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Endoscopic papillary large balloon dilatation (EPLBD) for the extraction of common bile duct stones (CBDS)

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ABSTRACT

Background and aim: endoscopic papillary large balloon dilatation (EPLBD) is increasingly accepted as an appropriate option for the management of difficult common bile duct stones (CBDS). This study aimed to evaluate the safety and efficacy of EPLBD with a relatively large balloon (15-20 mm) for the extraction of difficult CBDS.

Patients and methods: a total of 40 patients were recruited with obstructive jaundice and dilated CBD (≥ 10 mm) subsequent to a single large CBDS of ≥ 10 mm or multiple stones (≥ 3). All patients underwent endoscopic retrograde cholangio-

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pancreatography (ERCP) with limited sphincterotomy and large balloon dilatation followed by stone extraction using an extraction balloon or dormia basket, without lithotripsy, stenting or further ERCP sessions.

Results: successful stone extraction was achieved in 34 patients (85%) and stone extraction failure occurred in six patients (15%). Complications included minimal pancreatitis in four cases (10%), mild pancreatitis in two cases (5%), cholangitis in two cases (5%) and bleeding in two cases (5%). There were no recorded cases of perforation or mortality subsequent to the procedure.

Conclusion: EPLBD is a safe and efficient procedure for the extraction of difficult CBDS and may be advisable in patients with a bleeding risk or abnormal papillary anatomy.

Key words: Endoscopic papillary large balloon dilatation (EPLBD). Common bile duct (CBD). Endoscopic biliary sphincterotomy (EBS). Endoscopic retrograde cholangio-pancreatography (ERCP).

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is the first-line treatment for CBDS (1). It includes several techniques such as endoscopic biliary sphincterotomy (EBS), laser lithotripsy, endoscopic papillary balloon dilatation (EPBD) and endoscopic papillary large balloon dilatation (EPLBD) (2). EBS is the most commonly used technique for the removal of bile-duct stones. However, it has substantial procedure-related risks, such as hemorrhage and perforation, and also has an increased incidence of ascending cholangitis and *de novo* formation of bile-duct stones, especially in younger patients (3). Lithotripsy is a stone fragmentation procedure and is used to decrease the size of large stones to facilitate their removal or passage from the biliary or pancreatic ducts, or to dislodge impacted stones (4).

Endoscopic papillary balloon dilation (EPBD) is an alternative to EBS for the management of CBDS and was first described by Staritz et al. (5). This procedure is performed to expand the ampullary orifice with a balloon that measures less than 10 mm diameter, without performing an endoscopic sphincterotomy (6). The main

disadvantage of EPBD is the associated increased risk of pancreatitis (6). Furthermore, EPBD is limited in cases of large stones of more than 10 mm and wide EBS combined with ML are frequently required (7).

Ersoz et al. (8) described the technique of endoscopic papillary large balloon dilation in order to overcome these limitations in the formal ERCP techniques, especially with a large stone size or multiple stones. This involves the dilation of the biliary sphincter with a large-diameter (12-20 mm) dilation balloon after limited sphincterotomy. The length of sphincterotomy varies substantially between centers. However, most experienced endoscopists perform small or midsize EBS (i.e., 1/3 to 1/2 of the distance to the papillary roof) before large balloon dilation. This step is thought to reduce the bleeding risk (9).

Controlled radial expansion balloons (CRE) that deliver stepwise inflation are often preferred. The choice of balloon size varies among studies but many recommend limiting the maximum size of the balloon to the size of the native distal bile duct (10). The major endpoint for balloon inflation is the disappearance of the notch on the balloon under fluoroscopic guidance. The balloon is then kept inflated for different time periods ranging from 0 seconds to 2 minutes (11). It has been suggested that a persistent notch or continued resistance during balloon inflation at 75% of the manufacturers' maximum recommended pressure may be considered as a contraindication to EPLBD (12). EPLBD is an excellent option for the management of difficult CBDS. EPLBD may be prospectively applied in patients with complicated papillary anatomy, coagulopathy or those who cannot tolerate wide EBS or EPBD for any other reasons due to the minor incision required, short procedure time, reduced requirement for ML and the low frequency of adverse events (13). There is no increase in pancreatitis associated with EPLBD. This may be due to the fact that a prior EBS helps to separate the pancreatic orifice from the biliary orifice and guide the orientation of the dilated balloon towards the CBD. Thus, preventing pressure overload on the main pancreatic duct (14). The other possible reason may be the longstanding CBD stones, which lead to the dilation of CBD and make the papillary orifice persistently open (15). It has been suggested that post-procedure pancreatitis may not be associated with larger balloon size but more related to longer procedure

time and a less dilated CBD (16).

