

## **REVIEW OF MODERN NON-SURGICAL TOOLS APPLIED IN CARDIAC SURGERY**

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### **Abstract:**

Surgical intervention is commonly associated with the use of hardware that facilitates invasive medical treatment. Nowadays surgeons apply a new set of tools that help them anticipate the outcome of the intervention and define potential risk factors. Increasing patient migration inspired healthcare professionals to introduce universal standards of care, supported by medical guidelines and checklists. Today, prior to skin incision, every modern cardiac surgeon is enabled in the whole range of tools that are designed to increase patient safety and provide thorough information to the whole medical team.

**Key words:** *risk scales, checklist, cardiac surgery, medical guidelines*

### **INTRODUCTION**

Modern surgery is now reaching beyond equipment novelties and surgical skills. The treatment process involves procedures, standards, risk assessment, quality control, and guidelines. This has led into even higher complexity of any medical therapy, but also produced standardized care that can be and is reproducible across hospitals, countries and continents.

This paper brings an overview of tools that are already at hand of healthcare professionals. While individual items described below are of a different characteristics, when properly used they all combine into multidisciplinary approach that is aimed at the three basic components of modern healthcare: maximum safety level for the patient, high comfort level for the medical team, and optimum cost-effectiveness characteristics for the management and payers.

Nowadays medical treatment involves individual patient approach, constant progress of utilized operative techniques and applicable tools, and the need for simultaneous combination of clinical expertise, scientific knowledge, and economical consequences. Only proper (i.e. optimal) decision making process may result in uneventful treatment, fast recovery, excellent economic outcome, as well as minimized risk of medical, legal, and financial complications.

Healthcare is shifting towards standardized care. This involves implementation of different processes, from prediction models that allow assessment of risk of treatment, through checklists that have previously been used in airline industry, up to continuous introduction of medical guidelines that support decision-making process [1].

This evolution is in need to keep pace of technical progress, aging population, increased migration of societies, and limited economic resources. After all, it is the patient himself, who trusts the doctor's skill, knowledge and intuition that warrant optimal treatment of particular illness.

### **RISK SCALES AND PREDICTION MODELS**

Predicting mortality in cardiac surgery is critical for decision-making purposes, particularly when there are different treatment options available, as well as for monitoring innovations and outcome evaluation both at institutional and surgeon levels.

While most surgical complications are directly related to the intervention, some result from general patient condition or equipment failure. For the sake of their own peace of mind, and to improve treatment outcome, surgeons have sought for validated prediction models and risk assessment scales. These models are helpful in strategic planning of the intervention, as well as in clinical use to multidisciplinary shared-decision making. The latter is especially true in an era of expanding multimodality therapy for coronary artery and aortic valve disease where risk prediction plays an important role in determining which patients would benefit most from surgery, interventional or conventional therapy.

In cardiac surgery for example, where postoperative bleeding seems to be the most unwanted complication, it is actually neurological events (such as stroke) and kidney failure that threaten patient's life and its long-term quality. Surgeons need to make predictions on the prognosis of a treatment that helps them in the choice of therapy. Several prediction models have been developed with the main goal of estimating the risk of operative mortality for patients undergoing cardiac surgery. The most popular clinical prediction model is EuroSCORE that provides evidence-based input for shared decision-making by providing an estimate of the operative risk of patients undergoing cardiac surgery. The original EuroSCORE was developed from a large multinational European population and was a model predicting mortality based on 17 variables, either from a logistic regression equation or from an additive model. Numerous

institutions throughout the world have tested and validated EuroSCORE [2].

Many investigators have observed loss of calibration with the additive and logistic EuroSCORE, therefore an update of the EuroSCORE was warranted. One possible reason for the poor calibration of the original EuroSCORE score is that the score was developed from patients undergoing surgery almost 20 years ago. As surgical and perioperative care evolves and the impact of clinical variables change, prediction models therefore require revision. These factors may also vary between institutions and it is well known that the quality of care and comorbidities of patients differs between countries. The original EuroSCORE already identified major differences in the risk profile of national samples.

