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Surgery on the wrong side: Implication for the patient and the professional. Experience in a major ambulatory surgery of the foot unit[☆]

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Abstract Surgery of the wrong side is a very uncommon complication in orthopaedic surgery, but with serious consequences for the patient, the surgeon and the health institution, having to put all the necessary measures in place to prevent this occurring.

We have conducted a prospective study on the introduction of a protocol to prevent the surgery of the wrong side in 101 patients operated on for any foot disease in the Major Surgery Ambulatory Unit, performing three independent controls to verify the side: by the patient, by the nurse and by the anaesthetist. We review the information available of the side in the medical records and their correlation with the side operated on.

Almost a quarter of the patients, 24.8%, were not informed that they had to make a mark on the foot to be operated on. No mark was made by 18.4% of the patients informed to do so, with no relationship between age, gender, education level, to live alone or previous foot operations. There was a lack of noting the side in the documentation, with this omission being more frequent in the Orthopaedic and Traumatology and Anaesthesiology medical records. Nine cases of inconsistency in the surgical side were detected, all in patients who had previous surgery in any foot.

Marking of the side has been incorporated as routine practice in foot surgery, being beneficial for the safety of the patient, and should become normal practice in all surgical areas in the near future.

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PALABRAS CLAVE

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Marcaje

Cirugía del lado erróneo: implicación del paciente y los profesionales. Experiencia en la Cirugía Mayor Ambulatoria de la Unidad del Pie

Resumen La cirugía del lado erróneo es una complicación poco frecuente en cirugía ortopédica, pero con serias consecuencias para el paciente, el cirujano y la institución sanitaria, debiéndose poner todas las medidas necesarias para evitar que se produzca.

Hemos efectuado un estudio prospectivo de la implantación de un protocolo para prevenir la cirugía del lado erróneo en 101 pacientes intervenidos en la Unidad de Cirugía Mayor Ambulatoria (CMA) de cualquier patología del pie, realizándose tres marcajes independientes para la verificación del lado: por el paciente, la enfermera y el anestesta. Revisamos la existencia de la información del lado en los documentos de la historia clínica (HC) y su correlación con el lado operado.

Un 24,8% de los pacientes no fueron informados que tenían que realizarse una marca del pie a operar. Un 18,4% de los pacientes avisados no se marcaron, no existiendo relación con el sexo, edad, nivel de estudios, vivir solo o intervención previa de pies. En 37 pacientes existía una falta de anotación del lado en los documentos siendo más frecuente esta omisión en la HC de Cirugía Ortopédica y Traumatología y de Anestesiología. Se detectaron 9 casos de incongruencias de lado quirúrgico, todos en pacientes con cirugía previa de algún pie.

El marcaje de lado se ha incorporado como una práctica rutinaria en la cirugía del pie, siendo beneficioso para la seguridad del paciente, debiéndose convertir en un futuro próximo en una conducta habitual en todas las áreas quirúrgicas.

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Introduction

The concept of "wrong side surgery" appeared in 1995 when a man had the wrong leg amputated at the University Community Hospital in Tampa (Florida) and then needed to have the correct leg amputated as well.^{1,2} In 1999, the Institute of Medicine (IOM) published the book, "To err is human",³ concerning medical errors and patient safety, in which it was estimated that some 98,000 Americans could die each year due to preventable medical errors occurring in the hospital. The risk of complications is inherent in every surgical procedure, but there are situations that can be avoided. Some of these complications are "wrong patient", "wrong surgical procedure", "wrong site" and "wrong side".

"Wrong side surgery" is a rare complication in medical practice, but it is the one that can cause grave consequences for the patient, the surgeon and the hospital and also involves insurance companies. Legally, it falls under the classification of the *res ipsa loquitur* principle.⁴ Among all the surgical lawsuits for medical negligence, only about 2% are due to these errors, but 84% lead to a court-ordered compensation for the claimant, in comparison with 30% of all orthopaedic surgery lawsuits.^{5,6} This error affects all of the surgical specialties and can be caused by different circumstances: improper preoperative planning, failure of hospital control procedures, surgeon error or mistake in patient-surgeon communication. The problem lies in ascertaining the true status of this problem, given that many of these errors are not reported and only the cases that turn into lawsuits become known, so the real situation is

underestimated. Current data indicate that an orthopaedic surgeon has a 25% possibility of committing an irregularity of wrong side surgery during the course of a 35-year career.^{5,7} Kwan et al.⁸ indicated an incidence of 1 wrong side error per 112,994 surgeries, with a lawsuit being possible for this reason in any hospital every 5 or 10 years. Meinberg and Stern⁹ reviewed the incidence among hand surgeons, indicating that 21% had had a wrong side error in their professional careers and that the incidence of wrong side surgery was 1 out of every 27,686 operations on the hand.

