

# Improvements in Survival by Aggressive Resections of Hilar Cholangiocarcinoma

Hans U. Baer, M.D., Steven C. Stain, M.D., Ashley R. Dennison, M.D., F.R.C.S., Bernard Eggers, M.D., and Leslie H. Blumgart, M.D., F.R.C.S. (Ed.) (Eng.) (Glas.)

*From the Clinic for Visceral and Transplantation Surgery, Inselspital, University of Berne, Berne, Switzerland*

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The operative management of hilar cholangiocarcinoma has evolved because of advances in diagnostic imaging that have permitted improved patient selection, and refinements in operative techniques that have lowered operative mortality rates. Over a 4-year period, 48 patients with hilar cholangiocarcinoma were managed. Twenty-seven patients were treated by palliative measures. Preoperative investigation identified 29 patients who were judged fit for operation without proven irresectability by radiologic studies, and 21 of the 29 patients had tumor removal (72%). Twenty-three operative procedures were performed: local excision (n = 12) (two had subsequent hepatic resection), and hepatic resection primarily (n = 9). Eight patients had complications (35%), and one patient died (4.3%). The mean actuarial survival after local excision is 36 months, and after hepatic resection, 32 months. Palliation as assessed by personal interview was excellent for more than 75% of the months of survival. A combination of careful patient selection and complete radiologic assessment will allow an increased proportion of patients to be resected by complex operative procedures with low mortality rate, acceptable morbidity rate, and an increase in survival with an improved quality of life.

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Tumors at the confluence of the hepatic ducts, although unusual, are now increasingly recognized as a cause of obstructive jaundice.<sup>1</sup> The low resectability rate, varied natural history, and the rarity of lifelong cure have led some to adopt an attitude of therapeutic nihilism,<sup>2-4</sup> and acceptance of nonoperative methods of palliation.<sup>5-8</sup> During the last decade, however, advances in diagnostic imaging have improved patient selection,<sup>9-11</sup> and refinement in the techniques of tumor removal either by local excision, or in conjunction with hepatic parenchymal resection, has lowered operative mortality rates to acceptable levels and provided prolonged survival in such cases.<sup>12-20</sup> The developments in methods of

operative resection and palliative biliary enteric bypass have occurred concurrently with improvements in the methods of transtumoral stenting by metallic self-expandable stents.<sup>21-23</sup> An aggressive operative approach must be viewed in light of the palliation that can be achieved by the newer methods of radiologic stenting.

This report is an analysis of patients treated under the direction of one surgeon (LHB) using diligent preoperative investigation to direct a vigorous approach to resection, with a curative or palliative intent.

## CLINICAL MATERIAL

Forty-eight patients with histologically proven hilar bile duct carcinoma were treated between October 1986 and October 1990. Hilar cancers were defined as tumors arising from the bile duct epithelium, located between the cystic duct insertion and the secondary hepatic duct

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Address reprint requests to Leslie H. Blumgart, M.D., Gastric and Mixed Tumor Service, Box 249, Memorial Sloan-Kettering Cancer Center, 1275 York Avenue, New York, NY 10021.

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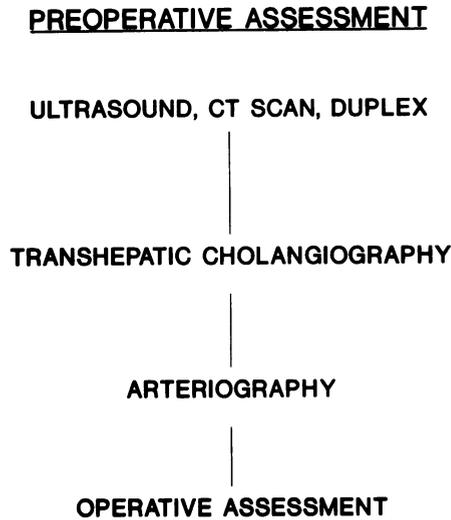


Figure 1. Preoperative assessment.

bifurcations. Primary carcinomas of the gallbladder were excluded. There were 25 men and 23 women, with a mean age of 62 years (range, 34 to 85). Although many patients had radiologic studies performed before referral, a standardized protocol was employed in patients primarily investigated at our institution (Fig. 1). Thirty-one of the 48 patients (65%) had previous biliary interventions at the time of referral (operations, 12; stents, 13; both, 6).

Preoperative radiologic criteria accepted as evidence of irresectability included extensive occlusion of the main trunk of the hepatic artery or portal vein, bilateral involvement of the major vascular branches, or unilateral vascular occlusion with extensive contralateral cholangiographic involvement. Vascular compression or localized involvement were not considered as contraindications to exploration with curative intent. All patients fit for operation and without proven irresectability by preoperative investigation had operative exploration for an attempt at curative resection.

