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Analysis of compliance with antibiotic prophylaxis in elective laparoscopic cholecystectomy in a hospital in Mexico

Análisis del cumplimiento de profilaxis antibiótica en colecistectomía laparoscópica electiva en un hospital de México

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Palabras clave:
Colecistectomía, infección asociada a la asistencia sanitaria, infección del sitio quirúrgico, laparoscopia, profilaxis antibiótica preoperatoria.

ABSTRACT

Introduction: The administration of preoperative antibiotic prophylaxis reduces the risk of surgical site infections. however, despite the existence of pre-established recommendations for its use, these are often not followed. **Objective:** To describe the compliance and results of preoperative antibiotic prophylaxis in patients undergoing elective laparoscopic cholecystectomy in our institution. **Material and methods:** An observational, longitudinal prospective and descriptive study was performed including patients undergoing elective laparoscopic cholecystectomy within our hospital from July 1 to December 31, 2018, in search of the development of surgical site infections and other complications. **Results:** 97% of patients (n = 162) were administered preoperative antibiotic prophylaxis. A correct prescription was found in only 54% of cases (n = 87). Only 1% of patients (n = 2) had surgical site infection. **Conclusions:** In our study, despite a low correct prescription of preoperative antibiotic prophylaxis, only 1% developed surgical site infection. Therefore, we support the arguments of some clinical practice guidelines not to prescribe it systematically, but to select patients according to their characteristics and risks.

RESUMEN

Introducción: *La administración de profilaxis antibiótica preoperatoria reduce el riesgo de infecciones del sitio quirúrgico; sin embargo, pese a que existen recomendaciones preestablecidas para su uso, éstas con frecuencia no se cumplen.* ***Objetivo:*** *Describir el cumplimiento y resultados de la profilaxis antibiótica preoperatoria en pacientes sometidos a colecistectomía laparoscópica electiva dentro de nuestra institución.* ***Material y métodos:*** *Se realizó un estudio observacional, longitudinal prospectivo y descriptivo que incluyó a los pacientes sometidos a colecistectomía laparoscópica electiva dentro de nuestro hospital del 1 de julio al 31 de diciembre de 2018 en busca del desarrollo de infecciones del sitio quirúrgico y otras complicaciones.* ***Resultados:*** *Al 97% de los pacientes (n = 162) se les administró profilaxis antibiótica preoperatoria, encontrándose una prescripción correcta en sólo 54% de los casos (n = 87). Solamente 1% de los pacientes (n = 2) presentó infección del sitio quirúrgico.* ***Conclusiones:*** *En nuestro estudio, pese a existir una baja prescripción correcta de profilaxis antibiótica preoperatoria, sólo 1% desarrolló infección del sitio quirúrgico, razón por la cual apoyamos los argumentos de algunas guías de práctica clínica de no prescribirla de manera sistemática, sino seleccionando a los pacientes de acuerdo con sus características y riesgos.*

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INTRODUCTION

Surgery site infections (SSIs) are defined as "surgical procedure-related infections that occur near the incision site within the first 30 days of the surgical procedure or within the first 90 days of an implant placement",[1] while healthcare-associated infections (HAIs) are

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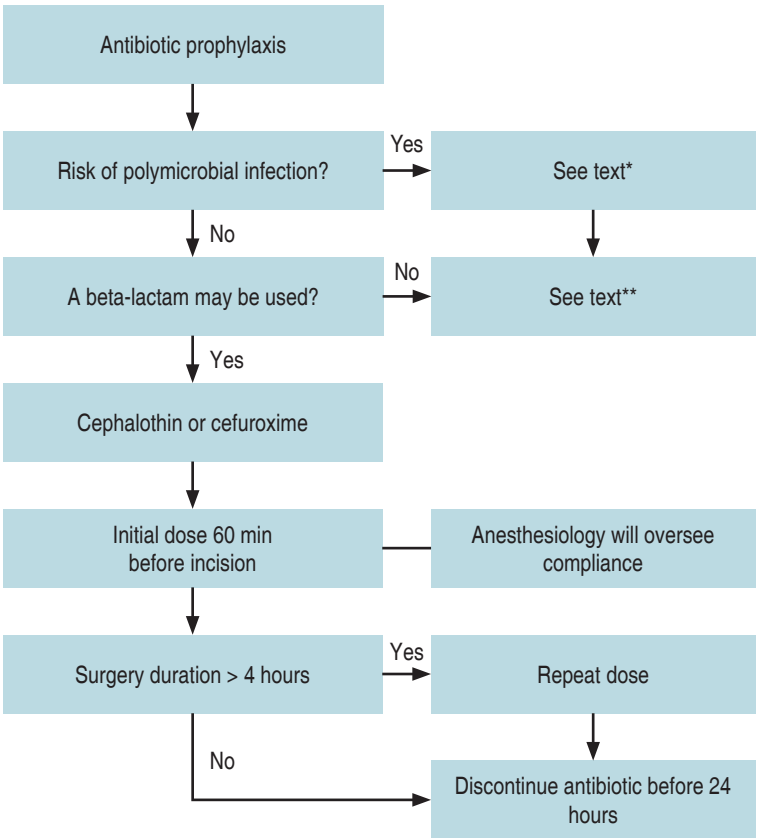
defined as "infections that patients acquire while receiving medical care". SSIs are the most frequently occurring HAI in low- and middle-income countries (LMICs), affecting up to one in three patients undergoing surgical procedures, and although they are seen less frequently in middle- and high-income countries (MHICs), they are still the second most frequent type of HAI in Europe and North America.[2]



