# One Per Cent Incidence of Recurrent Gallstones Six to Eight Years After Manometric Cholangiography

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**The national incidence of retained and recurrent common duct stones is between 2 and 7%. A prospective comparison of operative common duct pressure flow rates as opposed to operative cholangiography was commenced in 1968 to assay another diagnostic technique to assist in the reduction of this rather high incidence of recurrence. We are now reporting the 6–8 year follow-up data on the first 200 patients, 190 (95%) of whom were reevaluated in 1977. In our inital reports we were surprised to find that our accuracy with flow and pressure studies was 93%, not significantly different from that found with operative cholangiography (92%). The measurements of flow, resting pressure, and opening pressure in the patients with stones or strictures at the lower end of the bile duct were each significantly different from those found in normal ducts ($p < 0.001$). We considered normal flow to be 10 ml/min saline at 30 cm of pressure and normal intrabiliary pressure to be less than 16 cm of saline was measured through the cystic duct. To date only one individual has had to undergo reoperation for stones and another for recurrent biliary obstruction. A third individual is suspected of, but not proven, to have a retained stone. No patient who had a normal operative cholangiogram, flow and pressure studies, has had a late recurrence of stones. We have presented the specifications of a new catheter for performing flow and pressure x-ray studies, which we feel may be used to primarily evaluate the distal duct with greater accuracy and clarity. We think that this inexpensive but reliable method has an important place in biliary surgery, particularly where operative cholangiography may not be available, or, for one reason or another, is not reliable.**

SYMPTOMS ATTRIBUTABLE to residual gallstones and obstruction of the lower end of the bile duct are reported to occur in from two to 7% of patients undergoing cholecystectomy with or without common bile exploration.[2,8,16,20,24,26] We feel that any method which will find a greater proportion of the pathology at the primary procedure would be welcome. Furthermore, the number of fruitless choledochostomies with its associated increased morbidity and morality should be further reduced.

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Prior to the advent of operative cholangiography the only indications of stones or other abnormality of the distal bile duct were: a history of jaundice, acute pancreatitis, a raised bilirubin, alkaline phosphatase, or amylase, fever and chills suggesting cholangitis, or stones which were palpable in the common bile duct at the time of surgery. Further, most surgeons have considered an abnormally large common or cystic duct, or one with multiple small stones, to be an indication for a common duct exploration.

In 1947, 45% of all patients undergoing cholecystectomy at the Swedish Hospital in Seattle had common bile duct explorations. This figure decreased to 37.2% of 1,590 cases in the years 1948–1957, with 27.8% of those patients explored having common bile duct stones. The rate of exploration dropped again to 24.5% of the 2,235 cases done between 1958 and 1967, with 40.3% of the ducts explored containing stones. It was felt that the main reason for the reduction in the rate of exploration was the advent of operative cholangiography at this hospital in 1952[11]. In a study of 193 patients left with residual common duct stones, we noted that only 3.6% of the stones found in the common bile at the primary operation were palpable; a common bile duct over 10mm in diameter was found in only 20%; jaundice in 17%; pancreatitis in 7%; cholangitis in 3%; and cystic duct stones in 2.6%. It also has become apparent to us that many stones 3mm or less in diameter were not being routinely seen in operative cholangiograms and that obstruction of the lower bile duct due to fibrosis, pancreatitis, or carcinoma could not always be identified in routine cholangiograms.

It was for this reason that we became interested in manometric operative cholangiography as introduced by Caroli in 1946[5] as an additional means of evaluating the distal common bile duct and the sphincter of Oddi. This technique has been used by many surgeons with success, especially in Europe and South Amer-

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ica,[1,3–5,16,17,27] but it has not been popular in any English speaking countries.[6,7,9,17–19,21,22] The technique has been thought to be extremely helpful, especially in the detection of small stones in the distal bile duct and stenosis of the sphincter of Oddi.

