

Transduodenal Sphincteroplasty

5–25 Year Follow-up of 89 Patients

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Between 1957 and 1977, 95 patients underwent transduodenal pancreatic sphincteroplasty (TPS) for a diagnosis of recurrent pancreatitis. Five to twenty-five year follow-up was obtained for 89 patients (94%) and was analyzed by life-table method. Short-term successful outcome was defined as relief of symptoms (e.g., pain) for one to three years; long-term successful outcome was defined as those patients who remained symptom-free at time of last follow-up. Operative mortality was 4.2% (4 patients). Fifty-six patients (66%) had a successful short-term outcome. Of these, 13 patients had recurrence of symptoms: 7 occurred at 4 years, 5 at 5 years and 1 at 6 years. Preoperative factors associated with poor short-term outcome were previous upper abdominal surgery ($X^2 = 5.67$, $p < 0.05$) and frequent diarrhea ($X^2 = 6.18$, $p < 0.05$). Preoperative factors associated with poor long-term outcome were previous upper abdominal surgery ($X^2 = 7.82$, $p < 0.01$), heavy alcohol intake ($X^2 = 4.71$, $p < 0.05$), narcotic use ($X^2 = 5.68$, $p < 0.05$) and frequent diarrhea ($X^2 = 4.8$, $p < 0.05$). Morphine Prostigmin Test (MPT) was performed preoperatively in 78 patients (82%). A significantly greater proportion of patients with a rise in serum pancreatic enzymes secondary to MPT (MPT+) had a successful long-term outcome compared with those without such a rise (MPT-) (61% v 41%, $X^2 = 5.13$, $p < 0.05$). Furthermore, of the patients with a successful short-term outcome, 88% with MPT+ remained long-term symptom-free compared to 38.5% with MPT- ($X^2 = 8.36$, $p < 0.01$). We conclude that TPS can be a successful operation for acute recurrent pancreatitis. Previous upper abdominal operations, signs of more advanced pancreatic disease, preoperative narcotic use and alcohol abuse, were associated with a worse outcome and probably associated with chronic recurrent pancreatitis. Preoperative use of MPT, coupled with accurate clinical history, defined groups with different short- and long-term prognosis after TPS.

TRANSDUODENAL SPHINCTEROPLASTY for pancreatitis and papillary fibrosis has had a long and checkered career. Langenbuch is credited with suggesting, in 1884, that stenosis of the sphincter of Oddi might cause biliary symptoms and first proposed transduodenal di-

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vision of the sphincter.¹ The operation was subsequently modified by Kocher² in 1894, who advised suturing the cut edges of the papillotomy describing the procedure as an internal choledochostomy. It was Archibald,³ however, who designed a systematic surgical approach which resulted in the classic operation of sphincterotomy. In 1926, Del Valle^{4,5} of Buenos Aires achieved excellent results by "papillosphincterotomy" in a large number of patients suffering from the pain of what he described as a "sclerosing choledoch-Odditis."

In 1956, Doubilet and Mulholland⁶ published their results of sphincterotomy for pancreatitis, which they believed resulted from reflux of bile into the pancreatic duct. In 190 patients followed for 2 years they claimed 90% good results. Subsequent enthusiasm for this procedure was short-lived and, as a form of treatment for pancreatitis, sphincterotomy was virtually abandoned.

It was our feeling however that the cause of this syndrome was not biliary reflux but an outflow obstruction associated with an actively secreting organ,^{7,8} e.g., an obstructive pancreatopathy. In 1960, we⁹ proposed that the orifice of the duct of Wirsung should be enlarged in conjunction with ampullary sphincteroplasty. This concept was supported by the Marseilles Symposium of 1963,¹⁰ which distinguished between patients with a normal parenchyma, who could be relieved by nonresective measures (Sarles' Type II) and those with progressive parenchymatous disease who required resection (Sarles' Type III).

Further support for this concept was obtained by our observations^{11,12} that the orifice of the duct of Wirsung could be involved by a fibrotic process both in association with fibrosis of Oddi's sphincter as well as an isolated phenomenon localized to the orifice of the duct of Wirsung. Over a period of 25 years I have personally

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performed this operation of double sphincteroplasty, more aptly described as transampullary septectomy by Moody,¹³ in 114 patients. This report details our experience.

