

# Pancreatic sphincteroplasty: indications and outcome

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## Summary

Twenty patients received transduodenal pancreatic sphincteroplasty for one of three indications: post-cholecystectomy pain with a strongly positive Nardi test ( $n=5$ ), recurrent attacks of idiopathic acute pancreatitis ( $n=7$ ) and chronic pancreatitis ( $n=8$ ). Three patients had an accessory sphincteroplasty in addition to double sphincteroplasty at the major papilla (transampullary septectomy). Pain was relieved in four of the five post-cholecystectomy patients at a median 21 months after sphincteroplasty. On a scale from 0–10 the mean pain score decreased from 9.1 to 2.8, and the preoperative rise in serum amylase with morphine-prostigmine provocation was abolished. None of the patients with recurrent pancreatitis has had a further attack postoperatively, though one had transient pain without hyperamylasaemia. Performed as an adjunct to other pancreatobiliary procedures in five cases, sphincteroplasty has contributed to a satisfactory result in all but two of those with chronic pancreatitis. The only serious complication was an infected pancreatic collection in two patients with concomitant resection or drainage of the distal pancreas.

## Introduction

There is little doubt that stenosis of the papilla of Vater can cause both chronic abdominal pain and recurrent attacks of acute pancreatitis. Obstruction of the terminal bile duct causing pain with or without jaundice can be treated by endoscopic papillotomy (1). Obstruction of the terminal pancreatic duct causing pain with or without hyperamylasaemia requires a transduodenal operation. Pancreatic sphincteroplasty or transampullary septectomy (2) should permanently abolish stenosis at both sites.

Many patients with persistent pancreatobiliary pain who are considered for endoscopic papillotomy or surgical sphincteroplasty will already have undergone cholecystectomy. The difficulty in selecting appropriate patients from among the 5–10% of those with post-cholecystectomy pain is generally acknowledged. Endoscopic retrograde manometry may demonstrate increased pressure in one or other ductal system and can distinguish organic stenosis from spasm, but the technique

requires considerable expertise and has a high failure rate (3). Simpler but more controversial, the morphine-prostigmine provocation test (Nardi test) relies on reproduction of pain and a sharp rise in serum pancreatic enzymes (amylase, lipase) (4–6). A positive test requires a relatively normal pancreas secreting against a closed and competent sphincter.

In Britain about one-quarter of attacks of acute pancreatitis are of obscure aetiology, ie 'idiopathic' (7). The proportion declines if a meticulous search is made for small gallstones and other rare causes, and ERCP may reveal an anatomical abnormality in up to 45% of patients with recurrent 'idiopathic' pancreatitis (8). The finding of isolated dorsal pancreas (pancreas divisum) or papillary stenosis may then be an indication for an operative attack on one or other pancreatic papilla (9,10).

Incrimination of bile reflux in chronic pancreatitis led Doubilet and Mulholland to introduce biliary sphincterotomy for this disease in 1956 (11); both the hypothesis and the operation were quickly discarded. However, pancreatic sphincteroplasty could be a useful single or adjunctive procedure in a few selected patients with chronic pancreatitis, for example those with relatively mild disease and obstruction in the region of the ampulla (12).

This paper reports the outcome of pancreatic sphincteroplasty performed on the major papilla ( $n=20$ ) or minor papilla ( $n=3$ ) for one of three indications: pancreatobiliary pain plus a positive Nardi test, recurrent acute pancreatitis and chronic pancreatitis.

## Patients and methods

In a personal series 20 patients received transduodenal pancreatic sphincteroplasty between 1979–87. Sphincteroplasty of the major pancreatic papilla was carried out in each patient, and in three accessory sphincteroplasty was also performed. There were 11 women and 9 men with a mean age of 43 years. Operation was indicated for one of three different clinical syndromes (Table 1).

### 1 Post-cholecystectomy pain

Five patients had chronic disabling pain in the epigastrium or right hypochondrium and radiating to the back.

TABLE 1 Indications for pancreatic sphincteroplasty

	Patients	M	F	Mean age (yr)	Previous cholecystectomy	Alcohol abuse
Post-cholecystectomy pain	5	1	4	43	5	0
Recurrent pancreatitis	5	1	4	32	2	1
Chronic pancreatitis	2	2	0	59	0	0
	8	5	3	45	3	4

In each case pain antedated cholecystectomy (without choledochotomy) undertaken for gallstones 2–20 years earlier (median interval 3 years). Negative investigations included radiology and endoscopy of the upper alimentary canal, barium enema, excretion urography, liver function tests and serum amylase. All patients underwent ERCP: there were no gallstones and the retrograde pancreatogram was normal in each case. Consistent with previous cholecystectomy, the bile duct was mildly dilated (*c.* 12 mm diameter) in three patients; moderate dilatation (*c.* 15 mm) in the other two was confirmed at operation.

