



ORIGINAL ARTICLE

Duration of antibiotic therapy in patients with acute cholecystitis managed with cholecystostomy. Does it affect clinical outcomes?

Duración de la antibioticoterapia en pacientes con colecistitis aguda manejados con colecistostomía. ¿Afecta los desenlaces clínicos?

Santiago Salazar-Ochoa¹ , Camila Arias-González¹ , Santiago Barrantes-Moreno¹ ,
Sara Patiño-Franco¹ , Carlos Andrés Delgado-López²

- 1 MD, resident of General Surgery, Universidad Pontificia Bolivariana, Medellín, Colombia.
2 MD, specialist in General Surgery, Hospital Pablo Tobón Uribe, Medellín, Colombia.

Abstract

Introduction. In patients with acute cholecystitis who receive treatment with cholecystostomy, the optimal duration of antibiotic therapy is unknown. The aim of this work is to compare short courses of antibiotics (7 days or less) with long courses (more than 7 days) in this population.

Methods. We performed a retrospective observational cohort study which included patients diagnosed with acute cholecystitis, who received antibiotic therapy and were taken to cholecystostomy. Univariate analysis and logistic regression were performed to evaluate the association between clinical variables and the duration of antibiotic therapy. The main outcome evaluated was 30-day mortality.

Results. Seventy-two patients were included, 75% (n=54) received more than 7 days of antibiotics and 25% (n=18) received 7 or fewer days of antibiotics. Demographic data between both groups were similar (age, severity of cholecystitis, comorbidities). There were no significant differences in 30-day mortality between both groups. Antibiotic duration did not influence mortality at 30 days (OR 0.956 95% CI 0.797 - 1.146).

Conclusion. There are no significant differences in the clinical outcomes of patients with acute cholecystitis who undergo cholecystostomy and receive short courses of antibiotics compared to long courses.

Keywords: gallbladder; cholelithiasis; acute cholecystitis; acalculous cholecystitis; cholecystostomy; anti-bacterial agents.

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Corresponding author: Santiago Salazar-Ochoa, Carrera 6 A # 23 A sur - 85. Tel.: 3002205588

Email: santiago.salazar.ochoa1190@gmail.com

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Resumen

Introducción. En pacientes con diagnóstico de colecistitis aguda tratados con colecistostomía, el tiempo óptimo de duración de la terapia antibiótica es desconocido. El objetivo de este trabajo fue comparar los resultados clínicos en pacientes con diagnóstico de colecistitis aguda manejados inicialmente con colecistostomía y que recibieron cursos cortos de antibióticos (7 días o menos) versus cursos largos (más de 7 días).

Métodos. Se llevó a cabo un estudio de cohorte observacional, retrospectivo, que incluyó pacientes con diagnóstico de colecistitis aguda manejados con colecistostomía, que recibieron tratamiento antibiótico. Se hizo un análisis univariado y de regresión logística para evaluar la asociación de variables clínicas con la duración del tratamiento antibiótico. El desenlace primario por evaluar fue la mortalidad a 30 días.

Resultados. Se incluyeron 72 pacientes. El 25 % (n=18) recibieron terapia antibiótica por 7 días o menos y el 75 % (n=54) recibieron más de 7 días. No hubo diferencias significativas en la mortalidad a 30 días entre los dos grupos ni en las demás variables estudiadas. La duración de la antibioterapia no influyó en la mortalidad a 30 días (OR 0,956; IC_{95%} 0,797 - 1,146).

Conclusión. No hay diferencias significativas en los desenlaces clínicos de los pacientes con colecistitis aguda que son sometidos a colecistostomía y que reciben cursos cortos de antibióticos en comparación con cursos largos.

Palabras clave: vesícula biliar; coledocitis; colecistitis aguda; colecistitis alitiásica; colecistostomía; antibacterianos.

Introduction

Acute cholecystitis is one of the most frequent surgical entities and its main cause is cholelithiasis, which has a variable prevalence, between 11% and 35% in the world population^{1,2}. In Colombia, the incidence of gallstone disease is not defined, however, it mainly affects adult women, the mortality rate is higher in males, and the latter is an outcome directly related to the presence of comorbidities, such as diabetes mellitus and arterial hypertension, or a physical status classification according to the American Society of Anesthesiologists (ASA) III or IV^{3,4}.

Up to 20% of people with cholelithiasis will present some complication related to gallstones⁵, such as cholecystitis, acute pancreatitis and cholangitis, although the vast majority will remain asymptomatic over time. Acute cholecystitis is defined as an inflammation of the gallbladder, characterized by pain in the right upper quadrant of the abdomen, a positive Murphy sign, elevated acute phase reactants, and the presence of imaging signs of inflammation⁶.