A prospective study of operative manometric cholangiography was begun in Seattle in 1968 with the idea of assessing its value in reducing both the incidence of residual common bile duct pathology and the number of unnecessary bile duct explorations. The initial results of this study were previously reported.[10,13,25] A seven to nine year follow-up is now available on the first 200 cases studied, and the results will be re-examined in the light of a long-term follow-up.

## Materials and Methods

Manometry, cholangiograms and flow studies were performed on 199 patients undergoing 200 biliary operations in eight Seattle hospitals between 1968 and 1971. Most of the operative procedures were carried out at the University of Washington and Swedish Hospitals. There were 180 primary biliary procedures and 20 secondary procedures carried out. There was no special preoperative aside from a precaution insuring that the patient had not received any drug which would produce spasm of the sphincter (morphine, dilaudad, demerol (meperidine hydrochloride), codeine, *etc.*) for at least 90 minutes prior to manometry, by which time any direct effects of these drugs on the sphincter would have worn off. Most patients received atropine with premedication. In the first 99 patients the Fauré modification of the Caroli apparatus was used. The reservoir and tubing were filled with 15% solution of Hypaque® (sodium diatrizoate) taking care to exclude air bubbles. The cystic duct was cannulated with a Champeau metal cannula. The zero marked on the manometer scale was adjusted to the level of the common bile duct using 50 cm long metal rod which was attached to its spirit level. At the start of the observation the reservoir was held at the zero mark and clamps including the tubing were opened. The reservoir was then raised slowly at 1–2 cm intervals up the scale until continuous bubbling was seen at a steady pressure. A few bubbles went through the apparatus each time the reservoir was raised because of the rise in fluid level within the manometer. The lowest pressure at which continuous bubbling occured was called the opening pressure (OP) and it indicated the point at which the resistance of the sphincter had been barely exceeded. The first x-ray was taken at this point. The reservoir was then moved up to 50 cm and another cholangiogram x-ray taken promptly. The reservoir was then clamped off from the system and the radiopaque media was allowed to fall to a steady pressure which we called the resting pressure (RP) usually 2–3 cm below the opening pressure. We and the nurses found this apparatus somewhat complicated.

### *Flow Studies*

For this reason a modification of the apparatus described by Besançon[3] and Casal[4] was used in a second group of 101 patients. Because of its simplicity and the good results we have continued with an apparatus which consists of a barrel of a 50 ml glass syringe to which a gas-sterilized extension tubing was attached by an intervening stop-cock. The tubing was in turn connected to a plastic cannula made by the Cardiovascular and Special Instrument Division of the Becton-Dickinson Co. (SH 2311). This cannula is approximately 1 mm in internal diameter, and has a bulb about 15 mm from the tip, and two side-holes in addition to the distal opening. This is all gas-sterilized before the operation. A rubber stopper with a glass tube is placed in the barrel of a 50 ml syringe so that the glass tube is opposite the 10 ml mark (Figs. 1 and 2).

The cystic duct was cannulated in such a way that the tip of the cannula rested in the common bile duct. The lower end of the 30 cm steel ruler was placed at the level of the common bile duct with the lower end of the glass tube in the syringe held adjacent to the top of the ruler (Fig. 4). The stop-cock was then opened and saline was allowed to fill the bile duct until the rate of the bubbling became constant. The quantity of saline flowing out of the syringe in one minute was then measured. The syringe was then disconnected and another syringe

