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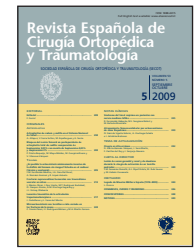

REVIEW ARTICLE

Wrong site surgery

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Abstract
The term "wrong site surgery" refers to surgery carried out on the wrong side, in the wrong anatomical area or in the wrong patient. It can also indicate that the surgical procedure employed was not the one intended. In spite of being a rather neglected topic, wrong site surgery is a fairly usual complication in a surgeon's professional life – orthopaedic surgery being the speciality most at risk. Media reports on this subject undermine the general public's distrust of the health care system, surgeons more often than not having to face serious legal consequences. There are at present several easy-to-apply protocols, among them those proposed by the American Academy of Orthopaedic Surgeons (AAOS) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), which can help preventing these unfortunate occurrences. They basically consist in checking the patient's details, marking the area to be operated and performing a final run-through just before starting the surgical procedure. It is of essence to introduce such a protocol in our own hospitals, with the support of all parties involved, in order to effectively address this problem.

PALABRAS CLAVE
Cirugía en sitio erróneo;
Error quirúrgico;
Lado erróneo;
Protocolo universal;
Suceso adverso

Cirugía en sitio erróneo

Resumen
El término ''cirugía en sitio erróneo'' engloba aquella cirugía que es realizada en el lado erróneo, en una zona anatómica errónea, en el paciente erróneo o en la que se realiza un procedimiento diferente al planeado. Pese a estar claramente poco comunicada, es una complicación frecuente en la vida profesional de un cirujano, siendo la cirugía ortopédica la especialidad con mayor riesgo. La repercusión mediática aumenta la descon-

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fianza en el sistema sanitario y las consecuencias legales para el cirujano son la norma. En la actualidad hay varios protocolos, entre ellos los propuestos para evitar esta complicación por la American Academy of Orthopaedic Surgeons (AAOS) y la Joint Comission on Accreditation of Healthcare Organizations (JCAHO), de fácil aplicación. Consisten básicamente en comprobar los datos del paciente, marcar la zona que se va a operar y realizar un ''tiempo muerto'', una comprobación final, justo antes de iniciar la cirugía. Es fundamental su implantación en los centros de España, con la colaboración de los diferentes estamentos, para una prevención efectiva de este problema.

Introduction

The term "wrong site surgery" refers to surgery performed on the wrong side, in the wrong anatomical area or in the wrong patient. It also includes performing the wrong procedure in the right patient. Although these errors have catastrophic consequences and in spite of the fact that this is an easily avoidable complication, reports of new cases of wrong site surgery are fairly frequent. Wrong site surgery results in a large amount of negative effects that affect both the patients' health (they suffer unnecessary damage and do not receive the treatment they require in a timely fashion) and the prestige and credibility of physicians and the healthcare center they belong to. It cannot be forgotten that these cases normally receive widespread media coverage, which goes beyond the doctor-patient relationship and affects the medical profession at large. New cases of wrong site surgery make patients develop negative perceptions of and a deep mistrust in the healthcare system.

Orthopedic surgery is a case in point. In the majority of cases, the surgeons has to deal with paired anatomical structures, on both sides of the patients' body, often without any external evidence of the nature of the problem, which of course makes error more likely.

In fact, errors in orthopedic surgery account for between 41 and 68% of total, followed by general surgery (20%), neurology (14%) and urology (11%)[1]. The most frequently affected anatomical area is the knee, followed by the foot and the ankle. Specifically, knee arthroscopy seems to be the most error-prone procedure[2].

Although confusion regarding the side to be operated may be understood, the 150 cases studied by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) merely account for 59% of wrong site surgery episodes. In 19% of cases, surgery was conducted in the wrong anatomical area; in 12% surgery was conducted in the wrong patient and in 10% the wrong procedure was performed in the right patient[1].

The incidence of these episodes would seem to be higher than initially believed, in spite of the scantiness of reports both in the medical literature and in specialized fora. Meimberg et al studied the incidence of wrong site surgery in the members of the American Society for Surgery of the Hand (ASSH)[3]. The Society's 1,560 members were administered a survey (response rate: 67%), which revealed that 21% of them had performed a wrong site surgery at least once and 16% had draped the wrong site and become aware of their error before starting the procedure. Two percent of respondents had erred on 2 occasions. The most common error (63%) was operating on the wrong finger. There was a significant correlation between the incidence of wrong site surgery and the annual number of surgeries performed, and a non-significant relationship with the age and length of service. Incidence was one case in every 27,686 procedures.