Clinical Material and Methods

The operation, which has been previously described,⁹ consists of a transduodenal ampullary sphincteroplasty of 1.5 to 2.0 cm combined with division of the septum, that makes up the floor of the common duct, and the roof of the pancreatic duct, so that a No. 3 Bakes dilator can be passed into the terminal pancreatic duct. (Fig. 1) Choledochostomy is not routinely performed. Pan-

creatography was done routinely, either at the time of operation or after surgery by ERCP. Only patients with a nondilated patent duct are included in this study, since significant duct dilation was considered to represent a more chronic form of this disease and better treated by lateral pancreatojejunostomy.¹⁴

Of the 114 patients studied, 19 had associated procedures such as vagectomy, gastrectomy, splachnicectomy, and hiatus hernia repair. These patients were discarded from the study, leaving 95 who had only a sphincteroplasty. In 42 of these whose gallbladder was still present cholecystectomy was also done. Six of the patients were lost to follow-up and four died after surgery, leaving 85 patients who are the subject of this report.

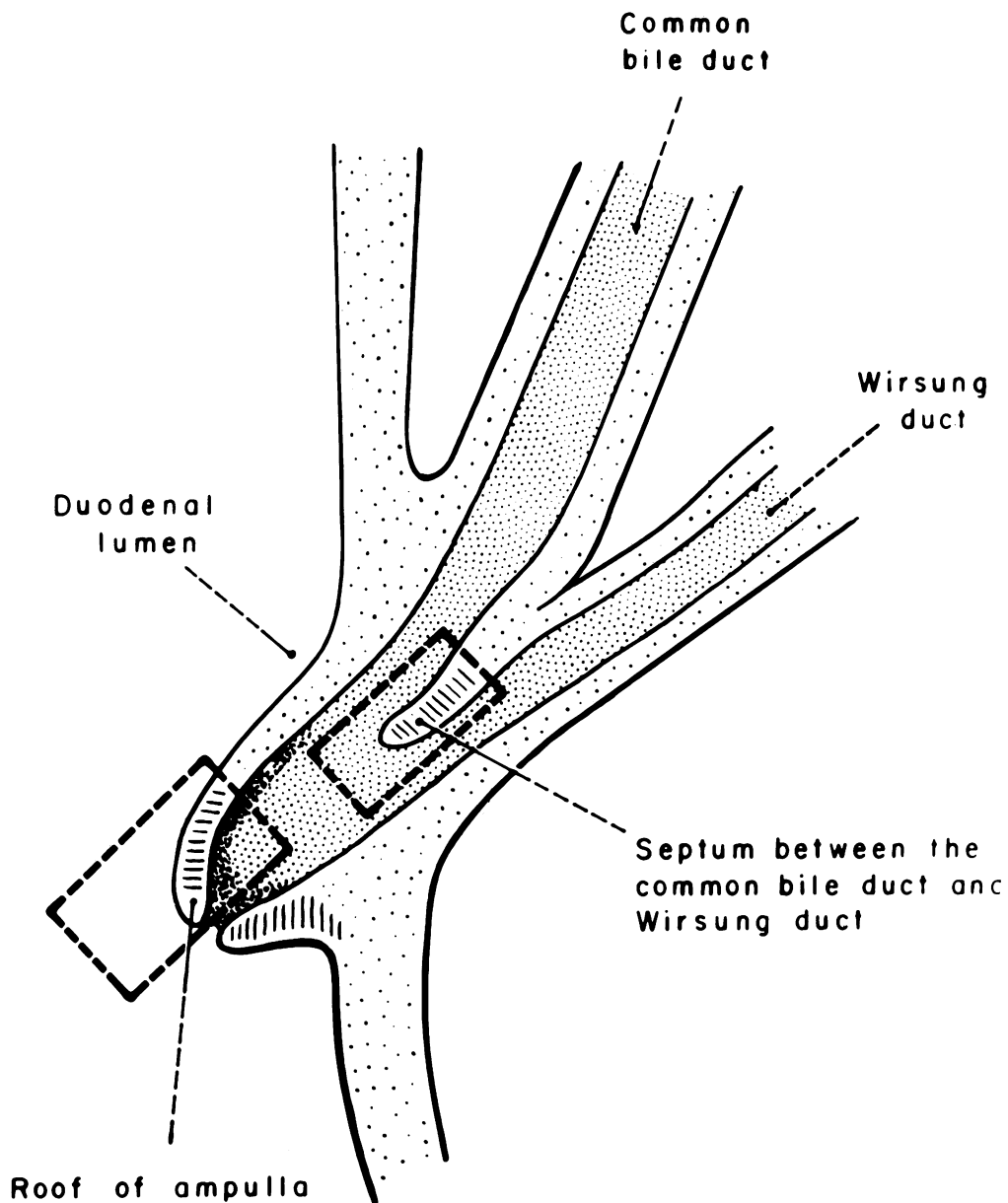


FIG. 1. Longitudinal section of the ampulla of Vater, common duct, Wirsung's duct, and duodenum. Dotted blocks represent sites of biopsies. Operative unroofing was carried further. (From Arch Surg 1966; 92:355.)

