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Compliance with antibiotic prophylaxis in spinal fusion surgery and surgical wound infection

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ABSTRACT

Background. Surgical wound infection is an important complication of spinal surgery. Antibiotic prophylaxis has served to decrease its rates significantly, with the ensuing reduction in hospital stay, costs, and morbidity and mortality. To date, a large assessment of the degree of compliance with antibiotic prophylaxis in spinal fusion surgery has not been undertaken in Spain with large prospective studies. We sought to assess the degree of compliance with our antibiotic prophylaxis protocol among patients who underwent spinal fusion surgery and its effect on surgical wound infection. **Material and methods.** A prospective cohort study was carried out. Six hundred and forty patients with at least 1-year clinical follow-up who underwent spinal fusion surgery were included. Percentage of administration and degree of compliance with protocol was studied. Both overall and the different aspects of prophylaxis received by patients to those stipulated in the protocol in force at our hospital were compared. Percentages of compliance were assessed and the effect of prophylaxis compliance on the incidence of infection was estimated using the Relative Risk. **Results.** The study covered 640 patients. Overall compliance with the protocol was 71.5% (95% CI = 67.9-75.1). The most frequent cause of non-compliance with the protocol was the duration of recommended antibiotic prophylaxis (77.8%). Incidence of surgical wound infection was 4.1% (95% CI: 2.5-5.5). No relationship was found between surgical wound infection and antibiotic prophylaxis non-compliance (RR 0.92, 95% CI = 0.38-2.22). **Conclusions.** Compliance and administration of antibiotic prophylaxis were high. Surgical wound infection rate was similar to those found in the literature although there is always room for improvement.

Adecuación de la profilaxis antibiótica en la cirugía de fusión espinal e infección de herida quirúrgica

RESUMEN

Antecedentes. *Las infecciones de herida quirúrgica son una importante complicación en la cirugía espinal. La profilaxis antibiótica ha servido para disminuir las tasas de infección con la consiguiente reducción en la estancia hospitalaria, costes, morbilidad y mortalidad. En España hay pocos estudios de evaluación de la adecuación de la profilaxis antibiótica en cirugía de fusión espinal.* ***Objetivo.*** *Evaluar la adecuación de la profilaxis antibiótica al protocolo de nuestro centro en pacientes que fueron sometidos a cirugía de fusión espinal y su efecto sobre la infección en herida quirúrgica.* ***Material y métodos.*** *Se llevó a cabo un estudio de cohortes prospectivo. Se incluyeron 640 pacientes que fueron sometidos a cirugía de fusión espinal y fueron seguidos clínicamente durante un año. Se estudió el grado de administración y adecuación de la profilaxis al protocolo hospitalario, de forma global y para criterio de evaluación: antibiótico de elección, vía de administración, dosis, tiempo de inicio y duración de la prescripción antibiótica. Se describieron las distribuciones de frecuencias y los porcentajes de adecuación al protocolo y la incidencia de infección de herida quirúrgica. El efecto de la inadecuación de la profilaxis sobre la infección de herida quirúrgica se estudió con el Riesgo Relativo.* ***Resultados.*** *El estudio incluyó 640 pacientes. La profilaxis se administró en 99.5% de los pacientes y la adecuación global al protocolo fue de 71.5% (IC95%: 67.9-75.1). La causa más frecuente de inadecuación al protocolo fue la duración de la profilaxis (77.8%). La incidencia de infección de herida quirúrgica fue de 4.1% y no se encontró relación entre la infección y la inadecuación de la profilaxis antibiótica (RR = 0.92; IC95%: 0.38-2.22).* ***Conclusiones.*** *La administración y la adecuación de la profilaxis antibiótica fueron altas. La incidencia de*

infección de herida quirúrgica fue similar a la encontrada en la literatura aunque siempre hay margen de mejora.

Key words. Antibiotic prophylaxis. Surgery. Spinal fusion. Surgical wound infections. Guideline adherence.

