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ORIGINAL ARTICLE

# Prevention of Surgical-Site Infection, Using a Modified Bundle

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**KEYWORDS**
Infection;
Surgical site;
Prevention;
Modified *bundle*

**Abstract**
Besides the usual measures to control surgical site infection (SSI) (instrument sterilisation, surgical wear, clean surfaces, HEPA filters, and correct surgical technique, etc), there are some simple measures, based on type I evidence which also work synergically (*bundle*): hair cutting with a machine instead of a razor, antibiotic prophylaxis, blood glucose monitoring and patient temperature during surgery. To this *bundle* of measures should be added another: antisepsis of the surgical field, on the patient and on hands and forearms, and surgical equipment. In the last few years alcohol solutions have been introduced in place of chlorhexidine and povidone iodide for antisepsis of surgical equipment, with very good results, and in a recent multicentre clinical trial (January, 2010) it was shown that 2%chlorhexidine in alcohol could reduce SSI by half compared to the use of povidone iodide. For these reasons, I believe that we should introduce these behavioural changes to reduce SSI, with a minimum of cost.


**PALABRAS CLAVE**
Infección;
Localización quirúgica;
Prevención;
*Bundle* modificado

**Prevención de la infección de localización quirúrgica, según un *bundle* modificado**

**Resumen**
Para controlar la infección de localización quirúrgica (ILQ) se han descrito, además de otras medidas habituales (esterilización de instrumental, atuendo quirúrgico, limpieza de superficies, filtros HEPA, correcta técnica quirúrgica, etc.), unas medidas sencillas, basadas en evidencia tipo I, que además actúan sinérgicamente (*bundle*): corte del vello con maquinilla en lugar de rasurado, profilaxis antibiótica, control de la glucemia y la temperatura del enfermo intraquirófano. A estas medidas del *bundle* habría que añadir otra: antisepsia del campo quirúrgico, en el enfermo, y de las manos-antebrazos, en el equipo quirúrgico. En los últimos años se están introduciendo soluciones alcohólicas en lugar de clorhexidina o povidona iodada para la antisepsia del equipo quirúrgico, con muy buenos resultados, y recientemente (enero, 2010) se ha demostrado con un ensayo clíni-

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co multicéntrico que la clorhexidina al 2% en alcohol puede reducir a la mitad la ILQ, respecto de la utilización de povidona yodada. Por todo ello, creo que debemos implementar estos cambios de conducta para lograr reducir, sin apenas coste, la ILQ.


Surgical-site infection (SSI) is one of the most serious complications in traumatological surgery, so attempts have been made to control it for many years through the application of peri-surgical antibiotic prophylaxis, together with the classical measures of surgical asepsis and discipline. At the Traumatology and Orthopaedics Departments of the La Paz University Hospital, we started systematic peri-surgical antibiotic prophylaxis (administered 30 min prior to surgery and up to 1-2 days afterwards) in patients subjected to surgery at the beginning of the 1980s and, in a short time, obtained a reduction of the incidence of SSI to one third.[1] Later, when antibiotic prophylaxis became commonplace, our effort has been to reduce it as far as possible, in other words to achieve a "single dose" that would not induce resistance to the antibiotic used (generally cefazolin or amoxicillin-clavulanic acid, although it is possible to substitute vancomycin in the case of betalactamic allergies), and also because it has been shown in a multivariate analysis of a sample of over 7,000 patients that lengthy prophylaxis (after checking for confounding factors dependent on the characteristics of the patient, length of stay, etc.) multiplies SSI by a factor of approximately 1.5.[2]

Lately,[3,4] descriptions have been published of measures that are simple to implement, yet essential to reduce the incidence of hospital infection, based on studies with evidence level I (clinical trials). In addition, these measures "synergize" with each other so that the use of all of them together implies a higher level of prevention than the sum of each one separately (known as *bundling*). The SSI bundle comprises:

1) *clipping* body hair instead of shaving it,
2) adequate *antibiotic prophylaxis*,
3) maintaining the patients' body *temperature* and
4) controlling *blood sugar*)

All of these can be summed up with the acronym "CATS", represented by the mnemotechnical image of this animal.

