Background—Percutaneous balloon valvotomy has become a common treatment of mitral stenosis, but the cost of the procedure remains a limitation in countries with restricted financial resources, leading to a frequent reuse of the disposable catheters. To overcome this limitation, a reusable metallic valvotomy device has been developed with the goals of both improving the mitral valvotomy results and decreasing the cost of the procedure.

Methods and Results—The device consists of a detachable metallic cylinder with 2 articulated bars screwed onto the distal end of a disposable catheter whose proximal end is connected to an activating pliers. By the transseptal route, the device is advanced across the valve over a traction guidewire. Squeezing the pliers opens the bars up to a maximum extent of 40 mm. The clinical experience consisted of 153 patients with a broad spectrum of mitral valve deformities. The procedure was successful in 92% of cases and resulted in a significant increase in mitral valve area, from 0.95 +/− 0.2 to 2.16 +/− 0.4 cm². No increase in mitral regurgitation was noted in 80% of cases. Bilateral splitting of the commissures was observed in 87%. Complications were 2 cases of severe mitral regurgitation (1 requiring surgery), 1 pericardial tamponade, and 1 transient cerebrovascular embolic event. In this series, the maximum number of consecutive patients treated with the same device was 35.

Conclusions—The results obtained with this new device are encouraging and at least comparable to those of current balloon techniques. Multiple uses after sterilization should markedly decrease the procedural cost, a major advantage in countries with limited resources and high incidence of mitral stenosis. (Circulation. 1999;99:793-799.)

Key Words: mitral valve ■ valvuloplasty ■ catheters

The therapeutic approach to mitral stenosis has evolved considerably since 1984, after the first report of percutaneous balloon mitral valvuloplasty (BMV) by Inoue et al. Since then, the technique has become an accepted alternative to surgical commissurotomy, especially in young patients with pliable valves, leading to comparable immediate and long-term results. To date, 2 techniques are applicable: the Inoue technique, which is by far the most often used worldwide, and the double-balloon technique. However, the cost of the procedure, which results principally from the price of the balloon catheter used, still remains a limitation to its application in countries with restricted financial resources, which are precisely those countries with the highest incidence of mitral stenosis. Consequently, most centers in developing countries reuse these balloon catheters several times, although they are provided as disposable catheters, thus introducing potential hazards due to imperfect sterilization and decreasing performance.

We developed a percutaneous valvulotomy device featuring a metallic valvotome instead of a balloon for opening the mitral valve, whose principle is basically similar to the metallic device (Tubbs dilator) used by surgeons for closed-chest mitral commissurotomy. The main advantage of this device would be the possibility of its being reused several times without any loss of performance after proper resterilization, and thus a decreased procedural cost. Other potential interests might be the improved efficacy and tolerance of the technique resulting from the mechanical properties of the device, which are aimed at acting principally on the mitral commissures.
TABLE 1. Demographic Data From 153 Patients

<table>
<thead>
<tr>
<th>Age, y (range)</th>
<th>36±15 (12–86)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of women (%)</td>
<td>98 (64)</td>
</tr>
<tr>
<td>NYHA class, n (%)</td>
<td>80 (52)</td>
</tr>
<tr>
<td>Atrial fibrillation, n (%)</td>
<td>73 (48)</td>
</tr>
<tr>
<td>Previous commissurotomy, n (%)</td>
<td>34 (22)</td>
</tr>
<tr>
<td>Echocardiographic score (range)</td>
<td>25 (16)</td>
</tr>
<tr>
<td>Left atrial diameter, mm</td>
<td>47±6</td>
</tr>
<tr>
<td>Associated MR (grade 1 or 2), n (%)</td>
<td>25 (16)</td>
</tr>
</tbody>
</table>

MR indicates mitral regurgitation.

The objective of the study was to evaluate the safety and the immediate results of this new technique.

Methods

Study Population
From November 1995 through January 1998, percutaneous mechanical mitral commissurotomy (PMMC) was performed at 14 centers in France, India, and Egypt. The Indian and Egyptian centers were selected on the basis of their very large experience in the field of BMV. A complete listing of centers with the main investigators is given in the Appendix.

