Egyptian Journal of Surgery Vol 27, No 2, April, 2008

ORIGINAL ARTICLE

ENDOSCOPIC MANAGEMENT OF POSTCHOLECYSTECTOMY BILE LEAK

By
Ayman Hassanen
Department of General Surgery, Minia University Hospitals, Egypt

Email: draymaanhassanen@yahoo.com

Aim: ***This prospective study was done to evaluate the results of endoscopic management of patients with post-cholecystectomy biliary leak.***
Methods: ***Between July 1999 and July 2005, 31 patients (18 men and 13 women, aged from 16 to 67 with mean age 49 + 12.1 years) underwent endoscopic management for postcholecystectomy bile leak in the Endoscopy Unit of Minia University Hospital.***
Results: ***In 29 of 31 patients (93.5%), endoscopic management was effective, safe, without mortality and the reported complications were treated by endoscopic management. The mean hospital stay for treatment of the leak was 6.1 + 4.3 days. During follow up, 60% of patients of major bile duct leaks developed biliary stricture formation and endoscopic management was repeated, which was successful in 50% of patients. Two patients of complete transection of common bile duct (CBD) underwent primary surgical therapy.***
Conclusion: ***Endoscopic management is safe and effective in the diagnosis and treatment of post-cholecystectomy bile leaks. Long-term results show that its efficacy and success is less in cases of major bile duct leaks due to subsequent biliary stricture formation. Surgical treatment is indicated in cases of complete transection of CBD and in cases of subsequent stricture formation.***

Keywords: ***Endotherapy, biliary injury, iatrogenic.***

INTRODUCTION

Bile leakage is a well-recognized complication of cholecystectomy with a reported incidence of 0.1% to 0.5% after conventional cholecystectomy[1-3] and 0.5% to 3% after laparoscopic cholecystectomy.[1,4] The majority of postcholecystectomy leaks occur from the cystic duct stump.[4,5] ERCP plays a definite role in establishing the diagnosis of biliary leak, and as a therapeutic modality by enabling endoscopic procedures such as sphincterotomy, nasobiliary drainage, stenting, or a combination of any of the above.[6,7]

In this prospective study, the aim was to evaluate the results of endoscopic management of patients with postcholecystectomy bile leak.

PATIENTS AND METHODS

Between July 1999 and July 2005, 31 patients with postcholecystectomy biliary leak were admitted to El-Minia University Hospital and included in this prospective study. Patients with post traumatic biliary leak were excluded from the study. A detailed informed consent was taken from all patients.

The mean time from cholecystectomy to ERCP was recorded. Clinical sheets were done for all patients. Relevant symptoms, signs, and biochemical test results were recorded, as well as the results of noninvasive imaging investigations (abdominal ultrasonograpy and/or CT scanning).

Antibiotic (third generation cephalosporin) was given intravenously one hour prior to the procedure and then every 12 hours for 2 days, or for 5 days if biloma was present. Patients were kept fasting for at least 6 hours before the procedure. An intravenous line was established in the right arm since the patients were positioned partially on the left arm and appropriate monitoring was initiated. Endoscopic procedures were performed with the TJF 200 side-viewing duodenoscope (Olympus Corp., Japan). A cholangiogram was performed in each patient and the leak was graded to be low or high grade. It was high grade if there was rapid extravasation of contrast from biliary tree with negligible intrahepatic duct filling. It was low if there was complete intrahepatic duct filling. Endoscopic sphincterotomy (ES) was performed if needed to facilitate stent placement.

If access to the bile duct could not be achieved by conventional methods, a needle knife papillotome was used for sphincterotomy. Stents or nasobiliary drainage tube (NBDT) were inserted according to standard techniques.

Stents or NBDT were removed after a follow-up cholangiogram to confirm healing of the leak. Patients were followed up after endoscopic therapy for a period of 36 months, with a mean of 36 + 11.3 months by serum bilirubin, alkaline phosphatase and abdominal ultrasonography.

Surgical treatment was performed if endoscopic treatment failed. Bismuth[8] classification for extrahepatic biliary injury was used in the operative cases as follow: Level 1, injuries involved the common duct with a normal hepatic duct stump of 2cm or greater; level II, injuries with a hepatic duct stump length of less than 2 cm; level III, high stricture with a preserved ductal confluence; level IV, destruction of confluence; level V injuries of the right sectorial duct with or without involvement of the common duct.