These patients were selected for operation from among others with post-cholecystectomy pain on the basis of a strongly positive Nardi test (4). Serum amylase was measured and symptoms recorded for 1 h after an intramuscular (i.m.) injection of saline and for 4 h after an i.m. injection of morphine 10 mg plus prostigmine 1 mg. The test was considered positive if the morphine-prostigmine injection reproduced pain and caused a fourfold elevation in serum amylase. In four patients the Nardi test was repeated postoperatively. Before and at least 1 year after operation patients were asked to record the severity of their pain on a linear analogue scale from 0 (absent) to 10 (unbearable).

## 2 Recurrent pancreatitis

Seven patients had had between 3 and 10 attacks of acute

pancreatitis during the previous 2–6 years. Most attacks were sufficiently severe to require hospital admission, and hyperamylasaemia was confirmed on these occasions. In between episodes patients were largely free of pain.

Five patients had little or no evidence of permanent pancreatic damage on ERCP or indeed at subsequent operation (Fig. 1). Repeated tests for gallstones had been negative; two had already had gallbladders removed, one of which showed cholesterosis. One girl who had previously abused alcohol continued to have frequent attacks of pain and hyperamylasaemia, despite removal of a normal gallbladder and cessation of drinking. The other two patients had evidence of permanent but limited pancreatic damage both on investigation (ductal changes, calcification) and at laparotomy (Fig. 2). They were considered to have acute-on-chronic pancreatitis. Two patients with recurrent pancreatitis had pancreas divisum with virtual agenesis of the ventral moiety (Fig. 3). In these two and one other endoscopic cannulation of the duct of Wirsung was difficult or impossible. Altogether three patients had Nardi tests.

## 3 Chronic pancreatitis

Eight patients had more constant pain with ductal changes of chronic pancreatitis. Symptoms had been present for between 1 and 20 years (median 3 years). Only one patient had a Nardi test. Intermittent ex-