In 1994, the Canadian Orthopaedic Association¹⁰ developed an educational programme to reduce the incidence of wrong side surgery error, including the "Operate Through Your Initials" campaign: they recommended that surgeons should write their initials, with a permanent marker, on the side to be operated before taking the patient to the operating theatre and that the surgeons should not perform the first surgical incision if they do not see their own initials.

In September 1997, the American Academy of Orthopaedic Surgeons (AAOS) established the Task Force on Wrong-Site Surgery to establish the prevalence of this error in orthopaedic patients and to give recommendations to prevent it, setting up some effective control systems.^{6,7} In 1998 the AAOS¹ carried out a study to assess the true situation for the period 1985-1995, identifying 331 legal claims for wrong side surgery. Most of the claims for this error (225 of the total, 68%) happened in orthopaedic procedures and practically all of them for surgeries in the hospital environment. The anatomical part most commonly involved was the knee, followed by the foot and the ankle.

The most common procedure was arthroscopy, followed by reconstructive foot surgery. The majority of these errors were discovered during the operations (60% of the cases). Information was also obtained from the State Volunteer Mutual Insurance Co. in Tennessee, from 1977 to 1997; the mean age of the surgeons involved in this type of error was 46 years, the mean patient age was 40.5 and all the cases occurred in hospital surgeries except for 1, which happened in an out-patient surgery centre. In response to this problem, from 1998 on the AAOS has organised educational programmes for all its members and recommends using a protocol to eliminate wrong side surgery in patients who undergo orthopaedic surgery, creating the Sign Your Site campaign.^{7,11} In this protocol, the surgeon, after establishing the side to be operated on, makes a mark in a visible area. Nearly 77% of the orthopaedic surgeons signed up, but only 45% of them followed the recommendations.^{5,7} The main problem is that some surgeons do not want to take the time to sign the site and to wait until the patients are anaesthetised to be able to initiate the operation.¹²

In February 2001, the New York State Department of Health (NYSDH) published a final report (the Preoperative Protocols Panel) on the preoperative steps to follow to prevent wrong side surgery. This emphasised greater communication among member of the surgical team and with the patient, with 3 independent verifications, including marking the side to be operated.¹³ The protocol assigns an important role to the nursing staff, who should ensure that the patient is the correct one, that consent has been signed by the surgeon, that the surgical side has been marked correctly, that the surgeon has checked the relevant radiographs and that the procedure has been planned.

In December 2001, the Joint Commission on Accreditation of Health Care Organisations (JCAHO) established the Sentinel Event Alert,¹⁴ gathering together 150 of these surgery errors, of which 76% were wrong side surgery. Of all of these, 41% corresponded to orthopaedic surgery procedures. The Joint Commission identified some factors contributing to increasing the risk of wrong side surgery, such as: emergency cases (19%), unusual physical characteristics such as morbid obesity (16%), time pressures to start or finish the procedure (13%), surgical equipment (13%), various surgeons on the case (13%) and various procedures in the same operation (10%). More than 1 factor is normally identified in these wrong side errors, but the majority are related to a failure in communication between the surgical team and the patient or the family.

The JCAHO¹⁴ recommends some strategies to prevent this error and establishes some processes to ensure correct operation by means of various steps: (1) marking the side to be operated; (2) using a list of verifications; (3) obtaining oral confirmation from the patient; (4) overseeing the fulfilment of these processes; and (5) considering giving the surgical team a time-out to confirm the correct patient, procedure and side. They recommend that the patient comment on the surgery and the side to be operated on with the medical team before the operation, assigning some responsibility to the patients themselves for preventing this error. Between 1995 and 2003, the JCAHO collected data on some 2299 sentinel events, of which 278 are wrong side surgery¹⁵ and, in

December 2003, established eliminating wrong side surgery as one of the 10 National Patient Safety Goals.^{7,12} They created a Universal Protocol¹⁶ to standardise the procedures to perform before initiating the surgery with the correct confirmation of a list of data, based on a consensus among experts from different specialties and backed by more than 40 medical associations. This protocol was established as obligatory after July 2004 for the organisations accredited by the JCAHO.¹² In the protocol, patients are required to be awake and conscious to confirm the surgery site, without any prior sedation, marking the side to be operated and implicating the patient and all the members of the surgical team in this marking.^{7,12,17} The Joint Commission's Sentinel Event Database currently receives about 9 voluntary reports a month concerning events related with wrong side errors, an increase in reports since the implementation of the Universal Protocol.^{2,18}

