Requiem for a good mechanical heart valve: Farewell to the Medtronic Hall valve

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I have just performed what, almost certainly, was the last implantation of a Medtronic Hall valve (Figure 1) worldwide, 37 years (almost to the day) after its first human implantation. In a press release, in September 2009, Medtronic announced "the very difficult decision to discontinue production of its mechanical heart valves. This decision will affect all models and sizes of our Advantage, Medtronic Hall and Hall Easy-Fit valves."[1] When the company ceased production of its single-disc mechanical heart valve prosthesis, we, in Coimbra, acquired a stock of several hundred units of this device and have continued using them until today. This, alone, shows how much we trusted it, near to dependence. In fact, I strongly believe that this was the best mechanical heart valve ever produced!

The Medtronic Hall valve was introduced to clinical use toward the end of 1977, initially with the designation of Hall–Kaster, after the names of the surgeon (Karl V. Hall) and the engineer (Robert L. Kaster) who developed it. It was a succedaneum of the Lillehei–Kaster (Medical Inc, Inver Grove Heights, Minn) prosthesis and came at the time when the Starr–Edwards (Edwards Lifesciences, Irvine, Calif) ball valve and the standard 60° Björk–Shiley (Shiley Inc, Irvine, Calif) tilting-disc valve dominated the mechanical heart valve scene. Both were hemodynamically inefficient because of the obstruction of the ball and the disc to central flow, and the latter would soon be plagued by complications, including strut fractures in successive alterations aiming at improving its efficiency, especially with the convex-concave model.

As its creators put it, "the constructional ambition of the Hall-Kaster pivoting disc valve was to guarantee prosthetic longevity and to improve the hemodynamic prosthetic performance."[2,3] This was achieved by innovations in the tilting axis, disc guidance mechanisms, and disc translational freedom, combined to improve flow through both orifices of the open valve. In addition, the disc was allowed to move downstream away from the housing during opening to reduce valve thrombosis.[4]

Early intraoperative and postoperative studies revealed low transvalvular pressure gradients and large effective orifice flow areas, and satisfactory flow was observed through both the major and minor orifices of the prosthesis. In vitro flow studies indicated that it had improved pressure decrease characteristics compared with the Lillehei–Kaster and the convexo-concave Björk–Shiley tilting disc valves.[5] In a prospectively randomized study against patients receiving Björk–Shiley aortic valves, Levang[6] demonstrated, by intraoperative measurements, better hemodynamic performance of the Hall–Kaster valve for corresponding sizes. This was allegedly the consequence not only of a better design, with a greater minor orifice size, but also of a less obstructive disc, with its 70° opening angle in the mitral position and 75° in the aortic position, by comparison with the 60° opening of the Björk–Shiley valve.[6-8]

In the year of 1977, I was a senior resident at the Department of Cardiothoracic Surgery of the University of the Witwatersrand in Johannesburg, South Africa. The department was chosen as one of only a few units worldwide to start simultaneous clinical use of the novel prosthesis, and I was part of the team who performed the first implantation there, having published the first follow-up results in 1983. We were using it in a predominant "third-world" population, in whom any valve prosthesis is subjected to a really challenging test.[9] Since then, I have, personally, implanted more than 3000 of these valves and published the first large series of 1000 implantations in 1988.[10] Wherever I worked, this became the preferred mechanical valve prosthesis.

In the ensuing decades, several groups published long-term follow-ups of the valve, demonstrating excellent outcomes with regard to global survival and survival free from reoperation, and low rates of thromboembolism and of prosthetic endocarditis, significantly better than those until then described for other valve prostheses.[11-14] At that time, the extremely low incidence of structural failure was striking, with a complete absence of housing fractures that was in marked contrast to what was then happening with the convex-concave model of the Björk–Shiley prosthesis, which would result in its withdrawal from the market. In fact, this resilience of the Medtronic Hall valve constituted the main reason for it to be selected for the first total artificial heart developed by Willem Kolff, Robert Jarvik, and William DeVries in 1982, and first implanted by the latter in 1984.[15]

Almost simultaneously, in 1977, the St Jude bileaflet prosthesis (St Jude Medical Inc, St Paul, Minn), today by

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FIGURE 1. Medtronic Hall valve (Easy-Fit model) (Medtronic Inc, Minneapolis, Minn).

far the most used heart valve prosthesis, with its more than 2 million implantations, was also launched. Based on a completely new concept, the St Jude valve was developed also with the aim to improve the hemodynamic efficiency of prosthetic valves, which was, undoubtedly, achieved. Nevertheless, several studies, some randomized, comparing the St Jude and the Medtronic Hall valves showed identical performance in all parameters in both the aortic and mitral positions.[14-19] Thus, these 2 prostheses became the mechanical valve substitutes of choice to most surgical groups around the world, although the Medtronic Hall valve remained as only second best.[20]

