Periendoscopic Care Continuum in Acute Cholangitis Caused by Common Bile Duct Stone

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ABSTRACT

Acute cholangitis (AC) is a biliary tract infection with in-hospital mortality rates reaching up to 14.7%. The underlying condition is biliary obstruction caused by benign and malignant etiologies, as well as bacteriobilia, with commom bile duct (CBD) stone being one of the most common causes. Currently, the diagnosis is validated using Tokyo Guidelines 2018 criteria. Acute cholangitis due to CBD stone should be managed in a comprehensive manner, i.e., periendoscopic care continuum, consisting of pre-endoscopic care, endoscopic management, and post-endoscopic care. Pre-endoscopic care is primarily comprised of supportive therapy, antibiotic administration, optimal timing of endoscopic retrograde cholangiopancreatography (ERCP), pre-ERCP preparation, and informed consent. Endoscopic management is biliary decompression with stone extraction facilitated via ERCP procedure. Selective biliary cannulation should be performed meticulously. Bile aspiration and minimal bile duct contrast injection should be done to minimize the worsening of biliary infection. Endoscopic biliary sphincterotomy, endoscopic papillary balloon dilatation, and/or endoscopic papillary large balloon dilatation are all safe procedures that can be used in AC. Special precautions must be undertaken in critical and severe acute cholangitis patients who may not tolerate bleeding, in whom endoscopic biliary sphincterotomy may be postponed to decrease the risk of bleeding, and biliary decompression may be only attempted without CBD stone extraction. Nasobiliary tubes and plastic biliary stents are equally effective and safe for patients who have only undergone biliary decompression. In post-endoscopic care, management of adverse events and observation of therapy response are mandatory.

Keywords: *Cholangitis; Common bile duct stone; Endoscopic retrograde cholangiopancreatography.*

INTRODUCTION

Acute cholangitis (AC) is an infection of the biliary tract with an in-hospital mortality (IHM) rate of up to 14.7%.[1] It is caused by biliary obstruction due to malignant and/or benign etiologies, which impairs physiologic bile flow and increases intraductal pressure, followed by subsequent bacteriobilia and bacterial translocation to systemic circulation.[2–4] A common bile duct (CBD) stone is one of the most frequent causes of AC.[4,5]

The criteria for diagnosing AC have evolved,

from Charcot's triad and Reynolds' pentad in the early days to the most recent Tokyo Guidelines 2018 (TG18) criteria.[6,7] Although its specificity (60%) is lower than its sensitivity (82%) in a recent study, TG18 remains a popular and well-established diagnostic criterion for AC.[5] The criteria comprise three parameters, e.g., inflammation, cholestasis, and imaging (**Table 1**). The severity of AC is divided into 3 entities, e.g., mild, moderate, and severe (**Figure 1**).[7]

The management paradigm for AC has shifted from surgery to primarily endoscopic biliary drainage with endoscopic retrograde cholangiopancreatography (ERCP).[8] The ground-breaking trial by Lai, et al.[9] showed decreased hospital mortality rate of AC due to CBD stones who underwent ERCP compared to surgery (10 vs. 32%, $p < 0.03$). Currently, ERCP is the mainstay endoscopic treatment for AC caused by CBD stone.[10]

It should be noted that there have been numerous advancements in the fundamentals of comprehensive care to improve the outcome of AC patients with CBD stones. Supportive therapy and antibiotic choices are rapidly progressing. Timing, preparation, and technical aspects of ERCP, as well as post-ERCP management have grown tremendously. All aspects are collectively entitled to periendoscopic care continuum and will be discussed thoroughly in this article. The continuum consists of pre-endoscopic care, endoscopic management, and post-endoscopic care (**Figure 2**).[2]

PRE-ENDOSCOPIC CARE

Pre-endoscopic care must be initiated as soon as the diagnosis is confirmed. Supportive therapy, antibiotic administration, ERCP optimal time determination, pre-ERCP preparation, and informed consent are the essentials.

