ORIGINAL ARTICLE

Antibiotic prophylaxis adequacy assessment and its influence on surgical site infection in peripheral vascular bypass surgery

Efecto de la adecuación de la profilaxis antibiótica en la incidencia de infección de sitio qruirúrgico en la cirugía vascular periférica

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Abstract

Objective: *We sought to assess the degree of antibiotic prophylaxis adequacy to our surgical antibiotic prophylaxis protocol among patients who underwent peripheral vascular bypass surgery.* **Materials and Methods:** *Prospective cohort study. Adequacy to protocol was studied by comparing the different aspects of prophylaxis received by patients to those stipulated in the protocol in force at our hospital. Incidence of surgical wound infection was calculated and the effect of prophylaxis inadequacy on the incidence of surgical wound infection was estimated using the relative risk.* **Results:** *The study covered 266 patients. Incidence of surgical site infection (SSI) after the follow-up period was 5.3% (95% Confidence interval [CI]: 3.0-9.4). Overall adequacy to the protocol of antibiotic prophylaxis was 91.0% (95% CI: 87.6-94.4). The most frequent cause of inadequacy to the protocol was time of initiation of antibiotic prophylaxis (94.1%). No relationship was found between SSI and antibiotic prophylaxis inadequacy (relative risk: 2.4; 95% CI: 0.49-12.5; p > 0.05).* **Conclusions:** *Global adequacy to protocol of antibiotic prophylaxis was high. The most frequent cause of inadequacy to the protocol was time of initiation of antibiotic prophylaxis.*

Key words: *Surgical wound infection. Cohort studies. Antibiotic prophylaxis. Peripheral vascular bypass.*

Resumen

Objetivo: *Buscamos evaluar el grado de adecuación de la profilaxis antibiótica a nuestro protocolo de profilaxis antibiótica quirúrgica entre los pacientes sometidos a cirugía de bypass vascular periférico.* **Material y métodos:** *Estudio de cohortes prospectivo. La adecuación al protocolo se estudió comparando los diferentes aspectos de la profilaxis recibida por los pacientes con los estipulados en el protocolo vigente en nuestro hospital. Se calculó la incidencia de infección de herida quirúrgica y se estimó el efecto de la inadecuación de la profilaxis sobre la incidencia de infección de herida quirúrgica mediante el riesgo relativo.* **Resultados:** *El estudio abarcó 266 pacientes. La incidencia de infección del sitio quirúrgico (ISQ) tras el periodo de seguimiento fue del 5,3% (intervalo de confianza [IC] del 95%: 3,0-9,4). La adecuación global al protocolo de profilaxis*

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antibiótica fue del 91,0% (IC 95%: 87,6-94,4). La causa más frecuente de inadecuación al protocolo fue el momento de inicio de la profilaxis antibiótica (94,1%). No se encontró relación entre ISQ e inadecuación de la profilaxis antibiótica (riesgo relativo: 2,4; IC 95%: 0,49-12,5; p > 0,05). **Conclusiones:** *La adecuación global al protocolo de la profilaxis antibiótica fue alta. La causa más frecuente de inadecuación al protocolo fue el momento de inicio de la profilaxis antibiótica.*

Palabras clave: *Infección de la herida quirúrgica. Estudios de cohortes. Profilaxis antibiótica. Bypass vascular periférico.*

Introduction

Healthcare-associated infections (HAIs) are undesirable complications that 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]. Surgical site infection (SSI) ranks first among HAIs[2], is the most frequent infection in surgical patients and its incidence is linked to specific surgical circumstances such as the surgical technique, intrinsic, and extrinsic patient-related factors[3,4]. Peripheral vascular bypass SSI is associated with significant morbidity and mortality and it occurs as frequent as 10- 20% in lower extremity revascularization procedures[5].

Antibiotic prophylaxis has shown a benefit in reducing the incidence of perioperative infection compared to placebo[6] and current guidelines recommend the use of first-generation cephalosporin agents for < 24 h in patients undergoing vascular surgical procedures[7]. The purpose of antibiotic prophylaxis is to prevent the growth of microorganisms in the surgical wound, which may contaminate the interstitial space, fibrin scaffolds, or hematomas. If the antibiotic used is sufficiently active against potentially contaminating microorganisms, and elevated drug levels are attained throughout the surgical procedure, then prophylaxis will generally prove effective[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 peripheral vascular bypass surgical (PVBS) wound infection surveillance and monitoring system. Accordingly, this study sought to assess the degree of adequacy to our antibiotic prophylaxis protocol among patients who underwent some procedures of PVBS and its effect on SSI.

