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Sequential treatment of common bile duct lithiasis: Our 14 years experience.

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Abstract:

Background:
Sequential treatment (ST) is one of the therapeutic options for common bile duct lithiasis (CBDL), combining two minimally invasive procedures: primary endoscopic sphincterotomy (ES), and secondary laparoscopic cholecystectomy (LC). The aim of our study is to evaluate this therapeutic option in our environnement, and compare its morbidity with the available medical litterature in the same subject.

Methods:
This is an uni-centric retrospective study conducted over a period of 14 years, collecting all patients who underwent ST of CBDL in our institution.

Results:
93 patients were included in the study with a sex ratio of 0.75. The mean age of our patients was 55 years. 54,83 % were classified as ASA I, 37,63% as ASA II, and 03,7 % cateorized as ASA III. The mean diameter of the main bile duct was 9.75 mm (5-14 mm). CBDL was suspected on clinico-biological predictive criteria and confirmed by bili-MRI in 63,44 % of cases and by endoscpic ultra-sonography in 42% of cases. The time between ES and LC varied from 01 day to 14 months with a mean of 63 days. The success rate of ST in our institution is 85%. The mortality rate was nil and the morbidity rate was 07,52. The ST with its good results could be the gold standard for preoperatively discovered CBDL. Only the adoption of close cooperation between surgeons and gastroenterologists is able to reduce the delay between its two procedures, to protect patients from possible recurrence of any biliary event.

Conclusions:
ST is a good treatment procedure in our environnement. To improve its results, this procedure must be performed by experienced operators, with the aim of reducing morbidity and mortality.

Keywords: sequential treatment-endoscopic sphincterotomy-laparoscopic cholecystectomy-morbidity- residual lithiasis-conversion.

1. Introduction :

Bile duct stones (choledocholithiasis) most frequently result from the migration of gallstones from the gallbladder into the biliary tree. Gallstones are the consequence of cholesterol supersaturation in bile, inappropriate

bile salt levels or function, and lack of contractility of the gallbladder wall because of the multifactorial effects of diet, hormones, and genetic predisposition [1,2]. In 10-18% of laparoscopic cholecystectomies, there is synchronous common bile duct lithiasis (CBDL) [3]. Half of the asymptomatic CBDL migrate within 6 weeks [2] and therefore treatment of CBDL should mainly be directed at forms complicated by angicholitis or pancreatitis [3]. Furthermore, choledocholithiasis is the leading cause of acute pancreatitis, which results in 275,000 hospitalizations annually at a cost of 2.6 billion dollars [4].

Endoscopic sphincterotomy (ES) as a treatment for CBDL has been performed since 1974 [5] and the first laparoscopic cholecystectomy (LC) was performed in 1987 [6].

Sequential Therapy (ST) is one of several treatment modalities for CBDL. It combines two minimally invasive approaches: a primary ES and a secondary LC. Due to the success of this approach, 150.000 ES are performed annually in the USA [7].

2. Materiels and methods:

This is a uni-centric retrospective study which took place over a period of 14 years devided in two sequences: first sequence from 02/01/2004 to 31/12/2015, and second sequence from 01/08/2019 to 31/12/2021 in collaboration with the General Surgery Department A of HCA and the Gastroenterology Department of the same hospital. The aim of our study is to evaluate the ST as a therapeutic modality for CBDL in our environment, and to compare our results with those of the available medical literature.

- ***Inclusion criteria:***

Patients with complicated or uncomplicated CBDL who have undergone ST.

- ***Exclusion criteria:***

- Already patients having cholecystectomy in their clinical story;
- Who had undergone surgical treatment of CBDL;
- With an associated malignant non-lithiasis biliary pathology (tumor, malignant stenosis);
- With a contraindication to ES or LC.

The study was based on anamnestic, clinical, biological, radiological, operative and hospitalization data in the archives (computerized or not) of the general surgery department A, and Gastro-enterology department of our institution. Those informations were collected with the help of a data processing form dedicated to each patient and meeting the objectives of the study.

The analysis of the results was based on Microsoft EXCEL 2013 software.
The ethic committee of our institution approved this work; and all the patients recruited give us their approbation after informed consent.