The reasons for suboptimal model performance are multifactorial. While conventional cardiovascular risk factors, such as renal failure and diabetes, are considered for inclusion in a model, less obvious factors may be valuable as well. A mismatch is frequently present between the model development patient cohort and the patient cohort that it is used for in practice; some patient subgroups are continuously under-represented.

Another reason for the poor calibration in the original EuroSCORE might be that a large number of risk factors in the model are highly correlated. It is important to recognize correlation between predicting variables, as the additional risk contribution of certain variables can in some part be explained by the effect of other variables. Some predicting variables may also be more important for some types of operations than for others. The large number of risk factors with potential interaction may overestimate risk in certain categories of patients (e.g. intermediate risk or extreme risk). Risk models are inconsistent in including variables and are missing several different yet important risk factors, although until now it has been unclear which factors need to be considered. Furthermore, different definitions are used for some of the risk factors, resulting in a different weighting of that factor between models [3].

## INSTITUTIONS

World Health Organization (WHO) is the directing and coordinating authority for health. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, and articulating evidence-based policy options.

WHO responds to current challenges in global healthcare addressing health objectives and strategic needs. During the past decade, health has achieved unprecedented prominence as a key driver of socioeconomic progress, and more resources than ever are being invested in health.

One of the greatest threats to international health security arises from outbreaks of emerging and epidemic-prone diseases. Such outbreaks are occurring in increasing numbers, fuelled by such factors as rapid urbanization, environmental mismanagement, the way food is produced and traded, and the way antibiotics are used and misused. To strengthen health systems areas being addressed include the provision of adequate numbers of appropriately trained staff, sufficient financing, and suitable systems for collecting vital statistics, and access to appropriate technology including essential drugs.

Evidence provides the foundation for setting priorities, defining strategies, and measuring results. WHO generates

authoritative health information, in consultation with leading experts, to set norms and standards, articulate evidence-based policy options and monitor the evolving global health situation.

WHO uses the strategic power of evidence to encourage partners implementing programs within countries to align their activities with best technical guidelines and practices, as well as with the priorities established by individual countries.

WHO participates in ongoing reforms aimed at improving its efficiency and effectiveness, both at the international level and within countries.

## WHY SAFE SURGERY IS IMPORTANT

**SAVE LIVES: Clean Your Hands** annual global campaign was launched in 2009 as part of a major global effort to improve hand hygiene in health care.

This initiative is part of the WHO Patient Safety First Global Patient Safety Challenge, 'Clean Care is Safer Care' program that was launched in October 2005.

The background for the above mentioned campaigns were terrifying medical statistics. There are more than 250 million surgical operations performed every year worldwide, which translates into every 25th human living on Earth being operated on. Mortality rates reach 4 to 8 deaths per 1 thousand operations in developed countries and are compared to 5-10 deaths per 100 operations in underdeveloped regions of the world. On average, an American citizen undergoes 7 surgical interventions during his lifetime. Surgical mortality rates are much higher as compared to fatal car accidents. According to panel experts at WHO, at least half of medical adverse incidents could have been avoided. As a result of their studies on the Safe Surgery Saves Lives campaign a medical checklist has been developed [4].

Surgical care has been an essential component of health care worldwide for over a century. As the incidences of traumatic injuries, cancers and cardiovascular disease continue to rise; the impact of surgical intervention on public health systems will grow.

Surgery is often the only therapy that can alleviate disabilities and reduce the risk for death from common conditions. Each year many millions of people undergo surgical treatment due to traumatic injuries, pregnancy-related complications, and to treat malignancies.

While surgical procedures are intended to save lives, unsafe surgical care can cause substantial harm.

The goal is to improve the safety of surgical care around the world by defining a core set of safety standards that can be applied worldwide. Four areas in which dramatic improvements could be made in the safety of surgical care have been identified: surgical site infection prevention, safe anesthesia, safe surgical teams and measurement of surgical services.

## CHECKLIST MANIFESTO

Checklist has been successfully introduced into air transportation, business industry as well as households. The simplest checklist example that is used by every housewife is any baking recipe.