Materials and methods

We conducted a prospective cohort study to assess compliance with the hospital's antibiotic prophylaxis protocol in PVBS and the effect of such compliance on the incidence of SSI. The assessment took place at a University Teaching Hospital and was performed by the Preventive Medicine and Vascular Surgery departments. The patients included in the study were those who had undergone above-knee PVBS from January 1, 2011, through December 31, 2018. The patients included underwent femorofemoral or femoropopliteal bypass procedures among the group with 39.29 code 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 PVBS procedures.

Sample size was estimated with a 95% confidence level, accuracy of 5%, expected compliance of 80%, and envisaged losses to follow-up of 5%. Based on these premises, a total study sample of 251 patients was deemed necessary. We obtained the Ethics and Research Committees approval to carry out the study and gave all patients informed consent to the work. Patients were selected by a process of consecutive inclusion. The exclusion criteria were as follows: confirmed existence or suspicion of infection at the date of intervention; or, having been on antibiotic treatment prior to the intervention.

The variables studied were age, sex, antibiotics, dosage, route of administration, time of administration, time of initiation and termination of surgery, existence or absence of infection, type of infection (superficial, deep incisional, or organ-space), and causative microorganism of infection. Microbiological studies to identify the microorganisms implicated were performed using MicroScan Walkaway (Siemens®). We recorded pre-surgical compliance and adequacy of antibiotic prophylaxis (appropriate or inappropriate) and the presence or absence of SSI. To this end, patients were clinically followed up for 1 year by reference to surgical wound progression, clinical profile, and microbiological results, as per the CDC definitions (Table 1)[1]. To comply with the CDC's maximum 1-year wound infection incubation period in surgery with implants, we studied incidence of SSI at 1 year of the surgical intervention, regardless of whether the patient

Table 1. Surgical wound infection criteria

– Isolation of a microorganism in the culture of the fluid drained.
– Purulent discharge from the incision, a deep area or organ - space.
– At least one of the following: pain or tenderness to touch or pressure, or localized inflammation (heat, redness, swelling).
– Abscess imaging displayed in a surgical revision.

Table 2. Antibiotic prophylaxis protocol

Prophylaxis	Antibiotic	Dosage	Route	Time
Standard	Cefazoline	2 g	Intravenous	30-60 min prior to surgery
Allergic patients	Vancomycin	1 g	Intravenous	30-60 min prior to surgery

was admitted or had been discharged. In the case of admitted patients, SSI was jointly evaluated by a preventive medicine physician and a surgeon. In the case of discharged patients, wound infection was evaluated, either at the hospital outpatient department if the patient had been examined there, at the emergency room if the patient had been attended there, by his/her general practitioner if the patient had been examined at the primary care unit, or by telephone call if the patient had attended none of the above-mentioned health care facilities.

A descriptive study of the sample was conducted, with qualitative variables being described with their frequency distribution (number and percentages) and compared using the Pearson's Chi-square or binomial tests, and quantitative variables being described with their mean and standard deviation (SD). We evaluated the normality criterion using the Shapiro-Wilk test and compared the quantitative variables using the Student's-t-test or the nonparametric Mann-Whitney test.

Adequacy to protocol of antibiotic prophylaxis was studied by comparing the different aspects of prophylaxis received by patients to those stipulated in the protocol in force at our hospital. Responsibility for administering the protocol shown in table 2 was borne by the anesthetists. During the study, protocol adequacy was assessed, both overall and individually, for all aspects envisaged. Incidence of SSI after the follow-up period was evaluated, and the effect of prophylaxis compliance on the incidence of infection was estimated calculating the Relative Risk (RR) of infection. To record the data, a purpose-made data-collection sheet and a relational, normalized database were designed in Microsoft Access®. All statistical analyses were performed using the SPSS v22 software program. Statistical significance was considered $p < 0.05$.

