VALVE REPLACEMENT WITHOUT PREOPERATIVE CARDIAC CATHETERIZATION: A 8 YEAR FOLLOW UP STUDY

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In 1978, valve replacement was performed in 305 patients at the Brompton Hospital, London. In 243 of them (group 1), cardiac catheterization had not been undertaken at the time of referal.

From this group, 184 patients were sent to surgery without cardiac catheterization (group 1 A) and 59 (group 1 B) were submitted to hemodinamic evaluation due to persistent doubt about the severity of the valve lesion and clinical evidence of aortic root disease or coronary artery disease. An additional 62 patients (group 2), who had already been catheterized, served as an index of conventional management.

Data from 247 patients were available at an eight year follow-up study. The majority of patients in all groups are free of symptoms. No differences regarding mortality, complications and clinical status was observed in the different groups of patients. It is concluded that it is possible to dispense with cardiac cathetenzation in the majority of patients requiring valve replacement.

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In a previous paper[1] we reviewed the results of valve replacement surgery performed during the course of one year (1978) in a population of patients, of whom only a minority underwent preoperative cardiac catheterization. Operative mortality was the same in catheterized and non-catheterized patients and after two year follow up there was no difference in survival or symptoms in these groups; in addition, no new "valve lesions" became apparent in uncatheterized patients. We concluded that routine cardiac catheterization was unnecessary before valve replacement and could be reserved for specific indications in some patients. This paper caused considerable controversy which still continues, with certain groups recommending cardiac catheterization and angiography for all patients undergoing valve replacement[2-4] and others not[1,5,6]. We therefore thought it worthwhile to review the same patients with 8 years of follow up from time of operation.

PATIENTS AND METHODS

In 1978, valve replacement was performed in 305 patients at the Brompton Hospital, London. In 243 of them (group 1) cardiac catheterization had not been undertaken at the time of referal. This decision was therefore delayed until clinical and echocardiographic information was available. Standard methods, including analysis of the history and physical signs, eletro-cardiogram, chest x-ray films and echocardiograms were used in all patients. Echocardiography was used not only to examine the anatomy of all four cardiac valves, but also to assess the physiological effects of valvar stenosis or regurgitation using the technique of M-mode digitization[7,8]. After this analysis, the diagnosis appeared unequivocal in the majority of patients (184), who were then referred for surgery without further evaluation (group 1B). However, in a minority (59), cardiac catheterization was performed (group 1A); the indications for this procedure included persistent doubt about the severity of the valve lesion, clinical evidence of aortic root disease, evidence of significant coronary artery disease or discordance between clinical and echocardiography data. During the same year an additional 62 patients, who had already had catheterization performed were referred from sources where the practice was to undertake invasive procedures in all patients being considered for operation

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(group 2). The patients in group 2 were unselected and served as an index of conventional management.

Symptoms of dyspnea and angina were noted in all patients and expressed in terms of the New York Heart Association classification[9]. The site and number of valves involved were recorded in addition to the aetiology of the valve disease. Patients undergoing first operations and those who had had previous open heart surgery (reoperations) were considered separately, as were those in whom emergency operations were undertaken.

Hospital (perioperative) mortality was arbitrarily defined as death occuring within four weeks of operation. At the time of surgery discrepancies between pre-operative evaluation and surgical findings were noted when present. Two year followup was available in all but 31 patients and eight year followup in all out 58 patients; these were patients who came from abroad and with whom we were unable to contact.

Fisher's exact probability test was used for comparison of factors between groups of patients.

RESULTS

The age distribution of the patients, their symptomatic status and the aetiology of their valve disease are as presented in our original paper[1].

Age ranges were similar with no significant differences between the three sub-groups; in all sub-groups the majority of patients were in the age range of 50-70.

In terms of symptomatic status, the majority of the patients were in New York Heart Association class 3 or 4, and a similar distribution between the various New York Heart Association classes was found in all three patient groups.

The aetiology of the valve disease—rheumatic, degenerative, bicuspid, calcific or other—was randomly distributed amongst the three groups.

In 17 patients previous aortic valve surgery had been performed and reoperation on the aortic valve was necessary for paraprosthetic leak in 10, leaking homograft in 3, infected prosthesis in 3 and for restenosis after a previous valvotomy in 1.

