DICTAMEN PERICIAL

RADICADO INTERNO DE C&C:	2024-09-13-0188
JUZGADO:	JUZGADO NOVENO ADMINISTRATIVO ORAL DEL CIRCUITO DE CALI
RADICADO:	2017-00306-00
DEMANDANTES:	YOVANNY EDUARDO AGREDA SANCHEZ; NOHRA ASTRID CORTES; Y OTROS
DEMANDADOS:	NACIÓN – MINISTERIO DE DEFENSA – EJERCITO NACIONAL - HOSPITAL REGIONAL MILITAR DE OCCIDENTE Litisconsortes: INSTITUTO DE RELIGIOSAS DE SAN JOSÉ DE GERONA - NECESARIOS CLÍNICA NUESTRA SEÑORA DE LOS REMEDIOS FUNDACIÓN SALUVITÉ Llamado en garantía: ALLIANZ SEGUROS S.A.
NOMBRE DEL PACIENTE:	YOVANNY EDUARDO AGREDA SANCHEZ

C&C Corporación

NIT 900.973.844-9

ESPECIALIDAD CIRUGIA GENERAL

C&C Corporación

Santiago de Cali, 05 de noviembre de 2024

ASUNTO: **ENTREGA DE DICTAMEN MÉDICO PERICIAL**

RADICADO INTERNO DE C&C:	2024-09-13-0188
JUZGADO:	JUZGADO NOVENO ADMINISTRATIVO ORAL DEL CIRCUITO DE CALI
RADICADO:	2017-00306-00
DEMANDANTES:	YOVANNY EDUARDO AGREDA SANCHEZ; NOHRA ASTRID CORTES; JUAN PABLO GYOVANNY AGREDA CORTES; ASTRID CAROLINA AGREDA CORTES
DEMANDADOS:	NACIÓN – MINISTERIO DE DEFENSA – EJERCITO NACIONAL - HOSPITAL REGIONAL MILITAR DE OCCIDENTE Litisconsortes: INSTITUTO DE RELIGIOSAS DE SAN JOSÉ DE GERONA - NECESARIOS CLÍNICA NUESTRA SEÑORA DE LOS REMEDIOS FUNDACIÓN SALUVITÉ Llamado en garantía: ALLIANZ SEGUROS S.A.
NOMBRE DEL PACIENTE:	YOVANNY EDUARDO AGREDA SANCHEZ
CEDULA DE CIUDADANIA:	12.982.362
EDAD:	51 AÑOS (Según historia clínica)
ESPECIALIDAD:	CIRUGIA GENERAL

Respetado Señor Juez

De manera atenta hacemos entrega del Dictamen Médico Pericial en el proceso en referencia. Dicho Dictamen es rendido por el Doctor CARLOS FERNANDO MUNAR, Médico Especialista en CIRUGIA GENERAL, FELLOW DE TRAUMA Y EMERGENCIAS, a través de C&C CORPORACIÓN

Para lo cual me permito allegar la siguiente documentación:

1. Copia del dictamen pericial (32 folios)
2. Oficio con la relación adjunta de los peritajes rendidos por el Doctor CARLOS FERNANDO MUNAR (01 folios)
3. Hoja de vida en 06 folios

Atentamente,

EDACSIL NARVAEZ
ASISTENTE ADMINISTRATIVO

C&C Corporación

Santiago de Cali, 05 de noviembre de 2024

ASUNTO: **ENTREGA DE DICTAMEN MÉDICO PERICIAL**

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ESPECIALIDAD:	CIRUGIA GENERAL

Respetado Señor Juez:

De manera atenta rindo informe de los peritajes realizados a través de **C&C CORPORACIÓN.**

PERFIL PROFESIONAL DEL PERITO

- Médico Cirujano de la Universidad Nacional de Colombia 1998
- Especialista en Cirugía General de la Universidad del Valle 2004

De acuerdo con el Código General del Proceso en su Artículo 226:

- Expreso que cuento con los conocimientos necesarios, soy imparcial y no tengo impedimento alguno en la peritación que elaboro.
- Anexo Hoja de Vida y los certificados de formación académica que me acreditan como idóneo para la presente evaluación pericial.
- La lista de proceso en los que he participado como perito se anexa a este oficio
- Declaro que los métodos, experimentos e investigaciones efectuados son los mismos que se emplean para la rendición de dictámenes periciales a través de C&C CORPORACIÓN.

- Declaro que los métodos, experimentos e investigaciones efectuados son los mismos respecto de aquellos que utilizo en el ejercicio regular de mi profesión, indicando que una cosa es la prestación de los servicios de salud y otra, muy diferente es la elaboración de dictámenes periciales.
- Manifiesto que el dictamen fue elaborado con la Historia Clínica suministrada por la parte interesada correspondiente al Paciente YOVANNY EDUARDO AGREDA SANCHEZ

Atentamente,

CARLOS FERNANDO MUNAR HOLGUIN
CIRUJANO GENERAL, FELLOW DE TRAUMA Y EMERGENCIAS
TP /1906-99

C&C Corporación

Santiago de Cali, 05 de noviembre de 2024

ASUNTO: **DICTAMEN MÉDICO PERICIAL EN LA ESPECIALIDAD CIRUGIA GENERAL**

RADICADO INTERNO DE C&C:	2024-09-13-0188
JUZGADO:	JUZGADO NOVENO ADMINISTRATIVO ORAL DEL CIRCUITO DE CALI
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IDENTIFICACIÓN DE QUIEN RINDE EL PERITAJE
(de conformidad al numeral 1 del artículo 226 CGP)

CARLOS FERNANDO MUNAR HOLGUIN, identificado con cedula de ciudadanía #79.789.340, Tarjeta profesional de médico 1906/99.

Soy médico general egresado DE LA UNIVERSIDAD NACIONAL DE COLOMBIA, en el año 1998, especialista en CIRUGIA GENERAL, egresado DE LA UNIVERSIDAD DEL VALLE en el año 2004, actualmente tengo 19 años de experiencia profesional como CIRUJANO GENERAL. Además, soy FELLOW DE LA SUBESPECIALIDAD DE CIRUGIA DE TRAUMA Y EMERGENCIAS EN LA UNIVERSIDAD DEL VALLE

De conformidad con lo dispuesto por el Código General del Proceso en su artículo 226, me permito hacer las siguientes declaraciones:

1. Actúo con completa autonomía e independencia profesional, de manera tal que mi opinión es independiente y corresponde a mi real convicción profesional sobre la materia de la experticia.

2. El dictamen fue elaborado directamente por este servidor.

3. Los exámenes, métodos, y parámetros de análisis utilizados para evaluar el caso y soportar mi opinión profesional para el dictamen, corresponden a los que utilizo de manera sistemática y usual para el ejercicio de mi profesión.

4. He sido designado como perito para la Corporación C&C.

5. No estoy incurso en ninguna de las causales del artículo 50 del CGP.

6. Acompaño a la presente, copia de los documentos que acreditan mi idoneidad sobre la materia objeto del dictamen.

FUNDAMENTO: Efectúo el presente concepto médico especializado con base en la copia de la historia clínica de la paciente YOVANNY EDUARDO AGREDA SANCHEZ

CUESTIONARIO PRESENTADO

1. **En la historia clínica del señor JOVANNY EDUARDO AGREDA SANCHEZ se puede evidenciar que hubo demora en la intervención que requería el paciente con urgencia y así mismo se puede corroborar que no se le prestó el servicio de unidad de cuidados intensivos a pesar de necesitarlo, lo cual configura pérdida de oportunidad**

   Si, hay una demora en la realización del procedimiento quirúrgico; pues el diagnóstico de colecistitis se realiza 1 mes antes (21.07.2015) de dicho procedimiento (27.08.2015) y los síntomas tienen evolución de meses previos al evento con múltiples consultas al servicio de urgencias (03-05-2015 / 07-05-2015 / 17-05-2015 / 12-07-2015 / 19-07-2015 / 21-07-2015) por dolor abdominal (epigástrico). Además, con una esofagogastroduodenoscopia sin hallazgos relevantes. La recomendación es llevar a extracción de la vesícula lo más pronto posible (primeras 72 horas), pues la colecistitis y el engrosamiento de la pared y el edema y cicatrización perivesicular son factores de riesgo para presentar esta complicación

2. **La historia clínica aportada al proceso es suficiente para tener por demostrada un incumplimiento de la *lex Artis*, o una relación de causalidad entre un evento adverso ocurrido durante el post operatorio de la colecistectomía y las complicaciones del paciente.**

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No. No hay nada contrario a la lex Artis en cuanto a los procedimientos quirúrgicos se refiere.

3. **Es normal que el paciente después de la cirugía Colecistectomía Por Laparoscopia tenga:**
   a. **Fuerte dolor abdominal**
   b. **Salida de material bilioso por dren hemovac,**
   c. **Coloración ictérica,**
   d. **Fiebre con escalofrío.**

   No, no es normal la presencia de estos signos y síntomas. La presencia de bilis por el dren, dolor abdominal e ictericia hacen sospechar de una lesión de vía biliar y debe ser remitido a un nivel donde se cuente con cirujanos experimentados en resolver estas complicaciones como en efecto se hizo en este caso desde el pop inmediato una vez se detectó la complicación.

4. **Puede determinar si el paciente JOVANNY EDUARDO AGREDA SANCHEZ tubo mala evolución posquirúrgica después de la Colecistectomía laparoscópica. Explique**

   Si, tuvo evolución clínica no satisfactoria. presenta dolor abdominal y fuga biliar secundaria a lesión intraoperatoria del conducto hepático evidenciada por el drenaje de bilis a través del dren de guardia con requerimiento de una derivación biliodigestiva para reconstruir la continuidad del tracto biliar por lo cual fue remitido tempranamente a un nivel donde fue atendido por cirujanos hepatobiliares y de trasplantes

5. **El reconocimiento temprano de las lesiones biliares es de suma importancia y limitar el retraso del diagnóstico es crucial para un resultado postoperatorio óptimo**

   Si, cuando se reconoce intraoperatoriamente y se reconstruye en el mismo acto quirúrgico, lo cual, sucede en pocas ocasiones. Cuando esta cirugía se realiza en el POP temprano, como en este caso, cuando la lesión se reconoció al día siguiente y es llevado a reconstrucción al 5 día donde se documenta y describe el tipo de lesión; de lo contrario se recomienda realizar tardíamente (6 semanas después del último procedimiento)

6. **La Lesión iatrogénica de la vía biliar que sufrió el señor JOVANNY EDUARDO AGREDA SANCHEZ pudo ser previsible. Explique el por que**

   Es probable, habiéndose llevado al procedimiento lo antes posible. La recomendación es realizar la COLELAP en los 3 a 5 días después, una vez hecho el diagnostico. El indicador a cumplir es 3 días, según las guías de práctica clínica. En este caso el diagnostico tomo varios meses con 4 reconsultas y el procedimiento se programó de manera ambulatoria electiva, cuando debió ser llevado como urgencia.

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7. **Ante la complicación que presento el señor JOVANNY EDUARDO AGREDA SANCHEZ, ¿debía valorarse la posibilidad de la conversión de la cirugía a un procedimiento abierto, de realizar una colangiografía intraoperatoria, o de realizar una colecistectomía subtotal o Ante esta dificultad, cuál sería la conducta médica?**

   En este caso no, pues no hay tal sospecha en el intraoperatorio, según la descripción quirúrgica. La vía abierta no es superior a la laparoscópica. Se inicia por laparoscopia, solo en algunos casos es necesario convertir la cirugía a laparotomía.

8. **¿cómo se evita el riesgo de la lesión de la vía biliar?**

   Siguiendo las referencias anatómicas (surco de roviere, ganglio cístico, triangulo de calot) y las recomendaciones como la visión crítica de seguridad de strasberg. Según la nota operatoria no se describe duda en la anatomía del árbol biliar.