The treatment of the 48 patients is outlined in Figure 2. Twenty-seven patients were palliated by biliary enteric bypass (n = 16), nonoperative transtumoral stent (n = 8), external percutaneous drain (n = 2), and one moribund patient received only supportive care. Twenty-nine patients had operative exploration with a curative intent. Resection of the tumor was possible in 21 patients, who form the basis of this report. Twelve patients had local excision of the tumor, two of whom were submitted to subsequent hepatic resection. Hepatic resection was performed primarily in nine patients. The feasibility of local excision may be suggested by preoperative investigations. A local excision may be possible if diagnostic studies have demonstrated vascular freedom and cholangiographic involvement up to, but not beyond, the second-

ary bifurcations of the hepatic ducts. Operative hilar exploration should confirm these findings, and in patients without adjacent quadrate or caudate hepatic lobar invasion, local excision is applicable. In selected cases, an elective palliative resection may be performed through an involved caudate ductal margin, and this option was chosen in five patients.

The operative techniques have been described previously in detail.<sup>24-26</sup> Briefly, local excision encompassed a low, supraduodenal division of the distal common bile duct and *en bloc* dissection of the gallbladder and hepatoduodenal lymph nodes, with skeletonization of the portal vein and hepatic artery. The proximal extent of bile duct transection was pursued as far above the tumor as technically possible. Hepatic resection included a similar hilar dissection with hepatic parenchymal division as well as the involved unilateral vascular structure or second-order bile ducts with the specimen. When necessary, portal venous reconstruction was carried out by direct anastomosis of the main trunk of the portal vein to its own right or left branch. The actuarial survival was analyzed by the Kaplan-Meier method, and compared by the Mantel Cox test. The quality of survival was assessed at personal interview.

**RESULTS**

A local resection was performed initially in 12 patients. Nine patients had an uneventful postoperative

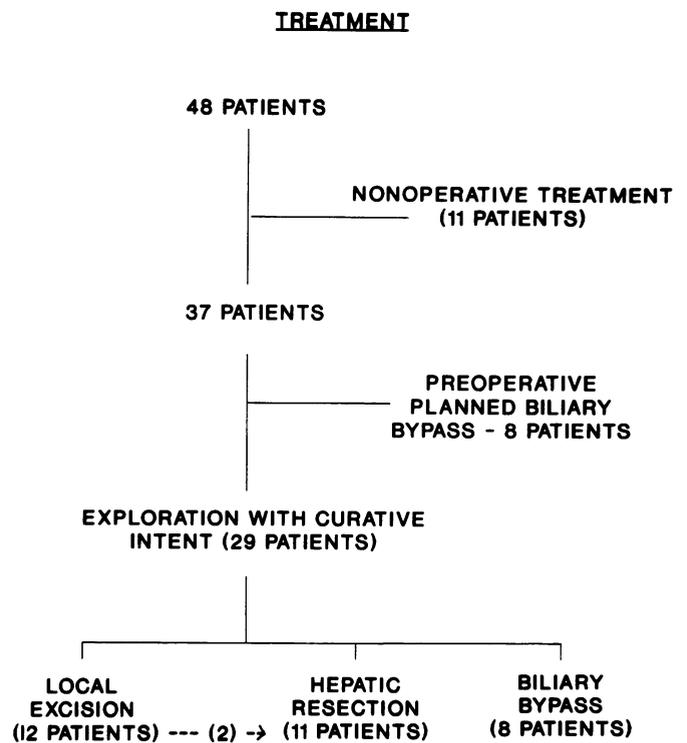


Figure 2. Treatment.

course after local excision, and although three patients suffered complications (25%), there were no deaths. One patient developed hepatic necrosis, and an extended right hepatectomy had to be performed on the fourth postoperative day. A biliary fistula occurred, which closed spontaneously at 10 days in the second patients, and the third patient had transient renal insufficiency, and a hepatic arterial branch pseudoaneurysm that was embolized. All three patients recovered completely. A palliative local resection was performed in one patient, who had a subsequent hepatic resection 3 months later.

Eleven patients were treated by hepatic resection, nine primarily, and two after initial local treatment (*vide supra*). An extended right hepatectomy with hilar excision and biliary enteric anastomosis was performed in six patients.<sup>27</sup> Two additional patients had an extended right hepatectomy and left hepatectomy with caudate lobe excision in association with excision of a segment of portal vein and primary venovenous anastomosis. The other three patients were treated by: an isolated caudate lobe resection, a caudate lobe resection with left hepatectomy (including liver segments II, III, IV), and a left hepatectomy.