An injury with a long segment of preserved common duct (Bismuth I) was reconstructed with a Roux limb of jejunum. An end-to- side single- layered anastomosis was created to the proximal end of the Roux limb. Fine-caliber interrupted absorbable sutures were employed. The anastomosis was drained with a T tube if adequate healthy proximal hepatic duct was available. If this was difficult, an alternative was to pass a catheter through the anastomosis via the Roux limb and then secured to the anterior abdominal wall. The left duct was used for anastomosis if the common bile duct length was insufficient (Bismuth II-V). The left hepatic duct was opened in its long axis on the anterior surface, and a side-to-side hepaticojejunostomy was created then stenting of the hepaticojej-unostomy was achieved.

Statistical analysis: Descriptive data were expressed as mean + standard deviation or medians and ranges for continuous variables and as number and percent for categorical variables.

RESULTS

Study population: Between 1999 and 2005, 31 patients underwent ERCP for postcholecystectomy bile leak. The patients were 18 men and 13 women, with a mean age of 49 + 12.1 years, range 16-67 years. The bile leak followed open cholecystectomy in 18 patients (58.1%) and followed laparoscopic cholecystectomy in 13 patients (41.9%). Seventeen patients (54.8%) were referred from other general hospitals.

Clinical presentations and investigations: The mean time from cholecystectomy to ERCP was 6.9 +3.2 days (range 1-53 days). Fifteen patients (48.4%) presented within 3 days of surgery, whereas 11 patients (35.5%) presented from 6 days to one month after the operation. Five patients (16.1%) were referred more than 1 month after cholecystectomy.

The presenting clinical features were shown in Table 1. Abdominal pain was the main presenting symptom being encountered in 25 patients (80.6%).

Table 1. Clinical presentation.

Clinical presentation	Number	Percentage
Abdominal pain	25	80.6
Biliocutaneous fistula	21	67.8
Nausea, vomiting	8	25.8
Jaundice	7	22.6
Biloma	7	22.6
Fever	7	22.6
Vomiting	6	19.3

In 7 patients (22.6%), transabdominal imaging with US and/or CT scanning revealed subhepatic fluid collections. In 8 patients (25.8%), exploratory laparotomy was undertaken before referral that failed to identify the site of leakage in each patient.

Biochemical test results immediately before ERCP were shown in Table 2.

Table 2. Biochemical tests results in 31 patients.

Test	Range	Mean + SD
BR (mg/dL)	0.9 – 12.8	5.8 + 2.8
AP(U/L)	59 – 1021	243 + 119.5
AST (U/L)	17 – 321	73+ 31.5
ALT(U/L)	25 – 365	82 + 36.5
WBC (cell/dL)	5300 – 20000	11.443 + 4.6

BR= bilirubin; AP= Alkaline phosphatase; AST= Aspartate aminotransferase; ALT= Alanine aminotransferase WBC= white blood cell count.

Endoscopic management: ERCP successfully demonstrated the precise location of the leak in all cases. In 16 patients (51.6%), it was from the cystic duct, 10 patients (32.3%) from the CBD and in 5 patients (16.1%) from the right hepatic duct (Table 3). During cholangiography, 22 patients (70.9%) were found to be low grade (Fig. 1) and 10 patients (32.3%) were high grade (Fig. 2). The CBD diameter was normal. The methods of endoscopic treatment and subsequent outcome for patients were shown in Table 3.

Fig 1. Cystic duct leak (low grade).

Fig 2. Common duct leak (high grade).

Four patients (12.9%) underwent endoscopic sphincterotomy (Fig. 3), 8 patients (25.8%) underwent endoscopic stenting, 14 patients (45.2%) underwent combined sphincterotomy and stenting (Fig. 4) and in 3 patients (9.7%), sphincterotomy and NBDT was done. Sizes of stents in 10 patients (32.3%) were 10F, and in 12 patients (38.7%) were 7F (one patient received two 7F stents); and in 3 patients (9.7%), a 7F NBDT was placed (Fig. 5). In 7 patients (22.6%), bilomas were detected and were evacuated by percutaneous drainage in 5 patients (16.1%) and open drainage in one patient (3.2%). In the last patient, no specific therapy was directed at the biloma itself and the treatment of the biliary leak was the only treatment used.