9. **Puede usted confirmar la magnitud de la lesión ocasionada durante el procedimiento quirúrgico COLECISTECTOMÍA POR LAPAROSCOPIA identificando con precisión los daños ocasionados: Teniendo en cuenta que el día 1 de septiembre se lleva a cirugía RECONSTRUCCIÓN DE LAS VÍAS BILIARES describen como hallazgos quirúrgicos:**

   > ***"PUERTO DE LAPAROSCOPIA A NIVEL UMBILICAL , SUBSXIFOIDEO Y TERCER PUERTO A TRAVEZ DEL CUAL SE DEJA DREN ABDOMINAL SOBRE REBORDE COSTAL BILIOHEMOPERITONEO DE APROX 400 CC HÍGADO DE BORDES REDONDEADOS GRAN REACCIÓN INFLAMATORIA COÁGULOS EN MODERADA CANTIDAD SOBRE LECHO VESICULAR GRAN ZONA DONDE SE EVIDENCIA QUEMADURA POR ELECTROBISTURÍ, CON EXTENSA PERDIDA DEL TEJIDO DEL CONDUCTO BILIAR , EL CUAL SE ENCUENTRA CON UNA SECCIÓN COMPLETA LA PORCIÓN PROXIMAL CLIPADA, PARCIALMENTE, DEVASCULARIZADA Y ESQUELETONIZADA HASTA LA CONFLUENCIA ARTERIAL HEPÁTICA DERECHA CLIPADA Y SECCIONADA."***

   Es una lesión extensa de la vía biliar principal en el conducto hepático común con daño tisular secundario a electrocoagulación (uso de la energía para hemostasia o detener el sangrado). Esta lesión requiere de reconstrucción biliar por derivación en Y de ROUX (hepaticoyeyunoanastomosis) y su evolución postquirúrgica es variable e individual, pero lo usual, cuando tal evolución es satisfactoria, son 15 días a 1 mes para retomar actividad diaria normal y tolerancia a la vía oral.

10. **¿El manejo de la complicación durante la reconsulta después del procedimiento quirúrgico: fue el adecuado? ¿teniendo en cuenta que se tenía evidencia de la salida de bilis a través del drenaje e incisiones quirúrgicas, de manera temprana se debió solicitar una ayuda diagnostica imagenológica como la tomografía de abdomen con el fin de**

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descartar la presencia de colecciones o abscesos?, ¿si además de lo anterior el paciente cursaba con respuesta inflamatoria se debió llevar a cirugía de manera temprana para el control de su proceso séptico?

No siempre es necesario el uso de imágenes y depende de la evolución del paciente, de signos y síntomas que hagan sospechar una colección y el tiempo del postquirúrgico; pues las colecciones no se organizan (localizan) si no hasta 5 o más días postquirúrgicos. La respuesta inflamatoria no necesariamente configura un cuadro infeccioso o sepsis, puede ser secundaria a mediadores inflamatorios sin presencia de infección, y la peritonitis por bilis al inicio y por varios días es de naturaleza química no infecciosa y la solución es el drenaje como se logra con el uso del mismo desde el intraoperatorio como en este caso. Se llevo de manera temprana, como está indicado, en los primeros 5 días. No se llevan de manera inmediata, pues se deben optimizar las condiciones para el procedimiento, corregir alteraciones hidroelectrolíticas, garantizar el estado de perfusión de los órganos y se recomienda que lo haga personal entrenado y experto en el manejo de esta complicación, así como se hizo.

11. **¿Para el diagnóstico de la lesión de las vías biliares lo más importante es la sospecha?, y ¿se debe sospechar una lesión de las vías biliares cuando se presenta un caso, como el que estamos analizando?**

    El alto índice de sospecha es necesario, pero por lo descrito en la cirugía no había tal sospecha. Se hace el diagnóstico de fuga biliar o lesión biliar intraoperatoria por la fuga de bilis en el primer día postoperatorio; pues es evidente que hay una fistula (fuga) biliar ante este hallazgo. Por tal motivo fue remitido a nivel superior para valoración y manejo por cirugía hepatobiliar.

12. **¿Fue negligente el equipo quirúrgico al no utilizar ayudas diagnósticas en el postoperatorio inmediato, para identificar tempranamente el daño de la vía biliar, a pesar de las complicaciones del procedimiento?**

    No, una vez se detectó la fuga biliar se remitió a nivel superior para realizar el manejo respectivo.

13. **La lesión de vía biliar (LVB) en el desarrollo de una colecistectomía es una de las complicaciones más graves y temidas en cirugía. Teniendo en cuenta que es un procedimiento tan frecuente, todo cirujano debe estar preparado para enfrentarla. Lo más importante es extremar de manera rutinaria las medidas de prevención, pero una vez que la lesión se ha producido, el futuro del paciente depende, directamente, del buen criterio del cirujano tanto para realizar un diagnóstico temprano como del enfrentamiento terapéutico que elija, en el caso del señor JOVANNY EDUARDO AGREDA SANCHEZ. ¿se puede decir que tuvo un diagnóstico tardío y en consecuencia el manejo terapéutico no fue oportuno?**

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No, el diagnóstico de la complicación no fue tardío; tanto este diagnóstico como el manejo fueron oportunos. El diagnóstico inicial, por el contrario, si fue equivoco, pues el paciente presento síntomas de 5 meses de evolución compatibles con cólico biliar que fue interpretado como gastritis y a pesar de la pobre o nula mejoría se persistió en esta orientación terapéutica, inclusive con una endoscopía que no explicaba los síntomas. En ese momento debía pensarse en otra etiología, pero aun dejando de lado la demora en el diagnostico que se confirma en la ecografía con hallazgos de colecistitis aguda del 21.07.2015, la oportunidad para llevar al paciente al procedimiento y resolver su cuadro clínico mediante la colecistectomía laparoscópica se da tardíamente (1 mes después) en contra de las recomendaciones dadas en la literatura incrementando así el riesgo de complicaciones.

ANALISIS TECNICO CIENTIFICO

a) ESTADO DE SALUD ANTERIOR: De acuerdo con la historia clínica, el estado de salud previo a la primera consulta en mayo de 2015 era bueno.

b) RESUMEN DEL EVENTO O ATENCION EN CUESTION: Se trata de un paciente de mediana edad quien consulta en un lapso de 5 meses al menos en 5 oportunidades. En un principio por un cuadro de dolor referido como torácico donde se sospechó y descartó etología coronaria. Reconsulta por persistencia de los síntomas donde a pesar del manejo no presenta mejoría hasta que finalmente en fecha de 21-07-2015 se realiza diagnóstico de colecistitis aguda confirmado en ecografía y donde **se decide dar manejo ambulatorio** para valoración por cirugía y programar colelap (colecistectomía por laparoscopia) la cual se realiza el 27-08-2015 con hallazgos de vesícula de paredes engrosadas con edema (inflamación) fibrosis (cicatrización) y cálculos. Se presento sangrado intraoperatorio, por lo cual, se deja dren testigo, en lecho quirúrgico con salida de bilis y dolor en área quirúrgica al día siguiente, razón por la cual se remite a nivel superior donde es valorado y llevado a cirugía de derivación biliodigestiva por el equipo de cirugía hepatobiliar y de trasplantes. Con evolución tórpida a largo plazo con eventos de colangitis a repetición por estenosis (estrechez) de la anastomosis en los siguientes 3 años, razón por la cual es llevado a nueva reconstrucción de vía biliar.

c) RELACION CAUSA EFECTO O NEXO DE CAUSALIDAD: El cuadro clínico por el cual consulta el paciente que consiste en inflamación aguda de la vesícula biliar secundaria a los cálculos como se confirma en ecografía del 21-07-2024 debía ser llevada a extracción quirúrgica de la vesícula a la mayor brevedad posible. La recomendación son 3 a 5 días, en este caso se tardó 1 mes en realizar el procedimiento; así pues, el proceso de inflamación de la vesícula que provoca los síntomas por lo cual es necesario llevar al paciente a cirugía, causa con el tiempo la distorsión de la anatomía y ese tiempo de evolución de la enfermedad determina el resultado de la complicación quirúrgica que presento el paciente y la necesidad de nuevos procedimientos para resolver dicha complicación.

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d) CONCLUSIONES: Paciente quien presentaba sintomatología sugestiva de colelitiasis sintomática y colecistitis, sin embargo, en su atención inicial se manejó con un diagnostico presuntivo de dispepsia y enfermedad acido péptica que no respondió al tratamiento terapéutico, lo cual lo llevo a reconsultar en varias oportunidades al servicio de urgencias, para el mes de julio de 2015, su condición clínica empeoraba por lo tanto las consultas fueron más frecuentes. Es así que para el mes de mayo en la consulta de urgencias se le ordena la realización de una endoscopia digestiva de manera ambulatoria, la cual tuvo una demora dos meses para su realización. Con este análisis en primera instancia pudo observarse que el diagnostico presuntivo inicial fue conservado pese a la pobre respuesta del proceso de evolución y recuperación del paciente, lo que significa que el diagnostico presuntivo inicial de dispepsia y enfermedad acido péptica, en palabras coloquiales "fue equivocado".

En julio se realiza la endoscopia digestiva ordenada desde mayo, cuyo resultado descarta una situación a nivel gástrico. En vista del resultado de la endoscopia, se orienta el diagnostico hacia una enfermedad de la vesícula confirmada por ecografía del 21-07-2024, y que en lugar de llevarse a cirugía oportunamente en unos 3 días como es la recomendación, SE DECIDIÓ DARLE DE ALTA y manejarlo de manera electiva ambulatoria, solo hasta 1 mes después le realizan la cirugía de vesícula, y esa razón es la que determina los hallazgos y la alteración de la anatomía de la vesícula por la cicatrización y la inflamación que lleva a que se tenga la complicación que presento el paciente y la necesidad de nuevos procedimientos para resolver dicha complicación. En términos generales se puede deducir que este paciente perdió tres oportunidades:

- ERROR DE DIAGNÓSTICO: este paciente fue tratado con un diagnostico presuntivo de dispepsia y enfermedad acido péptica cuando en realidad presentaba sintomatología sugestiva de colelitiasis sintomática y colecistitis.
- FALTA DE OPORTUNIDAD DIAGNOSTICA: en este caso pese a las repetidas consultas por urgencias al paciente finalmente se le realizo la endoscopia en julio 2015, dos meses después de su ordenamiento, la cual permitía descartar la enfermedad acido péptica e iniciar con la sospecha de enfermedad de la vesícula, lo que a su vez permitiría definir una conducta quirúrgica más inmediata antes de llegar a la alteración de la anatomía de la vesícula por la cicatrización y la inflamación.
- FALTA DE OPORTUNIDAD QUIRÚRGICA: este paciente fue llevado a cirugía colelap (colecistectomía por laparoscopia) un mes después del diagnóstico de colecistitis aguda, cuando la recomendación médica es intervenir en un periodo máximo de 3 a 5 días, en este caso, se demoró un mes, con hallazgos de vesícula de paredes engrosadas con edema (inflamación) fibrosis (cicatrización) y cálculos.

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3. Arasi Thangavelu, MD, FAAEM, Steven Rosenbaum, MD, FAAEM, and Devi Thangavelu, MD. TIMING OF CHOLECYSTECTOMY IN ACUTE CHOLECYSTITIS. The Journal of Emergency Medicine, Vol. 54, No. 6, pp. 892–897, 2018_ 2018 Elsevier Inc. All rights reserved. 0736-4679/$ - see front matter.

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ANEXOS

Stavros Gourgiotis, Nikitas Dimopoulos, Stylianos Germanos, Vasilis Vougas, Panagiotis Alfaras, Evangelos Hadjiyannakis. Laparoscopic Cholecystectomy: a Safe Approach for Management of Acute Cholecystitis. JSLS. 2007 Apr-Jun;11(2):219–224. PMCID: PMC3015721 PMID: 17761084	06 folios
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7	SEBASTIANA ESPERANZA QUIÑONES, MARIA DEL CARMEN CASTILLO QUIÑONES, Y OTROS	ABOG. JUAN DAVID HURTADO CUERO	CAJA DE COMPENSACION FAMILIAR DEL VALLE DEL CAUCA COMFENALCO VALLE DELAGENTE - SOCIEDAD N.S.D.R. S.A.S. (CLÍNICA NUESTRA), GRUPO OPERADOR CLÍNICO HOSPITALARIO POR OUTSOURCING S.A.S. "G OCHO S.A.S. – RICARDO MONTENEGRO OROZCO	JUZGADO SEGUNDO CIVIL DEL CIRCUITO DE CALI	2020-00208-00
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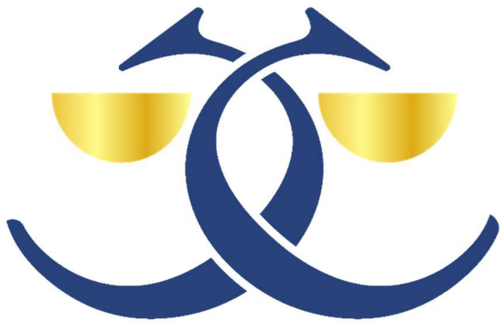

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SCIENTIFIC PAPER JSLS

Laparoscopic Cholecystectomy: a Safe Approach for Management of Acute Cholecystitis

Stavros Gourgiotis, MD, PhD, Nikitas Dimopoulos, MD, Stylianos Germanos, MD, Vasilis Vougas, MD, Panagiotis Alfaras, MD, PhD, Evangelos Hadjiyannakis, MD, PhD

ABSTRACT

Background and Objectives: Laparoscopic cholecystectomy (LC) is increasingly being used as an appropriate early treatment in patients with cholecystitis. This study evaluated the safety, effectiveness, and complications of LC in all cases of acute cholecystitis.