Palabras clave. *Profilaxis antibiótica. Cirugía. Fusión espinal. Infección de herida quirúrgica. Adhesión al protocolo.*

INTRODUCTION

Nosocomial infections (NI) are undesirable complications which occur during the hospitalisation of patients. They occur as a response to the presence of infectious agents or their toxins that were either not present or were in their incubation period at the date of the patient's admission,[1] and are complications arising from various medical-surgical interventions after 48 h of hospitalization.

Surgical wound infection (SWI) is the third leading cause of NI[2] after urinary tract and respiratory infections and its incidence is linked to specific surgical circumstances and intrinsic and extrinsic patient-related factors.[3] Surgical infection rates in orthopaedic surgery involving spinal fusion stand at around 3.5%[4] and translate as an increase in mean stay, a rise in healthcare costs and a decline in quality of life.[5]

Antibiotic prophylaxis is one of the most widely used preventive measures but its systematic use in clean surgery is controversial. Its adverse effects may outweigh the benefits resulting from a reduction in infection rates.[6] Optimal prophylaxis is that which ensures adequate concentration of the antibiotic of choice in blood, tissue and surgical site throughout the time during which the incision remains open and for a few more hours after it is closed.[7] It is thus fundamental for protocols to be implemented at hospitals, specifying antibiotic prophylaxis guidelines that are designed to enhance compliance and effectiveness.[8]

Our hospital has in place a protocol for antibiotic prophylaxis administration, drawn up and updated in line with the latest recommendations in the literature, as well as a spinal surgical site infection surveillance and monitoring system. Accordingly, this study sought to assess the degree of compliance with our antibiotic prophylaxis protocol among patients who underwent spinal fusion surgery and its effect on surgical wound infection.

MATERIAL AND METHODS

A prospective cohort study was conducted on the degree of compliance with antibiotic prophylaxis in spinal fusion surgery. The assessment took place at the Fundación Alcorcón University Teaching Hospital and was performed by the preventive medicine and orthopaedic surgery and traumatology departments. The patients included in the study were those who had undergone spinal fusion surgery. Table 1 shows a detailed list of the surgical procedures included, along with the pertinent codes of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) grouped under the Centres for Disease Control (CDC)/National Healthcare Safety Network FUSN procedures.

Sample size was estimated with a 95% confidence level, accuracy of 3%, expected compliance of 85% and envisaged losses to follow-up of 5%. A total 572 interventions were thus deemed necessary. We obtained the ethics and research committees approval to carry out the study. To ensure the sample size and include complete annual periods, study included patients operated from January 2007 to May 2012. The study finished in May 2013 to ensure a year's follow-up both clinical and epidemiological from the date of surgery for all the patients. To this end, patients were clinically followed up for one year by reference to surgical wound progression, clinical profile and microbiological results, as per the CDC definitions.[1] Exclusion criterion was defined as suspicion or confirmation of infection at the date of the intervention.

The study variables were age, sex, comorbidity, and the various aspects of antibiotic prophylaxis, including antibiotic of choice, route, dose, time of administration and duration. We recorded pre-surgical compliance with antibiotic prophylaxis (appropriate or inappropriate) and presence or absence of SWI. In long surgeries a second dose of antibiotic was administered during the surgical procedure. Swabs were taken when surgical wound infection suspicion. In the event of any SWI being registered, its depth (superficial, deep incisional and organ-space) and causative micro-organism were noted. Microbiological studies to identify the microorganisms implicated were performed using MicroScan Walkaway (Siemens®).

