Prognostic Factors in Bile Duct Carcinoma

Analysis of 96 Cases

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A computerized analysis of prognostic variables was performed in 96 proven cases of extrahepatic bile duct carcinoma treated over a 24-year period at UCLA. Forty-nine percent of the lesions were in the upper third of the bile ducts and 47% of these were resected, for an operative mortality rate of 23% and a maximum survival rate of 4.5 years. Palliative procedures in this region were associated with a 16% mortality rate and maximum survival rate of three years. The patients whose lesions were in the middle third suffered no operative mortality rate for resection or palliation and had a 12% five-year survival rate, with the longest survivor lasting 11 years. In the lower third lesions, 67% were resected by Whipple's procedures, for an 8% mortality rate and a five-year survival rate of 28% extending to nine years. Resection of these difficult carcinomas offers the best hope of survival but must be weighed against the high operative mortality risk in those lesions located in the hilar region.

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CARCINOMAS OF THE EXTRAHEPATIC biliary system are frustratingly difficult lesions with which to deal. Not only are these lesions frequently small and difficult to diagnose, they are often invasive of adjacent vascular structures and, hence, unresectable. Whereas these lesions have long been considered to be slow-growing, recent evidence shows them to be associated with overall poor survival rate. Adjunctive chemotherapy and/or radiation therapy have not been usually helpful in prolonging survival. Recently, to add to the complexities of these lesions, some have been found to be multicentric or diffuse within the ductal system.

In an effort to identify those factors associated with these carcinomas which might have prognostic value, the records of patients treated for this disease at UCLA Hospital and Clinics were reviewed.

Materials and Methods

The clinical courses of all patients with extrahepatic biliary tract carcinomas treated between November 1954 and June 1978 at the University of California, Los Angeles (UCLA) Hospital and Clinics were reviewed retrospectively. Carcinomas of the intrahepatic bile ducts, gallbladder, cystic duct, pancreas and ampulla of Vater were excluded. All diagnoses were confirmed by biopsy specimen or autopsy examinations.

Ninety six patients were reviewed; of these, 95 were operated on. One patient died awaiting surgery, and the diagnosis was confirmed at autopsy examination. Forty six patients (48%) had received one operation prior to definitive operation, and three patients had two operations prior to definitive operation. The average age of the patients at the time of definitive operation was 59.9 years (range: 24.9–82.8 years). There were 59 males and 37 females, for a male-to-female ratio of 1.6:1. Eighty four per cent of the patients were Caucasians, 6% Hispanic, 6% Oriental and 4% others.

The data were subjected to computer analysis according to location of lesion, as suggested by Longmire.[1] Most lesions were located in the upper third or confluence of right and left hepatic ducts and common hepatic duct (47 patients). The middle third area of the common bile duct from the cystic duct down to the pancreas accounted for 24 cases while only 18 patients had tumors in the lower third or intrapancreatic bile duct. Diffuse lesions or multicentric extensive ductal involvement was seen in seven patients (Fig. 1). The

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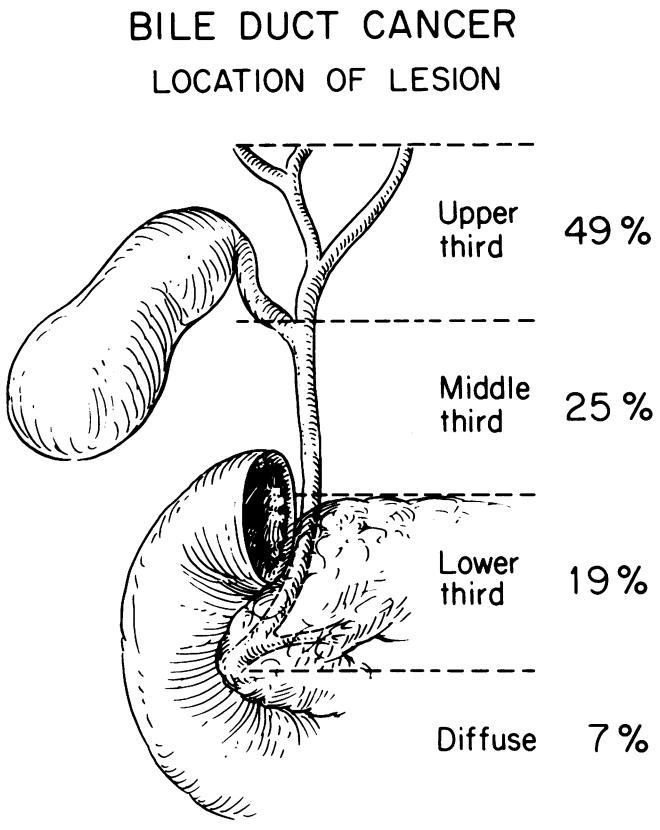

FIG. 1. Anatomic distribution of extrahepatic bile duct tumors.

types of operations, gross and microscopic pathologic findings, and postoperative therapy and survival rates were recorded. These variables were evaluated alone and by cross-reference to search for statistically significant prognostic indicators. All analyses were done by standard biomedical computer programs under the direction of the Department of Biomathematics, UCLA.