The incidence of wrong site surgery in spine surgeons could be much higher than this. Mody et al[4] administered a questionnaire to all of the 3,505 members of the American Association of Neurologic Surgeons (AANS); the response rate was 12% (98% were neurosurgeons). Fifty percent said that they had had at least one episode of wrong site surgery, 23% had had 2 episodes of wrong site surgery and 12.5% had had 3 episodes of wrong site surgery. This meant that wrong site episodes occurred once in every 3,110 procedures, a rate 9 times higher than that for hand surgery. Seventy one percent occurred in the lumbar region, 21% in the cervical region and 8% in the thoracic region. The incidence of wrong site surgery increased with age and length of time in practice. Annual risk decreased significantly with length of practice. The most experienced surgeons made fewer mistakes. All the surgeons that responded to the questionnaire used some method to prevent wrong site surgery (80% of them used intraoperative x-rays).

The American Academy of Orthopaedic Surgeons (AAOS) has established that the aggregate probability for an orthopedic surgeon who has been in practice for 35 years to suffer a wrong site surgery episode is 25%. This means that one in every 4 orthopedic surgeons will be confronted to this problem during their career[5].

Taking into account that according to the most optimistic data only 50% of surgeons report these occurrences, It can be estimated that the number of wrong site surgeries conducted in the United States ranges between 1,300 and 2,700[6]. Incidence is of one case a year in hospitals of more than 300 beds[7]. The number of cases where an erroneous procedure or treatment is applied could be even higher.

The following wrong site surgery-related risk factors have been identified:

—Emergency surgical procedures.
—Multiple and simultaneous surgeries in a patient performed by different surgeons.

—Multiple procedures conducted by a single team in the same patients (in orthopedic and trauma surgery, for example, in multi-trauma patients).
—Presence of obesity and/or deformities (these could hinder identification of the operative area).
—Unfamiliarity with the equipment to be used.

The AAOS has related wrong site surgery episodes with ambulatory surgery, especially in situations where the same surgeon carries out multiple surgeries in one single operative session, especially if 2 theaters are used at the same time. In this context, pressure to complete the procedure quickly can become a significant factor leading to error[2].

The majority of cases analyzed have revealed poor communication among surgical team members, and between these and the patient and his/her family. Organizational failures include the lack of protocols for site marking and verification, unavailability the patient's full clinical record in the operating theater as well as some distraction factors[2].

Legal consequences for the surgeon in the event of a lawsuit are obvious. Although claims related to wrong site surgery account for barely 2% of all lawsuits filed against orthopedic surgeons in the United States, in 85% of cases the judge decides in favor of the plaintiff and against the surgeon[2]. As stated by Levy in an AAOS newsletter, it is virtually impossible to succeed in getting a surgeon to be declared not liable in cases of wrong site surgery[8].

The legal situation in Spain is similar to that in the United States, since it is extremely difficult to please the case of a surgeon that has performed wrong site surgery. In these cases, the surgeon's error is used as a means to emphasize his/her guilt, that is, the adverse result serves the dual goal of justifying the damage caused to the patient and holding the blaming the surgeon for malpractice.

Although the majority of legal procedures undertaken to seek redress for these errors are settled in civil law courts, where the penalty consists in an economic compensation for the damage caused, on some occasions patients resort to the criminal jurisdiction, which means that the surgeon, apart from being required to pay a fine, may will be tried for a criminal offense. If convicted, s/he may be barred from practicing surgery for a period that will depend on the amount of damage caused, the degree of negligence involved and the interpretation the judge may make of the events. The worst case scenario (in particularly serious cases) is for the surgeon to be required to serve a prison sentence, which cannot be suspended if longer than 2 years.

History

In 1994, la Canadian Orthopaedic Association (COA) designed an educational program intended to bring down the incidence of wrong site surgery. For the first time, a recommendation was made for the surgeon to identify the specific area to be operated on with his/her initials using a permanent marking pen *("operate through your initials")*[9]. The number of wrong site surgeries has decreased in Canada since 1994.