Perforation is the most serious adverse event of EPLBD and is more likely to occur in those with a distal CBD stricture. Thus, appropriate patient selection is important (17). Generally, candidate patients for EPLBD may be those with CBD dilation but without strictures of the distal CBD and the size of the selected balloon should not exceed the maximal diameter of the CBD (14). Bleeding remains one of the most common adverse events. Self-limiting oozing during EPLBD is common and is not usually considered as a complication. Most bleeding episodes are described as mild to moderate and managed conservatively with a blood transfusion or endoscopic intervention (2). The frequency of cholangitis does not seem to increase after EPLBD. This may be due to the wider papillary access achieved with a large balloon inflation and effective biliary drainage, both of which contribute to prevent the obstruction of the ampullary orifice and relieve papillary edema (13). The aim of our study was to evaluate the safety and efficacy of EPLBD with a relatively large balloon (15-20 mm) for the extraction of a difficult CBDS ≥ 10 mm. Furthermore, the factors related to post-EPLBD complications were also evaluated.

Ethical clearance

This study adheres to the terms of the latest version of the Declaration of Helsinki for Medical Research and was approved by the ethical committee of the Assiut University Hospital in December 2011. A written informed consent was obtained from each patient included in the study.

PATIENTS AND METHODS

Patient recruitment

This prospective clinical study was performed at the GIT Endoscopy Center in the Assiut University Hospitals, Egypt, from March 2012 to March 2014. Forty patients with obstructive jaundice subsequent to CBDS were included. The diagnosis of CBDS was based on patient history, clinical examination and abdominal US and/or CT. Patients with a sufficiently dilated CBD (≥ 10 mm), large bile duct stones (≥ 10 mm) or multiple bile duct stones (≥ 3 stones) were included in the study and patients with

a CBD stricture, CBD ≤ 10 mm or malignant obstructive jaundice were excluded.

Endoscopic procedures

All patients who met the selection criteria underwent an ERCP with limited EBS, not exceeding 1/3 of the papillary roof and under cardiorespiratory monitoring. The size and number of stones and the diameter of the CBD were assessed using the initial diagnostic cholangiogram by a comparison of the diameter of the stone and CBD with the tip of the endoscope. EPLBD was performed using a dilation balloon, esophageal/pyloric of 15-20 mm in diameter. The maximum diameter of the chosen balloon did not exceed 2-3 mm above the diameter of the distal CBD. The balloon was gradually inflated to 15-20 mm with diluted contrast, using the corresponding pressure per surface inches (PSI). The sphincter was considered to be adequately dilated when the waist in the balloon disappeared completely on fluoroscopic examination. The fully dilated balloon was maintained for 30-60 seconds. If the waist of the balloon did not resolve or if an extensive narrowing was observed along the balloon, the pressure of inflation was not further increased in order to avoid perforation. Patients were observed for 24 hours for possible post-ERCP complications such as bleeding, perforation, and pancreatitis. Blood samples were taken for CBC in suspected bleeding cases four hours after the procedure and for pancreatic amylase for suspected cases of pancreatitis.

Measurement of outcome

Clinical follow-up and analysis of complete blood count and serum amylase were routinely performed on the day of the ERCP procedure for the close monitoring and early handling of possible complications. Severely ill patients, including patients with severe abdominal pain and significant bleeding were hospitalized for further diagnostic and therapeutic procedures.

Study definitions

The technical success of the procedure was defined as the complete removal of all stones, while patients who required stenting, lithotripsy, another ERCP session or

surgery were classified as a failure. The associated complications such as pancreatitis, bleeding and perforation were defined according to the consensus guidelines of Cotton et al. (18) as follows.