* Antibiotics recommended:

1. First choice:
   a. Cephalothin 1 gram intravenously within 60 minutes prior to incision.
   b. Cefuroxime 1.5 grams intravenously within 60 minutes prior to incision.
2. Alternative:
   a. Ampicillin/sulbactam 2 grams/1 gram intravenously within 60 minutes prior to incision.
   b. Cephalothin + metronidazole 500 mg intravenously or clindamycin 600 mg intravenously within 60 minutes prior to incision.

** Option in case the use of β-lactams is contraindicated: vancomycin 1-gram intravenous infusion within 120 minutes before the incision.

Figure 1: *Flow chart for preoperative antibiotic prophylaxis. Diagram developed from our hospital guide for surgical antibiotic prophylaxis.*

Preoperative antibiotic prophylaxis (PAP) is defined as "the prevention of infectious complications through the effective administration of antibiotics prior to contamination during a surgical procedure".[3] It combats bacterial contamination of tissues that under normal conditions are free of microorganisms and prevents endogenous or exogenous flora entering the surgical area from multiplying and favoring the development of infection.[4,5] In the vast majority of surgical procedures, the effective administration of PAP is usually recommended and, although institutions such as the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC),[1] the National Institute for Health and Care Excellence (NICE),[6] and the Infectious Diseases Society of America (IDSA),[3] among others, have published clinical practice guidelines (CPG) with precise recommendations on its management, it has been shown that these are not complied with on a daily basis and that PAP is often administered inefficiently and arbitrarily.[7] In our country, the Mexican Social Security Institute (IMSS), through the CPG "Prevention and diagnosis of surgical site infection", oversees the recommendations that are specifically applied in our territory,[8] and each hospital must adapt to those recommendations according to its antimicrobial resistance profile *(Figure 1)*. Adhering to them by making good use of antibiotics reduces antimicrobial resistance and improves the patient's prognosis.[9]

Elective laparoscopic cholecystectomy (LEC) is the most frequently performed abdominal procedure worldwide and is the treatment of choice for patients with cholelithiasis and acute cholecystitis.[10] Because of this, there have been multiple studies that have presented controversial results on the development of infections in this procedure. In 2010, Sanabria et al. conducted a Cochrane review that included 11 randomized clinical trials with 1,664 patients concluding that the clinical evidence was not sufficient to support or refute the use of PAP.[11] On the other hand, in 2018, Sajid and

his team conducted a systematic review and meta-analysis that included 25 randomized clinical trials with 6,138 patients with the same objective, obtaining statistically significant results in the control group and evidencing the importance of a correct PAP,[12] so it is evident the need to conduct new studies that have the ability to provide an enlightening answer to this problem.

The aim of this article was to analyze the PAP compliance of patients undergoing CLE in a tertiary hospital in Mexico City.

MATERIAL AND METHODS

An observational, prospective and descriptive longitudinal study was conducted, which was submitted for review by the Hospital Bioethics and Research Committee of our institution and was approved with the number 2018EXT295. The clinical records of all patients who underwent CLE within a third level hospital in Mexico City during the period between July 1 and December 31, 2018, were reviewed in search of the development of post-surgical complications.

