco-Doppler), sem reestenoses. Concluímos que em casos seleccionados de estenose mitral grave com válvula flexível, a valvulotomia pela técnica de balão de Inoue consegue um aumento da área valvular mitral superior a 100%, sem estenose residual e sem induzir regurgitação mitral iatrogénica significativa.

Summary in English: see page 391.

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Address for reprints

DR. P. A. RIBEIRO
MBC 16 King Faisal Specialist Hospital
PO Box 3354 Riyadh 11211 Saudi Arabia