The series included 153 patients with pure mitral stenosis and a broad spectrum of valvular deformity considered suitable for percutaneous valve dilation. The selection of patients for PMMC instead of BMV was related only to the presence in the hospital of 1 of the 3 lead authors of this article. The demographic data are shown in Table 1. Contraindications to the procedure were no commissural fusion, mitral regurgitation of Sellers grade >2, recent embolic event, and left atrial thrombus on transesophageal echocardiography, which was systematically performed within 2 weeks before the procedure.

The procedure for using this new device was approved by the ethical committee of each institution concerned and was performed with the patient’s informed consent.

Description of the Device
The device (Medicorp Inc) consists of a metallic dilator screwed onto the distal end of a disposable catheter. The entire system is made of 4 components, as follows:

The metallic dilator, made of stainless steel, when closed, is a cylinder 5 cm long and 5 mm wide, with a slightly tapered tip. The distal half of the dilator consists of 2 hemicylindrical bars 20 mm in length that can be opened out in parallel up to a maximum extent of 40 mm by a lever-arm system. The opening of these 2 bars leads to the separation of the commissures. Furthermore, the dilator contains an internal tube that allows the passage of a traction wire and also the recording of the distal pressures. The metallic head is screwed onto the distal end of the catheter and is detachable.

The catheter has a diameter of 13F (4.3 mm) and a length of 170 cm. Its proximal end has a connector for recording distal pressures, and it also allows connection of the activating pliers. Its distal end allows fastening of the dilator.

The metallic guidewire is made of stainless steel, with a length of 270 cm and a diameter of 0.035 in. A metallic bead 2 mm in diameter is soldered at the junction of the stiff core and the 10-cm-long floppy distal end. The guidewire is first positioned in the left ventricle; the commissurotome can then be advanced over it until the dilator crosses the mitral valve. Then, the guidewire becomes a traction system that allows the dilator to be opened. For that, the metallic bead is positioned in contact with the distal end of the dilator, and the guidewire is solidly locked into the commissurotome with a threaded fastener located on the activating plungers. Squeezing the arms of the pliers causes a backward traction of the guidewire and the metallic bead that is transmitted to the distal end of the dilator, thus forcing the distal bars to spread apart.

The activating plungers are attached to the proximal end of the catheter shaft. A manual pressure exerted on the arms of the pliers allows the dilator to open according to the mechanism described above, and the release of pressure closes the dilator. The activating pliers comprise several elements: (1) a caliper that allows the degree of opening of the bars to be altered from outside with the help of a cursor. The programmable degrees of opening are 30, 35, 37, and 40 mm; (2) a safety lock that prevents the complete closure of the dilator after the release of pressure exerted on the pliers (it holds the dilator open at 20 mm). To obtain a complete closure of the dilator after withdrawal from the mitral valve, this lock must be activated manually. This security system was designed to avoid any accidental extraction of valvular tissue; and (3) a threaded fastener, which is designed to block the metallic guidewire into the commissurotome at the time of opening.

After dilatation, the metallic dilator can be unscrewed from the catheter and can be sterilized by autoclave for reuse. The activating plungers and the guidewire can also be resterilized. Only the catheter is meant for single use.

Technique of PMMC
The technique, which is performed under local anesthesia and mild sedation, requires a transeptal antegrade approach. The entry site is the right femoral vein, which has to be punctured ≥2 cm below the inguinal ligament to avoid hindrance of the dilator.

