

# Common bile duct pressure after open intraoperative instrumentation in patients with uncomplicated choledocholithiasis

*Presión del conducto biliar común después de instrumentación transoperatoria abierta en pacientes con coledocolitiasis no complicada*

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## Abstract

**Background:** Common bile duct pressure (CBDP) after surgical exploration has not been fully detailed. The objective was to describe the changes of CDPB after open surgical exploration in patients with choledocholithiasis, considering clinical scenarios in remote locations. **Material and methods:** A before-after study was designed. Patients with choledocholithiasis who required an open cholecystectomy with exploration of bile ducts were included in the study. Open cholecystectomy was performed and perioperative T-tube CDPB was registered immediately after the procedure and weekly thereafter, with a 6 week follow-up. Control T-tube cholangiogram was performed at week 6 to exclude residual stones. Data were analyzed with T test for paired samples. **Results:** Thirteen patients were included (age range, 17-69 years;  $38.69 \pm 17.97$ ). Mean CDPB (cm H<sub>2</sub>O) registered were as follows: Initial = 19.5, week 1 = 16.2, week 2 = 14.3, week 3 = 13.0, week 4 = 12.1, week 5 = 11.1, and week 6 = 9.7. There were significant differences shown when comparing week 2 ( $p = 0.05$ ), week 3 ( $p = 0.036$ ), week 4 ( $p = 0.023$ ), week 5 ( $p = 0.010$ ), and week 6 ( $p = 0.004$ ) with the initial value. **Conclusions:** CDPB decreases between 2<sup>nd</sup> and 3<sup>rd</sup> post-operative weeks. The use of choledochomanometry is useful in clinical scenarios with no access to imaging or interventionism facilities as in remote populations or rural locations.

**Keywords:** Choledocholithiasis. Cholecystectomy. Common bile duct. Common bile duct pressure. Cholangiography. Common bile duct stones.

## Resumen

**Antecedentes:** La presión del conducto biliar común (PCBC) después de exploración quirúrgica no ha sido totalmente detallada. El objetivo fue describir los cambios de la PCBC tras exploración por coledocolitiasis. **Material y métodos:** Estudio de antes y después, en pacientes con coledocolitiasis, que requirieron colecistectomía con exploración de vías biliares, registrando la PCBC por 6 semanas. Con colangiografía por sonda en T en la semana seis. Análisis con T de Student para muestras pareadas. **Resultados:** Se incluyeron 13 pacientes (rango 17-69 años;  $38.69 \pm 17.97$ ). Las presiones medias del CBC fueron: Inicial = 19.5, semana 1 = 16.2, semana 2 = 14.3, semana 3 = 13.0, semana 4 = 12.1, semana 5 = 11.1 y semana 6 = 9.7. Se mostraron diferencias significativas al comparar la semana 2 ( $p = 0.05$ ), la semana 3 ( $p = 0.036$ ), la semana 4 ( $p = 0.023$ ),

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la semana 5 ( $p = 0.010$ ) y la semana 6 ( $p = 0.004$ ) contra el valor inicial. **Discusión:** La PCBC disminuye entre la segunda y la tercera semana posoperatoria. La coledocomanometría muestra ser útil en escenarios clínicos sin acceso a intervencionismo como en poblaciones remotas o localidades rurales.

**Palabras clave:** Choledocolitiasis. Colecistectomía. Coléodo. Presión del coléodo. Colangiograma. Litos en conducto biliar común.

## Introduction

Choledocholithiasis is a condition in which one or more gallstones are present in the common bile duct (CBD). Its prevalence is 10% to 20% in those with cholelithiasis, although the natural history of CBD stones is not well understood. Bile stones can be divided into two separate entities in relation to their site of origin; primary (bile ducts) and secondary (gallbladder). Secondary stones are by far the most common in America, including Mexico. These stones originate in the gallbladder and migrate to the CBD by means of the cystic duct<sup>1,2</sup>. The prevalence in Mexico was reported in the 1990's to be 14.3% (8.5% for men and 20.4% for women) in a large necropsy study<sup>3</sup>, and in a more recent study it was reported to be 13.2%<sup>4</sup>.

The goal of its management consists of clearing the CBD of stones by either endoscopy or surgery. Actual treatment options include endoscopic retrograde cholangiopancreatography (ERCP) with laparoscopic cholecystectomy (LC) or laparoscopic common bile duct exploration (LCBDE) with LC. Nevertheless, in developing countries it is not always a possibility, being forced to resort to open exploration of the CBD, which implies temporary CBD drainage by means of a T tube<sup>2</sup>.

However, after intraoperative exploration of the CBD, inflammatory changes secondary to manipulation could happen, and they may alter CBD pressure. In a study conducted in the late 1980s, it was found a fall from an initial CBD pressure value of  $17.2 \pm 1.9$ - $9.1 \pm 0.9$  cm bile on the seventh post-operative day, but exploration with metal instruments was avoided, and stone extraction was effected by irrigation and biliary balloon catheters<sup>5</sup>.

