European Review for Medical and Pharmacological Sciences 2019; 23: 3129-3141

Parallelism between risk and perception of risk among caregivers during anesthesia delivery

L. DINIA[1], F. MANGINI[1,2], M.A. MARELLA[3], F. FREZZA[1]

[1]Department of Information Engineering, Electronics, and Telecommunications, Sapienza University of Rome, Rome, Italy
[2]Santa Lucia Foundation, IRCCS, Rome, Italy
[3]U.O.C. Intensive Care and Anesthesia – Department Critical Area, Hospital Santa Maria Goretti (ASL Latina), Latina, Italy

Abstract. **The paper examines the different perceptions of risk associated with anesthesia systems from the viewpoint of the product manufacturer and the caregiver. Only a little research has been done with regard to the impact of perception of risk on patient safety in anesthesia. The role of the manufacturer in mitigating the perception of risk will be central for the work. The risk will be examined as the probability of negative occurrences based on the Medical Device Reportable (MDR) events for 2016 and 2017 and it will be examined how the caregiver perceives and manages these risks when delivering anesthesia. Analysis of the manufacturer's public Medical Device Reportable events data will be performed in the US market and will represent the actual risk achieved; this review will provide a perspective on how the risk is perceived and managed by the caregiver when delivering anesthesia. The goals of the paper are to highlight how the role of the manufacturers can have an impact on the reduction of perception of risk, increasing patient safety, and showing how the perception of risk is usually magnified by the hospital personnel.**

Key Words
Perception of risk, Risk, Patient Safety, Anesthesia, Improvement, MDR events.

Introduction

Anesthesia is the practice of inhaling specific drugs, as volatile anesthetics, to produce the total lack of awareness and pain during surgical procedures[1]. For the long anesthetic-surgical procedures, the modern general anesthesia consists of a mix of an administration of a drug both intravenously and through the respiratory tract with gases and narcotic vapors. Because of the several consequences that the patient could report after the procedures, the anesthesia is considered to be high-risk in the healthcare field. But what does risk mean? What is risky? When is the risk acceptable? These are all questions that needed to be clarified over the years and nowadays they are addressed through the risk assessment[2]. The general anesthesia is a complex pharmacological and neurological condition characterized by the following:

- suppression of all sensations;
- suppression of awareness;
- reflectivity control;
- fast and complete reversibility;
- absence of toxic phenomena on the organism;
- ideal scenario for the surgical procedure in the context of operating field[3].

When anesthesia became an independent branch of medicine, experts started to wonder what the risk was during an average procedure for the patient. The meaning of risk has had an evolution over the years; initially for the anesthetic risk was intended exclusively the death as a consequence of delivering anesthesia beyond of any surgical cause[3]. However, death is not the only risk that the anesthesiologist has to take into consideration. Since anesthesia became a common practice, there have been complications related to eyes, such as compressive phenomena and corneal trauma, and to upper limbs such as paralysis due to compression and stretching of the nerves. The use of resuscitation techniques has allowed to fully recover several patients from the operating table, even with neurological deficits often irreversible[3]. However, there are many mental conditions that can be triggered by an anesthesia procedure, and patients can develop post-traumatic stress disorder (PTSD) due to awareness with explicit recall during the general anesthesia[4,5].

Corresponding Author: Lorenzo Dinia, MD; e-mail: lorenzo.dinia@uniroma1.it

Even if anesthesia is safer than ever in the present, a culture of safety is spreading in the healthcare system, trying to minimize the risks even further with a continuous improvement approach to reach a higher quality of service/product provided. The quality of service depends on many variables that play fundamental roles in the healthcare system including the technology used, the level of training, personality type as well as the perception of risk that can compromise clinical procedures[6]. The anesthetic mortalities and especially the unpredictable ones are notably decreasing over the years thanks to the use of new drugs, the technological advancement, the easiness to obtain a biochemical result, the respiratory control, and the improvement and enhancing of a general monitoring. The anesthetic risk and its importance in preventing adverse related events are linked to a continuous development of anesthesia monitoring and homeostasis of the patient. Tendentially, anesthesiologists are risk-adverse and very careful about patient safety because anesthesia can be critical without even having any therapeutic benefits[7]. The perception of risk may be considered the same as the perception of beauty, temperature or health; there are objective measures but they are inadequate in themselves due to subjective perception[6]. Anesthesia delivery is a branch of medicine in which the risk-benefit assessment is critical, therefore, the handling and confidence in the use of the technology can have an important impact on patient safety. Approximately 87% of all incidents that threaten patient safety in the medical environments, where patient monitoring takes place, are caused by human factors, as confirmed by several studies over the years starting from 1950[6,8]. The results of these research were not comparable because of constraints in the methodologies and limitation in the scopes, but one important result that emerged was the presence of non-traditional investigations to identify the characteristics of mishaps and to suggest improvements in patient care[7].

Manufacturers, in partnership with government agencies, are working toward the continuous development of safer health environments. The needs and expectations of the patients, the confidence of the caregivers and the safe products must meet each other in order to reach a higher level of patient safety.

Risk Perception

The survival instinct of all organisms gives the ability to sense and avoid harmful environmental conditions[9]. Learning from past experiences is another ability owned by all living organisms[9]. Humans have a further capability to reduce the risk, which is to change the surrounding environment as well as to respond to it[9]. In any humans' activities, there are risks that have to be faced. According to different studies on the perception of the risk, the major determiner of the public perception and acceptance of risk is given by feelings of dread[10]. For this reason, people are much more concerned about nuclear power than X-Ray radiation from a medical diagnosis[10].

In the current society, the majority of people confide on intuitive risk judgments, called risk perception[9]. Risk perception has been studied scientifically in the same way as, for instance, physical and chemical processes[2]. The approaches to study the perception of risk are three: the axiomatic measurement paradigm, the socio-cultural paradigm, and the psychometric paradigm[2]. In the current paper, the first and the third approach will be touched upon through the examination of the factors that influence the risk perception in delivering anesthesia.