Methods: A retrospective study involved the patients who underwent LC for acute cholecystitis within 72 hours of admission. The preoperative diagnosis was based on clinical, laboratory, and echographic examinations, while the final diagnosis was confirmed by histopathological examination of the excised gallbladder.

Results: We identified 184 patients with acute cholecystitis. Intraoperative cholangiography (IOC) was not performed. Preoperative endoscopic retrograde cholangiopancreatography (ERCP) was performed in 62 patients (33.7%), and postoperative ERCP in 13 patients (7.1%). Conversion to open cholecystectomy was necessary in 19 patients (10.3%); 16 patients for severe inflammation and adhesions and 3 patients because of uncontrolled bleeding. The mean operative time was 68 minutes. No deaths occurred. The overall complication rate was 6% with 3 postoperative bile leakages and 2 nonbilious subhepatic collections. The mean postoperative hospital stay was 2.8 days.

Conclusions: LC is a safe, effective procedure for the early management of patients with acute cholecystitis. LC can be safely performed without routine IOC when ERCP is performed preoperatively on the basis of specific indications. Meticulous dissection and good exposure of Calot's triangle may prevent bile duct injuries.

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Key Words: Laparoscopic cholecystectomy, Acute cholecystitis, Open cholecystectomy, Intraoperative cholangiography.

INTRODUCTION

Acute cholecystitis (AC) often requires emergency admission to the hospital. The traditional treatment of AC was conservative followed by cholecystectomy, usually 6 weeks to 8 weeks after discharge, although early cholecystectomy in patients with AC was shown to be safe and effective many years ago.[1]

Laparoscopic cholecystectomy (LC) for an acutely inflamed gallbladder is technically more demanding than surgery for acute biliary pain without inflammation (biliary colic) because of severe inflammatory adhesions and distortion of the biliary anatomy; and the time interval from admission to surgery may affect conversion rates.[2–4] Because of perceived difficulties in dissection and the premise of unacceptably high complication rates, the presence of AC was once considered an absolute contraindication to the performance of LC. However, as experience with the procedure has increased and with improvements in available equipment, LC is increasingly being used as the initial surgical approach in the majority of patients with AC.[5,6] Randomized trials have also shown that early LC (within 72 hours of admission) for the treatment of AC is safe, feasible, and associated with a shorter hospital stay.[7–9]

In this study, we have retrospectively reviewed the early management of all patients admitted to the First Surgical Department at Evangelismos General Hospital of Athens with acute gallbladder disease over 7 years to evaluate whether LC within 72 hours of patients' admission predisposes to a high or low risk of complications, mortality, and conversion to open cholecystectomy and whether it reduces the postoperative length of hospital stay.

METHODS

Between January 1999 and December 2005, 184 patients were identified who were admitted to the hospital on an

emergency basis for acute gallbladder disease and underwent urgent LC within 72 hours. Of these patients, 107 (58.2%) were women and 77 (41.8%) were men. The mean age was 56.2 years (range, 23 to 71). The mean duration of symptoms was 2.3 days (range, 1.0 to 3.0).

The diagnosis of AC was based on clinical features (right upper quadrant tenderness with or without fever ≥37.5°C) and ultrasonographic features suggestive of inflammation (gallbladder wall thickness >5 mm, edematous wall, emphysematous wall, gallbladder distension, pericholecystic fluid, positive ultrasonographic Murphy's sign) and/or leucocytosis >10,000/μL. Bacteriological specimens were not collected routinely at the time of surgery. The diagnosis of AC was finally confirmed by histopathological examination of the excised gallbladder.

Data analyzed included demographic information, clinical presentation, and results of laboratory and imaging studies, initial surgical approach, operative data, and outcome (morbidity, mortality, and postoperative hospital stay). Patients with gallstone pancreatitis and gallstone ileus were excluded from the study.

Treatment

Three surgeons (VV, PA, and EH) with special interest in LC performed the procedures. The policy of our department required that all patients initially undergo LC; however, some of them were not suitable for LC because of anatomic or pathologic factors and were converted to open cholecystectomy.

Preoperative treatment included intravenous fluids and appropriate antibiotics (cephalosporin with metronidazole or clindamycin). These agents were continued for at least 24 hours in the postoperative period.

Preoperative assessment included abdominal ultrasound (US) and preoperative endoscopic retrograde cholangiopancreatography (ERCP). All patients underwent abdominal US, while preoperative ERCP was performed on the basis of the following indications: common bile duct (CBD) dilated more than 7mm, current or past jaundice, or abnormal liver function with high levels of bilirubin, liver enzymes, or alkaline phosphatase. Preoperative sphincterotomy and stone extraction were performed in all the patients with CBD stones.

In patients with perioperative hyperbilirubinemia without biochemical evidence of common bile duct (CBD) stones or ductal dilatation, the LC alone was performed with postoperative ERCP being reserved for patients whose bilirubin levels failed to normalize following surgery; while the patients with CBD stones at cholecystectomy or missed CBD stones underwent postoperative ERCP. Intraoperative cholangiography (IOC) was not performed in our series.

LC was performed by using the standard 4-trocar technique with the patient under general anesthesia with endotracheal intubation. Placement of the umbilical trocar was made under direct vision using the Hasson technique.[10] Patients underwent LC with several modifications to the standard surgical technique used as appropriate: decompression of a tense, distended gallbladder with an epidural needle to enable secure grasping of the fundus, placing of a suture to hitch the body of the gallbladder to the anterior abdominal wall to facilitate dissection in Calot's triangle, and blunt dissection to identify the cystic duct and removal of a perforated gallbladder in an endobag. The drain was not systematically left in the patient.

Table 1 shows the histological findings in patients who had early surgery, and **Table 2** lists the clinical, ultrasonographic, and laboratory findings.

RESULTS

Of the 184 patients identified, 150 (81.5%) had stones on preoperative US, and 34 (18.4%) had acute acalculous cholecystitis. The comorbid medical illnesses in 28 (15.2%) of the patients included hypertension (n=13), diabetes mellitus (n=8), ischemic heart disease (n=5), and chronic obstructive pulmonary disease (n=2).

Preoperative ERCP was performed in 62 patients (33.7%); CBD stones were found in 43 of these (69.3%). ERCP was also performed postoperatively in 13 patients (7%); in 4 patients, bilirubin levels failed to normalize following surgery, and 9 patients had CBD stones at cholecystectomy or missed CBD stones.

No mortality or major CBD injury occurred. The overall complication rate was 6% (n=11). Three patients had cystic duct stump leakage with biloma; these patients were man-

Table 1.
Histological Findings in 184 Patients With Acute Cholecystitis Who Underwent Early Laparoscopic Cholecystectomy

Finding	n (%)
Acute inflammation	138 (75)
Empyema	29 (15.7)
Gangrene	13 (7.1)
Gangrene with empyema	4 (2.2)

Table 2.
Clinical, Ultrasonographic, and Laboratory Findings in 184 Patients With Acute Cholecystitis Who Underwent Early Laparoscopic Cholecystectomy

Finding	n (%)
Clinical presentation	
Right upper quadrant pain	172 (93.5)
Fever	96 (52.2)
Jaundice	16 (8.7)
Ultrasonographic findings	
Gallbladder wall thickened >5 mm	129 (70.1)
Edematous wall	38 (20.6)
Pericholecystic fluid	17 (9.2)
Positive ultrasonographic Murphy's sign	27 (14.7)
Stones within gallbladder	150 (81.5)
Distended gallbladder	2 (1.1)
Emphysematous wall	6 (3.3)
Laboratory findings	
Leucocytosis	167 (90.8)
Elevated alkaline phosphatase	28 (15.2)
Elevated bilirubin	66 (35.9)
Elevated alanine aminotransferase	32 (17.4)
Elevated aspartate aminotransferase	21 (11.4)

aged successfully by endoscopic stent placement with percutaneous drainage of the biloma. Two patients had postoperative nonbilious subhepatic collection, which was aspirated under ultrasonographic guidance. The complications following LC are shown in **Table 3**.

Nineteen patients were converted to open cholecystectomy (10.3%). Sixteen patients who required conversion to open cholecystectomy had severe inflammation processes and severe adhesions that obscured the plane of dissection and anatomy around Calot's triangle and made further dissection hazardous; conversion was also necessary in 3 patients because of uncontrolled bleeding.

The median duration of surgery was 68 minutes (range, 51 to 98). The median postoperative hospital stay was 2.8 days (range, 2 to 7).

DISCUSSION

This study examined the urgent laparoscopic management of patients admitted for AC in a district general hospital. The study comprised a large series of patients with various ranges of AC managed laparoscopically, with a low conversion rate, acceptable operating time and complication rate and a short hospital stay. It was also demonstrated that patients with specific clinical and laboratory findings could be managed with pre- or postoperative ERCP with or without sphincterotomy without the performance of IOC.

AC is the chemical or bacterial inflammation of the gallbladder. Its severity ranges from mild edema and inflammation, constituting simple AC, to more severe disease with empyema and even hemorrhagic or gangrenous changes involving the wall of the gallbladder. Despite initial reservations regarding feasibility and safety of the procedure in AC, LC is increasingly being successfully used as the initial surgical approach in the majority of these patients.

The clinical presentation of AC comprises right upper quadrant pain, fever or jaundice, or both. Laboratory findings include liver function test abnormalities and leucocytosis. In this study, right upper quadrant pain and fever were observed in 93.5% and 52.2% of patients, respectively; jaundice was present in 16 (8.7%) patients. Leucocytosis and elevated bilirubin were the most common laboratory findings in 167 and 66 patients, respectively.

Abdominal US is the initial imaging modality of choice. The presence of gallstones, gallbladder wall thickening, and pericholecystic fluid are the most common ultrasonographic findings. The presence of air in the gallbladder wall, intraluminal membranes, and marked irregularity of the gallbladder wall are features more specific for gangrenous cholecystitis.[11] In our series, the most common ultrasonographic findings were stones within the gallbladder, gallbladder wall thickness >5 mm and edematous gallbladder wall. Based on clinical, laboratory, and imaging findings, a preoperative diagnosis of AC was made in all patients.

It has been suggested that the optimum timing for urgent

Table 3.
Complications Following Laparoscopic Cholecystectomy

Complication	No. of Patients
Cystic duct leak	3
Subhepatic collection	2
Respiratory infection	3
Wound infection	1
Umbilical hernia	2
Total	11/184 (6%)

cholecystectomy is within 72 hours of admission or within 7 days of the onset of symptoms.[12] Furthermore, failure to perform cholecystectomy within 72 hours of admission to the hospital might be an indication for interval cholecystectomy.[13] This was based on the finding that the conversion rate was seen to rise sharply after 72 hours from admission, negating the potential benefits of urgent surgery. Lo et al[7] observed that the presence of dense, fibrous adhesions in the delayed group made laparoscopic dissection difficult and unsafe. Furthermore, repeated attacks during the period of conservative treatment necessitated emergency surgery.[8] Others have found the optimum timing for surgery to be within 96 hours of admission, with longer delays leading to a rising conversion rate.[14,15] The present results support the findings of earlier studies; in our series, all patients underwent early LC within 72 hours from their admission.

Sixty-two patients in whom a high suspicion existed of choledocholithiasis (significantly abnormal liver function test results or an abnormal biliary tree on ultrasonography, or both) underwent preoperative endoscopic retrograde cholangiopancreatography (ERCP) because of the unavailability of suitable equipment for laparoscopic CBD exploration at our institution. Preoperative sphincterotomy and stone extraction were performed in all the patients with CBD stones (n=43). ERCP was performed postoperatively in 13 patients. Nine patients were found to have CBD stones at cholecystectomy or missed CBD stones; while postoperative ERCP was reserved for 4 patients whose bilirubin levels failed to normalize following surgery.

The rising conversion rate associated with a delay in urgent cholecystectomy is related to the stage of the acute inflammatory process. In the early edematous phase, a plane exists between the gallbladder and the surrounding viscera that assists in dissection. Once the inflammation begins to settle, scarring occurs that renders dissection more difficult. Other reported risk factors for conversion include old age,[14,16] large stones,[16] a nonpalpable gallbladder,[14] gangrenous cholecystitis,[14] and the presence of pericholecystic fluid or edema and thickening of the gallbladder wall.[17] It has also been suggested that the chronicity of gallbladder disease may be an important determinant for conversion to open surgery.[16] In the current study, 12 of 17 patients (70.6%) with gangrenous cholecystitis (gangrene or gangrene with empyema) and 6 of 17 patients (35.3%) with preoperative evidence of pericholecystic fluid collection on abdominal US underwent conversion to open surgery. Pericholecystic fluid obscures the anatomy and tissue planes, making dissection difficult. Three patients underwent conversion to open cholecystectomy because of uncontrolled bleeding. Conversion in these patients must, however, not be considered a complication, but rather an effort to prevent complications.

