others,[8] we consider the requirement for indefinite anticoagulation to be a considerable disadvantage. These figures do not take into account, of course, the substantial amount of time and inconvenience required for the long-term maintenance of proper anticoagulation control.

In our experience there have been no known instances of hemolysis in patients receiving xenograft valves in the absence of periprosthetic leak. We have noted this complication in approximately three percent of our patients receiving Starr-Edwards prostheses, although in no case has it been necessary to replace a noncloth-covered valve for this problem alone. The rate of occurrence of hemolysis associated with fully cloth-covered Starr-Edwards valves is not well defined; however, a finite incidence of low-grade ongoing hemolysis does exit in patients receiving these valves.[2] The long-term implications of this process are not known at present.

Endocarditis is a complication to which all patients with prosthetic valves remain susceptible indefinitely. Our data suggest that the rate at which endocarditis occurs in patients with xenograft valves does not differ significantly from the occurrence rate in those patients with Starr-Edwards valves, in either the aortic or mitral position. We have observed a total of six cases of endocarditis involving xenograft valves. Five of these cases involved aortic prostheses and one a mitral prosthesis. One of the aortic cases and the single case of mitral xenograft endocarditis underwent re-replacement of the infected prosthesis during the acute phase of endocarditis. Both patients died postoperatively. The remaining four patients recovered with antibiotic therapy alone; thus, bacterial invasion of the tissue valve does not necessarily lead to valve leaflet disruption.

Summary

We conclude on the basis of comparative data generated in our own institution that the Hancock xenograft valve compares quite favorably to the Starr-Edwards prostheses in regard to durability and susceptibility to endocarditis,and that it appears superior when thromboembolic rates, overall survival rates, and morbidity and mortality due to anticoagulant-associated hemorrhage are considered. The complications of thromboembolism and anticoagulation associated with Starr-Edwards valves have contributed importantly to the lower survival rates we have observed in such patients. The Hancock xenograft bioprosthesis appears, therefore, to be the valve of choice.

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Discussion

DR. ALBERT STARR (Portland, Oregon): These two presentations demonstrate the current choice that we now have in valvular prosthetic substitutes. On the one hand, we have bioprostheses capable of acting hemodynamically in a satisfactory manner and with a low incidence of thromboembolism, without the need for long-term anticoagulants; on the other hand, the durable type of mechanical prostheses.

Certainly, our current practice is to be certain that both of these types of approaches are available in the operating room, so that a prosthesis can be chosen for a patient, depending upon the patient's requirements and his ability to take anticoagulation.

I'd like to focus some attention on the problem of cloth wear. In Dr. Spencer and Dr. Isom's series of patients they noted this in only a small percentage of patients; but in those patients who were subject to reoperation for any reason, cloth tear is frequently noted. In our own experience, in about three out of four patients who

have reoperation following aortic valve replacement with a cloth-covered valve, we see cloth tear, perhaps asymptomatic. And this type of mechanical derangement of the valve is something that we should try to avoid if we possibly can.

And so, for this reason, from 1972 until the present, whenever we select a cloth-covered type of prosthesis, we prefer to use a valve in which cloth tear cannot occur.

(Slide) We have been using a modification of the prosthesis that Dr. Spencer's group has shown, the track valve, both in the mitral and in the aortic position.

(Slide) The next slide shows our results with this valve, compared with the other types of ball-valve prosthesis that we have been using, in terms of the need for removal. On the top curve is the noncloth-covered valve, which we still use in selective cases, which is 98% removal free at ten years. With the cloth-covered valve, with isolated mitral valve replacement, the need for removal, the percentage of patients that were removal free was 91% at the end of six years.

With the track valve, shown here, it's superimposed upon the non-cloth-covered valve, and so the track valve in the mitral configuration seems to provide us with a prosthesis that has the durability of the noncloth-covered valve, in terms of a very low reoperation rate.

(Slide) The next slide shows similar information with regard to the aortic valve, and the percentage of patients who were removal free in this actuarial analysis. For example, with the noncloth-covered valve the chance to be removal free at the end of ten years is 92%. However, with the cloth-covered valve you can see that by the eighth year the chance to be removal free is only 85%. The track valve, now in its fourth year of experience, follows the upper curve of the more durable noncloth-covered valve.

