Nature does nothing in vain, a word of caution

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Nature does nothing in vain, everything happens for a reason

The best therapy for our patients with extensive coronary artery disease is an aortic full arterial off-pump coronary artery bypass (OPCAB) coronary bypass procedure. This procedure is performed by a surgical team after conceptual, simulation, and scenario training in a departmental environment where a continuous early and late organizational learning process has been activated. This ideal approach has rewarded several units with exceptional results, but not unexpected since they apply in a translational form the science of learning and the science of industrial production. For most of the other units, the reality is very hard and seems self-destructive. Under the denomination of lesser-invasive approaches, often under peer pressure by the cardiologists, the wildest therapeutic options are proposed and applied, forgetting the basic sciences surrounding any implementation of a new production process.

In a pure semantic definition, invasive procedures are procedures that enter the body by cutting or puncturing the skin or by inserting instruments into the body. So, a catheter procedure, a hybrid procedure, and an open surgical procedure are all invasive. The added wording of "lesser or minimal" is a parametric definition and refers to a value one is able to measure in a quantitative manner. A patient is a complex ecosystem of mental and physical processes. A correct quantitative parametrisation of invasiveness needs therefore to be holistic and not to focus on one physiological system, as skin or bones.

Since February 25, 1964, when Vasilii Kolesov (1) performed the first sutured coronary bypass in a human, the cost benefit of this procedure has been of scientific interest.

From a medical perspective, the cost is expressed as the risk of the procedure. The oath of Hippocrates (2) forces the medical professional to "primum non nocere", or at least to reduce it to the minimum. Any process that reduces risk and impact, merits our attention; but we need to evaluate the effect on the human ecosystem, not on one particular process. On social media, we see competing videos of gradually smaller incisions in patients with gradually more extensive disease. A decrease in incision length can never be balanced by an increase of a more serious risk. For "market" reasons, "lesser" invasive approaches are promoted beyond their logical domains and give the impression, without early or late evidence, there is no more market for more traditional surgical revascularization methods, even off-pump and full arterial.

From a medical perspective, the benefit is the increase of quality and quantity of life after the procedure versus the expected quality and quantity of life without the procedure. Here two major problems arise. We have no or nearly no information about quality of life before or after surgery. We have even less information about the natural life expectancy of a patient with an extensive vessel disease and a series of co-morbidities. These two major problems make a fair comparison of a new therapeutic approach impossible.

This is also a health economic aspect. From a societal perspective, we cannot accept therapeutic approaches that explode the costs versus existing approaches, under the umbrella of "equipoise" or "non-inferiority" of certain outcome variables.

It is astonishing to observe that in 2022, the general concept of departmental standardization of a procedure has not been accepted in cardiovascular surgery as the first step towards an optimization of the cost-benefit balance. Conceptual learning demands not just standardization but documentation of every surgical step, and every team interaction. Any variability of that approach, as in lesser

invasive, demands appropriate documentation, including the monitoring of all system risks and all early and late benefits. This becomes massively visible in multi-institutional randomized trials when one studies the surgical arm: no standardization between or within institutions.

Nearly no cardiovascular surgeons have undergone formal structured simulation or scenario training of a surgical procedure, including deconstruction into teachable components, low-fidelity simulators, quantitative [objective structured assessment of technical skills (OSATS) (3)] and qualitative assessments and repeated simulation processes on virtual platforms. Other high-risk environments as the military, chemical and airline industry have included these learning processes since decades and obtain failure rates at the 5 and 6 sigma rates (4), whilst surgeons accept failure rates of 1 and 2 sigma. The learning process becomes permanent by looking at the different early and late outcome variables in a multivariate and time-related manner. Organizational short- and long-term databases and their strict analyses must close the quality circle of lesser invasive innovations. If it is the ambition of the surgical team to reduce risk and increase benefit with a lesser invasive approach, then these learning processes should precede a new approach. If it is the ambition to become well-known, then videos on social media are sufficient.

Any industrial process, interested to reduce risk and optimize benefit, would normally take an approach of incremental (5) improvement. John Kirklin learned his scholars to optimize every single step of the surgical process. Re-engineering stands in opposition to incremental improvements, in that the complete process is rewritten, starting from a white sheet and by all the involved parties. Re-engineering has the ambition to reduce or annihilate massively the early risk and preferentially also to improve late benefit. Reaching an equipoise of results of the traditional approach is a failure of reengineering. A massive reduction or annihilation of early risk without loss of benefit, as hoped for in extremely small skin incisions, demands most certainly a reengineering.

Under the perspective of "Primum non nocere", surgeons need to limit the incision and the invasiveness to the minimum required for a safe procedure. But reducing this incision will often increase the technicality. This can be compensated by appropriate simulation training. Let us not forget that the sternotomy was selected as the approach with the least pain and discomfort for the patient. The smallest skin incision with the least trauma on the bone structure is the catheter.

Vasilii Kolesov was already questioning if the extra-corporeal circulation was a mandatory component of the procedure and avoided the extra-corporeal circulation. Very few surgical teams have been able to implement this approach for all coronary artery bypass graft (CABG) surgery patients and all surgeons, and with failure rates at the 4 and 5 sigma level.

Combining a surgical and a catheter procedure in a hybrid approach of extensive coronary disease is a mathematical and an economical issue. The early risk of two different procedures is the summation of the two risks, the late benefit of two different procedures is the late benefit of the weakest of the two. The number of anastomoses of a procedure does not influence the early risk of surgical revascularization after correction for all variability. So, by definition, a hybrid procedure will always have an equal or higher early risk. As of yet, no publication has proven otherwise. Complete arterial grafting has shown its superiority in long term benefit. So there seems a mathematical logic that the more arterial grafts any approach will involve, the better the late benefit and inversely, the more percutaneous coronary intervention (PCI) any approach will demand, the lower the late benefit. So, extending the hybrid approach to more vessels will have its impact on the risk-benefit balance.

A borderline significant proximal lesion of the right coronary artery (RCA) has an extremely good late result in percutaneous approach and a lesser one in surgical revascularization. Complete arterial revascularization of the anterior, lateral, and posterior wall in combination with a PCI of the proximal RCA is probably a valid option.

A hybrid procedure involves two different procedures, using different materials with different medical teams, but optimally performed in the same theatre. So, the economic aspect of this approach will use more human, material, and financial resources.

The word robot comes from the Czech language and means nothing more than machine. Over the years the use of the word "robot" has been associated with three conditions: pattern recognition, decision making, and execution. The current surgical robots have none of these qualifications. It is possible that, in due time and through the application of the strictest learning processes, the anastomosis performed by the robot equals and even exceeds an OSATS-based quantitative assessment. But, most certainly, the demand in resources will even further explode.

The surgical community has not proven its ability to implement in a translational way the basic aspects of

process optimization, of early risk reduction and late result optimization. The aortic valve surgical replacement has lost massive market share, the mitral valve replacement/repair is undergoing a similar share loss. These therapeutic changes will be permanent unless health economics play their role. Clayton Christensen (6-8) has predicted this well in several manuscripts. He mentions market mechanisms, investments, and so many different related aspects. Coronary surgical revascularization has only a future in the strictest application of the science of learning, of process optimization and with an in depth understanding of the opportunistic and economic aspects of any variation in approach. Hybrid and robotic approaches might have an impact, but should not be the priority, at the benefit of the patient.

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Footnote

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