INTRODUCTION

Laparoscopic cholecystectomy is widespread and described in the medical literature for the first time in March 1987 by Mouret in Lyon, France, and later improved by Dubois. Currently it is the “gold standard” surgical procedure for cholecystectomy. Electively it has very low risk for infectious complications, having average infection rate between 0.4-1.1%. Many surgeons still use routine antibiotic prophylaxis. However, some authors have conflicting results endorsing its prophylactic use; also, there is an increase in the operation cost. Thus, there is controversy about the prophylactic routine, especially in low-risk patients.

Surgical infections constitute a significant proportion of infections in hospitalized patients. Bacteria are found in 90% of surgical incisions, increasing from beginning to end of the surgical procedure. The Center for Disease Control in the United States, indicate first generation cephalosporin (cefazolin and cephalothin), when necessary their use for prophylaxis on the biliary surgery. A large number of studies in the literature points to the non-use of antibiotic prophylaxis in laparoscopic cholecystectomy; however, many surgeons still use it routinely.

The aim of this study was to evaluate the need for antibiotic prophylaxis in elective laparoscopic cholecystectomy in patients at low risk for surgical site infection.

METHOD

It is a prospective randomized study, double-blind trial of 100 patients with low surgical risk with uncomplicated lithiasic cholecystitis undergoing elective laparoscopic cholecystectomy divided in two groups: group A (n=50), patients that received prophylaxis using intravenous Cephazolin (2 g) during anesthetic induction and group B (n=50), patients that didn’t receive any antibiotic prophylaxis. The outcome evaluated were infectious complications at surgical site. The patients were reviewed seven and 30 days after surgery. Results: There was incidence of 2% in infection complications in group A and 2% in group B. There was no statistical significant difference of infectious complications (p>0,05) between the groups. The groups were homogeneous and comparable. Conclusion: The use of the antibiotic prophylaxis in laparoscopic cholecystectomy in low risk patients doesn’t provide any significant benefit in the decrease of surgical wound infection.

ABSTRACT – Background: Elective laparoscopic cholecystectomy has very low risk for infectious complications, ranging the infection rate from 0.4% to 1.1%. Many surgeons still use routine antibiotic prophylaxis. Aim: Evaluate the real impact of antibiotic prophylaxis in elective laparoscopic cholecystectomies in low risk patients. Method: Prospective, randomized and double-blind study. Were evaluated 100 patients that underwent elective laparoscopic cholecystectomy divided in two groups: group A (n=50), patients that received prophylaxis using intravenous Cephazolin (2 g) during anesthetic induction and group B (n=50), patients that didn’t receive any antibiotic prophylaxis. The outcome evaluated were infectious complications at surgical site. The patients were reviewed seven and 30 days after surgery. Results: There was incidence of 2% in infection complications in group A and 2% in group B. There was no statistical significant difference of infectious complications (p=0,05) between the groups. The groups were homogeneous and comparable. Conclusion: The use of the antibiotic prophylaxis in laparoscopic cholecystectomy in low risk patients doesn’t provide any significant benefit in the decrease of surgical wound infection.

HEADINGS - Laparoscopic cholecystectomy. Antibiotic prophylaxis. Surgical infection.

Correspondence: Márcio Alexandre Terra Passos
E-mail: marciotpassos@uol.com.br

Financial source: none
Conflicts of interest: none

Received for publication: 13/01/2016
Accepted for publication: 12/04/2016

ABSTRACT – Background: Elective laparoscopic cholecystectomy has very low risk for infectious complications, ranging the infection rate from 0.4% to 1.1%. Many surgeons still use routine antibiotic prophylaxis. Aim: Evaluate the real impact of antibiotic prophylaxis in elective laparoscopic cholecystectomies in low risk patients. Method: Prospective, randomized and double-blind study. Were evaluated 100 patients that underwent elective laparoscopic cholecystectomy divided in two groups: group A (n=50), patients that received prophylaxis using intravenous Cephazolin (2 g) during anesthetic induction and group B (n=50), patients that didn’t receive any antibiotic prophylaxis. The outcome evaluated were infectious complications at surgical site. The patients were reviewed seven and 30 days after surgery. Results: There was incidence of 2% in infection complications in group A and 2% in group B. There was no statistical significant difference of infectious complications (p=0,05) between the groups. The groups were homogeneous and comparable. Conclusion: The use of the antibiotic prophylaxis in laparoscopic cholecystectomy in low risk patients doesn’t provide any significant benefit in the decrease of surgical wound infection.