But it would be necessary to add another measure to these 4 in the bundle: the antisepsis of the surgical team and the patient with alcohol-based solutions. I shall refer to these solutions below, providing evidence backing up the recommendation to change behaviour and the impacts of these changes in order to conclude with an image to complement that of the acronym CATS.

For more than 20 years alcohol-based solutions have been recommended for surgical antisepsis in various European countries and, since 2002, in the United States.[5-7]

At the end of the 1990s, publications[8-10] began to suggest that alcohol-based solutions have more anti-microbial efficacy than classical surgical scrubbing techniques (chlorhexidine at 4-5%, PVP-I at 7.5-10%), in terms of both the "transitory" and the "permanent" microbiota on the skin. On the other hand, alcohol-based solutions provide better protection for the user's dermis (less dryness and lower level of irritation) and without requiring scrubbing during application (lower level of dermal aggression).

The purpose of their use is the same as with classical antisepsis: to minimize the risk of surgical infection in the event that gloves tear, something that occurs in as many as 18% of operations.

In 2008, a Cochrane review[11] was published on the efficacy of surgical antisepsis to reduce surgical-site infection, comparing alcohol-based solutions to the other 2 classical antiseptics, povidone iodine and chlorhexidine. After the initial screening, looking for papers that were comparable and had the methodological rigour to allow conclusions to be drawn, they chose 11, one of which was ours,[8] precisely the only one to compare the three products indicated above in two types of trial, on volunteers and in real surgery. In that paper, published in 2000, it was clear that one of the alcohol-based solutions available at the time (with N-duopropenide) was more effective than chlorhexidine and this more than povidone iodide, on analysis of the microbial contamination on the hands of health-care personnel (comparing the microbiota of each volunteer before and after disinfection and after removing their gloves). The following year, Pietsch[9] also showed that, from the microbiological standpoint, chlorhexidine was worse than Sterillium® (alcohol plus a quaternary ammonium compound, mecetronium). But it wasn't until 2002, when Parienti[10] et al., in a multi-centric study with a 1.5-year follow-up, pointed out that these anti-microbial effects also had a repercussion in the form of a significant reduction in the infection of surgical wounds and they found that Sterillium was significantly better ($p<0.01$) than chlorhexidine.

In 2006, Rotter[12] compared three alcohol-based solutions (n-propanol at 60%, 2 propanol at 70% and ethanol at 80%, the most suitable concentrations for these alcohols) with chlorhexidine at 4% in 5 laboratories and, although there was a certain variation in the results of each laboratory (as the study was performed on volunteers, and the flora will never be identical in each group), the trend was constant, as n-propanol was better than 2-isopropanol, this latter better than ethanol and all of them superior to chlorhexidine at 4%.

But the great problem is that in several papers the alcohol-based solutions have been used with a variety of adjuvants, and the efficacy of these solutions can vary greatly, depending on the antiseptic accompanying the alcohol and even the emollients, as these protect the skin but also sometimes interfere with the product's microbicidal efficacy. That is why it is difficult to draw anything more conclusive than a "trend" for alcohol-based solutions in