Fig 3. Endoscopic sphincterotomy with a standard papillotome.

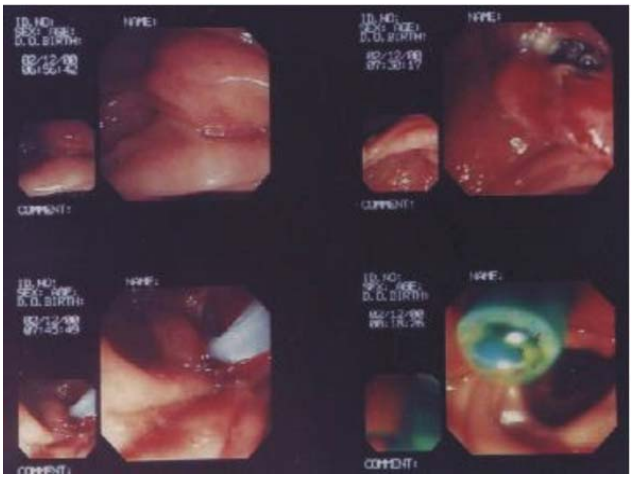

Fig 4. Continuous bile flow through large sized stent 10 French.

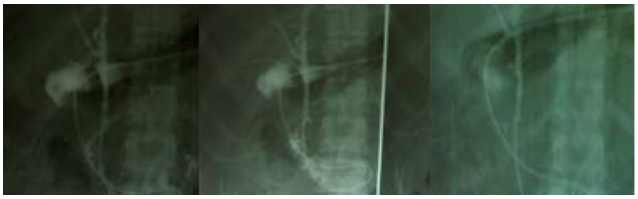

Fig 5. Nasobiliary cholangiogram to monitor the leak.

The 3 patients treated with ES and NBDT had the device in place for 2 weeks to monitor drainage from the duct leak (Fig. 5). The follow-up nasobiliary cholangiogram showed cessation of the leak and the tube was then removed.

Stents were left in place for 1 to 16 weeks, (mean 4.2 + 2.6 weeks). Four patients (12.9%) were successfully treated with ES alone Table 3.

The length of hospitalization after ERCP for treatment of leak ranged from same day discharge to 42 days with a mean length of hospital stay 6.1 + 4.3 days.

In total, 29 of 31 patients (93.5%) underwent initial successful endotherapy. The reported complications were treated effectively by endoscopic management. In 2 patients (6.4%), bleeding at site of sphincterotomy occurred and was controlled by coagulation current. In one patient, stent occlusion occurred after 1 month and was treated by stent exchange. In 2 patients (6.4 %), failure of endoscopic management was recorded due to completely transected CBD (Fig. 6) and surgical intervention was done.

The first patient had a long segment of preserved common bile duct (Bismuth I), and was treated by a Roux-en-Y choledochojejunostomy with stent for the anastomosis and drainage for the subhepatic space. This patient had successful outcome. The second patient had insufficient duct length for anastomosis, so left duct was used for anastomosis and hepaticojejunostomy was created. The patient developed biliary and enteric leakage and died from sepsis.

Endoscopic approach was safe and without mortality. The mean follow-up was 36 + 11.3 months after completion of endoscopic therapy. The follow up was done every three months by clinical examination, laboratory and abdominal ultrasonic examinations. No evidence of ductal dilatation or serum liver enzymes elevations has been noted in any of patients with cystic duct lesions. But, in 6 of 10 patients (60%) with major common bile duct leak, intrahepatic biliary radical dilatations and elevated alkaline phosphatase were observed. All patients were subjected to ERCP and stricture at the site of leak was detected. Endoscopic balloon dilatation was done for all patients and stents were applied. This was successful in 3 of 6 patients (50%). In the other 3 patients, there was recurrence of the biliary symptoms. A third ERCP was done and detected a tight stricture. The 3 patients were considered candidates for surgical treatment. Hepatico-jejunostomy was done with successful outcome, with no evidence for recurrence of biliary symptoms after a mean time of 20 + 9 months from the operation.

Table 3. Methods of endoscopic treatment and its outcome.