The AAOS and JCAHO recommend the use of the Universal Protocol,¹⁹ with marking the side to be operated in an easily visible way, as a simple protocol that takes little time.^{6,7,12} This protocol involves 3 simultaneous steps: (1) preoperative verification of the process, making sure that the relevant documents and studies are available and confirming the surgical procedure; (2) marking the site to be operated with a permanent, unmistakable mark in a place visible near the cutaneous incision, with the surgeon's initials being the recommended mark; and (3) time out before commencing the surgery for the final confirmation by all the surgical team members.^{15,17} The identifying mark for the side needs to be correct, simple, reproducible, not intimidating for the patient and easily seen by all of the surgical team.¹⁰ The final objective would be 100% adherence by the orthopaedic surgeons to the Universal Protocol, with a zero tolerance culture to achieve the elimination of this type of medical error.¹⁸

In Australia, the Australian Council for Safety and Quality in Health Care (ACSQHC), together with the Royal Australasian College of Surgeons (CCR) developed a protocol to prevent wrong patient and wrong side procedures.²⁰ This protocol (Ensuring Correct Patient, Correct Site, Correct Procedure) provides a standard process in which the site to be operated must be marked by the person in charge of the procedure or another team member who is completely informed about the operation, the mark must be unambiguous and near or in the incision area, and the mark must be sufficiently permanent and consistent and preferably placed when the patient is awake and before the patient is taken to the operating theatre.²¹

With respect to Europe, research was done in England in 2004 to ascertain the wrong side surgery occurrence and marking practices among the various professionals.²² Almost all of the orthopaedic surgeons marked the patient's skin before surgery (in contrast to the urologists and ophthalmologists, only 50% of whom did so) and believed that marking is essential for safety in surgical practice. The symbol used for the mark was generally an arrow drawn with a permanent marker. In 2005, the National Patient Safety Agency (NPSA) established a guide for preventing wrong side surgery, recommending that the surgeon or surgical assistant should draw the mark.^{22,23} This brought about a change in the surgeons' routines, with the figure for those who marked the side increasing from 48% to 85% after the establishment of

this rule.²⁴ In June 2008, the World Health Organisation established a checklist for surgical safety (WHO Surgical Safety Checklist) to reduce the number of errors during surgery,²⁵ in which a series of verifications of the patient, material, site and surgical procedure are performed. This checklist was adopted by the NPSA in January 2009, for its use in England and Wales.²³

In our country, the concern over the health care quality in orthopaedic surgery has increased,^{26–28} with one of the objectives being to lower the risk of wrong side surgery. However, there is no general consensus on using a protocol. The Ministry of Health and Consumer Affairs developed the Quality Plan for the National Health System²⁹ to insure correct healthcare performance throughout the nation. This plan is structured into 6 large groups, one of which is "Promote Clinical Excellence". Within this group, the strategy (consisting of improving the safety of patients seen in health centres) includes a section that establishes "Implement, through agreements with the Autonomic Communities, projects that promote and assess safe practices in 8 specific areas", and one of these areas is preventing wrong side surgery. At present, there is a Spanish version of the "Surgical Safety Checklist", recommended by the WHO; this is to be used in the hospital centres in our country and can be consulted on the official website of this organisation.²⁵ The Spanish version of the Universal Protocol can also be seen on the website of the JCAHO,¹⁹ with the slogan "¡Hable!" (Talk!), indicating the 3 steps in the process: (1) verification, (2) marking and (3) wait time.

We carried out this study with the following objectives: (1) establish the percentage of patients who get involved in marking the limb to be operated on so as to prevent possible surgery errors; (2) ascertain the risk points where a loss of information about the side to be operated may exist and could cause a wrong side surgery; and (3) raise the awareness of the patient and all the healthcare personnel involved in the surgical process of how important their participation is to prevent complications or mistakes in the surgery (wrong patient, wrong site, wrong side or wrong procedure).

Material and method

This study included a total of 101 patients, with a mean age of 58 years (range, 29–82 years). Of these, 91 were women (90.1%) and 10 were men (9.9%), with the mean age of the women being 59.35 years, older than that of the men (47.80), with a statistically significant difference ($P < .001$; Student's *t*-test). The operations were always performed on a single foot, with 52 right feet (51.5%) and 49 left (48.5%). All of the patients had their surgery between 7 January 2009 and 20 May 2009, in the outpatient major surgery (OMS) or short-stay surgery (SSS) units of the Hospital Clínic in Barcelona, for any reconstructive foot surgery.