The median duration of surgery (68 minutes) compared favorably with that reported in several randomized trials.[18,19] If severe adhesions were present, no additional trocars were placed, and the procedure was converted to the open technique. If the region of the gallbladder could be accessed, a careful evaluation of the gallbladder was carried out. Adequate healthy tissue was usually present more proximally in the region of the body and infundibulum. This allowed for grasping the gallbladder and providing the traction necessary for safe dissection in the region of the triangle of Calot. If the entire gallbladder was necrotic or if the severity of the inflammation precluded safe dissection, the procedure was similarly converted to an open one. The time taken to make these determinations did not add significantly to the duration of the surgery.

The overall complication rate in this series (6%) is lower than that observed in other large laparoscopic series for AC.[6,9,20] No mortalities or CBD injuries occurred. Three patients had cystic duct stump leaks and 2 had nonbilious subhepatic collections that were treated with conservative methods. The bile leakages mainly linked to an incomplete control of the cystic duct. We believe that in patients with an enlarged cystic duct because of inflammation or a stone, it is necessary to secure the duct with a suture or a loop. We also observed 1 wound infection, 2 umbilical postoperative hernias, and 3 respiratory infections. These results confirm that in LC the cosmetic results are improved and the rate of postoperative herniation and wound infections are decreased. Finally, the overall hospital stay was short in the present study. This is in accordance with other authors' reports.[6,18,20]

The present results support the idea that patients with specific clinical and laboratory findings can be managed with pre- or postoperative ERCP without the performance of IOC. The same results have also been reported in other studies.[21,22] However, controversy exists as to whether IOC should be performed routinely or selectively during LC. Some authors advocate routine use of IOC,[23,24] while others advocate selective IOC[25–27] when selection criteria, such as dilation of CBD, abnormal liver function tests, and history of jaundice are satisfied. Whether routine IOC reduces the incidence of CBD injuries or increases the incidence of asymptomatic or retained CBD stones, remains controversial. Ladocsi et al[27] showed that rou-

tine IOC did not increase CBD stone detection and did not decrease CBD injuries but increased the average duration of surgery, the total cost of the procedure, and the conversion rate to open surgery in comparison with the selective IOC. Some studies show a protective effect of IOC for CBD injuries,[28,29] while others conclude that routine IOC cannot completely prevent CBD injuries, but it may be helpful for the identification and repair of them.[23] In a prospective study of 3,145 LCs with routine IOC,[30] only 5 CBD injuries were identified intraoperatively; one of them occurred after a persistent attempt to perform cholangiography.

We are not convinced that the good results reported can be attributed to the routine use of IOC, because most of the CBD injuries occur during the dissection of the cystic duct before the performance of IOC. We believe that meticulous dissection with identification of anatomical landmarks is the key for safe LC, and IOC should not be used as a substitute for it.[31] IOC may decrease the incidence of CBD injuries or their extent, but this fact does not necessitate its routine use. IOC should be reserved for cases where doubt exists about the anatomy of the extrahepatic biliary tree or when CBD stones are suspected. In this study, patients with suspected CBD stones successfully underwent preoperative ERCP and CBD clearance because no facilities are available for laparoscopic CBD exploration at our institution. Thus, the use of IOC for detection of CBD stones was not necessary. We also did not use IOC for identification of anatomy. When in doubt, we converted to open surgery. One may argue that if we had performed an IOC our conversion rates could have been less. A definitive answer does not exist, but this is very likely. The optimal treatment of CBD stones is highly dependent on the available facilities. Preoperative ERCP, laparoscopic CBD exploration, conversion to open surgery, intraoperative ERCP, and postoperative ERCP are all acceptable for the management of CBD with a preference for minimal invasive techniques when they are available.

CONCLUSION

Early LC is a safe, effective procedure for managing patients with various ranges of AC. It is associated with low conversion and complication rates, reducing the length of overall hospital stay and improving the postoperative cosmetic results. When surgery is performed within 72 hours of admission, in experienced hands, LC represents the treatment of choice for AC. Pericholecystic collections and patients with gangrenous cholecystitis are associated with a higher risk of conversion to open cholecystectomy. LC can be also safely performed without IOC. ERCP should be performed preoperatively in patients in whom a high suspicion exists of choledocholithiasis or postoperatively on the basis of specific indications.

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Original Research Article

Early versus delayed cholecystectomy for cholecystitis at high risk of operative difficulties: A propensity score-matching analysis

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ABSTRACT

Background: Numerous studies have demonstrated the superiority of early (EC) over delayed (DC) cholecystectomy for acute cholecystitis (AC). However, none have assessed the effect of operative difficulty when reporting on treatment outcomes.
Methods: Outcomes of patients who underwent EC or DC between 2010 and 2019 were compared taking into account the operative difficulty evaluated by the Difficult Laparoscopic Cholecystectomy score (DiLC). For each patient, the DiLC score was retrospectively calculated and corresponded to the foreseeable operative difficulty measured on admission for AC. A propensity score was used to account for confounders. Primary endpoints were the length of stay (LOS) and the occurrence of a serious operative/post-operative event (SOE).
Results: DC in patients with DiLC≥10 reduced the risk of SOE without increasing the LOS. Conversely, DC in patients with DiLC<10 increased the LOS without improving outcomes. Multivariate analysis found EC in patients with DiLC≥10 as the main independent predictor of SOE.
Conclusions: Provided prospective validation, DC for AC in patients with DiLC≥10 seems safer than EC and is not hospital-stay consuming.

Introduction

Since its introduction in the late eighties, laparoscopic cholecystectomy has emerged as the gold standard for the treatment of acute cholecystitis.[1] Considerable debates exist concerning the optimal timing of cholecystectomy. Numerous studies demonstrated the benefits of operating patients during the index admission over delaying the cholecystectomy 6–12 weeks after the acute phase.[2–14] Indeed, early laparoscopic cholecystectomy (EC) is associated with a shorter hospital stay, similar conversion rate, and better patient satisfaction compared to delayed cholecystectomy (DC). Moreover, EC does not increase the risk of bile duct injury, bile leakage, or wound infection, and could even reduce the risk of post-operative complications.[7,8] Finally, EC precludes the risk of recurrent cholecystitis during the waiting period.[15]

Despite substantial advantages, the dogma of EC is still not widely accepted among surgeons. A recent observational study demonstrated that only 53% of patients in the United States and 16% in England benefited from EC.[16] Organizational issues account for a wide part of the observed resistance since many hospitals does not provide planned emergency theatre time for emergencies.[17] Another barrier is that major concerns limit the applicability of such guidelines into actual clinical practice. Specifically, none of the above-mentioned studies assesses the relevance of operative difficulties when selecting patients for EC or DC. Nevertheless, the operative difficulty can vary extremely from one patient to another when performing laparoscopic cholecystectomy for cholecystitis, depending on the patient's variables and the extent of inflammation or fibrosis.[18] Recently, the 2018 Tokyo Guidelines for the management of acute cholecystitis recommended surgeons "to take the difficulty of cholecystectomy into consideration in selecting a treatment method" without providing any risk-assessment models.[19] Integrating the expected operative difficulty of the cholecystectomy in selection algorithms could be of primary interest since post-operative outcomes in patients presenting a high risk of operative difficulty could be influenced by the timing of the

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Variables	Points
Sex	
Female	0
Male	2
Previous cholecystitis	
No	0
Yes	3
Neutrophil count (/μL)	
<8,000	0
8,000–11,999	1
12,000–15,999	2
≥16,000	4
Fibrinogen (g/L)	
<4	0
4–5.99	2
6–8.99	5
≥9	6
Alkaline phosphatase (IU/L)	
<80	0
80–159	1
≥160	3

Fig. 1. The Difficult Laparoscopic Cholecystectomy (DiLC) score. Adapted from The American Journal of Surgery, 212 (5), Bourgouin S, Mancini J, Monchal T, Calvary R, Bordes J, Balandraud P. How to predict difficult laparoscopic cholecystectomy? Proposal for a simple preoperative scoring system. 873–81, Copyright (2016), with permission from Elsevier.

surgery.

In 2016, our team developed the Difficult Laparoscopic Cholecystectomy (DiLC) Score (Fig. 1) to predict the operative difficulty of EC and to classify patients into four risk categories according to the probability of experiencing significant technical difficulties when performing laparoscopic cholecystectomy.[20] Comparison of surgical outcomes showed significant differences between the class of patients in terms of conversion rate, blood loss, operative time, morbidity, mortality, and length of stay. A particular class of patients with DiLC ≥10 has been identified to be at an extremely high risk of operative difficulties and subsequent complications. Questions thus arise concerning those patients with a DiLC ≥10 to know if DC could be safer than EC. The goal of this study is thus to compare the outcomes of early and delayed laparoscopic cholecystectomy performed for acute cholecystitis in patients with DiLC ≥10.

Material and methods

Study population

Medical charts of patients who benefited from a cholecystectomy for symptomatic gallstones between May 2010 and 2019 at Sainte-Anne Military Teaching Hospital were retrospectively identified using a prospectively maintained database declared to the Commission Nationale Informatique et Libertés (CNIL, French Data Protection Authority). Inclusion criteria for the present study were patients older than 18 years old who presented with acute calculous cholecystitis according to the Tokyo Guidelines 2013.[21] Patients with biliary colic, signs of concomitant choledocholithiasis revealed by pancreatitis or cholangitis, pregnant women, or intensive care unit acalculous cholecystitis were excluded.[22] The study protocol was approved by the Institutional Review Board of the hospital. Informed consent and patient approval were obtained prior to the initiation of treatment but were not required before data analysis due to the retrospective and anonymized nature of the study.

Management of acute cholecystitis

According to guidelines, the policy of our department is to operate acute cholecystitis during the index admission and to perform EC within up to ten days of symptom onset, provided the general condition of the patients allow them to withstand emergency surgery. The surgical technique of laparoscopic cholecystectomy has already been thoroughly described.[20] Antimicrobial agents were not routinely administrated unless the operation could not take place during the first 6 hours after admission, notably because of counter-indications to general anesthesia. In such cases, intravenous penicillin-based or cephalosporin-based agents associated with fluoroquinolone or metronidazole were given and laparoscopic cholecystectomy was planned as soon as the patient's condition improved.[23] Percutaneous transhepatic gallbladder drainage (PTGBD) was performed in case of failure of the first line antibiotics in association with a second line treatment, or in Tokyo Guidelines 2013 Grade III cholecystitis.[24] Patients who couldn't benefit from EC within ten days because of significant comorbidities were given full antibiotic treatment and were secondarily planned for DC at least six weeks after the index admission. For those patients, intravenous antibiotics were switched to oral antibiotics and patients were discharged home to continue treatment for a total duration of 15 days. Patients were then regularly checked at the outpatient clinic before the DC was planned in the day-care surgical unit. In case of failure for the first line antibiotics or when recurrent cholecystitis arose during the waiting period, a second line regimen was proposed combined with PTGBD. Rescue laparoscopic cholecystectomy was performed as a very last resort in the absence of clinical improvement despite optimal treatment.

Data collection and endpoints

Data were prospectively collected and included the timing of cholecystectomy, demographics, medical history and comorbidities, American Society of Anesthesiologist Physical Status classification (ASA score), Body Mass Index (BMI, kg/m2), DiLC score, reasons for delaying surgery, and the type and outcome of the medical treatment in case of DC. For the purpose of the current study, the DiLC score was retrospectively collected for each patient using laboratory data obtained on the day of admission for acute cholecystitis. Therefore, the DiLC scores presented in this study for EC patients correspond to the operative difficulty measured immediately before the cholecystectomy, while for DC patients, the values represent the operative difficulty the surgeon might have encountered if the cholecystectomy could have been achieved in an early setting. Failure of medical treatment for DC patients was defined as the need to proceed to rescue laparoscopic cholecystectomy. Operative variables concerned the type of surgical access, conversion, cholangiography and bile duct injury rates, operative time (min), need for subtotal cholecystectomy, and Estimated Blood Loss (EBL, mL). Post-operative data included the occurrence of post-operative complications according to Dindo-Clavien,[25] lengths of pre-surgical stay (LpreSS, from the day of admission to the day of surgery), post-surgical stay (LpostSS, from the day of surgery to the day of discharge), surgical stay (LSS, from the day of admission for surgery to the day of discharge), medical stay (LMS, defined as the length of the initial stay for patients delayed to surgery), and total length of stay (LOS) corresponding for EC patients to the LSS and for DC patients to the LMS added to the LSS and length of additional stays in case of readmission. Primary endpoints were the LOS (days)

and a composite endpoint defined as the occurrence of a severe operative or post-operative event following laparoscopic cholecystectomy including: (i) bile duct injury; (ii) failure of the laparoscopic access defined as a conversion to an open approach or a first intention laparotomy; (iii) major operative bleeding defined as EBL ≥200 mL; (iv) Clavien ≥3 complication. Secondary endpoints were each criterion of the composite endpoint independently assessed and the operative time, need for subtotal cholecystectomy, rates of cholangiography, and lengths of stays.