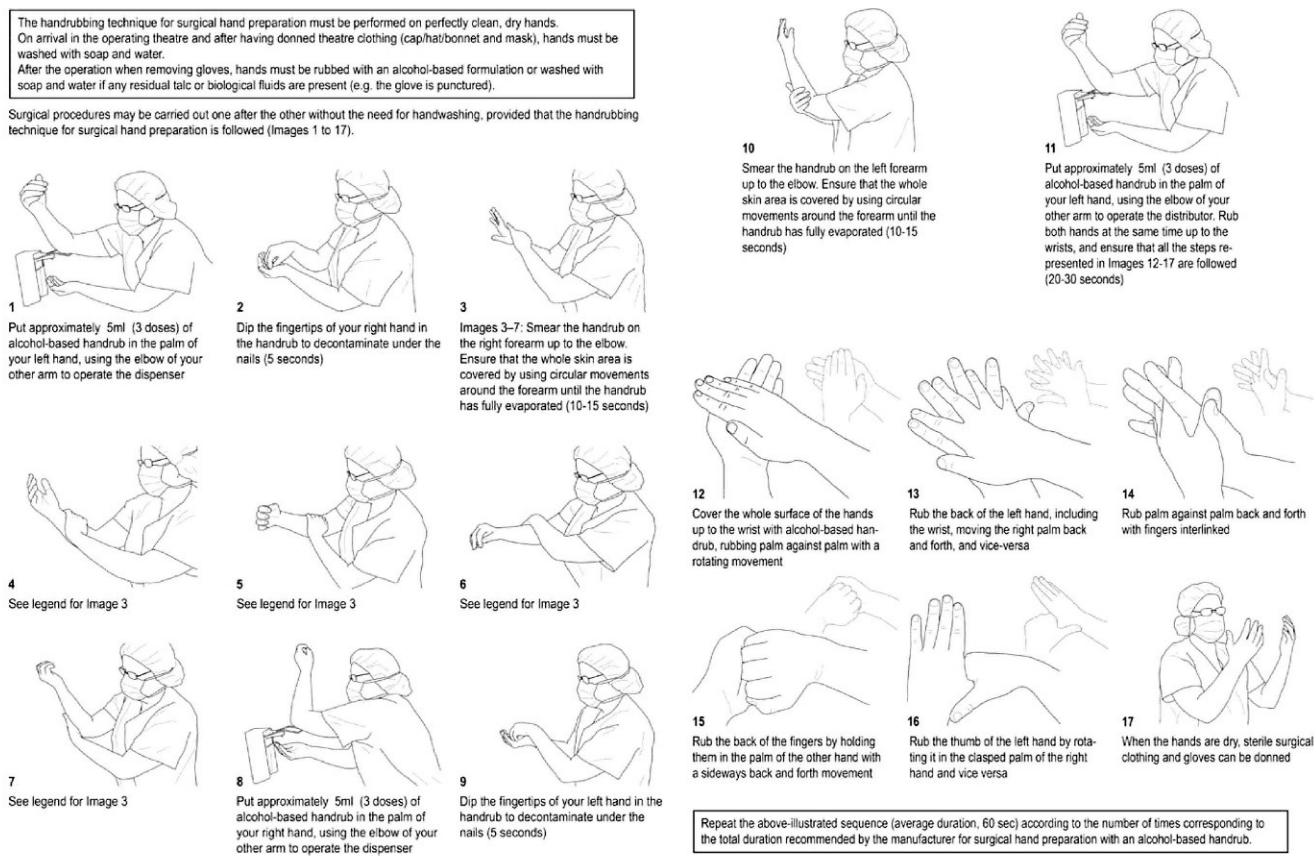


**Figure 1** Method for performing pre-surgical antisepsis of the hands. World Health Organization. Time recommended for the duration of the process: 3 min.

general, and that was the conclusion reached by the Cochrane Review.

In 2009, the WHO[13] ratified the use of alcohol-based solutions for pre-surgical cleansing with diagrams explaining how to perform the process (fig. 1). It takes only 3 min and does not require prior washing (except where the hands are visibly dirty) or scrubbing (implying less dermal aggression). Antisepsis of the sub-ungueal areas is achieved by depositing some of the alcohol-based solution in the palm of one hand and dipping the nails on the other hand into this liquid, moving the nails as if scratching the palm of the hand containing the alcohol-based solution. The same operation is repeated for the other fingers. The microbiological results of this technique are very good, compared with the habitual technique (washing with chlorhexidine or povidone iodine) and, above all, are distinguished by their greater residual efficacy,[1] maintaining the microbiota inside the glove under better control than with the classical washing technique, in which the surfaces of the hands were always re-contaminated by the emergence of the micro-organisms from their reservoirs in the sweat glands and hair follicles, so that, in long operations, we have encountered[8] situations in which it was even possible to have more contamination present than before the surgical washing (particularly with povidone iodine), whereas with the alcohol-based solutions this re-contamination was delayed, with very low counts being obtained (close to zero by the fingerprint technique). For this reason, when it is attempted to introduce this technique into surgery it is a good idea to carry out checks on the hands of the surgical team prior to and after antisepsis and again at the end of the surgical operation, so that each participant can come to his or her own conclusion, based on their own microbiota, the efficacy or otherwise of the alcohol-based solution, and weigh this result against other aspects of the technique, such as the smell (which some people dislike), etc. Figures 2 and 3 present some of the results obtained with our surgical teams in the initial phases for the introduction of this surgical antisepsis technique. In these figures it is possible to appreciate, in different types of surgery, that the overall effect is the almost total elimination of colony-forming micro-organisms and the maintenance of this level throughout the operation.