Postoperative follow-up data were available in 94% of the patients. The average length of follow-up was 23.3 months (range: 1–216 months). All survival data are based on documented follow-up information, from the time of definitive surgery to death or when last seen. In some instances, this method will underestimate the true length of survival because patients were dropped from the survival curve at the time of their last follow-up visit if they moved or declined further follow-up examinations. By this method, survival cannot be overestimated.

Results

Incidence

Over the past 24 years, there has been a steady increase in the incidence of extrahepatic biliary tract carcinomas treated at UCLA (Fig. 2). The current level of approximately six cases per year may reflect a maturing referral pattern and show a leveling trend.

Diagnosis

The predominant presenting symptom was jaundice, in 50% of the patients, followed by pain, in 29% of the patients; all other symptoms were much less common (Table 1). The patients underwent definitive operations an average of 4.9 months after their onset of symptoms. Those patients with lesions of the upper third of the bile

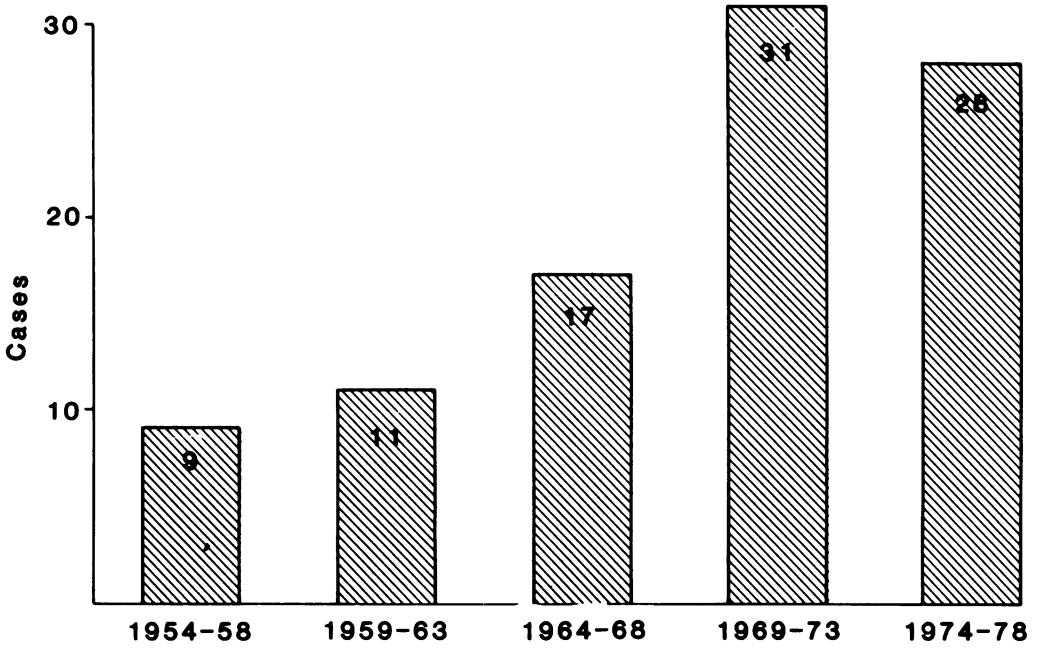

FIG. 2. The number of cases treated during the study period has increased steadily.

TABLE 1. *Predominant Symptom*

Symptom	Per Cent
Jaundice	50
Pain	29
Pruritis	5
Chills/fever	4
Others	12

TABLE 2. *Length of Symptoms Prior to Definitive Operation*

Location of Lesion	Months
Upper third	6.1
Diffuse	4.7
Middle third	4.1
Lower third	3.2

ducts were operated after a period of symptoms almost twice as long as those with lower third lesions (Table 2).

The mean total serum bilirubin level was 18.0 mg/dl (range: 0.6–63.0 mg/dl). Ninety one per cent of the patients had serum bilirubin levels greater than 2.0 mg/dl and 50% were greater than 13.0 mg/dl. Serum transaminase and alkaline phosphatase levels were uniformly abnormal in all patients. Over the course of 24 years, diagnostic tests have come and gone. Transjugular and transhepatic cholangiography were each 100% accurate in diagnosing 25 cases of biliary tract malignancy. The accuracy of ultrasonographic examination was 56% in nine patients. Endoscopic retrograde cholangiopancreatography was only 47% accurate, in seven patients, and this represents a learning curve since its inception at UCLA. Upper gastrointestinal contrast studies had a diagnostic accuracy of only 24% (Table 3).