Statistical analysis

Statistical analyses were performed using IBM SPSS 20.0 (IBM Inc., New York, NY, USA). Comparisons between EC and DC were conducted both on patients with DiLC ≥10 and <10 to ensure that the observed findings depended on the DiLC threshold effect instead of a sampling bias. Propensity score-matching analysis was used to achieve well-balanced inclusion covariates between groups. A propensity score, i.e., the probability for a patient to receive EC or DC, was derived for each patient from a logistic regression model in which potential confounders (age, gender, BMI, DiLC and ASA scores, and previous upper-abdominal surgery) were regressed onto treatment assignment as a binary outcome (EC or DC). Patients were then matched 1 DC for 2 EC without replacement using the nearest available metric matching method within calipers defined as 0.2 standard deviations (SD) of the logit of propensity score. The validity of the score was quantified by calculating the standardized differences for continuous and categorical covariates, and by verifying the well-balancing of inclusion characteristics after matching.[26] Categorical variables were expressed in terms of frequency (percentages) and continuous variables as the mean (±SD). Univariate analyses were conducted using a Student's t-test or a Mann–Whitney test for continuous variables, and a Chi-square test or Fisher's exact test for categorical variables as appropriate. Because of possible cross-over from DC to rescue laparoscopic cholecystectomy, results are presented by intention-to-treat and per-protocol analysis. Multivariate analysis to identify independent predictors of severe operative or post-operative event was performed using a backward stepwise logistic regression model adjusted for covariates with significance at $P \leq 0.2$ on univariate analysis. A two-tailed P-value ≤0.05 was considered statistically significant.

Results

One-thousand two-hundred and twelve patients were identified during the study period, including 417 acute cholecystitis. Among them, 20 patients were excluded because of acalculous cholecystitis or missing data. In all, 397 patients fulfilled the inclusion criteria and were selected for further analyses, including 68 DC and 329 EC (Fig. 2).

Surgery at high risk of operative difficulties (DiLC ≥10)

The DiLC score at the index admission was over 10 for 105 patients. Among them, 24 patients benefited from DC, and 81 from EC. Baseline characteristics of patients with DiLC ≥10 are presented in Table 1. Before matching, the DC group was comprised of significantly more ASA 3 patients and cardiac comorbidities. After matching, standardized differences were below 18% for all covariates, and baseline characteristics were all well-balanced between groups.

The mean delay to laparoscopic cholecystectomy for DC patients was 90 days (±41). Reasons for delaying cholecystectomy were: anticoagulant therapy for recent stroke, myocardial infarction or pulmonary embolism (n = 13); first external medical treatment and secondary transfer (n = 4); counter-indication to general anesthesia (n = 4); symptoms evolving for more than 10 days (n = 2); and recent laparotomy (n = 1). Three patients (12.5%) required PTGBD because of insufficient symptoms improvement and needed emergency rehospitalization. Among them, one patient finally needed rescue laparoscopic cholecystectomy. The postoperative course was marked by the need for endoscopic sphincterotomy because of gallstone-related cholangitis. Moreover, two patients required unplanned consultations during the waiting phase because of pain. In all, five patients (20.8%) required emergency consultation/hospitalization during the waiting phase, and one patient (4.2%) needed rescue laparoscopic cholecystectomy.

Post-operative outcomes are presented in Table 2. Comparison of primary endpoints by intention-to-treat and per-protocol analysis demonstrated significantly less severe operative or post-operative events in the DC group (4/24, 16.7% vs 33/48, 68.8%, $P < 0.001$) with similar total LOS (8.9 ± 6.1 days vs 9.8 ± 8.4 days, $P = 0.636$). Considering secondary endpoints, the LSS, including LpreSS and LpostSS, major bleeding, and conversion rates were higher in the EC group. Moreover, post-operative morbidity, especially Clavien ≥3 complications, became significantly higher in the EC group by per-protocol analysis. One patient experienced a BDI (cystic duct not individualized during surgery) revealed by post-operative bile leakage, and managed by endoscopic sphincterotomy and biliary prothesis. The operative time, rates of bile duct injury, subtotal cholecystectomy, and failure of cholangiography were not different between groups.

Surgery at low risk of operative difficulties (DiLC <10)

Two-hundred ninety-two patients had a DILC <10 at the index admission. Among them, 248 were scheduled for EC and 44 for DC. Baseline characteristics are summarized in Table 3. The DC group comprised significantly more men, but the difference disappeared following the propensity score-matching analysis, with standardized differences below 12%. All other baseline covariates were well-balanced between groups.

The mean delay to laparoscopic cholecystectomy in the DC group was 77.9 days (±42.4). Reasons for delaying cholecystectomy were: first external medical treatment and secondary transfer (n = 22); symptoms lasting for more than 10 days (n = 11); anticoagulant therapy (n = 5); counter-indication to general anesthesia (n = 3); and need for repatriation from a foreign country (n = 3). The index cholecystitis resolved spontaneously without any treatment for nine patients. All the others benefited from antibiotics. In two cases, PTGBD was required and permitted to resolve the crisis except for one patient who finally needed rescue laparoscopic cholecystectomy. Moreover, five patients were planned for rescue laparoscopic cholecystectomy because of recurrent symptoms despite the fact that they did not benefit from full second line treatment and PTGBD. The post-operative course of rescue laparoscopic cholecystectomy was uneventful for all but one patient who experienced acute coronary syndrome. Two more patients required emergency rehospitalization for antalgic treatment and three patients demanded unplanned consultations at the outpatient clinic. In all, 11 patients (25.0%) required emergency consultation/hospitalization during the waiting phase, and six patients (13,6%) needed rescue laparoscopic cholecystectomy.

Post-operative outcomes are summarized in Table 4. Considering primary endpoints, only the total LOS was significantly longer in the DC group (7 ± 9.3 days vs 4.9 ± 2.7 days, $P = 0.048$, intention-to-treat analysis). The difference disappeared in per-protocol analysis while the LSS, including LpreSS and LpostSS, became significantly shorter in the DC group. Four patients experienced BDI

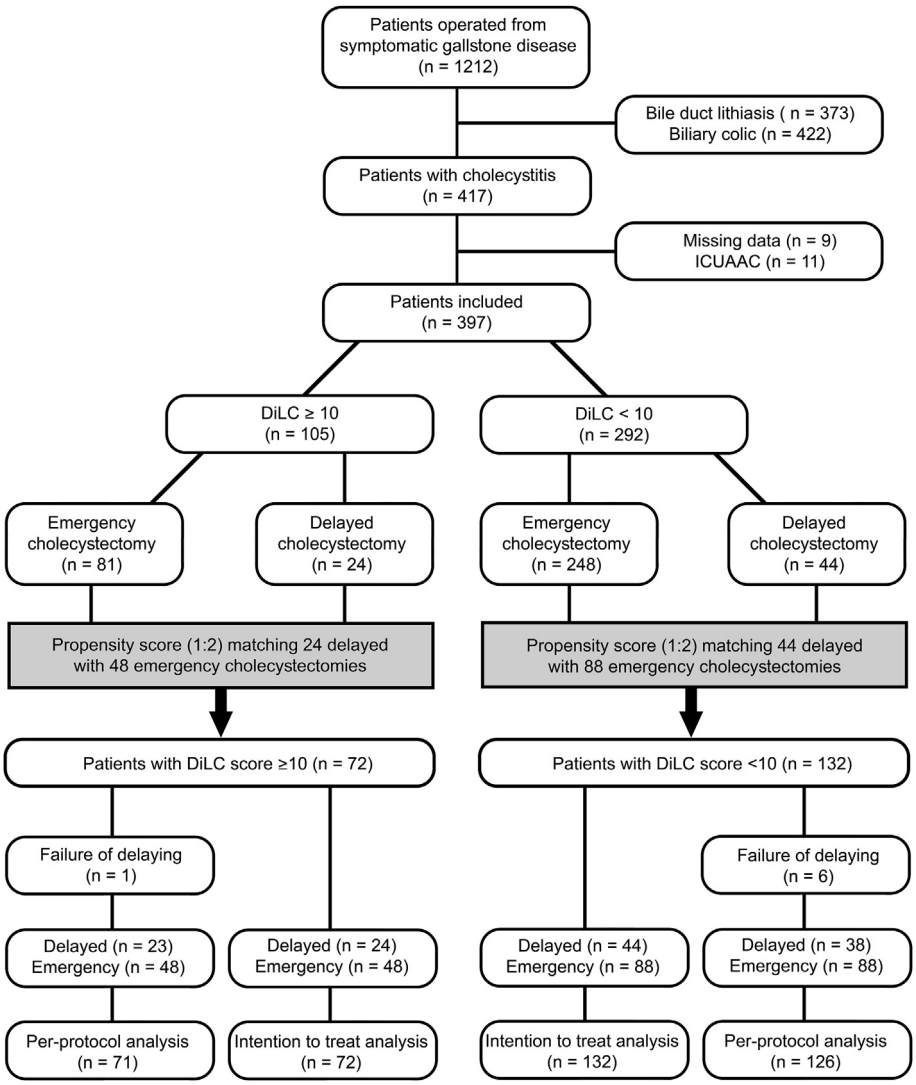

Fig. 2. Flowchart of the selection process for the study.* Intensive Care Unit Acalculous Cholecystitis.

during surgery: three of them corresponded to a cystic or common bile duct injury performed during the insertion of the cholangiography catheter, the last injury was a tearing of the cystic duct during dissection. All the injuries were diagnosed during surgery and sutured. Post-operative courses were uneventful. Secondary endpoints analysis did not reveal any significant differences between groups, either by intention-to-treat or per-protocol analysis.

Predictors of severe operative/post-operative outcome

The results of the multivariate logistic regression analysis are presented in Table 5. The model was adjusted on covariates likely to influence the outcome on univariate analysis. The variables found to be independent predictors of a severe operative or post-operative event were EC in patients with DiLC $\geq$10 (OR = 6.32, 95% CI 3.05–13.09) and the achievement of a subtotal cholecystectomy (OR = 4.41, 95% CI 1.32–14.68).

Discussion

This comparative analysis of propensity-score matched data focusing on the optimal timing for laparoscopic cholecystectomy in the setting of acute cholecystitis demonstrated that delaying patients who are at the highest risk of operative difficulties (DiLC $\geq$10) was associated with a decrease of severe operative or post-operative events and did not increase the total LOS. Delaying laparoscopic cholecystectomy furthermore decreased the risk of conversion to open cholecystectomy, major operative bleeding and the LSS. The post-operative morbidity, mortality, bile duct injury, subtotal cholecystectomy and cholangiography rates, and the operative time were similar between groups by intention-to-treat but differed by per-protocol analysis, suggesting an over-increase of the operative risk for rescue laparoscopic cholecystectomy. In patients at low risk of operative difficulties (DiLC <10), delaying laparoscopic cholecystectomy did not affect the post-operative course but significantly increased the total LOS with a similar effect of rescue laparoscopic cholecystectomy between intention-to-treat and per-protocol analysis with respect to the LSS.

The optimal timing of cholecystectomy for acute cholecystitis is a long-standing debate initiated with the onset of the laparoscopy for which surgeons feared that extensive inflammation caused dissection difficulties that might be a source of post-operative complications.[27] With the increase of the laparoscopic experience have more and more relevant studies challenged the dogma of

Table 1
Baseline characteristics of patients with DiLC ≥10.

