The Clinical Results in the First Five Hundred Patients with Mitral Stenosis Undergoing Valvuloplasty

By Laurence B. Ellis, M.D. and Dwight E. Harken, M.D.

A report is made of the clinical results in the first 500 patients operated on by mitral valvuloplasty in whom a preoperative diagnosis of predominant mitral stenosis had been made. The operation appears to offer some protection against late peripheral embolization.

Four hundred forty of 442 surviving patients have been followed for periods of from six months to five years. Seventy seven per cent of the entire group are significantly improved. Thirty one per cent have had one or more attacks of a postoperative syndrome, but in only 7 per cent has there been clear-cut evidence of active rheumatic fever. Improvement in objective clinical findings, in particular in cardiac murmurs, heart size and the electrocardiogram, have been less striking than the subjective improvement.

Surgical treatment for mitral stenosis has now existed for sufficient time and has been carried out on enough patients to permit evaluation of operative mortality and postoperative results for the first few years. The earlier efforts of Cutler, Graham and others were largely directed at the conversion of mitral stenosis into mitral insufficiency. It was argued that incompetence was to be preferred to obstruction. Soultar attempted digital dilatation and no doubt attained a remarkable degree of restoration of valve function in one patient. His effort was not sustained nor his contribution appreciated. The reactivation of surgical efforts in the field stemmed from consistently successful intra-cardiac surgery during World War II and a better appreciation of the significance of individual leaflet function. We have described elsewhere\(^1\) the development and details of the operation and the rationale for use of the term valvuloplasty, which we have given it. Smithy, a postwar pioneer in this field, unfortunately died before he could extend his initial experiences.\(^4\) Bailey with his collaborators\(^6\) in this country has termed his operation commissurotomy, and Baker, Brock and Campbell\(^10\) in England refer to it as valvulotomy and valvotomy.

The place of any operation in the treatment of a pathologic state must be judged by the following standards: The course of the disease under medical management; the operative mortality; the benefit to be derived from operation. It is our purpose in this article to present evidence dealing with the second and third points and to show that there is a useful place for mitral valvuloplasty in properly selected patients.

This report deals with our first 500 patients in whom a preoperative diagnosis of predominant mitral stenosis was made. The operative technic has been described previ-
ously by us⁸ and probably changed only qualitatively rather than in principle in this group of 500 patients. With confidence and skill gained through experience, the surgeon has been able to accomplish increasingly successful valvuloplasty by the appropriate use of his finger or a valvulotome, depending on the condition of the valve. Since embolization to peripheral arteries has proved to be a major problem at the time of operation, techniques to minimize this danger were adopted in the last 250 patients in this series. The possibility of intra-auricular thrombi being present is greatest in fibrillating patients, and, therefore, in all of these the auricle has been freely flushed before any intra-auricular manipulation. Because cerebral emboli have proved the most disastrous, it was also hoped that isolation of the cerebral circulation at the time of the greatest danger of detachment of emboli, as suggested by Bailey and his co-workers,¹¹ might be of value. This was accomplished by tapes passed beneath the innominate, carotid, and left subclavian arteries by which angulation of the vessels cut off the cerebral blood flow for periods up to 60 seconds. This interruption of cerebral flow can be carried out repeatedly, with rest and recirculation between manipulation. This maneuver has not prevented embolization and the anoxia that it produces may have caused more harm than the theoretical benefit it confers. This technique has been largely abandoned except in patients with calcification of the mitral valve when it is employed at the time that the calcified area is cut or fractured. The many clinical details that may improve the quality of valvuloplasty and may reduce the danger of embolus from the auricle or calcification are considered in a separate discussion.¹²

**Selection of Patients for Operation**

Our criteria for the selection of patients for operation have not materially changed since early in our experience.⁶ We believe now, as we always have, that patients should not be operated upon unless they are substantially disabled by their disease, and unless, in spite of medical treatment, they are going progressively downhill. The reasons for this attitude are obvious. Many persons may have a very benign form of mitral valve disease, and before the onset of symptoms it is usually difficult to foretell what the course of their illness will be; they may never need an operation. It must be remembered also that this operation, in its present form, is a palliative procedure, not a cure. The valve is not restored to normal, and other factors in the heart disease, not dependent on the mechanical obstruction, are not relieved. We are undoubtedly somewhat more liberal now than we were in accepting some patients with lesser degrees of disability, who find it difficult to accept their limitations for reasons of occupation or otherwise.