But we must not indicate solely the use of alcohol-based solutions, but have solid criteria for advising on the best, as some of these, due to their specific composition, are not as effective, even though the changes in their formulas are not completely observable. How can we choose the best for surgical antisepsis?

## Criteria for Choosing the Alcohol-based Solution

The first thing is to have available suitable studies assessing the efficacy of these alcohol-based solutions, for example

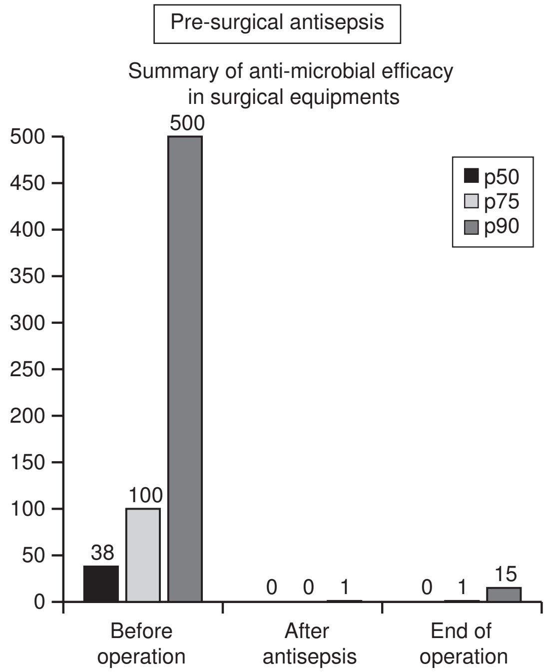


**Figure 2** Anti-microbial efficacy of the alcohol-based solution used at the La Paz Hospital. The number of cfu is represented as percentiles by population studied.

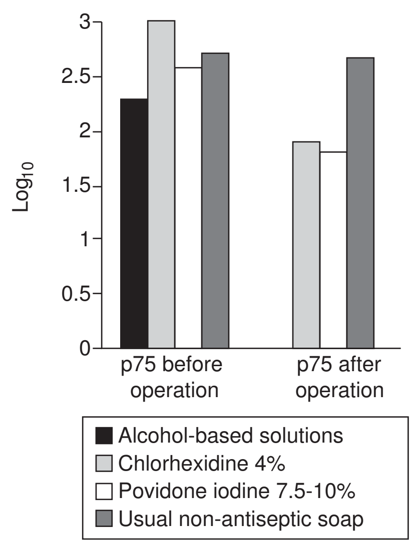


**Figure 3** Comparison of anti-microbial efficacy after using different solutions for surgical scrubbing. The Y-axis represents the $\log_{10}$ values of the cfu isolated on the fingers, prior to and after conclusion of the operation, in the p75 percentile of each product. Traumatological Surgery, La Paz Hospital.

the European standard EN 12791,[14-17] and so we shall briefly describe it here. This rules is a very appropriate one as it standardizes the evaluation of alcohol-based solutions and comes quite close to what clinical practice will be like, although it also has certain limitations that we must try to overcome.

A minimum of 20 volunteers are required to apply either a reference alcohol-based solution (n-propanol at 60°) or else a "test" alcohol-based solution (for assessment). Volunteers have to wait a week between the two applications for the flora to be re-established, so they will not be able to use any alcohol-based solutions or continue with the trial until this wash-out period has elapsed.