Laparoscopic cholecystectomy is the treatment of choice for acute cholecystitis^{6,7}. However, there is a group of patients who, due to the time of

evolution of the disease, associated comorbidities or clinical status, are not candidates for definitive surgical management at the time of diagnosis; in them, percutaneous cholecystostomy has been established as an alternative treatment⁸.

Currently, there are no international guidelines or consensus that establish the duration of antibiotic therapy in this population of patients, so in clinical practice the decision of the duration of antibiotic therapy and the antibiotic type depends entirely on the treating physician. The purpose of this study was to compare the clinical results in patients diagnosed with acute cholecystitis initially managed with cholecystostomy and who received short courses (7 days or less) of antibiotic treatment with those who received long courses (more than 7 days).

Methods

A retrospective analysis of patients older than 18 years treated during a period of 9 years (2013 to 2021) was carried out at the Pablo Tobón Uribe Hospital, in Medellín, Colombia, a fourth level hospital, who met the diagnostic criteria of the 2018 Tokyo guidelines (TG18) for acute cholecystitis⁶, who underwent cholecystostomy and who received

ved antibiotic treatment. The decision to perform cholecystostomy was made by the treating physician (general surgeon or hepatobiliary surgeon) based on the patient's clinical characteristics. The percutaneous cholecystostomy was performed by the institution's interventional radiology group, in most cases through the transhepatic route.

The severity of cholecystitis was established according to the TG18 criteria⁶ and it was evaluated whether the patients had systemic inflammatory response syndrome (SIRS) on admission, defined according to the criteria described by Davies and Hagen in 1992⁸. Patients with acalculous cholecystitis were included in the analysis since ultrasound has a sensitivity close to 84% to detect cholelithiasis.

Patients with a concomitant diagnosis of gallstone pancreatitis, cholangitis, and patients with positive urine cultures and/or tracheal aspirates were excluded, since another active infection at the time of acute cholecystitis diagnosis could influence the decision to discontinue or continue antibiotics. Patients who died before completing antibiotic therapy were also excluded to avoid bias when evaluating in-hospital mortality in the results.

Two groups of patients were compared: those who received antibiotics for 7 days or less (short courses) and those who received antibiotics for more than 7 days (long courses); the duration and type of antibiotic treatment was established at the discretion of the treating surgeon. The 7-day cut allowed a more homogeneous size of both groups. The persistence of SIRS and the need for vasopressor support 72 hours after cholecystostomy were evaluated as markers of clinical response to treatment. Acute cholecystitis recurrence was defined as any new episode of acute cholecystitis that occurred after a 48-hour period in which the patient was not receiving antibiotics and did not meet SIRS criteria. The primary outcome was 30-day mortality.

The sample size was for convenience (not probabilistic), and all patients diagnosed with acute cholecystitis that were identified in the institution's database were included. Data collection

was done manually by reviewing the electronic medical records of the patients.

Descriptive statistical methods were used in the univariate analysis. For the quantitative variables, measures of central tendency (mean, median) and dispersion (IQR interquartile range, standard deviation) were calculated; For the qualitative variables, absolute and relative measures (average) were calculated, the latter expressed as a percentage. Inferential statistical techniques were applied to search for the existence of a correlation between quantitative variables using the Pearson or Spearman tests, according to the frequency of the events found. To establish the association between qualitative variables, the dependent variable being dichotomous, the Chi-square test was used, with the risk calculation and its respective confidence interval. For the relationship between a quantitative and a qualitative variable, mean (Student's T) or median (Mann-Whitney U) differences were estimated, depending on the distribution of the quantitative variable in the different categories of the qualitative variable. Proportions for independent samples were compared according to the category of the variables with the Chi-square, Z tests or Fisher's exact test, as the case may be. For the clinical outcome of 30-day mortality, a binomial logistic regression was performed, with antibiotic duration and days of hospital stay as covariates. All analyzes were performed using the open access statistical software The Jamovi Project [Computer Software] version 1.6.7.0. (Available at <https://www.jamovi.org>).

Results

A total of 72 patients were collected and included in the analysis. Male gender (n=38) was slightly higher compared to female gender (n=34). 25% (n=18) received antibiotic therapy for 7 days or less and 75% (n=54) received more than 7 days; the minimum of antibiotic treatment was one day, and the maximum 40 days (Table 1). Between both groups of patients, age (75 vs 70 years; p=0.321), Charlson's comorbidity index (5.6 vs 5.7 points; p=0.859) and severity of cholecystitis according

to TG18 criteria, were similar. There were no differences regarding temperature, heart rate, mean arterial pressure, and leukocyte count between admission and control at 72 hours after cholecystostomy between both groups, expressed in table 1 as delta of each of these variables.

