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Editorial

Aortic valve surgery: time to be open-minded and to rethink

Successful treatment strategies for cardiovascular diseases have often been initiated and driven by surgeons, which is true for both coronary artery and valvular heart diseases. Radical excision of diseased tissue, repair and replacement strategies lead to long-term successful treatment of the underlying diseases and clearly improved patient outcome. For many surgeons it was and may still be hard to understand that balloon dilation and stenting of severely diseased arteriosclerotic coronary arteries could be competitive for bypass surgery. The impact of all interventional strategies was underestimated by the surgeons, which lead to the overwhelming development of a new discipline of interventional cardiology. They further developed and steadily improved such strategies, heavily supported by medical industry, which lead to a steady growth of PCI, by far surpassing CABG surgery worldwide. Right now interventional cardiologists supported by some cardiac surgeons are on their way to transform some conventional open surgical procedures into catheter-based less invasive interventions, such as valve repair and replacement. Most of the surgeons react very conservatively and some get themselves involved to evaluate such techniques in order to have a fair comparison and control.

Conventional aortic and mitral valve replacement is a routine procedure that has been performed safely for decades. The majority of patients present with severely calcifying aortic valve stenosis, accounting for approximately 10—30% of cardiac surgical workload. Resection of all calcified tissue with subsequent prosthetic heart valve implantation using a standard suturing technique has been the only definitive therapy. Excellent haemodynamic outcome and functional results are achieved, and good long-term performance of conventional prostheses has been proven by numerous studies. Can similar results ever be accomplished by balloon dilation and stent based valve implantation without complete resection of the heavily calcified cusps? This is hard to believe for most surgeons since balloon dilation of aortic valve stenosis alone did not lead to any convincing data.

Also, it is of interest to note that there obviously is a major cohort of patients with both severe aortic and mitral valve disease who are not being referred to surgery usually for the reason that the operative risks are considered to be too high. According to a recent survey of the European Society of Cardiology in 2003, only one-third of these patients underwent surgery.

Providing lower risk strategies and interventions may open potential treatment options. Surgeons should be part of it.

In parallel to excellent results with conventional aortic valve surgery, a steady increase in the individual patient risk profile becomes apparent. Moreover, aortic valve stenosis is a disease of the elderly people. Although healthy octogenarians can be treated safely with good outcomes, additional risk factors may account for increased perioperative morbidity and mortality. Amongst others these are cardiac related factors such as low ejection fraction, pulmonary hypertension, previous cardiac surgery or respiratory dysfunction, renal failure and previous neurological insults. Preoperative risk evaluation can be performed using scoring systems such as the EuroSCORE or the STS risk calculator. The statistical risk may be somewhat higher than the effective risk in experienced hands. In the end, individual and sometimes challenging decisions based on the surgeons' experience are required. Good surgical outcome remains the primary endpoint.

However, this is the time to rethink!

Do we need to care about a 20-year outcome in very old patients? In octogenarians with patent bypass grafts, does a potentially second or third reoperation for AVR necessarily need to be done through full sternotomy when taking the multiplied risks into account?

In view of increasing patient risk profiles, cardiac surgeons should eventually rethink their whole conventional strategy. This may include the evaluation and eventually adaption of new technical developments such as transcatheter valve implantation techniques into routine practice. Potential steps to minimize the risk of aortic valve surgery are obvious: (i) a minimally invasive access avoiding sternotomy, (ii) valve implantation on the beating heart avoiding cardiac arrest and (iii) off-pump valve implantation. There will be concerns with such 'revolutionary' approaches — definitely. 'Conventional outcomes are so good — we have done this successfully for years — why do we need to change'?

The answer is that time can neither be stopped nor turned backwards. Some foresight will be required for modern surgical practice in future. Insisting on conventional approaches may be sufficient at present but may imply regression in the future.

Thus there is an ultimate need to be open-minded and move forward. The application of transcatheter techniques for aortic valve implantation may lead, at least theoretically, to a significant decrease in perioperative trauma and

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eventually to a decrease in perioperative risk. This will ultimately be advantageous for our patients. Cardiac surgery is a very technical field and the surgeon is used to applying latest technological developments in routine practice. This is in strong conflict with some almost inherent concern with the introduction of new operative techniques. The routine cardiac surgeon seems to be quite conservative. Time to rethink!

Apparently new transcatheter aortic valve implantation techniques have been developed by different groups. The continuous efforts of the two cardiologists, Dr Cribier and Dr Bonhoeffer lead to the first successful percutaneous aortic and pulmonary valve implantation, which paved the way for further implants and studies during the past 4 years. Despite being at an early stage of development, several devices have already been introduced into clinical practice at selected centres. A number of different devices (maybe twenty or more) currently are under development. In parallel, several experimental studies on the in vivo function of new devices have been performed. Several of these studies deal with some technical aspects of transcatheter valve implantation with special focus on the surgical therapy using a transapical approach [1—4].