We established a protocol for marking the side to be operated, with the participation of the entire team involved in the surgical process and with that of the patients themselves and/or their relatives. This protocol set up "3 phases" that covered from the moment that the patient was included in the waiting list for reconstructive foot surgery, up to the

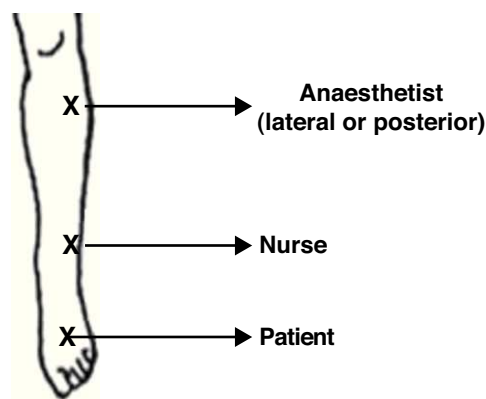


Figure 1 Diagram showing the different marks drawn on the foot to be operated.

moment in which the operation commenced. In Phase 1, in external consultation, the surgeon had to write down the surgery planned and the laterality in the case history (CH) of the patient, as well as on the surgical programming sheet. Later on, in the pre-anaesthesia visit, the anaesthesiologist had to check the laterality noted in the CH and confirm it with the patient, likewise writing down the side to be operated in the Anaesthesia informed consent (IC). In Phase 2, the day before the operation, the admission coordinator called the patient to notify them about the general measures and told them that they should make a mark in a visible place on the foot to be operated. In Phase 3, on the day of the operation, the various individuals responsible for the marking drew the different marks on the foot, according to the established design, with the following steps (Fig. 1):

1. The nurse receiving the patient confirmed that the patient had drawn a mark on the foot to be operated. If the patient had not done so, the "foot to be operated" was considered to be the one that the patient indicated orally.
2. It was confirmed that the side marked (or the side indicated by the patient, if not marked) coincided with the information indicated in the CH and on the surgical programming sheet filled in by the surgeon. If the side coincided, the nurse marked the limb to be operated in a visible place, different from where the patient's mark was. In case of doubt or inconsistency with the patient's documentation, the anaesthetist or surgeon responsible would be notified, who would make the decision and mark the limb in agreement with the patient or with the patient's relatives, if necessary.
3. The anaesthetist, together with the anaesthetic nurse, checked for the presence of the 2 marks and confirmed that the side coincided with the previous note on the Anaesthesia informed consent sheet and with what the patient him- or herself indicated. If these all coincided, a third mark was drawn on the lateral or posterior limb, so it would be seen if the patient were placed in prone decubitus position to carry out the appropriate anaesthetic block. In case of doubt or inconsistency, the surgeon in charge who would perform the surgery had to be consulted.

Table 1 Data collection sheet.

Side marking	Frequency	Percent	Cumulative percent
Right	32	31.7	31.7
Left	30	29.7	61.4
Not agreed	12	11.9	73.3
Not notified	25	24.8	98.0
No, answering machine message	2	2.0	100.0
Total	101	100.0	

- Before initiating the surgery, the surgeon confirmed the procedure to be carried out and the side to be operated on, consulting the documents and talking with the patient, and notified the patient of the surgical technique to be performed.
- Finally, if everything coincided, the surgical intervention was carried out. In the case of any doubts, the operation would be suspended and efforts would be made to clarify the situation.

The various members of the surgical team (nurses, anaesthetists and surgeons) wrote the information indicated in Table 1 in a data collection notebook (DCN). These data were included in an Access-2003 database, to permit statistical processing. The statistical analysis was carried out using SPSS for Windows (version 15.0). A descriptive assessment of the different variables was performed. Categorical variables were described with frequencies and percentages, and continuous variables with the mean and standard deviation, median and range. The chi-square test was used for the comparison between categorical variables, or Fisher's exact test if that was not possible. If the variables were dependent, we used McNemar's test and, if they were continuous, Student's *t*-test for independent data. To evaluate the concordance between the side operated and the 3 markings, the Kappa index was used. Statistical significance was set at 5%.

This study followed the "Code of Good Scientific Practices" for research projects for the Hospital Clínic in Barcelona. Including the patients in the study did not involve any alternations in the surgical process, so there was no prejudicial effect on the patients; to the contrary, it meant a potential benefit to ensure that there was no side-error. Despite telling the patients on the day before admission that they should mark the foot to be operated to prevent the foot on the wrong side from being operated, we did not inform them that they would become part of a study to establish the performance of marking and possible errors in information about side. The patients were not told this so as not to affect the fulfilment of the marking by the patient, as could be possible if they felt that they formed part of a hospital study.

Results

The majority of the patients, 89 of the 101 (88.1%), lived with a relative, while only 12 patients (11.9%) lived alone.

Table 2 Assessment of the marked side.

	Frequency	Percent	Cumulative percent
<i>Side mark missing</i>			
Three times	0	0	0
Twice	7	6.9	6.9
Once	30	29.7	36.6
Never missing	64	63.4	100.0
Total	101	100.0	

Twenty-two patients (21.8%) indicated that they had no formal education, 60 patients (59.4%) had finished basic education and 19 patients (18.8%) had post-secondary or university studies. No previous foot surgery had been performed on 42 patients (41.6%). The other 59 patients (58.4%) had undergone an operation on one or more feet, 25 on the right foot (24.8%), 27 on the left (26.7%) and 7 on both feet (6.9%).