A 8F Mullins catheter is used for the transseptal puncture. It is recommended that the septal puncture be made ≥2 cm below the usual site used in the Inoue technique to facilitate the trackability of the device across the valve. Subsequently, after septal puncture, an initial dose of heparin 2000 IU IV is administered (an additional dose of heparin 50 IU/kg will be administered after dilation of the atrial septum and confirmation of the absence of pericardial effusion. Both needle and dilator are removed, leaving the Mullins sheath in the left atrium. The left atrial pressure and the left atrioventricular gradient are then measured. Through the Mullins sheath, a left atrial angiogram can be performed by hand in the 30° right anterior oblique projection: the mitral valve is then clearly visible on the screen, and a diastolic frame of this angiogram is frozen on a second monitor to help position the dilator head at the time of dilation. Keeping the same projection, a floating balloon catheter (Critikon, USCI) is advanced through the sheath and used to cross the mitral valve. The distal end of the balloon catheter is positioned at the apex of the left ventricle, and the sheath is advanced over it, beyond the mitral valve orifice. The balloon catheter is then removed, and the guidewire of the device is advanced through the sheath in the left ventricle, the metallic bead being positioned at midventricle, ie, clearly beyond the mitral valve (Figure 1A). The Mullins sheath is then removed, and a 14F polyethylene dilator is advanced over the wire to enlarge the atrial septum puncture site. The same maneuver is then completed by additional dilation with an 18F dilator, which is also used to enlarge the femoral vein puncture site. As an alternative technique, a balloon catheter (8 mm in diameter) can be used for enlarging the septum and the femoral puncture site. The commissurotome is then advanced over the wire, and its distal end is placed across the mitral valve (Figure 1B). At that time, the guidewire is pulled back until the bead is firmly held against the tip of the valvulotome and then secured by squeezing the thread fastener of the pliers. The dilation can then be performed by squeezing the arms of activating pliers (Figure 1C). The desired degree of bar opening is obtained by use of the caliper. At least 2 openings of the dilating bars are performed. After dilation, the device is pulled back into the left atrium, with the guidewire in place in the left ventricle. The transvalvular gradient is assessed, the left atrial pressure being measured with the pressure line of the device. Whenever available, 2-dimensional (2D) echocardiography is performed to assess the quality of commissural splitting and to obtain a preliminary assessment of the mitral valve area. If necessary, an additional opening at a larger size can be made. After...
However, the planimetry was the reference method used for assessment of the results. The cardiac output could not be measured in the majority of centers, and thus, the valve area was not assessed by Gorlin’s formula.

Immediately before and after PMMC, the left and right heart pressures and the mean transmural pressure gradient were measured, and a left ventricular angiogram in the 30° right anterior oblique view was performed using the same amount and delivery rate of contrast to assess the left ventricular function and the presence and severity of any mitral regurgitation. A coronary arteriography was performed before PMMC in all patients with documented ischemia, and also in men >40 and women >50 years of age. Transatrial shunting was assessed after the procedure with transthoracic color flow Doppler and transesophageal color flow Doppler in a subset of 28 patients. The final echocardiographic results were recorded at day 1 after valvotomy. The procedural success was defined as a mitral valve area >1.5 cm² on the echocardiographic imaging performed 1 day after PMMC, in absence of Sellers grade ≥2 mitral regurgitation.

Statistical Analysis
Continuous variables are expressed as mean ± SD. Variation in continuous variables from baseline to day 1 after completion of PMMC was assessed with the paired Student’s t test or, when the sample size was small, with the Wilcoxon signed rank test. The following baseline variables were assessed as to their predictive role on post-PMMC mitral valve area and absolute variation in mitral valve area (difference between area after and before PMMC): the patient’s age, NYHA functional class, left and right hemodynamic variables, quantitative echocardiographic variables, echocardiographic score, mitral valve area, mean transmural gradient, degree of associated mitral regurgitation, and history of previous mitral commissurotomy. In addition, the extent of bar opening during commissurotomy was assessed. In univariate analyses, the following 2-sided statistical tests were used: for continuous variables, the Pearson correlation coefficient was estimated and tested to 0; for binary variables, the Mann-Whitney nonparametric test was used; for categorical variables with ≥2 levels, the Kruskal-Wallis nonparametric test was used. The variables that appeared to be significantly associated with the outcome (mitral valve area after PMMC and variation in mitral valve area) at the 0.10 significance level were further assessed by stepwise multiple linear regression with a threshold corresponding to a 0.05 significance level.

Results
Hemodynamic and Echocardiographic Results
PMMC could be achieved in 148 of the 153 patients (97%) and failed in 5. In 4 of these, it was not possible to cross the mitral valve with the Critikon balloon catheter in 3 cases and with the commissurotome in 1. The Inoue technique, which was then attempted, was successful in 2 patients and failed in the 2 others, who had a subsequent valve replacement. The fifth patient developed a pericardial tamponade and required emergency surgery. In this case, the transseptal puncture was made technically difficult by the marked thickness of the septum, and several punctures were attempted at various sites. The mitral valve was replaced, and the subsequent course was uneventful.