Regarding the relevant clinical outcomes (Table 2), no significant differences were found in terms of 30-day mortality. Two patients died in the group of less than 7 days (11.1%) and five patients died in the group of more than 7 days (9.2%) ($p=1.000$). ICU admission (5.5% vs 14.8%; $p=0.434$), organ failure (22.2% vs 35.1%; $p=0.390$), need for vasopressor support (5.5% vs 25.9%; $p=0.095$) and the presence of SIRS on admission (38.8% vs 50%; $p=0.413$) were more frequent in the group of more than 7 days, without having a statistically significant difference with respect to the other group. Only one patient (5.5%) in the group of less than 7 days and two

(3.7%) in the group of more than 7 days remained on vasopressor at 72 hours after cholecystostomy; while three patients (16.6%) in the group of less than 7 days and six (11.1%) in the group of more than 7 days persisted with SIRS at 72 hours.

The recurrence of cholecystitis was also similar between both groups (11.1% vs 7.4%; $p=0.635$). Hospital readmission at 30 days (50% vs 33.3%; $p=0.206$) and 90 days (44.4% vs 44.4%; $p=1.000$) was similar between both groups. Among the causes of readmission were pain at the insertion site of the cholecystostomy drain, changes in the appearance of the drain, accidental removal of the drain, and the presence of abdominal pain.

Bile culture was performed in 52 (72.2%) of the 72 included patients. Regarding the microorganisms isolated in the total number of cultures, 36.5% corresponded to *Klebsiella pneumoniae*, 28.8% to *Escherichia coli*, 17.3% to *Enterococcus faecalis*, and 11.5% to *Enterococcus gallinarum*.

Table 1. Demographic characteristics of patients who underwent cholecystostomy and who received antibiotic treatment at the Pablo Tobón Uribe Hospital, Medellín, Colombia. 2013 to 2021.

Variable	Antibiotics $\leq$ 7 days (n=18)	Antibiotics > 7 days (n=54)	p-value
Age, mean $\pm$ SD	75 $\pm$ 15.47	70.87 $\pm$ 13.44	0.321 *
Sex			
Male, n (%)	11 (15.3%)	27 (37.5%)	0.413 Δ
Female, n (%)	7 (9.7%)	27 (37.5%)	
Type of cholecystitis (n=68)			
Calculous	11 (16.2%)	42 (61.8%)	0.626
Acalculous	4 (5.9%)	11 (16.2%)	
Severity of cholecystitis			
Tokyo I	6 (8.3%)	9 (12.5%)	0.190
Tokyo II	9 (12.5%)	26 (36.1%)	
Tokyo III	3 (4.2%)	19 (26.4%)	
Charlson Comorbidity Index, mean $\pm$ SD	5.61 $\pm$ 3.82	5.76 $\pm$ 2.76	0.859
Leukocyte delta Ω , median (IQR)	5800 (10800)	3350 (6775)	0.160
Temperature delta Ω , median (IQR)	0.350 (1.175)	0.0 (1.075)	0.458
Heart rate delta Ω , median (IQR)	10 (17)	10 (22)	0.927
Mean arterial pressure delta Ω , median (IQR)	9.5 (14)	0 (21)	0.032

SD: standard deviation. * Mann-Whitney U test; Δ Chi square test; Ω Difference between admission and control at 72 hours. Source: Own authors.

Table 2. Important clinical outcomes according to the time of antibiotic therapy.

	Antibiotics $\leq$ 7 days (n=18)	Antibiotics > 7 days (n= 4)	p-value *
30-day mortality	2	5	1.000
Recurrence of cholecystitis	2	4	0.635
ICU admission	1	8	0.434
Organ failure	4	19	0.390
SIRS presence	7	27	0.413
SIRS persistence	3	6	0.682
Vasopressor use	1	14	0.095
Use of vasopressor 72 hours after cholecystostomy	1	2	1.000
Readmission to 30 days	9	18	0.206
90-day readmission	8	24	1.000

ICU: intensive care unit; SIRS: systemic inflammatory response syndrome. * The Chi square test or Fisher's exact test was applied, depending on the sample size. Source: Own authors.

In addition, different species of fungi such as *Candida albicans*, *Candida glabrata* and *Candida tropicalis* were isolated. It is important to clarify that, in 15 of these 52 patients, more than one microorganism was isolated simultaneously.