Table 3. Antibiotic prophylaxis adequacy

	Compliance (no.)	Compliance (%)	95% CI
Time of initiation	250	94.1	91.3-96.9
Duration	265	99.6	99.1-100
Route of administration	266	100	100-100
Choice of antibiotic	259	97.5	95.7-99.3
Dosage	266	100	100-100
Overall	242	91.0	87.6-94.4

Results

The study covered 266 patients. Of this total, 177 PVBS were performed on men (66.6%) and 89 on women (33.3%) ($p < 0.05$). The mean ages of the patients intervened were as follows: 54.8 years overall (SD = 15); 54.3 years (SD = 15) for men; and 55.3 years (SD = 16) for women ($p > 0.05$). The mean duration of the intervention was 234 minutes (SD = 91). Mean length of stay of patients without infection was 6.0 days (SD = 6) and 21 days (SD = 17) of those with infection. Femorofemoral bypasses accounted for 168 of the patients (63%) and femoropopliteal for 98 (37%).

Administration of antibiotic prophylaxis was indicated in all patients studied. Prophylaxis was administered to 262 patients, with a percentage of antibiotic prophylaxis administration of 98.5%. Administration of prophylaxis could not be documented in four patients then it was not registered. Overall protocol adequacy among patients to whom prophylaxis was administered, taking adequacy to all the criteria into account, was 91.0% (95% confidence interval [CI] = 87.6-94.4). Table 3 shows the percentages and total numbers of patients administered prophylaxis adequate to the protocol for each criterion studied. The most frequent cause of inadequacy to the protocol was time of initiation of antibiotic prophylaxis, followed by choice of antibiotic. A detailed breakdown of all causes of inadequacy is depicted in fig. 1.

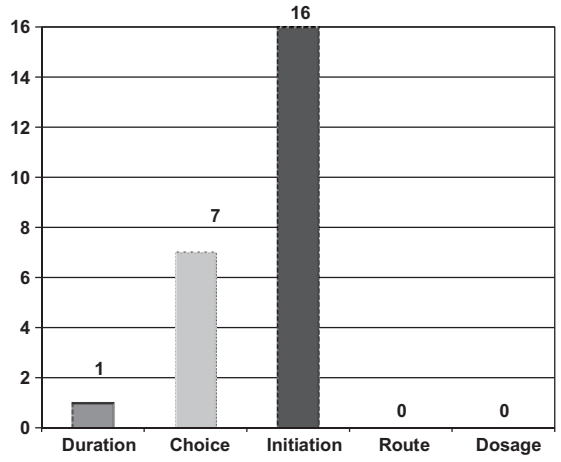

Figure 1. *Causes of non-compliance with the antibiotic prophylaxis protocol (n = 266).*

The overall incidence of infection after the follow-up period was 5.3 % (95% CI = 3.0–9.4), with six cases of superficial and eight cases of deep incisional SSI. The most commonly isolated microorganisms were *Staphylococcus aureus* and *Escherichia coli*. The microorganisms implicated in these infections are shown in Figure 2.

No relationship was found between having received inadequate antibiotic prophylaxis and incidence of infection (RR: 2.4; 95% CI: 0.49-12.5; p > 0.05)

Discussion

Control of SSI amounts to a standard of health care quality, in as much as it is essential for the safety of the patient intervened[9,10]. Any type of surgical intervention entails an increase in the possible risk of the patient suffering from an infection, which may either be manifested at the surgical site or be conveyed to more distal sites.

Prophylactic administration of antibiotics is a proven measure of efficacy for preventing and reducing the frequency of SSIs[11]. Accordingly, there are studies that report that prophylaxis is capable of preventing 56% of infections and reduces deep incisional infection by 47%[12]. Antibiotic prophylaxis has served to decrease SSI rates significantly, with the ensuing reduction in hospital stay, costs, and morbidity and mortality[13,14].

This study assessed the administration of antibiotic prophylaxis among patients undergoing PVBS and the degree of adequacy to the antibiotic prophylaxis protocol in place at our health center. As almost all the patients who were intervened received prophylaxis, this entailed a degree of administration close to 100%. Such a high percentage of administration was not attained in the bibliography consulted[15].

When all the factors were evaluated jointly, the overall percentage adequacy of prophylaxis proved to be 91.0%. This percentage is somewhat higher than the degrees of overall adequacy reported in the literature[16,17].