Performance of marking the foot to be operated by the patients themselves was assessed. Twenty-five patients (24.8%) had not been told by the individual in charge of coordinating hospital admission that they had to make a mark on the limb to be operated. The motive for this lack of information was attributed to 2 circumstances, and both were related to the lack of familiarity of the staff with this new situation. Not telling the patient occurred either because the person in charge of making this phone call on the day before admission had asked for a day off and his/her substitute was not aware of this new information, or because the surgical program had been altered the previous day and the person who handled the inclusion of a new patient for surgery on that same day did not know that he/she had to give this new recommendation. The rest of the patients, 76 (75.2%), had been notified that they had to mark the foot to be operated. In spite of this, 14 patients (18.4% of the patients notified and 13.9% of the total) showed up on the day of the operation without any mark. Twelve patients (11.9%) indicated that they had forgotten and the other 2 (2%) explained that they had not paid any attention when told. The other 62 patients (81.6% of the patients notified and 61.4% of the total) had in fact drawn a mark on the foot that they believed was to be operated (Table 2).

No significant difference was found in the marking of the foot to be operated with respect to age ($P = .629$; Chi-square), sex ($P = 1.0$), level of studies ($P = .574$) or antecedents of a previous operation on the foot ($P = .766$). Neither was there a significant difference based on living alone or with others; however, patients who lived alone did seem to tend to draw the mark less ($P = .080$).

We did not tell the patients what kind of mark they should draw. Practically all the patients who complied with the notification chose to draw an "X" on the dorsal part of the foot that was to be operated on. However, some of them had drawn it on the sole of the foot to avoid affecting the surgery. A few patients, all of them women, had chosen different marks: one patient drew a "flower", another patient drew a "cross", others made a "round stain" with red



Figure 2 Various images of marks made by the patients.

lipstick, another patient drew an ankle bracelet with a felt-tip pen, another made a round mark on the back of the foot, one relative had written the patient's name with a felt-tip pen and another patient had made a mark in the form of a cross with sticking plaster (Fig. 2).

Loss of and mistakes in the information on the side to be operated were also assessed, whether such information was on the CH from the Trauma and Orthopaedic Surgery (TOS) department, on the surgery program sheet (SPS) or on the CH from Anaesthesia (CHAN). Some errors in not recording or in the information itself were found for 37 patients (36.6%), for 30 patients in 1 of the documents and for 7 in 2 of the documents; there was no patient who was missing the note on the side to be operated in all 3 documents (Table 3). The lack of this information was seen in the CH from TOS in 21 patients (20.8%), in the SPS in 3 patients (3%) and in the CHAN in 20 patients (19.8%). Among the 7 patients who

were missing the annotation in more than 1 document, in 5 patients (5%), the error was in the CH from both TOS and CHAN (only present in the SPS); in 1 patient (1%), the note was missing from the TOS and SPS CHs; in another patient (1%), the side was not indicated in the CHAN and in the SPS. Consequently, of the 37 patients for whom there was missing information, in 7 of them (35%) the lack was produced in 2 of the documents that were taken into account to establish the side to be operated, with a potential risk of committing a wrong side surgery.

A mistake in the notes about the side to be operated (that is, in the patients for whom, in one of their documents, someone wrote down the side opposite to the side that really was to be operated) was found in 9 of the 101 patients (8.9%). This was classified as an "inconsistency in side to be operated" and might constitute a virtual risk in being capable of causing wrong side surgery. Among the 9 patients with inconsistency in side, the error was found in the TOS CH in 4 of them (44.4%), in the CHAN in 3 cases (33.3%) and in the SPS in 3 cases (33.3%). It is noteworthy that, for 1 patient, the side notation error occurred twice, in the CHAN and in the SPS. The case of greatest risk of making a wrong side surgery corresponded to a woman who had not drawn the mark on the foot that was to be operated on and for whom the side was not indicated on either the TOS CH or on the CHAN, with the SPS being the only document that made reference to the side to operate, but mistakenly, given that the patient indicated that she was to be operated on the side opposite to the one indicated on the SPS.

In spite of the lack of statistically significant differences between the side written down and the side operated on among the 3 documents, it can be stated that the TOS CH was

Table 3 Lack of the note in the patient's documents as to the side to operate.

	Frequency	Percent	Cumulative percent
<i>Side mark missing</i>			
Three times	0	0	0
Twice	7	6.9	6.9
Once	30	29.7	36.6
Never missing	64	63.4	100.0
Total	101	100.0	

the least reliable document, with the lowest Kappa index (0.875). No significant difference was observed in comparing the patients who had had previous foot operations with those who had never had foot surgery ($P = .301$). All 9 cases of side inconsistency were found among the patients who had received previous foot surgery, with statistical significance ($P = .01$, Fisher's exact test). If we add up the cases with missing side information or mistaken side errors, we have a total of 27 patients (45.8%); this represents a very high percentage of risk factors that might cause wrong side surgery.