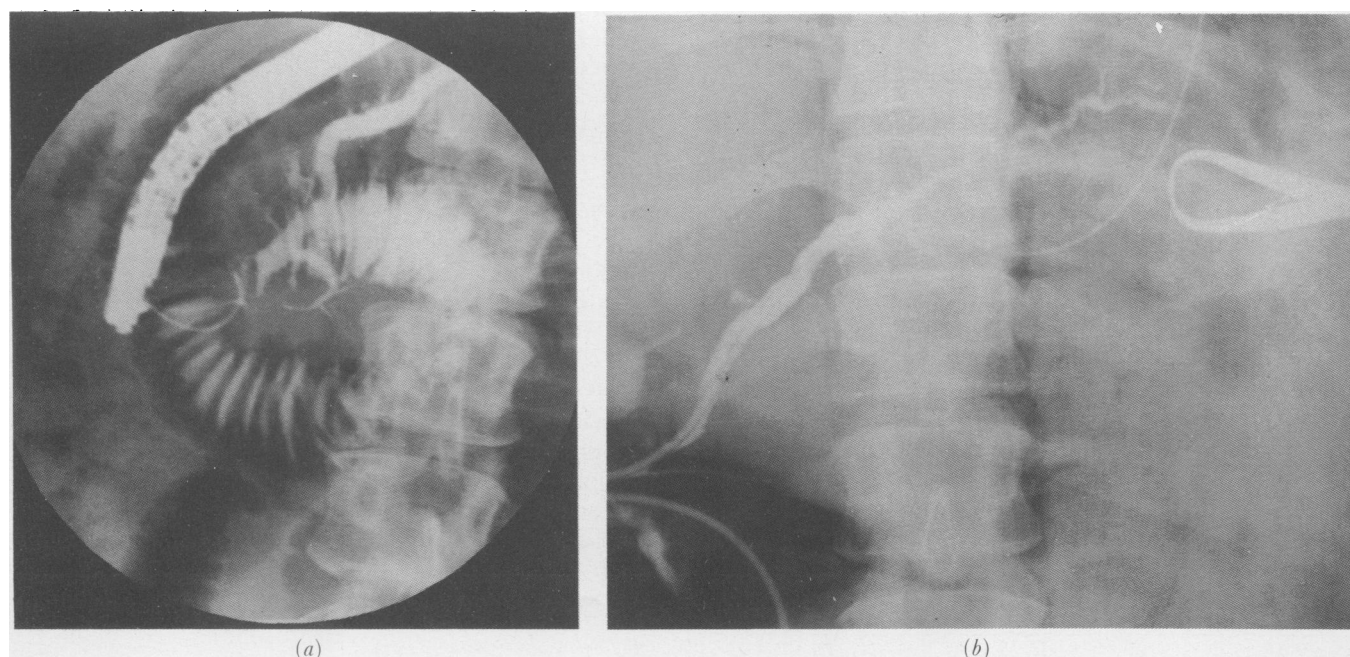


FIG. 1 Pancreatography in a 20-year-old girl with three previous attacks of acute pancreatitis. ERCP (a) shows slight dilatation of the pancreatic duct in the head of pancreas, which is confirmed by retrograde operative pancreatography (b) using an 8G catheter.

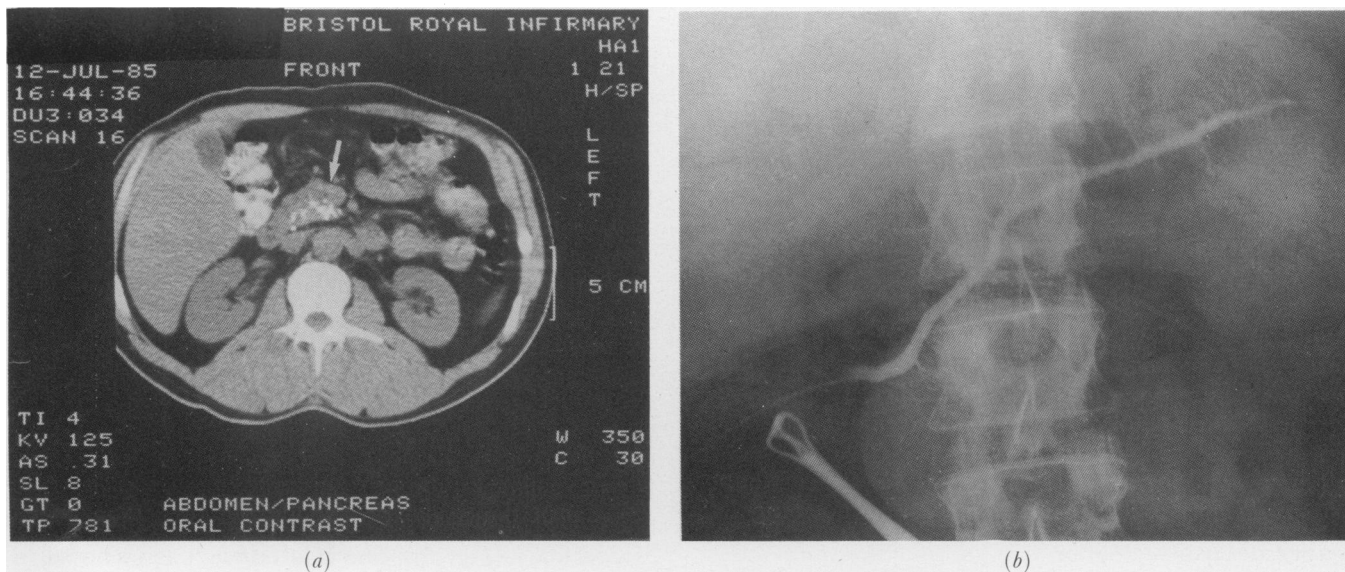


FIG. 2 Radiography in a 51-year-old man with recurrent pancreatitis for 2 years. The CT scan (a) shows calcification in the head of pancreas (arrowed). At operation the duct of Wirsung could not be found. Cannulation of the accessory papilla was difficult because of stenosis, but the duct of Santorini was radiologically normal (b).

