Patient safety in thoracic surgery and European Society of Thoracic Surgeons checklist

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Abstract: Improving patient safety seems to be a new interesting clinical subject but, in fact, it is no new. It has to do with one of the oldest ethical principles of our profession: curing and not harming. The important research that has been done in a short period of time has brought in new insight to this complex area that is fast developing. The creation of safety managing systems will allow coordinating efforts from very different, although complementary, areas to create real safety culture and safety climate in every organization. In the surgical settings, teamwork is basic to provide good quality of care. Safety leaders in every team have an important role in establishing priorities, summarizing proposals, coordinating efforts, launching new initiatives and transmitting that safety efforts are worth taken. Preparedness and anticipation are key points for avoiding most of the diverse types of patient harm that can occur. As has been published, a great number of errors can be avoided simply using crosscheck based on specialized checklist that reviews every important detail of the procedure. This strategy has been demonstrated very useful at other high risk industries such as aviation, nuclear or food management. The Safe Surgery Saves Lives program launched in 2002 by the WHO has taught us that improvement is possible using a simple checklist. More complex and detail checklist can be more adequate for more complex procedures and settings. The proposed ESTS checklist reviews different areas of possible error in deeper detail allowing the finest adjustment of the patient before the skin incision. It has been recently released to the general thoracic community and monitors its use and usefulness has to be warrantied.

Keywords: Patient safety; checklist; ESTS checklist; safe thoracic surgery

Introduction

An "adverse event" can be defined as any injury due to the medical care. They represent a major source of morbidity and mortality. It is surprising that, only during the twentieth century, clinicians, as a group, thought about "curing and not harming" as an innovative approach to medicine (1). The concept of avoiding patient harm was already stated in the Hippocratic Oath (2). Although this oath is not recognized in many countries of the world and has been modified on several occasions along history, the principle of "do no harm" is considered a basic ethical principle of our profession. Benefits always should outweigh any possible damage induced by the treatment (3).

Since the eighteen century, some important individual initiatives were dismissed (4). The most important difference with today's point of view is that the whole community agrees on the need to implement efforts protecting our patients. In the past, many initiatives were misunderstood by the medical community. As a result, some of the pioneers were isolated from social recognition and the proposed initiative was not implemented at that time. More recently, the importance of this ethical principle has grown progressively as quality of performance was measured.

Patient safety goes one step forward so it can be defined as the avoidance, prevention and amelioration of adverse

outcomes or injuries stemming from the process of healthcare. From a practical point of view, in most settings, this has to do with anticipating and reacting properly to an unexpected situation or problem. But patient safety is more because it is in charge of determining what is unacceptable to deliver better care (5).

The purpose of this paper is to review briefly what we know about patient harm, what we are working on to protect individual safety within the surgical field and to present a specific initiative: the ESTS checklist.

Patient harm: size matters

Fourteen years after the American report (1), many papers and reports had been published presenting the figures about the incidence and the impact of patient harm (6-11). What is common to all of them is the size of these figures. de Vries *et al.*, performed a systematic review about the incidence of in-hospital adverse effects and found that 1 out of 10 patients will suffer an adverse effect when receiving hospital care (7). According to a report published in 2008 (12), the WHO estimates that 7.5% to 10.4% of patients in acute care settings, in developed countries, experience an adverse drug event that results in 140,000 deaths annually in the USA alone. These adverse drug events affect the elderly especially with an estimation rate of 50 errors per 1,000 person-year in the USA. At least, 27% of these events are considered to be preventable. Data, also suggest, a rate of 6.3 adverse effects per 1,000 patient-days due to medical device problems within developed countries. The size of this problem can be magnified in the developing countries where medical equipment is often useless owing to the lack of resources. Up to 1 out of 4 patients, admitted to the Intensive Care Units in the world, will acquire an infection during the hospital stay. This infection will have an additional cost of US$7-8.2 billion annually in the USA to €800 million in the United Kingdom and France or US$48 million in Turkey.

