

Surgical infection in a videolaparoscopic colecistectomy when using peracetic acid for the sterilization of instruments

Infecção cirúrgica em colecistectomia videolaparoscópica usando ácido peracético como esterilizante dos instrumentais

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A B S T R A C T

Objective: To determine the frequency of surgical site infection in patients undergoing laparoscopic cholecystectomy with instruments sterilized by peracetic acid. **Methods:** We conducted a retrospective, cohort, descriptive, cross-sectional study. Peracetic acid has been used for sterilization following the protocol recommended by the manufacturer. We observed the criteria and indicators of process and structure for preventing surgical site infection pre and intraoperatively. For epidemiological surveillance, outpatient visits were scheduled for the 15th and between the 30th and 45th days after discharge. **Results:** Among the 247 patients, there were two cases of surgical site infection (0.8%). One patient was readmitted to systemic antibiotic therapy and percutaneous puncture; in the other the infection was superficial and followed at the clinic. **Conclusion:** Ethical issues prevent the conduction of a prospective study because of peracetic acid have been banned for the sterilization of instruments that penetrate organs and cavities. Nevertheless, these results encourage prospective case-control studies comparing its use (historical control) with ethylene oxide sterilization.

Key words: Surgical wound infection. Cross infection. Cholecystectomy laparoscopic. Peracetic acid. Sterilization.

INTRODUCTION

Despite important advances in the field of surgery and in the clinical management of the surgical patient, every procedure has a risk of infection that can cause serious physical, psychological and social complications and even death¹. In the prevention program developed by the World Alliance for Patient Safety by the World Health Organization (WHO), among the ten essential objectives for a safe operation it is recommended that the team will consistently use methods known to minimize the risk of surgical site infection (SSI)¹.

Infections related to healthcare are considered a public health problem, especially because they have been responsible for one in ten hospital deaths in the United States and it is assumed that in poorer countries this estimate is two to 20 times higher¹. SSI is the most common infections in surgical patients, followed by urinary and respiratory. The infected patient entails higher costs and increased length of stay, around 10 days, which economically means extra cost per patient for American standards¹⁻³.

Although Gram-positive bacteria are the main causal agents, there are large variations, and each service

must know the microbiota related to health care. Other agents, besides the germs of the intestinal microbiota (Gram-negative and anaerobic), are contaminants from various exogenous sources such as instruments and prostheses³.

Outbreaks of SSI by rapidly growing mycobacteria (RGM) have been reported around the world for over 20 years. Infections by this group of bacteria were associated with failures in the process of cleaning the instruments and medical devices⁴. Since 2005, several outbreaks of SSI by RGM were described in different Brazilian States, becoming a concern among regulatory agencies, especially ANVISA (Portuguese acronym for "National Sanitary Surveillance Agency"), due to the need for greater attention to the protocols for cleaning and sterilization of surgical materials. It was observed the appearance sanitizing agents-resistant bacteria⁴.

Infections of skin and subcutaneous by RGM manifest as nodular lesions, pyogenic abscesses, fistulas, acute inflammation with exudate output on the laparoscopy ports or surgical wound dehiscence⁵. Contamination leads to SSIs of difficult healing, resistant to commonly used antibiotics, spontaneous healing being rarely^{5,6}.

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During a phase of transition and epidemiological research, when glutaraldehyde and / or peracetic acid was employed for sterilization, ANVISA disclosed the occurrence of outbreaks by *Mycobacterium abscessus*, *M. chelonae* and *M. fortuitum* in patients of various public and private institutions undergoing surgical procedures, particularly in the ones performed by laparoscopy⁷.

To reduce costs in health care is critical to expanding the services supply. The safe reprocessing of medical and hospital equipment collaborates with this reduction⁸. The practice of reprocessing may result in the transmission of infectious contaminants and biofilm inside the instruments, if they are not properly reprocessed after each use⁸.

In February 2009, ANVISA, suspended the practice of performing chemical sterilization of instruments by immersion thermosensitive through the RDC 08⁹.

This study aims to determine the frequency of SSI in patients undergoing laparoscopic cholecystectomy (CVL) when peracetic acid was used as a sterilant.