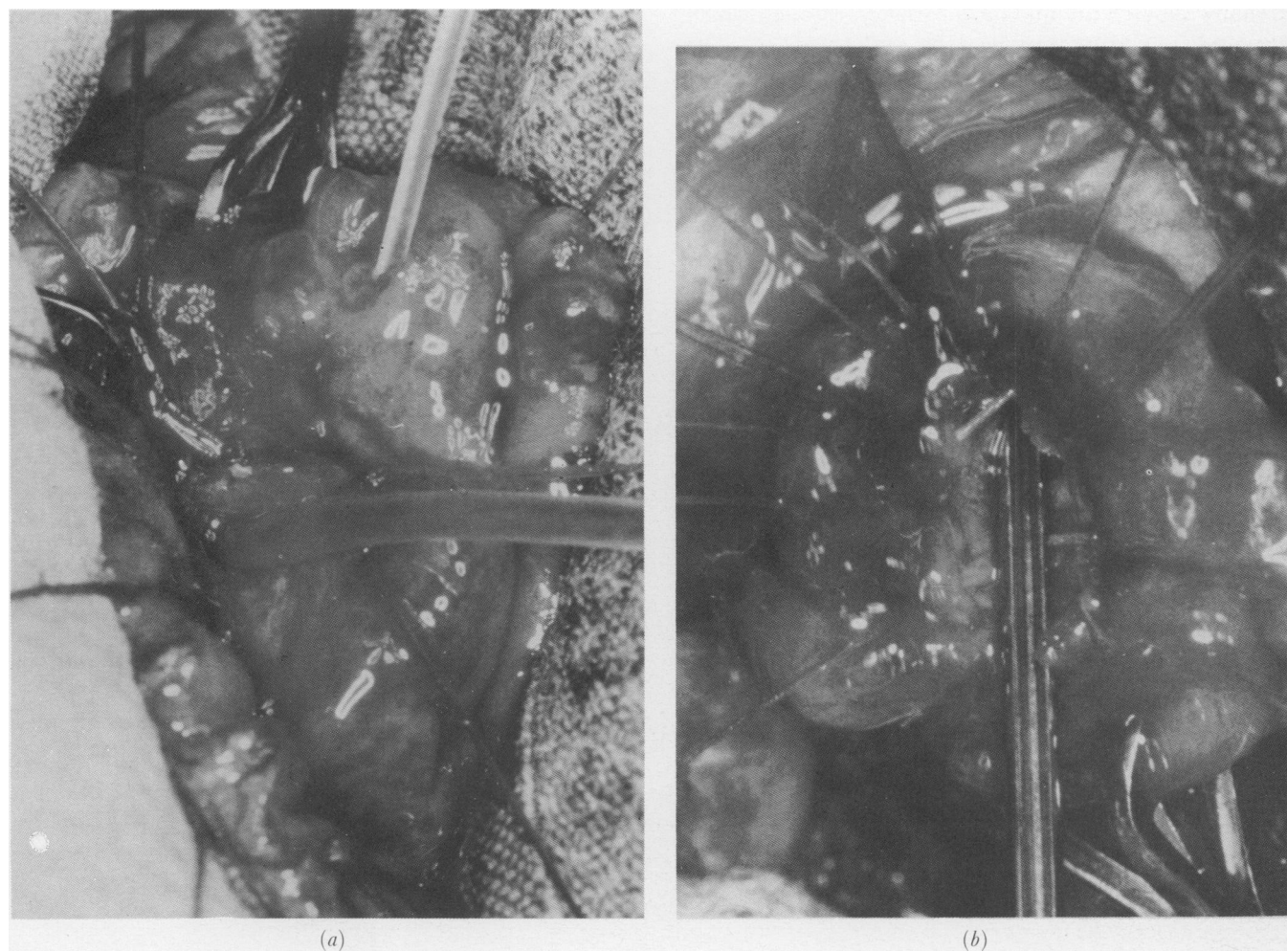


FIG. 3 Operative photographs in a 22-year-old man with six attacks of recurrent idiopathic pancreatitis. Following biliary sphincteroplasty (a) an 8G catheter passed readily up the bile duct. The duct of Wirsung could not be found. It required secretin to locate an ectopic accessory papilla anteromedial to the biliary papilla, which was cannulated with a 4G catheter (as shown). Following accessory sphincteroplasty (b) a grooved hernia director will readily enter the duct of Santorini. Pancreatitis has not recurred 3 years postoperatively.

acerbations of pain were generally not accompanied by elevation of serum amylase. One patient had undergone distal hemipancreatectomy for chronic alcoholic pancreatitis 5 years earlier with complete symptomatic relief until recently, when episodic pain recurred, together with hyperamylasaemia.

Pancreatic sphincteroplasty was combined with distal pancreatectomy, longitudinal pancreaticojejunostomy, extraction of a calculus from the pancreatic duct and revision of a choledochoduodenostomy in one case each. In six patients the main pancreatic duct was mildly dilated (*c.* 5 mm diameter) down to the papilla. The remaining two had gross ductal ectasia. One of these had longitudinal pancreaticojejunostomy plus accessory sphincteroplasty to drain a cystic duct of Santorini. The other was elderly (73 years old) with stones in the gallbladder and common bile duct, so pancreatic drainage was confined to transampullary septoplasty.

