



“Getting More Information”

Because the following document was developed a number of years ago, the contact information is no longer accurate. If you wish to contact the agency with questions, please use the following:

Mail: Office of Surveillance and Biometrics (HFZ 510)
1350 Piccard Drive
Rockville, MD 20850

FAX: 240-276-3356

Phone: 240-276-3357

Email: <mailto:phann@cdrh.fda.gov>

Important Information on Shiley C-C Valve Fractures

April 21, 1992

Dear Doctor:

Recent stories in the news media may have caused some confusion among physicians and patients about the risk of strut fracture associated with Bjork-Shiley Convexo-Concave (C-C) heart valves. I am particularly concerned that patients may have been misinformed about the need for prophylactic replacement of intact valves. I am writing to help clarify the situation and to provide you with the risk figures as we presently understand them.

The van der Graaf study

The February 1 issue of the Lancet¹ reported on a study performed in the Netherlands by van der Graaf, et al, which found a higher risk of strut fracture among some C-C valves than had been previously reported. The highest risks were found among the 70-degree C-C valves, which were never marketed in the U.S.

For the 60-degree C-C valve- -the model which was available in the U.S. - - the study reported ***increased fracture risks for the larger size valves (29-33 mm in diameter) implanted in the mitral position.***

Patients in this study who had the similar size 60-degree valves (less than 29 mm) did ***not*** experienced fracture rates substantially different from those previously reported; fracture risks for the smaller valves have consistently been much lower than for the larger ones. Likewise, patients with valves implanted in the aortic position, regardless of valve size, did ***not*** experienced fracture risk substantially different from those previously reported.

The new risk figures

For the 29-33 mm 60-degree C-C valves in the mitral position, the van der Graaf study shows that the fracture risk is roughly ***four times greater than the previously assumed.*** From these data, the following risk factors can be calculated for the 29-33 mm mitral valves:

- For valves welded before February 1, 1981, the calculated risk is roughly 25 per 10,000 per year.
- For valves welded between February 1, 1981 and June 30, 1981, the calculated risk is much higher: 109 per 10,000 per year, or roughly one percent per year. (The manufacturer later recalled all 29-33 mm valves welded during this time period that had not been implanted.)
- For valves welded after June 30, 1982, the van der Graaf study had too few patients to draw any conclusions about the fracture risk. The previous risk estimates for this group was 9 per 10,000 per year.

The age factor

The van der Graaf study reported that the fracture risk was about twice as high for patients who were under the age of 50 when their valves were implanted as for those who over 50 at the time of implantation. Because analysis has not been completed on the interaction between the risk due to age and the risk due to weld date, we cannot provide risk figures combining these two factors. We understand that the Shiley Heart Valve Research Center (Shiley) is currently analyzing these data and additional information will be provided as soon as it is available.

Patients at particular risk

The above information suggests that there are some patients whose fractures risk may be high enough to exceed the risk of reoperation. *They are in the subgroup with the 29-33mm mitral C-C valves that were subject to recall* - -the patients whose risk may be roughly one percent per year. This group comprises an estimated 2,200 people in the U.S., or about ten percent of C-C valve patients.

For these patients, the risk may be high enough to *consider* prophylactic valve replacement. For patients who were under 50 when their valves were implanted, the risk could be somewhat higher than one percent per year. Conversely, the risk for those who were over 50 could be somewhat less than one percent per year. In any case, the decision to reoperate must be made on an individual basis, weighing the fracture risk against the risk of the operation as well as the patient's lifestyle and desires.

Identifying patients with the recalled valves

Patients with the recalled valves- -the ones welded between February 1, 1981 and June 30, 1982- -can be identified by means of the valve serial numbers. We are requiring that Shiley provide you with the serial numbers of these recalled valves so that you can determine which of your patients may be in the high-risk group. Heart valve patients enrolled in the Medic Alert International Implant Registry may already know the serial numbers of their valves.

We are also requiring that Shiley send detailed information about the new risk estimates to physicians who are listed in the Medic Alert International Implant Registry as providing follow-up care for patients who have 29-33 mm mitral C-C valves. If you are listed in the registry, you will be hearing directly from Medic Alert. If you have C-C valve patients who are not yet listed in the registry, they can enroll at no cost by calling 1-800-245-1492.

In addition, we are requiring that Shiley contact C-C valve patients, through Medic Alert, to inform them about whether the new risk figures apply in their particular cases. Patients in the high risk will be advised to see their doctors to discuss how the new risk figures apply to them. Other C-C valve patients will be informed that their risk of fracture has not changed.

If you have other questions on the C-C valve, you can reach Shiley on 1-800-626-3363 between 8 a.m. and 5 p.m. Pacific Time, Monday through Friday.

I hope this letter helps clarify what we know at present about the fracture risk associated with the C-C valve. Again, please bear in mind that there are still unanswered questions to be resolved and that this is an interim report. Shiley will continue to analyze the new risk figures and we monitor this work. You will be hearing from them soon.

Sincerely yours,

James S. Benson

Director
Center for Devices
And Radiological Health

¹ Van der Graaf Y, de Waard F, van Herwerden L, Defauw J. Risk of Strut Fracture of Bjork-Shiley Valves. Lancet 1992; 339:257-61.