The classification, which has been employed, has been described elsewhere;³ it roughly corresponds to the functional classification of the New York Heart Association. This series includes no patients in group I, that is those without any significant symptoms. It includes only 13 in group II; these are patients who are handicapped by symptoms from their disease but in whom the condition is not particularly progressive. There are 342 in group III; patients suffering mainly from pulmonary symptoms which are progressive in nature and sufficiently handicapping so that ordinary activities are being significantly and increasingly limited. There are 145 in group IV; these being cardiac invalids, mostly suffering from chronic congestive failure.

**Operative Mortality**

The operative mortality is shown in table 1. This includes not only patients who died at operation, but also those who failed to rally in

<table>
<thead>
<tr>
<th>Patient Number</th>
<th>Group II and III</th>
<th>Group IV</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of Patients</td>
<td>Mortality %</td>
</tr>
<tr>
<td>1–100</td>
<td>59</td>
<td>14</td>
</tr>
<tr>
<td>101–200</td>
<td>74</td>
<td>3</td>
</tr>
<tr>
<td>201–300</td>
<td>76</td>
<td>7</td>
</tr>
<tr>
<td>301–400</td>
<td>72</td>
<td>4</td>
</tr>
<tr>
<td>401–500</td>
<td>74</td>
<td>2.7</td>
</tr>
</tbody>
</table>

---

¹⁰ We are Dr. Bailey and his co-workers.² Balinger and Bailey.³ Bailey and his co-workers.⁸ Dr. Bailey and his co-workers.
the postoperative period. The cases are divided into consecutive hundreds of patients. Since there are so few cases in group II and only one operative death, these are included with group III. It will be seen that in this category, after a relatively high mortality in the initial cases, the mortality experience has markedly improved so that it is under 3 per cent in the last hundred. Indeed, in the last 200 group III patients operated on since this series of 500 was complete, there has been only one death.

On the other hand, the death rate in the group IV patients has remained in the neighborhood of 25 per cent. This emphasizes the desirability of operating upon mitral disease patients before they reach this terminal stage, at which time the operative mortality is high and less dramatic results from the operation will usually be achieved.

The apparent lack of improvement in the operative mortality in group IV patients may be due to a number of factors and will be considered in a subsequent report. Suffice it to say that the dramatic improvement in technique, that is reflected in the reduction of mortality in group III patients to something that may now approximate 1 per cent, has probably been balanced in the group IV patients by better preoperative medical care that brings to operation patients who formerly succumbed before surgery. Furthermore, many of the patients now obtaining successful surgery formerly were not even considered for operative intervention. Thus better surgical technique and vastly improved postoperative regimen are certainly masked by a shift of preterminal patients into the operative experience.

When the effect of age on the operative mortality is considered (table 2), it will be seen that there is no clear trend toward increasing risk with advancing age, provided the distinction between group III and IV patients is maintained. Proportionately, a progressively larger number of patients fall into the group IV category as age advances.

Table 3 shows the effect of auricular fibrillation in increasing operative mortality. This is clear in the group II and III patients in the last 400 patients. Six patients in group III who were in normal sinus rhythm died in the first group of 100 patients as a result of technical problems related to operation, unsolved at that time. In group IV there were too few patients in normal sinus rhythm to be of statistical significance, but there was only one death in patients in normal rhythm as compared with a mortality of 31 per cent in the fibrillating patients. The relation of the operation to the precipitation of peripheral emboli will be discussed later.

**Follow-up Results**

There were 442 patients who survived the operation and of these all but two have been followed for a period of at least six months (table 4). Four hundred and nine have been followed from one to five years. The mean follow-up time for the entire group is 22 months.