Supportive Therapy and Antibiotic Administration

All patients arriving at the hospital emergency unit, including AC, must follow the airway, breathing, and circulation (ABC) protocol. Supportive therapy such as maintaining the patient's airway (A), achieving optimal oxygenation (B), and reaching good vascular perfusion (C) along with antibiotic therapy are the core objectives.[11]

Sepsis with severe AC is related to at least one of six organ dysfunctions.[7] The ABC approach ensures optimal oxygenation and perfusion for addressing these issues. To preserve tissue perfusion, intravenous fluid containing 30 ml/kg body weight of crystalloid should be started within 3 hours of admission. Fluid therapy must be administered with caution after initial fluid resuscitation to avoid pulmonary edema and increased mortality. It is recommended that the hemodynamic monitoring utilize dynamic measurements, such as the response to a passive leg elevation or a fluid infusion, stroke volume, or echocardiography.[12,13]

Antibiotic treatment should be initiated without delay. The choice depends on the overall

Table 1. Tokyo Guidelines 2018 Diagnostic Criteria for Acute Cholangitis[7]

A. Systemic inflammation	B. Cholestasis	C. Imaging
A1. Fever (temperature over than 38 degrees of Celsius) and/or shaking chills	B1. Jaundice (Total bilirubin ≥ 2 mg/dL)	C1. Biliary dilatation
A2. Laboratory data showing evidence of inflammatory response: - Leukocyte less than 4000 or more than 10,000/uL - C-reactive protein (CRP) ≥ 1 mg/dL	B2. Abnormal liver function test (more than 1.5 x upper limit normal) - Alkaline phosphatase (AP) - Gamma glutamyl transpeptidase (GGT) - Alanine aminotransferase (ALT) - Aspartate aminotransferase (AST)	C2. Evidence of etiology such as stricture, stent, stone, etc.
Suspected diagnosis of acute cholangitis: one item in A + one item in B or C		
Definite diagnosis of acute cholangitis: one item in A + one item in B + one item in C		

severity of the infection and its source, whether it was acquired in the community or a healthcare facility. For mild-to-moderate community-acquired AC, the Infectious Disease Society of America (IDSA) recommends cefazolin, cefuroxime, or ceftriaxone. However, in severe cases or following bilio-digestive anastomosis, the options are broader and include piperacillin-tazobactam, imipenem-cilastatin, meropenem, doripenem, cefepime ciprofloxacin, levofloxacin, with or without metronidazole.[14] Antibiotics regimen for acute cholangitis is also outlined in the Tokyo Guidelines 2018 (TG18).[7,15] Local antibiogram data can also help clinicians choose the right antibiotics. The optimal duration of antibiotics in AC is four to seven days after the source has been taken care of. The antibiotic choices and dosages are listed in **Figure 1** and **Table 2.**[15,16]

Determination of ERCP Optimal Timing

Defining the best timing of ERCP is crucial in AC. Emergent (within 48 hours of admission), urgent (more than 48 hours of admission), and elective biliary drainage are the most common terms. Several studies and guidelines link ERCP timing to a variety of outcomes such as in-hospital mortality (IHM), intensive care unit (ICU) stay, 30-day mortality, 30-day readmission, organ failure, and length of stay (LOS).[1,17,18] The TG18 advocated biliary drainage timing is initiated according to infection severity. However, it cannot precisely determine the timing of biliary drainage. Only in mild AC should biliary drainage be performed if there is no improvement in symptoms within 24 hours. For moderate cases, biliary drainage should be performed immediately. For severe ones, emergency biliary drainage should be performed as soon as possible.[7]

Table 2. Antibiotic Dosage in Acute Cholangitis[15,16]

Antibiotic	Dosage
Ampicillin-sulbactam	1.5 gram IV q.d.s.
Piperacillin-tazobactam	4.5 gram IV q.d.s.
Cefazolin	1-2 gram IV t.i.d.
Cefuroxime	1.5 gram IV t.i.d.
Ceftriaxone	2 gram IV o.d.
Cefotaxime	1 gram IV t.i.d.
Cefoxitine	1 gram IV t.i.d.
Cefepime	2 gram IV t.i.d.
Ceftazidime	2 gram IV t.i.d.
Cefoperazone-sulbactam	1.5 gram IV b.i.d.
Metronidazole	500 mg IV or PO t.i.d.
Ertapenem	1 gram IV o.d.
Imipenem-cilastatin	500 miligram IV q.d.s.
Meropenem	1 gram IV t.i.d.
Doripenem	500 miligram IV t.i.d.
Ciprofloxacin	400 mg IV b.i.d. or 500 mg PO b.i.d.
Levofloxacin	750 mg IV or PO o.d.
Moxifloxacin	400 mg IV or PO o.d.
Aztreonam	1 gram IV t.i.d.