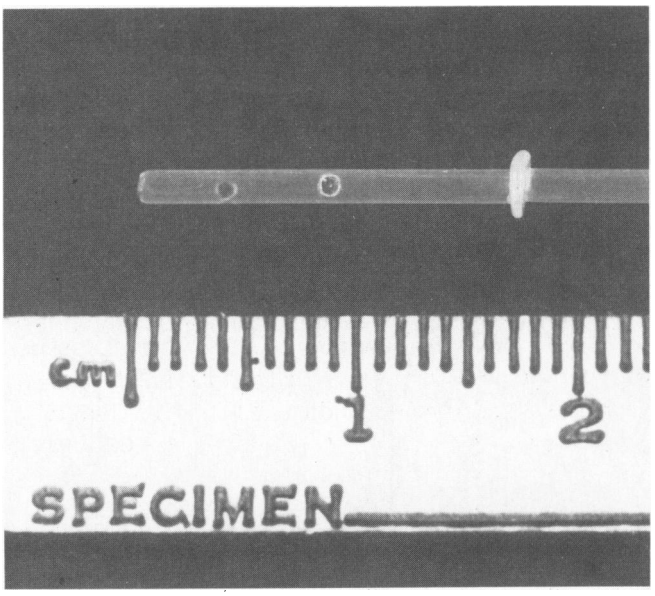


FIG. 1. The tip of the cannula used in the last 70 cases showing the side holes and the bulb used to tie it in after insertion into the cystic duct.

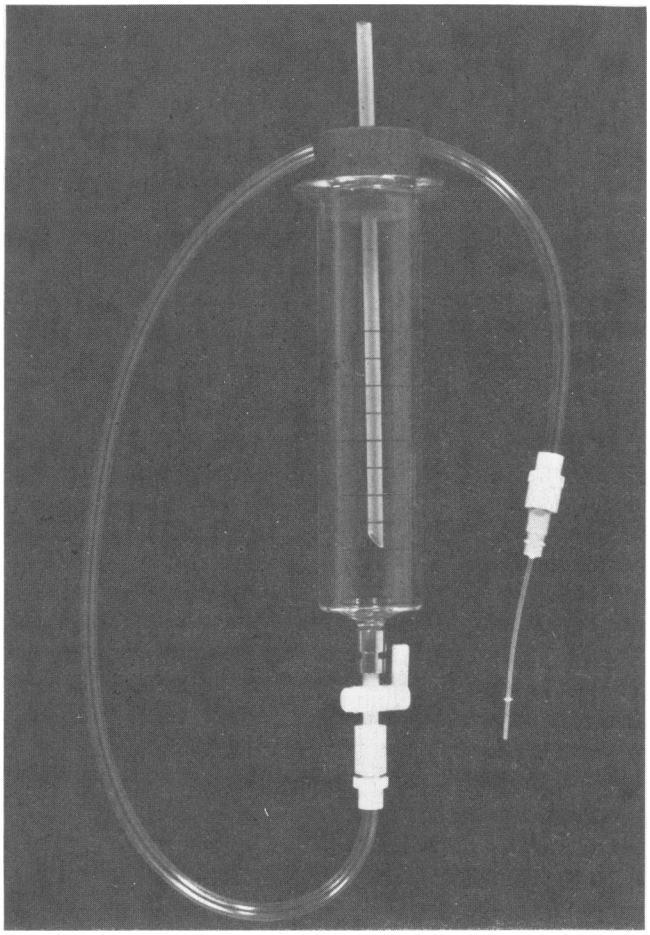

FIG. 2. The entire apparatus used now, including cannula, clear connecting tube, 50 ml syringe barrel, and contained constant pressure tube.

containing 15% Hypaque (sodium diatrizoate) was attached and cholangiograms were obtained. After the x-rays were completed the syringe was disconnected and the fluid in the tubing allowed to run into the common bile duct until it stopped dropping. The height of the fluid column above the common duct was measured with the ruler. This reading represented the resting pressure of the common bile duct.

Follow-up data was obtained by direct contact with the patient or his physician.

## Results

The operative cholangiograms were interpreted at the time of surgery as positive (showing pathology), negative (no pathology), or technical failures. The results are summarized in Table 1. The technical failures were chiefly due to problems with the cannula (Table 4). These fell from seven out of the first 50, to six each in the second and third 50 patients studied, and to one in the last 50, during which time we used only the new plastic cannula.

The results of manometry were interpreted as positive, negative, uninterpretable, or technical failures. On the basis of our prior studies and those of others, the highest normal opening and resting pressures were considered to be 15–16 cm of water.[6,7,9,14,18,19] In our series, any pressure 16 cm or greater was considered to be abnormal. Any flow rate greater than 10 ml/min at 30 cm of pressure was considered to be normal (extrapolating from the work of von Brücke[23] and Daniel.[6] A combination of the opening and resting pressures was used to determine normality in the first group, and in the latter group flow and resting pressure were used. If the two values disagreed, the combined manometry was considered to be equivocal.