Evaluation of the postoperative status of the patients has been based on all available information, including questionnaires to pa-

<table>
<thead>
<tr>
<th>Age in Years</th>
<th>Group</th>
<th>Number of Patients</th>
<th>Number of Operative Deaths</th>
<th>Operative Mortality %</th>
</tr>
</thead>
<tbody>
<tr>
<td>10–19</td>
<td>II &amp; III</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>IV</td>
<td>0</td>
<td>0</td>
<td>—</td>
</tr>
<tr>
<td>20–29</td>
<td>II &amp; III</td>
<td>67</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>IV</td>
<td>6</td>
<td>2</td>
<td>33</td>
</tr>
<tr>
<td>30–39</td>
<td>II &amp; III</td>
<td>148</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>IV</td>
<td>35</td>
<td>8</td>
<td>23</td>
</tr>
<tr>
<td>40–49</td>
<td>II &amp; III</td>
<td>122</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>IV</td>
<td>66</td>
<td>13</td>
<td>20</td>
</tr>
<tr>
<td>50–59</td>
<td>II &amp; III</td>
<td>14</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>IV</td>
<td>35</td>
<td>15</td>
<td>43</td>
</tr>
<tr>
<td>60–69</td>
<td>II &amp; III</td>
<td>0</td>
<td>0</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>IV</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Table 3.—Effect of Age of Patient on Operative Mortality**

<table>
<thead>
<tr>
<th>Group</th>
<th>Rhythm</th>
<th>Cases 1–100</th>
<th>Cases 101–500</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>No. Dead</td>
<td>% Dead</td>
</tr>
<tr>
<td>II &amp; III</td>
<td>AF</td>
<td>23</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>NSR</td>
<td>36</td>
<td>6</td>
</tr>
<tr>
<td>IV</td>
<td>AF</td>
<td>34</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>NSR</td>
<td>7</td>
<td>1</td>
</tr>
</tbody>
</table>
Table 4.—Duration of Follow-up of the First 500 Patients Undergoing Mitral Valvuloplasty

<table>
<thead>
<tr>
<th>Duration</th>
<th>No.</th>
<th>%</th>
<th>Total follow-up</th>
<th>Lost</th>
<th>Operative deaths</th>
<th>Total</th>
<th>Mean follow-up time, 22 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months–1 year</td>
<td>31</td>
<td></td>
<td></td>
<td>440</td>
<td>2</td>
<td>500</td>
<td></td>
</tr>
<tr>
<td>1–2 years</td>
<td>230</td>
<td></td>
<td></td>
<td>2</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2–3 years</td>
<td>127</td>
<td></td>
<td></td>
<td>58</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3–4 years</td>
<td>42</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4–5 years</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total followed</td>
<td>440</td>
<td></td>
<td></td>
<td>4</td>
<td>58</td>
<td>500</td>
<td></td>
</tr>
<tr>
<td>Lost</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operative deaths</td>
<td>58</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 5.—Follow-up Results in the First 442 Patients Surviving Mitral Valvuloplasty

<table>
<thead>
<tr>
<th>Status</th>
<th>Group II</th>
<th>Group III</th>
<th>Group IV</th>
<th>Total Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Improved</td>
<td></td>
<td></td>
<td></td>
<td>77</td>
</tr>
<tr>
<td>markedly</td>
<td>7</td>
<td>58</td>
<td>181</td>
<td>56</td>
</tr>
<tr>
<td>moderately</td>
<td>3</td>
<td>25</td>
<td>80</td>
<td>25</td>
</tr>
<tr>
<td>slightly</td>
<td>0</td>
<td>0</td>
<td>25</td>
<td>8</td>
</tr>
<tr>
<td>Unchanged</td>
<td>2</td>
<td>17</td>
<td>20</td>
<td>6</td>
</tr>
<tr>
<td>Worse</td>
<td>0</td>
<td>8</td>
<td>2.5</td>
<td>3</td>
</tr>
<tr>
<td>Late Deaths</td>
<td>0</td>
<td>8</td>
<td>2.5</td>
<td>10</td>
</tr>
<tr>
<td>Lost</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td>323</td>
<td>107</td>
<td>107</td>
</tr>
</tbody>
</table>

The results in each group are shown (table 5). In the group II patients all but two are clearly improved. In group III, eight have died, one of a noncardiac cause, and 28 are unchanged or worse than before operation. Five of these latter patients are disabled by the residua of operative emboli to such an extent that they have not been classed as better although in most of them the cardiac reserve has improved. The remaining patients in group III have improved, the vast majority markedly, which means that such patients are living essentially normal lives.