- Pancreatitis: increased serum amylase concentration of at least three times the normal level that occurred 24 hours or more after ERCP with concomitant new or worsening of abdominal pain.
- Cholangitis: fever due to subtotal or total obstruction of the biliary system, which was present for a minimum of 24 hours after ERCP.
- Hemorrhage: bleeding that occurred during or shortly after ERCP and associated with a hemoglobin drop of at least 3 g/dl. Immediate minor hemorrhage was carefully observed but this was not considered to be a complication.
- Perforation: radiological presence of contrast or air outside the confines of the bile duct and duodenum during or after ERCP and often seen on a plain abdominal X-ray immediately after the procedure.

The severity of pancreatitis was graded according to Ueno et al. modification (19) of the Cotton criteria as follows:

- Minimal: abdominal pain persisting for 12-24 hours with at least a threefold elevation of serum amylase concentration.
- Mild: clinical pancreatitis with at least a threefold elevation of serum amylase concentration that required 1-3 days of treatment.
- Moderate: requiring 4-10 days of treatment.
- Severe: requiring more than ten days of medication, or percutaneous or surgical intervention.

RESULTS

Forty patients with bile duct stone(s) meeting the inclusion criteria were enrolled in the study from March 2012 to March 2014. The patients' characteristics are shown in table 1. Twenty-two were male (55%) and 18 were female (45%) and the mean age was 49.5 years. The mean total bilirubin was 12.8 mg/dl and the mean direct bilirubin was 10.7 mg/dl. Some valuable clinical characteristics and risk factors for

the procedure are shown in table 2, including chronic liver disease in five patients (12.5%), a history of pancreatitis in two patients (5%) and the presence of periampullary diverticula in four patients (10%).

The radiographic and endoscopic parameters of the studied cases are presented in table 3. The mean stone size was 17 mm, the mean CBD diameter was 17.3 mm, the mean balloon size was 18.7 mm and the average balloon inflation time was 43.2 seconds. Most of the studied cases, 28 patients (70%), suffered multiple stones and 12 patients (30%) had a single large stone. The needle knife precut technique was only required in three cases (7.5%) with a difficult cannulation.

A successful stone extraction was obtained in 34 patients, with a success rate of 85%. Failure of stone extraction occurred in six patients, with a failure rate of 15%. Figure 1 shows the complications reported after the procedure including minimal pancreatitis in four cases (10%), mild pancreatitis in two cases (5%), cholangitis in two cases (5%) and bleeding in two cases (5%). Figure 2 shows endoscopic and screen views of successful balloon inflation and figure 3 shows a successful stone extraction with a typical rounded shape of SOD following EPLBD.

DISCUSSION

EPBD with a small balloon of 10 mm might have advantages for the preservation of sphincter function (20). However, EPBD has been reported to have a higher risk of pancreatitis than EBS and there is still a debate over the use of EPBD and the risk of developing pancreatitis following the procedure. Moreover, both EBS and EPBD have limitations for the extraction of large bile duct stones due to the frequent additional need for ML. Therefore, the technique of EPLBD using a balloon larger than 12 mm after mid-incision EBS was introduced for the removal of large CBD stones (21).

For proper patient selection, subjects included in the study already had a sufficiently dilated CBD subsequent to large stone(s). Furthermore, the risk of complications of EPLBD (especially perforation) increased with CBD stricture or small CBD diameter (17) and the presence of CBD stricture and papillary stenosis may constitute limiting factors for EPLBD (22). Thus, patients with CBD strictures or CBD diameter of 10 mm or less were excluded from the study. As the choice of balloon size has been variable

among studies, we used a maximum diameter of the balloon of 2-3 mm over the dilatation of the distal CBD, which has been shown to be safe in previous studies (16) .

The success rate for achieving stone extraction and complete CBD clearance in one session in our study was 85%. This is comparable to several studies on EPLBD that have demonstrated a relatively high technical success rate, ranging from 74 to 99% without ML for the removal of large bile duct stones (8,23). In a study conducted by Rosa et al. (14), the success rate of EPLBD for complete CBD clearance was 95.6%, which is remarkably higher than that of our study (85%). This higher success rate may be attributed to the use of more than one ERCP session, contrary to our single-session protocol. In addition, they defined the use of ML or stenting as a success, in contrast to our study, where we considered the need for ML or stenting as a failure.