Method of treatment	No. of patients	Site of leak			Technical success (%)	Leak healed (%)
		Cystic duct	Common bile duct	Right hepatic duct		
ES alone	4	1	1	2	100%	100%
Stent alone	8	5	3	0	100%	100%
ES and stent	14	7	4	3	100%	100%
NBDT*	3	3	0	0	100%	100%
Diagnostic ERCP only**	2	-	2	-	-	-
Total	31	16	10	5	93.5%	93.5%

* NBDT, Naso-biliary drainage tube.
** Two cases of complete transection of CBD with failure of endoscopic management.

DISCUSSION

The incidence of bile injury occurring in association with cholecystectomy ranges from 0.1% to 3% and is more common with laparoscopic cholecystectomy than with open procedure.[9] In the present study, the majority of biliary leak (58.06%) was after open cholecystectomy. This may be due to wide practice of open cholecystectomy in General Hospitals from which 17 cases (54.8%) were referred. However, in our department, we had 8 of 14 cases (57.1%) which were after laparoscopic cholecystectomy due to the wide practice of the laparoscopic technique in our department.

The clinical presentation of postoperative bile duct injury includes pain, fever, cholestasis, jaundice, persistent bile drainage through drains[10] which may persist for a few days to weeks.[11] In a study by Mergener et al.,[12] abdominal pain was the commonest symptom (93%). Similarly, in this study, the commonest clinical presentation was the abdominal pain (80.6%). The non specificity of abdominal pain is probably responsible for the delay in the diagnosis and delay in the referral to endotherapy. So the mean duration before presentation was 6.9 + 3.2 days after cholecystectomy.

Imaging studies are helpful for confirming the diagnosis and helping to decide upon subsequent therapy.[13] Abdominal ultrasonography and CT scan can detect intraabdominal bile collection[14,15] while ERCP provides an accurate diagnosis of the site of leak in the majority of cases. Percutaneous transhepatic cholangiography (PTC) may be performed to delineate the site of injury in cases of complete transection of CBD.[16] In the present study, PTC was done for two cases to better define the biliary anatomy in case of complete transection of CBD.

Once recognized, bile duct leak can be managed in several ways. Although laparotomy was the standard treatment in the past, endoscopic procedures have now replaced this procedure as the first line of management.[17,18]

Our study confirmed the findings of others[17,18] that endoscopic therapy in general is both safe and effective in management of postcholecystectomy biliary leak. All specific treatments were completed without major morbidity and in 29 of 31 cases (93.54%), permanent closure of the leak occurred. While the results for immediate surgical repair of bile duct injuries are less favorable and the associated morbidity and mortality rates are high.[19-23] In the present study, two patients of complete transaction of CBD needed an initial surgical treatment with successful outcome in the first patient and fatal outcome in the second patient.

In the present study, all specific endoscopic treatments achieved equally good results. ES or stents used alone and ES in combination with stents or NBDT were similarly effective. This observation tends to support the application of the simplest and least invasive method of management. The presumed benefit of an endoprosthesis or sphincterotomy is to reduce or eliminate the intraductal pressure gradient maintained by the sphincter of Oddi and to divert bile into the duodenum and away from the site of leakage. It is not known which method best achieves this goal. ES alone may fail when leaks are high grade. The CBD was not dilated as a result of decompression from the leak, and this has been considered a consistent observation made by others.[24,25] Sherman et al.,[26] reported a high complication rate (11%) for ES performed in patients with normal caliber bile ducts. In our study, ES was small to avoid such a high complication rate.

The use of NBDT in patients with biliary leaks gave favorable results. These catheters are easily placed without ES and can be removed without endoscopy, and serial cholangiography can be used to monitor the status of the leak.

Our results show that stents are effective in the treatment of patients with postcholecystectomy biliary leak.

In most reported series stents were inserted with the proximal end positioned above the site of leakage.[27-30] It is assumed without proof that mechanical occlusion of the breach in the bile duct by the physical presence of the stent is an added advantage for this method. In our study two patients with intrahepatic duct leaks were successfully treated with relatively short stents positioned below the leak, and others have treated similar patients with this technique with favorable results.[31] Biliary decompression through elimination of trans-papillary resistance is probably the most important function served by the stent.

It appears that the type of treatment chosen was influenced largely by the grade of the leak. Endoscopic stenting (7F) or NBDT was effective for closing low grade leaks. The use of ES and placement of stent (10F) was effective for closing high grade leaks, ES being performed largely to facilitate stent placement in these patients.