During the time that this study was carried out, we did not confirm any cases of wrong side surgery or of anaesthesia in the incorrect limb. The cases that presented an inconsistency in one of the various verification points were solved by the patients themselves when they confirmed the side to be operated.

Discussion

The JCAHO defines a "sentinel indicator or event" as an unforeseen incident that should not have happened and that can cause death or serious physical or psychological harm, or that carries the risk of causing them. Serious injuries specifically include the loss of limbs or of function. The phrase "or the risk of" includes any process whose repetition could have an adverse affect for the patient. A sentinel event is an alarm indicating the need for an immediate investigation and for an effective response.³⁰ The most frequent sentinel event in the USA is the wrong site surgery, with 13.1% of the total, there having been reports of 741 wrong site surgeries between January 1995 and December 2008.³¹ Our wrong side surgery can be considered as an indicator of health-care quality within a TOS service²⁶; it is an error that never should have happened and not a medical-surgical risk that the patient has to accept. Wrong side surgery is committed in symmetrical anatomical locations, happening most often in arthroscopic knee surgery, with foot surgery in second place.^{6,38}

The literature provides evidence that performing a list of verifications, before initiating surgery, reduces surgical complications^{32,33} and that marking the site to be operated decreases the incidence of wrong side surgery.¹⁴ It has been shown that simply instituting a protocol to prevent wrong side surgery increases the entire surgical team's sensation of safety.³⁴ Correct communication among all the medical team (surgeons, anaesthetists and nurses) and with the patients themselves seems to be fundamental in preventing wrong side surgery.^{4,7,12,14,34} Collaboration among the surgeon, anaesthesiologist and nurses in planning the surgery is essential to avoid potential problems,^{13,14,17,35} with the patients themselves or their relatives having a significant role in preventing these errors.^{7,12,15} The nursing staff should embrace an active attitude in the face of this problem, which is why some associations have adopted additional protocols to increase patient safety and have accepted the part of the responsibility that corresponds to them in the verification of the correct side in surgery.² In this study, we attempted to involve the patients themselves and all the staff related with the surgical process. We

achieved greater patient-nurse-anaesthesiologist-surgeon communication, which leads to greater patient safety in carrying out the correct surgery on the correct side.

Protocols to prevent wrong side surgery should be flexible enough for them to be adapted to the various circumstances and necessities of the surgical area in question, with the goal of improving patient safety. In our hospital environment, a high percentage of reconstructive foot surgeries are performed in the outpatient or short-term surgery units, where the patient is admitted on the same day as the intervention. This means that preoperative preparation is different from that of the patients programmed for admission the day before the surgery, where the nurse performs a prior interview in which the reason for admission is established and in which the limb that has to be operated on is shaved, prepared with an antiseptic wash and wrapped in gauze right on the ward, before transferring the patient to the surgical area, all of which can reduce the risk of errors. In addition, we must bear in mind that "wrong side surgery" does not affect only the surgery itself, but that wrong side errors of anaesthesia can occur in the cases in which there is a peripheral nerve block,^{35,39-41} as in the anaesthetic techniques used for surgery of the foot or ankle. Consequently, the side for the anaesthesia should also be confirmed. The Joint Commission identified Anaesthesiology as a specialty with a significant increase in the incidence of site errors, specifically in peripheral nerve and plexus blocks, which jumped from 2% in the 1995-2005 period to 16% in 2006.⁴² Carrying out a protocol to prevent wrong side surgeries in which only the surgeon involved intervenes forces this surgeon to talk to the patient and confirm the surgery and the side to be operated on before anaesthesia is given. This can cause a prolonged period of time elapsing before the following operation can be initiated and could make the surgical programming go more slowly. In our OMS and SSS units, various interventions are performed by each surgical team on the same day. This healthcare pressure means that, while the staff are performing one surgical intervention, the following patient is taken to the anaesthesia room to be prepared; this can mean that, in specific cases, the surgeon involved cannot communicate with the patient until she or he is already anaesthetised or even until the patient is in the operating theatre itself, representing a possible risk factor for performing anaesthesia and surgery on the wrong limb.^{14,40} However, it must also be considered that foot and ankle surgery usually involves regional anaesthesia using a popliteal nerve block, controlled by sonogram, for which the patient needs to be turned on the trolley and placed in prone decubitus position to be anaesthetised correctly. This circumstance can increase the risk of wrong side anaesthesia, given that the position of the limbs is changed⁴ and, in addition, this error can also be perpetuated, causing a greater risk of wrong side surgery. That is the reason why the anaesthetist's marking system must take this issue into account and the mark has to be drawn on the lateral or posterior side of the leg, so that it can be seen correctly if the patient has to be turned. It is important for the anaesthetist to participate in this verification of the side, given that cases of errors have also been detected when nerve blocks are performed, in spite of the fact that the surgeon