#### OPERATIVE TECHNIQUE

Through a longitudinal incision in the descending duodenum, the papilla is observed or palpated on the medial wall and drawn into the wound by Babcock's forceps. Following a biliary sphincteroplasty 15–20 mm in length, the orifice of the duct of Wirsung is identified on the lower lip of the ampulla at 5 o'clock. It will normally accept a 5G umbilical catheter, through which retrograde pancreatography can be performed (13). The common septum between the terminal portions of the bile duct and pancreatic duct is then incised for 10–15 mm, using fine-pointed scissors and sutures of 4/0 catgut or 5/0 Dexon® to coapt the mucosae. At the end of the procedure both ducts should be widely patent, presenting a double-barrelled appearance.

Various practical points have been found helpful. It is better not to apply forceps to the duodenal mucosa until the papilla has been discovered, otherwise instrumental trauma may obscure it. Faced with difficulty in finding the papilla, the supraduodenal bile duct is opened and an 8G Jaques catheter is passed from above. This manoeuvre also helps to identify a stenosed bile duct orifice if the initial sphincteroplasty enters the pancreatic duct. An elusive orifice of the major or minor pancreatic duct may be located after i.v. administration of secretin 1 U/kg, which produces a brisk flow of juice within one minute. A stenosed orifice of the pancreatic duct may require the passage of fine lacrimal probes before it will accept a cannula. Lastly, before incising the papilla or biliopancreatic septum, fine catgut stay sutures are placed on either side of the proposed line of cut.

## Results

#### PERIOPERATIVE COURSE

Of seven gallbladders removed at operation (Table II) three showed chronic acalculous cholecystitis, one gallstones, one cholesterosis and two were normal. Since 10 patients had already undergone cholecystectomy, only three retained their gallbladder. Before opening the duodenum in eight patients a soft catheter (6 or 8G) was passed down the bile duct through the cystic duct stump (*n*=3) or a supraduodenal choledochotomy (*n*=5); in four cases the catheter would not negotiate the papilla. In the remaining 11 patients the papilla was identified from below without difficulty, but in two of them it subsequently became necessary to pass a catheter from above to locate a stenosed biliary orifice after opening into the pancreatic duct. Intravenous secretin was needed to identify two stenosed ductal orifices of Wirsung and two ductal orifices of Santorini, one of which was ectopic (Fig. 3). The bile orifice was stenosed in eight patients, the duct of Wirsung in seven and the duct of Santorini in two. Overall 15 of the 20 patients had stenosis of at least one ductal orifice.

To amplify or update the ERCP findings, retrograde operative pancreatography was undertaken via the duct of Wirsung in 16 patients (once unsuccessfully) and via the duct of Santorini in three patients. Pancreatograms were abnormal in nine patients with relapsing or chronic pancreatitis. Biopsy of the biliopancreatic septum showed chronic inflammation or fibrosis in four of nine cases; fibrous nodules were observed in two of these patients. Following septoplasty extraction of a calculus from the pancreatic duct was successful in one patient but unsuccessful in another with more diffuse calcification. In eight patients with supraduodenal choledochotomy a T-tube was placed in the duct at the end of the operation. To minimise postoperative pancreatitis aprotinin (Trasylol®, 10<sup>6</sup> units) was administered i.v. in nine patients during the operation. Three patients underwent accessory pancreatic sphincteroplasty (Table II) either in addition to transampullary septoplasty (*n*=1) or when the duct of Wirsung could not be found (? agenesis) after opening the major papilla (*n*=2). Four patients had concomitant pancreatobiliary procedures, including 50% distal pancreatectomy, longitudinal pancreaticojejunostomy and conversion of a stenosed choledochoduodenostomy to a choledochojejunostomy Roux-en-Y (Table II). The last patient had a pinhole orifice of the duct of Wirsung which would scarcely accept the finest lacrimal probe (<1 mm diameter). After opening the orifice, ductal mucosa could not be clearly identified. A

TABLE II Operations performed

	Patients	Sphincteroplasty		Other drainage	Distal pancreatectomy	Cholecystectomy
		Major	Minor			
Post-cholecystectomy pain	5	5	0	0	0	0
Recurrent pancreatitis	{ acute { acute-on-chronic	5	1	1	1	2
		2	2	1	0	1
Chronic pancreatitis	8	8*	1	2	1	4

\* Including one patient in whom sphincteroplasty was repeated

TABLE III Outcome of pancreatic sphincteroplasty

	Patients	Postoperative complications	Symptoms		
			Resolved	Improved	Recurred
Post-cholecystectomy pain	5	0	2	2	1
Recurrent pancreatitis	acute	1	4	1	0
	acute-on-chronic	2	2	0	0
Chronic pancreatitis	8	3	4	2	2

conservative caudal pancreatectomy was therefore performed to allow prograde and subsequent retrograde pancreatography. Since an accurate sphincteroplasty could not now be achieved, lateral pancreatojejunostomy was carried out over a stenting tube.