However, there were some technical aspects of the implantation of the Medtronic Hall valve that raised some concerns among the surgical fraternity. Its higher profile in the opening position caused a few cases of immobilization of the disc in the mitral position because of impingement in the left ventricular wall or papillary muscles reported in the literature, mostly related to the use of excessively large sizes.[21] Also reported were some cases of intermittent nonclosure in the aortic position, presumably resulting from the wider angle of opening of the occluder, which could let it go beyond the axis of flow, depending on the orientation in the annulus.[22]

These complications were the downside of the construction characteristics of the valve and could easily be overcome by adjustment of the surgical techniques, especially by avoiding the use of large valves in the mitral position, which was safe because of their favorable hemodynamic properties, and by modifying the orientation of the opening of the disc in the aortic position, by rotation of the prosthesis in the annulus. Understandably, a significantly different design justified different techniques.[23,24]

On the other hand, obstruction by pannus was recently reported in valves that have been in place for up to 30 years,[25] which could be interpreted as related to the sewing ring made of Teflon (DuPont, Wilmington, Del), in contrast with the Dacron (DuPont) used in most other contemporaneous valves. However, this complication has been described in other prostheses, including the St Jude valve,[26] and none of the comparative studies demonstrated a difference in this regard. Nonetheless, these patients need regular follow-up for timely diagnosis of this potentially life-threatening prosthetic dysfunction.

With regard to the Achilles' heel of any mechanical prosthesis, the propensity to generate thromboembolic phenomena, the Medtronic Hall valve was always classified among the less thrombogenic.[27] Our own experience, with a third-world population, characteristically noncompliant to anticoagulation therapy, demonstrated a relatively low incidence of prosthetic thrombosis and systemic thromboembolism, by comparison with previously used mechanical prostheses, especially important in the mitral position.[10]

Why did this excellent valve lose in direct competition with the St Jude prosthesis in the 1980s and 1990s, especially when the last Björk–Shiley model (monostrut) was discontinued? To my mind, one of the main reasons was a lack of true determination of the manufacturer in defending and promoting their exclusive and almost flawless concept. Their marketing was far less "aggressive" than that of St Jude Medical, perhaps because the valve was then the only product of the latter, whereas Medtronic had many other products in their portfolio. On the other hand, the successive, and failed, Medtronic attempts to enter the bileaflet valve market did not contribute to the image and trust of the tilting-disc concept. In fact, the Medtronic Advantage bileaflet valve was never a competition to the St Jude valve, despite the fact that it showed comparable hemodynamic qualities.[28]

The St Jude valve was then considered by most surgeons to be a more forgiving valve than the Medtronic Hall valve, from the point of view of implantation technique, although it was never proven to be hemodynamically superior. That is, the St Jude valve won the war without ever winning a battle!

The Medtronic Hall valve was also a pioneer in technical modifications destined to improve conditions for implantation of larger prosthesis sizes in the small aortic roots, with the introduction of even sizes (first the 20 and then the 22 and 24), by modification of the sewing ring, a development in which I was personally involved and subsequently adopted, using different forms and concepts, by other manufacturers, including St Jude Medical.

Two-and-a-half decades ago, Dr Dwight Harken[29] defined the ''ten commandments'' of an ideal valve prosthesis. Until today, no valve has reached this ideal. However, in contrast to others, the end of the Medtronic Hall valve history was dictated more by marketing considerations than by scientific or technical reasons, as also happened more recently with the sudden and unexpected disappearance of a most used, and also pioneer in the field, porcine bioprosthesis.[30] Other examples of these purely marketing-related decisions have occurred, and a word of comfort is due to the hundreds of thousands patients currently bearing these prostheses who need not be concerned about their safety.

I, and I am sure others too, will miss the Medtronic Hall valve prosthesis. I will miss its soft, adaptable, easy-to-perforate Teflon sewing ring, in my opinion one of the most important technical qualities of the valve. I will miss being able to choose sizes that were perfectly matched by the accompanying sizers and, above all, corresponded well to the true size of the aortic annulus, rarely experienced with other prostheses. I will miss being able to, working through the orifices, reach the ventricular side to remove eventual protruding tissue remnants.

In recent years, a copy of the Medtronic Hall valve has been manufactured and commercialized by an Asian company, thus the valve has not been buried, but it remains to be seen whether this copy performs as the original.

Really, it is like seeing a friend or a lover departing forever! Farewell, Medtronic Hall valve.

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