The aim of this study is to describe the behavior of the intraluminal CBD pressure after open surgical instrumented exploration (Randall forceps) of the bile ducts in patients with uncomplicated choledocholithiasis.

## Materials and methods

A double blinded nonrandomized before-after trial was designed for common bile duct (CBD) pressure

measurement during and after open surgical management of uncomplicated choledocholithiasis at Hospital General de México "Dr. Eduardo Liceaga".

All patients gave their informed consent to be included in the study to be managed by elective open cholecystectomy and operative exploration of the common bile duct. Two patients were eliminated because they did not complete the follow-up period. The authors declare that the study was registered and authorized by the institution's research ethics committee in accordance with the 1975 Helsinki Declaration and its subsequent revisions (including the emanating from the 64<sup>th</sup> general assembly in Fortaleza, Brazil, in October 2013) in accordance with good clinical practices<sup>6</sup>, and was registered at ClinicalTrials.gov (NCT04968873).

During elective open cholecystectomy, a basal CBD manometry was obtained immediately after cholecystectomy, with a 10 Fr. silicone tube introduced into the cystic duct and connected to a glass manometer. The zero reference was set as the level of the cystic-choledochal junction. Pressure was expressed in cm H<sub>2</sub>O. After registering the baseline CBD pressure, a careful CBD intraluminal exploration (CBDE) was carried out with Randall forceps. A Foley catheter (12 Fr. Silicone-coated Foley catheter) was introduced into the cystic duct and saline water infusion was performed for lavage. Then, a T-tube (14 Fr, Kerr latex T-tube) was introduced into the CBD and the proximal end was externalized through an independent skin incision and fixed as routine.

A post-operative cholangiogram was obtained through the T tube and an initial CBD pressure was immediately registered after verifying no residual intraluminal stones, with the zero reference taken at the cystic-choledochal junction, in the mid axillary line. Thereafter a weekly follow-up was carried out for a period of 6 weeks (for study purposes) by another surgeon, totally blinded to the aim of the study and to the initial CBD lecture, adhering to the described method. Finally, liver function tests and a T-tube cholangiogram were carried out on all patients at week 6.

## Statistical analysis

The sample size ( $n = 15$ ) was calculated to reach a confidence level of 95% with a power of 90% for an expected difference of 4.2 (standard deviation of 4.8), based on the study reported by Csendes<sup>7</sup>. Accepting an alpha risk of 0.05 and a beta risk of 0.1 in a two-sided contrast, 15 subjects are required to detect a difference equal to or  $> 4.2$  units. A standard deviation of 4.8 is assumed. A tracking loss rate of 5% has been estimated.

Values were expressed as mean and standard deviation (SD) of the mean. For statistical evaluation, T test for parametric values was employed, considering significance at 5% level.

## Results

Twelve patients were female (92.6%) and one was male (7.6%), with a mean age of 38.69 years ( $SD \pm 17.75$ ) (Table 1). Initial liver function tests were abnormal in all 13 patients, with increased values of total and direct bilirubin, alkaline phosphatase, AST, and gamma-glutamyl transpeptidase.

Among the 13 patients studied, no complications were reported, but one maintained a high CBD pressure during all follow-up period because of residual choledocolithiasis. In the final T tube cholangiogram at week 6, a residual stone was evidenced and extracted through the existing fistula by an interventional radiologist. CBD pressure was monitored again, decreasing to normal parameters by week 8. Thus, it was excluded from the statistical analysis to assess the behavior of CBD pressures in the rest of the group.

Values of the CBD pressure evolution of all cases are shown in table 1. Initial mean CBD pressure was 19.5 cm H<sub>2</sub>O (highest value 38 cm H<sub>2</sub>O). Weekly mean values were decreasing constantly, at a mean rate of 1.59 cm H<sub>2</sub>O per week. Mean CBD pressures at weeks 1 and 2 were 16.21 cm H<sub>2</sub>O and 14.33 cm H<sub>2</sub>O, and when compared to mean CBD initial pressure, no significant differences occurred (week 1,  $p < 0.134$ ; and week 2,  $p < 0.05$ ). Meanwhile, the mean CBD pressures during weeks 3-6 were significantly low when compared to the mean initial CBD pressure (Table 2).

Values of the CBD pressure evolution for the case with the residual stone are shown in table 3, depicting a similar decrease as with the other cases, once the

residual stone was removed at week 6, to reach a normal value after week 9.

Final liver function tests were completely normal in all 13 patients, as well as final T tube cholangiogram (at week 6) in all cases but the one previously described to have had a residual stone.

## Discussion

At present, open choledochotomy still plays a role in cases diagnosed with choledocholithiasis with or without cholangitis, while endoscopic, percutaneous, or laparoscopic approaches failed, or are not available, as in remote populations or rural locations. Furthermore, it could also be used in the case of a preexisting open surgery that limits the application of endoscopic approaches, as in Roux-en-Y enteral reconstruction after gastrectomy<sup>8</sup>.

The residual stone rate of routine CBDE is about 7-11% and in recent studies < 6%. In addition, stones proximal to the cystic duct-CBD junction can be extracted in only 40% of cases, requiring either a laparoscopic or open choledochotomy<sup>9-11</sup>.