Summary of the steps in Standard 12791:

1) Hand wash with mild soap at 20%(linseed oil + potassium hydroxide, pH 10-11) for 1 min.
2) Rinse for 15 sec under running water and dry with a paper towel.
3) Collect microbiological samples from both hands. These will give the initial microbial counts.
4) Leave to dry.
5) Apply n-propanol at 60°, spreading it out well over all the surface of the hands as far as the wrists, keeping them damp for 3 min.
6) Collect microbiological samples from the right hand. This will be "Time 0".
7) A glove is placed on the left hand and the volunteer leaves for 3 hr.
8) On return after this time, the glove is removed from the left hand and a microbiological sample is taken, as in step 6. This will be "Time 3 hr".
9) Seeding, incubation and annotation of the number of colonies on each hand (*prior* to the application of alcohol), as well as those corresponding to times *0* and *3h after* applying the alcohol-based solution.
10) Calculation of the "immediate effect" (subtracting the $\log_{10}$ of those found at time 0 to the $\log_{10}$ of the colony-forming units on the right hand) and determination of the "long-term effect" ($\log_{10}$ of the colony-forming units on the left hand minus the $\log_{10}$ of those at time 3 hr).
11) After a week the experiment is repeated but the alcohol is replaced by the product to be assessed under this standard.

The study concludes with a summary describing the "immediate" and "after 3 hr" effects of the new product and the n-propanol (reference alcohol), as well as the statistical difference between both types of values for the test sample and the control sample. In order to pass the EN 12791 standard, the immediate effect of the test solution must not be statistically lower than n-propanol at 60° with a $p<0.1$. As n-propanol has hardly any residual action (on endogenous microbiota), then, if a "long-term effect" is claimed after 3 hr, the new product must be significantly superior to n-propanol at 60° ($p<0.01$).

By way of example, please refer to table 1, which sets out the last sheet of an EN 12791 report drawn up by the Autonomous University in Madrid.

N.B.: in the preliminary version of the Standard (pr-N 12791), the 3 hr result was only required to be "not inferior" (as in the immediate effect) and various articles based on that preliminary standard drew conclusions about a "prolonged effect" that would not be accepted as such today; as a result, it is necessary to be very careful about whether a report presented by a commercial company refers to the definitive standard (EN 12791) or its

**Table 1** Example of the last page of a report under the EN 12791 standard

| **Comparison of the values for the reference and test alcohol-based solutions (XXXXXX-solution) (Wilcoxon's test)** | | | |
|---|---|---|---|
| Effects assessed | Mean value of $\log_{10}$ for the reduction factor | | Significance of the difference [a] |
| | Test: XXXXXX | Reference | |
| Immediate effect | 2.76 | 1.52 | Sig. (p<0.01) |
| Effect after 3 hr | 2.41 | 1.33 | Sig. (p<0.01) |

The name of the product investigated has been replaced by XXXXXX. Therefore, XXXXXX is a suitable product for surgical disinfection of the hands and, in addition, it has a long-term effect.
Log: logarithmic; Sig.: significance.
[a] with or without Bonferroni's correction.

preliminary version pr-N 12791 (the latter should be rejected).

Advantages of the EN 12791 Standard:

It is (relatively) simple, it does not require the identification of micro-organisms and it is reproducible (in the sense that different laboratories indicate the same "ranking order" for different products tested, but not that the numerical results are similar or that any two reports can be compared directly to each other).

It allows self-correction by individuals (the $\log_{10}$ reduction is obtained for each volunteer and that corrected reduction is used for calculating the mean).

It is conservative in its "immediate effect", as it allows the $\log_{10}$ reduction to be lower than that of alcohol (providing it is not significantly lower). However, this does not happen with the sustained effect, as this must be greater than that of n-propanol at 60° with p<0.01.

It eliminates the "transient" microbiota of each volunteer with prior washing for 1 min., as the goal is the "resident microbiota".

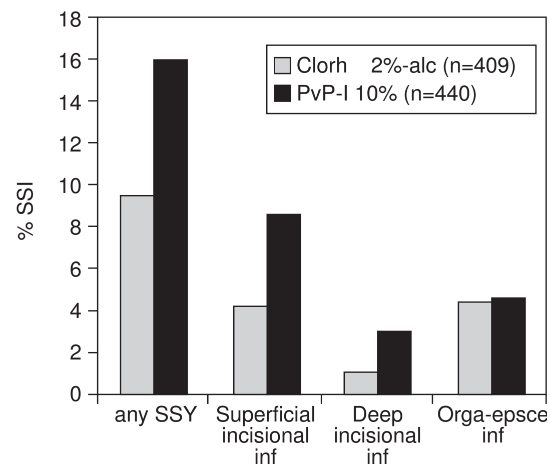


**Figure 4** Comparison of the surgical-site infection in two groups of patients, depending on whether surgical antisepsis is done with an alcohol-based solution or with povidone iodine.