METHODS

The study was approved by the Ethics Committee on Human Research of the IMIP under number 2025-10. Waiver of the term of free and informed consent of the patients was obtained because it was a retrospective study on secondary the database.

We conducted a descriptive, retrospective, cohort, cross-sectional study, through review of medical records for research of SSI in patients who underwent laparoscopic cholecystectomy in the period February 2008 to February 2009 in the FPMF / IMIP (Foundation Professor. Martiniano Fernandes / Institute of Medicine Professor Fernando Figueira, Recife, Pernambuco, Brazil). This institution serves only patients using the National Health System. We included in the study patients considered ASA I and II (score of the American Society of Anesthesiology) and excluded those who had multiple operations, those requiring conversion of laparoscopic procedure to laparotomic one and those who required reintervention.

During the study period, peracetic acid was the sterilization method, following the protocol recommended by the manufacturer. We recorded the criteria and indicators of process and structure for SSI prevention preoperatively and intraoperatively, as the time of preoperative hospitalization exceeding 24 hours ago, antisepsis of the operative field, control of circulation of professionals in the operating room, room door operation closed during surgery, glycemic control and tracking of surgical cases.

For the epidemiological surveillance of SSI, one outpatient return was scheduled for the 15th and between 30 and 45 days after discharge. The resident or the Nurse of the Surgical Clinic counseled the patient about wound care and warned of the need to return to the Service for

reassessment when there was fever or any change in the wound, such as pain, redness, local heat or presence of secretion. Between the 30th and 45th days after discharge, the patient was given the result of the histopathological examination of the surgical specimen. The diagnosis of SSI was carried out in the clinic by the surgeon after inspection of the wound following the diagnostic criteria established by ANVISA⁸.

A list of names was provided by the system of hospital management of patients undergoing cholecystectomy during the study period. Conference was held to confirm the laparoscopic approach. The completion of the form was accomplished by consulting on three sources: the patient charts, the anesthetic record and medical and nursing visit records; the surgical map; and the log book of return to the outpatient clinic.

We collected socio-demographic factors inherent to the preoperative clinical status of the patient (presence of hypertension, diabetes mellitus and other chronic diseases, continuous use of medication, hospital stay and preoperative ASA score), factors related to the surgical procedure (prophylactic antibiotics, type of anesthesia, duration of operation, cholangiography, drain placement and type of surgical findings), the length of hospital stay and the need for reintervention. Regarding SSI, we observed the classification of infection and clinical outcome.

After double typing and correcting inconsistencies, we obtained frequency distribution tables for categorical variables and measures of central tendency and interquartile range for continuous variables. The Fisher's test was used to compare proportions and the Kruskal-Wallis test for comparison of means.

RESULTS

We analyzed 595 patients who underwent cholecystectomy and 283 were excluded because cholecystectomy was not laparoscopic. Of the remaining 312 patients, 13 were excluded for conversion to open procedure and 52 (17.4%) considered lost for not having returned for follow-up. The remained 247 patients had their charts reviewed until two years after discharge.

The data for characterization of the sample are shown in Table 1. There was a predominance of females, 226 (91.5%), and of patients from Recife metropolitan region (89.5%)¹⁰. The age of patients ranged from 16 to 76 years, with a mean of 39 and a median of 40. The age group between 21 and 40 years comprised 127 patients, corresponding to 51.4% of the sample. Cholelithiasis alone was observed in 163 patients (66%), but about one quarter of the patients had hypertension and 1.2% diabetes. The association of these two diseases was present in six individuals (2.4%)¹¹.

Patients were admitted 24 hours before the operation and had hospital stay ranged from one to ten

days, with interquartile range of one to two days. About 9% (22) had stay equal to or more than three days^{11,12}. There were no deaths.

There were 136 (55.1%) ASA II patients. At the time of induction of anesthesia, antibiotic prophylaxis was administered in 196 (79.4%) individuals, general anesthesia was performed in 244 (98.8%) procedures, rachis and / or epidural in three (1.2%), always associated with general anesthesia¹³.

The duration of surgery varied from 40 to 165 minutes, with a median of 60 and 72% of patients underwent the procedure in up to 75 minutes¹¹.