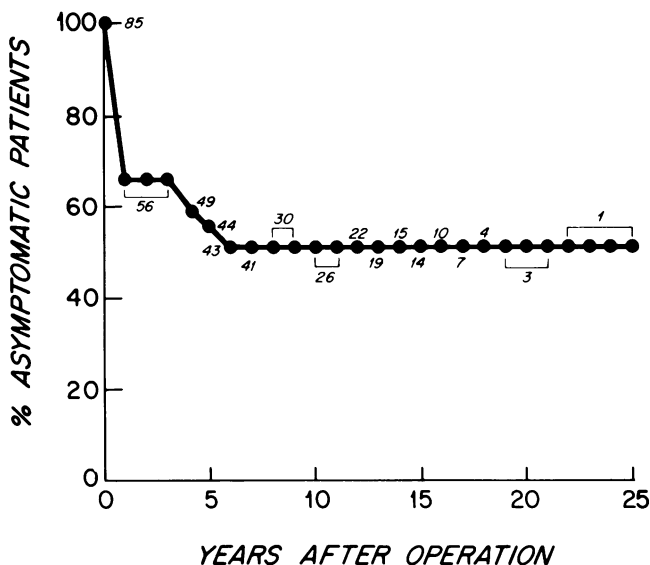


FIG. 2. Number of symptom-free patients following operation.

In this group there were 18 men and 77 women ranging in age from 12 to 75. All had a similar clinical presentation: recurrent bouts of epigastric pain radiating to the back which were unrelieved by medical measures. Forty-five had had up to four previous operations to relieve their pain. Thirty-one used pain relieving drugs and ten drank alcohol to excess. None had pancreatic calcification or biliary calculi.

A Morphine Prostigmin Evocative Test⁷ was done after surgery in 78 (82%). This consisted of an intra-

muscular injection of 10 mg of morphine and 1 mg of Prostigmin Methylsulfate. Serum amylase and lipase were measured before and 1, 2, and 4 hours after injection. A test was considered positive when enzyme levels rose to a value three times greater than normal. The value of this evocative test as a possible screening examination for patients with obstructive pancreatopathy has been supported by others.^{15,16}

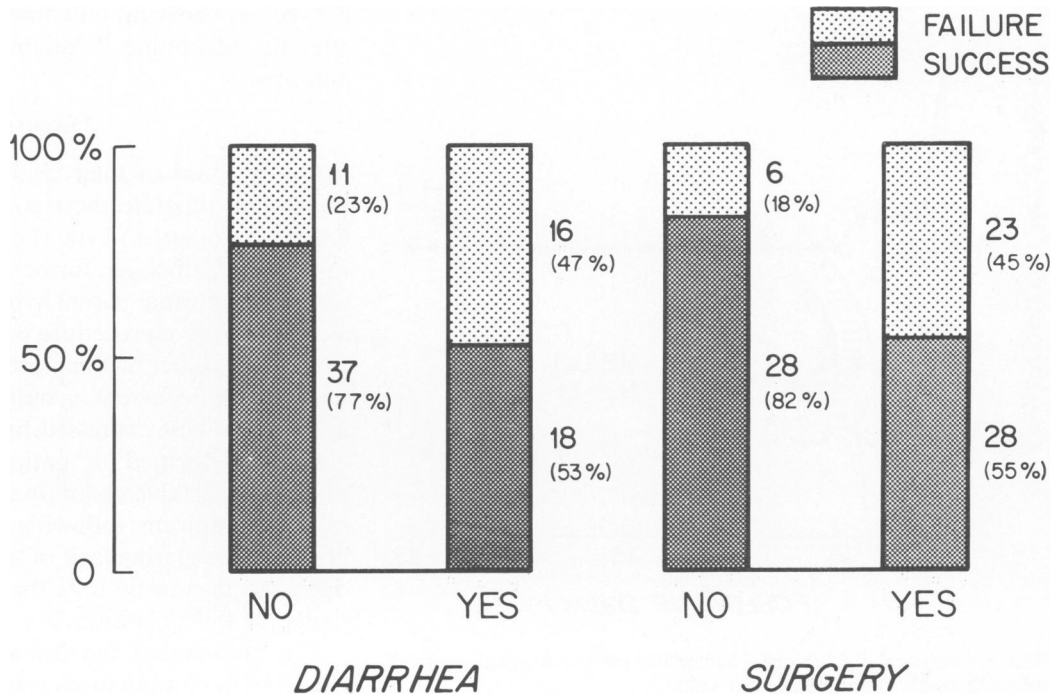
All 85 patients completed a detailed questionnaire with a personal or telephone follow-up. All data obtained was entered into a computer, programmed for statistical analysis and graphic printout and the data derived is presented here. A good result was considered as complete relief of symptoms.

