

**OUTCOME OF ENDOSCOPIC
CLEARANCE OF BILE DUCT STONES
AFTER ENDOSCOPIC
SPHINCTEROTOMY (ES):
HOSPITAL KOTA BHARU (HKB)
EXPERIENCE**

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VI) LIST OF ABBREVIATIONS, SYMBOLS OR NOMENCLATURE

ES - Endoscopic sphincterotomy

HKB - Hospital Kota Bharu

ERCP - Endoscopic retrograde cholangiography

CBD - Common bile duct

MRI - Magnetic resonance Imaging

MRCP - Magnetic resonance cholangiopancreaticography

χ^2 - chi-square

VII) ABSTRAK

LATAR BELAKANG: ‘Choledocholithiasis’ atau dikenali sebagai batu karang di salur hempudu umum (CBD stone) biasanya terdapat di kalangan pesakit yang menghidapi penyakit batu karang pundi hempudu. Penggunaan ‘endoscopic retrograde cholangiopancreatography (ERCP)’ dan ‘sphinterotomy’ (ES) semakin mengembang dalam rawatan ‘CBD stone’ pada masa ini. Lebih-lebih lagi, kadar morbiditi dan mortaliti agak tinggi dalam sesetengah kes di Malaysia .

OBJECTIF: Kajian ini adalah untuk mengkaji keputusan untuk mengeluarkan batu karang dengan menggunakan ERCP dan ES disertakan dengan pemecahan batu secara mekanikal ataupun elektrohyraulik, ‘Dormia basket’ dan katheter belon berdasarkan pada bilangan, lokasi dan size batu karang . Kajian ini juga dibuat untuk menilai komplikasi-komplikasinya.

METHODOLOGI: Kajian kes secara retrospektif untuk 111 pesakit ‘CBD stone’ yang telah menjalani ERCP dari Januari 2003 sehingga Desember 2005 di Hospital Kota Bharu (HKB). Data pesakit-pesakit yang memenuhi syarat-syaratnya dikumpulkan dan kadar pengeluaran batu karang serta komplikasinya dianalisiskan dengan SPSS software (versi 11.0).

KEPUTUSAN: ERCP serta ES telah dijalankan pada 111 pesakit dan didapati bahawa batu karang berjaya dikeluarkan sebanyak 68 (61.3%) pesakit. 71 (64%) daripada mereka adalah perempuan manakala 40 (64%) pesakit adalah lelaki. Umur median untuk lelaki adalah 54 tahun manakala perempuan adalah 49 tahun. Kebanyakan daripada mereka adalah perempuan dimana terdapat 51 (63.8%), 40 (64.5%) dan 50 (66.7%) kes dengan batu karang <10mm, berada di lokasi distal salur hempudu dan mempunyai lebih

daripada satu batu karang. 'CBD stones' yang <10 mm dan berada di lokasi distal didapati lebih mudah dikeluarkan. Bilangan batu tidak mempengaruhi proses pengeluaran 'CBD stone' dalam kajian ini. Secara keseluruhan, komplikasi berlaku pada 14 (12.6%) pesakit dimana 4 (3.6%) pesakit berlaku pendarahan, 8 (7.5%) pesakit menghadapi penyakit 'acute pancreatitis' dan hanya 1 (0.9%) pesakit menghadapi jangkitan kuman di salur hempedu dan kebocoran usus. Tiada kematian dilaporkan dalam kajian ini. Kajian ini juga menunjukkan 7 (6.3%) pesakit memerlukan pembedahan dimana 2 pesakit dijalankan pembedahan 'emergency' untuk komplikasi tersebut dan 5 pesakit lain memerlukan pembedahan secara terbuka pada salur hempedu umum (CBD exploration) selepas didapati gagal dalam pengeluaran batu karang dengan ERCP.

KESIMPULAN: Kajian ini menunjukkan bahawa ERCP serta ES adalah efektif, selamat dan mudah dijalankan. Kajian ini telah menunjukkan bahawa batu karang yang kecil (<10mm) dan berada di lokasi 'distal' lebih mudah dikeluarkan. Bilangan batu tidak mempengaruhi proses pengeluaran 'CBD stone' dalam kajian ini. Kajian ini telah menunjukkan kadar komplikasi yang memuaskan samada di HKB jika dibandingkan dengan kajian lain di dunia. Tetapi kriteria yang lebih menyeluruh serta sampel size yang lebih besar diperlukan untuk memastikan rawatan yang lebih berkesan pada masa depan.

VIII) ABSTRACT

BACKGROUND: Choledocholithiasis or common bile duct (CBD) stones are still frequently encountered in cholecystectomy patients. The use of endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic sphincterotomy (ES) in the management of CBD stones has progressed tremendously. However, the controversy is still present in Malaysia as its morbidity and morbidity can be significant.

OBJECTIVE: The present study is designed to assess the results of endoscopic clearance of CBD stones after ES in relation to the number, location and size of the stone with help of mechanical or electrohydraulic lithotripsy, Dormia basket and balloon catheter. It is also to evaluate its complications.