In our study, a failure to fully inflate the dilatation balloon to the optimal diameter with a subsequent failure to achieve stone extraction and complete CBD clearance occurred in six patients (15%). The main cause in all cases was presence of a CBD stricture with persistence of the waist of the dilatation balloon.

There are serious complications such as severe pancreatitis and bile duct perforation caused by large balloon inflation. However, recent data has suggested that EPLBD is an effective procedure that does not cause complications if performed under strictly established guidelines (23,24). However, there are still some concerns about the risk of pancreatitis, which is multifactorial and with several suggested mechanisms. These include the direct physical compression effect of the balloon on the papilla, pancreatic duct orifice, or parenchyma that may induce peripapillary edema or spasm of the sphincter, in addition to repeated bile duct cannulation or trans-papillary manipulation due to the difficulty of cannulation or stone extraction, which may induce edema or spasm. This, in turn obstructs the flow of pancreatic juice and eventually induces pancreatitis (25). As the major factor in the induction of pancreatitis following EPLBD is unclear, many ERCP endoscopists still have concerns and are reluctant to use larger balloons over 12 mm in size (2,26).

In our study, the frequency of pancreatitis after EPLBD was only 10% for minimal pancreatitis, 5% for mild pancreatitis and there were no cases of severe pancreatitis.

Thus, the frequency of pancreatitis in our study was not higher than that of most previous EPLBD series that demonstrated relatively low rates of pancreatitis (8,23). Female gender, younger age, previous history of pancreatitis and the use of precut sphincterotomy are predictors of post-ERCP pancreatitis (27). These data were significant in our study and included the following. There were two patients with a previous history of pancreatitis, three patients (7.5%) with a difficult cannulation and subsequent use of precut sphincterotomy and the number of younger female patients was relatively high. Four (10%) patients developed minimal pancreatitis according to Ueno et al. (19). They received proper treatment including nil by mouth (NPO), rectal NSAIDs and monitoring for 8-10 hours and subsequent discharge after a complete recovery. Another two (5%) cases developed mild pancreatitis; one was a 28-year-old female with a previous history of calculous pancreatitis. Both patients were admitted for three days and received therapeutic and supportive measures including (NPO), adequate hydration using normal saline and intramuscular diclofenac and were subsequently discharged after a full improvement.

Our data showed that the risk of pancreatitis following EPLBD increases with a smaller diameter of CBD. Two patients (50% of cases with minimal pancreatitis) had a CBD diameter of 13 mm and another two (100% of cases with mild pancreatitis) of 12 mm. Thus, EPLBD is not recommended for patients with smaller degrees of CBD dilatation. These findings of our study are in good agreement with many studies that have proposed that an appropriately dilated CBD may be very important when EPLBD is applied (16,28).

Generally, our data supported the proposal that an increased balloon size and direct physical compression effects by the balloon itself are not a major cause of post-procedural pancreatitis. Furthermore, the most important risk factors that are predictive of pancreatitis after EPLBD are prolonged cannulation time, smaller degree of CBD dilatation and a longer stone removal time (16,23).

There were five (12.5%) patients with liver cirrhosis and four (10%) patients with periampullary diverticula included in the study and both are considered as risk factors for bleeding during ERCP (29). However, there were only two (5%) cases of immediate, minimal and intra-procedure bleeding that were easily controlled by

balloon tamponade of the sphincterotomy site. This finding is consistent with many previous studies (13,30,31) which report EPLBD as an attractive procedure for patients with a bleeding tendency and/or liver cirrhosis, as well as for those with an anatomical aberration of the papilla.

Acute cholangitis, as a complication following EPLB, is usually mild, and severe acute cholangitis have nevertheless been described (9). This important previous finding is consistent with our study, with two cases (5%) of mild acute cholangitis. Both cases were treated according to Tanaka et al. (32) by intravenous injection of a combination antibiotic ampicillin/sulbactam, twice daily, for three days with a full improvement.

The main limitation of our study was the fact that it was a non-comparative, one-arm treatment analysis in a single center with many younger patients of less than 60 years of age with a possible higher risk of pancreatitis. In addition, the long-term complications of EPLBD such as loss of sphincter of Oddi (SOD) function and stone recurrence have not yet been assessed.