Results

Fifty-six (66%) of these patients had a successful short-term outcome for up to 3 years. Subsequently, 13 developed recurrent symptoms, leaving 43 (50%) with good long-term results (e.g., symptom-free at this time, a minimum of 5 years) (Fig. 2). All patients who were symptom-free at the end of 5 years remained so for the entire follow-up period.

Preoperative factors associated with poor short-term outcome were previous upper abdominal surgery and frequent diarrhea (greater than 3 times per week). The presence of either reduced the chances for a good outcome by 30% (Fig. 3). There was no correlation with the type of operation which had been previously performed. Presence of both diarrhea and previous abdominal sur-

FIG. 3. Influence of diarrhea or previous major surgery on successful outcome.



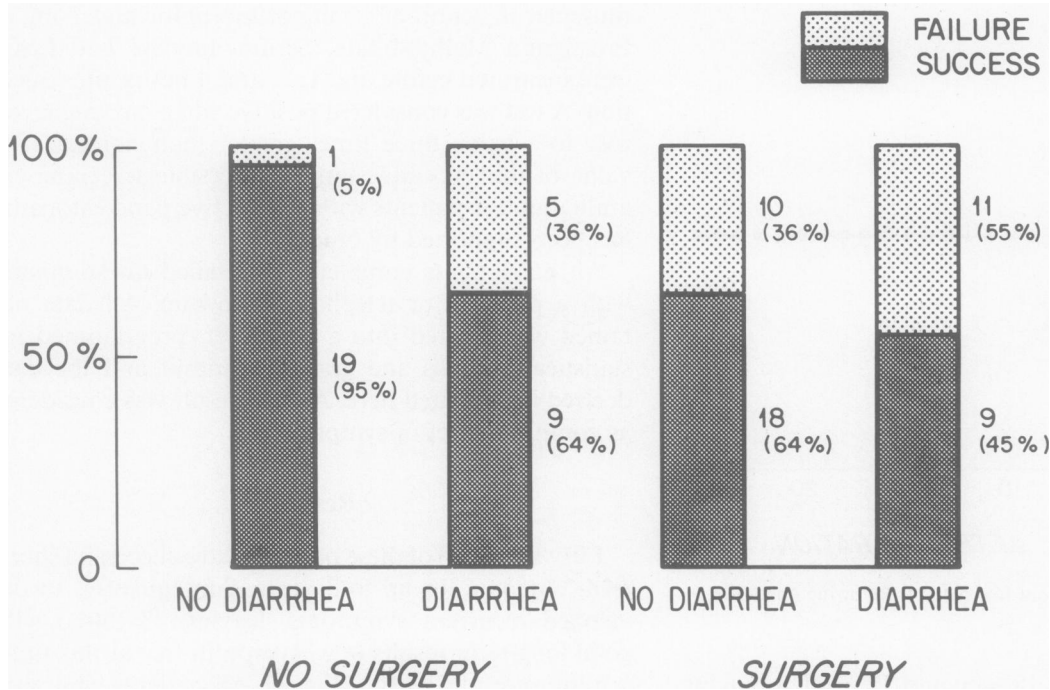


FIG. 4. Influence of combination of diarrhea and major surgery on successful outcome.

gery resulted in an even greater differential (Fig. 4). In reviewing the value of the Morphine Prostigmin Test as an indicator of successful outcome, it was observed that it had no predictive value insofar as short-term results were concerned. However, when positive, it predicted 60% successful long-term outcome and, when negative, predicted only 28% good results (Fig. 5). On a long-term basis, previous abdominal surgery and diarrhea were again found to have statistical significance as predictors

and, in addition, drug and alcohol abuse also augured a poor result (Fig. 6).

When these short- and long-term predictors are combined with a positive or negative Morphine Prostigmin Test, varying degrees of success can be predicted, ranging from 80% good results in the previously unoperated patient with a positive evocative test to total failure in the alcoholic with a negative test (Fig. 7). It should be noted that there was no significant statistical correlation between a successful outcome and reproduction of pain after the Morphine Prostigmin Test or fibrosis of the ampulla.