Table 1. Procedures studied and ICD-9-CM codes.*

Code	Intervention
81.0	Spinal fusion
81.00	Spinal fusion, not otherwise specified
81.01	Atlas-axis spinal fusion
81.04	Dorsal and dorsolumbar fusion of the anterior column, anterior technique
81.05	Dorsal and dorsolumbar fusion of the posterior column, posterior technique
81.06	Lumbar and lumbosacral fusion of the anterior column, anterior technique
81.07	Lumbar and lumbosacral fusion, transverse process technique
81.08	Lumbar and lumbosacral fusion, posterior technique

*International Classification of Diseases, Ninth Revision, Clinical Modification.

Table 2. Summary of antibiotic prophylaxis protocol for spinal surgery.

Guideline	Antibiotic	Dose	Route	Initiation
Standard	Cefonicide	1 g	Intravenous	30-60 min prior to surgery
Allergic to beta-lactam antibiotics	Vancomycin	1 g	Intravenous	60-90 min prior to surgery

A descriptive study of the sample was conducted, with qualitative variables being described with their frequency distribution (number and percentages) and compared using the χ^2 or exact-Fisher's test. Quantitative variables were described with their mean and standard deviation (SD) or their median and interquartilic range (IQR). The normality criterion was evaluated using the Saphiro-Wilk test. Two-category quantitative variables were compared using the Student's-*t* test.

Degree of compliance was studied by comparing the different aspects of prophylaxis received by patients to those stipulated in the protocol in force at our hospital. Protocol compliance was assessed, both overall and individually, for all aspects envisaged. Responsibility for administering the protocol shown in table 2 was borne by the anaesthetists and assessment of antibiotic prophylaxis compliance was anonymous by checking medical records without informing anaesthetists in order to ensure blindness.

Incidence of SWI after the follow-up period was evaluated, and the effect of prophylaxis compliance on the incidence of infection was estimated using the Relative Risk (RR) of infection with its 95% confident interval.

To record the data, a purpose-made data-collection sheet and a relational, normalised database were designed in Microsoft Access®. All statistical analyses were performed using the SPSS v19 statistical programme. Statistical significance was considered $P < 0.05$.

RESULTS

The study covered 640 patients. Of this total, 284 were performed on men (44.5%) and 356 on women (55.5%) ($P = 0.005$). The mean ages of the patients intervened were as follows: 57.5 years overall (IQR = 30-63); 56.3 years (IQR = 29-64) for men; and 58.1 years (IQR = 27-67) for women ($P = 0.48$).

In all the cases studied, administration of antibiotic prophylaxis was indicated by the characteristics of the intervention of spinal fusion. Prophylaxis was administered in 635 interventions (99.2%). We could not document administration of prophylaxis in 5 patients. Overall compliance with the protocol, taking all the different aspects into account, was 71.5%, (95%CI = 67.9-75.1), and was inadequate in 181 patients (28.5%). Inadequacy occured in 189 prophylaxis administrations and in 8 patients there were more than one cause of inadequacy. Table 3 shows the degree of compliance with and adaptation to the protocol shown by the different aspects of antibiotic prophylaxis. Among the causes of non-compliance with the protocol listed above, duration of recommended antibiotic prophylaxis warrants special mention. This inadequacy was due to the fact that more than one dose was administered instead of administering only one dose as specified in the protocol. Median time of administration before surgery was 33 min (IQR = 28-39). Choice inadequacy accounted for 17 patients to whom neither cefonicide nor vancomycin were administered. They were rather adminis-

Table 3. Degree of compliance of antibiotic prophylaxis (n = 635).

	Compliance (n)	Compliance (%)	95%CI
Time of initiation	604	95.1	93.4-96.9
Longer duration	494	77.8	74.5-81.1
Dosage	635	100	99.4-100
Route of admin.	635	100	99.4-100
Choice of antibiotic	618	97.3	96.0-98.7
Overall	454	71.5	67.9-75.1