Operations

The 95 patients underwent a total of 171 operations at referring hospitals and at UCLA. These consisted of: exploratory laparotomies in 41 patients (24%); T-tube placements in 56 patients (33%); U-tube placements in six patients (3%); cholecystojejunostomies in six patients (3%); choledochojejunostomies and hepaticojejunostomies in 37 patients (22%); cholangiojejunostomies in 10 patients (6%); and Whipple procedures in 15 patients (9%). Of the 95 definitive operations, 50 were for resection of tumors and 45 were for bypass or explorations only (Table 4). The order in which these operations were most frequently used is choledochojejunostomy, Whipple's procedure, cholangiojejunostomy, T-tube placement, U-tube placement, cholecystojejunostomy and exploratory laparotomy only.

Operative Mortality Rate

Operative mortality rate was 12% for the entire series. When examined by type of operation the surgical mortality for exploratory laparotomy was 0%; for intubations by either T-tube or U-tube it was 12.5%. The biliary-enteric anastomoses for resection or palliation carried a 13% mortality rate but Whipple's radical pancreaticoduodenectomy carried only an 8% operative mortality rate. When analyzed for resection of tumor versus palliative procedure, there was no difference between the 12% operative mortality rate in 50 patients with resection and 11% mortality rate in 45 patients who underwent palliative procedures (Table 4).

Survival

Location of Lesion

The cumulative postoperative survival rate for the entire series from the date of definitive operation was 50% at nine months and 8% at five years (Fig. 3). When analyzed according to the location of the lesion, the survival data were: upper third lesions, 50% survival rate at 8.9 months and 0% at five years; middle third lesions, 50% survival rate at 10.1 months and 12% at five years; lower third lesions 50% survival rate at 21.1 months and 28% survival at five years (Fig. 4). For the lesions that occurred in the middle and lower thirds, there are survivors at 11 years and nine years, respectively (Table 5).

Operation

T-tube or U-tube placement was associated with a 50% survival rate at 10.5 months, and a five-year survival rate of 7%. Combined choledocho- or cholangiojejunostomy procedures were associated with 50% survival rate at 14.3 months, and a 9% five-year survival rate. When Whipple's procedure was performed for middle or lower third lesions, it had a 50% survival rate of 19.5 months and a 27% five-year survival rate (Fig. 5), and this was statistically different from the other two types of procedures ($p = 0.0001$).

TABLE 3. *Tests*

	No. Performed	Accuracy (%)
Transhepatic cholangiogram	13	100
Transjugular cholangiogram	12	100
Ultrasound	9	56
ERCP	7	43
Upper gastrointestinal series	33	24

TABLE 4. *Results of Operations*

Location	Patients	Resected		Palliated		Total Mortality Rate
		Number	Mortality Rate	Number	Mortality Rate	
Upper third	47	22	23%	25	16%	19%
Middle third	24	16	0	8	0	0
Lower third	18	12	8%	6	0	6%
Diffuse	6	0	0	6	16%	16%
	95*	50	12%	45	11%	12%

* One patient died before operation.

The overall comparison of survival for patients undergoing resection versus bypass operations demonstrated no significant difference, however, due to the poorer results of resection in the large group of patients with lesions of the upper third of the bile ducts.

Pathology

The gross pathologic findings, as determined at operation, was found to be local lesions only in 58% of the patients; in 7%, the lesions were diffuse in the ductal system. There was no statistically significant difference in survival rates among these categories. There was spread of tumor within the hepatoduodenal ligaments in 15% of the patients and to the liver in 18%. Distant organs were involved in only 2% of the patients (Table 6).

The microscopic pathologic findings, as determined by UCLA Staff pathologists, were divided into well-differentiated (46% of the lesions); poorly-differentiated (25% of the lesions); papillary (20% of the lesions) and sclerosing (9% of the lesions). Papillary lesions were associated with a 22.3 months 50% survival rate and a 31% survival rate at five years, as compared with a 9.8 months 50% survival rate and an 8% five-year survival rate for well-differential lesions. Sclerosing lesions did slightly better than the well-differentiated. The survival rates for patients with poorly-differentiated lesions were about the same as those of patients with well-differentiated tumors (Fig. 6). None of these differences were statistically significant.

Postoperative Therapy

Postoperative chemotherapy and/or radiation therapy were given to patients depending on individual