Six of the 11 patients treated by hepatic resection had an uncomplicated postoperative course, and four developed complications (36%) (perihepatic abscess, 2; sterile biloma, 2). One patient died (hepatic resection, 8.3%), because of hepatic necrosis after hepatic arterial ligation performed at left hepatectomy at which resection of the caudate lobe resection and portal vein reconstruction were also performed.

The transected caudate lobar ducts required special attention in eight patients, six after local excision, and two after hepatic resection. The caudate ducts were simply oversewn in six, and one of these developed a bile fistula that closed spontaneously. In two patients, large caudate ducts were anastomosed to the jejunal loop.

Previous biliary intervention influenced the management. Resection could be performed in 12 of the 17 patients (71%) without previous biliary intervention. The tumor could be removed in only nine of 31 patients (29%) with prior intervention, and in seven of these nine there was residual tumor histologically proven after operation.

## SURVIVAL

Eight patients have died 6 to 27 months after operation, and 12 are alive 10 to 58 months after surgery. The mean survival determined by the Kaplan-Meier method is 36 months (Fig. 3). There is no statistical difference in actuarial survival after local excision (mean, 36 months) or after hepatic resection (32 months) ( $p = 0.93$ ) (Fig. 4).

Eleven patients were disease free after local excision ( $n = 6$ ) or hepatic resection ( $n = 5$ ), and their actuarial

mean survival is 40 months. Nine patients had positive margins ( $n = 7$ ) or local metastases ( $n = 2$ ), and their mean survival is 21 months. This difference does not reach statistical significance ( $p = 0.296$ ) (Fig. 5).

An excellent quality of survival was defined as a return to work or to the previous level of activity, requiring only routine follow-up visits. A fair level of palliation was described as occasional signs of cholangitis with mild weight loss, but active and providing self-care with no more than one hospitalization required per year. Patients with poor palliation had episodes of recurrent jaundice requiring more than one hospitalization or biliary intervention per year. The proportion of the months of survival in which the patient experienced an excellent or fair palliation are plotted with crude survival in Figure 6.

## DISCUSSION

The natural history of untreated hilar cholangiocarcinoma is dismal, with a mean survival of less than 3 months.<sup>25</sup> The progression in the symptoms of jaundice, pruritus, cholangitis, and liver failure are responsible for this poor prognosis, and result in an extremely poor quality of life. Palliative approaches employing either transtumor stenting or biliary enteric bypass can improve the survival of these patients, but the mean survival time is less than 12 months.<sup>26,28-31</sup> The encouraging results of local or hepatic resection at several specialist hepatobiliary centers has prompted an aggressive approach to resection<sup>13-20,32</sup> in the hope of increasing the length of survival, but also in providing an improvement in the quality of life, and a potential for cure.

Radiologic assessment was designed both to identify patients with clearly irresectable tumors, and to determine the extent of resection that would likely be necessary to achieve complete tumor removal. Such information allows the evaluation of the proposed operative procedure in light of the patient's general medical condition. If a palliative rather than a curative procedure is planned, a biliary enteric bypass can be performed without extensive hilar exploration necessary to operatively determine irresectability. Additionally, nonoperative palliation by percutaneous or endoscopic stent placement may be considered. Initial reports suggest that metal self-expandable biliary stents may prove to be a reasonable nonoperative alternative to biliary enteric bypass.<sup>21-23</sup> The senior author, however, has no long-term survivors of histologically proven cholangiocarcinoma after either palliative biliary bypass or stent placement.

As imaging modalities improve, it is important to remember that only patients with unequivocally irresectable tumors should be denied an operative assessment for possible tumor removal. Recent refinements have

