



A FOLLOW UP STUDY OF PATIENTS WITH TRANS-DUODENAL SPHINCTEROPLASTY

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ABSTRACT:

Biliary stasis leads most commonly to a multitude of biliary diseases. Cholecystectomy is the commonest operation performed on the biliary tract. The multiple common duct stones, impacted stones, retained stones, biliary sludge are some of the conditions that necessitate various invasive procedures. To study of patients with trans-duodenal sphincteroplasty. A questionnaire was prepared and sent to 90 patients operated at Nehru Hospital attached to Postgraduate Institute of Medical Education and research. The various investigations to which the patients were subjected were- laboratory investigations, radiological investigations, endoscopic investigations. Postoperative hospital stay was for a minimum of 7 days and maximum of 44 days. On follow up, 13 out of 20 patients were asymptomatic, 4 were symptomatic with mild symptoms. The present study was carried out on 90 patients attending surgical OPD between 1988-1990. Mean age in females was 46 years and in males 52 years. The distribution of symptoms according to clinical diagnosis were noted. Transduodenal sphincteroplasty is a safe and effective permanent biliary drainage procedure.

KEYWORDS:

Sphincteroplasty, Cholecystectomy, Biliary diseases.

INTRODUCTION

Biliary stasis leads most commonly to a multitude of biliary diseases, leading to stone formation and their recurrences. This is mirrored in geriatric patients with long history of biliary lithiasis, which results in their inability, they also have increased incidence of pathological changes, in both liver and biliary tree to empty the biliary system adequately. On the top of that they also have increased incidence of pathological changes in both liver and biliary tree histology. Various biliary drainage procedures hence are the attempts at achieving free biliary flow¹. The multiple common duct stones, impacted stones, retained stones, biliary sludge are some of the conditions that necessitate various invasive procedures.

Cholecystectomy is the commonest operation performed on the biliary tract. As compared to males, females are more common (below 35 yrs) to develop

cholelithiasis^{1,2}. Cholecystectomy was first performed for gall stones in 1882 by Langenbuch of Berlin, who even suggested that the common duct might be opened for removal of stones contained therein. Residual or recurrent stone incidence after choledocholithotomy has been found to be 10% and even after negative duct exploration it is about 5%. After exploration it is even higher (25%) with an operative mortality twice that of primary choledochotomy³.

Choledeotomy is a basic premise to an approach to the prophylaxis and treatment of common duct stones by permanent biliary drainage procedures. The available modalities are choledochoduodenostomy, choledochojunostomy, trans duodenal sphincterotomy, transduodenal sphincteroplasty and endoscopic sphincterotomy.

Conditions for which sphincteroplasty is performed are, in cases of primary ductal explorations for

impacted stones, stenosis of the papilla when 3 mm size Bakes' dilator cannot be negotiated, short benign distal strictures, irremovable hepatic duct stones, mud, sludge, stasis, stone due to chronic distal duct obstruction, multiple common bile duct stones, leading to doubtful clearance of the duct and for re-explorations in the cases of residual stones and sump syndromes^{4,5}.

Transduodenal procedures for biliary drainage have an advantage of dependant duct drainage. Visualization of sphincter, removal of impacted stones, and dealing with ampullary stenosis. In addition, it avoids long-term complications like, sump syndromes and resulting cholangitis and pancreatitis. It is, however, contraindicated in cases where, the bile is clear, stones are of gall bladder origin, only a few large stones are present, papilla is more than 3 millimetres in diameter, preoperative cholangiogram is normal and intraoperatively performed choledochoscopy reveals a clear common duct, a long distal stricture, lower duct anatomical aberrations, sand in distal duct pathologies like inflammations etc⁶.

When the common duct is much dilated, a choledochoduodenostomy is preferable depending on the common bile duct diameter. Sphincteroplasty is preferred when the duct is less than 15 mm size. If it be between 15 to 25 mm either a choledochoduodenostomy or transduodenal sphincteroplasty may be done. Above 25 mm size the choice is of choledochoduodenostomy.

Long term complications of choledochoduodenostomy are seen in the form of restenosis of the stoma, cholangitis, and pancreatitis. Post operative pancreatitis is a complication of transduodenal sphincteroplasty associated with a mortality rate of 1 to 2%⁷.