In 1997, the AAOS organized a working group devoted to wrong site surgery, which issued a series of recommendations in the form of a program labeled "Sign Your Site"[10]. The group analyzed wrong site surgery episodes drawn from legal claims. The protocol proposed consists of the following measures:

1. Review patient clinical record before s/he enters the operating theater and confirm with the patient his/her identity, the procedure to be performed as well as the anatomical area and the side to be addressed.
2. Mark the surgical site with surgeon's signature, making sure that the signature falls within the sterile field once the draping has been completed.
3. A "time out" should take place prior to the procedure. All members of the team should participate in this last verification.

Since then, several awareness-raising campaigns have been conducted among AAOS and COA members, with the programs being implemented on a voluntary basis. In 2002, 78% of AAOS members knew about the program and 46% used it in daily practice[11].

The JCAHO, which is the main healthcare accreditation organization in the United States, has recorded wrong site surgery episodes since 1998; in 2003 it created the Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery, based on the consensus of experts from the relevant clinical specialties and professional disciplines and endorsed by more than 40 professional medical associations and organizations; this protocol is similar to the AOOS program mentioned above. From 1 July all organizations accredited by JCAHO are required to comply with the Universal Protocol, which shows the interest of the U.S. authorities in eradicating this problem[12]. The protocol has recently been modified, with the new model due to come into force on 1 January 2009 (fig. 1).

In the last few years, the World Health Organization (WHO) also became involved in the preservation of patient safety and the analysis of wrong site surgery[13]. The WHO has included prevention of wrong site surgery in its "Solutions for Patient Safety" program.

Pre-procedure verification

Therefore implementation of the Protocol begins at the first visit of the patient. At that stage it is important to correctly record the patient's personal details as well as the diagnosis and the surgical procedure that will be conducted. The information in the clinical record and in the informed consent form must coincide as regards the type of procedure to be performed and the side on which it will be carried out; informed consent must be obtained during one of the patient's visits rather than immediately prior to surgery[14].

It is of essence to verify the patient's identity since 2 different patients may have the same name and surname. In Spain it is possible for a patient to reach the operating theater without having been seen by the surgeon in charge of the procedure, which could constitute a risk factor for wrong site surgery and further emphasizes the need to collate detailed clinical data and to clearly specify in the

Conduct a pre-procedure verification process

Objective To make sure that all relevant documents and related information or equipment are available before the start of the procedure and that they:
□ are correctly identified and labeled
□ match the patient's identifiers*
□ are consistent with the patient's expectations and the team's understanding of the intended patient, procedure, and site*

Before the procedure, the health care team uses a pre-operative checklist (paper or electronic) or other medium such as a white-board to conduct the pre-procedure verification process.

Verify the availability of
□ Relevant documents, such as the history and physical, pre-anesthesia assessment
□ Accurate, complete, and signed procedure consent form*
□ Correct and properly labeled diagnostic and radiology test results
□ Any required blood products, implants, devices or special equipment

Times to verify
□ When the procedure is scheduled
□ When the patient is pre-admitted for testing and assessment
□ When the patient is admitted to or enters the facility
□ Before the patient leaves the pre-procedure area or enters the procedure room
□ Anytime the patient is transferred to another caregiver during the procedure

* Whenever possible, involve the patient in these verification processes.

The team must address missing information or discrepancies before starting the procedure.

Mark the procedure site

Objective To identify without ambiguity the intended site for the procedure.
A licensed independent practitioner (or other provider who is privileged or permitted by the hospital to perform the intended procedure) marks the procedure site. This individual will also be involved directly in the procedure and will be present at the time the procedure is performed.

Mark all procedures that involve incisions, percutaneous punctures, or insertion of instruments. Take into consideration:
□ Surface
□ Spine level
□ Specific digit or lesion to be treated
□ Laterality. For procedures involving laterality of organs but where the incision(s) or approaches may be from the mid-line or from a natural orifice, mark the site and make a note of the laterality.

The mark is made
□ Before the patient is moved to the location where the procedure will be performed and with the patient involved, awake and aware, if possible.
□ At or near the procedure or incision site. Other non-procedure site(s) are not marked unless necessary for some other aspect of care.
□ Using the surgeon's or proceduralist's initials (preferably), with or without a line representing the proposed incision. The type of mark made should be used consistently throughout the hospital.
□ Using a marker that is sufficiently permanent to remain visible after skin prep and draping. Adhesive site markers are not to be used as the sole means of marking the site.
□ For spinal procedures, the mark is made in the general spinal region and the mark is made in addition to special intraoperative radiographic techniques used for marking the exact vertebral level.