ABSTRACT – Background: Elective laparoscopic cholecystectomy has very low risk for infectious complications, ranging the infection rate from 0.4% to 1.1%. Many surgeons still use routine antibiotic prophylaxis. Aim: Evaluate the real impact of antibiotic prophylaxis in elective laparoscopic cholecystectomies in low risk patients. Method: Prospective, randomized and double-blind study. Were evaluated 100 patients that underwent elective laparoscopic cholecystectomy divided in two groups: group A (n=50), patients that received prophylaxis using intravenous Cephazolin (2 g) during anesthetic induction and group B (n=50), patients that didn’t receive any antibiotic prophylaxis. The outcome evaluated were infectious complications at surgical site. The patients were reviewed seven and 30 days after surgery. Results: There was incidence of 2% in infection complications in group A and 2% in group B. There was no statistical significant difference of infectious complications (p=0,05) between the groups. The groups were homogeneous and comparable. Conclusion: The use of the antibiotic prophylaxis in laparoscopic cholecystectomy in low risk patients doesn’t provide any significant benefit in the decrease of surgical wound infection.

ABSTRACT – Background: Elective laparoscopic cholecystectomy has very low risk for infectious complications, ranging the infection rate from 0.4% to 1.1%. Many surgeons still use routine antibiotic prophylaxis. Aim: Evaluate the real impact of antibiotic prophylaxis in elective laparoscopic cholecystectomies in low risk patients. Method: Prospective, randomized and double-blind study. Were evaluated 100 patients that underwent elective laparoscopic cholecystectomy divided in two groups: group A (n=50), patients that received prophylaxis using intravenous Cephazolin (2 g) during anesthetic induction and group B (n=50), patients that didn’t receive any antibiotic prophylaxis. The outcome evaluated were infectious complications at surgical site. The patients were reviewed seven and 30 days after surgery. Results: There was incidence of 2% in infection complications in group A and 2% in group B. There was no statistical significant difference of infectious complications (p=0,05) between the groups. The groups were homogeneous and comparable. Conclusion: The use of the antibiotic prophylaxis in laparoscopic cholecystectomy in low risk patients doesn’t provide any significant benefit in the decrease of surgical wound infection.
cholangiography. It was used NNIS index (National Nosocomial Infections Surveillance, 1991) in order to classify the patients with equivalent risk for postoperative infection in laparoscopic cholecystectomy.4,22,24,25,29 This index establishes the risk of infection of different surgical patients where the risk factors are: a) preoperative assessment score of the American Society of Anesthesiologists (ASA) 3, 4 or 5; b) classification of the operation as contaminated or infected; and c) duration of the procedure. The NNIS index can have values from 0 to 3 (Figure 1) wherein each risk factor is worth 1 point in the score calculation. This classification is simpler to use than others, because the ASA score - it is the variable that measures the intrinsic risk of infection - is much easier to recover from patient charts than the number of diagnoses at hospital discharge and, also can be computed before discharge. The duration of the surgery is indexed to specific surgical procedures, taking into consideration, therefore, the complexity of the procedure. The score NNIS ranges from 0 to 3, with intention to indicate increased risk of infection at the surgical site.

FIGURE 1 - Risk index of surgical site infection by NNIS system

| Risk factor                                      | Score |
|-------------------------------------------------|-------|
| Evaluation ASA: 3, 4 or 5                       | 1     |
| Classification of contaminated or infected wound| 1     |
| Surgical time: greater than 75 percentile for the procedure | 1     |

Exclusion criteria were: presence of acute cholecystitis and/or cholecdocholithiasis; use of antibiotics within 48 h prior to surgery; conversion to laparotomy; patients with renal or hepatic impairment; any state of immunosuppression; regular use or the last 30 days of immunosuppressive drugs; and not signing the consent form.

Patients were allocated through electronic draw, and the results for each patient were placed in sealed envelopes, which were delivered to anesthesiologists responsible for the anesthetic procedure, that ministered or not antibiotics without the surgeon’s knowledge.