Within 24 h of operation an elevated serum amylase was recorded in 13 patients with a median peak value of 1600 i.u./l (range 800–8000, normal <300 i.u./l). In each case the value fell sharply between 24 and 48 h and returned to normal by 5 days; no patient displayed clinical signs of acute pancreatitis. Two patients had a wound infection. Another two with additional pancreatic procedures developed left-sided collections of infected pancreatic juice requiring either operative or percutaneous drainage.

#### OUTCOME

Symptomatic results are summarised in Table III.

**1 Post-cholecystectomy pain** The preoperative Nardi test was strongly positive in all five patients. Typical pancreatobiliary pain was reproduced within 1–2 h of morphine-prostigmine injection. Serum amylase increased five- to nineteenfold above the upper level of

normal (300 i.u./l) or six- to twentyfourfold (median elevenfold) above baseline values (Fig. 4). Postoperatively these patients have been followed for a median of 21 months (range 15–36 months). In two patients pain is virtually abolished, in two it is greatly reduced but in one it persists, though less intensely than before. In this last patient repeat ERCP shows both ducts are widely patent, of normal calibre and draining freely. The Nardi test was uniformly negative when repeated 1–15 months after operation in four patients; there was little or no pain (although there was still some nausea) and serum amylase scarcely rose above the normal range. The mean preoperative pain score was 9.1 (range 7.4–9.8), falling to 2.8 (range 0.6–5.3) on outpatient review.

**2 Recurrent pancreatitis** Two of the three preoperative Nardi tests were equivocal (Fig. 4). In one the basal serum amylase was already elevated (760 i.u./l), and it merely doubled in response to morphine-prostigmine. Another patient showed the greatest enzyme response of all, a remarkable fortysevenfold rise in serum amylase, but experienced no pain whatsoever. The third had a positive test with reproduction of pain and a fourfold elevation in amylase.

None of the seven patients has had a documented attack of acute pancreatitis following sphincteroplasty at a median follow-up of 18 months (range 6–48 months). One was readmitted with a short-lived attack of pain but no increase in serum amylase; the others are symptom free. Two patients in this group retain their gallbladder.

**3 Chronic pancreatitis** The one preoperative Nardi test was completely negative (Fig. 4); it was carried out in a patient with previous distal hemipancreatectomy. The eight patients have been followed for a median of 48 months (range 15–100 months). Four have had a complete symptomatic cure, including one man who died of cerebral haemorrhage at 30 months. Two are much improved but still experience episodic pain requiring analgesics. Two unsuccessful results are discussed below.

In one patient sphincteroplasty abolished pain immediately, but after 18 months symptoms returned exactly as before. Neither duct could now be cannulated endoscopically and repeat operation was performed. Following limited caudal pancreatectomy a prograde pancreatogram showed stenosis of the orifice of the duct of Wirsung; a repeat transduodenal sphincteroplasty was undertaken since the pancreatitis did not seem particularly severe. Once again initial pain relief was complete, but the patient relapsed and required regular opiates (pethidine 500 mg/day). One year after the second sphincteroplasty a conservative proximal pancreato-

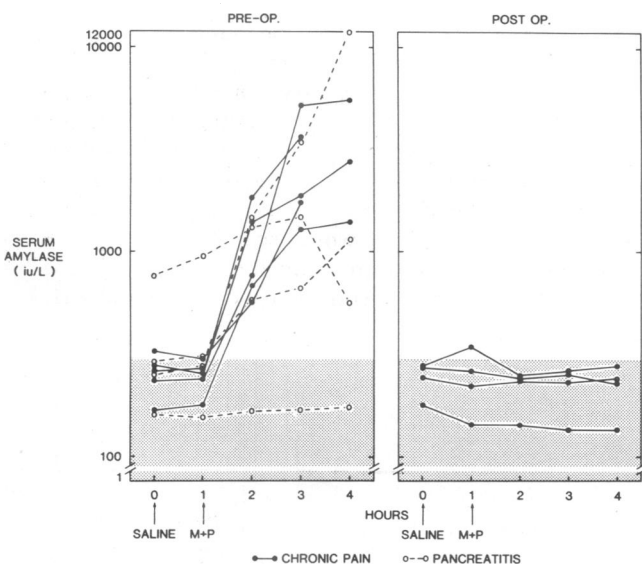


FIG. 4 Results of the Nardi test before and after pancreatic sphincteroplasty. Five patients with chronic pain (solid lines) had more than fivefold elevation in serum amylase after morphine-prostigmine (M+P), but operation abolished the response. Of four patients with pancreatitis (dotted line) only one had a truly positive response.