This sparse data gives a global idea of the magnitude of what patient harm means. Preventable medical errors cost a large amount of money and they produce an enormous personal cost not only in human lives but also in disability, loss of personal satisfaction and loss of general faith in the health care system (13). They have medical, legal, social and emotional implications.

Safety management: why measure

Safety management is related to a broad variety of activities

that have to do with all aspects of healthcare itself and includes activities not only from caregivers but from policymakers, regulators and patients.

Since the beginning of global interest in patient safety, a lot of research has been dedicated to develop wide-ranging systems for measurement and monitoring safety issues. This is a difficult task because it has to include data and details from a broad spectrum of areas. There is no doubt that improving patient safety culture and climate decreases patient harm as it has been demonstrated worldwide reducing the number of catheter bloodstream infections as a result of local, evidence-based initiatives (14) among others but still there is a long way to go.

From other high risk industries such as nuclear, aviation, food management or oil manufacturing we have learnt that information of safety alone is of little use. Patient safety needs an organized broad approach which is referred to as safety management system (SMS) (15). SMS receives and combines data from leading an minor indicators to measure, monitor and manage safety performance constantly (15). SMS is composed of policies, structural elements, strategies, means to measure and review safety performance and feedback for final improvement. Although a great part of what we have now has evolved directly from other industries; developed tools, methods and techniques of these industries cannot always be applied to the health care system so further research is necessary.

As it is inferred, measurement should be used to understand, detect and improve. It is a means to an end not the end in itself. But the real difficulty is measuring what really matters. What are the most appropriate metrics to measure? At present there are not clear protocols to evaluate whether safety efforts are reducing the risk of events that cannot be measured as rates (16). Root cause analysis, global trigger tool, patient thermometer, safety case discussions and simple regular morbidity and mortality rounds, for example, are well described tools for understanding, monitoring and evaluating patient safety (17).

Surgical preventable errors: a major concern

It is estimated that 234 million operations are performed globally each year (18). In industrialized countries major complications are reported to occur in 3% to 6% of inpatient surgical procedures, with permanent disability or death rates of 0.4% to 0.8%. The WHO estimates that surgical adverse events account for 48% of all adverse events recorded and affect about 2% of all hospitalized patients (12)

and, what is more important, 50% of them are considered to be preventable (8,19).

The delivery of safe effective surgical care is complex (20). Adverse events can occur almost in any step of the health care procedure and are due most to faulty systems, processes and conditions that lead people to make mistakes or fail to prevent them (1). In 1990, Caplan *et al.* (21), published that respiratory events were responsible for 34% of all anesthetist claims in the US. Eighty-five percent of this adverse events ending in death or in cerebral damage, 72% of the problems were considered preventable simply by improving monitoring. For example, esophageal intubation was responsible for the negative outcome in 18% of the cases. In almost half of these cases, unfortunate auscultation of breath sounds did not identify the cause of the inadequate ventilation. The general spread of a new technique raises a general concern about safety compared to previous methods so prospective comparative studies for safety assessment should be conducted (22).

There are a special group of negative outcomes: wrong-site, wrong procedure and wrong patient operations are the "never events" group (23). This group encompasses one of the most unacceptable medical errors. Of great concern were the data presented by Kwaan *et al.* (24), that found that wrong-site non-spine procedures were infrequent (1 every 112,994) but protocols used to control this adverse event might have prevented only 62% of the cases of such unacceptable outcome. When assessing the place where the first error took place, they found that 9 out of 13 patients were wrongly assigned preoperatively. The absence of specific protocols preclude that the previous errors were corrected and the harm prevented. There are a certain number of well recognized risk factors for never events outcomes. For example: several surgeons involved in one procedure or multiple procedures for one type of operation, time pressure, emergency surgery, abnormal patient anatomy or morbid obesity (25). Not all specialties have the same risk being orthopedics surgery one with the highest risk of all (26) and being extremely rare in the general thoracic settings (27).