Discussion

On the basis of their clinical presentation, it is impossible to separate these patients with recurrent pancreatitis into Sarles' Type II or III. Yet, this is of utmost importance, since the former, with acute recurrent disease and a normal parenchyma, should respond well to a decompressive procedure when obstruction is present, whereas the latter, with progressive pathology, will eventually have recurrent symptoms. This diagnostic dilemma was best expressed by Longmire,¹⁷ who stated: "When performed in patients with so-called unexplained intractable abdominal pain, the high recurrence rate of symptoms following sphincteroplasty has emphasized the glaring lack of any specific, objective, preoperative diagnostic tests that we can use to select patients for this operation."

The finding that diarrhea and previous surgery could singly, or in combination, result in a significantly poorer

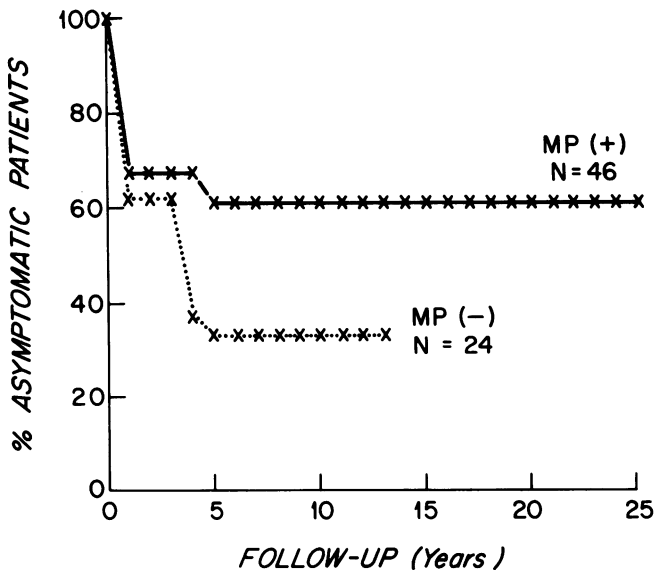


FIG. 5. Comparison of successful outcome in patients who had positive or negative Morphine Prostigmin Tests.