Initial clinical studies on transfemoral and transapical aortic valve implantation are being performed at present. The manuscript on 6 months follow-up results after transapical aortic valve implantation published in this issue is from the group from Vancouver that is on the real forefront of clinical application. They performed the first successful human transapical aortic valve implantations using an oversizing technique, starting in November 2005 on a compassionate use basis in patients deemed as having an excessive operative risk. Recently their initial results in seven patients have been published [5], and now they present early (6 months) follow-up data in four survivors [6]. The present information on persistently good valve function after hospital discharge probably is the most important message from this publication. Good valve function had already been proven in patients receiving a 23 mm Cribier-Edwards™ prosthesis via a transfemoral approach from 2002 onwards by Cribier [7]. The stringent application of the oversizing concept of 2—3 mm by the Vancouver group, implanting a 26 mm prosthesis only, has led to more successful haemodynamic and clinical outcomes. Further clinical studies under ethical approval for operable but high-risk surgical patients are under way. Thus we can anticipate more and more scientific information in the exciting field of transcatheter aortic valve implantation in the near future. Time to rethink!

Another paper in this issue focuses on a specific device for left ventricular apical closure when using such new minimally invasive transapical techniques [8]. This is an elegant study demonstrating the effectiveness of device closure after transapical access. The superior results when using a cuffed device are clear indicators of a further technical development in this field. Transapical access usually can be performed without problems when using Teflon reinforced purse-string sutures. Fragile tissue, however, may lead to technical difficulties, especially when closing larger holes while being off-pump in high-risk elderly patients. Under such circumstances the newly developed closure device may be used for safe and efficient closure of the transapical access. One of the most important aspects of the transapical approach is the unlimited feasibility even in presence of large sheaths, up to 30 French or more. With the help of standard purse-string sutures or a closure device, there is no real limitation in size. This will allow surgeons to implant the most advanced, possibly cuffed prostheses to achieve optimal results in comparison to the transfemoral approaches with potential size limitations.

Surgeons always have been on the forefront of developing new and excellent therapeutic strategies in medical history. Vaccination by Jenner and cardiac catheterization by Forssmann are only two of those examples that have been persistently condemned by medical colleagues for years as recently pointed out in an excellent article by Lewis on the CTS*Net* [9]. With new techniques, immediate acceptance cannot be expected by everyone, but new techniques should be fairly evaluated on a scientific basis. Definitive judgement can only be performed after performing controlled, if possible, randomized clinical studies. As such, surgeons are the most experienced physicians offering definitive treatment for aortic valve disease — for decades. To further direct the development, as well as to aim at optimal results with transcatheter valve implantation for the ultimate sake of our patient's, surgeons have to stay in the game. Surgeons have to actively take part in the developments designing future joint inclusion criteria and performing comparative and eventually randomized clinical trials. In parallel, retraining with the new catheter-based techniques will be required. Last but not the least 'the transapical approach may be the first clear pathway for cardiac surgeons to acquire and use catheter-based and image-guidance skills, especially if the procedure starts to replace traditional surgical valve replacement in higher risk patients' [10]. Transcatheter valve implantation is an exciting new field with a strong surgical interest where surgeons should also be open to learn about transfemoral valve implantation themselves. A surgical OR for the future should implement high quality X-ray imaging such as in the catheterization laboratory. Thus the concept of a hybrid OR needs to be further applied.

The clinical introduction of new techniques will always be discussed by the medical societies. There will always be criticism. However, potentially excellent developments that will lead to a significant decrease in the invasiveness of a standard surgical procedure should be favourably judged with an open mind. With our yet limited experimental and clinical experience in transapical and transfemoral transcatheter aortic valve implantation, we have to say that this is one of those very promising techniques, even though we were non-believers 4 years ago.

It is one of the few extremely innovative techniques that may even revolutionize the whole cardiac surgical practice in some years. Patient selection criteria should remain at present for high-risk candidates though may be changed after future successful studies. In addition this is an emerging field for the further establishment of a true team approach: Surgeons and cardiologists are working together in a hybrid operation theatre. Eventually a new speciality of patient and disease oriented physicians, valve specialist in this example, may evolve. Time to rethink!

Despite all excitement, there are still pitfalls in the new transcatheter techniques. Risk for paravalvular leakage probably is the biggest issue at present. Newer valves may

come up with additional cuffs that would lead to a better sealing around the prosthesis towards potentially severely calcified native aortic valve cusps and annulus. In addition, a cuff material with gradual dilatative properties or even active sticking properties towards the calcified annulus may be advantageous. Further technical developments will come in future, leading to better functional outcomes. Future use of nanotechnology may lead to a complete shift in dimensions towards significantly smaller devices. At present relatively large diameter sheaths will be required for the insertion of larger and eventually cuffed prostheses. With the safe transapical approach this can be accomplished in a standard fashion. Thus in order to further develop the new transcatheter techniques we have to keep the final goal of perfect valve function without leak in mind.

In summary, conventional surgery remains the golden standard for the definitive treatment of patients with significant aortic valve disease. Transcatheter valve implantation techniques have been successfully introduced into early clinical practices. Further developments will come, and surgeons with all their expertise in the treatment of valvular heart disease need to be part of it. Cardiac surgeons have to rethink conventional aortic valve surgery and adapt the exciting new approaches of transapical and also transfemoral transcatheter valve implantation techniques. Times are changing and surgeons should be prepared.

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