We have divided the 200 studies into six groups according to the x-ray and manometry results as illustrated in Table 6 (Fig. 3). Both manometry and x-ray were successful in 158 patients (79%). Groups I, II, and III are included in this group of patients. Group I consisted of 121 patients in which both manometry and x-ray

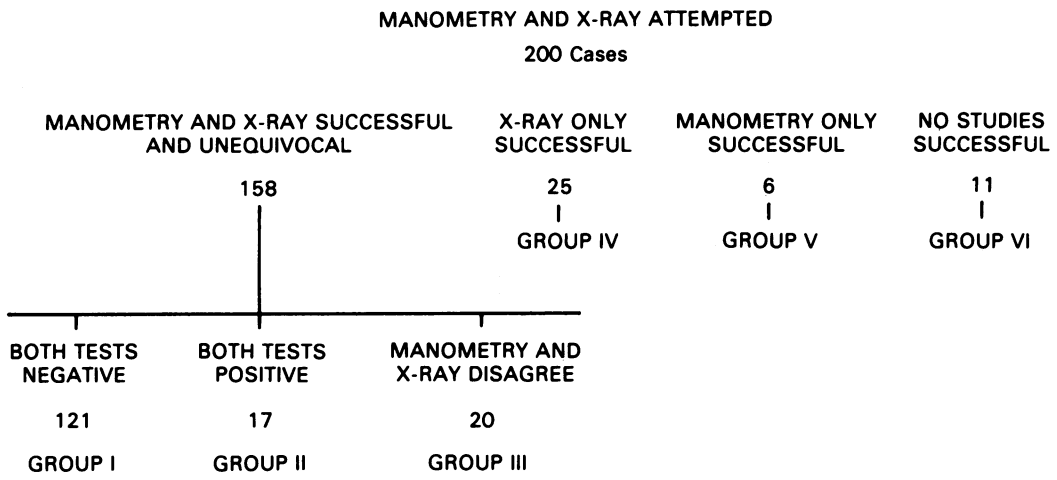


FIG. 3.