Checklist phenomenon is contained in its simplicity. It combines current standards of care, facilitates communication, promotes teamwork and, most importantly, limits the loss of vital information. Every checklist reminds of things that can be otherwise overseen, and can be used as a strat-

egy to overcome failures by introducing discipline into every action [5].

Checklist maintains control over common causes of complications and deaths in the OR. The four most frequent incidents include: infections, bleeding, anesthesia, and unplanned course of events. Prophylaxis in the three first instances is achieved through exchange of brief information on infection status, blood preparation, and readiness of the anesthetic equipment to monitor and conduct anesthesia. The biggest hurdle comes with unpredicted complications, and there has been no procedure developed to prevent such situation. Chances are that if a complication occurs or unforeseen circumstances take place information exchanged during checklist review will result in effective teamwork that will allow for successful completion of the procedure. Short presentation of the operating team uncovers the anonymous new members and makes them become a part of the group. People who know each other's names are better collaborators, as every team consists of group of people, but not every group of people makes a team. Checklist turns the group of people surrounding the operating table into a uniform team [6].

Although formal and detailed, a properly designed checklist maintains equilibrium between individual freedom and discipline, personal skills and algorithms, and teamwork.

Checklist should be verified at three stages of surgery: before anesthesia, prior to skin cut, and during final wound closure. In airline industry these points refer to boarding, takeoff and landing. Several simple questions allow putting basic things in order in advance instead of unnecessary panic and nervous situations focused rather on witch hunting than real problem solving [7].

## MEDICAL GUIDELINES

Medical societies now urge healthcare professionals to evolve from individual decisions to team consensus, where instead of the particular illness a patient as a complex human nature is diagnosed. When independent specialists review the case, standardized steps to follow have been designed as guidelines to ease the decision-making process.

Guidelines aim to present all the relevant evidence on a particular clinical issue in order to help physicians to weigh the benefits and risks of a particular diagnostic or therapeutic procedure. They are helpful in everyday clinical medical decision-making.

A great number of guidelines have been issued in recent years by the European Society of Cardiology (ESC) as well as by other national and international societies and organizations. Because of their impact on clinical practice, quality criteria for the development of guidelines have been established, in order to make all decisions transparent to the user. The authority and validity of guidelines can be guaranteed if they are developed in an unquestionable decision-making process.

Guidelines summarize and evaluate all evidence available on a particular issue with the aim of assisting physicians in selecting the best management strategies for an individual patient with a given condition, taking into account the impact on outcome, as well as the risk-benefit-ratio of particular diagnostic or therapeutic means. Guidelines are not substitutes for-, but complements to, textbooks. Guidelines and recommendations should help physicians to make decisions in their daily practice. The responsible physician must

make final decisions concerning an individual patient, though.

It has become evident that application of guidelines improves the quality of clinical practice. Some surveys have shown that the intended end-users are sometimes unaware of the existence of guidelines, or simply do not translate them into practice, so this is why implementation programs for new guidelines form an important component of the dissemination of knowledge. Implementation programs are needed because it has been shown that the outcome of disease may be favorably influenced by the thorough application of clinical recommendations. Thus the task of writing guidelines covers not only the integration of the most recent research, but also the creation of educational tools and implementation programs for the recommendations. The loop between clinical research, writing of guidelines and implementing them into clinical practice can only then be completed if surveys and registries are performed to verify that real-life daily practice is in keeping with what is recommended in the guidelines [8].

## CONCLUSIONS

The European Association for Cardio-Thoracic Surgery is establishing a quality improvement program with international database as an important component – the score can be used to evaluate cardiac surgery practice in Europe.

The practical outcome of the introduction of the above-described tools is that they play an important role in medical decision-making. In cardiac surgery, where medical intervention is one of the most invasive, proper assessment of preoperative risk factors combined with intraoperative standardized checklist verification if all guidelines and recommendations have been put in place may save patients' lives and surgeons' nightmares.

Although each of the above-described tools can also be characterized with its limitations, healthcare professionals should not distance themselves from these modern tools of patient care.

The guidelines do not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with that patient. It is also the health professional's responsibility to verify the rules and regulations applicable to drugs and devices at the time of prescription.

