



Original article

Efficacy of Fibrin-sealants in Reducing Biliary Leakage Following Laparoscopic Common Bile Duct Exploration[☆]

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A B S T R A C T

Introduction: In spite of the acquired experience with laparoscopic common bile duct exploration (LCBDE) for choledocholithiasis management, there is still a risk of biliary leakage of 5–15% following choledochotomy closure. We evaluate the usefulness of fibrin-collagen sealants to reduce the incidence of biliary fistula after laparoscopic choledochorrhaphy.

Methods: We report a retrospective analysis of 96 patients undergoing LCBDE from March 2009 to March 2017, whose closure of the bile duct was completed by antegrade stenting and choledochorrhaphy or by performing a primary suture. The study population was divided into two groups according to whether they received a collagen-fibrin sealant covering the choledochorrhaphy or not, analyzing the incidence of postoperative biliary fistula in each group.

Results: Thirty-nine patients (41%) received a fibrin-collagen sponge while the bile duct closure was not covered in the remaining 57 patients (59%). The incidence of biliary fistula was 7.7% (three patients) in the first group and 14% (eight patients) in the second group ($P = .338$). In patients who underwent primary choledochorrhaphy, the fibrin-collagen sealant reduced the incidence of biliary leakage significantly (4.5% vs 33%, $P = .020$), which was a protective factor with an odds ratio of 10.5.

Conclusion: Fibrin-collagen sealants may decrease the incidence of biliary fistula in patients who have undergone primary bile duct closure following LCBDE.

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Eficacia del sellante de fibrina-colágeno para reducir la incidencia de fístulas biliares tras la exploración laparoscópica de la vía biliar

RESUMEN

Palabras clave:

Coledocolitiasis

Exploración laparoscópica vía biliar

Sellantes biliares

Fístula biliar

Introducción: A pesar de la experiencia existente con la exploración laparoscópica de la vía biliar principal (ELVBP) en el tratamiento de la coledocolitiasis y de su eficacia bien demostrada, hay un riesgo de aparición de fístulas biliares de entre un 5 y un 15% tras el cierre de la coledocotomía. Evaluamos la utilidad de los sellantes de fibrina-colágeno para reducir la incidencia de fístulas biliares tras la coledocorráfia laparoscópica.

Métodos: Presentamos un análisis retrospectivo de 96 pacientes diagnosticados de coledocolitiasis sometidos a ELVBP desde marzo de 2009 a marzo de 2017. El cierre de la vía biliar se completó mediante coledocorráfia tras colocación de stent plástico transpapilar (CS) o realizando una sutura primaria (CP). La población de estudio fue dividida en dos grupos: pacientes con coledocorráfia cubierta con una lámina de colágeno-fibrina (GL) y pacientes con coledocorráfia sin cubrir (GSL). Se presenta el análisis de incidencia de aparición de fístulas biliares postoperatorias.

Resultados: Treinta y nueve pacientes (41%) fueron incluidos en el grupo GL, mientras que el grupo GSL fue formado por los 57 pacientes restantes (59%). Se demostró la homogeneidad de los grupos. La incidencia de fístulas biliares fue del 7,7% (3 pacientes) en el primer grupo y del 14% (8 pacientes) en el segundo ($p = 0,338$). La lámina de fibrina-colágeno redujo la incidencia de fístulas biliares de forma significativa en el subgrupo de los pacientes con CP (4,5% vs 33%, $p = 0,020$), siendo un factor protector con una odds ratio de 10,5.

Conclusión: La lámina de fibrina-colágeno aplicada sobre la coledocorráfia tras un cierre primario de la vía biliar puede tener un papel importante en la reducción significativa de la incidencia de fístulas biliares postoperatorias.

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Introduction

It has been reported that between 10 and 15% of patients referred for laparoscopic cholecystectomy present with choledocholithiasis.¹⁻³ However, a consensus on the best therapeutic approach for bile duct stones has not yet been reached. At present, endoscopic retrograde cholangiopancreatography (ERCP), followed by laparoscopic cholecystectomy (LC) in a second step, is the preferred option in most centers.^{4,5} Despite this, the results of the endoscopic approach and laparoscopic common bile duct exploration (LCBDE) and LC in the same procedure are similar in terms of efficacy and associated morbidity.^{1,6-16} One of the reasons that LCBDE has not become the gold standard for the treatment of choledocholithiasis is due to the technical difficulty and the morbidity associated with the closure of the choledochotomy after the extraction of the calculi. Traditionally, a Kehr T-tube has been used to protect the choledochorrhaphy from biliary fistulae. However, the morbidity associated with the drain tube itself and its withdrawal has led to the progressive replacement of this technique in recent years with the closure of the bile duct protected by transpapillary plastic prostheses or by performing a primary choledochorrhaphy.¹⁷⁻²² Even so, the incidence of biliary fistulae after LCBDE varies between 5 and 15%,^{11,20,22} the main complication being associated with the procedure.

In 2004, a collagen sponge coated with human fibrinogen and thrombin²³ appeared on the market, which was originally used as a hemostatic in liver surgery to cover the transection site.^{24,25}

Subsequently, it was found that the collagen component adds tissue sealing properties, due to which its use has been extended to other purposes. There have been reports of the usefulness of fibrin-collagen patches to reduce the appearance of biliary fistulae after hepatectomy.^{26,27} However, there are no studies in humans that determine the efficacy of biliary sealing to protect choledochorrhaphy after LCBDE. The objective of the present study is to determine the usefulness of fibrin-collagen sealants to reduce the incidence of biliary fistulae after laparoscopic choledochorrhaphy.

Methods

Patient Selection

We performed a retrospective analysis of 96 consecutive patients diagnosed with choledocholithiasis by magnetic resonance cholangiopancreatography (72 cases), transabdominal ultrasound (19 patients), computed tomography (3 cases) and endoscopic ultrasound (1 case). The remaining patient was diagnosed by intraoperative cholangiography. All patients underwent elective LCBDE surgery at our medical center between March 2009 and March 2017. The protocol for the treatment of choledocholithiasis included LCBDE and LC for all patients, except patients who did not present a dilated bile duct (<9 mm measured on imaging tests) were cholecystectomized or had limited quality of life with important comorbidity ruling out surgery. These patients underwent ERCP, with or without subsequent LC.

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