All patients older than one year who underwent CLE within the study time were included (n = 227), while those whose trans-surgical findings conditioned the administration of antibiotics therapeutically were excluded (n = 60). It was not necessary to eliminate clinical records due to ambiguity or lack of information. A total of 167 clinical records were considered for the analysis. The study variables

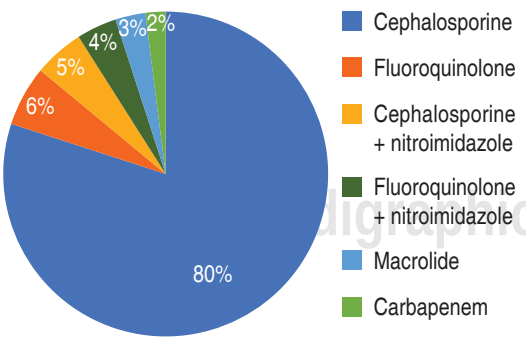


Figure 2: *Groups of antibiotics most frequently administered as part of preoperative antibiotic prophylaxis. Figure elaborated from our results.*

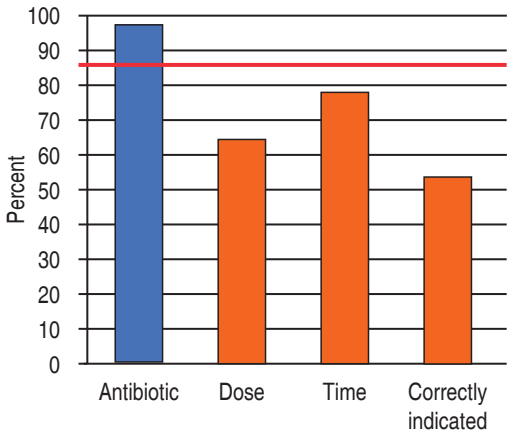


Figure 3: *Prescription of preoperative antibiotic prophylaxis (antibiotic, dose, and time). Figure elaborated from our results.*

were gender, age, allergies, comorbidities (smoking, overweight, obesity, type 2 diabetes and immunosuppression), diagnosis, PAP (antibiotic, dose, and time), development of ISQ, Clavien-Dindo scale, days of in-hospital stay (DEIH) and readmission. The information from the medical records was captured in electronic format for statistical analysis, which was carried out with the Statistical Package for the Social Sciences (SPSS) v.24 software to obtain measures of central tendency and dispersion.

RESULTS

Of the patients who underwent CLE, 44% were male and 56% were female. The mean age was 48 years (SD ± 15.36). The most common admission diagnosis was cholelithiasis in 88% (n = 147) of the cases, followed by polyposis in 9% (n = 15), dyskinesia in 2% (n = 3), and others 1% (n = 2).

Of the patients, 43% (n = 72) reported active smoking, while the most common comorbidities were overweight in 67% (n = 112) of cases, obesity in 26% (n = 43), type 2 diabetes in 15% (n = 25) and immunosuppression in 4% (n = 7).

Of the patients, 14% (n = 23) reported being allergic to at least one antibiotic, with penicillin allergy being the most common in 57% (n = 13) of the cases.

Ninety-seven percent (n = 162) of patients were administered PAP, with cephalosporins being the most frequently administered antibiotic group in 80% (n = 130) of cases *(Figure 2)*.

The dose was correct in 65% of the cases for which antibiotics were indicated (n = 105), while the time for adequate administration was met in 78% of the patients (n = 126) *(Figure 3)*; however, when analyzing the three PAP variables (correct time, antibiotic used and adequate posology), the latter was correctly indicated in only 54% (n = 87) of the cases.

Of the patients, 2% (n = 4) had postsurgical complications: 1% (n = 2) had surgical site infection and 1% (n = 2) had other complications, while only one patient was classified as grade IV on the Clavien-Dindo scale (anaphylaxis).

The mean in-hospital length of stay was 2.05 days (SD ± 1.22) and readmission was necessary in only 2% (n = 3) of cases.

Additionally, information on 3% (n = 5) of patients who underwent CLE but did not have PAP administered on the surgeon's indication, is shown in *Table 1*.

DISCUSSION

SSIs and the complications arising from them are a frequent and potentially lethal problem that represents a significant increase in morbidity and mortality, hospital length of stay and healthcare costs,[13] and can be associated with any type of surgical procedure. In 2013, the European Centre for Disease Control and Prevention (ECDC) conducted a study in 16 countries where it reported that the highest cumulative incidence according to the type of surgical procedure was presented by colon surgery with 9.5 cases per 100 operations, followed by coronary revascularization surgery with 3.5 cases, cesarean section with 2.9 cases and cholecystectomy with 1.4 cases.[14] The cumulative frequency of SSI in LSC in our hospital for the study period was 1.19 cases per 100 LSC operations. In the results it is mentioned that 1% corresponds to two patients out of 167 studied, so the numbers do not coincide, and they are slightly lower than those reported in the literature.

In our study, 93% of patients who underwent CLE were overweight or obese, 43% smoked, 15% had type 2 diabetes, and 4% were immunosuppressed, significantly increasing the risk of developing SSI.