As quoted by Cahow (1983), "it is important for clinical surgeons, to periodically review the procedures which we have come to accept over the years as both safe and effective" concepts regarding procedures keep changing with time, but it is the

results and efficacy of procedures which determine their validity and practice⁸.

On the basis of these facts a follow up study of patients with transduodenal sphincteroplasty was undertaken in the Department of General Surgery, Nehru Hospital attached to Postgraduate Institute of Medical Education and Research, Chandigarh with the aim Long-term results and efficacy and complications (both subjective and objective) of this procedure.

MATERIALS AND METHODS

A questionnaire was prepared and sent to 90 patients operated at Nehru Hospital attached to Postgraduate Institute of Medical Education and research, Chandigarh for transduodenal sphincteroplasty and out of 90 patients 38 responded. Ten patients reported that they were well and asymptomatic so did not come for further studies. In 8 patients, all the tests, though they were asymptomatic could not be performed. Twenty patients were thoroughly studied for various clinical, biochemical and radiological parameters and inferences drawn thereof regarding efficacy and complications of the procedure. Follow up was both subjective and objective. Follow up period varied between 6 months to 11 years and 6 months. The period of the study between 1988-1990. The study undertaken was as follows:

On follow up evaluation was carried out in 3 headings:

- (a) History
- (b) Clinical profile
- (c) Investigations

1. History was recorded under:

Data at the time of previous surgery

Details of surgery were recorded from the old files of the patients

- 1) Presenting features
- 2) Preoperative investigations and diagnosis
- 3) Intraoperative findings and indications for surgery
- 4) Postoperative course.

History on follow up

A detailed history regarding

- (i) Recurrence of pain, fever with rigors, jaundice, nausea, vomiting etc.
- (ii) surgical procedures
- (iii) Associated medical problems, if any.

2. Clinical profile

On presentation at the out-patients-department of surgery, a thorough general physical examination and

examination of various body systems was undertaken and significant findings noted down in the Performa.

3. Investigations

The various investigations to which the patients were subjected were-

- (i) laboratory investigations
- (ii) radiological investigations
- (iii) Endoscopic investigations.

RESULTS

Table No: - 1 Age and Sex Distribution

Age Range in years	Males	Females	Total
20 to 40	0	5	5
40 to 60	6	5	11
60 to 80	1	3	4
Total	7	13	20

Out of the 20 patients, 7 were males and 13 females. Their age at surgery ranged from 21 to 78 years (with a mean of 48 years). Mean age in females was 46 years and in males 52 years.

Table No:- 2 Previous Surgical Procedures

SR.No	Previous Surgery	No of Patients
1	Cholecystectomy + Choledocholithotomy	5
2	Choledocholithotomy alone	1
3	Choledocholithotomy with T-tube Drainage	1

Seven of the patients studied had previously been operated on their biliary tracts at about a period of 3 months to 1 year earlier, of which 5 had cholecystectomy done in addition to common bile duct exploration and t-tube drainage.

Table No:- 3 Clinical Presentation

Clinical Diagnosis	No of Patients	Pain	Jaundice	Fever	Wt. Lose
Residual Stones	5	4	3	1	0
Biliary Lithiasis	12	12	10	5	4
Pancreatitis	2	2	1	0	1
Cholangitis	1	1	1	1	1
No calculous obstruction	0	2	0	2	0

The distribution of symptoms according to clinical diagnosis is shown in table 3.

Table:- 4 Diagnostic Preoperative Investigations

Diagnosis	OCG	PTC	ERCP	USG	TTC
Cholelithiasis	1	-	-	3	1
Gall stones	-	-	-	-	-
CBD stones	-	3	3	-	-
Hepatic duct stones	-	-	-	-	1
Residual stones	-	-	-	-	3
Pancreatitis	-	-	1	-	-
Cholangitis	-	1	-	-	-
Noncalculous Obstruction	-	1	-	-	2
Total	1	5	4	3	7

Preoperatively on investigating for precise diagnosis, oral cholecystography (1), percutaneous transhepatic cholangiography (5), endoscopic retrograde cholangiopancreatography (4), ultrasonography (2) and T-tube cholangiography (7).

Table: - 5 Postoperative Hospital Stay

Number of Days	Number of Patients
0 to 10	4
10 to 20	9
20 to 30	3
30 to 40	3
More than 40	1
Total	20

Postoperative hospital stay was for a minimum of 7 days and maximum of 44 days.