3. Results :

The number of patients is 93 with a sex ratio of 0.75 (53 women and 40 men). The average age of our patients is 55 years (extremes 19-86 years). The average body mass index of our patients is estimated at 25.83 with extremes ranging from 20 to 37.11.
Regarding the American Anesthesiology Scoring (ASA): 51 patients are classified in category I (54,83%), 35 in category II (37,63%), three patients in category III (03,2%) and five uncategorized (05,37%). The duration of symptoms was 6 months with extremes ranging from one day to two years. The symptomatology was dominated by angiocholitis in 31 patients (33,33%), pancreatitis in 15 patients (16,12%), and a combination of the two pathological entities in 13 cases (14%). Only colic hepatitis in 23 cases (24,73%) and imprecise symptomatology in ten cases (10,75%). In total, 63,44% of the cases were complicated forms of CBDL.
Liver function tests were abnormal in 68,88% of cases and normal in 13% (12 patients) and unspecified in the remaining 18,27%. The different types of biological abnormalities were cholestasis with accompanying cytolysis in 33 patients (35,48%), isolated cholestasis in 17 cases (18,27%).
Investigations for the common bile duct (CBD) consisted of trans-parietal ultrasound in all patients. Bili-MRI in 38 patients (40,86%), abdominal CT scan in 30 patients (32,25%), bili-MRI combined with endoscopic ultra-sonography (EUS) in 21 patients (22.58%) and EUS alone in 18 patients (19,35%).
On the first endoscopic step, the average diameter of the CBD was 09.75 mm (extremes 05-
19,4). The number of stones found varied from 01 to 49 stones. The average size of the stones was 10 mm (05-20 mm). Sphincterotomy allowed the removal of stones in 70 cases (75.25%), a negative sweep ("white sphincterotomy") was noted in 16 cases (17.2%). The removal or not of stones after ES was not mentioned in 07 cases (07,52%). The instrumental method used in the extraction of lithiasis was the balloon in 70 % of cases, the Dormia probe in 30 %, and the combination of both devices in 7 % of cases. The procedures associated with ES consisted of two papillary biopsies, the placement of a biliary stent in three cases, a pancreatic stent placement in three cases also in order to prevent an acute pancreatitis.
Vacuity of the main bile duct was achieved after the first attempt in 79 cases (84.94%), after the second attempt in ten cases (10.75%) and after the third attempt in four cases (4.3%).

The morbidity of this first endoscopic stage of the ST, consisted of 04 post-ES pancreatitis (Clavien and Dindo Grade III), as well as a serious digestive haemorrhage requiring a stay in intensive care unit in one case (Clavien-Dindo Grade IV). This brings the overall morbidity of this first stage endoscopy to 05.37%, with no statistical difference between the two sequences in term of morbidity. The average time between ES and CL was 63 days with extremes ranging from one day to 14 months in the first sequence, and extremes ranging from 11 days to 10 months in the second sequence. This abnormal delay between the two procedures is essentially due to a lack of coordination between the two unities (Surgery department A and endoscopy). In the second sequence, the Covid 19 pandemic by considerably disrupting the care pathway for patients, has not helped matter.

In the stage of surgery, pneumoperitoneum was induced mainly by open laparoscopy in 92 cases, and by Palmer needle in one case. The average duration of the LC was 86 minutes with extremes ranging from 30 to 180 minutes. The conversion to open cholecystectomy concerned nine patients (09,67 %). The reasons for this conversion were shielding of the subhepatic region in five cases, the presence of a cholecysto- duodenal fistula in two cases and the presence of pediculitis hindering the dissection of the biliary tripod in two cases, and preventing the safety critical view of the cystic pedicle elements from being obtained.

We collected two residual lithiasis (02,15 %) treated by laparotomy with a cholecyctomy and choledocotomy with placement of a Kehr drain (T-Tube) after having ensured the vacuity of the CBD by intraoperative cholangiographic control.

The morbidity of CL was biloma in one case (Clavien and Dindo grade IIIb), and acute renal failure in an another patient (Clavien and Dindo grade I) that progressed favourably after initiation of a rehydration regimen, which brings the rate of surgical morbidity to 02,15%.

There was no mortality in the whole series. And the global morbidity of the ST in our serie is 07,52%.

4. Discussion :

There is no consensus for selecting the best tool to the diagnosis of CBDL. The table 1 summarises the diagnostic and therapeutic strategy according to the degree of suspicion of choledocolithiasis.

Table 1: Proposed strategy to assign risk of choledocholithiasis and manage patients with symptomatic cholelithiasis based on clinical predictors according to Buxbaum and al [8].