Characteristics	Before Matching				p-value	After Matching				p-value
	Delayed (n = 24)		Early (n = 81)			Delayed (n = 24)		Early (n = 48)		
	n	(%)	n	(%)		n	(%)	n	(%)	
Sex (male)	18	(75.0)	60	(74.1)	0.927	18	(75.0)	34	(70.8)	0.709
ASA score					0.113					0.271
1	0	(0.0)	4	(4.9)		0	(0.0)	0	(0.0)	
2	2	(8.3)	19	(23.5)		2	(8.3)	2	(4.2)	
3	20	(83.3)	46	(56.8)		20	(83.3)	35	(72.9)	
4	2	(8.3)	12	(14.8)		2	(8.3)	11	(22.9)	
ASA score ≥3	22	(91.7)	57	(70.4)	**0.034**	22	(91.7)	46	(95.8)	0.596
Age, *mean (±SD)*	70.7	(11.5)	73	(11.1)	0.377	70.7	(11.5)	72.9	(11.8)	0.464
BMI, *mean (±SD)*	27.6	(4.3)	27.4	(4.7)	0.856	27.6	(4.3)	27.3	(5.3)	0.829
DiLC score					0.433					0.504
10	15	(62.5)	39	(48.1)		15	(62.5)	25	(52.1)	
11	3	(12.5)	16	(19.8)		3	(12.5)	10	(20.8)	
12	5	(20.8)	14	(17.3)		5	(20.8)	8	(16.7)	
13	0	(0.0)	8	(9.9)		0	(0.0)	4	(8.3)	
14–15	1	(4.2)	4	(4.9)		1	(4.2)	1	(2.1)	
Comorbidities										
Neurologic	5	(20.8)	14	(17.3)	0.692	5	(20.8)	11	(22.9)	0.841
Pulmonary	6	(25.0)	18	(22.2)	0.776	6	(25.0)	13	(27.1)	0.850
Cardiac	21	(87.5)	51	(63.0)	**0.025**	21	(87.5)	36	(75.0)	0.356
Vascular	6	(25.0)	22	(27.2)	0.833	6	(25.0)	15	(31.3)	0.582
Abdominal Surgery	9	(37.5)	31	(38.3)	0.946	9	(37.5)	21	(43.8)	0.612
Upper	5	(20.8)	8	(9.9)	0.152	5	(20.8)	7	(14.6)	0.502
Lower	9	(37.5)	23	(28.4)	0.395	9	(37.5)	16	(33.3)	0.726

Significant values are in bold-type.

delaying cholecystectomy. Nowadays, expert group guidelines, on the basis of randomized clinical trials and meta-analyses, seemed to have answered the question: acute cholecystitis shall be operated on in an early setting because of similar post-operative outcomes with shorter length of stay and subsequent better cost-effectiveness.[2–14] If the statistical methodology of such studies is hardly objectionable, their main weakness is that they consider each cholecystitis to be equivalent to another and thus cannot adjust outcome analyses between groups based on the cholecystitis severity or operative difficulty. Taking into account the operative difficulty has been newly considered in the 2018 Tokyo Guidelines updates for moderate cholecystitis.[19] Although recognition of

Table 2
Post-operative outcomes of patients with DiLC ≥10.

Characteristics	Intention to treat analysis				p-value	Per-protocol analysis				p-value
	Delayed (n = 24)		Early (n = 48)			Delayed (n = 23)		Early (n = 48)		
	n	(%)	n	(%)		n	(%)	n	(%)	
Composite Endpoint	4	(16.7)	33	(68.8)	**<0.001**	3	(13.0)	33	(68.8)	**<0.001**
Post-operative morbidity	3	(12.5)	15	(31.3)	0.147	2	(8.7)	15	(31.3)	**0.042**
Clavien 1–2 complications	1	(4.2)	3	(6.3)	1.000	1	(4.3)	3	(6.3)	1.000
Clavien 3–4 complications	2	(8.3)	8	(25.0)	0.479	1	(4.3)	8	(25.0)	0.255
Biliary fistula	1	(4.2)	4	(8.3)	0.659	1	(4.3)	4	(8.3)	1.000
Respiratory distress syndrome	0	(0.0)	2	(4.2)	0.549	0	(0.0)	2	(4.2)	1.000
Cardiac arrythmia	0	(0.0)	1	(2.1)	1.000	0	(0.0)	1	(2.1)	1.000
Renal infarction	0	(0.0)	1	(2.1)	1.000	0	(0.0)	1	(2.1)	1.000
Choledocholithiasis	1	(4.2)	0	(0.0)	0.333	0	(0.0)	0	(0.0)	–
Clavien 5 (mortality)	0	(0.0)	4	(8.3)	0.294	0	(0.0)	4	(8.3)	0.297
Clavien ≥ 3	2	(8.3)	12	(25.0)	0.121	1	(4.3)	12	(25.0)	**0.048**
Failure to laparoscopy	1	(4.2)	14	(29.2)	**0.014**	1	(4.3)	14	(29.2)	**0.027**
First intention laparotomy	1	(4.2)	6	(12.5)	0.412	1	(4.3)	6	(12.5)	0.415
Conversion to open	0	(0.0)	8	(16.7)	**0.048**	0	(0.0)	8	(16.7)	**0.047**
Bile duct injury	0	(0.0)	1	(2.1)	1.000	0	(0.0)	1	(2.1)	1.000
EBL ≥ 200 mL	1	(4.2)	24	(50.0)	**<0.001**	1	(4.3)	24	(50.0)	**<0.001**
Blood transfusion	0	(0.0)	4	(8.3)	0.294	0	(0.0)	4	(8.3)	0.297
Subtotal cholecystectomy	2	(8.3)	5	(10.4)	1.000	2	(8.7)	5	(10.4)	1.000
Cholangiography (failure)	4	(16.7)	17	(35.4)	0.168	4	(17.4)	17	(35.4)	0.167
Operative time *(min)* mean (±SD)	122.5	(36.9)	126.1	(33.3)	0.681	119.8	(35.1)	126.1	(33.3)	0.467
LSS *(days)* mean (±SD) *	3.7	(2.6)	9.8	(8.4)	**<0.001**	3.5	(2.5)	9.8	(8.4)	**<0.001**
LpreSS	0.9	(1.4)	2.6	(3.2)	**0.013**	0.9	(1.4)	2.6	(3.2)	**0.017**
LpostSS	2.8	(2.1)	7.2	(7.5)	**0.007**	2.6	(1.8)	7.2	(7.5)	**0.005**
LMS *(days)* mean (±SD) *	5.2	(5.6)	–	–	–	5.0	(5.6)	–	–	–
LOS *(days)* mean (±SD) *	8.9	(6.1)	9.8	(8.4)	0.636	8.5	(5.9)	9.8	(8.4)	0.504

Significant values are in bold-type; * LSS = Length of Surgical Stay, LpreSS = Length of pre-Surgical Stay, LpostSS = Length of post-Surgical Stay, LMS = Length of Medical Stay, LOS = total Length Of Stay.

Table 3
Baseline characteristics of patients with DiLC <10.

Characteristics	Before Matching				p-value	After Matching				p-value
	Delayed ($n = 44$)		Early ($n = 248$)			Delayed ($n = 44$)		Early ($n = 88$)		
	n	(%)	*n*	(%)		*n*	(%)	*n*	(%)	
Sex (male)	33	(75.0)	111	(44.8)	**<0.001**	33	(75.0)	70	(79.5)	0.552
ASA score					0.513					0.551
1	8	(18.2)	34	(13.7)		8	(18.2)	11	(12.5)	
2	17	(38.6)	125	(50.4)		17	(38.6)	43	(48.9)	
3	18	(40.9)	82	(33.1)		18	(40.9)	30	(34.1)	
4	1	(2.3)	7	(2.8)		1	(2.3)	4	(4.5)	
ASA score ≥3	19	(43.2)	89	(35.9)	0.356	19	(43.2)	56	(63.6)	0.448
Age, *mean (±SD)*	61.1	(16.6)	63.9	(15.9)	0.303	61.1	(16.6)	62.8	(16.8)	0.584
BMI, *mean (±SD)*	27.6	(4.6)	27.3	(4.5)	0.674	27.6	(4.6)	27.6	(3.9)	0.999
DiLC score					0.266					0.651
0	0	(0.0)	6	(2.4)		0	(0.0)	0	(0.0)	
1	0	(0.0)	9	(3.6)		0	(0.0)	0	(0.0)	
2	2	(4.5)	27	(10.9)		2	(4.5)	8	(9.1)	
3	3	(6.8)	25	(10.1)		3	(6.8)	5	(5.7)	
4	7	(15.9)	31	(12.5)		7	15.9)	13	(14.8)	
5	13	(29.5)	35	(14.1)		13	(29.5)	14	(15.9)	
6	7	(15.9)	38	(15.3)		7	(15.9)	13	(14.8)	
7	3	(6.8)	24	(9.7)		3	(6.8)	9	(10.2)	
8	4	(9.1)	30	(12.1)		4	(9.1)	14	(15.9)	
9	5	(11.4)	23	(9.3)		5	(11.4)	12	(13.6)	
Comorbidities										
Neurologic	9	(20.5)	29	(11.7)	0.111	9	(20.5)	10	(11.4)	0.161
Pulmonary	2	(4.5)	28	(11.3)	0.278	2	(4.5)	13	(14.8)	0.143
Cardiac	20	(45.5)	87	(35.1)	0.188	20	(45.5)	53	(60.2)	0.533
Vascular	6	(13.6)	21	(8.5)	0.275	6	(13.6)	5	(5.7)	0.119
Abdominal Surgery	20	(45.5)	117	(47.2)	0.833	20	(45.5)	29	(33.0)	0.161
Upper	3	(6.8)	28	(11.3)	0.594	3	(6.8)	5	(5.7)	1.000
Lower	15	(34.1)	92	(37.1)	0.703	15	(34.1)	21	(23.9)	0.214

Significant values are in bold-type.

difficult procedures is made on the basis of operative findings, rendering the applicability of guidelines difficult when it comes to select patients for a treatment method, the whole idea that patients at high risk of operative difficulties could benefit from a delayed procedure was introduced.[28] Our study is, in that sense, the very first to assess the outcomes of early and delayed laparoscopic cholecystectomy according to the foreseeable risk of operative difficulty and has first demonstrated that delaying laparoscopic cholecystectomy for high-risk patients is safer and, secondly, that this strategy is not hospital-stay consuming, which is a novelty compared to the results of the above-mentioned studies. Moreover, the fact that these findings were not reproduced in patients with DiLC <10, in which results were similar to other studies, reinforces the relevance of the DiLC threshold effect instead of discussing a sample bias, suggesting that if most cholecystitis should undergo EC, some of the selected patients could benefit from DC.

The decrease in the total LOS is the main argument supporting EC as most of the studies did not find any significant difference in complications rates.[4,6] In a recent meta-analysis, the mean difference in the LOS reached four days between meta-groups, but the LpostSS were similar.[13] This difference is related to the need for DC patients to be hospitalized twice: one for the treatment of the acute phase, the second for the surgical treatment.[3,4,11] A similar result has been found in our study for patients with DiLC <10, with the LOS being significantly longer by three days in the DC group, corresponding to the LMS. On the contrary, the LOS were not different between groups among patients with DiLC ≥10, despite the addition of a mean medical stay of 5.2 days (±5.6). However, the LSS in DC patients was decreased by nearly six days compared to EC by means of day-care surgery and because of the decrease of LpostSS related to the drop of Clavien ≥3 complications in DC patients who had a successful medical treatment. This result suggests that the increase of the LOS in delayed patients can be outweighed by better management of the surgical stay and post-operative outcomes.

In our study, the main outcome was a composite endpoint gathering severe operative and post-operative events defined as all events significantly deviating from a normal laparoscopic cholecystectomy, including bile duct injury, failure of laparoscopy, major bleeding or Dindo-Clavien ≥3 complications. The rationale was that proposing a DC implies the exclusion from emergency management, suggesting that risks that are usually assumed when operating on in an emergency can no longer be accepted for planned procedures. Composite measures have already been used in previous studies and helped to highlight differences between groups using outcomes whose significance could not have been reached by independent analyses, within the limit that each covariate will be given the same statistical weight.[11] In our study, significant differences were found in favor of DC for the composite endpoint in high-risk patients by per-protocol and intention-to-treat analysis, suggesting that the differences were not only the result of cross-over of patients who benefited from rescue laparoscopic cholecystectomy in case of medical treatment failure.

The readmission and failure of medical treatment rates in the DC group were 20.8% and 4.2% in patients with DiLC ≥10, respectively, and 25% and 13.6% in patients with DiLC <10. These rates are consistent with those observed in the literature.[4] However, slightly higher rates in low-risk patients could suggest a possible underestimation of the cholecystitis severity with subsequent undertreatment of these patients. Indeed, nine patients did not receive any antibiotics in the first intention and, despite local guidelines, there was great variability in the management of recurrent symptoms and medical treatment failures before planning rescue laparoscopic cholecystectomy. This finding raises the question about the optimal management of treatment failure and the place of

Table 4
Post-operative outcomes of patients with DiLC <10.