METHODOLOGY: Retrospective case review of 111 patients with CBD stones who had undergone ERCP from January 2003 to December 2005 in Hospital Kota Bharu (HKB), Kelantan. Data of those patients who fulfilled the criteria were documented and the clearance rate as well as the complications of the procedure were analysed using SPSS software (version 11.0).

RESULTS: ERCP with ES was attempted in 111 patients and stone clearance was successful in 68 (61.3%) patients. 71 (64%) were female and 40 (36%) were male. The median age of male was 54 years old and of female was 49 years old. Female patients predominantly presented with smaller (<10 mm), distally located and multiple stone. There were 51 (63.8%), 40 (64.5%) and 50 (66.7%) female patients with smaller, distally located and multiple CBD stones respectively. CBD stones which were <10 mm and distally located had more successful clearance while the number of stone showed no statistical difference. Complications occurred in 14 (12.6%) patients, bleeding in 4

(3.6%) patients, acute pancreatitis in 8 (7.5%) patients, sepsis or cholangitis as well as perforation each in 1 (0.9%) patient and no death was reported. Lastly, 7 (6.3%) patients needed surgical interventions and 2 of them had undergone emergency laparotomy for the complication and 5 patients required CBD exploration after failure to retrieve the stone by ERCP.

CONCLUSIONS: This study suggested that ERCP with ES continue to play an important and effective role in the management of CBD stones. Stone extraction by ERCP and ES has been found to be effective, safe and easy to perform. More importantly, it also has demonstrated that the smaller (<10mm) and distally located stones were easier to retrieve regardless of the number of stones in the CBD. Moreover, an acceptable complication rate for endoscopic therapy of CBD stone in HKB was found comparable to elsewhere in the world. However, more stringent criteria with larger number of cases, review, and ongoing practice are needed to ensure optimal benefit to patients in the future.

INTRODUCTION

1) INTRODUCTION

Common bile duct (CBD) stone also known as choledocholithiasis, is defined as presence of the gall stone in common bile duct (CBD). Choledocholithiasis occurs as a result of either the primary formation of stones in the CBD or the passage of gallstones from the gallbladder through the cystic duct into the CBD. Bile stasis, bactibilia, chemical imbalances, pH imbalances, increased bilirubin excretion, and the formation of sludge are among the principal factors thought to lead to the formation of these stones (Blumgart *et al.*, 2000). These stones are differentiated by their chemical composition and they can be classified into cholesterol stones, black pigment stones and brown pigment stones (Trotman and Soloway, 1982). Cholesterol stones are composed mainly of cholesterol and pure cholesterol stones are rare (Blumgart *et al.*, 2000). Black pigment stones are usually found in patients with hemolysis and hepatic cirrhosis which consist predominantly of polymerized bilirubin and also calcium salts occasionally. Lastly, brown pigment stones are made up of a mix of black pigment and bile lipids and more often found in the biliary tree than in the gallbladder. They are usually attributed to the bacterial infection, and occasionally to parasitic worm infestation. (Trotman and Soloway, 1982).

About 10-15% of people with gallstones will develop stones in the CBD (Moreaux, 1994, Morgenstern *et al.*, 1992). Symptoms are usually not present unless obstruction of the common bile duct occurs. Obstruction of the CBD by gallstones leads to symptoms and complications that include pain, jaundice, cholangitis, pancreatitis, and

sepsis. Even after the gallbladder is removed, a stone may remain in the common bile duct causing episodic pain or jaundice (Binmoellar *et al.*, 2001).

Choledocholithiasis complicates the workup and management of cholelithiasis, necessitates additional diagnostic and therapeutic procedures, and adds to the morbidity and mortality of gallstone disease (Shah *et al.*, 2001). Management of choledocholithiasis has been the subject of much debate over the past several years, especially with the advent of new laparoscopic techniques and greater experience with endoscopic procedures like endoscopic retrograde pancreaticholangiography (ERCP) (Binmoellar *et al.*, 1994).

As far as the endoscopic clearance of CBD stone based on the number, location and size of the stones are concerned, no similar study was done before in Kelantan and elsewhere in world. The present study is aimed to assess the results of endoscopic clearance of CBD stones after ES in relation to the number, location and size of the stones with help of mechanical or electrohydraulic lithotripsy, Dormia basket and balloon catheter. It is also to evaluate its complications.

LITERATURE REVIEW

2) LITERATURE REVIEW

2.1) BACKGROUND

The incidence of CBD stones among patients undergoing cholecystectomy is approximately 10-15% and the incidence of CBD stones unsuspected on preoperative investigations but found by routine on table cholangiography (OTC) is about 3-5% (Bergamaschi *et al.*, 1999). If the CBD stones left untreated, they can lead to significant morbidity and mortality (Shah *et al.*, 2001). The management of such condition has progressed tremendously but controversy still exists as to the ideal management, laparoscopic exploration or endoscopic retrograde pancreaticography (ERCP) with sphincterotomy.