Probability	Predictors of choledocholithiasis	Recommended strategy
High	Common bile duct stone on US/cross-sectional imaging or Clinical ascending cholangitis or Total bilirubin >4 mg/dL and dilated common bile duct on US/cross-sectional imaging	Proceed to ERCP
Intermediate	Abnormal liver biochemical tests or Age >55 years or Dilated common bile duct on US/cross-sectional imaging	EUS, Billi-MRI, laparoscopic IOC, or intraoperative US
Low	No predictors present	Cholecystectomy with/without IOC or intraoperative US

IOP : Intra-operative cholangiography.

However, an important consideration is the cost of EUS, particularly if anesthesia services are used for sedation, and the fact that it is operator-dependent. Those diagnosis tools (Bili-MRI, EUS) may select the patients to avoid an unecessary sphincterotomy when showing a free common bile duct from lithiasis.

There are several treatment options for CBDL (Table 2).

Table 2: The different treatment modalities for CBDL.

1. SE before CL
2. SE+CL on the same day ("Appointment" or “Rendez-vous” technique)
3. SE after CL
4. All laparoscopic (CBD > 6mm)
5. Open treatment (conventional)
6. Medical treatment + armed surveillance (Asymptomatic calculi < 4mm)

However, there is no consensus on the best modality for the management of CBDL [9]. This decision depends on the patient's septic and haemodynamic status and the expertise of each center. In patients with gallstone pancreatitis without cholangitis or biliary obstruction/choledocholithiasis we recommend against urgent (within 48 hours) ERCP (Endoscopic Retrocholangiopancreatography) with strong recommendation and a low quality of evidence [4].

ST is increasingly used in the treatment of CBDL. It could be the gold standard for preoperatively discovered CBDL [10,11]. In our series, it mainly concerned complicated CBDL (63,44% of cases).

The rate of ES without extraction ("white ES") in our study was 14.28%. The rate of "white ES" varies from 15 to 25% in the literature [8].

In patients with large choledocholithiasis (over 10 mm in diameter), we suggest performing large balloon dilation (LBD) after sphincterotomy rather than endoscopic sphincterotomy alone with a moderate quality of evidence [4]. Teoh et al reported that overall cost of hospitalization was less for ES-LBD, $ (U.S.) 5025 (interquartile range [IQR], 4150- 5235), than ES, $6005 (IQR, 4462-5441) [12].

If the conventional approach (ES with more or LBD) fails, the intraductal approach (lithotripsy or laser) should be used.

Plastic and covered metal stents may facilitate removal of difficult choledocholithiasis but require planned exchange or removal. Stent favors removal of challenging choledocholithiasis by fragmentation by direct mechanical friction and by inducing papillary dilation [6].

In our series, there are on average quite long delays between ES and LC (63 days or 09 weeks). In the literature, there are proponents of short delays (72 h) [13] and those of long delays (04-06 weeks or more) (14). Long delays between the two procedures would expose patients to more biliary events, and each episode of pancreatitis and cholangiotis has its own morbidity and mortality, and increases the cost of management. The mortality rate of ES varies in the literature between 0.2-2.3% and the morbidity rate between 5 and 9.8%. [10, 11, 15-16]. In the case of sphincteroclasia for large stones, this morbidity could be as high as 15%. In our study, mortality was nil and morbidity was 07,52%.

The mortality of LC in the literature is less than 01%, and the morbidity varies from 04% to 17% [17, 18]. In our series, the mortality of LC is nil, and the morbidity is low at around 02.15%.

The conversion rate found in our series, which is 09,67%, is in line with the literature (04-30%) [19]. The overall success rate of the ST procedure is 71%, in our study it was estimated at 85 %. The main independent factor for failure of the procedure is the presence of a choledocholithic obstruction [20].

The rate of residual lithiasis in the literature is 02% [21] in our study it was estimated at 02,15% including Mirizzi syndrome type II in one case that was treated by intra-operative cholangiography with T-tube placement (Figure 1). Our Mirizzi syndrome was completely ignored by ERCP, but in the medical litterature ERCP is well established as a method to diagnose Mirizzi syndrome and temporize biliary obstruction with biliary stent placement before definitive surgical treatment. Larger series revealed a success rate of 75% to 91% for cholangioscopy-guided intraductal approaches to treat Mirizzi syndrome [22,23].