In 42 patients, reoperation was performed on the mitral valve; in 21 this was required after previous valvotomy or repair, and in 21 for complications of previous valve replacement including paraprosthetic leak (11 patients)á obstruction (6 patients), recurrent emboli (2 patients) or infection (2 patients).

Two other patients needed reoperation; restenosis of both aortic and mitral prosthesis had occurd in one patient and restenosis after mitral valvotomy with an aortic paraprosthetic leak had occurred in the other.

Emergency operations were performed in 16 patients of whom only 3 underwent cardiac catheterization, one with an aortic paraprosthetic leak, one with thrombosis of a mitral valve prosthesis, and one with a mitral valve paraprosthetic leak. All three died at operation or in the first 48 hours. The remaining 13 patients underwent surgery without catheterization; 1 had acute infective endocarditis on an otherwise normal aortic valve, 6 required replacement of an aortic valve prosthesis (for infection in 2, paravalvular leak in 4), 4 required replacement of a mitral valve prosthesis (for clotting in 3 and paravalvular leak in 1), and 2 had a mitral valve replacement for mitral regurgitation in the presence of severe left ventricular disease. Except for this last patient, all survived the operation.

TABELA 1—Hospital Mortality

Patients	No. of patients	Mitral Valve		Aortic Valve		Aortic and Mitral Valves		First and reoperation combined
		First	Reoperation	First	Reoperation	First	Reoperation	
		no. of deaths						
Group 1A (Elective Catheterization)	59	—	1	1	1	3	1	7/59(12)
Group 1B (No Catheterization)	184	2	2	2	1	3	3	13/184 (7)
Group 2 (Routine Catheterization)	62	3	—	3	—	1	1	8/62 (13)
Total	305	5/112 (4)	3/27 (11)	6/79 (8)	2/17 (12)	7/53 (13)	5/17 (29)	28/305 (9.2)

Figures in parenthesis denote percentage.

Hospital mortality has been fully descriped in our previous paper[1]. A synopsis of- the results is shown in table 1. There is no significant difference between groups 1 and 2 for any procedure, single or double valve replacement, first operation or reoperation. However the mortality for all single valve replacement taken together is significantly higher in group 2 (routine catheterization) than in group 1B ($p < 0,05$).

After two years from operation data were available on 274 of the original 305 patients, the remainder being from abroad and difficult to contact. There were 11 deaths in all during this period (group 1A = 6; group 1B = 4; group 2 = 1) giving total two year cumulative mortalities of 13 (23%), 17 (11%) and 9 (15%) respectively for each group. There was no significant difference in two year mortality between group 1B (no catheterization) and group 2 (routine catheterization).

During this two year period no patient had evidence of additional valvar or other lesion that might have been missed at the first operation. There was also no difference in the proportion of asymptomatic patients between the different groups and the distribution of symptomatic patients between the various NYHA subgroups was the same.

At the time of original evaluation, coronary arteriography was considered necessary in 28 of 62 patients in group 2 and in 23 of 59 in group 1A; abnormal findings were noted in 17 patients demonstrating lesions requiring bypass grafting in 5. There was no relation between the presence of coronary artery disease and the valve involved. Significant angina occurred in only 2 patients in the two year follow up period, both of whom had had aortic valve replacement and both of whom had normal pre-operative coronary angiograms. Angina had been the dominant symptom in 13 patients who underwent aortic valve replacement and in 5 who underwent double valve replacement, all without pre-operative cardiac catheterization. None of these patients-had post-operative recurrence.

After eight years, data were available on 247 patients, a further 27 patients having been lost to follow up since documentation two years after surgery. (6 group 1A, 16 group 1B and 5 group 2). Additional mortality over the six year period was 9 in group 1A, 26 in group 1B and 10 in group 2 giving 8 year cumulative mortalities in the three groups of 22, 43, and 19 respectively. If expressed as a percentage of patients followed up for 8 years the relative figures are 44% (group 1A), 31% (group 1B) and 33% (group 2). In group 1A late deaths (2-8 years) were due to prosthetic valve problems (leak) in 1 case, infective endocarditis in 1 case, unrelated causes in 4 cases and sudden death in 3 cases. Only 1 of the last 3 cases underwent post mortem examination and this showed acute myocardial infarction. Although cardiac catheterization hall been performed in this patient before surgery, coronary anatomy was not studied as the patient had no pain preoperatively. In group 1B late deaths were due to prosthetic valve problems (leak/thrombosis) in 9 cases, infective endocarditis in 1 case, unrelated causes in 8 cases, myocardial infarction in 2 cases and patients dying with myocardial infarction had had no previous angina. One of the 6 cases of sudden death had post mortem examination and no cardiac abnormality was found. In group 2 late death was due to prosthetic valve problems (leak/thrombosis) in 4 cases, infective endocarditis in 1 case, unrelated causes in 3 cases and sudden death in 2 cases: no post mortem studies were performed on the 2 sudden deaths.