The first open surgical exploration of the CBD was performed by a surgeon from Switzerland called Ludwig Courvoisier in 1889 (Clair *et al.*, 1992). Ever since then, the management of CBD stones has gradually progressed from open approach to one of a minimally invasive approach such as ERCP. ERCP was firstly introduced in 1974 and subsequently followed by the introduction of endoscopic sphincterotomy (ES) by Professors Classen from Germany and Kawai from Japan more than a quarter of century ago (Kawai *et al.*, 1974, Classen and Demling, 1974). Since then, ES has become a popular procedure for diagnosing and treating CBD stones. It was initially used only to treat older and less healthy patients, the results were, however, so promising and the mortality so low that young and healthier patients also became candidates for ERCP with ES.

ERCP has now challenged the laparoscopic approach of managing CBD stones which was initiated after the introduction of laparoscopic cholecystectomy by Dubois from France in 1989 (Dubois *et al.*, 1989). Although the effectiveness of laparoscopic CBD exploration has been documented in many studies, it is still not normally practiced for CBD stones management especially in HKB as well as Hospital Universiti Sains Malaysia (HUSM) in Kelantan.

2.2) ENDOSCOPIC SPHINCTEROTOMY (ES)

ES defined as the incision of the papilla of Vater and sphincter of Oddi muscles to open the terminal portion of CBD. This is carried out with a sphincterotome (Figure 2.1), which consists of a Teflon catheter with a cautery wire exposed for a length of 20-30mm near the tip (Binmoellar *et al.*, 2001). After deep bile duct cannulation, the sphincterotome is retracted until one half to two thirds of the wire length is exposed outside of the papilla. The sphincterotome-cutting wire is “bowed” until it comes in contact with the roof of the papilla. Applying intermittent bursts of diathermic current makes the incision. The length of the incision may range from 0.5 to 1.5 cm, depending on the size of the stone to be extracted and the anatomical variation of the sphincter. The length of the intraduodenal portion of the CBD will limit the maximum extent of the cut.

The safety of sphincterotomy has been well documented. A retrospective series of 546 patients over 8 years reported an overall complication rate of 5.4%, with 0.3% mortality. Specific complications were bleeding in 2.4%, pancreatitis in 0.5%, perforation in 0.4%, and cholangitis in 1.3% of the patients. Surgical intervention was required in 0.9% because of its complications. (Coppola *et al.*, 1997).

Late complications of sphincterotomy occur primarily because of recurrent stones or papillary stenosis. These include biliary colic, cholangitis, and pancreatitis. Risk factors include a gall bladder in situ, large bile duct diameter, and periampullary diverticuli. More than 90% of patients with recurrent stones can be managed effectively with repeat ERCP and sphincterotomy (Sugiyama and Atomi, 1998). Concern has been

raised that ablation of the sphincter and access of bacteria to the biliary system may result in an increased incidence of cholecystitis and cholangitis. However, long-term follow-up studies have not substantiated this. There is also no evidence of an increased risk of bile duct or gallbladder cancer after sphincterotomy (Sugiyama and Atomi, 1998).



Figure 2.1. A sphincterotome, which consists of a Teflon catheter with a cautery wire.

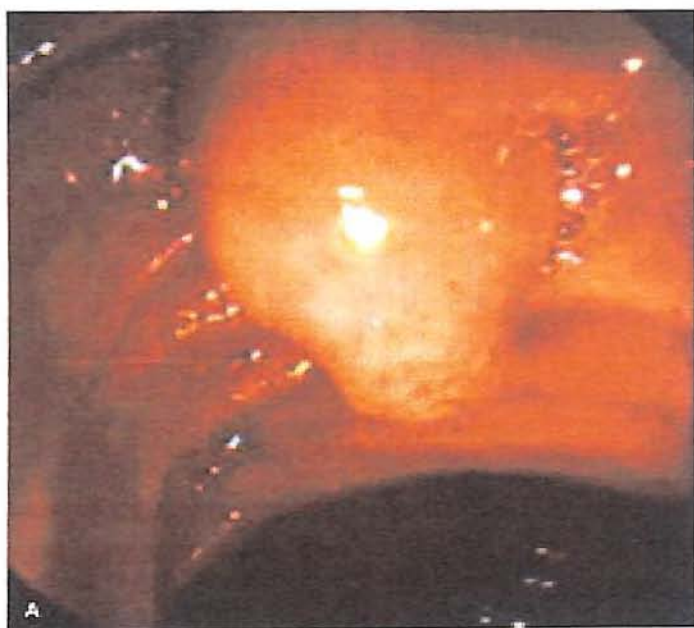


Figure 2.2. A normal papilla before ES.



Figure 2.3. A sphincterotome, which was making incision on the papilla and sphincter muscle.



Figure 2.4. A papilla after ES.