Patients were divided into two groups: A, received prophylactic cefazolin 2 g intravenously during anesthesia; and B, which received no antibiotic. The operations were performed at the University Gaêre Guinle Hospital – UNIRIO, Rio de Janeiro, RJ, Brazil. The groups were compared for age, gender, comorbidities, surgical time and the calculation of the NNIS score. The outcome was infectious complications on surgical site, ie surgical wound infection and superficial/deep abscesses. The patients were evaluated in seven and 30 days after the operation.

Clinically infectious complications were defined by the typical signs of local or systemic infection as: axillary temperature > 37.8°C (excluding the 1st postoperative day), tachycardia, asthenia, accompanied by local pain or purulent collection on surgical site, or signs of inflammation in the wound with no purulent secretion with microbiological confirmation, even without clinical signs of systemic infection.20 Every discharge from the surgical wound was sent for culture and antibiogram.

Statistical analysis

The results of the complications and mortality were expressed as percentage. Comparisons between the groups were performed by Chi-square test, implemented by SPSS 20. Distributions of continuous variables observed in the groups were expressed as mean and standard deviation and compared using the Student t test. P values <0.05 were considered statistically significant.

RESULTS

The study population had a mean age of 48±13.63 years and consisted of 81% of women. Approximately 59% were classified as ASA I; surgery had an average duration of 77±28.70 min, and from all patients two (2%) had infection one in group A and one in group B. No differences were found between the groups in terms of mean age (p>0.05) or the time of surgery (p>0.05). No associations were observed between the ASA and the use of antibiotic prophylaxis (p>0.05) or gender (p>0.05). They also found no associations between the use of antibiotic prophylaxis and the occurrence of infections postoperatively (p>0.05).

DISCUSSION

The use of prophylactic antibiotics in surgery still causes controversy among surgeons. One should take into account that their misuse increases the rate of infection and involves unnecessary cost. There is evidence that there is no indication of antibiotic use in clean and potentially contaminated operations, where the risk of surgical site infection is up to 5%. However, in daily practice is not unusual use of prophylactic antibiotics is common in these situations.

According to the Center for Disease Control - USA most postsurgical infections are acquired during the surgical procedure, and good technique is crucial to its prevention. In addition, the center published consensus on surgical site infection prevention in which they emphasized the main points of prevention; among them; the administration of antibiotics must be taken intravenously as a single dose or while the operation is being performed, or at most for a few more hours after skin closure, not exceeding 24 h.21

The literature, in most studies, demonstrates that there is no need for antibiotic prophylaxis in laparoscopic cholecystectomy. Ruangsin et al.10 studying 299 patients in a prospective randomized study showed no significant benefit in reducing the incidence of postoperative infection. Similarly other authors referred the same results11,12,13,14,15,16,17,18.

Graham17 auditing 111 surgeons in Great Britain and Ireland involving over 7,000 laparoscopic cholecystectomies pointed out that more than 20,000 doses of antibiotics were used unnecessarily. A similar study involving 13,911 patients also found no benefit in prophylactic antibiotic administration, as well as Kacelnik18 in Norway.

Meta-analysis22,23 Studying antibiotic prophylaxis in laparoscopic cholecystectomy in randomized trials with a significant number of patients (n=1937) also demonstrated that prophylactic antibiotics are not required for elective laparoscopic cholecystectomy in low risk patients.11,12

Moreover Matsui et al.13 in randomized controlled clinical study of 1038 patients who underwent laparoscopic cholecystectomy observed a significant decrease in the incidence of infectious complications in the group receiving antibiotic prophylaxis. They also reported decreased hospitalization costs due to lower rate of infection. However, we should make some considerations regarding this article. The time of postoperative hospital stay of 3-5 days is much higher than the expected 24-48 h; they included distance infections in the results - urinary tract, respiratory, prostatitis, colitis and fever - in the first 24-48 h as evidence of infection running away from the goal of antibiotic prophylaxis, which is the surgical site. Another finding conflicting in this paper is the prophylactic dosage performed in a total of three doses of 1 g of cefazolin: first, immediately before the skin incision and the second and third 12 h and 24 h, against the international guidelines that limit antibiotic dose at induction of anesthesia and repeated or not during operation in relationship to the extension of the operation. And finally, when comparing this Matsui13 paper with existent meta-analyses22,23 is observed less scientific relevance in the Japanese study.