Numerous studies on the risk perception confirmed the initial hypothesis that the risk can be quantifiable and predictable[2]. The judgment of lay people about the risk is related to many different factors as shown in the flowchart in Figure 1 for anesthesia delivery, *vs.* the clear experts' judge based on the technical estimates of annual fatalities[2]. Many models have been created and developed to represent the relationship among perceptions, behaviors and qualitative characteristics of hazards such as voluntary, chronic, common, certainly not fatal, immediate, known to science, not controllable, news[2]. These qualitative factors are just a few and each hazard has a unique pattern of qualities. A number of these qualitative risk characteristics make up a hazard's profile and they tend to be correlated with one another, for example, a risk that is voluntary is likely also to be controllable and well-known[2].

Although the dangerous and harmful events are real and objective and the risk can be numerically determined, the subjective perception of the risk plays a fundamental role introducing uncertainties in the outcomes and compromising the resulting behaviors[2]. For each person, the risk perception is based on objective factors but also on past experiences, and nowadays it is very much influenced by the news media too[1]. One of the main perceptions that the Americans are facing is that the risk today is greater than in the past and the phenomenon will continue

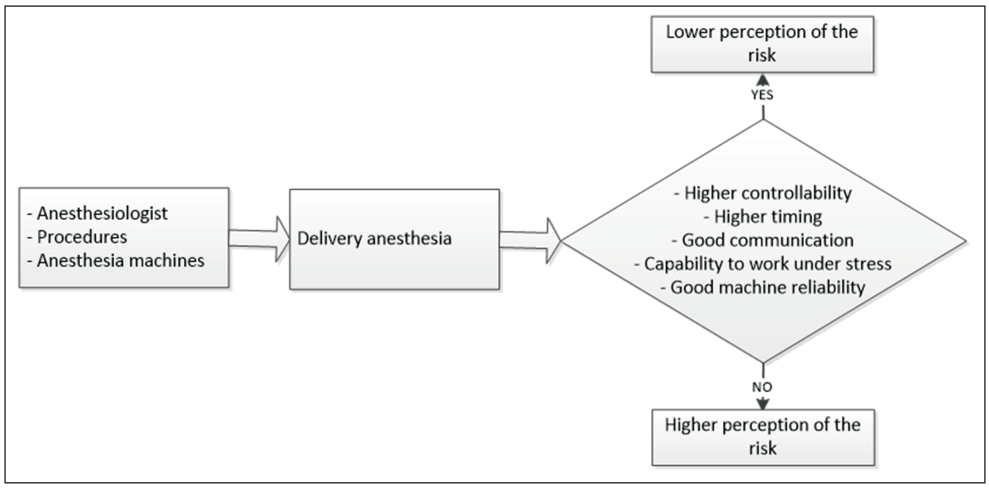

Figure 1. Perception of risk flowchart in delivering anesthesia.

to increase[1]. Naturally, this perception does not necessarily match the actual scenario that is based on the real negative occurrences, and therefore many factors have to be taken into account when the perception of risk is analyzed. Perception of risk can also have an impact on the society as on how information is reported, and the adverse events about a minor or major accident could be amplified and spread out affecting many other areas[2]. An example was given by the seven deaths due to the Tylenol tampering that, at the end, resulted in more than 125,000 stories in several printing media, causing a damage to the Johnson & Johnson Company (New Brunswick, NJ, US) of more than a billion dollars due to the damaged image of the product[2]. According to psychological studies, there are two fundamental ways in which humans process information: the former is a fast, mostly automatic, evolutionarily older system, not very accessible to the conscious awareness and control; while the latter is a system regulated by algorithms and rules, and is much slower and effortful[2]. In delivering anesthesia, all these aspects are playing an important role generating variability in the outcome of a specific event. Knowing the weaknesses and the criticalities during the anesthesia procedures, the operators can be educated and trained in order to keep them under control in case of any accidental event, following the system of rationality and conscious awareness.

Factors Impacting the Risk Perception

The risks are perceived by people according to the physiological orientation, the characteristics of the risk itself and other objective factors.

Controllability

The chance of an unexpected adverse event that cannot be controlled increases the perceived severity of the risk[6]. Human beings prefer to take risks that can be controlled in some ways, allowing them to take actions. The perception that a risk is in control gives a sense of safety, downgrading the perceived severity of the risk[6]. Another important aspect is the voluntarism of taking a risk. The perception of the specific risk will be downgraded, as confirmed for example by the difference in attitude towards the risk of contracting a Human Immunodeficiency Virus (HIV) infection from promiscuous sexual behaviors compared to the one from contaminated blood products[6]. The latter magnifies the perception of the risk, even if the outcome is the same. An anesthesiologist with high self-control and great knowledge about anesthesia will have a lower perception of risk compared to his colleagues, improving patient safety.

Sense of Timing

An immediate adverse event gives a higher severity of the risk perception compared to a delayed event[6]. This outcome is logical because, during an event that is delayed, there is time to take action[6]. Also, a transient or permanent hazard gives a different risk perception with the latter perceived as more threatening[6]. Anesthesia, with its sudden adverse events and its severity, is therefore generally perceived as a very risky medical practice[6].

Personal Characteristics

The perception of the risk also depends on the personality type of the individual. According to Gaba[7], one of the main experts in studying human factors related to anesthesia, the individuals

that embark the road to be anesthesiologists are typically a particular kind of person who looks for excitements in doing their work[6]. They are just attracted by the highest risk of the world of anesthesia[6]. This aspect can have an influence on how the objective risk is perceived by an anesthesiologist compared to a generic nurse or to external clinical personnel.

The mass media and the spread out of adverse anesthesia-related events have contributed to better identify the anesthesia practices and procedures[11,12]. Usually, a patient shows distress and anxiety before anesthesia. The distress is a psychological and physical illness that comes from the awareness of an imminent hazard and it is characterized by widespread fear which varies from disquiet until to panic attack. The anxiety can be constitutional of the patient (anxiety-personality) or it can come from the surgical context (anxiety-status). The anxiety that comes from either the anesthesia or the surgery does not have necessarily a negative impact on the perioperative period, and in other words, it is a normal psychological predisposition that allows the patient to overcome the procedure at best. Clinical studies highlighted difficulties to evaluate the degree of anxiety of the patient during the pre-anesthetic consultation because, if the anxiety can be expressed, it is often removed by introvert patients[13].