In conclusion, EPLBD is an effective and safe procedure for the management of difficult CBD stones. Due to the minor EBS, the reduced requirement for ML and stenting and the low frequency of complications, EPLBD may be the subsequent preferred procedure in patients with complicated papillary anatomy, liver cirrhosis and coagulopathy. In addition, this procedure may be used in patients who cannot tolerate other ERCP procedures for any other reason. Further studies are required to confirm the current conclusions.

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Table 1. Clinical criteria of the studied cases (n = 40)

Clinical details	
Age (years)	
Mean ± SD	49.5 ± 10.06
Range	(28-69 years)
Sex	
Male (n %)	22 (55%)
Female (n %)	18 (45%)
Total bilirubin (mg/dl)	
Mean ± SD	12.8 ± 4.8
Range	(5.5-22)
Direct bilirubin (mg/dl)	
Mean ± SD	10.7 ± 4.9
Range	(4-20)

Table 2. Risk factors of the studied cases (n = 40)

Risk	n (%)
Liver cirrhosis	5 (12.5%)
Previous pancreatitis	2 (5%)
Periampullary diverticulum	4 (10%)

Table 3. Endoscopic parameters of the studied cases

Stone size mm	
Mean ± SD	17 ± 2.03, range: 11-20.4
Stone number	
Single n (%)	12 (30%)
Multiple n (%)	28 (70%)
CBD diameter mm	
Mean ± SD	17.3 ± 2.03, range: 12-20
Cannulation time in minutes	
Mean ± SD	5.4 ± 1.4, range: 4-10
Size of the balloon	
Mean ± SD	18.7 ± 1.5, range: 15-20
Balloon inflation time in seconds	
Mean ± SD	43.2 ± 6.1, range: 33-52
Precut techniques	
n (%)	3 (7.5%)

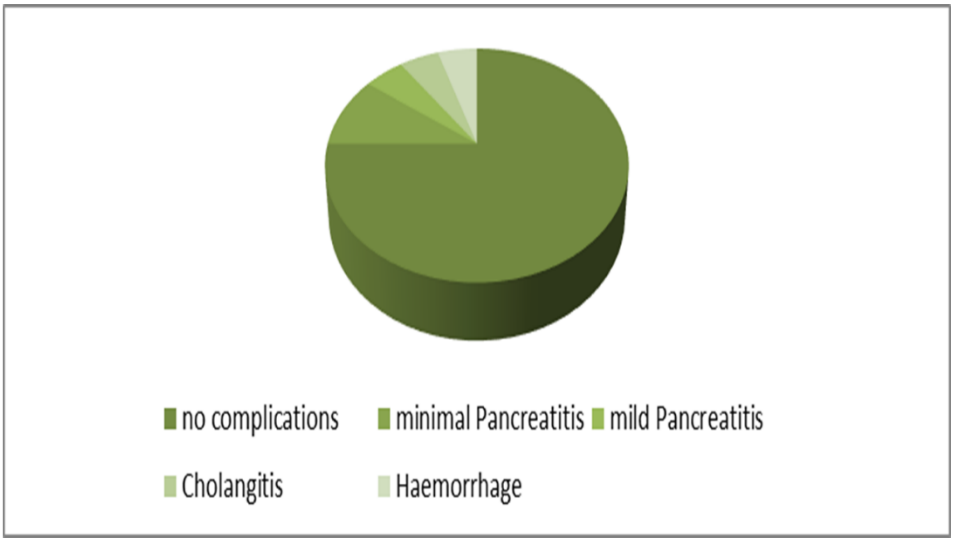

Fig. 1. Complications after the procedure.