In contrast to TG18, according to the European Society of Gastrointestinal Endoscopy (ESGE) 2019 guideline, patients with severe, moderate, or mild AC must undergo biliary drainage within 12 hours, 48-72 hours, or electively. The supporting data were obtained from 12 retrospective studies with evidence of very low to low quality.[10] In AC, the American Society for Gastrointestinal Endoscopy (ASGE) 2021 guideline suggests performing ERCP within 48 hours of admission, despite the extremely low evidence quality. ERCP performed within 48 hours of admission resulted in lowered IHM than ECRP performed after 48 hours.[19] It should be noted that currently available data stems from observational studies only.

Several systematic reviews and meta-analyses (SRMA) addressing this issue have been published. Iqbal, et al.[1] collected data from observational studies and two national databases to discover the influence of ERCP timing on AC patients' in-hospital mortality (IHM). It was found to be lesser in AC patients who underwent emergent ERCP in observational studies (Odds ratio [OR] 0.52; 95% confidence interval [CI], 0.28-0.98), as well as in database studies (OR 0.58; 95% CI 0.52-0.64). Subgroup analysis revealed that patients with mild-moderate (OR 0.51; 95% CI, 0.30-0.85) and severe (OR 0.41; 95% CI 0.17-0.98) AC who underwent emergent ERCP had a lower risk of IHM. Another SRMA was conducted by Du, et al.[18] by collecting observational study data and demonstrated an IHM decrease in AC patients who underwent ERCP < 24 vs. ≥ 24 hours (OR 0.81; 95% CI, 0.73-0.90), < 48 vs. ≥ 48 hours (OR 0.57; 95%

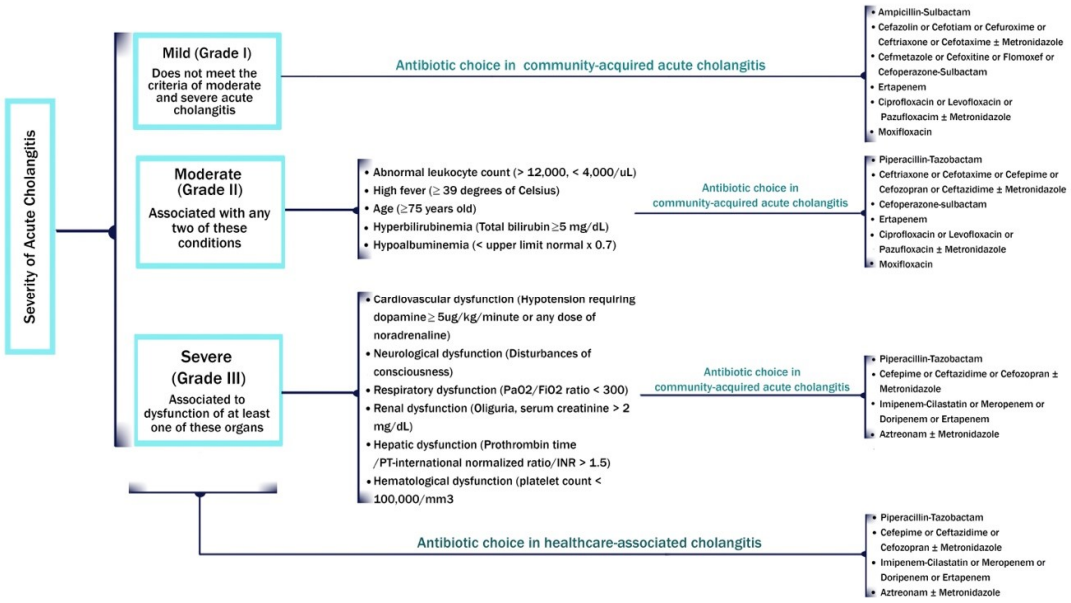

Figure 1. Severity of acute cholangitis and antibiotic choices.