Communication

The communication is the act to translate the population risk data into clinical risk information that can be easily understood by everyone[6]. There are different categories of communication: verbal, written, with graph, charts or maps. In anesthesia, the purpose has always been to share the risk in terms of words or numbers that better convey the right information[6]. Usually, the risk converted into a probability format is not completely understood by the major part of people[6]. The problem of specific probability could be interpreted subjectively by each person without a statistical background. Just thinking about the communication of risk to patients gives the criticality of this aspect. One of the duties of the doctors is to explain the nature, the purpose and all other risk factors of the procedure in non-technical language. Usually, the concept of risk is not clearly defined by the doctor and this results in a lack of sufficient information provided to patients. The way in which risk information is presented heavily affects the perception of risk by doctors, nurses, and patients, hereby influencing decision-making[14]. Giving emphasis on the positive aspects of surgery results will have a persuasive effect on the patients to agree to treatments even if the two statements are objectively equal. Saying that the therapy is 70% effective has a different perception than stating that has a 30% of failure rate. This is known as positive framing and has an important impact on the perception of the risk[14].

Machine Reliability

Reliability plays a key role in the caregivers' perception of risk. Expectations concerning the life of an anesthesia machine may vary and may affect how the risk is perceived. Reliability is the ability of a product to perform its intended function over a period of time and under prescribed environmental conditions[15]. The main factors that can affect the reliability, and thus the perception of risk, are improper design, poor construction materials, faulty manufacturing of assembly, inappropriate testing, damages during shipment, improper start-up, physical damages, lack of maintenance, just to name a few[15]. This explains why the manufacturer must pay attention to the customer's expectations concerning the product's intended life and environmental condition for use. An anesthesia machine that has several failures over its life increases the perception of risk of the operators in using it, that's why it is very important also to adopt a preventive maintenance program to increase the effectiveness, to lower the risk of failure, and to increase component life.

Critical Relationship Between Anesthesia Delivery and Patient

One of the main aspects of the evaluation of anesthetic risk is the clinical status of the patient before the surgery. Regarding this aspect, a large portion of anesthesiologists refers to the "American Society of Anesthesiologist" (ASA) classification which considers the patients divided into 5 classes (Table I) depending on their "physical status"[16].

Table I. Event result distribution for 2016 and 2017.

Class	Physical Status
I	A healthy patient
II	A patient with mild systemic disease
III	A patient with severe systemic disease that is a constant threat to life
IV	A patient with incapacitating disease that is a constant threat to life
V	A moribund patient who is not expected to live 24 hours with or without surgery
E	Emergency case

The E letter is added to the classes of Table I when the operation is carried out in an emergency. The ASA classification is not a direct formulation of the anesthetic risk; it is often used thanks to the simplicity and great predictive value. The main weaknesses of the ASA classification are ignoring the age of the patients, the type of surgery and the type of anesthesia. Moreover, some complications in delivering anesthesia are unpredictable like anaphylactic reactions, prolonged curarization, and incidents due to human errors or machine failures. Despite these considerations, the ASA classification is a useful indicator[13]. A patient that is classified ASA3 or ASA4 makes the anesthesiologist be alert and it justifies specific anesthetic techniques and monitoring devices, like, for instance, in the case of super obese patients[17].

In the clinical practice, the use of systematic tests for evaluating the level of anxiety of the patients is not feasible. The empathetic and careful attitude of the anesthetist and the collected information play an essential role in reassurance from eventual expressed and hidden fears.

Critical Relationship Between Anesthesia Machine and Operator

The set-up of the anesthesia machine in the operating room can also lead to errors. Figure 2 shows a typical anesthesia machine set-up in a hospital. The configuration of cables, hoses, and different surgery tools can be messy and lead to human errors. A neat and organized configuration can reduce the operator's perception of risk because it provides the feeling of shorter response time in case of emergency.

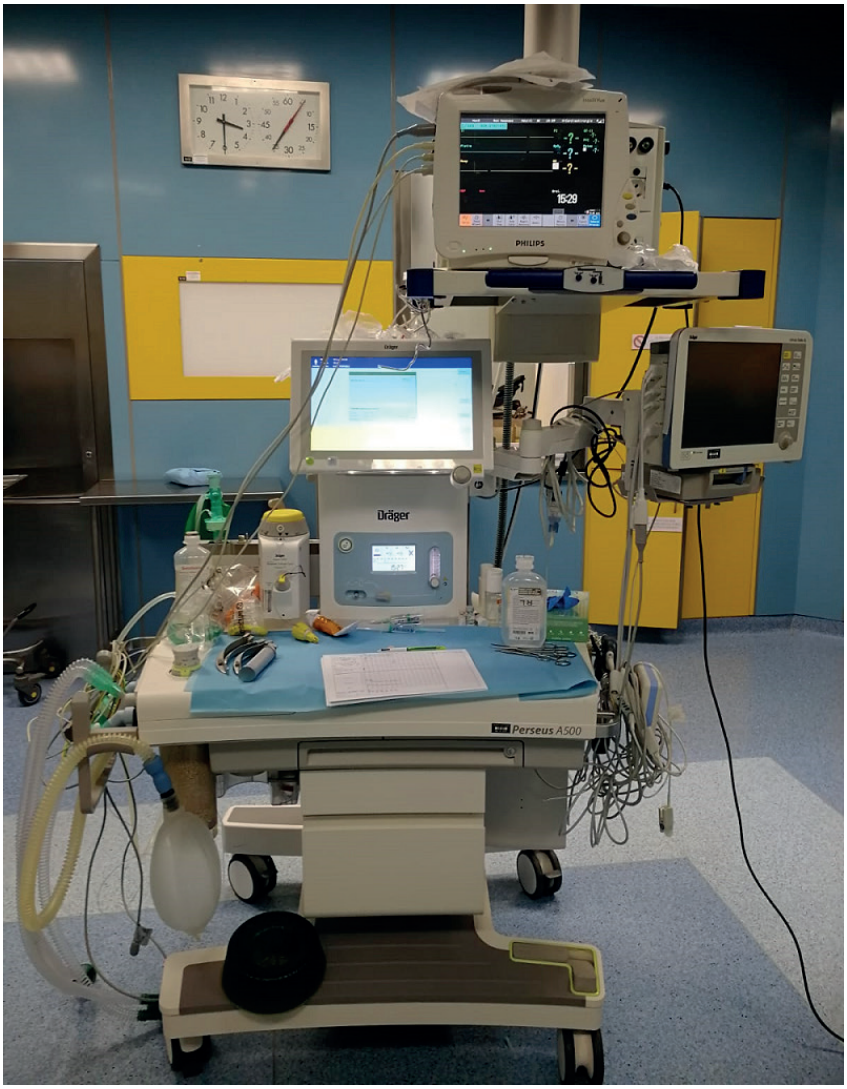

Figure 2. Typical anesthesia machine set-up during a case.