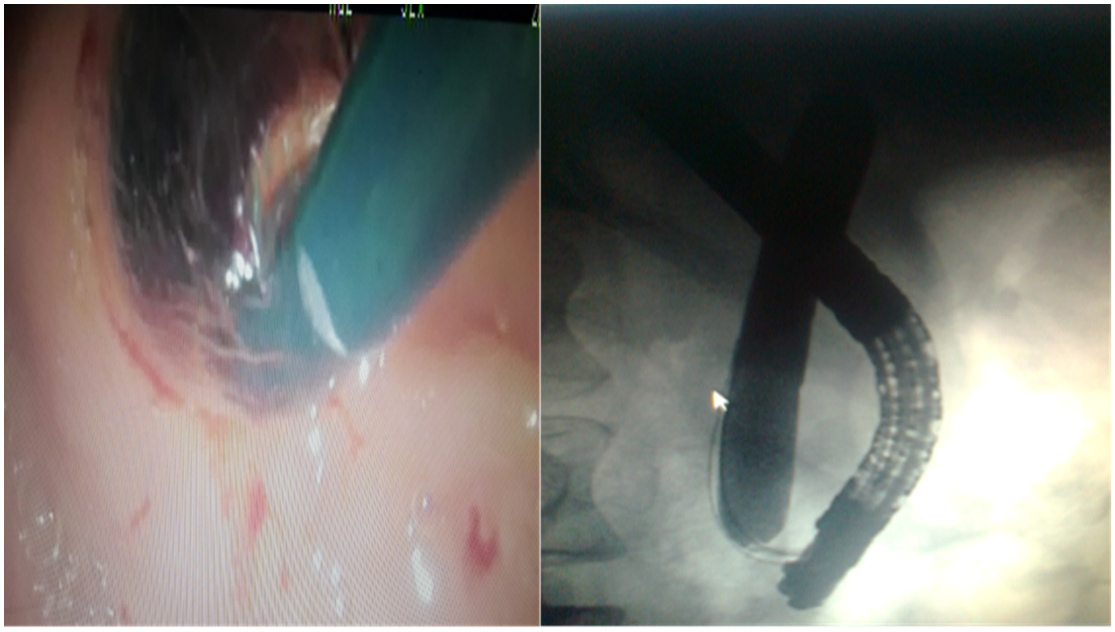

Fig. 2. Endoscopic and screen views show a successful balloon inflation.

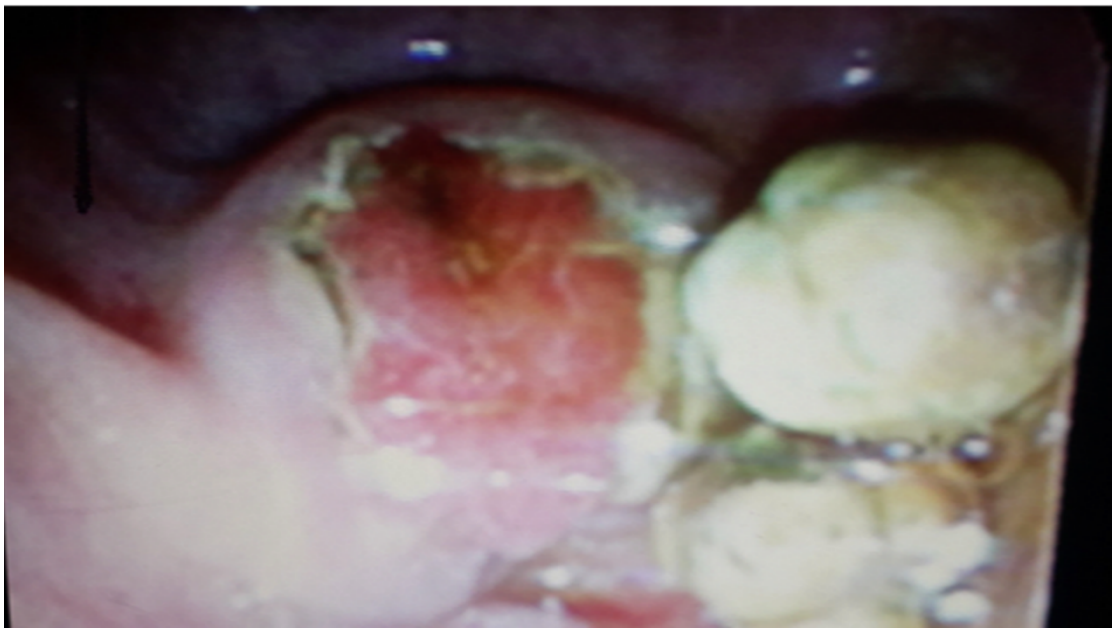

Fig. 3. Successful stone extraction with a typical rounded shape of SOD following EPLBD.