The results in group IV have also been strikingly good (table 5). Ten have died, one of whom succumbed to a noncardiac illness. Fifteen are unchanged or worse. Two of these are disabled as the result of operative or postoperative emboli although their cardiac status is better. The other patients in group IV are better, and more than half of the entire group have been strikingly improved. Since patients in this group were cardiac invalids, we have been somewhat more liberal in our definition of “marked improvement” and have so classified patients who can now carry on sedentary occupations and who require only a minimum of diuretic therapy.

Operative and Postoperative Embolization

Of particular interest is the effect of the operation on the precipitation of peripheral emboli and on the incidence of emboli developing at some late date after the operation.

Operative emboli detached from the thrombus in the left auricular appendage at the time of operation or from a calcific fragment of a fractured mitral valve constitute a major hazard of the procedure both in regards to mortality and in producing serious sequelae, usually in the form of cerebral hemiplegia, which may be disabling. Table 6 shows the incidence of these operative emboli in patients with and without auricular fibrillation. It will be seen from the table that the incidence of peripheral embolization is considerably higher in the patients who were fibrillating than in nonfibrillators, and in patients of group IV as compared with those of group III. It is of interest that of those patients in normal sinus rhythm who developed operative emboli, all but two had definitely calcified valves, and in these two, information was not clear as to whether or not calcification was present.

Of particular interest is the effect of the operation on the incidence of late peripheral
emboli. The danger of such emboli in patients with mitral stenosis, particularly in those in auricular fibrillation, is very real and is often one of the chief reasons for considering mitral valvuloplasty. Seventy-nine of the patients in this series of 500 had had one or more peripheral embolic episodes at some time prior to operation. All but eight were in auricular fibrillation at the time of operation, and some of these eight had had paroxysmal fibrillation in the past. None of these eight developed emboli at the time of operation, but 17 of the 71 in auricular fibrillation did. This is an incidence of 25 per cent in this relatively small group; emboli being more frequent in the group IV patients (33 per cent) than in group III (19 per cent). If these patients surmounted the hurdle of the operation, however, the chances of developing a late operative embolus are small. In the entire group of 440 surviving patients who have been followed for an average period of 22 months, or the equivalent of more than 800 patient years, there have been only five patients who have developed such peripheral emboli although more than half were fibrillating. It is our belief that this operation decreases the possibility of late embolization substantially.

We might interject here that subsequent studies may be expected to show that the techniques of avoiding operative emboli are improving.

**Does the Stenosis Recur?**

A crucial question is: Do the fractured valves again seal together and does the stenosis recur? We cannot give the answer as to the permanence of this operative relief, particularly since so little is known regarding the basic factors which lead to tight mitral stenosis and which usually develops insidiously many years after the first occurrence of overt rheumatic fever. However, this study supplies evidence concerning the results in the first five years postoperatively.

The most impressive evidence that the operation confers a genuine and lasting benefit is that in the overwhelming majority of instances, the improvement shown by the patients has been for the entire period of ob-

---

**Table 6.—Incidence of Operative Peripheral Embolization in Fibrillating and Nonfibrillating Patients**

<table>
<thead>
<tr>
<th>Case No. of Patients</th>
<th>Rhythm</th>
<th>Group III</th>
<th>Group IV</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>No. of Pat</td>
<td>No. with Embol</td>
</tr>
<tr>
<td>1-100</td>
<td>AF</td>
<td>23 3 (1)*</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>NSR</td>
<td>36 2 (1)</td>
<td>6</td>
</tr>
<tr>
<td>101-200</td>
<td>AF</td>
<td>29 1 (0)</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>NSR</td>
<td>45 4 (0)</td>
<td>11</td>
</tr>
<tr>
<td>201-300</td>
<td>AF</td>
<td>34 2 (2)</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>NSR</td>
<td>42 1 (1)</td>
<td>2</td>
</tr>
<tr>
<td>301-400</td>
<td>AF</td>
<td>30 5 (0)</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>NSR</td>
<td>42 0 (0)</td>
<td>—</td>
</tr>
<tr>
<td>401-500</td>
<td>AF</td>
<td>33 1 (0)</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>NSR</td>
<td>41 0 (0)</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>AF</td>
<td>149 12 (3)</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>NSR</td>
<td>206 7 (2)</td>
<td>3</td>
</tr>
</tbody>
</table>

* Numbers in parentheses denote number of fatal emboli.