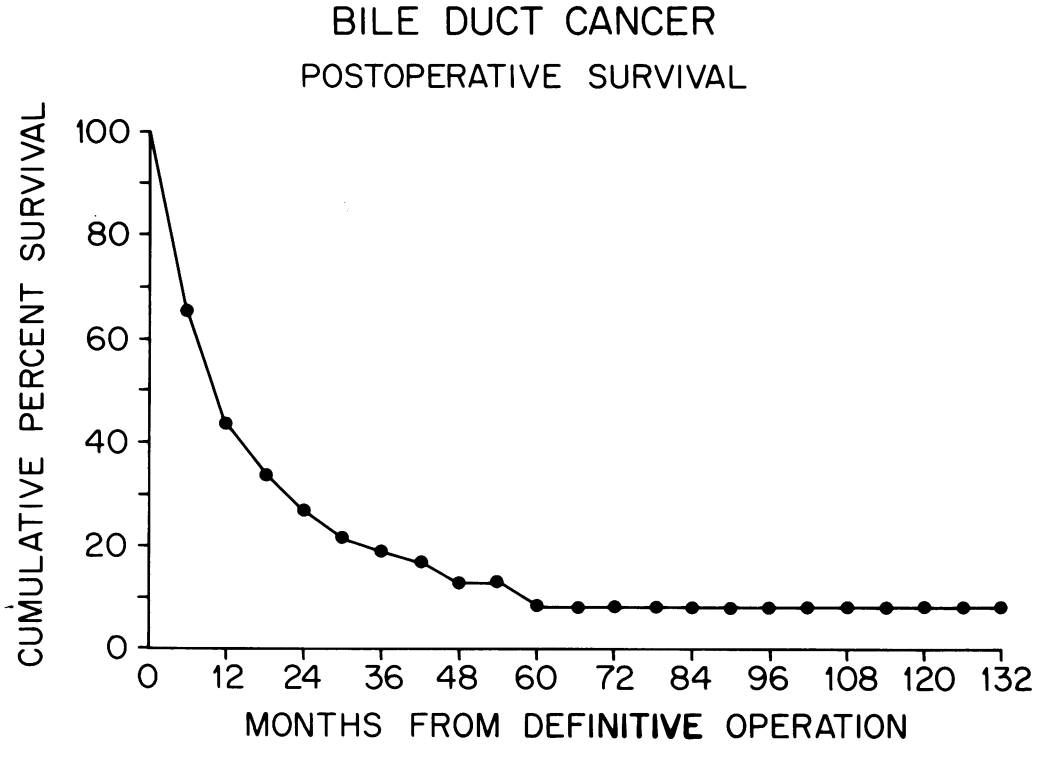

FIG. 3. Postoperative survival curve for all patients in the series.

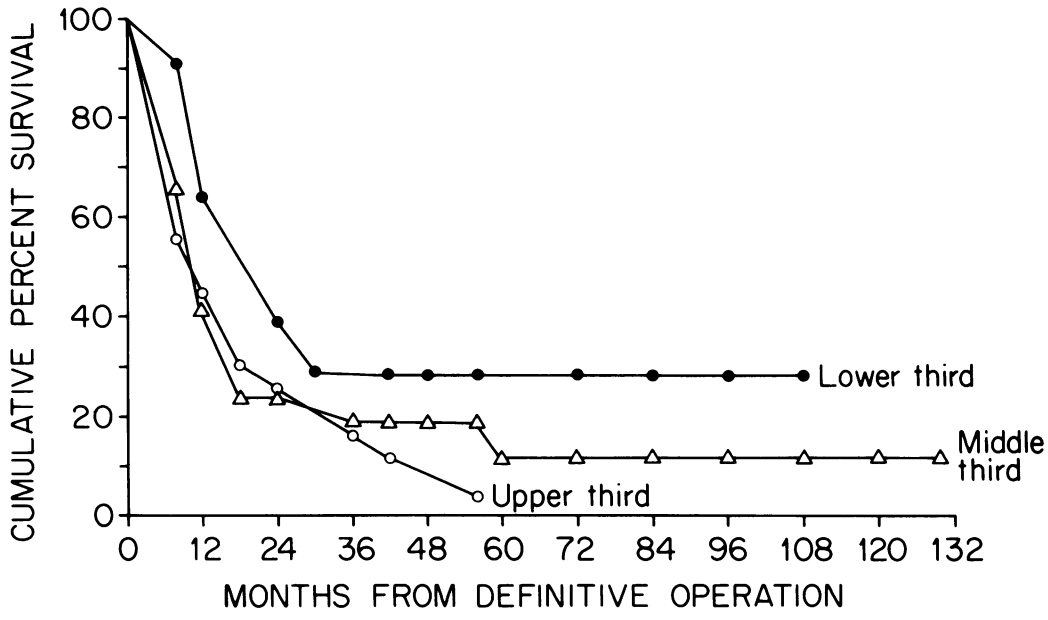

FIG. 4. Postoperative survival curves according to location of the lesion within the biliary system. Differences between the groups are not statistically significant.

indications. Thirty patients (32%) received some sort of therapy after operation. Chemotherapy alone, with single or combination drugs, was used in 18 patients; irradiation alone was used in 7 patients and in combination with chemotherapy in 5 patients. There was no statistically significant difference in the survival rates of these patients, but there are some interesting individual observations. Three patients survived an average of 31 months following palliative choledochojejunostomy and combination chemotherapy and radiation.

Cause of Death

The exact cause of death was often difficult to ascertain but, in the majority of patients (63%), death was directly related to the biliary tract; *i.e.*, progressive or recurrent tumor, liver failure, cholangitis or biliary fistulas. Other causes of death, in decreasing frequency, were sepsis, pneumonia, gastrointestinal bleeding, pulmonary embolus and renal failure.