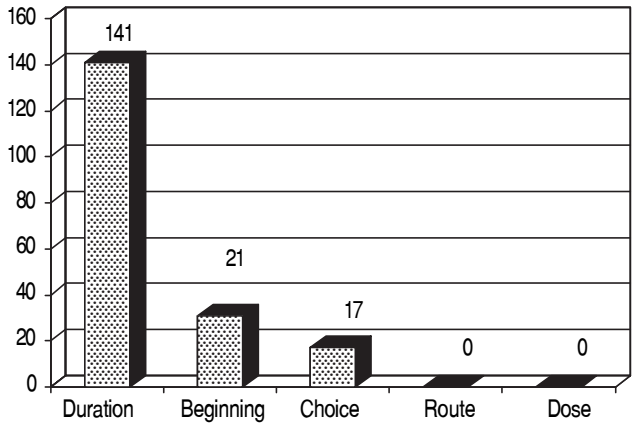

Figure 1. Causes of non-compliance with the antibiotic prophylaxis protocol (n = 189).

tered cefazolin (9), ciprofloxacin (5) and amoxicillin/clavulanic (3). A detailed breakdown of all causes of non-compliance is depicted in figure 1.

Overall incidence of infection after the follow-up period was 4.1% (95%CI = 2.5-5.5), with 12 cases of superficial and 14 cases of deep incisional or organ-space surgical site infections. Sixty-nine percent of infections were diagnosed during hospitalisation and 31% after discharge. There were 24 positive microbiological samples in the patients with surgical wound infection and the most frequent microorganisms were negative coagulase *Staphylococcus* (21%) and *Staphylococcus aureus* (21%). Two of the patients were diagnosed of surgical wound infection only by clinical characteristics then there were no positive microbiological samples. The microorganisms implicated in these infections are shown in figure 2.

No relationship was found between SWI and antibiotic prophylaxis non-compliance (RR = 0.92, 95%CI: 0.38-2.22). Regarding comorbidity, the most important risk factors found were a prevalence of diabetes mellitus of 13%, obesity 12%, COPD 6%, cancer 6% and renal insufficiency 3%. Patients with diabetes mellitus (RR = 2.88; CI95%: 1.31-6.36) and COPD (RR = 4.66; CI95%: 2.01-10.8) had a higher surgical wound infection risk.

DISCUSSION

Surgical wound infection is an important complication of spinal surgery. Antibiotic prophylaxis has served to decrease SWI rates significantly, with the ensuing reduction in hospital stay, costs, and morbidity and mortality. There are studies which show that antibiotic prophylaxis is capable of preventing more than 50% of infections.[9,10] Two recent meta-analyses showed that antibiotic prophylaxis was beneficial in spinal surgery, even in cases where expected infection rates without antibiotic treatment were low,[11] and that it was effective in terms of reducing risk of infection in all types of surgery.[12]

Our study focused on assessing the administration of antibiotic prophylaxis in patients who underwent back surgery involving spinal fusion. As almost all the patients who were intervened received prophylaxis, this entailed a degree of compliance of close to 100%. Such a high degree of compliance was not attained in the bibliography consulted.[13] It is important to note that the assessment was made without the knowledge of the anaesthetists, thus preventing their attitude from influencing the high degree of compliance of administration of antibiotic prophylaxis and controlling the Hawthorne effect.

When all the factors were evaluated jointly, overall percentage compliance of prophylaxis proved to be 71.5%. This percentage is somewhat lower than the degrees of overall compliance reported in the literature, though these refer to multiple surgical procedures and not specifically to spinal surgery.[14,15]

If one addresses each of the protocol criteria individually (time of initiation of prophylaxis, duration of prophylaxis, route of administration, dose and