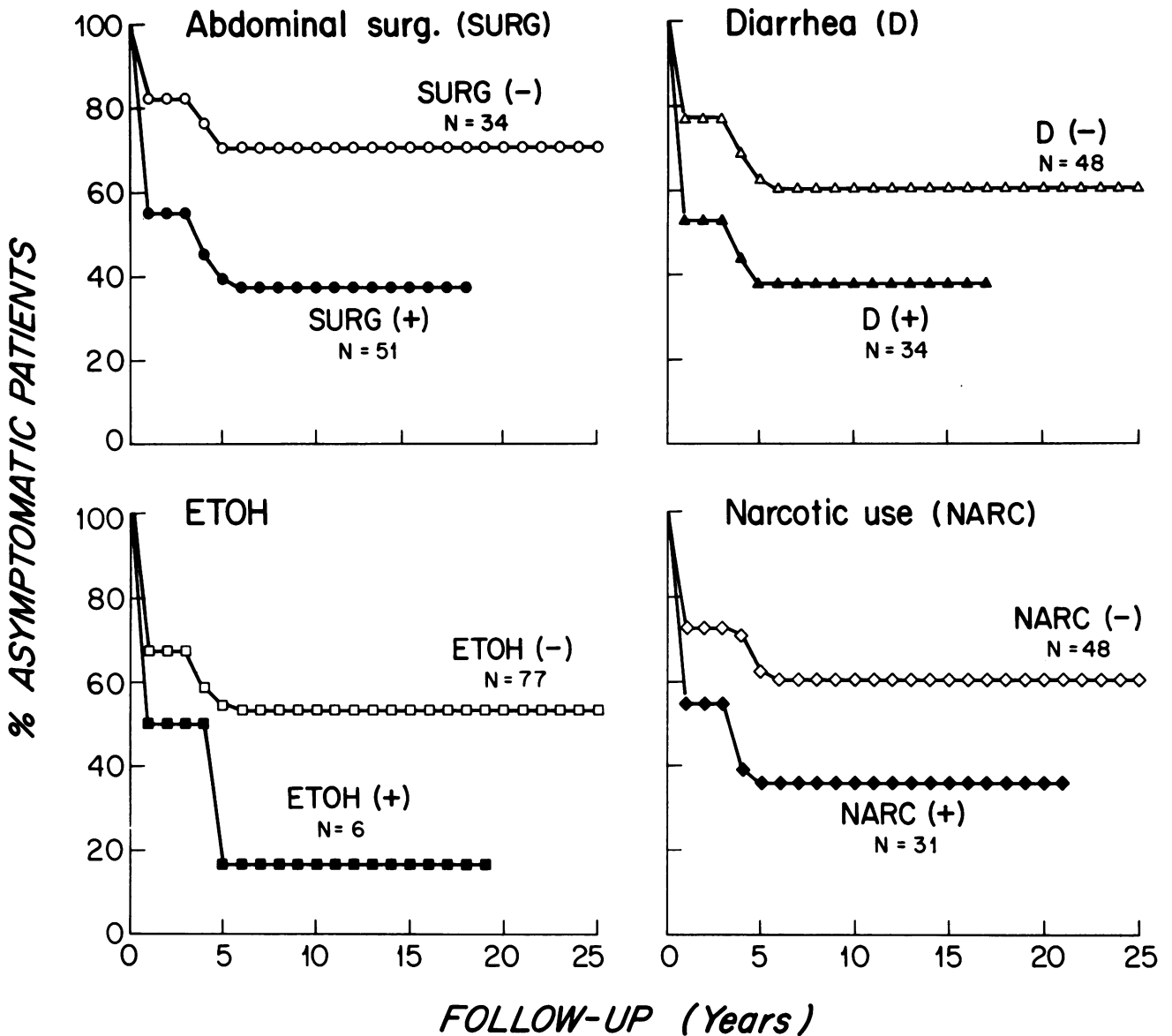


FIG. 6. Long-term effect of abdominal surgery, diarrhea, alcoholism, and drug use on successful outcome.

outcome may signal that these may be patients with early exocrine insufficiency and long-standing disease suggestive of Sarles' Type III. The poor results associated with alcoholism and drug dependency are well recognized and, again, should alert us to the fact that we are dealing with a type of disease which will not respond to decompressive measures.

The lack of correlation between inflammatory changes in the sphincter and a good result is not surprising, since papillary pathology may result from either a primary stenosis resulting in acute pancreatitis or secondary involvement by diffuse and progressive chronic pancreatitis. The fact that the Morphine Prostigmin Evocative

Test was not found to be any type of predictor on a short-term basis may be due to the fact that its possible value was completely overshadowed by the influence of the previous short-term factors. Since there were no recurrences after 5 years, one might assume that at least 50% of these patients were suffering from acute pancreatitis, and the other half who relapsed represented those with chronic pancreatitis or technical failure, *e.g.*, restenosis or inadequate decompression.

The relative success of the evocative test as a long-term predictor was impressive, particularly when coupled with one of the other factors. Patients with a positive test and no previous surgery had an 80% chance