Table: - 6 To Sum Up On Follow Up

Asymptomatic	12 (65%)
Mild Symptoms requiring no treatment	4 (20%)
Severs symptoms requiring further management	3 (15%)

On follow up, 13 out of 20 patients were asymptomatic, 4 were symptomatic with mild symptoms.

Table: - 7 Biochemical Investigations (N=20)

Serum bilirubin (0.8-1.2 mg/100 ml)	Less than 1.2 mg%	15
	More than 1.2mg%	2
Serum proteins (5.5 gm/100 ml)	Less than 5.5 mg %	1
	More than 5.5 mg%	19
Serum albumin (3.0 gm %)	Less than 3 mg%	2
	More than 3 mg%	18
Serum globulin (2.0 gm/dl)	Less than 2 mg%	0
	More than 2mg%	20
Blood sugar (80-120 mg%)	Less than 120 mg%	18
	More than 120 mg%	2

All 20 cases were investigated and had hemogram, coagulation parameters, liver function tests, serum amylase and blood sugar.

Table:- 8 Radiological Findings

Plain AXR (n=19)	Aerobilia	19
	Reflux	15
Barium Meal (n=18)	Jejunal Diverticulum	1
	Duodenal Diverticulum	1
	Growth at D1 D2 level	1
	Normal Study	9
Ultrasonography (n=18)	Aerobilia	2
	Abnormal Study	
	Periampullary Growth	1
	Renal Calculus	1
	Incomplete Study	5
ERCP (n=2)	CBD Stricture	1
	Periampullary Growth	Failed

Table: - 9endoscopic Findings (N=13)

Patulous Opening with Free Bile Egress	11
Normal Upper GI Mucosa	11
Periampullary Growth	1
D1 D2 Growth	1

DISCUSSION

Trans duodenal sphincteroplasty as a surgical procedure for permanent biliary drainage was introduced to improve upon the results of sphincterotomy for acute relapsing pancreatitis by Jones in 1952⁹. A decade later it was performed for choledocholithiasis. Thereon it became more and more popular for recurrent or residual choledocholithiasis.

The incidence of choledocholithiasis has been found to increase with advancing age. It is more commonly found in females (due to increased frequency of choledocholithiasis per se in the female population). Furthermore it is seen at a younger age group in female². The same was the case in our study, where most of the patients were between 40 and 60 year of age (11/20- 55%) and 25% of the patients were females below the age of 40 years. In a study by Stefanini et al¹⁰, in a follow up on 712 patients of transduodenalsphincteroplasty, 63% patients were females and 37% males, 85% of the cases were between 40 to 60 years of age. This correlates well with our study where in 65% were of females, 35% males and 55% cases between 40 to 60 years age group.

The commonest clinical presentation of patients was with painful jaundice seen in 11 of 20 cases (55%). Two patients had painless jaundice. Antrum and Hall report 53% of painful jaundice, overall incidence of jaundice being reported as 63%². In our study it was 65% (13 of 20 cases). In another series by Kozloff et al in a follow up of 75 patients of TDS, admission was seen in 6% cases and in 10% cases pancreatitis was an associated pathology¹¹. In our study, 1 patient (5%) had cholangitis and 2 (10%) had pancreatitis.

Seven of our patients had undergone previous biliary surgery (35%) in our study. Thomas and Nicholson in their follow up study reported 24 of 53 cases as previously operated on the biliary tract (47%)⁷. In a report by Stuart and Hoerr¹² of 46 cases had undergone previous biliary operations¹². Five of 7 cases in our study had previous cholecystectomy done while 2 had their gall bladders left in situ.

Indication for transduodenalsphincteroplasty in all previous series of study has been predominantly choledocholithiasis. In our study, 10 patients were operated for choledocholithiasis, and 3 out of these 10 had correlates well with other authors (22 out of 46 cases in a series by Stuart and Hoerr 1972)¹². Stefanini et al had 76% of choledocholithiasis cases of which 12% were of residual stones. Ampullary stenosis was seen in 13 of 20 cases in this study. Two had associated common duct calculi, 2 cases had ampullary stenosis with biliary und, and 2 cases had pancreatitis associated with ampullary stenosis¹⁰. Stuart and Hoerr¹² in their study reported 28 out of 48 patients of transduodenalsphincteroplasty to be having ampullary stenosis of which 2 had associated pancreatitis as well, and 19 had associated choledocholithiasis.