(Slide) Now, in addition, the track valve seems to function like the cloth-covered valve in terms of low incidence of thromboembolism. Here you see in this curve the track valve following the course of the cloth-covered valve, with 85% of the patients embolus free by six years following isolated mitral valve replacement.

So that I believe we have to focus our attention on the permanent type of prosthesis that will not be susceptible to mechanical derangement, if possible, and I believe that the track configuration does add this to the cloth-covered valve, and retains the low thromboembolic rate of that type of prosthesis.

DR. JAMES ROYAL MALM (New York, New York): I'd like to briefly review our own experience with the ball valve and with the xenograft at the Columbia Presbyterian Hospital, mainly to at least eliminate the excellent California weather as one factor in the survival rates.

(Slide) In our series of ball-valve prostheses, some 848 ball-valve prostheses, mainly of the Starr-Edwards type, but 200 of the Cutter-Braunwald type, this was the initial operative mortality, and our actuarial curves were quite similar to those presented. Up to the first 12 years this actuarial is minus the first 30 mortality, and you will notice at five years the survival rate is 65%, and it drops to almost 40% after 12 years.

(Slide) Our experience with the Hancock xenograft is a somewhat smaller series, but absolutely comparable in terms of severity of disease, with an over-all reduction in operative mortality.

(Slide) The follow-up on this particular xenograft series was of interest, with follow-up now into the third year, with an embolus rate of less than two per cent in both the mitral and aortic group, the mitrals receiving anticoagulants for a three-month period; only three surgical valve-related complications, and no valve failures.

(Slide) This is the comparative actuarial curves on all the ball-valve prostheses, the Cutter-Braunwald prostheses and the Hancock prostheses, at twenty-four months. This is 80% now. A small group of these now extended to 36 months are in a straight line of survival. And while in the past we have ascribed this fall-off in the survival rate primarily due to patient disease, one can't help but conclude from this that many of these are in some way prosthetic-related late deaths.

So that, first of all, the prosthesis, and particularly the track valve, is a very noisy valve, and patients do object to the click. The very low incidence of embolus in the xenograft, the lack of need for long-term anticoagulation, and the rather excellent long-term survival make this a very desirable prosthesis.

DR. CHARLES R. HATCHER, JR. (Atlanta, Georgia): I too would like to congratulate both groups on splendid results and excellent presentations, and present just a bit of our data, which I feel tends to support the conclusion of the Stanford group.

In a recent two and one-half year period 250 Hancock valves were inserted in 315 patients at Emory University Hospital. Aortic valve replacement carried a four per cent operative mortality and a one per cent late mortality; mitral valve replacement, a nine per cent operative and a two per cent late mortality; and multiple valve replacement a six per cent operative mortality and four per cent late mortality.

(Slide) The complication rate was low. Only 16 patients in the series were anticoagulated. Anticoagulation is reserved for mitral patients with marked left atrial enlargement, chronic atrial fibrillation, or known atrial thrombus.

(Slide) Hemodynamic improvement in these patients was quite gratifying.

The major disadvantage of the porcine heterograft has been the high gradients noted in recatheterization of some of the smaller-size valves in either position in certain of our patients. We therefore at present use a No. 29 or larger mitral valve and a No. 23 or larger aortic valve. If necessary, the aortic root is enlarged by carrying a transverse aortotomy through the noncoronary sinus and a few millimeters into the anterior leaflet of the mitral valve.

In children, or in cases of extremely small aortic annulus, a vertical aortotomy is carried across the annulus, with the creation of a ventricular septal defect; a patch then being employed to close the VSD serves to attach a portion of the enlarged annulus to the prosthetic valve, or to the heterograft valve, and to close the aortotomy. The associated right ventriculotomy may be closed with or without the use of a small additional patch.

(Slide) I think you can see the VSD created here, a triangular portion of the patch sutured. A prosthesis of any size can be used in a child or adult with a small annulus, sutured to the mid-portion of the patch, and then this portion is used to close the aortotomy.

It would seem that the advantages of the heterograft are becoming more apparent as our experience accumulates.