Intraoperative cholangiography was performed in three (1.2%) patients and the drain was placed in seven (2.8%)¹⁴.

Laparoscopy identified no significant intraoperative findings in 181 (73.3%) cases. Thickened-wall gallbladder was the most common macroscopic alteration reported in the surgical records (22.7%). In this sample, only one (0.4%) patients required reintervention.

Among the 247 who returned to the institution for follow-up at the outpatient postoperative visit, two cases of SSI were diagnosed (Table 2). One patient had deep SSI (subphrenic abscess); he was readmitted to systemic

Table 1 - Frequency distribution of patients undergoing laparoscopic cholecystectomy, according to sociodemographic conditions before, during and after surgery and the presence of surgical site infection.

Variable	N (247)	%	Variable	N (247)	%
Gender			Surgical time in minutes		
· Male	21	8.5	· < 60 minutes	14	5.7
· Female	226	91.5	· 60 a 120 min	205	83.0
			· > 120 min	28	11.3
Age (years)			Cholangiography		
· 16 a 19	06	2.4	· Yes	3	1.2
· 20 a 64	221	89.5	· No	244	98.8
· 65 a 76 years	20	8.1	Drain placement		
Origin			· Yes	7	2.8
· Metropolitan Recife	221	89.5	· No	240	97.2
· Interior	25	10.1	Type of surgical findings		
· Another state	1	0.4	· Adherence	5	2.0
Associated Diseases			· Gallbladder with thickened wall	56	22.7
· Hypertension (HBP)	60	24.3	· Drilling	3	1.2
· Diabetes (DM)	3	1.2	· Bleeding	1	0.4
· SH + DM	6	2.4	· Other	1	0.4
· Other	15	6.1	· None	181	73.3
· None	163	66.0	Reintervention		
Continuously Used Medication			· Yes	1	0.4
· Yes	75	30.4	· No	246	99.6
· No	172	69.6	Length of hospital stay		
ASA score			· 1 day	177	71.7
· ASA I	111	44.9	· 2 days	48	19.4
· ASA II	136	55.1	· > 3 days	22	8.9
Prophylactic Antibiotic			Surgical site infection		
· Yes	196	79.4	· Yes	2	0.8
· No	51	20.6	· No	245	99.2
Type of anesthesia			Rate of infection		
· General	244	98.8	· Superficial	1	0.4
· Raque anesthesia	1	0.4	· Deep	1	0.4
· Epidural	1	0.4			
· General + epidural	1	0.4			

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antibiotic therapy and percutaneous pigtail drainage catheter. During hospitalization specimens for AFB (acid-fast bacilli) were collected, as well as culture for pyogenic bacteria and RGM, whose results were negative. The length of hospital stay for treatment of deep SSI was 14 days. Another patient had superficial SSI and was accompanied with outpatient local treatment.

Patients who did not use antibiotic prophylaxis (1/51) had a 3.9 times higher frequency of SSI when compared to those who received antibiotic (1/196), but the prevalence ratio was not statistically significant ($p = 0.37$)⁵.

The two patients who developed SSI had longer mean duration of surgery in minutes (minimum time = 90, mean = 105, maximum time = 120) when compared to

the 245 who did not have SSI (minimum time = 40, mean = 60; maximum time = 165)¹. The comparison between the means, according to the Kruskal-Wallis test, was close to statistical significance ($p = 0.054$).

DISCUSSION

In Western countries the relative frequency of SSI corresponded to 15-20% of all cases of infections related to health care, with an incidence of two to 15 infections per 100 patients undergoing general surgery¹³. In 2009, a global challenge was launched by the WHO for Patient Safety, which has as its motto "Safe Surgery Saves Lives", to minimize or eliminate the risk of SSI. This retrospective

Table 2 - Characteristics of patients undergoing laparoscopic cholecystectomy according to the presence of surgical site infection (SSI).