An anesthesia machine can be affected by several failure modes, categorized into the 4 groups below:

- pneumatic leak;
- display assembly failure;
- electronic failure;
- vaporizer and gas module failures.

The impact that these failures have on the perception of risk is very critical both in case of real failures and apparent ones. An aspect that increases the breakdown rate for the anesthesia machines is the use of improper cleaning agents (not-recommended by manufactures) or improper cleaning methods; this contributes to giving an impression of unreliable devices, increasing the perception of risk.

Statistics on the Perception of Risk

Anesthesia is a branch of medicine where adverse events are more frequent than in many other branches. Precise and accurate reporting of adverse events and errors are considered to be necessary for improving patient safety[18] because "you can't fix what you don't know about"[19]. Despite the expectation that adverse events are reported correctly, usually attitude, emotional and possible human errors during the procedures may bias the reporting of these events[18].

In the hospitals, and especially in the operating rooms, where the anesthesia machines are used, there are physicians, nurses, anesthesiologists, patients, and each one has different ways to describe the same event and to perceive risks[20].

Many studies have been conducted to analyze the tendency of adverse events in anesthesia over the years. In a 2012 study, 4244 anesthesia procedures were analyzed, with 1.25% having complications. This result was compared to the previous year with a percentage of complications of 5.4%[21]. A tendency to reduce the number of complications was noticed[21]. The reduction of adverse events was the result of continuous reporting that led to an increase of awareness of the events and an adoption of preventive measures[21].

The perception of risk was also analyzed during the researches to explore acceptable critical practices in anesthesia. Workplace observations and interviews, directed by Smith et al[22], were conducted with anesthesiologists and anesthetic staff. 19 interviews and over 130 hours of observation were recorded[22]. During the course of 50 anesthetic procedures, 103 minor events were observed. None of them was considered by the caregiver important enough to offer the potential to improve safety[22]. An interesting result showed that during the departmental meeting at the hospital, the medical staff discussed just 28 of these events and just 5 of them were considered critical[22]. The conclusion of this study gave the opportunity to focus on how the words "acceptable" and "critical" were perceived and, thus, how the risk was perceived. Unfortunately, this subjective perception affects the formal reporting of the adverse events[22]. During the interviews at the hospital personnel about critical cases, two factors seemed to be very important in affecting the procedures. The first is the controllability, which means to be in control or having the perception to be in control; giving some doctors the license to downgrade some high-risk events. The second is the miscommunication among the different figures working in the operating room about the risk, where each one is having a different perception. According to the result of the study conducted by Smith et al, anesthesiologists perceive adverse events as "significant moments" in the acquisition of their expertise[22], fundamental to improve the controllability and timing for the likely future of critical events. At the same time reporting adverse events could lead to criticism and censure from colleagues[22]. For this reason, sometimes they are not reported, since they considered them as not critical.

According to further past studies, the equipment is involved approximately in between 15%-30% of all the intraoperative problems, and the delivery equipment for anesthetic and oxygen is responsible for most of the failures[23]. Human error seems to be responsible for around 90% of the failures involving the anesthesia equipment[23]. According to another study[24], the actual equipment failure constitutes just about 15% of the total number of preventable incidents and 82% of the incidents for the total number of the anesthesia procedures involves human errors. By understanding where these user errors originate from, design changes or other remedies can be adopted and patient safety can be improved.

Characterization of the Risk

Risk has different meanings: it can be intended for example as hazard, as probability, as consequence, as potential adversity or threat, and this is another reason that often causes issues in communication[2].

In this paper, the risk is the probability of negative occurrences based on the MDR events. In Figure 3, a fish-bone diagram shows the main causes of risk in anesthesia, viewed as causes of adverse events.

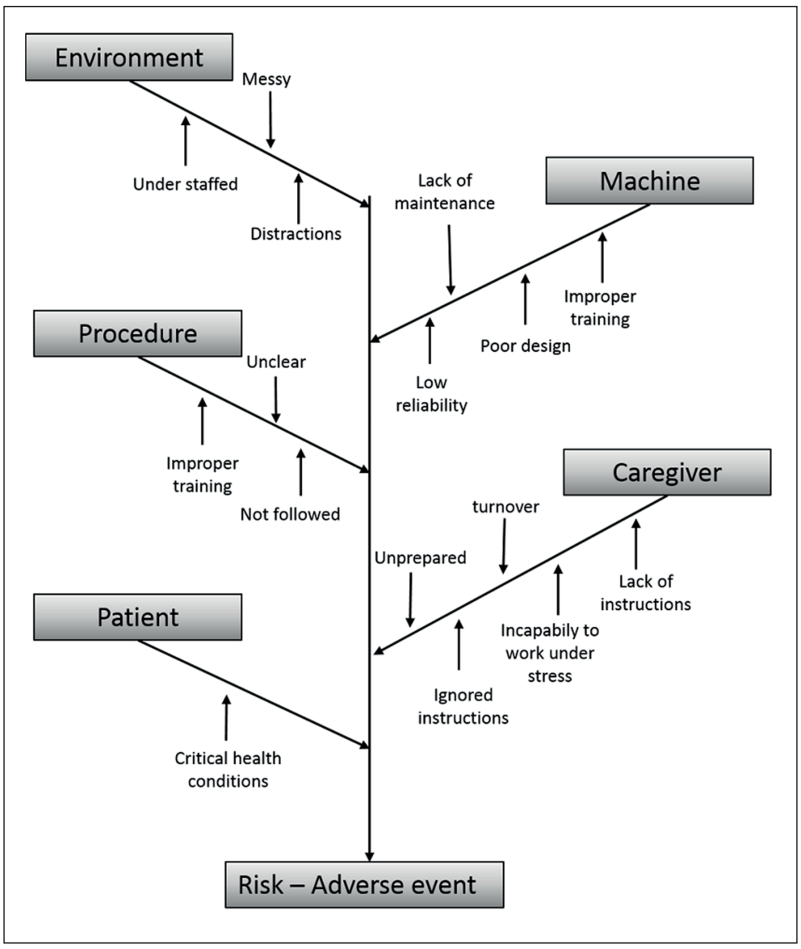

Figure 3. Cause-and-effect diagram for risk-adverse events.