CI, 0.51-0.63) and < 72 vs. ≥ 72 hours (OR 0.32; 95% CI 0.15-0.68) within admission. Lyu, et al.[20] also found lower IHM in AC patients who underwent ERCP < 24 vs. ≥ 24 hours (OR 0.83; 95% CI 0.75-0.92) and < 48 vs. ≥ 48 hours (OR 0.57; 95% CI 0.52-0.64).

Other clinical outcomes have been evaluated, as well. Iqbal, et al.[1] conducted three observational studies and discovered no difference in the 30-day mortality odds between AC patients who had emergent ERCP versus urgent ERCP (OR 0.39; 95% CI 0.14-1.08). However, based on national databases studies, there was a difference in 30-day mortality between AC patients who underwent emergent ERCP versus urgent ERCP (OR 0.44; 95% CI 0.30-0.67). The LOS was shorter in patients who underwent emergent ERCP compared to those who underwent urgent ERCP (mean difference of 5.56 days, 95% CI -1,59 to -9.53). Persistent organ failure did not differ statistically between AC patients who had ERCP within 24 hours and those who had it done after 24 hours (OR 0.69, 95% CI 0.33-0.46)[1]. In contrast, Du, et al.[18] discovered a lower likelihood of persistent organ failure in patients who underwent emergent ERCP as opposed to urgent ERCP (OR 0.51; 95% CI 0.31-0.86). Patients who underwent emergent ERCP had a shorter ICU stay (mean difference 1.6 days, 95% CI 0.2-3.0) and a lower 30-day readmission rate (OR 0.6, 95% CI 0.509-0.72) than patients who had urgent ERCP.[18]

Based on the existing data, earlier ERCP improved most of the clinical outcomes in AC patients. It is suggested to perform emergent ERCP in patients with AC, as IHM, 30-day mortality, organ failure, LOS, ICU stay, and 30-day readmission were reduced. ERCP performed within 24 hours of admission is also advantageous in terms of reduced IHM and LOS, but not 30-day mortality. If resource constraints are considered, ERCP could be completed in less than 24 hours in certain cases, such as severe AC.

Pre-ERCP Preparation

Before performing ERCP, it is vital to perform a pre-procedural assessment that includes medical history, physical examination, laboratory, and imaging studies. Data of antiplatelet and/or anticoagulant, comorbidities (such as liver cirrhosis, heart disease, pulmonary disease), clinical condition, size, and cause of biliary obstruction will assist endoscopist in deciding the safest and most evidence-based intraprocedural management.[2]

In critical patients with CBD stones, severe AC, and valvular heart disease, the appropriate decision might be a biliary decompression only instead of complete primary endoscopic therapy to remove the stone. Those patients are

at excessive risk of bleeding and will require anticoagulant therapy as soon as possible after ERCP.[19]

Post-ERCP pancreatitis (PEP) should be anticipated in all patients planned for ERCP, including AC cases. The specific measures are outside this article's scope. The pre-ERCP general approach for PEP prevention is risk factor evaluation, rectal non-steroidal anti-inflammatory drug (NSAID) administration and/or lactated ringer infusion, pancreatic stent insertion, and sublingual glyceryl nitrate (GTN).[21,22]

Informed Consent

Obtaining the consent of the patient and family is of utmost importance. Treatment with an endoscopic procedure, such as ERCP, is helpful in AC with CBD stones, but it is not without risk and has some limitations. Before the day of the procedure, the endoscopist should thoroughly discuss all aspects of ERCP, as well as pre-and post-endoscopic management. Informed consent is a part of a medicolegal document that should be completed.[23]

The endoscopist must explain the ERCP procedure overview, indication, potential benefit, complication risk, complication management, limitation, and alternative treatment. It is possible to establish an effective endoscopist and patient/family relationship.[23]

ENDOSCOPIC MANAGEMENT

Endoscopic retrograde cholangio-pancreatography is the established procedure for AC due to CBD stone. Biliary drainage and complete stone removal can be accomplished with ERCP[10]. There exist some specific issues in each step of ERCP for managing AC and CBD stone that need to be discussed further.