Characteristics	Intention to treat analysis				*p*-value	Per-protocol analysis				*p*-value
	Delayed ($n = 44$)		Early ($n = 88$)			Delayed ($n = 38$)		Early ($n = 88$)		
	n	(%)	*n*	(%)		*n*	(%)	*n*	(%)	
Composite Endpoint	15	(34.1)	21	(23.9)	0.214	10	(26.3)	21	(23.9)	0.769
Post-operative morbidity	8	(18.2)	9	(10.2)	0.198	7	(18.4)	9	(10.2)	0.205
Clavien 1–2 complications	4	(9.1)	6	(6.8)	0.731	4	(10.5)	6	(6.8)	0.474
Clavien 3–4 complications	4	(9.1)	2	(2.3)	0.095	3	(7.9)	2	(2.3)	0.161
Choledocholithiasis	0	(0.0)	2	(2.3)	0.552	0	(0.0)	2	(2.3)	1.000
Biliary fistula	1	(2.3)	0	(0.0)	0.333	1	(2.6)	0	(0.0)	0.302
Stroke	1	(2.3)	0	(0.0)	0.333	1	(2.6)	0	(0.0)	0.302
Myocardial infarction	1	(2.3)	0	(0.0)	0.333	0	(0.0)	0	(0.0)	–
Post-operative hemorrhage	1	(2.3)	0	(0.0)	0.333	1	(2.6)	0	(0.0)	0.302
Clavien 5 (mortality)	0	(0.0)	1	(1.1)	1.000	0	(0.0)	1	(1.1)	1.000
Clavien $\geq$ 3	4	(9.1)	3	(3.4)	0.221	3	(7.9)	3	(3.4)	0.365
Failure to laparoscopy	5	(11.4)	6	(6.8)	0.373	3	(7.9)	6	(6.8)	1.000
First intention laparotomy	1	(2.3)	2	(2.3)	1.000	1	(2.6)	2	(2.3)	1.000
Conversion to open	4	(9.1)	4	(4.5)	0.439	2	(5.3)	4	(4.5)	1.000
Bile duct injury	3	(6.8)	1	(1.1)	0.108	3	(7.9)	1	(1.1)	0.082
EBL $\geq$ 200 mL	7	(15.9)	16	(18.2)	0.745	4	(10.5)	16	(18.2)	0.426
Blood transfusion	2	(4.5)	0	(0.0)	0.109	2	(5.3)	0	(0.0)	0.096
Subtotal cholecystectomy	5	(11.4)	3	(3.4)	0.116	3	(7.9)	3	(3.4)	0.365
Cholangiography (failure)	10	(22.7)	18	(20.5)	0.763	8	(21.1)	18	(20.5)	0.939
Operative time *(min)* mean (±SD)	120.3	(59.5)	119.9	(34.8)	0.960	111.3	(49.9)	119.9	(34.8)	0.271
LSS *(days)* mean (±SD) *	4.3	(5.2)	4.9	(2.7)	0.379	3.1	(4.3)	4.9	(2.7)	**0.005**
LpreSS	0.9	(1.6)	1.1	(1.2)	0.503	0.6	(1.0)	1.1	(1.2)	**0.033**
LpostSS	3.3	(4.3)	3.8	(2.3)	0.445	2.4	(3.9)	3.8	(2.3)	**0.021**
LMS *(days)* mean (±SD) *	2.7	(4.9)	–	–	–	2.4	(5.1)	–	–	–
LOS *(days)* mean (±SD) *	7	(9.3)	4.9	(2.7)	**0.048**	5.5	(8.9)	4.9	(2.7)	0.589

Significant values are in bold-type; * LSS = Length of Surgical Stay, LpreSS = Length of pre-Surgical Stay, LpostSS = Length of post-Surgical Stay, LMS = Length of Medical Stay, LOS = total Length Of Stay.

PTGBD as a first or second-line therapy in the medical treatment of cholecystitis. Indeed, rescue laparoscopic cholecystectomy performed in the case of treatment failure seemed to be all the more at risk of complications. Stratifying patients by DiLC showed that in high-risk patients, the significance of differences in global and grade $\geq$3 complications rates found by per-protocol analysis disappeared by intention-to-treat analysis. Similar results were found in low-risk patients with respect to the LSS. These results suggest rescue laparoscopic cholecystectomy to be at high risk of complications, directly impacting the total LOS. There is thus a need for studies aiming to standardize the medical treatment of acute cholecystitis in order to decrease the rate of treatment failure and avoid the need for rescue laparoscopic cholecystectomy.

Our study is the first to take into account the operative difficulty in the assessment of surgical outcomes following an early or delayed laparoscopic cholecystectomy. The propensity-score matching analysis was performed to address confounders at inclusion, and the results are sustained by powerful statistical

Table 5
Multivariate logistic regression analysis for severe operative or post-operative events.

Characteristics	Severe operative/postoperative event				*p*-value		Odds ratio	95% (CI)
	yes = 73	(%)	*no* = 131	(%)	Uni.	Multi.		
Age $\geq$ 75 years								
Yes	29	(39.7)	38	(29.0)	0.118	–	–	–
No	44	(60.3)	93	(71.0)				
BMI $\geq$ 35 kg/m^2								
Yes	7	(9.6)	6	(4.6)	0.160	0.172	2.35	(0.69–8.05)
No	66	(90.4)	125	(95.4)				
Early surgery with DiLC $\geq$10								
Yes	33	(45.2)	15	(11.5)	**<0.001**	**<0.001**	6.32	(3.05–13.09)
No	40	(54.8)	116	(88.5)				
Gender (male)								
Yes	50	(68.5)	105	(80.2)	0.062	0.115	0.56	(0.27–1.15)
No	23	(31.5)	26	(19.8)				
ASA $\geq$ 3								
Yes	51	(69.9)	68	(51.9)	**0.013**	–	–	–
No	22	(30.1)	63	(48.1)				
Subtotal cholecystectomy								
Yes	10	(13.7)	5	(3.8)	**0.009**	**0.016**	4.41	(1.32–14.68)
No	63	(86.3)	126	(96.2)				
Cholangiography (failure)								
Yes	24	(32.9)	25	(19.1)	**0.027**	–	–	–
No	49	(67.1)	106	(80.9)				

Significant values are in bold-type.

analyses, including multivariate logistic regression analysis finding the EC for patients with DiLC ≥10 to be the strongest predictor of adverse events. However, some limits have to be noted. First, propensity scores only adjust confounders related to observed characteristics. Possible confounders, such as surgeon's skill in laparoscopy, have thus not been adjusted on, possibly explaining the residual imbalance of covariates despite propensity score-matching analysis as quantified by calculation of the mean and proportion standardized differences, and the higher rate of laparotomy compared with rates usually observed in literature and in our own series.[20] Secondly, to avoid unmatched DC patients, we choose to match DC to EC patients. However, more than 90% of delayed patients with DiLC ≥10 was ASA 3 explaining the very high rate of ASA 3 patients in matched EC patients, and possibly reflecting the high rate of Clavien ≥3 complications in this series. Thirdly, it should be noted that the DiLC score has been created using a retrospective series and is not yet validated on prospective data. Finally, the lack of standardization for medical treatment and the absence of decision-making algorithms for failure cases do not allow us to draw firm conclusions with respect to readmission and failure rates. Therefore, the higher rate of treatment failure in low-risk DC patients has been interpreted as undertreatment of patients whose cholecystitis severity was disesteemed but could also be construed as a low rate of treatment failure in high-risk patients due to overtreatment of the crisis.

Conclusions

To the extent of the limits discussed above, and provided the validation of the DiLC score, DC for acute cholecystitis in patients at high risk of operative difficulties appears to be safer than EC with respect to the occurrence of serious operative or post-operative events and does not increase the total LOS. Further studies should determine the optimal medical treatment of acute cholecystitis in the setting of delayed surgery and provide decision algorithms for the management of failures. This study could constitute a first landmark for the initiation of new randomized clinical trials on the optimal timing of cholecystectomy according to the expected operative difficulty.

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Declaration of competing interest

The authors have no conflicts of interest to declare.

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TIMING OF CHOLECYSTECTOMY IN ACUTE CHOLECYSTITIS

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□ **Abstract—Background: Cholecystitis is an inflammation of the gallbladder that most commonly occurs as a result of obstruction of the cystic duct by gallstones. The current standard of treatment for acute cholecystitis is cholecystectomy. Objective: Our goal was to discuss the benefits of and compare early laparoscopic cholecystectomy and delayed laparoscopic cholecystectomy in the treatment of acute cholecystitis. Materials and Methods: A Medline literature search was performed dating from January 1982 to July 2015. We limited the search to human studies written in English and using the keywords "Acute Cholecystitis," early vs. delayed laparoscopic cholecystectomy, surgical management, and surgical complications. Results: There were 225 articles reviewed, of which 25 met criteria for selection. Our recommendations are based on these 25 articles. Conclusion: Early laparoscopic cholecystectomy is preferred over delayed, due to overall better quality of life, lower morbidity rates, and lower hospital cost. Ultimately, management of acute cholecystitis by emergency physicians should be made based on patient's clinical status and available resources in their particular hospital.** © 2018 Elsevier Inc. All rights reserved.

□ **Keywords—cholecystitis; early; late; cholecystectomy; gallbladder; abdominal pain; complications; postoperative complications**

INTRODUCTION

Acute cholecystitis (AC) is an acute inflammation of the gallbladder, whereas biliary colic is symptomatic cholelithiasis without inflammation. Gallstones are present on ultrasound in over 90% of cases of AC. In the remaining 5–10% of cases gallstones are not identified, and hence are referred to as "acalculous cholecystitis" (1). AC is caused by obstruction to gallbladder drainage, leading to an increase in intraluminal pressure, gallbladder distention, and wall edema that may progress to venous and lymphatic obstruction, ischemia, necrosis, and perforation (1). Persistent obstruction causes a mediating chemical inflammatory response that may result in bacterial contamination causing AC, ascending cholangitis, and possibly, pancreatitis. Symptoms of AC are typically right upper quadrant or epigastric pain that persists beyond 6 h. It starts as a visceral-type pain that usually changes from dull and poorly localized to somatic-type pain that is sharp and localized to the right upper quadrant, radiating to the back, right scapula, or right clavicular area. Associated fever, chills, nausea, vomiting, and anorexia are common (2).

According to the National Institutes of Health, more than 20 million people in the United States have gallstones, and in 1991 approximately 600,000 underwent cholecystectomy (3). Recent articles indicate that the annual rate of cholecystectomy is now as high as 1.5 million per year.

Controversy exists about the best timing for cholecystectomy. There are mainly two approaches to dealing with this common disease process: early surgery vs. initial conservative treatment whereby antibiotics are

Table 1. Details of the Reviewed Articles

	Publications	Grade	Quality	Comments
1	Yusoff et al., 2003	F	Good	Guidelines Summary of pathophysiology, clinical presentation, diagnoses, and various treatments for cholecystitis and acalculous cholecystitis.
2	Halachmi et al., 2000	C	Adequate	Prospective cohort Laparoscopic cholecystectomy for acute cholecystitis: How do fever and leukocytosis relate to conversion and complication? Article addresses if fever and raised white cell count is associated with conversion and complications of laparoscopic cholecystectomy in acute cholecystitis, and if it should be used in the decision-making of the type of procedure to be performed on the patient.
3	NIH Consensus development conference statement; 1992	F	Good	Guidelines An NIH summary and statistical review of gallstone-induced cholecystitis and laparoscopic cholecystectomy. This article gives a good statistical number for cholecystitis and cholecystectomy in the United States.
4	Lai et al., 1998	A	Good	Retrospective cohort This article addresses early or delayed laparoscopic cholecystectomy for patients with acute cholecystitis. It also addresses the benefits of early laparoscopic cholecystectomy on the total hospital stay.
5	Eldar et al., 2002	D	Average	Retrospective study of patients having laparoscopic cholecystectomy converted to open surgical procedure in acute cholecystitis.
6	Pisanu et al., 2001	D	Good	Retrospective study comparing early surgical treatment of acute cholecystitis leading to lower postoperative morbidity rate and significantly earlier patient discharge, vs. open cholecystectomy group, which contains a higher postoperative morbidity rate.
7	Yetkin et al., 2009	D	Good	Retrospective cohort This article addresses the laparoscopic management of acute cholecystitis and the conversion rates to open cholecystectomy in patients with severe inflammation and adhesions obscuring the plane of dissection and anatomy around Calot's triangle.
8	Addison et al., 1988	D	Outstanding	Retrospective cohort This article compares early vs. late cholecystectomy in patients older than 70 years. They conclude that early cholecystectomy even in patients over 70 and with serious complications of acute gallbladder disease, is recommended despite high attendant mortality.
9	Knab et al., 2014	F	Good	Guidelines This article addresses the pathophysiology and gold standard treatment of acute cholecystitis.
10	Overby et al., 2010	F	Outstanding	Guidelines This is an article from the Society of American Gastrointestinal and Endoscopic Surgeons addressing the guidelines for the clinical application of laparoscopic cholecystectomy for gallstones and acute cholecystitis.
11	Ching-Ning et al., 2012	A	Good	Retrospective cohort This article addresses the timing of laparoscopic cholecystitis between early and delayed. They conclude that early laparoscopic cholecystectomy leads to shorter hospital stay.
12	Peng et al., 2005	D	Good	Retrospective cohort This article addresses the role of laparoscopic cholecystectomy in the early management of acute calculus cholecystitis and recommends that the surgery be performed within the first 48 h of admission.
13	Norrby et al., 1983	C	Good	Prospective cohort This article addresses early cholecystectomy for acute cholecystitis where surgery is performed within 7 days of onset of symptoms, leading to a shorter hospital stay in the early surgical group and therefore, decrease in insurance payments, and decrease in loss of work capacity.
14	Gurusamy et al., 2013	D	Good	Retrospective cohort This article addresses early vs. delayed laparoscopic cholecystectomy and the fact that the early cholecystectomy group had a statistically decrease in mean hospital stay, decrease in mean operating time, and decreasing mean return to work numbers.
15	Winbladh et al., 2009	A	Adequate	Retrospective cohort This article addresses percutaneous cholecystectomy and procedures performed in elderly or critically ill patients with acute cholecystitis