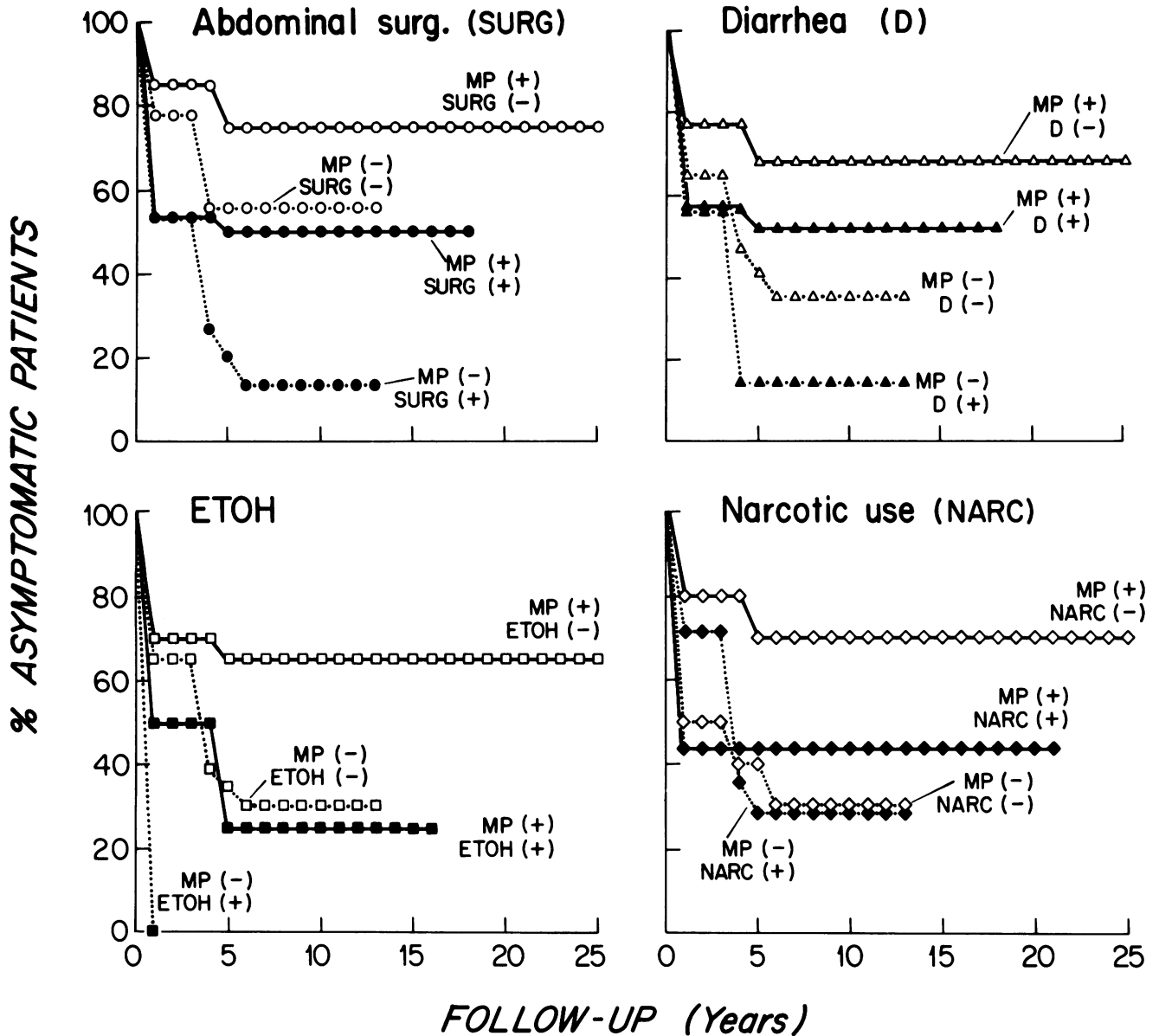


FIG. 7. Successful outcome when result of Morphine Prostigmin Test combined with history of previous surgery, diarrhea, alcoholism, or drug abuse.

for a good outcome, while a previously operated patient with a negative test had only a 15% possibility. It was tempting to combine the evocative test with more than one of the other predictors, but the resultant numbers in each group were then too small to be statistically significant.

We would suggest that those patients that can respond with serum enzyme elevations to an evocative test are more likely to represent those with a functioning parenchyma, *e.g.*, Sarles' Type II or early Type III, while

those who do not respond may already reflect the parenchymal deficiency of Type III. Hedberg¹⁸ has recently suggested combining ultrasound observation of the biliary and pancreatic ducts with the Morphine Prostigmin Test. Our initial studies have shown biliary and pancreatic ductal dilation synchronous with enzyme elevation (Fig. 8). This finding is in accord with observations that increased pancreatic duct pressure occurs in pancreatitis.¹⁹

It is well known that administration of morphine can

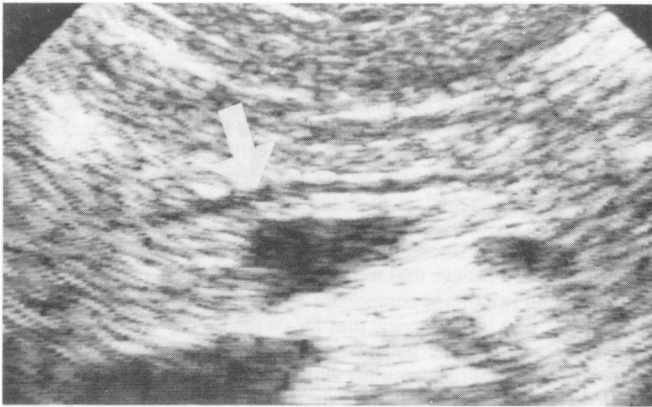


FIG. 8. Ultrasound study performed in course of a positive Morphine Prostigmin Test. The pancreatic duct (arrow) which is normally barely visible has dilated to 3 times its prestimulation diameter.

result in serum enzyme elevations in normal people. We make no claim to the specificity of the Morphine Prostigmin Test as a diagnostic agent in pancreatic disease. It has however, in the absence of other information, been of value in the management of these difficult situations.^{7,15,16} Experience may indicate that serum lipase elevations may be more reliable than amylase measurement.¹⁵ I have found reversion to normal in a limited number of tests done after surgery.

Serum enzyme elevation, duct dilatation, and increased ductal pressure argue eloquently that an obstructive process plays a role in certain forms of recurrent pancreatitis and that it is in this type of disease that sphincteroplasty may be effective. Further experience with this and similar tests may help us select those patients who will benefit from drainage operations, and save those who will not benefit from unnecessary surgery.