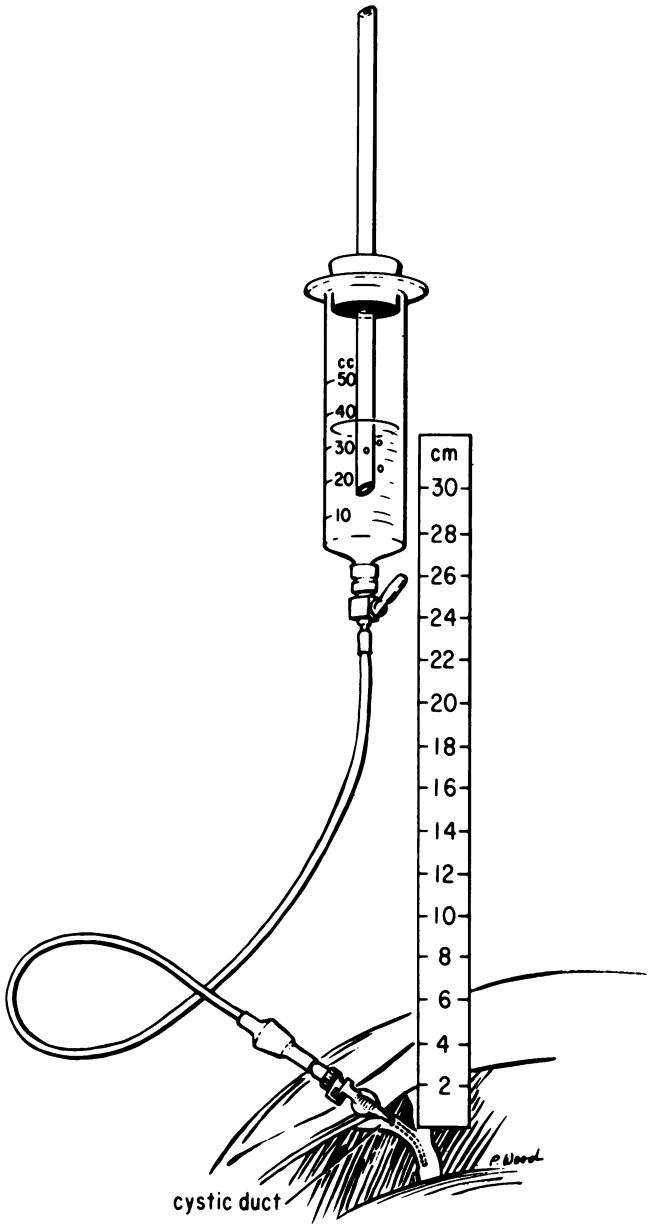


FIG. 4. Schematic drawing of the apparatus connected with the patient.

indicated no pathology. In this group were 15 common bile duct explorations where no significant pathology was found. The reasons for exploration are shown in Table 2. Sphincteroplasties were performed in the 8 patients with pancreatitis in the hope that decompression of the pancreatic duct would prevent further attacks. The other explorations were because of multiple small gallbladder stones, cystic duct remnant, pain and fever, an enlarged common bile duct, and a technical error. 106 further patients in Group I did not have a common bile duct exploration. In 96 of these the operative diagnosis was cholecysterolosis, cholecystitis, or cholelithiasis with no other problem. Three patients had pancreatitis without gallstones, two had a cystic duct or gallbladder remnant, and five had a cholecystectomy performed where no biliary or pancreatic pathology was found. Most patients have done well with no late reoperations (Table 3). There have been two instances of recurrent pancreatitis, both in patients who had pancreatitis without gallstone disease at the time of the original operation.

TABLE 1. *Immediate Results of Flow and Pressure Studies*

| | Number of Attempts | Positive | Negative | Uninterpretable | Technical Failures |
|---|---|---|---|---|---|
| Cholangiography | 200 | 30 | 153 | — | 17 ( 8.5%) |
| Resting pressure only | 200 | 40 | 139 | — | 21 (10.5%) |
| Flow only | 101 | 13 | 79 | — | 9 ( 4.5%) |
| Flow and pressure | 101 | 13 | 76 | 3 | 9 ( 4.5%) |

Group II included 17 cases in which both x-ray and manometry were positive. Common duct explorations were performed in all of these patients and pathology was found in every instance. Common bile duct stones were found in 11 instances. Four patients had pancreatitis with such severe stenosis of the distal duct that a choledochoenterostomy was required. One patient had common bile duct obstruction secondary to tumor. The last patient had stenosis of the sphincter of Oddi. Again there were no late reoperations in the patients contacted (Table 3). Those still alive have no evidence of significant biliary pathology.

Group III includes 20 cases where the x-ray and manometric studies disagreed. In 14 instances, the manometry was positive and x-rays were interpreted as negative. Ten of the 14 ducts were explored with five instances of small common bile duct stones, three of stenosis of the sphincter, and one of sclerosing cholangitis originally reported as carcinoma. One explored duct and four unexplored ducts had no demonstrable pathology at the time of the operative procedure. None of these five have had any problems since the time of surgery. Thus manometry was correct in nine of these 14 patients and x-rays in five out of 14.