The length of time to closure of the bile leak was from 4 to 6 weeks which appeared to be a reasonable period for healing in most patients and this was consistent with findings of others.[5,15,32-34]

The mean hospital stay for treatment of the leak was 6.1 + 4.3 days. The need for percutaneous or surgical drainage of a biloma was the primary reason for prolongation of hospital stay. Patients who have undergone endotherapy for biliary injuries require long-term follow-up.[34-36] This should, at a minimum, include serum liver function tests every 3 months and repeated ultrasound examinations in patients in whom recurrent biliary colic or serum liver test abnormalities develop. In patients with major CBD leaks[19] but not in patients with cystic duct leaks,[20] stricture formation was an important problem. The results of the present study were similar during the follow up period. In 60% of patients with major bile duct injuries, stricture formation occurred. This complication was not detected in cases of cystic duct leaks.

REFERENCES

1. Khan MH, Howard TJ, Fogel EL, Sherman S, McHenry L, Watkins JL et al. Frequency of biliary complications after labaroscopic cholecystectomy detected by ERCP: experience at a large tertiary referral center. Gastrointest Endosc. 2007;65:247-52.

2. Bridges A, Wilcox CM, Varadarajulu S. Endoscopic management of traumatic bile leaks. Gastrointest Endosc. 2007;65:1081-5.

3. Gouma DJ. Bile duct injury during laparoscopic and conventional cholecystectomy. J Am. Coll Surg. 1994;178:229-33.

4. Barkun AN, Rezing M, Mehta SN, Pavone E, Landry S, Barkun JS, et al. Postcholecystectomy biliary leaks in the laparoscopic era: risk factors, presentation, and management. Gastrointest Endosc. 1997;45:227-82.

5. Ryan ME, Geenen JE, Lehman GA, Aliperti G, Freeman ML, Silverman WB, et al. Endoscopic intervention for biliary leaks after laparoscopic cholecystectomy: a multicenter review. Gastrointest Endosc. 1998;47:261-6.

6. Zacks SL, Sandler RS, Rutledge R, Brown RS. A population based cohort study comparing laparoscopic cholecystectomy and open cholecystectomy. Am J Gastroenterol. 2002;97:334-40.

7. Chow S, Bosco JJ, Heiss FW, Shea JA, Oaseem T, Howell D. Successful treatment of postcholecystectomy bile leaks using nasobiliary drainage tube and sphincterotomy. Am J Gastroenterol. 1997;92:1839-43.

8. Bismuth H, France D, Corlette MB. Long term results of Roux-en-Y Hepaticojejunostomy. Surg Gynecol Obstet. 1978;146:161-7.

9. Chaudhary A, Negi SS, Puri SK, Narang P. Comparison of magnetic resonance cholangiography and percutaneuos transhepatic cholangiography in the evaluation of bile duct strictures after cholecystectomy. Br J Surg. 2002;89:433-6.

10. Flum DR, Koepsell T, Heagerty P, Sinanan M, Dellinger P. Common bile duct injury during laparoscopic cholecystectomy and the use of intraoperative cholangiography. Arch Surg. 2001;136:1287-92.

11. Cseendes A, Navarrete C, Burdiles P, Yarmuch J. Treatment of common bile duct injuries during laparoscopic cholecystectomy: Endoscopy and surgical management. World J Surg. 2001;10:121-5.

12. Mergener K, Strobel J, Sukocki P, Jowell P, Enns A, Branch S et al. The role of ERCP in diagnosis and management of accessory bile duct leaks after cholecystectomy. Gastrointest Endosc.
1999;50:527-31.

13. Sawaya DE, Gohnson LW, Sittig K, McDonalds JC, Zybary GB. Iatrogenic and non iatrogenic extrahepatic biliary tract injuries: A multi institutional review. Am Surg. 2001;67:473-7.

14. Zhou PH, Liu FL, Yao LQ, Qin XY. Endoscopic diagnosis and treatment of postcholecystectomy syndrome. Hepatobiliary Pancreatic Dis Int. 2003;2:117-20.

15. Sandha GS, Bourke MJ, haber GB, Kortan PP. Endoscopic therapy for bile leak based on a new classification: results in 207 patients. Gastrointest Endosc. 2004;60:576-74.