Influence of Location of Lesion

Lesions of the Lower Third of the Bile Ducts

The factor most responsible for differences in survival rates appears to be the location of the lesion. Lesions that occurred in the lower third of the bile ducts were more often resectable. These 18 patients underwent Whipple procedures or biliary enteric anastomoses, for a total operative mortality rate of only 6%. The histologic findings of lower third lesions were also more favorable, with 26.7% being papillary tumors and 46.7% well-differentiated lesions.

Lesions of the Middle Third of the Bile Ducts

Lesions of the middle third of the bile ducts were predominantly treated by resection and biliary-enteric anastomosis in 57% of the patients, or Whipple procedure in 10% of the patients. Palliative intubation was performed in 33% of the patients. No patient in this group died during operation. Poorly-differentiated lesions accounted for 27.3% of the lesions found in this location, with papillary and well-differentiated tumors accounting for 18.2% of the lesions, each.

Lesions of the Upper Third of the Bile Ducts

The majority of patients (47) had tumors in the difficult upper third region. These patients presented later in the course of their illnesses, and the lesions were more difficult to resect in this area. Resection with biliary-enteric anastomosis was performed in 47% of the patients, but 51% of the patients underwent intubation, alone, and 2% exploration only. The operative mortality rate for patients who underwent operations in this region was, likewise, higher, at 19%.

TABLE 5. *Postoperative Survival Rate (%) by Location of Lesion*

Years	Overall	Upper Third	Middle Third	Lower Third
1	43	45	40	63
2	27	25	28	38
3	18	15	18	28
4	13	4	18	28
5	8	0	12	28
	to 11 yrs		to 11 yrs	to 9 yrs

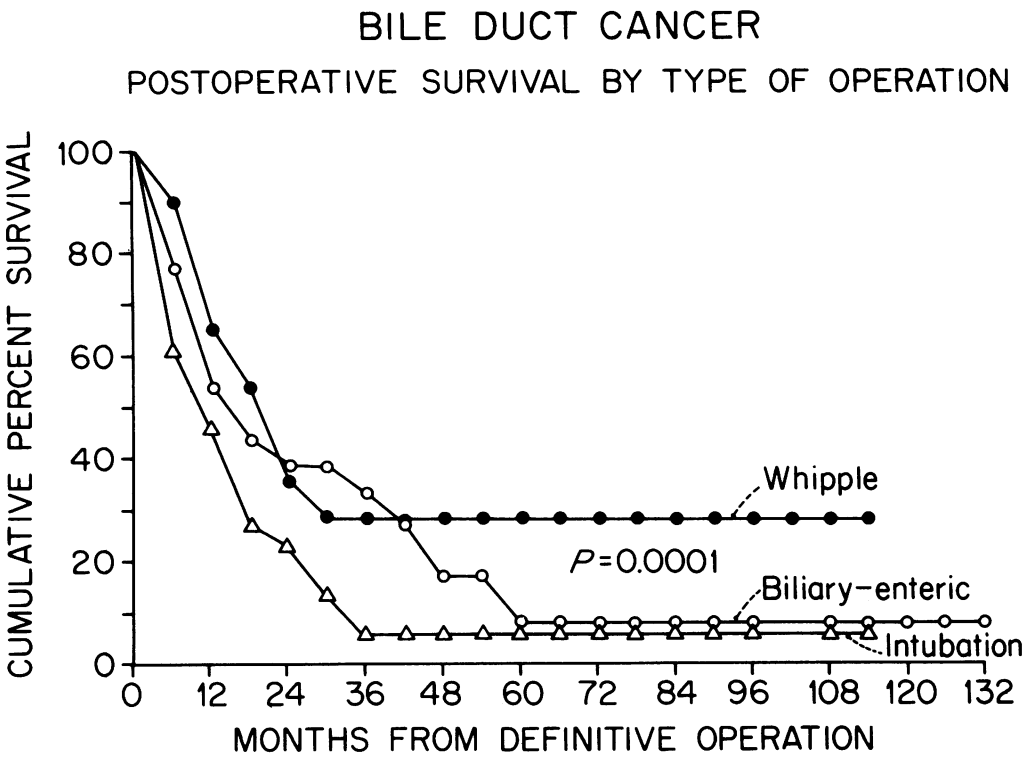

FIG. 5. Postoperative survival curves according to type of operation performed. When Whipple's procedure could be done for middle or lower third lesions, survival was significantly better.

Resection was associated with a 23% operative mortality rate and intubation with a 16% operative mortality rate. There is a slightly better, but statistically insignificant, difference in survival for patients who underwent for resection versus bypass of upper third lesions (Fig. 7). Pathologic examination demonstrated a predominance of well- and poorly-differentiated lesions (37.2% and 16.3%, respectively) with only 9.3% papillary lesions. Patients with lesions in this region presented later, the lesions were more difficult to resect, had a higher associated operative mortality rate, less favorable microscopic pathologic factors, and, consequently, a shorter period of survival.