During the follow up period 2-8 years, no patient in group 1A, 2 patients in group 1B and 1 patient in group 2 developed angina. The patient in group 2 had undergone coronary artery surgery at the time of initial valve replacement. The 2 patients in group 1B both had mild angina responding to medical therapy. No patient had evidence of additional valvar lesions that might have been missed at first operation or which were severe enough to cause symptoms or necessitate further operation.

Eight years following surgery, the majority of patients remained relatively asymptomatic. Thus, 27 of 28 patients (96%) in group 1A, 87 of 97 patients (90%) in group 1B and 32 of 38 patients (84%) in group 2 were in New York Heart Association class 1 or 2.

During 2-8 years postoperatively complications occurred in 8 patients who had undergone mitral valve replacements in 1978, in 6 cases this was due to the development of significant paraprosthetic leak caused by bacterial endocarditis and in 2 due to calcification of a xenograft valve. One of these 8 patients also required aortic valve replacement for progression of previously known aortic valve regurgitation.

Complications occurred in 8 patients who had aortic valve replacements in 1978. In 5 this was due to paraprosthetic leak (2 required valve replacement), in 2 due to chronic thrombosis on the valve and in one case urgent surgery was required for acute valve obstruction. One of these 8 patients undergoing further aortic surgery also required mitral valve replacement for progression of previously known mitral regurgitation. In patients who had had combined aortic and mitral valve replacements in 1978 complications over the 8 year follow up period included a cerebrovascular accident in one from thrombosis on a mitral valve and another required second aortic and mitral replacement due to paraprosthetic leak and xenograft calcification.

DISCUSSION

In patients with valvular heart disease, a combination of clinical examination together with simple non-invasive investigations (including ECG, chest xray and echocardiography) allows a comprehensive diagnosis to be made in the majority of patients. Echocardiography has been clearly shown to provide not only anatomical information but also physiological information on the effects of valvar stenosis or regurgitation[7,8]. For this reason we consider it safe and justifiable to dispense with invasive investigation except under clearly defined circumstances. As can be seen from this long term follow up of a cohort of 305 patients undergoing valvular surgery, this practice has not resulted in excessive mortality or morbidity over an 8 year period.

What are the possible disadvantages of this method of management? Firstly, patients may have been denied surgery because cardiac catheterization was not undertaken. This possibility can not be excluded but we consider it unlikely because cardiac catheterization would have been performed unless the valve disease was considered mild on both clinical and echocardiographic grounds. Secondly, severe coronary artery disease may have been missed that might have resulted in increased operative mortality or angina after operation. This was clearly not the case in our patients since there was no increase in operative mortality in group 1B or excessive angina in this group in the 8 year follow up period. A potential problem may of course arise where the coexistence of valvular and severe coronary artery disease in coincidential, the patients being asymptomatic from the coronary artery disease viewpoint, but having significant artery stenosis[10-14]. With these patients the question arises as to whether coronary artery bypass surgery should be performed routinely in addition to valve replacement. To answer this question we should be sure that the additional surgery does not increase the operative risk and does improve long term prognosis. We feel that these points have not as yet been addressed in a formal manner and ideally the question requires a prospective randomised study. To date this study has not been performed and there is therefore as yet no clear directive to routine clinical practice. If it could be convincingly shown that coronary artery grafting improves long term prognosis in patients undergoing valve replacement then the extra effort to detect it might be justified. Other considerations also militate against routine myocardial revascularization at the time of valvular surgery namely:—1) coronary artery bypass prolongs the operative procedure with longer cardiopulmonary bypass times; 2) coronary artery disease may progress after initial valve replacement and Bonow e al[6] have observed an equal frequency of angina pectoris in patients after valve replacement whether or not they underwent concomitant myocardial revascularization; 3) after successful aortic valve replacement, left ventricular mass and tension fall so that majority of patients become angina free despite persistent coronary artery luminal narrowing.