TABLE 2. *Reasons for CBD Exploration in Group I*

| Reason | Number |
|---|---|
| Pancreatitis | 8 |
| Multiple small stones | 2 |
| Technical error | 2 |
| Cystic duct remnant | 1 |
| Pain and fever | 1 |
| Enlarged CBD | 1 |

TABLE 3. *Combined Follow-up Chart*

| Groups | I | II | III | IV | V | VI | Totals |
|---|---|---|---|---|---|---|---|
| Asymptomatic | 79 | 6 | 12 | 20 | 2 | 6 | 125 |
| Vague abdominal problems | 25 | 1 | 3 | | 2 | 3 | 34 |
| Recurrent pancreatitis | 2 | | | | | 1 | 3 |
| Biliary reoperation | | | 1 | 1 | | | 2 |
| Suspected recurrence | | | 1 | | | | 1 |
| Dead of other causes | 10 | 7 | 3 | 3 | 3 | 2 | 25 |
| Lost | 5 | 3 | 0 | 1 | | 1 | 10 |
| Totals | 121 | 17 | 20 | 25 | 6 | 11 | 200 |

Six of the Group III patients had positive x-ray findings and negative manometry. All six ducts were explored and stones were found in the common or hepatic duct in four instances. X-rays were correct in four of these six patients and manometry in two of them. There were two negative explorations, later attributed to air bubbles. Late follow-up of the patients in Group III (Table 3) indicated that there were two patients with recurrent problems. The first was a 58-year-old man who had negative x-rays with positive manometry. He had a hard, fibrotic pancreas, and had previously undergone cholecystojejunostomy for suspected carcinoma. Cholecystectomy and sphincteroplasty were performed. A biopsy of his papilla revealed papillitis and fibrosis. Postoperatively he continued to have problems with jaundice and pancreatitis with the result that he had a reoperation one and one-half years later with a second manometic cholangiogram. Choledochoduodenostomy was done at that time. He has been asymptomatic in the ensuing nine years. The second, a 67-year-old man had normal manometry and abnormal x-rays. Cholecystectomy and common duct exploration were performed at which time a single stone was found in the common bile duct. A five mm dilator passed easily through the sphincter. The patient did well initially but recently has had several episodes of colicky abdominal pain with elevations of alkaline phosphatase and bilirubin. While an intravenous cholangiogram showed a 15 mm duct with no stones, it is possible that he has recurrent stones. He is not interested in further surgery.

Group IV includes 25 cases in whom only x-ray studies were successful and unequivocal. There were seven positive cholangiograms and all seven had common bile duct explorations. One exploration was negative but pathology was found in the other six: three had stones, two stenosis, and one a tumor. Two ducts with normal cholangiograms were explored with no pathology being found. The 16 patients with unexplored ducts showed no common duct pathology at surgery and have had no biliary problems since then. One patient in this group had a second biliary procedure. This 16-year-old girl initially had a cholecystectomy and sphincteroplasty because of common duct stones and recurrent acute pancreatitis on this basis. It is now felt that she had congenital pancreatitis. She developed recurrent bile duct obstruction which required a reoperation for removal of further bile duct stones, and a choledochoduodenostomy.

Group V contains six patients in whom manometry was successful and x-rays were not. Two of the three who had positive manometry had their ducts explored. One had stenosis and inflammation of the sphincter. X-ray was not attempted in the second with a pancreatic tumor. The other four ducts appeared normal at the time of surgery and these four patients have had no biliary problems during the follow-up (Table 3).

Group VI contains 11 patients in whom neither study was possible. One common bile exploration in this group was done in a patient with pancreatitis and no gallstone disease. A sphincteroplasty was performed on the pancreatic duct. This patient has had recurrent pancreatitis but there have been no other significant late problems (Table 3).

The combined follow-up data for all patients is shown in the right hand column of Table 3. Good follow-up information was obtained in 95% of the patients after seven to nine years.

## Discussion

Manometric cholangiography has been easy to perform. It adds less than five minutes to the normal operative procedure. The flow and pressure measurements used in the last 101 patients were considerably easier to perform than measurements carried out earlier with a Caroli apparatus. We were upset by the number of technical failures (Table 4) and inconclusive studies in the earlier patients. Still there was only one technical failure in the last 50 patients in the series as opposed to seven in the first 50, and six each in the second and third 50. We failed to take cholangiograms in 17 out of the 200 patients (8.5%). The new plastic cholangiography catheter used in the last 80 patients has been much easier to use than the metal Champeau catheter which we used in the earlier cases.