Typically, in the healthcare system the tendency is to evaluate the hazards through risk management, which are all the policies and procedures to the task of analyzing, evaluating and controlling the risk, and through risk control, which is a process with the purpose of reducing risks and maintaining risks under control. Severity, occurrence, and detectability are the three factors used to assign the priority in order to control specific risks. According to psychologists, people are more afraid of risks that are more severe but with a low probability than they are about the contrary risks[6]. To measure the risk in the past, some mathematicians tried to quantify risks introducing expectation value defined as follows:

Expectation value = probability × severity (1)

The risk is quantified by manufacturers as the product of:

$$R = S \times O \times D \quad (2)$$

where R is the measure of risk, S is the severity, O the occurrences and D the detectability. The use of severity and detectability provide an estimation of the risk but, because they are subjective and culturally constructed, it can never actually be measured[6].

The Medical Device Reportable events are used to quantify the actual risk according to the manufacturer.

Risk as Adverse Events Reported

In the US market, there are more than 50,000 anesthesia machines and this market worldwide was estimated at US$8.1 billion in 2013 and it is projected to reach US$11.8 billion by 2020[25].

The actual risk is based on the Medical Device Reportable events collected over 2016 and 2017. The analyzed data in this study were collected by MAUDE (Manufacturer and User Facility Device Experience), a database where manufacturers, importers, and device user facilities submit MDR events to FDA (Food and Drug Administration). In Figure 4 the distribution of MDR events

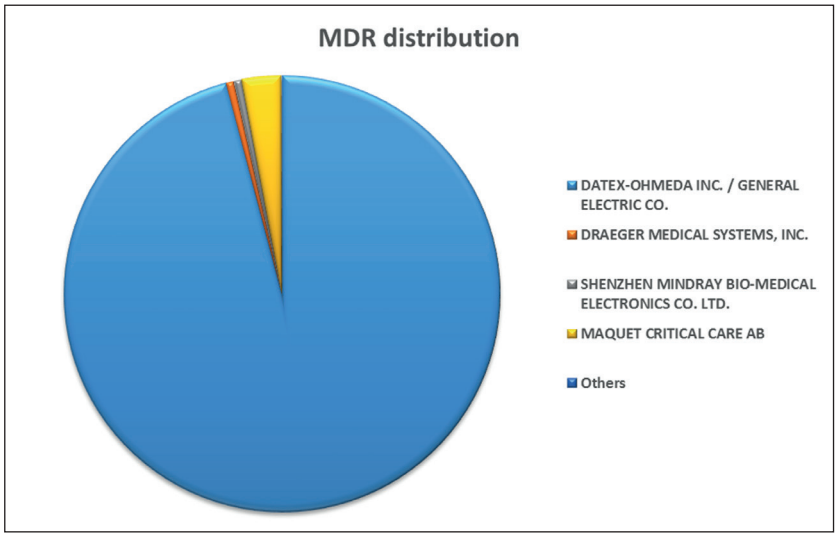

Figure 4. Distribution of medical device reportable events in US market over 2017.

reported by the main manufacturers for 2017 is shown. Datex-Ohmeda Inc./General Electric CO. (Boston, MA, US) reported 2135 events, Draeger Medical Systems, Inc. (Lubecca, Germany) reported 13 events, Shenzhen Mindray Bio-Medical Electronics CO. LTD. (Shenzhen, China) reported 10 events, and Maquet Critical Care AB (Rastatt, Germany) reported 65 events. For these events, the manufacturer "became aware of that reasonably suggested that a device has or may have caused or contributed to a death or serious injury or there was a malfunction that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health"[26]. "Cause or contribute means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including an event occurring as a result of failure, malfunction, improper or inadequate design, manufacture, labeling or human error"[26].

A manufacturer can follow the FDA regulations - 21 Code of Federal Regulations part 803 - with two different approaches. The first is a more conservative one, while the second is more radical, reporting almost only cases in which adverse patient events were reported by the caregivers. General Electric CO. reported around 96% of the total MDRs, suggesting that they might have a conservative approach in submitting MDRs and because they might have the biggest portion of the US market[27].

Figure 5 shows the distribution of the event type for the total MDRs reported in 2016. The category malfunction is 98.93% of the total MDRs, while the death is 0.37% and the injury is 0.70%.

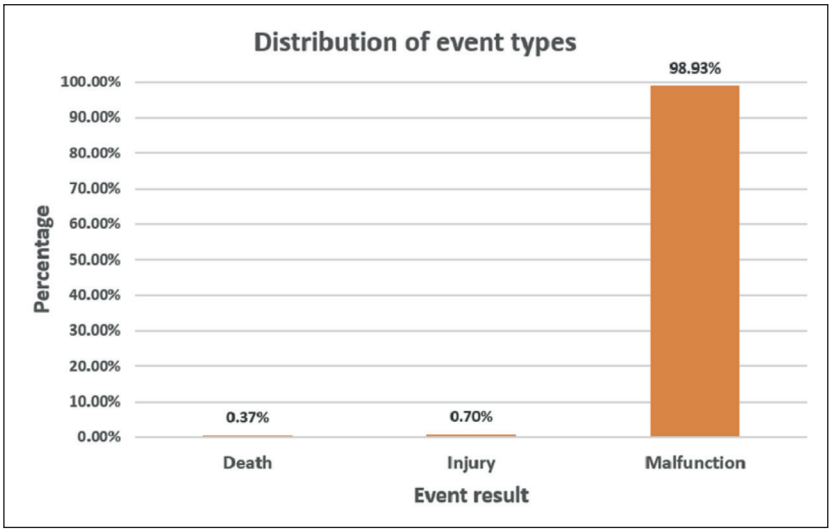

Figure 5. Percentage distribution of event types for the MDR events reported in US over 2016.