But won't SSI be more directly related to the contamination of the patient's skin, particularly that occurring during or shortly after the operation, due to the emergence of micro-organisms from reservoirs in the sweat glands and hair follicles in the peri-incisional area? This endogenous contamination is inversely related to the residual effect of the antiseptic used on the patient.

The antiseptic most commonly used for the antisepsis of patients' skin prior to surgery is povidone iodine, not only because of its antiseptic efficacy, but also because of the ease with which the areas of application can be identified (except in certain patients, such as newborn infants or after Caesarean sections,[18] due to the risk of absorbing iodine); nonetheless it has little residual efficacy on endogenous microbiota. For this reason, it will be understood that the most logical approach is to verify whether or not the application of a product with a greater residual anti-microbial effect on the patient's skin than povidone iodine brings about a reduction in the incidence of SSI.

This is what has been done[19] in a clinical trial with over 400 patients in each arm published at the start of this year in the N Engl J Med. The paper investigated the incidence of SSI in patients subjected to clean-contaminated surgery, among those in whom povidone iodine was applied for pre-surgery antisepsis with respect to those who were given chlorhexidine at 2% in isopropyl-alcohol (ChloraPrep®, a solution used in venopuncture and other uses since the end of the last century). The efficacy of this latter alcohol-based solution has been enormous, much greater than was expected *a priori*, as the incidence of SSI fell to almost a half, both in surface wounds and in deep wounds, and it even reduced the infections of organs or spaces, although this fall was not significant with the *n* of 400. In addition, this drop occurred in different types of clean-contaminated surgery. The main data are detailed in figure 4, prepared on the basis of the tables shown in this clinical trial.

The underlying reasoning for the preceding experiment can also be applied to clean surgery (perhaps even more strongly as, in the case of such operations as traumatological or cardiac surgery, etc., the residual effect on the patient's endogenous microbiota in the peri-incisional area may be of even greater value), although a larger number of patients will be required to show statistical significance as this surgery has a lower incidence of SSI, but the relative risk (RR) of using alcohol-based solutions versus povidone iodine must be at least similar to that of the previous clinical trial.

It should be recalled that the application of alcohol-based solutions for surgical antisepsis must only be *done with undamaged skin*, not on wounds or mucosae (consideration should also be given to their application on the groin or under the arms). In addition, another restriction on this indication for alcohol-based solutions should also be noted: newborn children with a gestational age of less than 37 weeks, for at least their first two weeks of life, as this is the time associated with the greatest capacity to absorb substances applied to the skin, due to the lack of maturity of the corneal stratum. Finally, these alcohol-based solutions with chlorhexidine at 2% must have the same contraindications as specified for chlorhexidine digluconate in aqueous solution.

This chlorhexidine-alcohol solution can be purchased (Chlora-Prep or a formula with chlorhexidine at 2% in isopropanol at 70º, available in Spain) or else it can be prepared at the hospital pharmacy. Some of the new formulas with chlorhexidine at 2% incorporate a colouring agent to achieve the same outstanding advantage of povidone iodine. This may help with its use, although care will need to be taken as the colouring agent may be hard to remove later, leaving the skin with a stain that prevents correct observation after surgery. But could we use alcohol-based solutions already in use for the antisepsis of the surgical team? The answer is probably yes, but it is necessary to show that these solutions are as effective as chlorhexidine at 2% in isopropanol at 70° and that they do not produce any harmful effects in their application on the patient's undamaged skin prior to surgery (for example, scarring problems due to the emollients?). *In vitro* we have obtained $\log_{10}$ reductions of 2 solutions that met the EN 12791 standard in its two times, initial and after 3 hr (in other words, they had a sustained effect), similar to that of chlorhexidine at 2% in isopropanol, using micro-organisms from ICU patients, but it is necessary to confirm these experiments with other *in vivo* tests using the normal microbiota of healthy volunteers.