Finally, important valve lesions might have been underestimated by our approach but no patients required further surgery for previously undiagnosed valve lesions in our 1B group over a 8 year follow up period. In addition cardiac catheterization must no longer be considered as the definitive investigation in all cases of valvular heart disease.

With the advent of new non-invasive diagnostic techniques such as 2D echo and Doppler echocardograhic it is, now necessary to question the need for invasive investigations even if in the past they have been regarded as a “gold standard”. Using cardiac catheterization, estimates of valvar regurgitation by contrast accummulation are subjective and semiquantitative at best; in addition accurate quantification of stenosis or regurgitation may be difficult in the presence of left ventricular disease.

Since the publication of our original paper[1] further strength to our case has been provided in a paper reported by Hall et al using methods virtually identical to ours[15]. In their study 106 patients with valvular heart disease in whom valve surgery was considered were studied prospectively. After clinical and non-invasive investigations a specific surgical recommendation was made in 62 including the operation required. Cardiac catheterization was then performed and the decision for operation was confirmed in all 62. In 16 of these patients, the surgeon was asked on the basis of non-invasive investigation to inspect a second valve about which there was doubt but in only 6 cases of these was the doubt resolved by cardiac catheterization. In 44 cases cardiac catheterization was advised because doubt remained after clinical and non-invasive assessment. This usually occurred in patients with aortic and mitral involvement or with respiratory disease. Nine patients had mild disease echocardiographically and this was confirmed by catheter in all. Virtually identical results were described in a further study by Alpert et ale in a series which included 78 patients with valvular heart disease in whom correct management was predicted in 76 patients on the basis of clinical findings and non-invasive investigation. The 2 exceptions were those in whom angiography showed valvular regurgitation to be unexpectedly severe. In 82 patients with uncomplicated mitral stenosis considered for operation and studied by cardiac catheterization, Effrom et al[17] found that prospective clinical and M-mode echocardiographic features of mitral stenosis were reliable indicators of disease in all patients. Also this approach is now being adopted by paediatric units and Moraes et al[18] now use non-invasive investigations routinely for pre-operative evaluation of valvular heart disease and follow up of their large post-operative series[19]. Evidence is thus accumulating that quantification of valve disease is possible on the basis of clinical findings and echocardiography. Patients with mild disease are not being operated on unnecessarily nor are those with severe disease being missed.

We recognize that our patients may not be typical of patients seen in all centres in the Western World in terms of age or incidence of coronary artery disease, but we believe the policy outlined above may be even more applicable in developing countries where facilities may be limited. In the Western World hitherto unproved benefits must not be translated into a rea-son for performing invasive investigations routinely.

We conclude that it is possible to dispense with cardiac catheterization in the majority of patients requiring valve replacement surgery without affecting quality of diagnosis, hospital or long term mortality or the extent of symptomatic relief. Our 8 year follow up reinforces this message.

RESUMO

Em 1978, substituição de valvas cardíacas foi realizada em 305 pacientes em Brompton Hospital, Londres. Em 243 (grupo 1) o cateterismo cardíaco não foi realizedo no tempo em que os pacientes foram referidos. Deste grupo, 184 doentes foram enviados para a cirurgia sem cateterismo (grupo 1-A) e 59 (grupo 1-B) foram submetidos a avaliação hemodinâmica por dúvida acerca da severidade da lesão valvar e da evidência clinica de doença da aorta ou doença coronariana. Um grupo adicional de 62 pacientes (grupo 2) que já havia sido cateterizado, serviu como índice comparativo da conduta convencional.

Num seguimento de 8 anos, dados sobre 247 pacientes foram obtidos. A maioria dos doentes de todos os grupos está assintomática. Não se observaram diferenças com relação a mortalidade, complicações e situação clinica nos diferentes grupos. Conclui-se que é possível dispensar cateterismo cardíaco na maioria dos doentes que necessitam substituto valvar.

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