Have a defined, alternative process for
□ Patients who refuse site marking
□ Cases in which it is technically or anatomically impossible or impractical to mark the site, such as mucosal surfaces, perineum, premature infants
□ Minimal access procedures to treat a lateralized internal organ, whether percutaneous or through a natural orifice. The intended side is marked at or near the insertion site.
□ Interventional procedure cases for which the catheter/instrument insertion site is not predetermined. For example, cardiac catheterization, pacemaker insertion.
□ Teeth. The operative tooth name(s) and number are indicated on documentation or the operative tooth (teeth) is marked on the dental radiographs or dental diagram.

Final confirmation and verification of the site mark takes place during the time-out.

"Time out" before starting the procedure

Objective To conduct a final assessment that the correct patient, site, positioning, and procedure are identified and that all relevant documents, information, and equipment are available.

Procedural team members include: the proceduralist(s), anesthesia providers, circulating nurse, operating room technician, other active participants who will participate in the procedure when it begins.

The time-out is
□ Initiated by a designated member of the procedural team
□ Ideally done before the patient receives anesthesia—including general/regional, local and spinal—unless contraindicated. If not done before anesthesia administration, the time out is done before starting the procedure.
□ Performed to confirm each subsequent procedure before it is initiated (when two or more procedures are being done on the same patient).

During the time-out
□ Other activities are suspended, to the extent possible without compromising patient safety, so that all relevant team members are focused on the active confirmation of the correct patient, procedure, site and other critical elements of the procedure.
□ All team members use interactive verbal communication. Any team member is able to express concerns about the procedure verification. If responses vary, the organization's process for reconciling differences is used.

The time-out addresses
□ Correct patient identity
□ Confirmation that the correct side and site are marked
□ An accurate procedure consent form
□ Agreement on the procedure to be done
□ Correct patient position
□ Relevant images and results are properly labeled and appropriately displayed
□ The need to administer antibiotics or fluids for irrigation purposes
□ Safety precautions based on patient history or medication use

Each organization defines a standardized procedure for the time-out, including a defined process for reconciling differences in responses.

The completed components of the Universal Protocol are clearly documented.

Figure 1 2009 Version of the JCAHO Universal Protocol for Preventing Wrong Site Surgery[28]. ©The Joint Commission, 2008. Reprinted with permission.

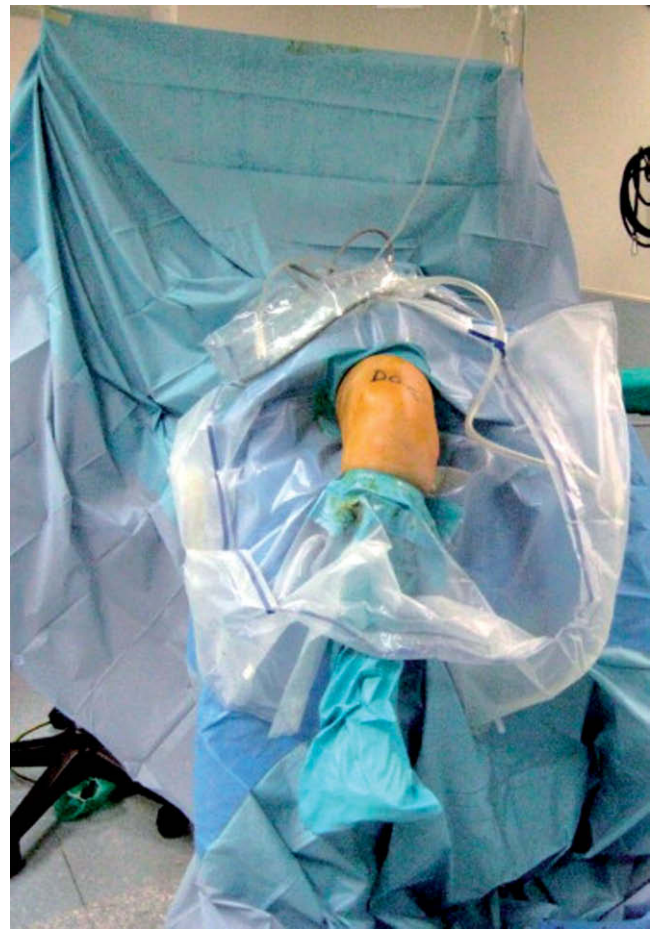

Figure 2 The doctor's signature must be clearly visible following preparation of the sterile field.

informed consent form the type of procedure and the side where it will be performed.