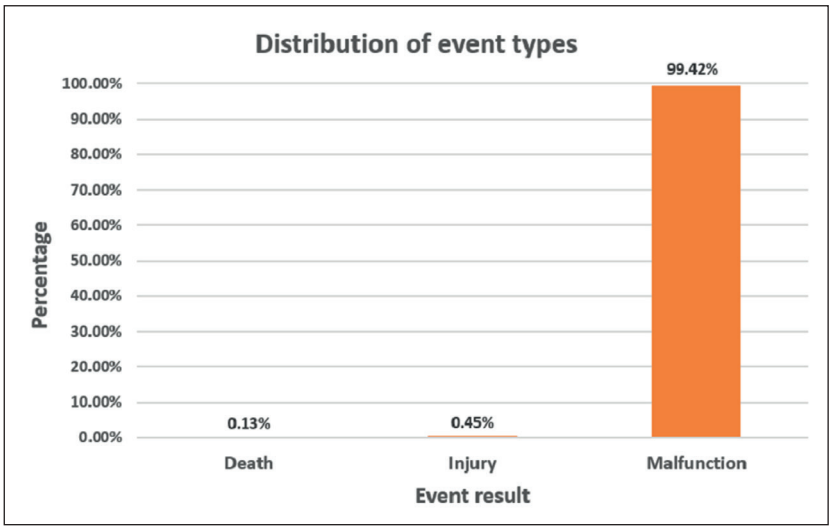

Figure 6. Percentage distribution of event types for the MDR events reported in US over 2017.

Figure 6 shows the distribution of the event type for the total MDRs reported in 2017. The category malfunction, 99.42% of the total MDRs, contains the category of human error, which provides a measure of the actual risk from the manufacturer perspective.

The comparison, in Table II, between the 2016 and 2017 shows an improvement in term of numbers of deaths and injuries, even though a higher total number of MDRs was reported in 2017 with respect to 2016. The total MDRs reported to FDA in 2016 is 2135, with 8 cases of death and 15 injuries. In 2017 the total MDRs reported is 2226 with a decrease of deaths and injuries, 3 and 10 respectively. The increase of MDRs in 2017 is the result of the market growth for anesthesia machines. The decrease of deaths and serious injuries is due to better training of the hospital personnel year by year and a higher devices reliability.

Figure 7 shows the distribution of MDRs reported in the US over 2017. An increasing trend, shown by the dotted linear regression, is displayed over the year as well as a slightly higher distribution during the summertime and the last two months of the year.

Table II. Event result distribution for 2016 and 2017.

	Event result			
	Death	Injury	Malfunction	Tot
2016	8	15	2112	2135
2017	3	10	2213	2226

[a]Comparison of event results for 2016 and 2017

The comparison between the MDRs reported in 2016 and 2017 (Figure 8) highlights an increasing trend each month, passing from 2016 to 2017. As stated above, this trend is the result of an abnormal growth of the anesthesia machine market with new hospital personnel in need of training on even more complex software and hardware. This trend suggests a tendency of an increasing number of MDRs reported in the following years.

A review of some of these reports provides an estimation of the actual risk based on the percentage of human errors. Some Draeger Medical Systems, Inc. (Lübeck, Deutschland) and Shenzhen Mindray Bio-Medical Electronics Co. Ltd. (Shenzhen, China) MDRs were reviewed.

As discussed above, the total number of adverse events in delivering anesthesia are mainly caused by factors that do not involve the anesthesia machines. An accurate analysis was performed for 13 events, and it was found that the devices performed according to the manufacturer's specifications in almost all the circumstances and external factors, were responsible for the failures[27]. In three of these adverse events, the conditions of the patients were already very critical before the beginning of the procedure with severe pulmonary diseases, pulmonary hypertension (HTN), and swings in heart rate and blood pressure. For these three cases, there were no signs of malfunctions for the machines, but the critical conditions of the patients and the risk of negative consequences during and after the surgery increased the caregiver's perception of risk, therefore possibly blaming the machines for unrealistic failures. A further high-risk event was reported when smoke was coming out of a machine

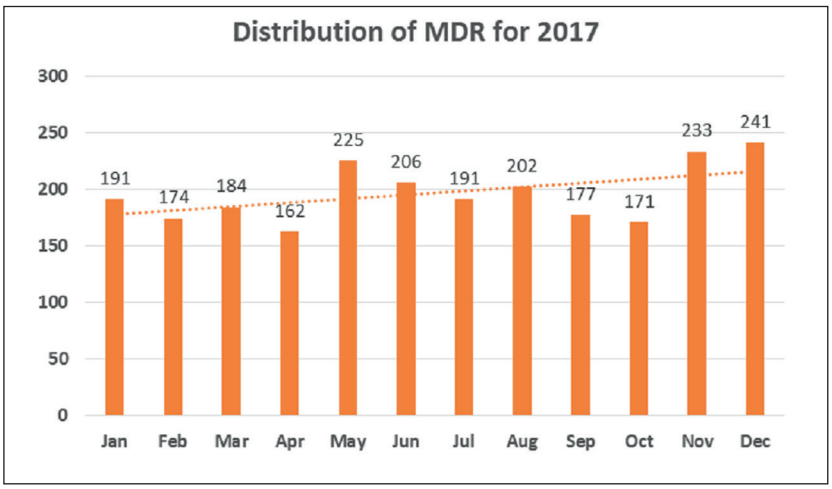

Figure 7. Distribution of MDR events reported in US over 2017.

before it was used on a patient. In this case, an investigation by Mindray DS USA, Inc. (Mahwah, NJ, USA) showed traces of liquid on top of the machine with the liquid entering the device making contact with the electronic parts. The outcome for the hospital personnel could have been tragic because of negligence or carelessness. In another adverse event reported, the patient was bagged manually by the anesthetist for the entire duration of the surgery. The customer stated that the device was delivering low volume during automatic ventilation. It was discovered during the investigation that the customer did not follow the instruction on the absorbent canister and neither the instruction on the wrap of the soda-lime absorbent, forgetting to remove the plastic wrap from the top of the part. Another event was related to a unit that did not work properly, which caused the automatic ventilation to stop, and multiple doctors incurred in this accident. After the deep investigation, Draeger stated that the hospital needed just a deeper training and no malfunctions were confirmed.