The NNIS system is considered standard for predicting risk

ABCD Arq Bras Cir Dig 2016;29(3):170-172
of surgical site infection. It should be considered as precipitating factor for infection in surgical site, in addition to the comorbidities of the patient, contamination potential of the procedure, completion time in larger procedure over percentile 75 and laparoscopic cholecystectomy longer than 120 min.23

In this series the patients were similar considering NNIS score, demonstrating the homogeneity of the groups as low risk for surgical site infections. The incidence of infection was small, 2% in each group, with no difference between making or not antibiotic prophylaxis. The literature has also shown that antibiotic prophylaxis does not have significant role in the prevention of surgical site infection in laparoscopic cholecystectomy and increases the costs of the procedure, so discouraging its routine use.

### CONCLUSION

The use of antibiotic prophylaxis in laparoscopic cholecystectomy have no benefit in reducing the incidence of surgical site infection.

### REFERENCES

1. Abaid RA, Cecconello I. Simplified laparoscopic cholecystectomy with two incisions. Arq Bras Cir Dig. 2014 Apr-Jun;27(2):154-6.
2. Castro PM, Akerman D, Munhoz CB, Sacramento Id, Mazzurana M, Alvarez GA. Laparoscopic cholecystectomy versus minilaparotomy in cholelithiasis: systematic review and meta-analysis. Arq Bras Cir Dig. 2014 Apr-Jun;27(2):148-53.
3. Chang WT, Lee KT, Chuang SC, Wang SN, Kuo KK, Chen JS, Sheen TM. Identifying patients at high risk of surgical wound infection. Am J Med. 1991; 1991(96):51-6.
4. Culver DH et al. Surgical wound infection rates by wound class, operative procedure and patient risk index. Am J Med. New York 1991; v. 91, n. 3, Suppl. 2 : S152-S157.
5. Dubois F, Berthelot G, Levard H. Laparoscopic cholecystectomy: historic perspective and personal experience. Surg Laparosc Endosc. 1991; 1(1):52-7.
6. Graham HE, Vasireddy A, Nehra D. Anational audit of antibiotic prophylaxis in elective laparoscopic cholecystectomy. Ann R Coll Surg Engl. 1991; 1991(1):52-7.
7. Haley RW, Culver DH, Morgan WM, White JW, Emori TG, Hooton TM. Identifying patients at high risk of surgical wound infection. Am J Epidemiol. 1985; 121(2):206-15.
8. Higgins A, London J, Charland S, Ratzer E, Clark J, Haun W, Maher DP. Prophylactic antibiotics for elective laparoscopic cholecystectomy: are they necessary? Arch Surg. 1999; 134(5):611-3; discussion 614.
9. Jaafar G, Persson G, Svennblad B, Sandblom G. Outcomes of antibiotic prophylaxis in acute processus in a population-based gallstone surgery registry. Br J Surg. 2014 Jan;101(2):69-73.
10. Kacelnik O, Alberg T, Mjaland O, Eriksen H, Skjeldstad FE. Guidelines for antibiotic prophylaxis of cholecystectomies in Norwegian hospitals. Surg Infect (Larchmt). 2013; Apr;14(2):188-91.
11. Kacelnik O, Alberg T, Mjaland O, Eriksen H, Skjeldstad FE. Guidelines for antibiotic prophylaxis of cholecystectomies in Norwegian hospitals. Surg Infect (Larchmt). 2013; Apr;14(2):188-91.
12. Kumar A, Patodia M, Pandove P.K., Sharda, V.K., Pahwa, S. Role of antibiotic prophylaxis in laparoscopic cholecystectomy: A randomized prospective study. Journal International Medical Sciences Academy 2013; 26 (4): 209-211.
13. Matsui Y, Sato S, Kakib M, Toyokawa H, Yanagimoto H, et al. Antibiotic prophylaxis in laparoscopic cholecystectomy: A randomized controlled trial. PloS ONE 2014; 9(9): e106702.