Safe surgery saves lives: the World Health Organization initiative

Probably one of the key points in patient safety is anticipation of possible problems. Anticipation and preparedness are critical components of safety. The importance of these elements is well stressed in other high-risk areas like

emergency interventions as in case of fire (28). In surgery as well in all these high-risk areas, another important point should be emphasized: teamwork (29-31). Teamwork is based on communication. The better it is, the better the results will be. Different aspects of communication such as assertiveness, team decision making and team briefing are basic requisites that need training in order to achieve the proposed change in safety attitudes of the team (32). It has been verified that systematic use of checklists improves all this aspects (33).

In 2007, the WHO launched the program call *Safe Surgery Saves Lives* attempting to achieve a reduction in the number of preventable surgical errors based on a three stage surgical checklist (34). Based on an extensive review of epidemiological data organized to prioritize which were the most important topics that contribute to unsafe care within the surgical field, the group proposed a checklist that includes details that try to overcome the gaps between in-charge teams and different stages of the procedure. A great effort of preparedness and anticipation is summarized in this checklist. Another important aspect, regarding the effectiveness of the checklist is how the cross check is carried out. Different videos are available for proper training. Another relevant issue about surgical checklist is that they are effective. An interesting study has been performed using a stepped wedge cluster randomize controlled methodology that shows that the progressive introduction of the checklist, after adjusting for different confounding factors, decreased significantly the in-hospital mortality (35).

The European Association of Cardiothoracic Surgery (EACTS) in 2012 reviewed relevant and available evidences and recommendations in order to design specific checklists (36). They designed documents for thoracic and cardiac procedures and one common for cardiopulmonary transplant. Checklists are simple and easy to use. The thoracic one includes few implementations over the one proposed by the WHO (33).

A new tool: the ESTS checklist

Soon after the creation of the quality of life and patient safety committee in the society, a limited an informal questionnaire was launched to the different country representatives within the society in order to know the degree of interest and implementation of safety initiatives in each county. From the answers, it was inferred that western European countries were already working and implementing different safety initiatives. But at that

moment, in some eastern European countries, safety culture was not a priority.

The WHO checklist (34) is a basic, wide range document developed to fit in any surgical case in any settings all around the world. Thoracic surgeons are working in very complex units and performing very complex procedures that need the highest quality of safety to achieve the best possible results. Then, we wanted to create a checklist that

A

EUROPEAN SOCIETY OF THORACIC SURGEONS
ESTS

Patient label

ESTS SAFE SURGERY CHECKLIST

Date of Surgery:........./........./..........　　HIV/Hepatitis ☐　　Procedure:

BEFORE INDUCTION ON ANAESTHESIA: SIGN IN			
Patient identity checked	☐ Correct	☐ WRONG (Report)	
Consent checked	☐ Present	☐ Missing (Rectify before proceeding)	
Surgical side marked	☐ Yes	☐ Not marked (Confirm)	☐ N.A.
Patient known ALLERGY?	☐ No	☐ Yes: ☐ DRUGS ☐ LATEX ☐ OTHER	
Anticoagulation/Antiagregation adjustment performed?	☐ Non Applicable (NA) ☐ Yes	☐ No (Report)	
Premedication needed?	Profilactic Antibiotics ☐	Steroid Replacement Regimen: Yes ☐　　N.A. ☐	
Patient ASA class reported?	☐ Yes	☐ No (Confirm before proceeding)	
Anaesthesia safety check complete	☐ Yes	☐ No (Report)	
Fiberoptic Bronchoscope available	☐ Yes	☐ No (Report)	
Essential Monitory	☐ ECG ☐ Pulseoximetry	☐ Capnography	☐ ABP
Patient warming system	☐ Yes	☐ No (Inform)	
DVT prophylaxis	☐ Compression Stockings	☐ SQ Heparin	☐ N.A
Foreseeable patient anaesthetic problems	☐ No	☐ Yes, specify:	
Difficult airway	☐ No	☐ Yes ☐ Equipment/assistance available	
Risk of 500ml>blood loss	☐ No	☐ Yes ☐ Adequate IV acceses/ fluids planned	
Nursing team confirm equipment sterility	☐ Yes	☐ No (Report)	☐ N.A.
Surgical technical equipment available and checked?	☐ Yes	☐ No (Report)	☐ N.A.
Necessary implants on stand by	☐ Yes	☐ No (Report)	☐ N.A
BEFORE SKIN INCISION: TIME OUT			
Role and name of team members clear	☐ Yes	☐ No (Clarify)	
Surgical team confirm surgical site	☐ Yes	☐ No (Clarify)	
Surgical team confirm surgical procedure	☐ Yes	☐ No (Check and confirm)	
Surgical team confirm operative duration	☐ Yes	☐ No (Check and confirm)	
Essential images displayed	☐ Yes	☐ No (Display) ☐ N.A.	
Correct surgical position checked	☐ Yes	☐ No (Check before proceeding)	
Surgical site infection preparation	☐ Yes	☐ No (Prepare before proceeding)	
Foreseeable surgical problems	☐ No	☐ Yes, specify	
BEFORE LEAVING THE OR: SIGN OUT			
Counting of instruments, swabs, and sharps is complete?	☐ Yes	☐ No	☐ N.A.
Have the specimens being labeled appropriately?	☐ Yes	☐ No	☐ N.A.
Postoperative medical orders complete?	☐ Yes	☐ No	☐ N.A.
Any equipment problems to report?	☐ Yes	☐ No	☐ N.A.
SIGNATURES			

Nurssing staff　　　　　　　　　　Anesthesia　　　　　　　　　　First Surgeon

B

COMMENTS TO REPORT (IF APPROPRIATE):

NURSSING STAFF:

Signature

ANAESTHETIST:

Signature

FIRST SURGEON:

Signature

Figure 1 (A) ESTS checklist: obverse; (B) ESTS checklist: reverse. ESTS, European Society of Thoracic Surgeons. Available online: www. ests.org/safe_surgery.aspx

fitted the high requirements these complex procedures are demanding. Using the three stages format, we developed a new checklist (*Figure 1*) making more emphasis in accurate preparation of the patient (before induction on anesthesia). It is true that problems can appear also during the intraoperative period and after leaving the operating room, specially, because communication between successive teams may fail. During discussion, it was considered that the items already present at the WHO checklist were precise enough and needed no change. Furthermore, increasing

the awareness at the beginning of the procedure makes the whole process safer. Future analysis will agree or not with this statement.

As it was commented before, a great part of the problems are related to a wrong preoperative evaluation or assignation (24). Many of these problems, if detected, can be solved before proceeding. This was one of the main ideas when designing the document: if anybody during the crosschecking process detects a standard deviation, he or she has to know what to do next. Here, in every item,

S150

Novoa. ESTS checklist: an useful tool in general thoracic surgery

when a problem is detected, a short command will tell the person in charge how to proceed. Sometimes the command is to report the problem. This is another utility of this document: being an onsite reporting system (*Figure 1B*) to collect information from simple incidents to near-misses (without harm) or accidents (with harm). It can be argued that reporting systems are recommended to be confidential and voluntary but having real time prospective data will increase the quality of these notifications.

Finally, it is important to stress the fact that the ESTS checklist has been translated to 10 different languages in order to provide a ready to download document to those surgeons that need it. As more new languages are enrolled within the society more translations will be provided.

In conclusion, patient safety is becoming an important area of research and improvement to offer the best quality of care as possible. The ESTS checklist integrates the basic values introduced by the WHO to perform the preoperative cross check and introduces several innovations. These innovations are mainly related to several aspects of the preoperative allocation and preparation of the patient and try to anticipate and avoid some of the mistakes detected in previous works on this topic.

Acknowledgements

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