Selective Biliary Cannulation, Bile Aspiration, and Contrast Injection

After properly positioning the side view endoscope facing Vater's papilla in the second part of the duodenum, selective biliary cannulation (SBC) is performed using a sphincterotome loaded with guidewire according to standards of practice. Cannulation may be easier in AC due to CBD dilatation or enlarged papillary orifice following spontaneous stone passage. On the contrary, cannulating AC patients with an impacted stone in the ampulla may be difficult. Fistulotomy and free-hand needle knife sphincterotomy are the methods of choice for dealing with this type of issue.[2] Wire-guided or contrast-guided cannulation can be used to achieve deep biliary cannulation. The wire-guided technique is preferred because it has been proven to have a lesser risk of PEP compared to contrast-guided cannulation.[24–26]

Bile should be aspirated following successful deep biliary cannulation for two main reasons. Firstly, bile aspiration will reduce biliary duct pressure and further decrease the risk of worsening biliary infection. Secondly, the obtained bile fluid can be sent to a laboratory for culture and resistance to identify the culprit pathogen and antibiotic susceptibility.[2] Gromski, et al.[27] studied bile culture and resistance of patients with suspected AC. From 721 ERCP, 662 (91.8%) bile cultures were positive. Approximately, 81.6% of those 662 bile cultures were polymicrobial. The identified microbes were 448 *Enterococcus spp.* (67.7%), 295 *Klebsiella spp.* (44.6%), 269 *Escherichia coli* (40.6%), 235 *Viridans group streptococci* (35.5%), 189 *Candida spp.* (28.5%), 52 *Pseudomonas spp.* (7.9%), 64 anaerobes (9.7%; 53 *Clostridium spp.* and 11 *Bacteroides spp.*) and 32 *Staphylococcus aureus* (4.8%). About 7.9% and 3.6% of *Enterobacteriaceae* were resistant to extended-spectrum beta-lactamases and carbapenem, respectively.[27] Another study by Kruis, et al.[28] showed positive bile cultures in 90 (97%) of 93 patients who underwent ERCP. The culture results were monomicrobial in 34 (39%) patients and polymicrobial in 53 (61%) patients and revealed 35 *Klebsiella* (39%), 35 *E. coli* (39%), 38 *Enterococcus* (42%), 13 *Staphylococcus* (14%), 12 *Enterobacter* (13%), 1 *Bacteroides* (1%), 18 *Streptococcus* (20%), 1 *Acinetobacter* (1%), 8 *Citrobacter* (9%), 8 *Candida* (9%).

The bile culture and sensitivity provide a framework for informing endoscopists about the causative pathogens and guiding them in antibiotic selection. It is suggested to obtain bile fluid from all patients with AC to generate data on pathogens mapping and antibiotic susceptibility

to guide antimicrobial choice. After bile fluid aspiration, contrast injection into the bile duct should be limited to minimize the worsening of biliary infection.[2] A cholangiogram should be evaluated afterward to identify any CBD stones or CBD dilatation.

Endoscopic Biliary Sphincterotomy (EBS)

Endoscopic biliary sphincterotomy (EBS) is the next step in ERCP in which the sphincter of Oddi is incised using cutting wire in the sphincterotome to facilitate CBD stone extraction or stent insertion. Although it is a valuable technique, EBS is not risk-free.[2] Bleeding related to EBS is significant in acute cholangitis as shown in several publications. A landmark study by Freeman, et al.[29] showed post-EBS hemorrhage occurred in 17 (35%) of 339 patients with acute cholangitis (adjusted OR 2.59, 95% CI 1.38-4.86, p< 0.001). Sugiyama, et al.[30] compared endoscopic nasobiliary drainage (ENBD) with EBS (group one) versus ENBD without EBS (group two) in acute cholangitis. EBS-related bleeding occurred in group one (3 patients, 4%), but not in group two.

An SRMA conducted by Sawas, et al.[31] revealed no differences in drainage insertion success rate, drainage effectiveness, PEP, procedural duration, perforation, cholecystitis, and 30-day mortality rate between EBS and non-EBS groups in severe AC. However, bleeding episode was significantly found only in EBS compared to the non-EBS group (Relative risk 8.58; 95% CI 2.03-36.34). In mild-moderate AC, a prospective trial by Liang, et al.[32] showed no difference in post-EBS hemorrhage between mild versus moderate AC with CBD stones (1 vs. 0 cases). There is currently no data comparing EBS-related bleeding in AC patients with CBD stones with those in non-AC patients.