Variables	Without surgical site infection	With surgical site infection	
	N=245 (98.2%) [†]	Patient 1	Patient 2
Age in years (min and max age; medium. IQR [‡])	16 a 76; median=39; IIQ=29 e 51	35	51
Female gender	224 (91.4)	yes	yes
Preoperative stay (days)	1	1	1
Origin – Recife e surroundings (RMR)	219 (89.4)	São Paulo (RMR)	Recife
Comorbidity	HAS [§] = 58 (23.7); none = 163 (66.5)	HAS	HAS
Cotninus use of medication	73 (29.8)	Sim	Sim
American Society of Anesthesiology (ASA) score	ASA II= 134 (54.7)	II	II
Antibioticprophylaxy	No - 50 (20.4)	Sim	Não
Type of Anesthesia	General - 242 (98.8)	General	General
Surgical Time in minutes (Min and max ;medium. IIQ) ^{Q%}	40 a 165; median= 60; IIQ=60 e 85	90	120
Use of drains	6 (2.4)	Sim	Não
Cholangiography	3 (1.2)	Não	Não
Type of surgical finding – n (%)			
· Adhesion	4 (1.6)	Adhesion	None
· Thickened-wall gallbladder	56 (22.9)		
· Perforation	3 (1.2)		
· Bleeding	1 (0.4)		
· Other	1 (0.4)		
· None	180 (73.5)		
Reintervention	1(0.4)	No	No
Post-discharge follow-up with 15. 30. 45 days	245 (100)	Yes	Yes
Classification of surgical site infection		Deep	Superficial
Readmission at the Hospital	3 (1.2) [¶]	Yes	No
Total time of hospital stay in days (min and max; median. IQR)	1 a 10; median=1; IIQ=1 a 2	2 in first admission and 14 days when readmitted	2

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[†] N () = absolute number and percentage; [‡] IQR - interquartile range; [§] HAS- hypertension; ^{Q%} comparison between average, Kruskal-Wallis $p = 0.054$; [¶] three patients were readmitted due to clinical reasons.

study, which analyzes data for the years 2008 and 2009, showed two (0.8%) SSI cases in 247 patients undergoing laparoscopic cholecystectomy without clinical or bacteriological diagnosis of RGM.

One should consider the limitations inherent to a retrospective study, with review of medical records that may result in various biases arising from the lack of data and / or reliability of the existing. To minimize these biases, the authors resorted to consult other sources, such as registration and nursing evolution, besides the book of outpatient postoperative visits.

When compared to laparotomy, laparoscopic cholecystectomy's main characteristics are of decrease surgical trauma, less organic repercussion, lower metabolic, inflammatory and immunological reaction, representing a benefit to the patient⁷. The use of peracetic acid sterilization securely offered the patient a new technology that was able to minimize costs¹⁵. It should be noted that the use of peracetic acid for sterilization of laparoscopic instruments was the prevailing practice allowed by ANVISA and that the frequency of 0.8% of SSI in laparoscopic cholecystectomy in this study can be considered below the estimated (2.8%) for the time. This study evaluated only patients operated at one single institution and one surgical specialty, this assessment being limited to the routine processes of cleaning and sterilization of this institution, specific for cholecystectomy.

The post-discharge surveillance of SSI will necessarily reflect the variety of hospital operations, human resources and information needs with varying levels of success.

The methods include direct examination of the wounds of patients during follow-up visits, review of medical records and surveys by phone or email with patients and surgeons^{1,16}. For the epidemiological surveillance of SSI at FPMF / IMIP, patient return occurs in two periods, 15 and 30 to 45 postoperative days, but the patient can return to the Service at any time, when identifying any change in the wound. The return to the clinic was not observed in 17.4% of cases, considered lost. These patients may not have sought the service for not having infectious complications or having SSI, but living in distant regions, with difficulty in accessing help in another service. Strategies to increase this return are being studied by the surgical team.

According to data of the National Investigation of Outbreaks and Adverse Events in Health Services (RENISS) the median time to onset of symptoms of SSI is around 17 to 31 days. The second mandatory outpatient evaluation is scheduled for 30 to 45 postoperative days. Hospital records were reviewed by the researchers about one to two years after the completion of laparoscopic cholecystectomy, long enough for the return of any patient with infectious complications have been reported in the medical record¹⁷. Epidemiological data of patients in relation to gender did not differ from the literature, where

the frequency of women undergoing cholecystectomy varies between 62 and 90%¹⁰. In this series, the frequency of women was 91.4%, with a ratio of approximately 11 women to one man (Table 1). Regarding age, epidemiological studies based on autopsy showed cholelithiasis in adults with higher prevalence among people over 50 years old. The occurrence in children is rare and happens to be most common during adolescence¹⁰.