The nursing staff must independently verify the clinical documentation before the patient enters the theater[7].

Marking the procedure site

The operative side should be marked with a permanent marker and the mark must be remain visible after draping has been completed (fig. 2).

The marking must be done while the patient is still conscious and before s/he is transferred to the operating theater[7]. Patient collaboration is necessary to check the side on which surgery will be performed and the type of procedure that will be carried out, but as neither the patient nor his/her family are fully reliable, the clinical record and the informed consent form must be verified as well.

The initial COA protocol included the use of the surgeon's signature as a mark; it even proposed the performance of the surgical incision through that signature.

Likewise, the AAOS' "Sign Your Site" campaign defended the use of the surgeon's initials. The JCAHO's Universal

Protocol states that the operative site must be marked but does not specify what type of mark should be used, which it leaves up to the surgeon. The type of marking should always be the same and must be known by the entire operative team.

Some authors believe that the surgeon should perform a negative mark (i.e. writing the word "NO" on the opposite site or side) rather than affixing his/her initials on the correct limb or site[15,16]. Negatively marking the opposite site would only serve as a guide to avoid side-related but not site-related errors. For example, the word NO should be written on each one of the fingers on a hand that will not be operated. This formula is discouraged in the Universal Protocol.

There may be concern that the use of ink might increase the risk of infection. However, this risk due to the use of non-sterile indelible ink has been dismissed by several experimental studies[17,18]. In addition, it must be remembered that anatomical landmarks are marked with non-sterile indelible ink before preparation of the sterile field in many surgical procedures.

Marking the operative site with an X is also discouraged since it may cause confusion (is that the site to be operated or to be avoided?). Moreover, cases have been reported where the X mark has been transferred from one foot to the other when the dorsum of one foot contacted with the sole of the other, which opens the way for error.

Preferably, the mark must be performed by the surgeon in charge of the surgery. On some occasions it can be made by assistants or residents, provided that the surgeon has checked it before the start of the procedure. In the event of multiple procedures, each one of the operative sites must be marked.

Under no circumstances should be patient be told to make the mark. The role of the patient in wrong side-related error prevention was studied in 100 consecutive patients subjected to foot and ankle surgery. These patients were instructed to write the word "NO" on the contralateral foot before surgery. Only 59% of them complied with the instructions correctly, which revealed lack of collaboration or poor Communications with the surgeon. In patients who had sustained occupational hazards the percentage of compliance fell to 33%[9].

"Time out" before starting the procedure

"Time out" is a final check that must be carried out before the start of the procedure. It requires the participation of the entire surgical team. This step will be entrusted to a previously appointed team member, often the circulating nurse, who will be able to access the clinical documentation. Therefore "time out" involves an active discussion where all team members will carry out a last check of identity, operative side, type of procedure and required implants. This discussion may include the complications that can be expected during surgery and the measures available to address them, or the need for preoperative antibiotic administration.

Participation of the entire team is fundamental; every member must be made aware of the necessity that they should raise with the surgeon any doubts they may entertain with respect to the surgery. On some occasions, when the surgeon enters the theater the patient has already been positioned and the specific instruments, for example the arthroscopy tower, have already been placed on one side, which may induce the surgeon to choose the wrong side. According to the study by the AAOS working group, in 46% of cases the blame corresponds only to the surgeon, but in 41% of cases it is the surgical team that has draped the wrong side[10].

It is important to promote a culture base don patient safety by building team spirit in the operating theater, improving Communications between surgeons, anesthesiologists, nursing staff, orderlies, etc[20].

Some authors are in favor of conducting the "time out" prior to anesthetic induction, where the circulating nurse will only deliver the needle required for anesthesia after making sure that the side and the site have been correctly identifiedo[21]. Likewise, it would be an option not to deliver the scalpel blades to the scrub nurse until the "time out" has been completed[7].

It may be necessary to carry out a new "time out" if different procedures have to be performed in the same patient, especially if the patient has to be changed from a supine to a prone position, where side-related confusion could be more likely.