The maximal extent of bar opening was 40 mm in 114 patients (77%), 37 mm in 24 (16%), and 35 mm in 10 (7%). The mean number of openings was 3.4 ± 1.6. A successful result was obtained in 141 of the 153 patients enrolled (92%) and in 141 out of the 148 patients (95%) in whom PMMC was actually performed. The technique resulted in a significantly increased valve area, as shown in Table 2. At day 1, the mitral valve area had increased from...
0.95±0.2 to 2.16±0.4 cm² (P<0.001). Bilateral splitting of the commissures was noted in 129 patients (87%). According to the echocardiographic score, the mean post-PMMC mitral valve areas were 2.21±0.3 and 2.11±0.35 cm² in patients with scores <8 (87 patients) and ≥8 (61 patients), respectively, a nonsignificant difference. As shown in Figure 2, the increases in valve areas were comparable up to a score of 12.

The mean duration of the procedure from the time the septal puncture was completed to the withdrawal of the catheters (which was recorded in the last 108 patients) was 31±14 minutes.

Complications
In addition to the above-mentioned case of hemopericardium with tamponade (which resulted from the transseptal catheterization), severe complications occurred in 3 patients in whom PMMC was actually performed. One patient developed a massive (grade 4) mitral regurgitation and required urgent mitral valve replacement, with uneventful outcome. The regurgitation was related to a transverse tear of the anterior valve leaflet. Another patient developed a severe (grade 3) mitral regurgitation, with uneventful clinical course. On echocardiographic follow-up at 2 months, the mitral regurgitation was moderate and the patient was asymptomatic. Another patient developed a transient episode of aphasia with mild facial hemiparesis, with complete recovery within hours after the procedure.

On transthoracic color flow Doppler, transseptal shunting was not detected or was trivial after the procedure. In the subgroup of 28 patients who also had transesophageal color flow Doppler, transseptal shunting was detected in 2 patients, trivial in 22 and small in 2.

Changes in mitral regurgitation are shown in Figure 3. In addition to the 2 patients mentioned above who developed a severe mitral regurgitation (grades 3 and 4), mitral regurgitation was increased by 2 grades in 2 patients only and by 1 grade in 14; it decreased by 1 grade in 15 patients and was unchanged in the remaining 115. In 3 patients treated during the first half of this study and in whom a mitral regurgitation with no hemodynamic consequences (grade 1 in 1 patient and grade 2 in 2 patients) was observed after PMMC, a small piece of tissue was found hooked to the tip of the dilator after PMMC. In 1 case, the tissue corresponded to a chorda. In the other 2 cases, histological examination showed evidence of valvulitis, confirming the valvular apparatus as the source of tissue. These events led us to improve the device by developing a safety lock, which is described above. Since then, no extraction of tissue has been observed.

There were no other complications. The in-hospital follow-up was uneventful in all cases, and the patients were discharged an average of 2 days after the procedure.

Predictive Role of Baseline Variables on Changes in Mitral Valve Area
From univariate analyses, post-PMMC valve area was positively correlated with baseline mitral valve area (P=0.002) and extent of bar opening (P=0.007) and negatively with echocardiographic score (P=0.0003). The absolute variation in mitral valve area was positively correlated with systolic pulmonary pressure (P=0.026) and mean transvalvular gradient (P=0.032), negatively correlated with patient age (P=0.02) and baseline valve area (P=0.0001), and there was a nonsignificant trend for a negative correlation with extent of bar opening (P=0.087). From stepwise multiple linear regression, we found that baseline mitral valve area (P=0.026) and extent of bar opening (P=0.046) were the only 2 variables significantly and independently associated with post-PMMC valve area or with absolute variation in valve area (P<0.0001 and P=0.048, respectively).

Discussion
Our report shows that a percutaneous mitral valvulotome can be used successfully and safely to treat rheumatic mitral stenosis.