It is obvious that although EBS comes with the risk of bleeding, it can be safely performed in mild and moderate AC. However, in severe AC, the decision to perform EBS is influenced by various considerations. Biliary decompression without EBS may be attempted directly in critically ill, hemodynamically unstable, or impaired coagulation patients who cannot tolerate bleeding.

Endoscopic Papillary Balloon Dilatation (EPBD) and Endoscopic Papillary Large Balloon Dilatation (EPLBD)

Endoscopic papillary balloon dilatation (EPBD) is a technique using a balloon placed in the biliary orifice, which is inflated between 6-10 mm, and followed by bile duct stone extraction. It is performed usually in cases of coagulopathy or cirrhosis to lower the risk of hemorrhage or in conjunction with mini sphincterotomy to extract CBD stones.[6,33] Currently, there is no evidence of EPBD and EBS risk in AC patients.

Endoscopic papillary large balloon dilatation (EPLBD) resembles EPBD but with a larger balloon inflation diameter, spanning 12-20 mm. Its indication is to assist in the removal of large CBD stones (equal to or more than 15 mm).[33] The risk of EPLBD in AC has been shown by Lee, et al.[34] They compared concurrent EST and EPLBD (group A) versus delayed EPLBD after EBS (group B) in 68 non-severe acute cholangitis patients. Overall, post-ERCP adverse events were higher in group A versus group B (17.1% vs. 0%, p = 0.025). Post-ERCP pancreatitis, bleeding, and perforation rates in group A were 11.4%, 1%, and 1%, respectively, whereas none occurred in group B. It is postulated that in acute cholangitis, the inflamed bile duct is frail and prone to bleeding and perforation after endoscopic invasive manipulation, such as concurrent EBS and EPLBD.[34] However, the sample size was small, and it needs further RCT to confirm consistent findings.

The majority of severe AC patients presented with coagulopathy. EPLBD is suitable for this condition. International consensus guideline panel in 2016 suggested EPLBD without EBS over concurrent EBS and EPLBD in coagulopathy.[33]

Biliary Decompression Only or Complete Endoscopic Therapy?

Biliary decompression and CBD stone extraction via ERCP have the benefit of reducing hospitalization compared to biliary decompression alone. Nevertheless, the

detrimental effect of combination therapy is bleeding.[19]

Hemodynamically unstable patients may not endure intra or post-ERCP hemorrhage. A biliary decompression-only strategy should be considered for those patients. Similar considerations might be applied for those who are coagulopathic and/or consuming antiplatelet/anticoagulant and those who would need to have anticoagulant restarted soon after EBS, for example in patients with mechanical heart valves.[19]

Nasobiliary Tube versus Plastic Biliary Stent for Biliary Decompression

Biliary decompression through ERCP is one of the cornerstones in the management of AC. The choice between NBT and plastic biliary stent has been a subject of research initiated in early 2000. Lee, et al.[35] published the first randomized controlled study (RCT) comparing NGT versus plastic biliary stent in 2002. They studied 74 patients with AC; 40 underwent NBT placement and 34 underwent plastic biliary stent deployment. There were no differences in 12-hour clinical progress after ERCP, post-ERCP complications, early complications of NBT or plastic biliary stent, inotropic drug requirement, 30-day mortality, or stone clearance after a second ERCP. However, by using a 10 cm visual analog scale (VAS), patients in the NBT group were more uncomfortable compared to the stent group. (Mean [SD] VAS score of NBC group 3.9 [2.7] vs. stent group 1.8 [2.6]; p = 0.02). Another RCT by Sharma, et al.[36] in 2005 showed no significant differences between the NBT group (75 patients) versus the plastic biliary stent group (75 patients) in AC in terms of clinical improvement and safety.

Studies have shown that both NBT and plastic biliary stents are efficacious and safe in AC patients. Choosing between these two accessories depends on clinical conditions and availability. In delirium or elderly patients, NBT is prone to dislodgement, whereas a plastic biliary stent is not. However, NBT has the advantage of easy monitoring for biliary fluid/pus.