---

servation. Only one patient in group II, 18 in group III and 12 in group IV, a total of 31, have regressed substantially after a definite improvement persisting six months or more. These are now being studied in detail by us. In fifteen of these there were factors present which might explain the regression. These factors are: associated aortic valvular disease, poor operative fracture or leaflets that could not be mobilized, significant mitral insufficiency found to be present at the time of operation, or rheumatic fever occurring at some time since operation. About five we have as yet inadequate information. There are 11 regressions after an initial improvement for which there is not apparent a possible explanation. One cannot deny the possibility of refusion of the valve cusps in this small group, but the persistent good results in most of our patients suggest that this is most uncommon. Many of the so-called refusions of valve cusps undoubtedly represent operations in which initially only dilatations were effected by the surgeon's exploring finger and in which the valves resumed their former size after a few weeks or months of this dilatation. In some of our own earlier cases, when the surgeon still lacked technical experience, only a dilatation or an inadequate fracture was effected. Five of these patients
have been reoperated upon for mitral stenosis. In every instance a note was made at the original operation that only dilatation or inadequate fracture was accomplished. These patients improved substantially for a period of six months to a year and then regressed more or less to their former condition. At the second operation, a more effective valvuloplasty was accomplished and the patients are again improved.

These unsatisfactory "dilatations" may well explain some of the 11 otherwise unexplained regressions. They are further examples of the fact that valvuloplasty can be qualitative. This quality should continue to improve.

**Postoperative Syndrome**

Others have noted the frequent occurrence postoperatively of a complex of symptoms first described by Soloff and his associates and believed by them to represent reactivation of rheumatic fever. We have called it the "postoperative syndrome" since we are not convinced that it is always rheumatic fever. Indeed, it probably represents a mélange of conditions. The most striking manifestations of this syndrome are chest pain and fever. The chest pain may be of various types. It may be a deep, boring pain over the precordial area or pain which is difficult to distinguish from the intercostal pain common following thoracotomies; sometimes the pain is of the pleural type and may occur on either side; it may be noticed in the left shoulder.

Together with pain and fever, the syndrome may be characterized by pneumonitis on one or both sides, or by pleurisy either dry or with effusion. We have not included in this group postoperative manifestations within two or three weeks of operation, unless they are very clear rheumatic fever, because of the difficulty of distinguishing them from the pericardial reaction which is inevitable after operation in these patients, and the pleural reaction secondary to the operation. Many patients also have shown a tendency to develop congestive symptoms following operation for a few weeks or even months. Inasmuch as there has been a profound change in the status of the hearts of persons successfully operated upon for mitral stenosis, it is usually unnecessary to attribute this to active carditis. It is obvious that the left ventricle has been protected by the severe degree of mitral stenosis in these patients, and when an effective fracture of the mitral valve has been made, this ventricle is called upon to do a great deal more work. It would not be surprising, therefore, if some degree of left ventricular failure occurred postoperatively, and it may take months before the left ventricle hypertrophies enough to accommodate itself to the increased work load it is called upon to carry. This would appear to be a physiologic adjustment to the change in the hemodynamics.

The majority of these patients with the postoperative syndrome were not personally observed in the attacks, which occurred after they had left the hospital, and we are dependent on information from them and their attending physicians. In some instances, no doubt, they reported attacks of incidental pneumonitis, bronchitis, exacerbation of the intercostal pain of the operative incision, and so forth, so that our reported percentage is undoubtedly a maximum. A further complicating factor has been a troublesome intercostal neuritis that occurred not infrequently in our earlier experience when Effocaine was used in the hope of preventing the postoperative intercostal pain. We found, as has been found elsewhere, that a neuritis resulted in a good many of these patients. This has been presumed to be due to the agent mentioned.