It becomes even more important that units and surgeons calculate their own risk-adjusted mortality ratio. The model is probably more reliable in the prediction of death over a wide range of risk groups rather than the prediction of the vital status of an individual patient.

Models with only a few parameters are quite stable and estimating a few calibration parameters might be enough. The inclusion of a greater number of variables increases the risk of errors that can be caused by differences in the interpretation of definitions, typing errors or conflicting chart information, and will likely result in missing data. The balance between the number of variables and model performance should be carefully considered; too many variables will decrease the user-friendliness of a model. On the other hand, ignoring some these variables may produce a model with a modest predictive performance.

Despite the usefulness of currently applied risk scales, it remains challenging to develop a risk model that performs accurately across the spectrum of low-, intermediate- and high risk patients evaluated for cardiac surgery. Particularly in high-risk patients, risk models have been shown to be

poorly calibrated and to over-predict mortality. There is currently more need for risk models that not only focus on mortality but also on postoperative complications and the development of procedure-specific models. As clinicians are confronted with more elderly patients, it might also be useful to focus on specific subsets of patients. A prognostic model is only useful if its predictions are at least as accurate as those of the doctors who would use it.

Individuals who are proficient in their job oppose every checklist. Although it is very unlikely that they will cause a fatal error, any medical treatment has now become such a complex process that it involves a whole team of workers. It is this constantly changing environment that endangers the successful outcome of the procedure and the patient's long-term quality of life.

The above described tools are the most commonly applied to facilitate safe medical treatment – the only treatment that can actually save lives. That said, it needs to be reinstated that non-surgical tools have saved many patients from unnecessary or fault treatment.

## REFERENCES

- [1] Hrapkowicz T., Maruszewski M., Kempa A., Michalik K., Zacny B.: Decision making process in cardiac surgery – concept of building an expert system. Management Systems in Production Engineering. 2013, No 1(9), pp. 26-31.
- [2] EuroSCORE II, illum qui est gravitates magni observe. Sergeant P., Meuris B., Pettinari M. Eur J Cardiothorac Surg. 41(4), 2012, pp. 729-31.
- [3] Head S.J., Osnabrugge R.L., Howell N.J., Freemantle N., Bridgewater B., Pagano D., Kappetein A.P.: A systematic review of risk prediction in adult cardiac surgery: considerations for future model development. Eur J Cardiothorac Surg. 43(5), 2013, pp. 121-129.
- [4] Haynes A.B., Weiser T.G., Berry W.R., Lipsitz S.R., Breizat A.H., Dellinger E.P., Herbosa T., Joseph S., Kibatala P.L., Lapitan M.C., Merry A.F., Moorthy K., Reznick R.K., Taylor B., Gawande A.A.; Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med. 360, 2009, pp. 491-499.
- [5] Gawande A.: The checklist manifesto. How to get things right. Picador, New York 2010.
- [6] de Vries E.N., Prins H.A., Crolla R.M., den Outer A.J., van Andel G., van Helden S.H., Schlack W.S., van Putten M.A., Gouma D.J., Dijkgraaf M.G., Smorenburg S.M., Boermeester M.A.; SURPASS Collaborative Group. Effect of comprehensive surgical safety system on patient outcomes. N Engl J Med. 363, 2010, pp. 1928-1937.
- [7] Kucewicz-Czech E., Karolak W.: Potęga checklista. Kardiachirurgia i Torakochirurgia Polska. 3, 2012, s. 394-395.
- [8] Vahanian A., Alfieri O., Andreotti F., Antunes M.J., Barón-Esquivias G., Baumgartner H., Borger M.A., Carrel T.P., De Bonis M., Evangelista A., Falk V., Lung B., Lancellotti P., Pierard L., Price S., Schäfers H.J., Schuler G., Stepinska J., Swedberg K., Takkenberg J., Von Oppell U.O., Windecker S., Zamorano J.L., Zembala M.; ESC Committee for Practice Guidelines (CPG); Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC); European Association for Cardio-Thoracic Surgery (EACTS).: Guidelines on the management of valvular heart disease (version 2012): the Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). Eur J Cardiothorac Surg. 42(4), 2012, pp. 1-44.

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