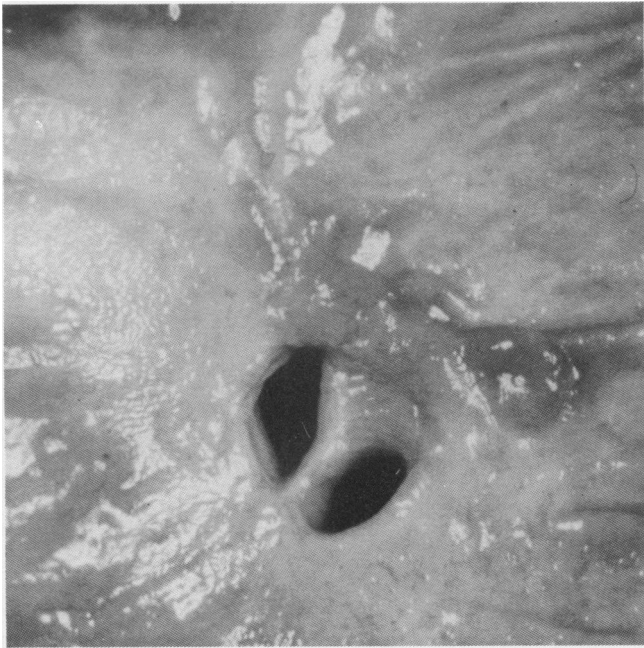


FIG. 5 Pancreatoduodenectomy specimen in a 40-year-old woman with chronic pancreatitis of unknown cause. One year after a repeat sphincteroplasty both the bile duct and the duct of Wirsung are widely patent.

duodenectomy was successfully performed. The resection specimen showed that both ductal orifices were widely patent (Fig. 5).

The last patient developed transient pain and hyperamylasaemia 7 months postoperatively and continues to have niggling epigastric pain. This was the man with previous distal pancreatectomy for alcoholic pancreatitis, in whom unsuccessful attempts were made to dislodge calculi from the pancreatic duct at the time of sphincteroplasty. Completion pancreatectomy is the only residual surgical option, but the patient has neither diabetes nor steatorrhoea at present.

### Discussion

The clearest indication for pancreatic sphincteroplasty is probably recurrent idiopathic pancreatitis in patients with suspected papillary stenosis or pancreas divisum. ERCP is a crucial investigation in such patients, and the inability of an experienced endoscopist to cannulate the pancreatic duct may be taken as evidence of stenosis (14). Cannulation of the accessory papilla was unsuccessful in the two patients with pancreas divisum, and this is usually the case (10,15,16). In recurrent acute pancreatitis (as opposed to non-specific abdominal pain) the Nardi test is probably superfluous; it may also be difficult to interpret and could theoretically precipitate another attack of pancreatitis. Frequent attacks of acute pancreatitis in a young patient who does not abuse alcohol are an indication for laparotomy. If biliary disease is then excluded, it would seem sensible to proceed to sphincteroplasty at one or other papilla. Certainly the results in this small series have been gratifying. All six non-alcoholic patients have been relieved of further attacks, while in the seventh (who previously abused alcohol) the frequency and intensity of pain is much reduced.

Pancreas divisum (isolated dorsal pancreas) has been identified on ERCP in 12–25% of patients with

idiopathic recurrent pancreatitis (8,15,17) but only 3% of those with non-specific pain (17). In Warshaw's experience accessory sphincteroplasty was successful in 18 of the 19 patients with clearcut stenosis at the minor papilla, including 13 of the 15 with discrete attacks of acute pancreatitis, but the results have been less reliable in other series (10,16). Two patients had a tiny orifice of the duct of Santorini and have been cured of their recurrent pancreatitis by accessory sphincteroplasty. The contribution of an isolated dorsal pancreas to chronic pancreatitis is much less certain, though such a link has been postulated (18). We have found limited periductal fibrosis in a small number of patients undergoing caudal pancreatectomy for pancreas divisum (19). However, the anomaly was not encountered among 67 patients with sphincter operations for mild or moderate pancreatitis in Boston (12) nor yet among some 50 patients with severe chronic pancreatitis on whom I have operated in Bristol.