Comparison With the Results of Balloon Techniques
These results are encouraging and at least comparable to those reported with the use of balloon catheters. At day 1 after
PMMC, the mean valve area was 2.16±0.4 cm² for the entire series, a 127% increase from baseline. Several reports have confirmed that the final valve area was a significant predictor of favorable long-term outcome. The abundant literature concerning the immediate results of BMV shows that the postvalvotomy valve areas obtained are slightly less with the Inoue technique (≤2 cm² in the majority of reports) than with the double-balloon technique. In a meta-analysis of the international experience in which the 2 techniques were compared, the mitral valve area reached an average of 1.84 cm² with the Inoue technique and 1.93 cm² with the double-balloon technique. As shown in Figure 2, the valve area remained roughly constant up to a score of 12, but the limited number of patients with a score >10 (n=11) has to be taken into account in this statement. The score was not independently associated with post-PMMC valve area and absolute increase in valve area. This observation is in agreement with a previous report but in opposition to other studies in which valve morphology appeared to be an important predictor of immediate outcome.

The very limited incidence of complications in this first series of patients is noteworthy. Only 1 patient had a stroke with minimal and transient clinical consequences. The incidence of embolic events after BMV is reported to be in the range of 1% to 4% despite the use of routine preoperative transesophageal echocardiography. In 1 case, a pericardial tamponade occurred after the transseptal puncture. Cardiac perforation with subsequent tamponade is a well-known life-threatening complication of BMV, with an incidence of 1% to 9% in the literature. It can result from inadvertent atrial perforation during the transseptal catheterization or from perforation of the left ventricle with guidewires in the double-balloon technique. Despite the necessity of placing a guidewire in the left ventricle with this new technique, the risk of ventricular perforation seems to be decreased by the high flexibility of the distal 10 cm of the wire, the stability of the dilator head during opening (due to the uninterrupted blood flow through the valve orifice), and the traction with subsequent backward movement of the wire associated with the opening process. However, the lower puncture site required for this technique might increase the potential risk of cardiac perforation in less experienced hands.

Of the 148 patients, only 2 (1.4%) developed severe mitral regurgitation after PMMC, and urgent surgery was necessary in 1. In these 2 cases, the complication was unpredictable. Strikingly, no increase or even a decrease in mitral regurgitation was noted in 119 patients (80%), a rather unusual feature after BMV. The incidence of severe mitral regurgitation after BMV in the literature varies between 1.4% and 7.5%, and does not appear to be different with the single- or double-balloon technique. Finally, no significant transseptal shunting could be detected after PMMC by transthoracic or transesophageal color flow Doppler. However, oximetry was not used in the study because it was not usually performed in the majority of centers. With BMV, the incidence of residual transatrial shunting varies between 2.5% and 87%, depending on the modality of assessment. However, regardless of the technique used, most of the transatrial shunts closed spontaneously during follow-up.

Ben Farhat et al reported recently in a randomized study that the results of closed surgical commissurotomy were less good than those of BMV and open commissurotomy, with a mean increase in valve area to only 1.6 cm² versus 2.2 and 2.2 cm², respectively. These results are in agreement with previous reports but disagree with other studies showing comparable results after BMV and closed surgical commissurotomy. Despite the resemblance of the instrument used in closed surgical commissurotomy and in PMMC, the 2 techniques differ by many aspects, such as the self-positioning of the dilator’s bars in the commissures. Furthermore, with PMMC, the immediate evaluation of the hemodynamic and echocardiographic results after dilation offers the possibility of subsequent additional dilator opening to a larger size when needed.

Technical Considerations

The training requirement for such a procedure is in the range 8 to 10 cases for any investigator with a good experience of BMV, and less for those with previous experience with the double-balloon technique.

Crossing the Septum and the Mitral Orifice

Despite the length, caliber, and inescapable rigidity of the metallic dilator, the device could easily reach the mitral valve in the vast majority of cases. However, in 3 patients with a very thick septum, additional dilatation of the septal puncture site with an 8-mm balloon was necessary. During the opening phase, the dilator was perfectly stable, and the hemodynamic tolerance was good because of the noninterrupted blood flow.