Although patients over 14 years of age are treated at FMPF-IMIP, in this study only 2.4% were under 19 years, which is consistent with the literature. However, about half of patients undergoing laparoscopic cholecystectomy were between 21 and 40 years old, a population younger than expected, suggesting that more studies should be performed to verify the association with dietary habits, pregnancy and other factors^{10,14}.

The probability of postoperative infection takes into account the characteristics and the patient's clinical condition and the factors associated with the type of surgery and perioperative period⁴. Comorbidities play an important role in determining infection¹³. As the main objective of the study was to determine the frequency of SSI in low-risk patients, for whose procedure laparoscopic material was sterilized with peracetic acid, we used scores ASA I and II, which reflect the preoperative state to minimize confounding factors¹³. The operations are predominantly elective, and cholelithiasis without associated disease was observed in approximately two thirds of cases.

Both CDC and ANVISA reinforce the guidance that the prolonged preoperative length of hospital stay favors replacing the endogenous flora of the patient, increasing the risk of acquiring multidrug-resistant micro-organisms^{1,3}. These patients had only one day of inpatient preoperative stay, and had early discharge¹.

The beneficial effect of antibiotic prophylaxis in the prevention of SSI in laparoscopic cholecystectomy is controversial, but in this study we identified two cases (0.8%) of SSI, where a patient received antibiotic prophylaxis and the other not^{18,19}. Although there was a higher risk of SSI among patients who did not receive antibiotic prophylaxis, the ratio of prevalence was not statistically significant.

Prolonged operations have higher probability of infection and increased operative time can be related to the technique and skill of the surgeon, deficiencies in the organization of the surgical material and human resources available.

For operations of the digestive tract lasting less than 120 minutes, a rate of 1.5% is reported, compared with 10.7% in those lasting for more than four hours⁵. In patients with SSI in this study, surgical procedures lasted between 90 and 120 minutes, longer than the average observed in patients who had no infection, with a difference close to statistical significance ($p = 0.054$).

In 247 cases retrospectively studied, we detect the occurrence of SSI in two cases (0.8%), which probably reflects the quality of the product and the process used in

the sterilization of equipment used to perform the laparoscopic cholecystectomy. It is suggested that future studies address other institutions that have the same service profile to determine the incidence of SSI and to enable the comparison of methods of laparoscopic sterilization of instruments.

Ethically it is not permitted to carry out a prospective study, as peracetic acid has been banned for the sterilization of instruments that penetrate organs and cavities. Nevertheless, these results encourage prospective case-control studies comparing the use of it (historical control) with sterilization by ethylene oxide.

R E S U M O

Objetivo: Determinar a frequência de infecção de sítio cirúrgico em pacientes submetidos à colecistectomia videolaparoscópica usando o ácido peracético como esterilizante. **Métodos:** Foi realizado estudo retrospectivo descritivo do tipo coorte transversal. O ácido peracético foi usado para esterilização seguindo protocolo preconizado pelo fabricante. Foram observados os critérios e indicadores de processo e estrutura para prevenção de infecção de sítio cirúrgico no pré e intraoperatório. Para a vigilância epidemiológica, consultas ambulatoriais eram agendadas para o 15º e entre o 30º e 45º dias após a alta. **Resultados:** Entre 247 pacientes foram diagnosticados dois casos de infecção de sítio cirúrgico (0,8%). Um paciente reinternou para antibioticoterapia sistêmica e punção percutânea; no outro, a infecção foi superficial e acompanhada ambulatorialmente. **Conclusão:** Eticamente não é permitida a realização de um estudo prospectivo pelo fato do ácido peracético ter sido proibido para a esterilização de instrumentais que penetrem em órgãos e cavidades; contudo, estes resultados encorajam estudo prospectivo caso-controle, comparando o uso dele (controle histórico) com a esterilização por óxido de etileno.

Descritores: Infecção da ferida operatória. Infecção hospitalar. Colecistectomia laparoscópica. Ácido peracético. Esterilização.

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