In all the 13 events reviewed, the risk perceived by the caregiver was extremely high because of the consequences that the patients could have had[27]. During the adverse events, the caregiver perceived a high-risk due to a reduction of the controllability, an increase of the severity for the crucial timing in taking decisions, an altered communication due to the status of stress, and a perception of failure of the device. All these factors contributed to an increase in the perception of risk tremendously. The proper investigations following the events showed that for 12 out of 13 events the root cause was the human error. The events were caused by improper behavior/distraction or very critical conditions of the patients before the cases.

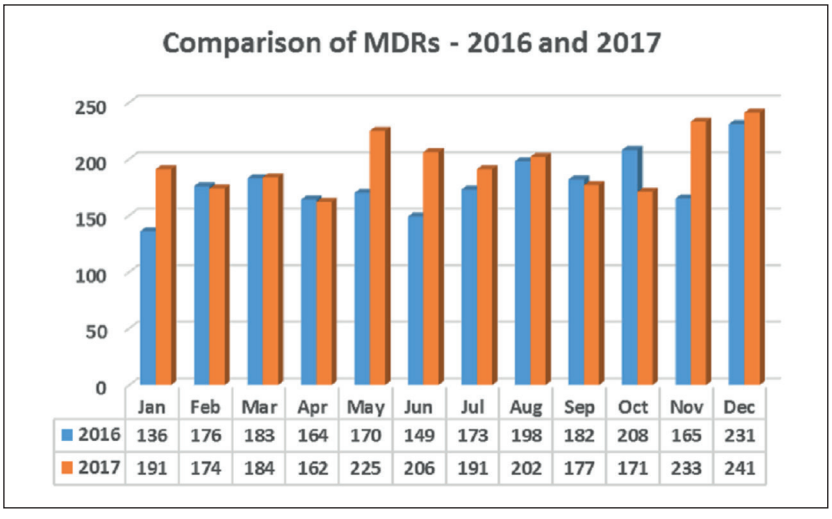

Figure 8. Comparison of MDR events reported in US for 2016 and 2017.

Discussion on the Improvements

From an analysis of the MDR events, a tremendous educational value can be obtained for the manufacturers and the hospital personnel in order to find preventative and corrective measures to improve patient safety. After reviewing the data, it can be evaluated if the design changes on the devices may be necessary or if a different and longer training needs to be offered to the caregivers. Unfortunately, even though the potential of collecting complaints is known, much clinical personnel lack to report complications because of the sense of fear or guilt coming from the other colleagues[22]. In this context, the work of the manufacturer is crucial in training the caregiver on the use of the machines, but also to raise awareness of the importance of reporting events to improve the work quality of anesthesiologists and to increase the patient safety. When either an emerging or a recurring issue is identified by a manufacturer after the investigation, a risk assessment is required. The risk is assessed to understand if actions have to be taken just to improve the performance and the quality of the device or if any corrective action should be taken because the risk needs to be reduced for the public health. From the analysis of the adverse events of 2017, it was found that the human error was almost the only root cause, sometimes showing negligence, improper behaviors and carelessness from the caregiver[27]. Also, the lack of familiarity with the anesthesia machine is a source of errors, because of the perception of not being completely in control of the equipment. These two aspects can be improved with new methods of training, reducing the perception of risk in delivering anesthesia.

Assigning an arbitrary number to the anesthetic risk that has a general application does not fit the clinical needs. Since the first procedures, the anesthesiologists felt the need to give a numerical evaluation of the risk that a specific case could have had for a patient. In this context, the first scores were created with a 1 to 3 scale for the importance of the case and from 1 to 3 depending on the critical conditions of the patient[3]. The two scores were summed obtaining a value between 2 and 6 that still indicates a risk factor[3].

According to prior studies, people with strong initial opinions are hard to change their ideas even in the presence of evidence[9]. This behavior depends on how the information is interpreted[9]. One innovative way of presenting the same information about risk is to reinforce positive statements to alter people's attitude and perception, for example, showing the survival rates instead of the mortality rates[9]. In the last years, many engineering improvements have been made on the anesthesia machines to prevent human errors, for instance, through manufacturing the cylinder and gas hoses with specific keys in order to avoid the connection at the wrong place. All these technological solutions have the purpose to improve patient safety through a reduction of errors.

One of the causes of errors that can have an important effect on the perception of the risk is the physical and mental condition that the clinicians and anesthesiologists have while practicing. When the medical operators are under fatigue, illness or stress[7] the risk could increase, affecting the final performance of the procedure and reducing patient safety. Sometimes, indeed, the caregiver is forgetful or distracted during the set-up phase of the device and this can negatively impact the good outcome of the procedure. Nowadays, the anesthesia machines have several automatic preliminary tests that can help the work of the clinicians, but at the same time errors can be made by skipping some of these fundamental tests (mostly leak tests). As discussed in the prior section, some operations have to be performed by the clinicians manually, such as removing the plastic cover on the soda-lime absorbent for the CO_2 before installing the same in the machine. Even if there are clear labels on the part and on the machine, the risk to make errors is around the corner. A solution for the reduction of human errors can be provided with the use of checklists[20]. Anytime during the start-up phase, the operator responsible for the functional checks should be filling a detailed checklist, signing the final report. This measure would reduce the opportunity to make errors due to distractions, lack of following the procedures properly and wrong initiatives due to different attitude and perception. Even though the checklists have great potential to reduce risks and to improve safety, they are underused[20] for different reasons. A great improvement in delivering anesthesia can be made by a specific training through the simulations of real cases[23]. Many studies showed that hospital personnel learns much more during emergencies and unexpected events than during routine cases. The confidence and the knowledge of the anesthesiologists can be improved during the simulation to lead to a deeper understanding of how the device works, and thus to be more reactive in the potential adverse situations[23]. A further factor that in-

creases the perception of risk in anesthesia is the use of non-recommended and aggressive cleaning solutions to prevent that germs and bacteria could spread out and create infections. Often this behavior affects the quality and the performances of devices because during the pre-market tests only a specific range of cleaners and disinfectants are approved. The result is a reduction of the reliability of the devices, increasing the perception of risk. The use of appropriate labels or markings on the chassis of the devices may help to discourage the use of non-recommended cleaning agents and to educate hospital personnel. From the analysis of the adverse events reported, the episode with smoke coming out of a machine provides hints on the importance of education. Negligence, incompetence, and carelessness are sometimes responsible for adverse events. Greater responsibility and common sense could be increased with courses in which basic concepts, combined with graphic examples of the consequences, are explained.