had previously marked the limb to be operated on, errors caused by various circumstances that can arise in the surgical area and that can affect attention as to the surgical side.^{4,35,39} That is why various institutions have recommended performing the 'pre-anaesthetic verification of side'.^{40,42} In our study, the anaesthesiologist assumes his or her responsibility at the time of performing the correct anaesthetic procedure on the correct side, with the surgeon being absent during this process; this optimises time during the anaesthetic preparation of the patient in such a way that when the surgeon confirms the procedure and the side to be operated, the patient is already blocked and the waiting time to initiate the surgery on this patient is reduced.

The patients themselves are the parties most interested in having the surgery performed correctly and on the correct side. They can provide indispensable help in the process of checking and confirming the side to be operated, with correct communication between the patient and all the members of the surgical team being one of the most important factors in confirming the correct side.^{19,36} The protocols to prevent wrong side surgery attribute part of the responsibility to the patient, involving the patient in the process of limb marking.^{12,14} In spite of this, the patient presently continues to play a passive role during the preoperative period. Some projects have been carried out to increase patient involvement. DiGiovanni et al.³⁷ told their patients that they had to write 'No' with a permanent marker on the foot or ankle that was not to be operated on, following the AAOS recommendations, so that they would not be operated on the wrong side. Surprisingly, only 63% of the patients made the mark on the limb, with there being a significant association between not drawing the mark and having undergone previous surgery on the same foot or ankle. This suggests that we have to educate our patients better about their important role in active prevention to avoid complications, such as wrong site surgery. In our study, 13.9% of the patients did not draw a mark on their foot, possibly because the patients themselves are not used to this procedure; this indicates that we should provide better information to the patients from the moment they are included in the list for surgery, during the preoperative anaesthetic visit and on the day before their admission, emphasising the importance of limb marking. We also found more missing side notations (32.2%) or side inconsistencies (15.3%) in the written CH documents for the patients who had previously undergone some foot operation.

The manner of drawing the mark on the limb to be operated varies greatly, depending on the surgeons and on the hospital institutions. The AAOS and the JCAHO recommend that the surgeon should write her or his initials, with a permanent felt-tip pen, in the area or near the area to be operated on.^{6,12,19} Some authors indicate that drawing an 'X' can lead to confusion, because the patient can transfer this mark to the contralateral leg upon crossing legs, meaning that both legs are marked with an 'X', while the initials would give rise to an inverse image.^{10,12} Marking the healthy leg that should not be operated on (wrong leg, 'No', etc.) can fail and cause errors.¹⁰ Drawing an 'X' on the surgery site is not acceptable, given that it is not sufficiently clear (it is unclear whether the place where

the 'X' is drawn is the one that should be operated or the one not to be operated on)^{1,15} and adhesive markers should not be used as the sole method of marking the spot to be operated.¹⁹ Even some electronic instruments have been designed, which use an adhesive radiofrequency-controlled identifier,^{43,44} which emits an acoustic signal if the patient, procedure and side to be operated on have not been confirmed. Another proposal has been circular bands in a more proximal area of the limb to be operated,⁴⁵ taking into account that the anaesthetic blocks are often performed in an anatomical region different from the one where the surgeon has to operate and that the patient's position sometimes has to be changed. Marking the area where the surgery is to be performed could present a potential risk of infection, which is why some surgeons opt for writing 'No' on the side that must not be operated on,³⁶ but it has later been shown that making a mark on the incision site did not cause an increase in the percentage of infection.¹⁰ Generally speaking, marking the place where the incision is to be performed is carried out with a non-sterile felt-tip marker, which is usually used for several patients, but it has been demonstrated that marking the surgical site with a non-sterile marker does not contaminate the surgical site and, after sterilisation with an iodine solution, no contamination exists in this area.^{46,47} It has also been proven that preoperative marking does not trap bacteria under the place of the mark, so it does not contaminate the surgical wound either.⁴⁸