If one addresses each of the protocol criteria individually (time of initiation of prophylaxis, duration of prophylaxis, route of administration, dose, and choice of antibiotic), it will be seen that the degree of adequacy exceeded 90% for each of these aspects. These percentages are in a range equal to or higher than those found in the literature[18-20]. The individual criteria studied displayed uneven degrees of protocol adequacy, with the initiation of prophylaxis ranking lowest, with a percentage adequacy of 94.0%. Insofar as choice of antibiotic administered was concerned, percentage adequacy was 97.5%, which is a good result with little leeway for further improvement. Adequacy in terms of duration, dosage, and route of administration was almost 100%. Whereas in other studies consulted, it was a duration of prophylaxis that registered the highest percentage of inadequacy[21], in our case, it was time of initiation and the choice of antibiotic.

Our principal aim was to assess antibiotic prophylaxis adequacy and its possible relationship with a greater occurrence of SSIs. No relationship was found between the inadequate antibiotic prophylaxis and SSI. The case of patients with inadequate administration due to the time of initiation was the single aspect to display the lowest degree of compliance with the protocol. It was inappropriate because the antibiotic had been administered not within the recommended time. This is a very important, much discussed aspect[22] 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 that 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 liters after administration of fluids[23]. In all of our patients antibiotic prophylaxis doses were repeated due to the length of the surgical procedures and that could have guaranteed the necessary concentration of antibiotics in the interstitial space.

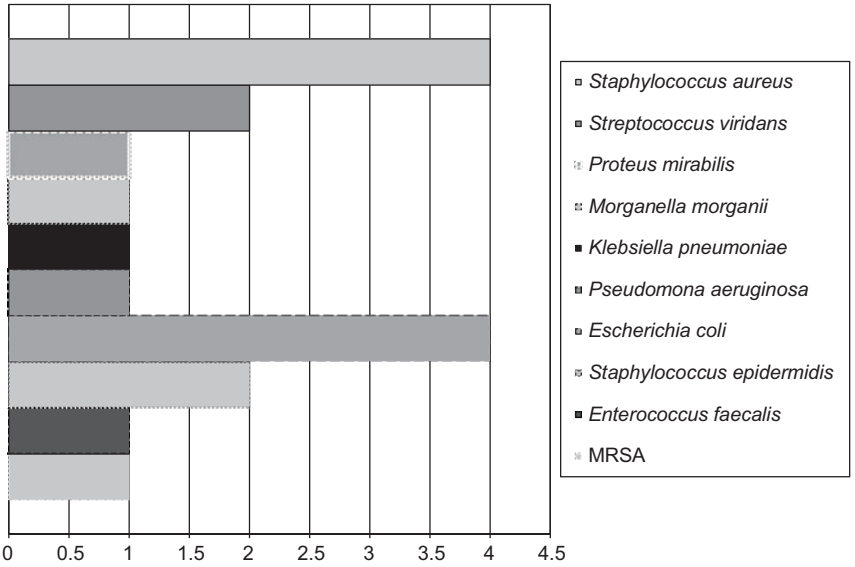

Figure 2. *Aetiology of surgical site infections (n = 18).*

In the case of patients with inadequate prophylaxis due to the choice of antibiotic, the sample was smaller, and so we do not know whether this result may lack the necessary accuracy, though we did attempt to ensure this when calculating the sample size. It is equally plausible, however, that despite having switched antibiotics and not having administered the one defined in the protocol, the antibiotic chosen might nonetheless have been effective against the flora at our health center, with the result that this change might not have affected incidence of infection. It is important, not only to administer antibiotic prophylaxis adequate to the defined protocols, but also to assess adequacy so as to take the necessary measures targeted at improving such prophylaxis and reducing SSI incidence as far as possible.

Although adequacy to antibiotic prophylaxis in PVBS was high, the number of SSIs is a parameter that can be improved. Incidence of infection in our case series was somewhat lower than that published by the CDC[24,25] and other studies[26,27] for this procedure and similar to those in our field of influence[28]. 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 1 year after surgery when implants were left in place after the procedures. This should have result in an appropriate estimated incidence.

Actions targeted at preventing infections are always a cost-effective measure[29,30] which, in a context of limited resources, must be viewed as added value, both from a financial point of view and from the stance of ensuring improvement in the quality of care and patient safety. As a result of our assessment some measures were taken, such as communicating 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 in an early future.

The most commonly isolated microorganisms were Staphylococcus aureus and Escherichia coli, according to the series reviewed[31,32].

Conclusions

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 the incidence of SSI as much as possible. In our study both percentages of administration and adequacy 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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Conflicts of interest

The authors declare that they have no conflict of interest

Ethical disclosures

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

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

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