Thirty-one per cent of our patients have had one or more attacks of the postoperative syndrome following their discharge from the hospital after operation. Eighteen per cent had a single attack; in 13 per cent the attacks were recurrent. In some cases these attacks have recurred up to four years after operation. In 30, or 7 per cent, there was fairly good clinical evidence of rheumatic fever or arthritis. Further study is needed to elucidate the exact nature of these attacks and their relationship to the operative procedure. They have not proved to be sufficiently disabling in themselves, nor to have altered the improved status of our patients to a degree that would signifi-
cantly affect the overall operative benefit. Most of these patients have been treated with penicillin or other antibiotics at the time of these attacks and some have been given aspirin. Whether either of these types of treatment has altered the course, we do not know, since for the most part the attacks have been benign and have subsided within a week or two. All of our patients who are not sensitive to penicillin have been on prophylactic penicillin following operation. There has been no correlation between the presence of Aschoff bodies found in the biopsy of the auricular appendage of patients and the development of these attacks, and no evident correlation with their age and the severity or type of their symptoms prior to operation.

Objective Clinical Findings

A study is now in progress of the results of a follow-up examination on as many of these patients as possible, the examination being made personally by one of us or our associates. The results will be reported in detail elsewhere. A preliminary report on 67 of these patients is included here chiefly to show that the evaluation of their present status, based on our personal examinations, agrees closely with the evaluation made independently on the basis of questionnaires and similar information (table 7). On the whole, the personal examination revealed somewhat more favorable status than the questionnaires, but in no instance was there a marked discrepancy nor change of more than a single grade in the scale of improvement; for example, from "slightly improved" to "moderately improved" or from "slightly improved" to "unchanged." This close correlation between these two methods of evaluation in a significant sample of the whole group is evidence in favor of the validity of the evaluation of the entire series of 500 patients. Table 8 shows the present status of these patients classified according to the classification of the New York Heart Association with their status by this classification prior to operation.

Only a general statement will be made at this time regarding the objective findings in these patients. For the most part there has been neither dramatic nor consistent change in heart murmurs. Frequently the diastolic murmur has decreased and rarely has disappeared. In some instances an apical systolic murmur has appeared or has increased and occasionally it has decreased. There has also been no consistent changes in heart size. In a few instances it has become smaller and the pulmonary artery and its branches usually are smaller. The electrocardiogram for the most part has shown no change. Hence it can be said that the objective changes following mitral valvuloplasty are usually not striking.

Discussion

The literature is now replete with articles published on various phases of the operative relief of mitral stenosis. Those that are pertinent to this discussion and which bear on the clinical results following the operation are for the most part in agreement with the general conclusions reached in the present study.\(^5, 10, 14-27\) Most of such published studies, however, deal with relatively few patients and with patients followed for only a short period of time. As we have emphasized previously, and has been noted by others both on clinical

| Table 7.—Evaluation of Follow-up Status of Patients Personally Examined |
|--------------------------|------------------|------------------|
|                          | Questionnaires   | Examination      |
| Improved                 |                  |                  |
| markedly                 | 41               | 38               |
| moderately               | 9                | 14               |
| slightly                 | 12               | 11               |
| Unchanged                | 5                | 4                |
| Total                    | 67               | 67               |

<table>
<thead>
<tr>
<th>Table 8.—Preoperative and Postoperative Status of 67 Patients According to Classification of New York Heart Association</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative Classification</td>
</tr>
<tr>
<td>------------------------------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>II</td>
</tr>
<tr>
<td>III</td>
</tr>
<tr>
<td>IV</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>
grounds and as a result of hemodynamic studies, the improvement of these patients is
often progressive over many months. This is undoubtedly due to the fact that the pul-
monary vascular changes have regressed slowly over a period of months and that ad-
justments of the heart itself may also take place slowly. In the more seriously disabled
patients, regression of changes in liver function as a result of the lessened congestion of
the liver may also take place slowly.

Soloff and his associates\textsuperscript{28, 29} have pointed
out some of the problems in the evaluation of
patients postoperatively and have indicated
that the objective signs of cardiac improve-
ment, particularly as to heart size, have
lagged far behind subjective improvement.
For this reason, and also because, in their
experience, even the subjective improvement
has not been too striking, they have ques-
tioned the advisability of operations for
mitral stenosis in many patients with mitral
valve disease.

It is difficult to get statistics on comparable
groups of patients treated surgically and non-
surgically. This is particularly true in our
group III patients who, as stated, are sub-
stantially disabled and going downhill. In
view of the downhill course of these patients,
it would seem likely that their outlook for
continued life is not good; however, we have
no statistics on patients of this type. The
group IV patients are terminal cases, cardiac
invalids. We previously reported\textsuperscript{28} a series of 19
such patients who were acceptable for opera-
tion, but who refused it. Seventeen of the 19
were dead within one year.