Thus, the results of the present study lead to a series of clinical relevant observations.

First, CBD pressure after open surgical exploration significantly decreased week by week, being the first significant decrease near the 3<sup>rd</sup> week. Apparently, surgical manipulation (Randall forceps exploration) causes CBD intraluminal inflammatory changes that tend to maintain a high CBD pressure, reaching its peak by the end of the 2<sup>nd</sup> week. Then, the inflammation progressively decreased to permit intraluminal pressure to reach physiologic parameters. Thus, CBD intraluminal manometry could be used to indirectly monitor the inflammatory process of the ampulla of Vater.

Second, the previous studies have described that CBD pressure was higher in patients with CBD stones compared to patients without them<sup>4,6,12</sup>. In this study, one patient maintained high CBD pressure values during the entire evaluation period. At the end of follow-up period, the T tube cholangiogram demonstrated the presence of a residual stone, which was successfully removed by the endoscopist after which the same pattern of decreasing CBD pressure was observed. During the post-operative period, findings of CBD pressure values higher than 20 cm H<sub>2</sub>O<sup>7,12</sup> suggest the possibility of a persistent inflammatory process or an obstruction of the lumen (residual stone). Again, it allows us to assume that the use of choledochomanometry can be useful, mostly in clinical

**Table 1. Demographic characteristics and individual common bile duct pressure by week**

Age	Sex	Surgery	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 9	Week 12
51	Male	38.0	19.7	18.2	15.7	13.7	13.1	9.5	NA	NA
54	Female	17.3	13.0	12.7	11.6	10.6	9.7	9.2	NA	NA
61	Female	15.3	13.8	11.0	10.2	8.5	9.2	8.7	NA	NA
52	Female	16.9	14.7	13.3	8.0	8.0	9.0	9.3	NA	NA
17	Female	19.2	15.8	13.2	12.2	11.7	10.1	9.0	NA	NA
18	Female	20.5	20.2	17.3	14.6	13.3	12.6	10.2	NA	NA
34	Female	16.1	13.9	11.3	10.8	10.4	10.2	9.8	NA	NA
19	Female	18.7	16.4	13.1	14.4	17.0	12.8	10.3	NA	NA
32	Female	21.6	21.0	20.0	17.6	15.8	14.0	11.6	NA	NA
18	Female	21.6	18.7	17.1	18.0	16.2	13.3	12.0	NA	NA
69	Female	17.8	14.3	12.8	11.3	10.1	9.6	9.4	NA	NA
36	Female	11.0	13.0	12.0	11.6	9.7	9.4	8.0	NA	NA
42	Female	21.1	23.5	24.0	22.2	23.3	21.6	19.8	15.6	9.1

NA: not available

**Table 2. Mean common bile duct pressure by week**

Moment	n	Mean CBDP (cm H <sub>2</sub> O)	Range (cm H <sub>2</sub> O)	Statistical comparison (p)
Surgery	12	19.50	11–38	-
Week 1	12	16.21	13–21	Initial versus week 1 (0.134)
Week 2	12	14.33	11–20	Initial versus week 2 (0.050)
Week 3	12	13.00	8–18	Initial versus week 3 (0.036)*
Week 4	12	12.08	8–17	Initial versus week 4 (0.023)*
Week 5	12	11.08	9–14	Initial versus week 5 (0.010)*
Week 6	12	9.75	8–12	Initial versus week 6 (0.004)*

\*Significant (T-test for one sample). CBDP: Common bile duct pressure, n: sample

**Table 3. Common bile duct pressure of patient with residual stone**

Moment	CBDP (cm H <sub>2</sub> O)
Intraoperative	21.10
Week 1	23.50
Week 2	24.00
Week 3	22.20
Week 4	23.30
Week 5	21.60
Week 6	19.80
Week 9	15.60
Week 12	9.10

CBDP: common bile duct pressure

scenarios with no access to imaging or interventionism facilities as in remote populations or rural locations. Furthermore, it is a usual practice in Mexico, that senior residents serve in rural hospitals at least during a 4-month period, where there is a lack of facilities for this kind of surgical procedures, making this practice to become a feasible option.

Thus, in countries where there is a lack of medical funding in public medical care services, this procedure could be an alternative in the follow-up period.

Finally, surgeons must provide different alternatives in therapeutic and diagnostic approaches to the

patient. Cholangiomanometry proves to be a complementary, accessible, inexpensive, safe, and efficient method for patients with choledocholithiasis.

## Conclusions

The common bile duct pressure decreases between the second and third postoperative weeks. Choledochomanometry let us monitor CBD pressure

and is a useful approach in clinical scenarios as remote populations or rural locations with no access to endoscopic facilities.

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## Conflicts of interest

The authors declare no conflicts of interest.

## Ethical disclosures

**Protection of humans and animals.** The authors declare that no experiments on humans or animals were performed for this research.

**Confidentiality of data.** The authors declare that they have followed their center's protocols on the publication of patient data.

**Right to privacy and informed consent.** The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the corresponding author.

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