DISCUSSION

DR. ROBB H. RUTLEDGE (Fort Worth, Texas): Dr. Nardi has shown us that transduodenal sphincteroplasty, accompanied by a sphincteroplasty of the pancreatic duct, is a successful operation for acute recurrent pancreatitis. We are indebted to both him and Dr. Bartlett for their original report, back in 1960, and now for this long-term follow-up. Even with the help of ERCP examinations, it is difficult to pick out the patients who will benefit from this surgery.

I rely heavily on the clinical history, and routinely use the morphine prostigmine test. A positive test, coupled with a strong clinical history, is quite helpful. A negative test, or a positive test unsupported by other evidence, is not as reliable.

(Slide) My technique of sphincteroplasty is very similar to Dr. Nardi's. I continue the sphincteroplasty just beyond the color change of the

References

1. Grage TB, Laher PH, Imamoglu K, Wangenstein OH. Stenosis of the sphincter of Oddi. A clinicopathologic review of 50 cases. *Surgery* 1960; 48:304.
2. Kocher T. Ein fall von choledochoduodenostomia interna wegen gallensteines. *Korrespondenz-blatt fur aerzte* 1895; 7:193.
3. Archibald E. Ideas concerning the causation of some cases of pancreatitis. *Can JMS* 1913; 33:263.
4. Del Valle D, Donovan R. Coledoco-Odditis esclero-retractil cronica. Concepto clinico y quirurgica. *Arch Argentinos enf ap Digestiv y Nutricion* 1926; 1:4.
5. Del Valle D, Sanchez-Zinny J, Figueroa MA. Papillosphincterotomy indications et resultats. *Rev Intern Hepat* 1965; 5:775.
6. Doubilet M, Mulholland JH. Eight years study of pancreatitis and sphincterotomy. *JAMA* 1956; 160:521.
7. Nardi GL, Acosta JM. Papillitis as a cause of pancreatitis and abdominal pain: role of evocative test, operative pancreatography, and histologic evaluation. *Ann Surg* 1966; 164:611.
8. Acosta JM, Nardi GL. Papillitis: inflammatory disease of the ampulla of Vater. *Arch Surg* 1966; 92:354.
9. Bartlett MK, Nardi GL. Treatment of recurrent pancreatitis by transduodenal sphincterotomy and exploration of the pancreatic duct. *New Engl J Med* 1960; 262:643.
10. Howat HT. Symposium in Marseilles. *Gut* 1963; 4:416.
11. Acosta JM, Nardi GL, Civantos F. Distal pancreatic duct inflammation. *Ann Surg* 1970; 172:256.
12. Acosta JM, Civantos F, Nardi GL, Castleman B. Fibrosis of the papilla of Vater. *Surg Gynecol Obstet* 1967; 124:787.
13. Moody FG, Berenson MM, McCloskey D. Transampullary septectomy for post-cholecystectomy pain. *Ann Surg* 1977; 186:415.
14. Warsaw AL, Popp JW Jr, Schapiro R. Long-term patency, pancreatic function, and pain relief after lateral pancreatojejunostomy for chronic pancreatitis. *Gastroenterology* 1980; 79:289.
15. Gregg JA, Taddeo AE, Milano AF, et al. Duodenoscopy and endoscopic pancreatography in patients with positive Morphine Prostigmin tests. *Am J Surg* 1977; 134:318.
16. Madura JA, McCammon RL, Paris JM, Jessep JE. The Nardi test and biliary manometry in the diagnosis of pancreatobiliary sphincter dysfunction. *Surgery* 1981; 90:588.
17. Longmire WP, in discussion of Moody FG, Berenson MM, and McCloskey D. Transampullary septectomy for post-cholecystectomy pain. *Ann Surg* 1977; 186:422.
18. Hedberg SH. Personal communication.
19. Bradley EL. Pancreatic duct pressure in chronic pancreatitis. *Am J Surg* 1982; 144:313.

mucosa of the duodenum and the bile duct, because this is the margin of the superior choledochal sphincter. Then I use a No. 5 plastic feeding tube to calibrate the pancreatic duct. If the tube passes easily, I tend to leave the pancreatic duct alone. If there is a stenosis, I do an ampullary septectomy. Calibration of the pancreatic duct is a very important part of every sphincteroplasty.

(Slide) Although I have been very pleased with transduodenal sphincteroplasty and ampullary septectomy for acute recurrent pancreatitis, I have actually used sphincteroplasty more often as a primary drainage procedure, to prevent some of these postcholecystectomy problems. At the original operation, I routinely measure the width of the bile duct before any manipulation is done, then do the operative cholangiogram, remove the gallbladder, and frequently calibrate the ampulla through the cystic duct stump, to select those patients who will benefit from a sphincteroplasty or a choledochoduodenostomy. (Slide) Using this ap-