It is true that the changes in physical finds-
ing are much less striking in our experience
than the subjective improvement or the in-
creased work capacity of these patients, and
this holds true also in regard to some of the
reported physiologic studies of circulatory
function by cardiac catheterization. However,
at the Second World Congress of Cardiology,
a number of papers were presented showing a
very favorable effect on cardiovascular phys-
ology, particularly when measured several
months after operation, and confirming a
good many prior published reports of similar
nature. It must be remembered that this
operation is not curative; it is merely a pallia-
tive procedure, but often a very effective palliative procedure. It does not prevent the
recurrence of rheumatic fever; in fact there is
some evidence that rheumatic fever may occur
more commonly following it than in patients
unoperated upon. It does not prevent bacterial
endocarditis, and where there is chiefly myo-
cardial failure and valvular obstruction is not
the important factor, it will not return such
patients to health.

It is of course impossible to attribute the
subjective improvement always to the me-
chanical effect of improved valve function
produced by this operation. One cannot rule
out other factors, such as the psychic effects
of the procedure, and the fact that in some
instances these patients have had more careful
medical regulation subsequent to operation.
However, patients with significant elements of
symptomatology due to anxiety neurosis were
excluded from the operation so far as possible,
and most of the patients returned to the care
of their own physicians after the operation,
and on the whole have received less rather
than more medical supervision. Other con-
siderations also bear on this point. Thus, the
improvement of these patients has for the
most part been progressive over the first post-
operative year and in almost all instances has
been maintained during the period of observa-
tion. If the effects of the operation were largely
psychic, one would expect the improvement to
be immediate but less persistent. In addition,
we are now in the process of analyzing in more
detail a number of factors that affect the late
results, and these, which will be reported else-
where, show that good or poor results are in
the aggregate dependent on factors having to
do with the mitral stenosis per se, the severity
of preoperative stenosis, the degree of calcifica-
tion, the success in producing an adequately
enlarged orifice, the amount of associated
mitral insufficiency and other similar in-
fuences.

The 442 patients of the series surviving
operation have had a death rate of 2.2 per
cent per year, with death rates in groups III
and IV of 1.5 per cent and 5.1 per cent, re-
pectively. The operative risk in group II and III patients is low, less than 3 per cent and may now approximate 1 per cent. The risk in group IV patients is still high, but is acceptable in view of the gravity of their sickness. When the fact is added that a high proportion of those suffering have had the downhill course of their disease reversed and have been restored to comfortable and useful lives, the evidence is conclusive that mitral valvuloplasty confers a genuine benefit on properly selected patients with handicapping symptoms.

**SUMMARY**

A report is made of the clinical results in the first 500 patients operated by mitral valvuloplasty in whom a preoperative diagnosis of predominant mitral stenosis had been made. The progressive improvement in operative mortality in group III patients has been discussed. It is now less than 3 per cent and may approach 1 per cent. Certain factors affecting mortality have been considered, as well as the relation of operation to preoperative and postoperative embolization. The operation appears to protect against late peripheral embolization.

Four hundred forty of 442 surviving patients have been followed for periods of from six months to five years. The results in the various groups are described. Of the entire group, 77 per cent are significantly improved, and the improvement has been persistent in all but a small number; 31 per cent have had one or more attacks of a postoperative syndrome, characterized particularly by chest pain and fever, but in only 7 per cent has there been clear-cut evidence of active rheumatic fever. Improvement in objective clinical findings, in particular in cardiac murmurs, heart size and the electrocardiogram, have been less striking than the subjective improvement.

**REFERENCES**


The Clinical Results in the First Five Hundred Patients with Mitral Stenosis Undergoing Valvuloplasty

LAURENCE B. ELLIS and DWIGHT E. HARKEN

_Circulation_. 1955;11:637-646
doi: 10.1161/01.CIR.11.4.637

_Circulation_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 1955 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/11/4/637

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in _Circulation_ can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to _Circulation_ is online at:
http://circ.ahajournals.org//subscriptions/