Both the definition and the predictive value of a positive Nardi test are open to question. The original criteria were reproduction of pain plus a fourfold elevation of at least one serum pancreatic enzyme, ie amylase, lipase or amidase (4). Others have taken either pain or raised enzymes as indicating a positive test, accepting anything from a two- to fivefold elevation in amylase (or lipase) or even a rise in liver enzymes (5,6,14,20–22). In considering a major operation I have felt it right to adopt Nardi's original and relatively stringent criteria, namely both pain and a fourfold increase in serum amylase in response to morphine-prostigmine. Can the Nardi test select out a group of patients with abdominal pain who will benefit from division of the sphincter? Certainly elevations in serum amylase and lipase and liver enzymes have been found in healthy volunteers (albeit without pain) (20–22), and morphine-prostigmine can reproduce the typical pain of irritable bowel syndrome (21). Combining the clinical and biochemical criteria should increase its sensitivity, however. In any case no other test has yet been shown to be superior, though various groups have advocated ultrasonography during pancreatic stimulation and manometry by the endoscopic, transhepatic or intra-operative routes (23).

It has been suggested that ERCP manometry is a more reliable technique than the Nardi test for demonstrating serious sphincter dysfunction (23), but in one series neither test could predict the result of endoscopic papillectomy (1). Unfortunately ERCP manometry is not always feasible for technical reasons, failing in up to 46% of patients (3). Furthermore, pressures tend to be measured either at an unidentified point in the sphincter of Oddi or within the distal bile duct (22,24) rather than the pancreatic duct (3), which could make just as important a contribution to epigastric pain that radiates to the back. If so, surgical drainage of both ducts should be the aim. Several reports endorse the value of the Nardi test in identifying appropriate patients. Thus the test was positive in only 23 of 70 patients with suggestive symptoms, but 17 of these turned out to have stenosis of the papilla or major pancreatic duct (14). Elsewhere 50 patients were chosen for sphincteroplasty on the basis of a positive test; intra-operative manometry was abnormal in 39, papillary biopsies showed inflammation or fibrosis in 36 and a good result was obtained in no less than 44 (ie 80%) (6). Nardi himself found that the preoperative response to morphine-prostigmine could discriminate

between success and failure 5 years after transduodenal sphincteroplasty (25). The operation effectively abolishes the response to morphine-prostigmine, as demonstrated in our patients and elsewhere (6,25). Satisfactory results in four out of five of the present patients encourage me to continue using the Nardi test to help select patients with post-cholecystectomy pain for sphincteroplasty. The test is simple and safe and at the very least can identify those in need of further investigation.

In established chronic pancreatitis sphincteroplasty has a very limited role. It can facilitate retrograde pancreatography (if ERCP is inadequate) and extraction of ductal calculi and should relieve a localised ductal stenosis immediately adjacent to the papilla. Long-term relief of symptoms may be anticipated in about 40% of patients with relatively mild disease, especially if they abstain from alcohol, and the short-term benefit is greater (12). In the present series six of eight patients have had a useful response, but sphincteroplasty was only an adjunct to other pancreatobiliary procedures in five patients and biliary disease predominated in another two. The last patient came to repeat sphincteroplasty and finally to proximal pancreatectomy. It might have been better to resort to resection at an earlier stage, although the immediate improvement after each sphincteroplasty was dramatic and symptoms always seemed disproportionate to the severity of underlying disease.

Pancreatic sphincteroplasty can be a safe and relatively straightforward operation with potential application in three different clinical settings. The most serious complication, an infected collection of pancreatic juice, was only seen in two patients with an additional assault on the body of the pancreas. Transient postoperative hyperamylasaemia was common (65%) but unimportant; it only failed to develop when operative pancreatography was omitted or there was extensive chronic pancreatitis. The incidence of acute pancreatitis in other series is 8–10% (2,6), and there is also a risk of duodenal fistula, which can be fatal (6,12). Since pancreatitis might result if the duct of Wirsung is injured or occluded by sutures, identification and cannulation of its orifice should be a routine part of any transduodenal sphincteroplasty. When the bile duct or either pancreatic duct is stenosed (75% of the cases presented here), location of the orifice may necessitate a protracted search, sometimes assisted by passing a choledochal catheter from above or administering secretin. In 19 of the 20 patients it was then possible to proceed to an accurate transampullary septoplasty, but in the last case amputation of the tail of pancreas was required first to locate the duct of Wirsung and then to ensure its safe drainage.

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