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Review on balloon aortic valvuloplasty: a surgeon's perspective in 2008

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Abstract The article by Sack and co-workers published in this issue presents the results of a retrospective study on the treatment of severe calcified aortic stenosis (AS) by means of balloon aortic valvuloplasty (BAV) in the elderly patient. While arguing that BAV should be used in patients unfit for surgical aortic valve replacement (AVR) due to relative contraindications their results reveal widely unfavourable outcomes particularly with regard to survival and mortality rates. In contrast, surgical AVR yields excellent results in the mid- and long-term follow-up even in a high-risk patient population. In the rare case of real contraindications to surgical AVR transcatheter valve implantation techniques seem to be the more adequate alternative today.

Key words valvuloplasty – aortic – elderly – valve replacement – percutaneous

The article by Sack and co-workers published in this issue presents the results of a retrospective study on the treatment of severe calcified aortic stenosis (AS) by means of balloon aortic valvuloplasty (BAV) in the elderly patient. This technique had been established in the mid-1980s but has meanwhile been largely abandoned due to disappointing medium- and longterm-outcomes. In this article it has been re-evaluated in the light of new balloon catheters along with the technique of rapid ventricular pacing at the time of BAV. Seventy-five patients with a mean age of 78 ± 7 years and a mean European system for cardiac operative evaluation (EuroSCORE) risk of $24.4 \pm 19.5\%$ were included. The procedural success rate was 73%. Procedure-related serious adverse events (SAE) such as stroke, myocardial infarction, arrhythmia or vascular complications occurred in 17% of all cases. Patient survival rates are being stated as 70% after 6 months and 60% after 1 year. Mortality rises to 35% after the first 6 months in patients over

72 years of age. The study shows improved survival after BAV as compared to the natural course of AS. Still mortality rates remain unsatisfactorily high and as surgical strategies in aortic valve disease yield excellent results even in high-risk patients the following issues need to be critically discussed.

Most of the patients selected for BAV do not seem to be unfit for surgical aortic valve replacement (AVR) from a surgeon's point of view. The process of decision making in the selection of patients remains widely unclear. Were all cases discussed with a cardiac surgeon? And were patients deemed unsuitable for surgery rejected by more than one surgeon? Plain refusal of the operation by the patient as stated in the material and methods section for a number of cases cannot be an adequate indication for BAV.

While it is true that risk evaluation of operative candidates by means of the EuroSCORE is a common scoring procedure, the hereby predicted early mortality rates do not really correspond to the actual 3

outcome after surgical AVR in the elderly. Two recent studies described the actual in-hospital mortality in the discussed patient population to be about half of what EuroSCORE had predicted [1, 3], so that some authors conclude: "EuroSCORE overestimates the mortality in this high-risk group of patients" [4]. By no means does a EuroSCORE of 20% or higher imply inoperability as stated by Sack and co-workers, especially when considering the devastating prognosis for the untreated patient suffering from AS. The sum of a number of patient-related issues such as leftventricular dysfunction, chronic pulmonary disease or elevated serum creatinine definitely increases the relative risk for an adverse outcome. In our opinion, however, there was only one patient presenting with a real contraindication for surgical AVR, which is circular calcification of the ascending aorta, the so-called porcelain-aorta. This condition presents a highly probable risk of cerebro-vascular embolism after aortic cross clamping and thus excludes these patients from the option of surgical AVR.

In their results section the authors state the following outcomes. One patient died during BAV resulting in a peri-procedural mortality of 1.3%. This is slightly lower compared to the literature where the rates are 3%-5%, although the cited articles have to be considered historical since they were published more than 15 years ago [11]. A more recent study finds in-hospital mortality after BAV in octogenarians to be about 6% [14]. However, further follow-up reveals survival rates of 70% after 6 months and 60% 1 year after BAV. When looking at those patients aged 72 years and over mortality rises to 35% after the first 6 months after intervention. These rates match those described in another recent study on BAV in an elderly population. Shareghi et al. [14] found survival to be 56% after 1 year, 38% after 2 years and 29% after 3 years. These are essentially the same results as in older series [13], with the majority of deaths classified as cardiac. With respect to the results after surgical AVR it needs to be stated that the given references are historical [6] and comprise of very low case numbers only (n = 33-35). In the modern literature addressing the topic of surgical AVR in elderly patients results are much more favourable. Peri-operative mortality ranges from 3.8% to 6.2% in these large cohorts (n = 438 - 1,308) [2, 8, 10], making operative treatment no more hazardous than BAV. In addition, surgical AVR yields excellent mid- and long-term results. Survival rates 1 year after surgery range between 80% and 95%. Mid-term outcome is still very good at 71%-75% after 4 years [1-3]. These data show that survival is only slightly impaired by surgery due to a certain peri-operative mortality but in the further course life expectancy almost equals that of an age-matched population [1]. The present study does not comment on the long-term results after BAV as the latest follow-up is 12 months.

One major drawback after BAV is known to be restenosis of the aortic valve. A recent study states the recurrence of stenosis to be present in the vast majority of patients in a time frame of 6–24 months [7]. However, this aspect is not even mentioned by the authors. In comparison, there is virtually no recurrence of aortic valve disease after surgical AVR due to the advanced age of patients.

With regard to other SAE there is no significant advantage of BAV over surgical AVR. Occurrence of peri-interventional stroke was 1.3% in the present study as in the literature [7] with historic studies describing a much higher incidence. Sack and coworkers state the incidence of cerebro-vascular events after surgical AVR as 5%–15% but in more recent surgical studies the rates are considerably lower at 1%–5.8% [3, 12]. Furthermore vascular complications at the site of catheter insertion are quite common after the interventional approach, frequently necessitating secondary vascular surgery.

In the rare case that surgical AVR should not be possible in high-risk patients due to real contraindications there are today better alternatives to surgery than BAV. In recent years transcatheter valve implantation techniques have been described by various groups. Percutaneous aortic valve implantation in humans was first performed by Cribier and co-workers in 2002 [5] via a femoral venous antegrade access. Subsequently other approaches like the femoral transarterial retrograde procedure [9, 15, 17] or the transapical technique [16] have been developed. While still being in its infancy this new technique possibly has the potential to benefit certain patients in the short and long term, especially those who are poor candidates for surgical valve replacement. If there is any indication for BAV today it may be as an emergency measure in patients with cardiogenic shock or as a palliative treatment of endstage patients.

Surgical AVR is a very safe procedure since it can be performed with low operative risk and excellent mid- and long-term outcomes even in a high-risk patient population and represents the gold-standard in the treatment of aortic valve disease. Particularly with regard to short- and long-term survival rates surgical AVR is clearly superior to BAV, which can produce disastrous results in the mid- and long-term follow-up and should be used only for very limited indications. Still more so since the newly emerging technique of interventional valve implantation seems to be the more adequate alternative for patients with contraindications to surgical AVR.

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