White (1978) while describing indications for transduodenalsphincteroplasty reports 129 cases of TDS of which 62 cases had choledocholithiasis, 45 cases had pancreatitis, 2 had periampullary carcinoma, 5 were of injury to the pancreas, 22 had postcholecystectomy syndrome while 3 had an abnormal sphincter¹³. In our study final indications of transduodenalsphincteroplasty were decided intraoperatively, ampullary stenosis (7), multiple CBD stones with doubtful clearance (3), impacted ampullary stones (4) retained CBD stones (4) and chronic relapsing pancreatitis with ampullary stenosis and sludge (2).

The average post operative hospital stay in our study was of 12 days. An average of 10 days post operative stay has been reported by Giraldo and Legros. Endoscopic sphincterotomy has a relatively much shorter post operative hospital stay provided no major complications arise.

Amongst the early post operative complications, none of our patients had pancreatitis. The maximum reported incidence of pancreatitis is 3%. Cholangitis was noted in 3 of our cases (15%). This figure is much higher than the reported incidence which ranges

between 1 to 3% with a maximum of 7.1% (choi et al 1969)¹⁴. Wound infection was seen in 3 cases, two of which had total wound dehiscence requiring resuturing (15%). Stefanini et al¹⁰ report a 30% wound infection rate while Lygidakis¹⁵ reported only 5% incidence. The same author reported 3% incidence of respiratory infections. It was seen in one of our patients too (5%). In a follow up study on 712 cases one patient of subphrenic abscess was recorded by Stefanini et al (1984). One of our patients also had this complication (5%). Upper GI bleeding was seen in 2 of our cases reported incidence being 5 to 10%¹⁵. One patient in our study had post operative acute renal failure. Lygidakis in his series of 712 cases had 3 cases of renal failure out of which 2 died. Thrombophlebitis is seen in 4 patients. Stuart and Hoerr reported 3 cases in 31 of their patients in 1972¹⁵.

Other reported complications of DVT, biliary cutaneous fistulae, hemoperitoneum, pancreatitis, ileum etc. Were not seen in our study. Incidence of post operative complication varies in each series¹². In our study 15 such complications were noted in 10 of the cases. Ten patients had no post operative complications.

On Follow Up

Post operative major symptoms were seen in only 3 cases (15%). One had the final diagnosis of carcinoma of the pancreas (the pre operative diagnosis was chronic pancreatitis). Another patient with pre operative diagnosis of chronic pancreatitis had lower CBD stricture. The third was possibly not related to the surgical procedure or pre operative diagnosis as her biliary system was unaffected, this patient had disseminated malignancy with unknown primary site. Three patients complained of occasional dyspepsia for which no definite cause could be found. One patient had right sided renal calculus for which she is now under treatment. Thirteen of the patients were totally asymptomatic (65%).

There were no abnormalities in hemogram of these patients. Two patients who were clinically jaundiced

did have deranged coagulation parameters. The same patients had raised serum bilirubin as well with significant rise in alkaline phosphatase as well (30 KAU). Serum protein values were within normal limits. Hyperamylasaemia was found in 5 of the 20 cases but could not be correlated either to the clinical or further investigation profile of the patients. Stahl et al in a comparative study on long term results of surgical biliary drainage for partial biliary obstruction caused by chronic pancreatitis with no drainage, have studied various biochemical parameters and state that definite incidence of abnormal biochemical parameters cannot be quoted as it greatly varies depending on the various complications that an individual patient develops. However, raised values of serum alkaline phosphatase definitely indicate some degree of obstruction to the biliary system¹⁶.

Radiological and endoscopic findings were more informative. Plain X-ray abdomen was done in 19 of 20 patients of which pneumobilia indicating air in the biliary tree due to loss of sphincteric mechanism was seen in 8 of the patients (43.8%). In sphincterotomy cases Burmeister has recorded 42% of 47 cases of aerobilia with no reflux of contrast on barium study and in 23% aerobilia associated with reflux. In surgical study aerobilia was noted in 11% cases by there (1984) after 20 to 25 years also. No increase in incidence of cholangitis has been reported to be associated with these findings.

CONCLUSION

The conclusions drawn from this study were:

Transduodenalsphincteroplasty is a safe and effective permanent biliary drainage procedure. It has a high success rate in treatment of choledocholithiasis, residual stones, ampullary stenosis and impacted calculi. The abnormalities detected on follow up of these patients represent development of an independent lesion.

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