Discussion

It is estimated that, in 1981, there will be 13,000 new cases of cancer involving the liver and biliary passages in the United States—a number more than half that of pancreatic cancer and representing approximately 7% of all new cancers of the digestive tract.[2] In this same year, 9400 deaths are predicted from these same tumors. While cancer of the bile ducts represents only a part of this overall figure, there is evidence that the incidence of this disease is increasing in the United States.[3] Whether this apparent increase in bile duct cancer represents a change in etiologic factors or is due to better diagnosis by newer techniques introduced in the past few years will be a subject for future study.

TABLE 6. *Gross Pathology at Operation*

Pathologic Finding	Per Cent
Localized lesion	58
Diffuse in duct	7
Spread to	
liver	18
hepatoduodenal ligament	15
distal organs	2

In many series of biliary carcinoma, cancer of the bile ducts accounts for 28–33% of the cases, with gallbladder cancer being the more common type seen.[4,5] The differences in these two types of cancers have been apparent to clinicians over the years. Gallbladder cancer is more common in females than males (7:1), whereas the reverse is true for extrahepatic biliary cancer.[5] Gallstones are associated with gallbladder cancer in over 85% of the cases; however, they are found in only around 30% of the patients with bile duct cancer.[6] Finally, gallbladder cancer appears to be much more virulent in its course, with operative resection not often possible and with very short survival rates after operation. Thus, it is important to separate extrahepatic bile duct cancer from cancer of the gallbladder in analyses of prognostic factors.

In this retrospective review, the location of the lesion appeared to bear the most important relationship to

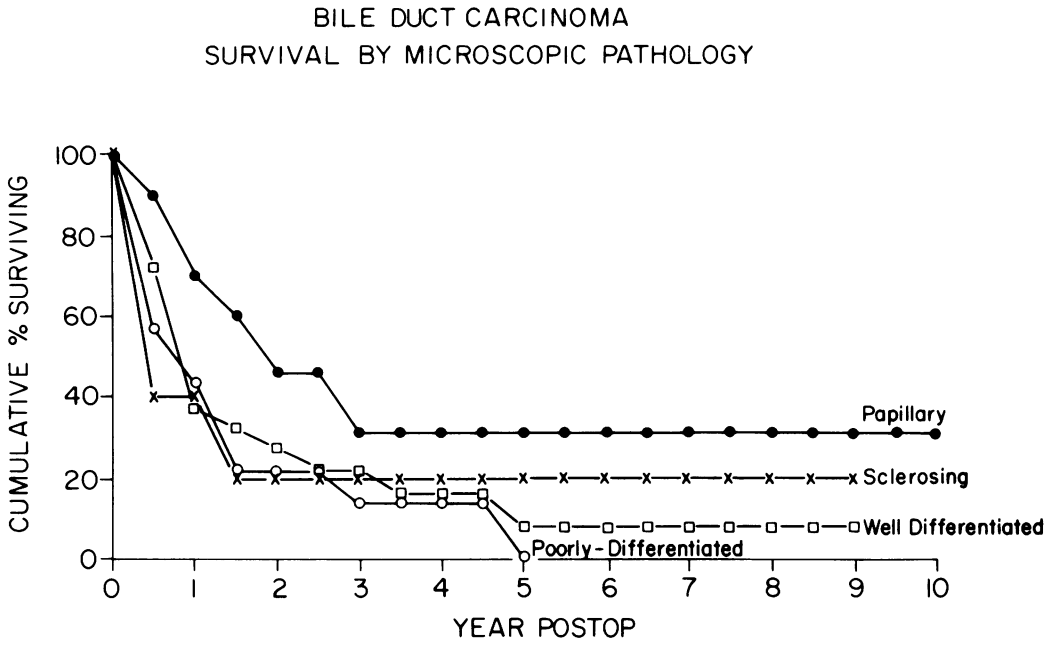

FIG. 6. Postoperative survival according to microscopic pathology of the lesions. Differences between groups are not statistically significant.