16. Prat F, Pelletier G, Ponchon T, Fritsch J, Meduri B, Boyer J. What role endoscopy plays in the management of biliary complications after laparoscopic cholecystectomy? Endoscopy. 1997;29:341-8.

17. Agarwal N, Sharma BC, Gargs, Kumar R, Sarin SK. Endoscopic management of postoperative bile leaks. Hepatobiliary pancreatic Dis Int. 2006;2:273-7.

18. Al-Ghnaniem R, Benjamin IS. Long term outcome of hepaticojejunostomy with routine access loop formation following bile duct injury. Br J Surg. 2002;89:1118-24.

19. Archer S, Brown D, Smith C, Branum G, Hunter G. Bile duct injury during laparoscopic cholecystectomy. Ann Surg. 2001;234-8.

20. Neuhaus P, Schmidt SC, Hintze RE, Alder A, Veltzke W, Langrehr JM et al. Classification and.treatment of bile duct injuries after laparoscopic cholecystectomy: Chirurg. 2000;71:166-73.

21. Kune G. Bile duct injury during cholecystectomy: causes, prevention and surgical repair. Aust N Z J Surg. 1979;49:35-40.

22. Katsinelos P, Kountouras J, Paroutoglon G, Beltsis A, Zavos C, Chatzimavroudis G et al. The role of endoscopic treatment in postoperative bile leaks. Hepatogastroentrol. 2004;53:156-70.

23. Kaffes AJ, Hourigan L, Luca ND, Byth K, Williams SG, Bourke MJ. Impact of endoscopic intervention in 100 patients with suspected postcholecystectomy bile leak. Gastrointest Endosc. 2005;61:269-75.

24. Katsinelos P, Kountouras J, Paroutoglou G, Chatzimavroudis G, Germanidis G, Zavos C et al. A comparative study of 10-Fr vs. 7-Fr straight plastic stents in treatment of postcholecystectomy bile leak. Surg Endosc. 2007;22:4-13.

25. Carr-Locke AD. Biliary stenting alone versus biliary stenting plus sphincterotomy for the treatment of post –laparoscopic cholecystectomy bile leaks. Eur J Gastroenterol Hepatol. 2006;18:1053-5.

26. Serman S, Ruffolo TA, Hawes RH, Lehman GA. Complications of endoscopic sphincterotomy: a prospective series with emphasis on the increased risk associated with sphincter of Oddi dysfunction in nondilated bile ducts. Gastroenterology. 1991;101:1068-75.

27. Braghetto I, Bastias J, Csendes A, Debandi A. Intraperitoneal bile collections after laparoscopic cholecystectomy: causes, clinical presentation, diagnosis amd treatment. Surg endosc. 2000;14:1037-41.

28. Elmi F, Silverman WB. Nasobiliary tube management of post cholecystectomy bile leaks. Gastrentrol. 2005;39:441-4.

29. Huang GS, Lichtenstein DR. Postcholecystectomy bile leak: what is the optimal treatment? Gastrointest Endosc. 2005;4:276-78.

30. Davids PHP, Rauws EHJ, Tutgat GNJ, Huibregtse K. Postoperative bile leakage: endoscopic management. Gut. 1999;33:1118-22.

31. Toriuni D, Ruchim M, Goldberg M. Transnasal biliary drainage for treatment of common bile duct leakage and bile peritonitis. Dig Sci. 1989;34:315-9.

32. Foutch PG, Harlan JR, Hoefer M. Endoscopic therapy for patients with postoperative biliary leak. Gastrointest Endosc. 1993;39:416-21.

33. Korzarek RA, Traverso LW: Endoscopic stent placement for cystic duct leak after laparoscopic cholecystectomy. Gastrointest Endosc. 1994;37:71-3

34. Parlak E, Cicek B, Disibeyaz S, Kuran SO, Oguz D, Sahin B. Treatment of biliary leakages after cholecystectomy and importance of stricture development in the main bile duct injury. Gastroentrol. 2005;16:21-28.

35. De Santibanes E, Palavecino M, Ardiles V, Pekolj J. Bile duct injuries: management of late complications. Surg Endosc. 2006;20:1648-53.

36. Loperfido S, Angelini G, Benedetti G, Chilovi F, Costan F. Major early complications from diagnostic and therapeutic ERCP: a prospective multicenter study. Gastrointest Endosc. 1999;50:143-4.