POST-ENDOSCOPIC CARE

Post-endoscopic care focuses on procedure-related adverse events (AE) and response to treatment. Prompt and early recognition of adverse events' symptoms and signs is important. The most prevalent AE are PEP, bleeding, and perforation. Symptoms such as abdominal pain, nausea, vomiting, hematemesis, melena, abdominal distension, and fever should be sought. Physical signs such as blood pressure, heart rate, temperature, respiratory rate, and peritoneal irritation should be regularly observed. Hemoglobin, amylase, and lipase must be checked whenever indicated. Bleeding, PEP, and perforation must be treated accordingly.[2,22]

Response to treatment must be observed. Clinical (abdominal pain and fever subside) and laboratory improvement (leukocytosis, C-reactive protein, hyperbilirubinemia decrease) can usually be appreciated within 24 hours of ERCP. Persistent or worsening of the clinical

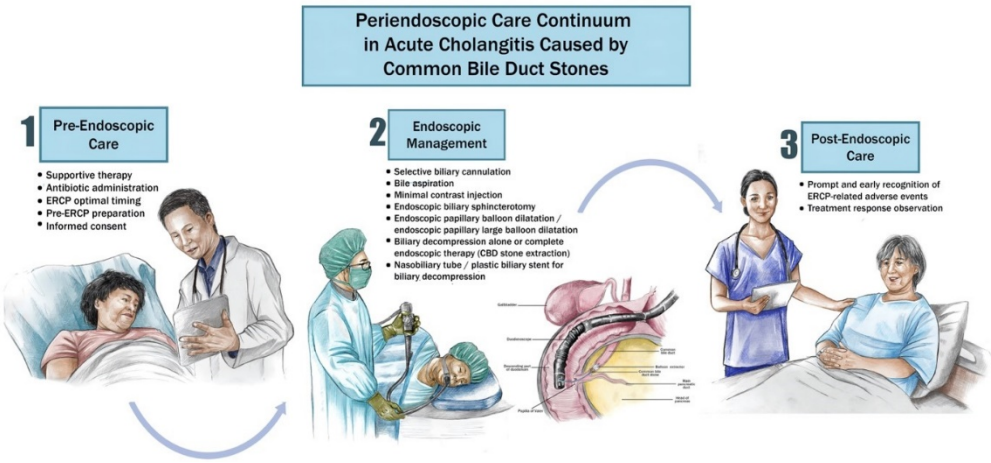

Figure 2. Periendoscopic Care Continuum in Acute Cholangitis Caused by Common Bile Duct Stone.

condition may be indicators of incomplete biliary drainage or other infections such as acute cholecystitis, liver abscess, or pneumonia. Abdominal ultrasound (US) is the chosen modality to assess the existence of unresolved biliary dilatation after initial ERCP that may need subsequent ERCP or other biliary drainage procedures. Abdominal US is also useful in determining the possibility of a liver abscess or acute cholecystitis. If pneumonia is suspected as another source of infection, a chest X-ray should be ordered. Antibiotics must be administered appropriately.[2]

CONCLUSION

Acute cholangitis should be correctly diagnosed using TG18 criteria. The most common etiology of AC is CBD stones. Periendoscopic care continuum is imperative in such cases. It consists of pre-endoscopic care, endoscopic management, and post-endoscopic care. In pre-endoscopic care, supportive therapy and antibiotics should be given as early as possible. ERCP must be accomplished preferably within 48 hours of admission. Performing ERCP requires a complete medical history, physical examination, laboratory, and imaging before the procedure. Informed consent should be conducted in a good manner. Selective biliary cannulation should be followed by bile aspiration for culture and resistance data, as well as minimal contrast injection to prevent the worsening conditions of AC. Endoscopic biliary sphincterotomy and EPBD/EPLBD can be safely done in patients with mild-moderate AC with CBD stones with special considerations for severe cases. In patients with severe AC who may not endure the procedure, biliary decompression alone may be the best option, followed by complete endoscopic therapy in a separate session. NBT and biliary stents have equivalent efficacy and safety for biliary decompression. Observation of potential adverse events connected to ERCP, as well as patient responses to treatment are the primary focuses of post-endoscopic management.

CONFLICT OF INTEREST

There are no potential conflicts of interest.

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