prognosis. Those lesions located in the upper third of the extrahepatic biliary system are most often unresectable at all and, when resected, are often incompletely removed. Bismuth and Corlette described a series of 80 patients with tumors at the hilus, of which, only four (5%) could be resected.[7] Similarly, Ross, Braasch and Warren[6] reported that of 103 cases of proximal bile duct tumors they were able to resect 12 (12%). Fortner and associates[8] reviewed 26 patients with lesions of the upper third, of whom, nine had been resected (35%)—three of these by total hepatectomy and liver transplantation. Their operative mortality rate of three of the six patients treated by resection points to the hazardous nature of such operations. Akwari and Kelly,[9] however, were able to resect four of 38 tumors (11%) without a death. Lees et al. found that in none of their 36 patients with carcinomas of the upper third of the bile duct system could the lesion be resected.[10] At the other end of the resection spectrum is a report by Launois et al., who resected hilar tumors in 11 of 19 patients (58%) in a four-year period for an operative mortality rate of 18% and a mean survival rate of 1.4 years, with the longest survival period being 3.2 years.[11] Our resectability rate for upper third lesions was 22 of 47 patients (47%), with a mortality rate of 23%. Several of the lesions were removed incompletely in order to facilitate biliary reconstruction and drainage, and the longest survival period was 4.5 years. Details of earlier cases and operative techniques have been previously described by Longmire and associates.[12] On the other hand, bypass of these lesions by intubation or anastomosis was associated with a 16% mortality rate and a survival rate which was somewhat less than, but not statistically different from, that of resection (Fig. 7). The authors' approach to these lesions now, therefore, is to resect those that are clearly localized and not involving adjacent vascular structures and intubate all others. Terblanche has stated that U-tube palliation and radiotherapy should be used for all lesions of the main hepatic duct junction.[13] The role of postoperative adjunctive irradiation and/or chemotherapy must be defined by prospective controlled studies in these patients.

Lesions of the middle third of the bile ducts were

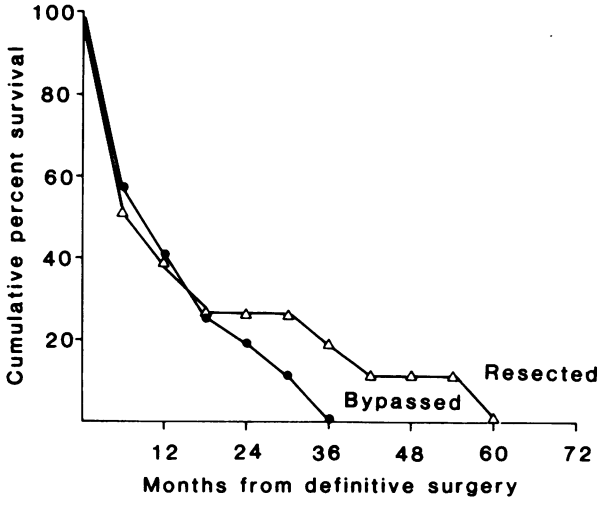

FIG. 7. Postoperative survival for upper third lesion patients showed a slightly better, but statistically insignificant, result for resection versus bypass.

resectable in 67% of the authors' patients, with no deaths during operation. In general, these resections were accomplished by resection of the tumor and performing a Roux-en-Y hepaticojejunostomy, but, in three instances, Whipple's procedure was used. The overall five-year survival rate for this group of patients was 12%, with one patient still alive 11 years after resection.

The lesions of the lower third were associated with the best results of surgical therapy in this series. Not only did patients with this type of lesion present earlier in their course for definitive surgical therapy, the lesions tended to be the more favorable type of microscopic lesion, that of the papillary form of the bile duct carcinoma. Whipple's procedure was used in two-thirds of these patients, for an 8% operative mortality rate. The ability to perform Whipple's procedure for these lesions (and those in the middle third) gave the most significant improvement in survival rate of all the prognostic factors examined. Palliation was most often by proximal biliary-enteric anastomosis and the mortality rate for these procedures was nil. Overall survival rate of 28% at five years reflects the ability to resect most of these lesions. It is clear that while palliation may be associated with a survival period of many months, resection carries the hope of cure, and our longest survivor in this group is alive nine years after resection.

The diffuse lesions of the biliary ducts have been more frequently recognized since the introduction, in 1972, of routine operative choledochoscopic examination in all patients where the bile duct is opened or where radical pancreaticoduodenectomy is contemplated.[14]

The current operative approach to lesions of the bile duct at UCLA is to open the duct above or below the obstructing lesion and thoroughly visualize it by choledochoscopic examination. Punch biopsy specimens are obtained under direct vision, to confirm the diagnosis. While awaiting the frozen section reports, the remainder of the bile duct system is visualized and biopsy specimens are obtained from any suspicious areas. In patients presenting with lower lesions of the third, we have observed multicentric malignant lesions in the proximal ductal system as well and, thus, have been able to rule out a radical resection of the lower third as being of any value. To date, we have not observed these small lesions to occur in ducts distal to lesions of the upper third.

Routine choledochoscopic examinations in all cases of choledochotomy for gall stones has yielded at least three cases, in the past two years, of small distal bile duct carcinomas which would have been overlooked without choledochoscopic examination after removal of common bile duct stones. Each of these patients underwent Whipple procedures and the pathologic examination of the tissue indicated that the resections were curative.

Future therapeutic advances in this increasingly common disease will depend on earlier diagnosis, refinement of operative techniques and staging and the prospective evaluation of newer adjuvant therapies.