Whatever the alcohol-based solution chosen, it must be used as follows for clean-contaminated surgery and I feel that they would also be useful in clean surgery (with the exceptions referred to earlier of mucosae, newborns, etc.): repeated applications with a dressing or towel on the patient, with 30 sec rest, to allow evaporation, until a time of 3 min has elapsed, leaving the solution to dry for *at least* 1 min after the last application.

Thus, I conclude with a summary of the measures with demonstrated efficacy for the reduction of SSI, as expressed in the bundle for this kind of infection (*clipping* the patient's hair instead of shaving it, adequate *antibiotic prophylaxis*, maintain the patient's body *temperature* and control blood *sugar*) and which should be complemented with something that indicates the Application of an Alcohol-based Solution, both on the patient and on the surgical team, in other words adding "A"s to CATS to give Ace of Cats? (fig. 5). As a slogan, "use an Ace to control SSI" or "when operating, keep this ace up your sleeve", etc.

However it is memorized, we must recall that we have available a number of simple and highly effective measures for reducing SSI, although the ideal is to *monitor for greater compliance* in order to ensure that this is as high as possible.

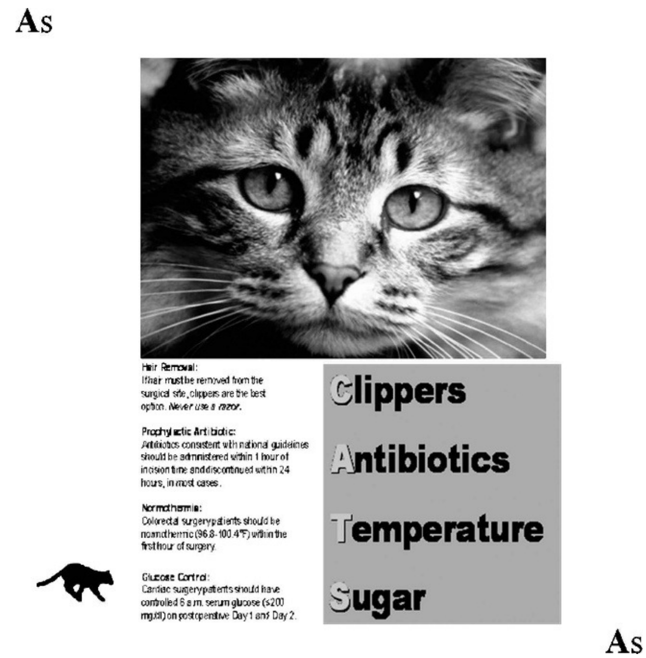


**Figure 5** Modified bundle for the prevention of surgical-site infection.

Of course, in addition to the preceding SSI prevention measures described in the bundle, we have to add others that may vary depending on the type of surgery, such as a prior stay in hospital, the correct surgical garb / intra-operating room discipline and instruments, as well as an adequate level of temperature, humidity and contamination (controlled by HEPA filters, at least in such operations as cardiac surgery, orthopaedics for major joints and the cleaning of surfaces, at least twice a day, once before the start of surgical activities and again at their conclusion), with the possibility of also using intestinal decolonization, hyperoxygenation, etc., in certain types of surgery and, finally, the most important but hardest to standardize: the correct surgical technique.[20]

Other risk factors for SSI, such as the type of surgery (risk coded by the ASA index or NNIS, etc.), alterations in immunity, malnutrition, obesity or even smoking have an impact on the amount of SSI[20-23] and these must all be taken into account when making comparisons of the incidence of this complication, but they are impossible (intrinsic to the operation to be performed) or very difficult to change, so they have not been discussed in this revision.

Another paper[24] also published in the N Engl J Med has brought up another subject that complements the measures referred to in the modified bundle: the reduction in SSI by acting on the colonization of the patient with *S. aureus*. To this end, in clean or clean-contaminated surgery, during the days prior to the operation, decolonization takes place by body washes using chlorhexidine and nasal application of mupirocin. They obtained a good effect, but they restrict the indication to those patients colonized by this micro-organism, meaning a prior screening is required and this may limit its application. In any case, it is also a strategy that could be implemented without excessive cost; in fact, the nasal mucosa is decolonized in several hospitals with mupirocin, for instance, before cardiac surgery, regardless of whether or not the patients are colonized by *S. aureus*.

## Conflict of interests

The authors declare that they have no conflict of interests.

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