The time that elapses between verifying the side to be anaesthetised or operated on and the moment in which this is done has been shown to be directly proportional to the possibility of making a wrong side mistake. This stems from the fact that during this period there may be numerous factors of distraction.^{37,39,40} That is the reason why repeated marking during the preoperative process and verifications at different times (reception of the patient, before administering the anaesthesia and before performing the surgery) has a high probability of preventing a wrong side anaesthetic or surgical error, with the way such marking on the limb is carried out being possibly less important. Establishing a protocol with 3 separate markings on the limb to be operated represents a few additional advantages added to the other protocols existing in current surgical practice. Patient collaboration, by drawing the first mark on the limb, establishes a highly important first confirmation in the surgical process and can make the patients feel part of this concern and be more alert at the moments of administering the anaesthesia and preparing the limb that is to be operated on. Secondly, the nurses adopt a significant role by drawing a second mark when the patient is received, and by verifying the side according to the patient's indication and what is written in the case history as well, confirming that the information is correct. Verifying the side and drawing a third mark on a different spot before administering the anaesthesia block prevents loss of information during the time lapsed and ensures correct performance of anaesthesia in the correct side, granting the anaesthesiologist responsibility for their anaesthetic act. The surgeon's final verification of the side that is to be operated on, before initiating the surgery, confirms that the entire process has been carried out correctly and that the side anaesthetised corresponds with the side that should

be operated, giving the surgeon the responsibility of operating on the correct side. The surgeon who is to perform the operation is just another piece of the surgical team who performs a last verification of the side to undergo surgery, which is confirmed by the presence of the other marks.

The cooperation of all the staff who intervene in the surgical process in marking the limb to be operated minimises the possibility of errors,^{7,12,13,35} while simultaneously allowing dynamic surgical activity without affecting patient safety. Permanent, effective communication between the entire surgical team and the patient must exist, to be able to detect possible errors before they occur.⁴ Kwan et al.⁸ reviewed 13 cases of wrong side medical errors and indicated that, under ideal conditions, just the performance of the Universal Protocol could have prevented a third of these errors (8 cases). In our opinion, establishing a protocol to prevent wrong side surgery should be adapted to the characteristics of the area where the surgery takes place, taking care to avoid complexity and redundant steps that do not usually provide greater safety or additional benefits. However, there are undoubtedly multi-factor causes that must be taken into account to prevent complications such as wrong side surgery and any strategy in this sense needs to involve and make changes in the behaviour of both the surgical staff and the patients themselves.

Fortunately, wrong side surgeries are rare, which make it logistically difficult to evaluate the effectiveness of the various measures that are established to prevent it. Nonetheless, the simple performance of a verification protocol before initiating surgery can, just by itself, reduce the perception of risk of committing wrong side errors and can increase the sensation of safety for the patient and for the personnel who intervene in the surgical process. In addition, such a protocol promotes collaboration and coordination among the various members of the team (surgeons, anaesthesiologists and nurses). The simple protocol of marking the side to be operated has made it possible for us to raise awareness of how important it is to prevent these errors and to establish behavioural changes that may be beneficial for patient safety. Some of the surgeons and anaesthetists who participated in this study assessed the missing information on or errors committed in writing down the side to be operated and show greater attention when making a note in the case history of the limb that is to be operated on. Side marking has been incorporated as a routine practice in our foot surgery, undoubtedly being beneficial to patient safety. However, incorporating this practice likewise for medical residents in surgery and in anaesthesiology and for nursing and medical students present in the surgical area should shortly become standard behaviour in all the surgical areas.

No protocol alone can prevent all the cases of wrong side surgery and the responsibility for ensuring the correct operating site will depend in each case on only the vigilance of the entire surgical team. The patients themselves must likewise be given a significant role in this prevention and they must be made aware that their collaboration is essential for the surgical process to take place without incidents.

Conclusions

Even though this study may be limited because of the small number of patients included and the results cannot be given as conclusive, various points of risk that could lead to committing wrong side surgery have been detected and efforts should be made to correct them.

A total of 25 patients (24.8%) had not been told that they had to draw a mark on the foot that was to be operated on, possibly due to the new establishment of this protocol and the fact that the staff was not accustomed to it. Fourteen patients (13.9%) did not draw a mark on their foot, despite having been told how important it was in preventing surgical errors; this indicates that not all of the patients assume their role in preventing wrong side surgery. No risk group was found in terms of age, sex, level of studies, living alone or previous foot operation. The lack of the note as to the side to be operated was more frequent in the case histories from TOS and Anaesthesia, with this being a risk factor that the surgical team should take into account. We also detected 9 cases of inconsistency in the side noted on at least 1 written document in the case histories, which entails a greater risk of operating on the wrong side and which should not have occurred. Patients with previous foot surgery have a higher percentage of missing side notations (32.2%) and of inconsistencies in the side to be operated (15.3%) than do the rest of the patients; this difference is statistically significant, so special care needs to be taken with this type of patient to prevent wrong side surgery.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this investigation.

Confidentiality of Data. The authors will declare that they have followed the protocols of their work centre on the publication of patient data and that all the patients included in the study have received sufficient information and have given their informed consent in writing to participate in that study.

Right to privacy and informed consent. The authors must have obtained the informed consent of the patients and/or subjects mentioned in the article. The author for correspondence must be in possession of this document.

Conflict of interests

The authors have no conflicts of interest to declare.

Level of evidence

Level IV evidence.

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