Blood cultures were performed in 37 (51.3%) of the 72 patients included; the most common microorganisms isolated being *Salmonella*, *Klebsiella pneumoniae*, *Enterococcus cloacae*, *Proteus mirabilis*, *Klebsiella oxytoca*, and *Streptococcus anginosus* (each 5.4% of the number total blood cultures taken). No patient in the study presented *Clostridium difficile* infection as a complication associated with the use of antibiotics. The most used antibiotic was piperacillin/tazobactam (65.2%), followed by ciprofloxacin (34.7%) and ampicillin/sulbactam (33.3%).

In the binomial logistic regression analysis for the 30-day mortality outcome, an OR of 0.956 (95% CI 0.797-1.146; p=0.625) was found for the duration of the antibiotic, and for the days of hospital stay the OR was 1.019 (95% CI 0.920-1.129, p=0.711).

Discussion

The duration of antibiotic therapy in patients with acute cholecystitis managed with cholecystostomy

continues to be a matter of debate due to the limited current evidence on the subject. The results of this study show that there are no significant differences in terms of 30-day mortality, recurrence of cholecystitis, persistence of SIRS at 72 hours after cholecystostomy, and the need for prolonged vasopressor support between both groups.

The duration of antibiotics in these patients seems to be determined eventhough by clinical factors related to patients, and by the preferences of the treating physician, which explains, as our study shows, a great variability in this regard. In general, there is a tendency to prolong the antibiotic in seriously ill patients, with organ failure, multiple comorbidities, or who are admitted to the ICU.

In the different management guides there are recommendations that vary, both in the number of days of antibiotic therapy and in the studies on which these recommendations are based. The guidelines for intra-abdominal infections of the Infectious Diseases Society of America (IDSA) ⁹ recommend that the intra-abdominal infectious focus be drained within the first 24 hours of admission, and if the patient has sepsis or septic shock, the origin should be drained as soon as posible. This section also applies to

patients diagnosed with acute cholecystitis who are taken to cholecystostomy.

The authors recommend giving antibiotics for the shortest time possible to avoid microbial resistance and the adverse effects associated with prolonged use of antibiotics, establishing cycles of 5 to 7 days in those patients in whom control of the source of infection is not going to be carried out. But in cases in which control of the source of infection is carried out, such as in patients with acute cholecystitis managed with cholecystostomy, antibiotic treatment should not be given for more than 4 days. This recommendation is applicable to patients who present improvement in their clinical symptoms and paraclinical parameters, without bacteremia or immunosuppression, and who do not present with sepsis or persistent septic shock⁹, since the literature is lack in these patients and it is not possible to make any recommendation. Quitar: to he patient. Additionally, short courses of antibiotics are not recommended for patients with bacteremia due to Gram-positive cocci, some fungal or viral infections, or in those in whom the presence of a multi-resistant microorganism has been demonstrated¹⁰.

The TG18 guidelines⁶ recommend a duration of antibiotic therapy of 4 to 7 days in those patients in whom the source of infection has been controlled; however, this recommendation is limited only to those patients with grade III acute cholecystitis. It should be remembered that the criteria established by this guide to define grade III acute cholecystitis are based on the presence of organ failure, so many patients who are managed with cholecystostomy, due to the time of evolution or associated comorbidities, escape this recommendation.

The most recent guidelines for the management of intra-abdominal infection, which were published in 2021, in a collaboration between the World Society of Emergency Surgery (WSES), the Global Alliance for Infections in Surgery (GAIS), the Surgical Infection Society-Europe (SIS-E), World Surgical Infection Society (WSIS), and the American Association for the Surgery of Trauma (AAST)¹¹, do not make a clear recommendation

on the number of days of antibiotic therapy in patients who undergo cholecystostomy due to complicated acute cholecystitis or those who are not candidates for definitive surgical management.

Both guidelines recommend the initial use of broad-spectrum antibiotics, according to local epidemiology, since the definitive results of microbiological cultures usually take 3 to 4 days. Subsequently, therapy must be adjusted according to the sensitivity profile of the isolated microorganisms, although there is limited evidence with good clinical results on the use of narrow-spectrum antibiotics in patients with moderate acute cholecystitis managed with cholecystostomy¹².

In the case of our study, and as previously mentioned, the most widely used antibiotic was piperacillin, a broad-spectrum penicillin, which, added to a beta-lactamase inhibitor, such as tazobactam, offers adequate coverage not only for enterobacteria, but also for the *Enterococcus* spp, and the majority of anaerobic bacteria¹³, which are described in different series as the main pathogens that trigger biliary infections¹⁴, which also agrees with our findings, since *Klebsiella pneumoniae* was the microorganism most often isolated.