Positioning the Device Across the Mitral Valve

An optimal positioning of the dilator across the valve before opening can be achieved by several means: (1) a satisfactory position is generally obtained when the distal half of the dilator is located slightly ahead of the aortic orifice, which is indicated by the presence of a pigtail catheter placed against the aortic leaflets; (2) when available, the left atrial angiogram obtained after transseptal catheterization is helpful to locate the free edges of the valve; (3) the transition between the left ventricular and left atrial pressure curves gives an excellent indication of the location of the border of the mitral valve; this can be observed during the withdrawal of the Mullins sheath after the guidewire has been positioned in the left ventricle or by recording these pressures by use of the pressure lumen of the dilator; (4) on-line transthoracic 2D echocardiography is frequently used and is an excellent way of optimizing the position of the device; and (5) the resistance to the device opening is well perceived while the arms of activating pliers are squeezed, and this confirms the accurate positioning of the dilator.

Extent of Bar Opening

The extent of bar opening appeared to be a significant predictive factor of the immediate PMMC results. The device sizing was not made according to the measurement of the mitral annulus. In adult patients with a body surface area >1.50 m² and without severe valvular calcifications, we
usually open the device to 40 mm at first. In other patients, we
start with 37 mm (or 35 mm in children), with a stepwise
increase in opening according to the results.

Mechanism of Action
Before this clinical study was begun, the ability of this device
to enlarge a stenosed mitral orifice was evaluated on 3
postmortem specimens with severely fibrotic and calcified
fused leaflets. The device opened up to 40 mm was able to
markedly enlarge the valve orifice, primarily by separating
the fused commissures without any injury to the leaflets or
the chordae. In clinical practice, this device was shown to act
mainly by direct stretching and subsequent separation of the
commissures as assessed by 2D echocardiography, which
could be performed on-line during PMMC in \( \approx 50\% \) of cases.

Economic Aspects
An important potential advantage of the metallic dilator is
the expected decrease in procedural cost. Although the
price of the device (when made on a large-production basis) remains undetermined at the present time, we
believe that it should be comparable to that of an Inoue balloon catheter. However, the detachable metallic head
allows multiple safe reuse after sterilization by autoclave,
as for any other metallic surgical tool. We have already
performed 35 consecutive procedures with a single device
without any deterioration of the dilator components. Thus,
it is expected that the final cost per patient will be
markedly lower than that of the balloon catheters in current
use. This should be considered a major advantage, partic-
ularly in countries with limited financial resources.

Future of the Procedure
This first clinical experience with the new technique is
promising. A multicenter prospective international registry is
currently ongoing that will definitely determine the benefits,
limitations, and cost-effectiveness of the procedure. A French
prospective study also started in January 1998 with the goal
of assessing the immediate as well as the long-term results of
the technique. Finally, a randomized study comparing this
technique with the current balloon techniques is scheduled to
start in the course of this year.

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Appendix
Listing of Centers and
Corresponding Investigators
France: Hôpital Charles Nicolle, Université de Rouen: A.
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Paré, Neuilly sur Seine: H. Leriche, MD. Clinique de la Louvière,
Lille: P. Rocha, MD.

India: Apollo Hospital, Hyderabad: P.C. Rath, MD. GB Pant
Hospital, New Delhi: R. Arora, MD; G.S. Kalra, MD. Civil Hospital,
Ahmedabad: S. Dani, MD. Jayadeva Institute of Cardiology, Ban-
galore: C.N. Manjunath, MD. Manipal Heart Foundation, Bangalore:
S. Chandra, MD. Sri Ramachandra Hospital, Chennai: J.S.N.
Murthy, MD. Railway Hospital, Chennai: S. Rajagopal, MD; K.
Abraham, MD. Ruby Hall Hospital, Pune: Dr P.C. Grant. Military
Hospital Cardiothoracic Center, Pune: M.S. Kumar, MD; S.
Kashyap, MD. Egypt: National Heart Institute, Cairo: A. El-Togbi,
MD. Al-Azhar University, Cairo: M. El-Sayed, MD.

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Percutaneous Mechanical Mitral Commissurotomy With a Newly Designed Metallic Valvulotome: Immediate Results of the Initial Experience in 153 Patients
Alain Cribier, Hélène Eltchaninoff, René Koning, Pratap C. Rath, Ramesh Arora, Adel Imam, Mustapha El-Sayed, Sameer Dani, Geneviève Derumeaux, Jacques Benichou, Christophe Tron, Satej Janorkar, Gérard Pontier and Brice Letac

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