DR. DWIGHT C. MCGOON (Rochester, Minnesota): We all hope that the newer valves will be improved valves, but I would like to raise certain questions relative to the comparisons, with the realization that none of us have been able to achieve true randomization, or true comparability. I would like to direct my questions particularly to Dr. Griepp, et al. with respect to comparability of patients.

I believe I am correct in saying that during the time that their experience with Starr-Edwards valves was being accumulated, they were also operating on patients and inserting tissue valves of another type; namely, homograft valves. And although they have assured us that the groups are comparable in terms of age and other categorizations, I would like to know how selection was determined, as to whether a patient received a Starr-Edwards valve or a homograft valve during the time when the prosthetic valve experience was being accumulated.

Certainly, if the tissue valve, namely, the Hancock valve and its similar types, has an Achilles' heel, it must be with respect to its durability. And I question whether the comments that it provides an improved long-term patient survival and satisfactory durability can be justified on the basis of an average follow-up of 1.2 years for the aortic valves and 1.8 years for the mitral valves.

DR. PHILIP E. OYER (Closing discussion): In regard to Dr. McGoon's questions pertaining to our previous homograft experience, I would say that this data was accumulated largely before I

was at Stanford, and therefore I cannot comment on these studies in detail. However, I can say that there was some selection of those patients to receive homograft valves. In other words, the homograft patients did tend to be younger patients who were felt to have a longer survival outlook, and therefore it was felt at the time that the homograft valve would be better for them. As reported earlier, however, preoperative hemodynamic parameters for these patients were quite similar to those of patients receiving Starr-Edwards valves in this earlier series. The present series of xenograft patients on whom we are reporting today, however, were not selected in any way. Virtually all patients undergoing valve replacement at Stanford now receive xenograft prostheses. Although the various series of patients with which this report is concerned are, in fact, consecutive, and therefore subject to the limitations of any consecutive studies, the patients were quite closely matched as determined by numerous preoperative factors which are outlined in more detail in the manuscript. It is true that coronary bypass grafting was performed more frequently in conjunction with valve replacement over the last two or three years as compared to earlier years when our Starr valve experience was accumulated. In spite of the shortcomings of comparing consecutive series of patients, I believe this sort of data from a single institution is still frequently more instructive than that generated from comparison of interinstitutional data, since patient-associated variables, major differences in operative technique, etc. may enter in and are much more difficult to control and evaluate. Dr. McGoon's further point concerning durability of the xenograft valve is well taken. It is true that the average follow-up in our series of xenograft patients was only approximately one and one-half years. The average follow-up figure, however, is somewhat deceptive since the calculation of the average follow-up includes patients who only very recently received their valve. Accordingly since new xenograft patients are continually being entered into the series, the average duration of follow-up is not built up very rapidly Of more importance, I think, is the maximum follow-up duration which as I pointed out earlier is now five and one-half years for the mitral xenograft. Although there are admittedly relatively few patients followed this long postoperatively, the fact that we have seen only three primary tissue failures in this entire series, and only one of these was actually a tissue disruption, is, I think, extremely encouraging in regard to the long-term durability of this valve.

In regard to Dr. Hatcher's comments concerning gradients associated with the xenograft valve, I would point out that this has been more of a problem in the aortic area than in the mitral area. There is now available a modified orifice valve for placement in the aortic position. *In vitro* studies have indicated that gradients across the valve are significantly reduced.

DR. O. WAYNE ISOM (Closing discussion): We haven't used the track valve at our institution for two reasons: 1) because of the reported noise problem, and 2) because of Dr. Starr's report of the increased thrombogenicity of the valve off anticoagulants.

With regards to Dr. Malm's and Dr. Hatcher's comments, I would just say that I think Dr. McGoon made my point, in that both these series started in 1974. We are certainly encouraged by the data generated since 1971 from Stanford, and we look at that with expectant eyes. However, if you took our patients and just started following them since 1971 and 1972, our survival curves would be very similar to that obtained by the California group. Our emboli would be very similar. I would also point out that a lot of things have changed in the past four or five years, and some of the improvements that we see in survival and in complications may be due to improved techniques.