"Time out" can be performed with a checklist, which can contain the different stops that need to be covered for the final verification.

Spine

As we have said, 50% of spine surgeons will have one wrong site surgery episode during their professional career, mostly connected with operating on the wrong anatomical area[4]. The North American Spine Society (NASS) has developed the SMaX protocol, which builds on JCAHO's Universal Protocol by adding systematic performance of intraoperative x.rays intended to allow the surgeon to accurately identify the area to be addressed by means of bony landmarks. The most common error in spine surgery is to perform a simple lumbar discectomy at a level above the one initially planned; this can be explained by the fact that it can sometimes be difficult to reliably locate the levels of the lumbosacral junction[22].

As the surgical team's experience increases, the need to check the position of the implants may decrease; however, it is still necessary to radiologically check that the right level is being addressed since this may be an important precaution in the event of a potential lawsuit.

What to do in case of error?

In the event of performing wrong site surgery, the surgeon must protect his/her patients' interests and take a clear and sincere attitude with respect to the events that have taken place. This means that as soon as the error becomes evident the necessary medical action must be taken to mitigate its effects as much as possible[23].

If the surgeon becomes aware of his error intraoperatively s/he must act in accordance with the type of anesthesia used[24]:

If general anesthesia was used, the surgeon must perform the planned procedure on the right side, unless there are medical reasons for not doing so; and if the patient has given his consent for it, his/her family must be informed of the adverse incident.

In the case of local or regional anesthesia, if the patient is capable of correctly understanding information imparted to him/her, the el surgeon must clearly tell him/her what happened and advise him/her on the steps that need to be taken. The surgeon must sincerely answer the patient's questions and act on the basis of the latter's wishes.

If the error is discovered postoperatively, the physician must inform the patient and, if possible, recommend the course of action that must be followed to fix the error promptly.

In any case, healthcare professionals should not forget that they are bound by a series of ethical and legal rules and that they are obliged to comply with both. Indeed, according to the Ethical Code of the Spanish Medical Association ethical norms must be observed by all medical practitioners.

Ethical norms require that medical practitioners should protect their patients' safety. More specifically they require that physicians should: a) protect their patients' safety as these "*are entitled to receive care that is of high human and scientific quality*" (Art. 18 of the Ethical Code); b) record all medical interventions in the patients' clinical record (Art. 13 of the Ethical Code); and c) inform patients about their condition (Art. 10 of the Ethical Code).

With respect to legal norms, it must be remembered that Article 4 of the Spanish law regulating patient autonomy (Act 41/2002) grants patients the *"right to be provided, further to being subjected to a medical procedure, with all the information related to the same."* This right is logically related to the obligation of medical practitioners to inform patients, an obligation which corresponds particularly to the physician in charge. Likewise, Act 41/2002 imposes on physicians the duty to document their interventions in the patient's clinical record so that any information relevant for proper patient care can be documented; the Law also expressly stipulates that the O.R. report is compulsory.

All of this means that a physician that has conducted wrong site surgery is both ethically and legally bound to inform the patient about this adverse event as soon as possible and make sure this fact is recorded in the patient's clinical record through the O.R. report, the follow-up notes or the discharge report.

Without prejudice of the previously mentioned ethical and legal obligations, it should not be forgotten that deliberately concealing wrong site surgery episodes, apart from infringing the law and the norms of ethics, contributes to the deterioration of the doctor-patient relationship, which results in damaging consequences for healthcare staff since patients or their relatives, suspicious about the dearth of information and presuming that the available information may have been manipulated, may resort to the legal system to find out what really happened[24,25]. Concealing the truth from the patient or trying to justify the error invoking medical reasons (especially considering its obviousness) will only entail negative consequences[26]. It is a proven fact that admitting his/her error will cause the surgeon fewer problems in the long run than trying to conceal it, notwithstanding the fact that this admission could result in the patient filing a damage claim (civil jurisdiction), which will always be less distressful than being involved in a criminal procedure.

Reporting adverse events

The fact that wrong site surgery should remain underreported because of the shame associated with these events has led to a situation where related situations and risk factors are still ill known.

In the United States, a total of 5-8 cases are made known to JCAHO every month, with no reduction in the number of reports having been recorded since the introduction of the Universal Protocol in 2007. This may be explained by several factors. The first is that adverse events are now reported more than before. The second refers to the failure healthcare institutions in general to enforce the Protocol. The third could be an inappropriate implementation of the Protocol because of poor interpretation or the absence of a culture conducive to leadership in the management of healthcare risk and to quality assurance.