The overall accuracy of x-ray manometry as determined from operative findings and follow-up data has been summarized in Table 5. The results from pressure

TABLE 4. *Reasons for Technical Failure: 20 Patients*

| Reason | Number |
|---|---|
| Cannula too large | 10 |
| Cannula twisted | 7 |
| Catheter too small | 1 |
| Leak around catheter | 1 |
| Unknown | 1 |

TABLE 5. *Accuracy of Studies*

| | Uninterpretable | False Negative | False Positive | Accuracy |
|---|---|---|---|---|
| Clinical signs only | 0 | 18/200 | 22/200 | 40/200 (80%) |
| Cholangiography | 0 | 3/183 | 9/183 | 12/183 (93%) |
| Resting pressure only | 0 | 11/179 | 7/179 | 18/179 (90%) |
| Flow only | 0 | 5/91 | 3/91 | 8/91 (91%) |
| Flow and pressure | 3 | 5/89 | 2/89 | 7/89 (92%) |
| Manometry and cholangiograms agree | 0 | 0/138 | 0/138 | 0/138 (100%) |

TABLE 6. *Manometry and X-ray Attempted: 200 Patients*

| Group | # Cases |
|---|---|
| Manometry and X-ray Successful and Unequivocal | |
| I. Both Tests Negative | 121 |
| II. Both Tests Positive | 17 |
| III. Manometry and X-ray Disagree | 20 |
| IV. X-Ray Only Successful | 25 |
| V. Manometry Only Successful | 6 |
| VI. No Studies Successful | 11 |
| Total | 200 |

alone, flow alone, flow and pressure, and x-ray alone, vary from between 90–93% accuracy. The greatest accuracy occurred when manometry and cholangiograms agreed, as in Groups I and II, where the accuracy was 100%.

We found 11 cases of distal common bile duct pathology (nine from Group III and two from Group V) which were not revealed by x-ray. One of these patients had a tumor which had not been recognized before the test was performed. The other ten had common bile duct disease which was not obvious, which was not noted on x-ray, and which probably would have gone undetected if manometry had not been performed. Five of these patients had small stones, four had stenosis of the papilla, and one had a sclerosing cholangitis. On the other hand the cholangiograms revealed pathology in four cases where manometry was negative and six instances where manometry was unsuccessful. For this reason we recommend that both modalities be used.

We were particularly interested to note that none of the patients in whom both manometry and x-ray were negative (Group I) had any bile duct pathology at surgery or during the late follow-up period. The 106 patients in this group who did not have common bile duct explorations have had no evidence of recurrent disease of the biliary tree.

Our results indicate therefore that radiologic and manometric studies of the bile duct are complimentary. Each has advantages. Manometry is particularly useful in revealing small stones and diseases involving the papilla with almost the same accuracy as cholangiography. Cholangiography is more useful in revealing stones well away from the sphincter of Oddi. The accuracy of manometry and cholangiography is greater than with either test by itself.

One upsetting aspect of this study was that 60 (30%) of the 200 patients had a common bile duct exploration, 21 (35%) being explored unnecessarily. 15 Group I tests where both tests were negative were unnecessarily explored. We felt that unnecessary exploration might have been avoided if more faith had been placed in the flow and pressure results.

We are, however, impressed that only three out of the 200 patients in this study have any evidence of recurrent biliary problems. Only two of the patients have been reoperated to date. This results in less than half the number of reoperations of any other reported series.

## Conclusions

We feel that our studies have shown that manometric cholangiography, particularly flow and pressure studies, are easy to perform and useful in making the diagnosis of pathology of the distal common bile duct. We currently feel that flow and pressure studies should be carried out as a routine in all patients undergoing cholecystectomies as well as operative cholangiography. If both bests are positive, the common bile duct should be explored. If one test is positive, the duct should be explored unless there is an obvious technical error. If neither test is positive we hesitate to explore the common bile duct even in the face of traditional indications for exploration. A flow and pressure study by itself has an accuracy so close to that of operative cholangiography, that this approach might be used as a screening test in instances where cholangiography is not readily available.