According to the Institute of Medicine (IOM), an excellent healthcare delivery system is based on preventing errors, on learning from errors that do occur, and on a comprehensive culture of safety[28]. Manufacturers play a key role in improving the quality of care delivered. The IOM defines patient safety as "the prevention of harm to patients"[28].

According to the IOM: "the biggest challenge to moving toward a safer health system is changing the culture from one of blaming individuals for errors to one in which errors are treated not as personal failures, but as opportunities to improve the system and prevent harm"[29].

Conclusions

The direct contact between the patient and the anesthesiologist, before the procedure, is an essential step to assure an optimal final outcome of the anesthetic procedure. Even though the perception of the risk is often magnified because of factors such as distractions, lack of confidence in using the equipment, and miscommunication between the hospital personnel, just to cite few, the supervision of the anesthesiologist is crucial to reduce the actual risk, avoiding adverse events due to the misuse of anesthesia machine or to errors in the clinical procedure, which together are more than 80% of the total incidents. The comparison between the MDRs reported in 2016 and 2017 showed a growing trend suggesting a tendency of an increasing number of MDRs reported in the following years also due to a market growth. The analysis in the current paper shows that the perceived risk of the hospital personnel is usually higher than the actual risk quantified through the quality management system by the manufacturers.

Conflict of Interests

The Authors declare that they have no conflict of interests.

References

1) Branca FP. Fondamenti di Ingegneria Clinica. Springer, 2002.
2) Slovic P, Weber EU. Perception of risk posed by extreme events. Conference on Risk Management Strategies in an Uncertain World Conference, 2002.
3) Bellucci G, Damia G, Gasparetto A. Trattato enciclopedico di anestesia, rianimazione e terapia intensiva. Anestesiologia generale, Piccin – Nuova Libraria, 1990.
4) Aceto P, Perilli V, Lai C, Sacco T, Ancona P, Gasperin E, Sollazzi L. Update on post-traumatic stress syndrome after anesthesia. Eur Rev Med Pharmacol Sci 2013; 17: 1730-1737.
5) Radovanovic D, Radovanovic Z. Awareness during general anaesthesia – implications of explicit intraoperative recall. Eur Rev Med Pharmacol Sci 2011; 15: 1085-1089.
6) Adams AM, Smith AF. Risk perception and communication: recent developments and implications for anesthesia. Anaesthesia 2001; 56: 745-755.
7) Gaba DM. Anaesthesiology as a model for patient safety in health care. BMJ 2000; 320: 785-788.
8) Walsh T, Beatty PC. Human factors error and patient monitoring. Physiol Meas 2002; 23: R111-R132.
9) Slovic P. Perception of risk. Science 1987; 236: 280-285.
10) Slovic P, Peters E. Risk perception and affect. Psychological Science 2006; 15: 322-326.
11) Moerman N, Van Dam FSAM, Oosting J. Recollections of general anaesthesia: A survey of anaesthesiological practice. Acta Anaesthesiol Scand 1992; 36: 767-771.
12) Swinhoe CF, Groves ER. Patients' knowledge of anaesthetic practice and the rôle of anaesthetists. Anaesthesia 1994; 49: 165-166.
13) Haberer JP. Consultation préanesthésique. Encyclopédie Médico-Chirurgical 2001; 36: 1-12.
14) Malenka DJ, Baron JA, Johansen S, Wahrenberger JW, Ross JM. The framing effect of relative and absolute risk. J Gen Intern Med 1993; 8: 543-548.
15) Summers DCS. Quality. Pearson Education, 2006.
16) Osswald PM, Swars O, Levfke P. 10 scores, scorning and outcome: correlation between preoperative assessment and post-operative morbidity and mortality of non-hospitalized and hospitalized patients. Int J Surg 1998; 12: 471-483.

17) Siampalioti A, Karavias D, Zotou A, Kalfarentzos F, Filos K. Anesthesia management for the super obese: is sevoflurane superior to propofol as a sole anesthetic agent? A double-blind randomized controlled trial. Eur Rev Med Pharmacol Sci 2015; 19: 2493-2500.

18) Heard GC, Sanderson PM, Thomas RD. Barriers to adverse event and error reporting in anesthesia. Anesth Analg 2012; 114: 604-614.

19) Bagian JP, Lee C, Gosbee J, DeRosier J, Stalhandske E, Eldridge N, Williams R, Burkhardt M. Developing and deploying a patient safety program in a large health care delivery system: you can't fix what you don't know about. Jt Comm J Qual Improv 2001; 27: 522-532.

20) Winters BD, Gurses AP, Lehmann H, Sexton JB, Rampersad CJ, Pronovost PJ. Clinical review: checklists - translating evidence into practice. Crit Care 2009; 13: 210-218.

21) Belavic M, Lončarič-Katušin M, Žunič J. Reducing the incidence of adverse events in anesthesia practice. Period Biolog 2013; 115: 145-148.

22) Smith AF, Goodwin D, Mort M, Pope C. Adverse events in anaesthetic practice: qualitative study of definition, discussion and reporting. Br J Anaesth 2006; 96: 715-721.

23) Dalley P, Robinson B, Weller J, Caldwell C. The use of high-fidelity human patient simulation and the introduction of new anesthesia delivery system. Anesth Analg 2004; 99: 1737-1741.

24) Cooper JB, Newbower RS, Long CD, McPeek B. Preventable anesthesia mishaps: A study of human factors*. Qual Saf Health Care 2002; 11: 277–282.

25) Industry Experts. Anesthesia Devices – A Global Market Overview, 2013.

26) U.S. Food & Drug Administration. Code of Federal Regulations Title 21 part 803, 2016.

27) Dinia L, Mangini F, Frezza F. Can the perception of risk be decreased among caregivers during anesthesia delivery?, 2018 IEEE International Symposium on Medical Measurements and Applications (MeMeA), 2018.

28) Aspden P, Corrigan JM, Wolcott J, Erickson SM. Patient safety: achieving a new standard for care. Washington DC: National Academies Press (US), 2004.

29) Institute of Medicine (US) Committee on Quality of Health Care in America. Crossing the quality chasm: a new health system for the 21st century. Washington DC: National Academy Press (US), 2001.