(*Continued*)

Table 1. Continued

	Publications	Grade	Quality	Comments
16	McGillicuddy et al., 2012	D	Average	Retrospective cohort This article addresses the increased postoperative morbidity in elderly patients, the need for medical management, and subsequent cholecystectomy in patients with recurrent acute cholecystitis.
17	Epocrates; 2014 (online)	F	Good	Guidelines This article addresses the statistical epidemiology of acute cholecystitis, with pathophysiology and treatment recommendations.
18	de Mestral et al., 2013	D	Good	Retrospective cohort This article addresses the fact that in delayed cholecystectomy, only half the patients undergo surgery. This leads to a high mortality rate and an increase in complications.
19	Gelbard et al., 2014	D	Good	Retrospective cohort This article addresses early vs. delayed laparoscopic cholecystectomy in patients with diabetes.
20	Ozkardeş et al., 2014	C	Good	Prospective cohort This article compares the clinical outcome and cost of early vs. delayed laparoscopic cholecystectomy in patients with acute cholecystitis.
21	Ma & Cline, 2012	F	Outstanding	Textbook review Summary, pathophysiology, clinical presentation, diagnoses, and various treatments for cholecystitis.
22	Gutt et al., 2013	A	Outstanding	Prospective cohort This is the (Acute Cholecystitis – early laparoscopic surgery versus antibiotic therapy and Delete Elective Cholecystectomy) ACDC study the largest, randomized trial for laparoscopic cholecystectomy within 24 h of hospital admission or initial antibiotic treatment. It addresses the decrease in mean morbidity rate, decrease in mean hospital stay, and total hospital cost.
23	Jancin, 2013	F	Outstanding	Review and recommendation of ACS This is an article in the American College of Surgeons (ACS) News, which addresses the early surgery recommendations and discusses the ACDC study.
24	Vollmer et al., 2017 (online)	F	Outstanding	Textbook review This article reviews early vs. late cholecystectomy, antibiotics in low-risk patients or more conservative procedure in high-risk patients.
25	Zafar et al., 2015	A	Good	Retrospective cohort This article addresses and reinforces the growing evidence in support of performing early laparoscopic cholecystectomy for acute cholecystitis, and addresses improvement in mortality, length of stay, complications, and cost.

NIH = National Institutes of Health.

utilized until there has been complete resolution of the inflammation, followed by delayed laparoscopic cholecystectomy (DLC) several weeks later (4).

METHODS

This was a structured review of the literature on the topic of acute cholecystitis. A literature search of the National Library of Medicine's Medline database's PubMed system was performed and limited to studies published from January 1982 to July 2016. Inclusion criteria were all studies involving only human subjects and containing the keywords: acute, cholecystitis, acute cholecystitis, early versus delayed laparoscopic cholecystectomy, cholecystectomy, surgical management, and complications. Studies included for the final detailed review were limited to clinical trials, randomized controlled trials, prospective trials, retrospective cohort trials, guideline statements, meta-analysis, general review cases, and case reports in human subjects. The level of evidence was assigned a grade using the definitions as noted in Table 1, and were based on reference focus, specific research design, and methodology (1–25). Each of the selected articles was subjected to a detailed review by the main author and assigned a Quality Ranking based on critical assessment of quality of the design and methodology. The grading system utilized was based on the American Academy of Emergency Medicine clinical practice committee methodology for literature review and evaluates the quality of manuscripts. This includes design consideration (e.g., focus, model structure, presence of controls) and methodology consideration (actual methodology utilized). The definitions of the Quality Ranking scores are included in Table 2.

Independent and joint review of the articles, as well as discussion among the authors, was undertaken to provide

Table 2. Literature Search

Tier 1
Keywords used in search: Dabigatran AND Reversal
Database searched: PubMed
Dates searched: From 2010 to 2017
Limits applied
Limit: Human
Limit: Adult
Limit: English
Final search results with # of references: 315
Tier 2
Keywords used in search: Dabigatran AND Bleeding
Database searched: PubMed
Dates searched: From 2010 to 2017
Limits applied
Limit: Human
Limit: Adult
Limit: English
Limit: Core clinical journals
Final search results with # of references: 337

the best recommendations and conclusions presented in this paper. The references were sorted into three categories: supportive, neutral, and opposed. Table 2 lists the supportive references along with the appropriate location using both Grade and Quality of Evidence.

Finally, recommendations were made based on the review of the literature and assigned a level of recommendation, which is defined in Table 3. The definitions of the Quality ranking scores are included in Table 4. Recommendations were made based on the review of the literature and assigned a level of recommendation which is defined in Table 5.

RESULTS

Recommendation 1: Laboratory Testing in Acute Cholecystitis

Bacterial pathogens present in 50–80% of these cases include enteric bacteria like *Escherichia coli*, *Klebsiella*, and *Enterococcus*. One study concluded that fever was associated with advanced AC; leukocytosis was commonly found in those patients over the age of 45 years (2). Patients with complicated AC were noted to have elevated C-reactive protein. However, neither symptoms nor laboratory values have been found to be very specific or sensitive to the diagnosis of acute cholecystitis (1).

Level of recommendation: B

Table 3. Definitions of the Criteria Used in Assigning a "Grade of Evidence Review" to the Articles

Grade A	Randomized clinical trials or meta-analyses (multiple clinical trials) or randomized clinical trials (smaller trials), *directly* addressing the review issue
Grade B	Randomized clinical trials or meta-analyses (multiple clinical trials) or randomized clinical trials (smaller trials), *indirectly* addressing the review issue
Grade C	Prospective, controlled, nonrandomized, cohort studies
Grade D	Retrospective, nonrandomized, cohort or case-control studies
Grade E	Case series, animal/model scientific investigations, theoretical analyses, or case reports
Grade F	Rational conjecture, extrapolations, unreferenced opinion in literature, or common practice

Recommendation 2: Antibiotics and Intravenous Fluids for Acute Cholecystitis

Patients with acute cholecystitis should be admitted to the hospital for supportive care, which includes intravenous fluid therapy, correction of electrolyte disorders, and control of pain. Antibiotics may also be indicated. Patients have often been ill for days prior to seeking medical attention, making intravenous hydration and correction of any associated electrolyte disorders an important initial measure in the first 24 to 48 h after admission (24).

Level of recommendation: B

Recommendation 3: Ultrasound and HIDA Scan for Acute Cholecystitis

Hepatobiliary (HIDA) ultrasound is the initial diagnostic study of choice (22). Biliary scintigraphy is the gold standard for diagnosis of acute cystic duct obstruction. However, this has reduced specificity in patients with hepatic impairment, patients on parenteral nutrition in a fasting state, and in patients with chronic cholecystitis (1).

Level of recommendation for ultrasound: B

Level of recommendation for HIDA scan: A

Recommendation 5: Surgery for Acute Cholecystitis

Cholecystectomy remains the reference standard for the treatment of AC in patients under the age of 70 years (16). Optimal timing of surgery for acute cholecystitis remains controversial: either early surgery shortly after hospital admission or delayed elective surgery after conservative treatment with antibiotics. In one study, early laparoscopic cholecystectomy (ELC) for AC was superior to DLC as it results in an overall better quality of life, with a decreased waiting period for surgery and shorter hospital stay without any significant difference in perioperative mortality and morbidity. Patients who are eligible for laparoscopic cholecystectomy, presenting with symptoms of < 7 days duration, should have ELC done, preferably within 48 h of admission (12).

In a large, more recent randomized trial (Acute Cholecystitis–early laparoscopic surgery versus antibiotic therapy and Delete Elective Cholecystectomy [ACDC]),

Table 4. Definitions Used to Assign a "Quality Ranking Scores" for the Included Articles

Ranking	Design Consideration Present	Methodology Consideration Present	Both Considerations Present
Outstanding	Appropriate	Appropriate	Yes, both present
Good	Appropriate	Appropriate	No, either present
Adequate	Adequate with possible bias	Adequate	No, either present
Poor	Limited or biased	Limited	No, either present
Unsatisfactory	Questionable/none	Questionable/none	No, either present

laparoscopic cholecystectomy within 24 h of hospital admission was shown to be superior to the conservative approach when concerning morbidity and costs. Therefore, we believe that early laparoscopic cholecystectomy should become the therapy of choice for acute cholecystitis in operable patients if General Surgery and the operating room is available at the time of diagnosis (4).

Level of recommendation: A

DISCUSSION

Cholecystectomy remains the reference standard for the treatment of AC in patients under the age of 70 years. However, the optimal time to perform laparoscopic cholecystectomy was unclear until recently. A recent article performed a prospective study and concluded that laparoscopic cholecystectomy performed within 2 days of presentation of acute cholecystitis yielded the best outcomes and lowest costs (25). Perioperative mortality rates in the elderly or critically ill are high (up to 19%) because these patients have increased comorbidities and are less suitable candidates for general anesthesia (16). In this population, percutaneous cholecystostomy (with an 80% improvement within 5 days of placement) or intravenous antibiotics may be chosen as initial management (17). However, there is still some debate about the management of the cholecystostomy tube and subsequent need for cholecystectomy. Risk factors for complications and predictors for failure of conservative treatment in patients over age 70 are diabetes, distended gallbladder, and persistently elevated white blood cell count (18). Although percutaneous cholecystostomy is often performed with the intention of performing a delayed cholecystectomy, less than half of these patients actually end up having surgery. High mortality and likely ongoing contraindications to surgery preclude definitive intervention in most of these patients, however, they do have the risk of gallstone-related complications leading to emergency department (ED) visits with subsequent high rates of hospital admission (19). In the elderly, due to mortality and morbidity, surgery may be scheduled after initial conservative treatment.

Table 5. Supportive Evidence (Article # Referenced)

Quality/Grade	A	B	C	D	E
Outstanding	22			2, 4, 5, 6, 7, 8	10, 21, 23
Good		20	13	11, 12, 14, 15	1, 3, 9, 17
Adequate				16, 18, 19, 25	24
Poor					
Unsatisfactory					

CONCLUSION

The controversy surrounding timing of laparoscopic cholecystectomy continues. In the United States, surgeons have conflicting responses over the surgical treatment of AC. Some prefer the ELC approach, and others elect DLC. The "largest-ever" randomized trial study presented at the annual meeting of the American Surgical Association in 2013 discussed that the most optimal intervention for AC in operable candidates is early cholecystectomy. Although, as previously mentioned, early cholecystectomy is preferred in most cases, the final decision should be made based on the patient's clinical status and the availability of resources in that particular hospital. Emergency physicians are on the front line of patient care and treatment. This article is meant as a guide to help emergency physicians provide timely and safe treatment based on best practice to their patients presenting with acute cholecystitis in the ED.

Final Recommendations

1. Consult your on-call surgeon (or designated surgeon) for that shift.
2. Disposition of the patient:
   A) After the on-call surgeon is consulted, timing of cholecystectomy should be based on the surgeon's evaluation and decision. If the patient is symptom free and the surgeon wishes to discharge the patient with follow-up in their office, a follow-up appointment should be set up prior to being discharged.
   B) Admit patient to surgical service, or the hospitalist service (as in some hospitals, the hospitalists admit all patients).
3. Make certain that the patient understands the plan and agrees to it.

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HOJA DE VIDA

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Especialista en Cirugía General

a

Carlos Fernando Munar Holguín

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En testimonio de ello le expide el presente Diploma y lo refrenda con el sello de la institución. En la ciudad de Santiago de Cali, Valle del Cauca,
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ESP	Local	ESPECIALIZACION EN CIRUGIA GENERAL	2004-09-17	78557	COLEGIO MEDICO COLOMBIANO
UNV	Local	MEDICINA	1999-08-20	1908	COLEGIO MEDICO COLOMBIANO

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