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## Discussion

Dr. Frank G. Moody (Salt Lake City, Utah): Dr. White and his colleagues in Seattle have done us a service by continuing to pursue their interest in radiomanometry. This is a technique that has been used for about 30 years in Europe, and apparently with good success. In America there has been sporadic application, and, actually, great reluctance to use it; and I guess that relates, possibly, to its lack of specificity and reproducibility.

For example, if both tests are consistent and positive, then you'll always find pathology in the duct. Therefore, that would mean to me that the cholangiography would be equally good, and I guess Dr. White would agree with that, because he stated that the manometry could be used in the place of cholangiography in this situation.

Now, if the manometry is positive and the cholangiography is negative for identifying pathology, then you have a 35% false-positive rate, which is extremely high for any type of diagnostic procedure that one can apply clinically.

We have taken this problem to the laboratory, and we have studied rhesus monkeys in a restraining chair, developing flow/pressure relationships, without any type of medication in these animals, and we've found that on any given day, indeed, we could get reproducible curves, but on other days we couldn't reproduce the same curves.

We became curious about this and decided to test it on the opossum so we could place electrodes into the sphincter and measure the spike potentials. The reason why we used the opossum is that their sphincter of Oddi is outside the duodenum. We chose to study the GI hormones, rather than the neural control of the sphincter, and we found very early that glucagon, cholecystokinin and, to our surprise, pentagastrin caused a marked increase in the spike potentials and a decrease in the rate at which materials could be perfused through the common bile duct in these critters.

I suspect that these hormones, possibly, are playing a role in Dr. White's patients. Now, I realize that they can't be quantitated or measured; but one might be able to overcome this by using some type of a dilatory substance on the papilla, and I wonder if, indeed, you did use amyl nitrite in some of your studies.

In addition, did you also make measurements after you removed the stones, or cut the sphincter?

I hope that Dr. White and his colleagues will continue to try to apply this particular technology. In some way, it's helping them, because a 1% incidence of overlooked stones is really a tremendous accomplishment. I imagine it relates more, however, to their very careful attention to detail in their cholangiography, and in their way that they actually carry out the explorations of the ducts, rather than to the value of this particular test.

Dr. George D. Zuidema (Baltimore, Maryland): I would like to comment on several points which Dr. White's manuscript has raised.

First of all, going back to the presentation which Dr. Egdahl made earlier, we would all agree that it's important to avoid unnecessary common duct explorations. It's been shown to double the mortality and to increase the hospital stay by five days, not to mention the additional discomfort which the patient experiences. Therefore, any test which would improve the accuracy of diagnosis should conceivably be of considerable help.

The basic idea, then, is to improve the accuracy of common duct exploration.

Now, let us take a quick look at the various groups which Dr. White showed us; I'd comment on two of them. First of all, in Group 4, with 25 patients in whom the x-ray examination was successful, there was only one unnecessary common duct exploration. In Group 1, however, with 121 patients, in which both the radiology and the manometry were satisfactory, there were 15 negative common duct explorations.

It seems to me that some of these may have occurred when they were gaining experience with the technique; but at any rate, the unnecessary operations were there.

The technique, it seems to me, has some advantages and some disadvantages. I think that in taking it up we would all probably experience the same kind of learning curve which Dr. White and his colleagues showed, with a relatively high incidence of technical failures early in the experience.

There is a major problem, however, which is hard to get around. If we were to rely on the manometry alone, we would have the problem of detecting intrahepatic stones. For this reason, I feel that it's unlikely that the cholangiography used alone as a screening test would be very helpful, because I think if we were to take one examination, we would probably get more information from a cholangiogram. There might conceivably be an advantage in the obese patient, where we're all familiar with the technical problems associated with cholangiography.

Now, this study is based on a simple hydraulic system, and therefore should lend itself to the construction of a model where one can vary the size of the stones within the model, the rigidity of