Additionally, ciprofloxacin, the second most used antibiotic in our study and also considered a broad-spectrum antimicrobial, offers adequate coverage in cases of acute cholecystitis¹⁵. In our setting, this antibiotic is not commonly used as an empirical antibiotic due to local bacterial resistance rates, but it is widely used when there are cultures that demonstrate adequate sensitivity to it.

However, one of the most worrisome adverse effects of the use of antibiotics is *Clostridium difficile* infection, an entity that has been considered the main cause of colitis associated with the use of antibiotics and that occurs more frequently during the first month after the use of antimicrobials treatment, especially quinolones and broad-spectrum penicillins¹⁶. It is important to highlight that in none of the patients included in our study this microorganism was isolated and there were no readmissions due to signs or symptoms suggestive of *Clostridium difficile* colitis.

Perhaps one of the most dramatic changes in clinical practice regarding the duration of

antibiotic therapy in patients with intra-abdominal infection occurred after the publication of the STOP-IT study¹⁷, in which patients were randomized into two groups with complicated intra-abdominal infections and with adequate control of the source, including percutaneous drainage; one group received antibiotics up to 2 days after resolution of SIRS (control group) while the other group received 4 days of antibiotic treatment (experimental group). At the time of the results analysis, no statistically significant differences were found in terms of mortality, surgical site infection, and recurrence of intra-abdominal infection, so the authors concluded that in patients with intra-abdominal infections in whom adequate source infection control was performed, short courses of antibiotics (approximately 4 days) were associated with clinical outcomes similar to long courses (approximately 8 days). However, it is worth mentioning that in this study patients with biliary infection only corresponded to 9.7% in the experimental group and it is unknown how many of these patients were diagnosed with acute cholecystitis and were managed with cholecystostomy.

The results of our study are consistent with previous reports in the literature regarding the duration of antibiotic therapy and its association with clinical outcomes in patients with acute cholecystitis managed with cholecystostomy¹⁸.

There are several limitations of this study that must be taken into consideration, among which are its retrospective nature and the fact that it was carried out at a single center. Additionally, it is possible that some of the patients have been readmitted to other medical centers, which would cause loss of data in the analyzes performed. Despite being a small sample, the number of patients is similar to other published series¹⁸.

Our findings provide information that could support, together with the emerging literature, the use of short courses of antibiotics in patients with acute cholecystitis managed with cholecystostomy, taking into account that prolonged use of antibiotics is associated with an increase in the number of days of hospital stay and costs to the healthcare system, an increase in patient complications, such as *Clostridium difficile* infection, and

an increase in the rates of bacterial resistance, an aspect currently considered a public health problem worldwide.

Conclusions

The administration of a course of 7 days or less of antibiotic was compared with a course of more than 7 days, during a period of 9 years, in which percutaneous cholecystostomy was performed for the treatment of 72 patients with acute cholecystitis and there were no statistically significant differences in terms of mortality, readmission, ICU stay or use of vasopressors. These findings support the limited current literature suggesting that short courses of antibiotics are not associated with worse clinical outcomes, and therefore this could be a clinical practice for general surgeons to consider.

Compliance with ethical standards

Informed consent: This study is a retrospective chart review, and as such, there is no need for informed consent. The design and methodology of this work was approved by the ethics committee of the Pablo Tobón Uribe Hospital, in Medellín, Colombia.

Conflict of interest: none declared by the authors.

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Author's contributions

- Conception and design of the study: Santiago Salazar-Ochoa, Camila Arias-González, Santiago Barrantes-Moreno, Sara Patiño-Franco, Carlos Andrés Delgado-López.
- Acquisition of data: Santiago Salazar-Ochoa, Camila Arias-González, Santiago Barrantes-Moreno, Sara Patiño-Franco.
- Data analysis and interpretation: Santiago Salazar-Ochoa, Camila Arias-González, Santiago Barrantes-Moreno, Sara Patiño-Franco, Carlos Andrés Delgado-López.
- Drafting the manuscript: Santiago Salazar-Ochoa, Camila Arias-González, Santiago Barrantes-Moreno, Sara Patiño-Franco, Carlos Andrés Delgado-López.
- Critical review and final approval: Santiago Salazar-Ochoa, Camila Arias-González, Santiago Barrantes-Moreno, Sara Patiño-Franco, Carlos Andrés Delgado-López.

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