Long Term Biocompatibility of Non-Coronary Cardiovascular Devices: Limited Knowledge – Significant Clinical Implications

Matthias Sigler

1Pediatric Cardiology and Intensive Care, Georg-August-University Goettingen, Robert-Koch-Str 40, D-37099 Goettingen, Germany

A considerable number of cardiovascular devices have been introduced into the field of interventional therapy of congenital heart defects—especially during the last two decades [1-3]. Nowadays, more and more lesions can be treated in the cath lab. Subsequently, more and more patients live a long time with metal and/or textile devices in their body. Of course, clinical data have been published on interventional cardiovascular devices. However, the majority of these publications focus on feasibility and safety of the implantation procedure as well as clinical results. In contrast, limited data have been reported on in vivo-biocompatibility and long-term local tissue reactions [4,5]. Finally, even less publications are available on clinically relevant problems related to interventional cardiovascular devices. Thromboembolic events with embolisation, residual shunting, dislocation of the device, and growing thrombus formation on the device have been reported in literature [6-9]. On the other hand, the number of major events is very small in the light of total, of currently about 200,000 occlusion devices implanted in cardiac septal defects.

As a pediatric cardiologist, I am happy to be able to offer a therapeutical approach to a cardiac defect avoiding open heart surgery for certain types of congenital heart defects. But at the same time, I am concerned about the lack of information on long term effects of the incorporated foreign material. I would like to tell parents about the fate of the septal occluder six or seven decades after implantation in their child.

It’s not that we know nothing: It has been shown that neo-endothelialisation rapidly proceeds and usually is completed 3 to 6 months after implantation [10,11]. Within occlusion devices, initial deposition of fibrin and blood cells could be demonstrated to be transformed into fiber-rich granulation tissue with a chronic inflammatory response [4,5]. The time course of this process was clearly material-dependent [12]. And it has been shown that findings in explanted human septal occlusion devices closely corresponded to findings in animal studies [13]. But for gaining all these information, careful and skilled work-up of explanted devices is necessary. In addition, experience is needed in cardiovascular pathology for assessment of findings. The only proposal for evaluation and judging biological responses to medical devices is the ISO 10993-6: 2007. But suggestions in this document are very vague and leave much space for subjective interpretation.

Taken together all information that we have on biocompatibility of cardiovascular devices we have reason to believe that our patients do not take an intolerable risk when they receive a permanent device. But believing is not enough in this context. For the sake of safety of our patients we need as much information as possible. And for that reason it should be mandatory that all data on animal experiments should be made public prior to approval for clinical application by local authorities. And moreover every one of us should take care that every device that was explanted (for whatever reason) should undergo careful and thorough histopathological work-up in order to learn more about long-term tissue reactions and possible problems with regard to the highly promising field of interventional therapy of cardiovascular lesions.

References