Earlier diagnosis will be facilitated by heightened physician suspicion in patients with subtle signs of postprandial abdominal discomfort, itching or elevated alkaline phosphatase levels even in the absence of jaundice or hyperbilirubinemia. The improved modalities of "skinny needle" transhepatic cholangiography or endoscopic retrograde cholangiography, when used early, in such cases, should lead to earlier diagnosis and therapy. Evander and associates, from the University of Lund, have reported a 53% success rate with percutaneous fine needle aspiration biopsies of bile duct tumors guided by selective angiography or percutaneous transhepatic cholangiography.[15]

Operative therapy is the treatment of choice and resection of the lesion should be performed if at all possible. In view of the high risk of resection of upper third lesions, only those which can clearly be widely removed should be resected. The lower risk of death with intubation of these lesions and the similar survival curves for the patients who underwent resections and bypasses mitigates against attempting resection except when it is likely to be curative in this region.

Future studies of newer chemotherapeutic agents and radiation therapy are certainly indicated in patients who cannot undergo resection for cure. Pilepich and Lambert have reported encouraging results in a small group of patients treated with radiation therapy as an adjunct to surgical resection or as the sole means of therapy.[16] On the other hand, Ingis and Farmer have indicated that radiation and/or 5-fluorouracil therapy did not increase the survival rate over surgery alone, in their series.[17] These conflicting reports should be prospectively evaluated in a similar group of patients. In order to do this scientifically, a system of clinical staging of these tumors must be developed and cooperative trials begun in several institutions.

Summary

This retrospective review has identified survival factors in a group of 95 surgically-treated patients with bile duct cancer. Patients with lesions located at the confluence of the right and left hepatic ducts or common hepatic duct were the largest single group treated. Patients in this group presented later in their course, had the highest operative mortality rate and the poorest

postoperative survival rate, whether the lesion was resected or not when compared with patients with lesions in other areas. By contrast, the best prognosis was found in patients with lesions of the lower third of the bile ducts which could be resected by Whipple procedures ($p = 0.0001$). Patients with papillary type carcinomas survived longer than those with well- or poorly-differentiated tumors, but this difference was not statistically significant. Using these observations, the hypothetical patient who would have the best chance of survival is one who presents within the first three months of onset of symptoms and is found to have a papillary type carcinoma of the lower third of the bile duct, which is resected by a Whipple procedure.

Acknowledgment

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Discussion

DR. JOHN TERBLANCHE (Cape Town, South Africa): I will confine my remarks to the lesions in the upper third (slide), the most frequent group in this series. I have two questions for Dr. Tompkins. First, one wonders whether their rather disappointing results with palliative surgical treatment could have been due to the inclusion of the better-risk patients and those with smaller lesions in the resection group, and whether, if these had been included in the palliative group, the results might have been better. Second, I urge that lesions situated truly within the hilus, and which I believe usually originate in the left or right main hepatic duct areas, should be treated differently from those that arise within the common hepatic duct area. The latter are easier to resect. My associates, and I have an 18-year survivor after resection of a lesion arising in the common hepatic duct, whereas we have not resected any of the lesions arising in the main hepatic duct junction area.

(slide) I thought it may be of interest to update our published data. Fifteen of the 26 patients were operated on between 1968 and 1972. They constitute a personal series that has been followed prospectively up to the present time. On analysis in 1979, two were alive at eight years. Currently, one is still alive. At the time of analysis, of the 13 who died, eight had survived for longer than one year, with the longest survival periods being 5, 3, 3, 2¾ and 2¼ years, respectively. I draw your attention to the fact that the average age of those who died in less than one year was 79 years. Thus, two-thirds of the patients survived for longer than one year. If you are doing radical resections, the results must be measured against what can be achieved by palliative surgical treatment with or without radiotherapy.

The U-tube procedure was developed during the course of the management of these 15 patients. It was used in eight and combined with radiotherapy in four. We added radiotherapy because the first patient operated on with the Altemeier dilatation with T-tube stenting had radiotherapy and survived for five years. Notice that our two long-term survivors had a U tube plus radiotherapy. I agree with Dr. Tompkins that a prospective study is required to assess the role of radiotherapy.

(slide) We still dilate the lesion using Bakes dilators. We have recently used the choledochoscope, as Dr. Tompkins mentioned, with a biopsy attachment, after dilatation, to obtain biopsy material for histology.

(slide) I believe it is important to bring out the U tube as low as possible on the anterior surface of the liver. This is achieved by passing the Bakes dilator up from below and forcing it out through the surface of the liver. A stout thread is tied to the dilator and pulled back through the liver and out of the choledochotomy incision below. The U tube is attached to the thread and pulled up from below. It is technically easier to pull it up from below than down from above.

(slide) Dr. John Cameron presented the straight transhepatic tube to this society three years ago. The U tube has at least two advantages. It is easier to replace, and it can be held in place easily without attaching it to the skin by using a cross-piece attached to the U tube. Thus, the patient does not have the discomfort of having anything attached to the skin. As soon as possible after operation the U tube is converted into a circle or O tube, which means that bile can flow either way around the tube and back through the biliary tree into the intestine. The U tube is not an external fistula, as has been misquoted on more than one occasion.

Finally, a complication has occurred in our two long-term patients. (slide) This patient is currently alive, working and well