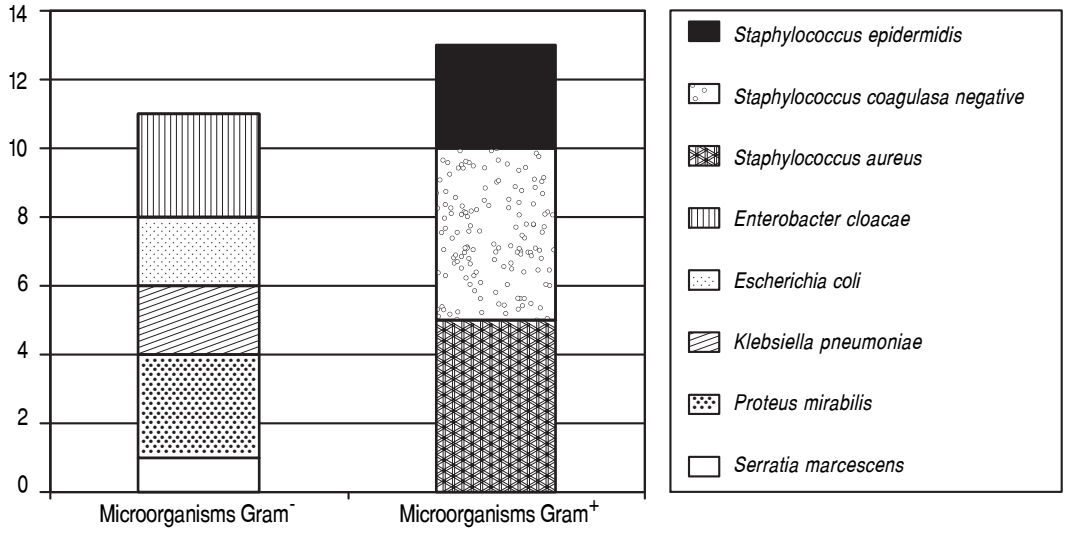

Figure 2. Aetiology of surgical site infections.

choice of antibiotic), it will be seen that, save for duration of prophylaxis, the degree of compliance exceeded 90% for each of these aspects. These percentages are in a range equal to or higher than those found in the literature.[14,16]

With respect to the duration of antibiotic prophylaxis, the single aspect to display the lowest degree of compliance with the protocol, it was inappropriate because the antibiotic had been administered for longer than the recommended time. This is a very important, much discussed aspect[17] in the field of antibiotic prophylaxis. Today it is known that the antibiotic dose used should be one whereby values above the minimum inhibitory concentration are obtained for a time which is appreciably longer than that of the surgical procedure. The dose should be repeated if the intervention lasts longer than twice the half-life of the antibiotic or there is a loss of blood of more than 1.5 L after administration of fluids.[18] There is one study which shows the time during which prophylaxis is administered as an independent risk factor for the appearance of SWI.[19] At all events, rather than seeking to assess the technical aspects of the protocol or the risk factors implicated in the infection as do other studies,[20-22] our study sought to assess protocol compliance in order to identify points for improvement. However, as duration was longer than that indicated in the protocol, its effect could have been not to increase the incidence rate of infection but rather to diminish it, although it can result in higher costs of hospitalisation and microbiological resistance.[23] In our case series diabetes mellitus and COPD were risk factors of surgical wound infection as communicated by other authors.[24,25]

Incidence of infection in our case series was somewhat higher than that published by the CDC[1] and other studies[26] for this procedure and similar to those in our field of influence.[27] When it comes to estimating incidence of surgical infection, follow-up time constitutes an essential point of this study, since our cases were evaluated within one year after surgery then implants were left in place after the procedures. This should have result in an appropriate estimated incidence with no bias.[28]

As a result of our assessment some measures were taken, such as communicate the results to the physicians in charge and all the healthcare team and we focused on the in place protocol to remind it and to try to improve the adherence to its recommendations. The result of this intervention will be assessed at an early future.

CONCLUSION

Stress should be laid on the importance of the implementation and ongoing assessment of antibiotic prophylaxis protocols in surgery, so as to be able to take timely measures targeted at reducing incidence of SWI as much as possible. In our study both compliance and adaptation of antibiotic prophylaxis were high but there is always room for improvement and, in this regard, the active participation of all professionals involved is vital.

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