It is necessary to build channels to anonymously communicate these episodes, either through professional associations or scientific societies, in order to establish the factors most frequently related to these occurrences in the Spanish medium.

It would be important to report not only the incidents that actually occur but also the "near-misses," i.e. occasions in which for example the contralateral limb was prepared –and even draped –but the surgeon became aware of the error before starting the procedure. Awareness of these "near misses," which are 5 times more frequent than the actual incidents, World provide a better understanding of the risk factors involved[7].

From what has been said, it can be concluded that wrong site surgery is one of the chief adverse events that may arise in a surgical procedure. In order to minimize adverse incidents as much as possible, several countries have put in place specific reporting systems which, in addition to recording these events, provide information about what has caused them. The United States has pioneered the use of these systems, which have been developed either officially by some of the States or by independent organizations devoted specifically to patient safety and healthcare quality.

Study of the data reported to these systems has made it possible to develop guidelines that, by incorporating certain regulated processes, allow the surgeon to prevent such adverse events as wrong site surgery.

Nonetheless, in Spain there is a lack of dedicated reporting systems for hospital adverse events that may serve as fluent communication channels thereby helping understand the causes of adverse incidents and prevent their occurrence. The Government is developing a blueprint for such a system at a nationwide level, but the

legal challenges such a project will have to surmount are quite formidable. We should not forget that in Spain the shearing out of competencies between the Central Government and the different regions prevents the creation of a National System with binding powers if it has not been previously approved by all 17 autonomous regions. In addition, there is a second difficulty: what kind of liability may be derived from the events reported to this system and how would the former affect the practitioners involved. For example, what would happen if wrong site errors were reported that could generate a civil or even a criminal liability?, or worse still, what would happen if, reporting to these systems was not voluntary but rather mandatory?

While these legal problems are solved, Spain will lack a nationwide reporting system for adverse events and will therefore continue to have less information on these incidents that, say, the United States, which impairs our capacity to analyze these situations and makes it more difficult to create specific tools to address them. All of this means that our only resource will still be the international registers and, specifically, the materials published by JCAHO, WHO and AAOS.

Conclusions

The incidence of wrong site surgery episodes in a surgeon's career is high, but its incidence when set against the number of procedures is relatively low. Therefore it is difficult to determine whether these protocols do have a real impact.

Given that in Canada there is only one insurance company that covers medical malpractice, the incidence of these episodes is well understood: between 1994 and 2001 there was a 64% decrease as a result of the implementation of the COA Program[9]. Eighty percent of wrong site surgeries reported in Canada in 2000 (all of them in the knee) had not been marked.

Kwan et al report that only 62% of cases in a series of 25 errors could have been prevented using the Universal Protocol, which shows that not all episodes are preventable[27]. Non preventable errors included deficiently marked imaging tests, multiple operative lesions (cysts and lipomas), the surgeon making deliberate changes in the operative side in patients with bilateral involvement, and mistaken resection of the second rib instead of the first in a case of thoracic outlet syndrome.

It cannot be said that these episodes "just happen"; they result from a series of errors that succeed one another from patient presentation to arrival in the operating theatre. These errors demonstrate the existence of poor communication between members of the surgical team with one another and with the patient.

It is essential for these protocols for wrong site surgery prevention to be mandatorily included in the organizational rules of all Spanish hospitals; i.e., they should not be a mere option Leith in the hands of the surgeon. It is also fundamental to promote the involvement of all the different professionals who make up the surgical team. These concepts should be part of resident physician training programs.

The JCAHO Protocol is flexible enough to be used as a guide to create a specific protocol for every hospital that is adjusted to each center's needs. If self-regulation cannot be achieved through scientific and professional societies, public opinion and the law-maker will sooner or later jump in to fill the void.

These patient safety protocols are now part of the minimum requirements for patient management on a par with a sound preoperative examination or obtaining an informed consent. Therefore a surgeon who does not comply with these simple steps will place his/her patients at risk and will be legally helpless if an adverse incident occurs. Unfortunately, these episodes are not wholly preventable, even when a protocol is used. This should stimulate continued efforts to study the possible causes of such events and propose improvements in prevention systems.

Conflict of interests

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