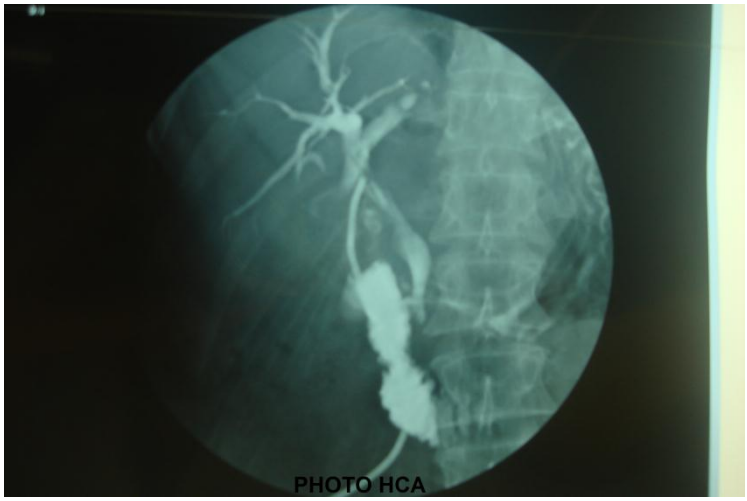

Figure 1: Peri-operative cholangiography view of a Mirizzi syndrome type 2 which was ignored in the ERCP step, and pushed as to a conversion at the step of LC. The T-tube was placed into the bilio-biliary fistulae after removing a large stone.

In the Cochrane Data base meta-analysis of 07 trials with 746 patients, the comparison of the following treatment modalities: appointment technique

(rendez-vous) with ES followed by LC and LC followed by ES showed identical morbidity and mortality. Similarly, there was no statistically significant difference between the residual lithiasis rate and the conversion rate. However, the parameters relating to quality of life, hospital stay and cost were not specified [19]. The disadvantages of the appointment technique are the presence of two different teams, imposing positions on the patient which can be uncomfortable for both parties. In addition, the procedure is time-consuming, and both endo and exo-luminal insufflation (pneumoperitoneum) causes mutual discomfort [24]. In a randomized trial comparing LC-BDE versus ERCP followed by LC, Bansal et al determined that the former was less costly with an incremental cost effectiveness ratio, measuring the difference in cost versus effect of the 2 approaches, of $1182.70 [25]. Finally, Borreca proposes an alternative to the appointment technique, an ultra- rapid ST, thus shortening the time between the two procedures through better logistics. This ultra- rapid ST shortened the hospitalization time compared to a classic ST (p: 0.001) and also significantly reduced the rate of residual lithiasis (p: 0.002 and OR;14,13) [26].

The overall cost of ST has been estimated at 4000 $a in both China and Ukraine. In Italy, this procedure is charged at 7000 $ [21, 23]. In Algeria, the approximate cost of a ST procedure in private practice is estimated at 200,000 Algerian dinars. In our series, the cost of the procedure was not evaluated because in hospital practice, the cost of this procedure is more difficult to assess. It is estimated between 20,000 and 30,000 Algerian dinars. Totally laparoscopic treatment of CBDL is an elegant treatment option that avoids ES and its morbidity and mortality [10, 24]. It is especially interesting in elderly subjects with comorbidities to limit the number of procedures. However, it requires a certain laparoscopic expertise and more material resources (a 30 degree optic and a 05 mm flexible choledoscope). The latter option allows for a reduction in the length of hospital stay. Its success rate sometimes exceeds 89% [26].The surgeon can resort to drainage of the CBD by different procedures (trans-cystic drain, stent or Kehr drain) or resort to an ideal choledocotomy without drainage [10, 27-29]. Morbidity is dominated by biliary leaks in 09 to 24 % and mortality is around 02 % [21]. In the Gantois study, the success rate of all-laparoscopy procedure is 92.5%, compared to a success rate of only 73.8% for ST in a population of subjects aged over 75 years [9].

The main limitation of our study is that it is retrospective and small in number due to its single-centre nature, and the choice of ST as the therapeutic modality for CDCL was essentially linked to the technical platform.

5. Conclusion :

With low morbidity and zero mortality, ST is a good option in our environment. Despite its minimally invasive nature, this therapeutic modality should be reserved for complicated forms of CBDL. Prior information of patients on the risks of ST is essential. A rigorous multidisciplinary selection of patients to benefit from this procedure must be carried out to reduce the rate of "white" SE without stone extraction. Close coordination between gastroenterologists and surgeons is trivial to reduce delays between the two procedures.

Conflict of interest: The authors have declared no conflicts of interest related to this article.

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