Recent research has contrasted the information shown in different guides with respect to the principles established in the literature and experimentally, showing the lack of knowledge and arbitrary use of various antibiotics in multiple surgical centers.[15] As a general rule, the time of administration of PAP should be one hour prior to the surgical incision, being usually a first or second generation cephalosporin the antibiotic of choice *(Table 2)*, while as an alternative for patients with a history of known allergy to penicillin, vancomycin or clindamycin can be administered.[8,16] In addition, periodic evaluation of the epidemiological and microbiological situation of each institution, the availability of supplies

Table 1: Summary of the clinical history of patients who did not receive preoperative antibiotic prophylaxis.

Patient	Age	Sex	Diagnosis	Comorbidity	Allergies	PAP	SSI	IHSD	Reinstatement
1	48	Female	Polyposis	Overweight	Denied	No	No	2	No
2	50	Male	Polyposis	Overweight	Denied	No	No	2	No
3	29	Female	Cholelithiasis	Overweight	Denied	No	No	4	No
4	43	Female	Cholelithiasis	None	Denied	No	No	2	No
5	55	Female	Cholelithiasis	Overweight and T2D	Denied	No	No	1	No

PAP = preoperative antibiotic prophylaxis; SSI = surgical site infection; IHSD = in-hospital stay days; T2D = type 2 diabetes.
Table based on our results.

Table 2: Recommendations for the use of preoperative antibiotic prophylaxis.

Type of surgery	Recommended prophylaxis	Recommended prophylaxis in case of allergy to β-lactams	Level of evidence
Laparoscopy:			
Elective (low risk)	None	None	A
Elective (high risk)	Cephalothin Ceftriaxone Amoxicillin-clavulanate	Clindamycin or vancomycin + aminoglycoside or fluoroquinolone Metronidazole + aminoglycoside or fluoroquinolone	A
Biliary:			
Open procedure	Cephalothin Ceftriaxone Amoxicillin-clavulanate	Clindamycin or vancomycin + aminoglycoside or fluoroquinolone	A
Gastroduodenal	Cephalothin	Clindamycin or vancomycin + aminoglycoside or fluoroquinolone	A
Intestinal:			
With obstruction	Cephalothin	Clindamycin or vancomycin + aminoglycoside or fluoroquinolone	C
No obstruction	Cephalothin + metronidazole	Metronidazole + aminoglycoside or fluoroquinolone	C
Appendiceal*	Cephalothin + metronidazole	Clindamycin or vancomycin + aminoglycoside or fluoroquinolone Metronidazole + aminoglycoside or fluoroquinolone	A
Colorectal	Cephalothin + metronidazole Amoxicillin/clavulanate Ceftriaxone + metronidazole Ertapenem	Clindamycin + aminoglycoside or fluoroquinolone Metronidazole + aminoglycoside or fluoroquinolone	A

* Uncomplicated appendicitis.
Table adapted from: Mexican Institute of Social Security.[8]

and the particularities of the medical specialties should be considered in order to determine the rotation and modifications in the antibiotics to be used.[5,15]

In our study, 97% of the patients were administered PAP, showing a high percentage of compliance in this aspect; however, the wrong dose was administered in 35% of the cases without complying with the recommendations in terms of application time in 22% of the patients, evidencing the lack of homogeneity in the criteria applied by different surgeons.

When analyzing the results of the three variables that were considered to determine whether the prescription was correct (antibiotic, dose, and time), an optimal indication was only achieved in 56% of the cases and despite this, only two patients in the sample developed SSI.

Regarding the five patients who underwent CLE, but who did not receive PAP due to preference or omission of the treating physician, none presented clinical manifestations compatible with an infectious process, their length of stay in hospital was

like that of the rest of the population (2.20 vs. 2.05) and in no case was hospital readmission necessary.

Overall, both the low incidence of SSIs, despite the incorrect administration of PAP, and the absence of SSIs, and the lack of administration of PAP generate controversy as to whether its use is necessary on a routine basis. It should be considered that the arbitrary use and abuse of antibiotics in both ambulatory and hospitalized patients is accompanied by an increase in the appearance of new infections, adverse reactions and antimicrobial resistance, so that the prevention, approach and management of SSIs should be an active, continuous and primordial attitude for all personnel involved in health care and especially for the surgeon, who should also monitor their possible appearance during the postoperative period to enable him to make an early diagnosis with the aim of providing timely treatment.[13]

CONCLUSIONS

In our study, the optimal prescription of PAP was complied with in approximately half of the cases and despite this, only a minimal percentage of patients developed SSI, which is why we support the arguments of some CPGs not to prescribe it systematically, selecting patients according to their characteristics and risks. However, we consider that studies with a rigorous scientific methodology are required to issue final recommendations. In the meantime, we conclude that it is imperative to formalize continuous updating programs to standardize the criteria under which PAP is administered as well as to implement checklists to guide surgeons in their decision making.

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