14. McGuire M, Shea J A, Schwartz J S. Infection and antimicrobial use in laparoscopic cholecystectomy. Infect Control Hosp Epidemiol. 1999; 20(9):624-6.
15. Mourret P. From the first laparoscopic cholecystectomy to the frontiers of laparoscopic surgery: the futures prospectives. Dig Surg. 1991; 8:124-5.
16. Naqvi MA, Mehrjai E, Ajaz R, Mian A., Role of prophylactic antibiotics in low risk elective laparoscopic cholecystectomy: is there a need? J Ayub Med Coll Abbottabad. 2013; Jan-Jun: 25(1-2):172-4.
17. Nogueira AC, Ramos MC, Galvao-Neto MS, Gus J, Bastos EL, Zundel N. Total clipless cholecystectomy by means of harmonic sealing. Arq Bras Cir Dig. 2015;28(1):53-6. doi: 10.1590/S0102-67202015000100014.
18. Ruanxins S, Laohawiriyakarn S, Sunpaweravong S, Mahattanobon S. The efficacy of cefazolin in reducing surgical site infection in laparoscopic cholecystectomy: a prospective randomized double-blind controlled trial. Surg Endosc. 2015 Apr; 29(4): 874-81.
19. Sallum RA, Padrão EM, Szachnowicz S, Seguro FC, Bianchi ET, Cecconello I. Prevalence of gallstones in 1,229 patients submitted to surgical laparoscopic treatment of GERD and esophageal achalasia: associated cholecystectomy was a safe procedure. Arq Bras Cir Dig. 2014 Apr-Jun;28(2):113-6. doi: 10.1590/S0102-67202015000200007.
20. Sanabria A, Dominguez LC, Valdivieso G, Gomez G. Antibiotic prophylaxis in patients undergoing elective laparoscopic cholecystectomy. Cochrane Database Syst Rev. 2012.
21. Shah JN, Maharjan SB, Paudyal S. Routine use of antibiotic prophylaxis in low-risk laparoscopic cholecystectomy is unnecessary: a randomized clinical trial. Asian J Surg. 2012; Oct;35(4):136-9.
22. Sharma N, Garg PK, Hadke NS, Choudhary D. Role of prophylactic antibiotics in laparoscopic cholecystectomy and risk factors for surgical site infection: a randomized controlled trial. Surg Infect (Larchmt). 2010 Aug;11(4):367-70.
23. Sheba JA, Healey MJ, Berlin JA, Clarke JR, Malpet PF, Staroscik RN, Schwartz JS, Williams SV. Mortality and complications associated with laparoscopic cholecystectomy. A meta-analysis. Ann Surg. 1996; 224(5):609-20.
24. Shindholm VH, Veenu V, Paschal P, Chaudhry R, Karam A. Factors influencing wound infection following laparoscopic cholecystectomy. Trop Gastroenterol. 2003; 24(9):209-211.
25. Souza HP, Breigeiron R, Cunha HM, Deves E. Antibiotic profile in laparoscopic cholecystectomy. J Hepatogastroenterology 2009; May-Jun;56(91-92):589-92.
26. Turk E, Karagulle E, Cardocoglu K, Taran H, Moray G. Effect of cefazolin prophylaxis on postoperative infectious complications in elective laparoscopic cholecystectomy: a prospective randomized study. Iran Red Crescent Med J. 2013; 15(7):581-6.
27. Yan RC, Shen SQ, Chen ZB, Lin FS, Riley J. Role of prophylactic antibiotics in laparoscopic cholecystectomy in preventing postoperative infection: a meta-analysis. J Laparoendosc Adv Surg Tech A. 2011; May;21(4):301-6.
28. Yanni F, Mekhail P, Morris-Stiff G. A selective antibiotic prophylaxis policy for patients undergoing elective laparoscopic cholecystectomy: a prospective study. J Laparoendosc Adv Surg Tech A. 2011; May;21(4):301-6.
29. Yanni F, Mekhail P, Morris-Stiff G. A selective antibiotic prophylaxis policy for patients undergoing elective laparoscopic cholecystectomy: a prospective study. J Laparoendosc Adv Surg Tech A. 2011; May;21(4):301-6.