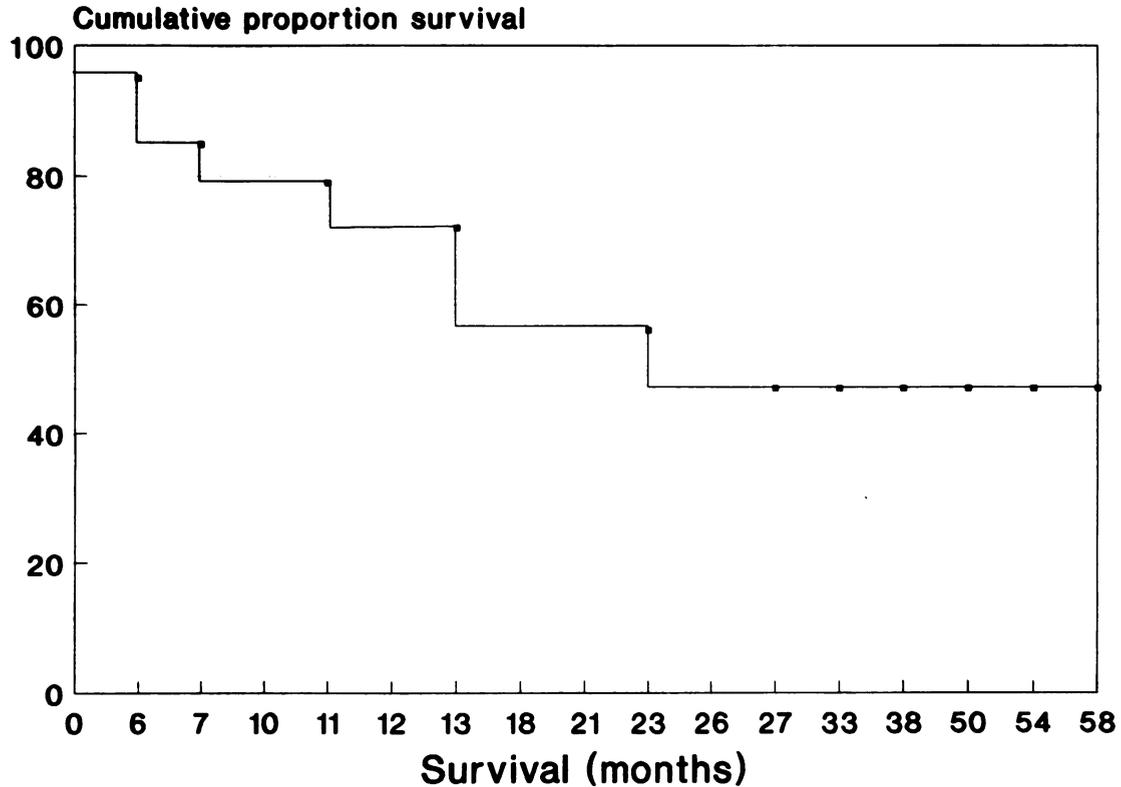


Figure 3. Actuarial survival (20 patients).

improved preoperative planning, and a preliminary report indicates that duplex sonography may be equal to arteriography in the definition of hilar vascular anatomy (unpublished observations). As compared with operative findings, the hilar vascular involvement was accurately predicted by duplex in 19 of 22 patients (86%), and by hepatic arteriography and indirect portal venography in 18 (82%).

In the current study, 29 of the 48 patients (60%) were radiologically assessed as potentially resectable. These 29 patients were explored with an intent to perform a curative resection, and 21 of these were resected (72%). Using a similar radiologic protocol at Hammersmith Hospital, the senior author previously reported 13 of 37 (35%) patients with hilar tumors to be potentially resectable, and only five of the 13 could be resected at operation (38%).<sup>33</sup>

Prior biliary stent or operation has been shown to increase the risk of perioperative complications and reduce the chance of a successful resection due to the dense periductal inflammation and fibrosis in the porta hepatis.<sup>31</sup> In the current series, only 29% of the patients with prior biliary intervention could be resected, and seven of these had residual tumor. By comparison, 70% of those without prior intervention were resected. It is clear that the initial operation is the best opportunity to effect a safe, complete resection. If a surgeon encounters an unexpected hilar tumor at operation, and is unprepared to

deal effectively with the lesion, the patient is best served by calling for assistance or immediate abdominal closure with prompt referral to a specialist. Opening the bile duct and placing a stent or T-tube across the tumor may temporarily relieve the jaundice, but in all probability will make a subsequent curative resection difficult or impossible.

The increased proportion of patients resected (44%) has been due in part to an increased willingness to perform major hepatic resections. This developing philosophy reflects the recognition that not only could the patients tolerate the more extensive procedure, but also that the results of operative tumor removal produced an excellent quality of life and a worthwhile prolongation of life. It generally had been assumed that adopting a more aggressive surgical policy in the treatment of hilar cholangiocarcinoma was inevitably accompanied by an increased mortality rate. This series clearly demonstrates that this is not the case, and although there was significant perioperative morbidity (30%), there was only one death in 23 operative procedures in this selected group of patients (4.3%), less than or equal to the results of operative palliation, or nonoperative stenting.<sup>5-7,21-23,28-31</sup> These results are encouraging in view of the known impaired nutritional status and immune responses of the deeply jaundiced patient,<sup>34,35</sup> and the subsequent increase in infectious complications.<sup>36,37</sup> Preoperative bili-



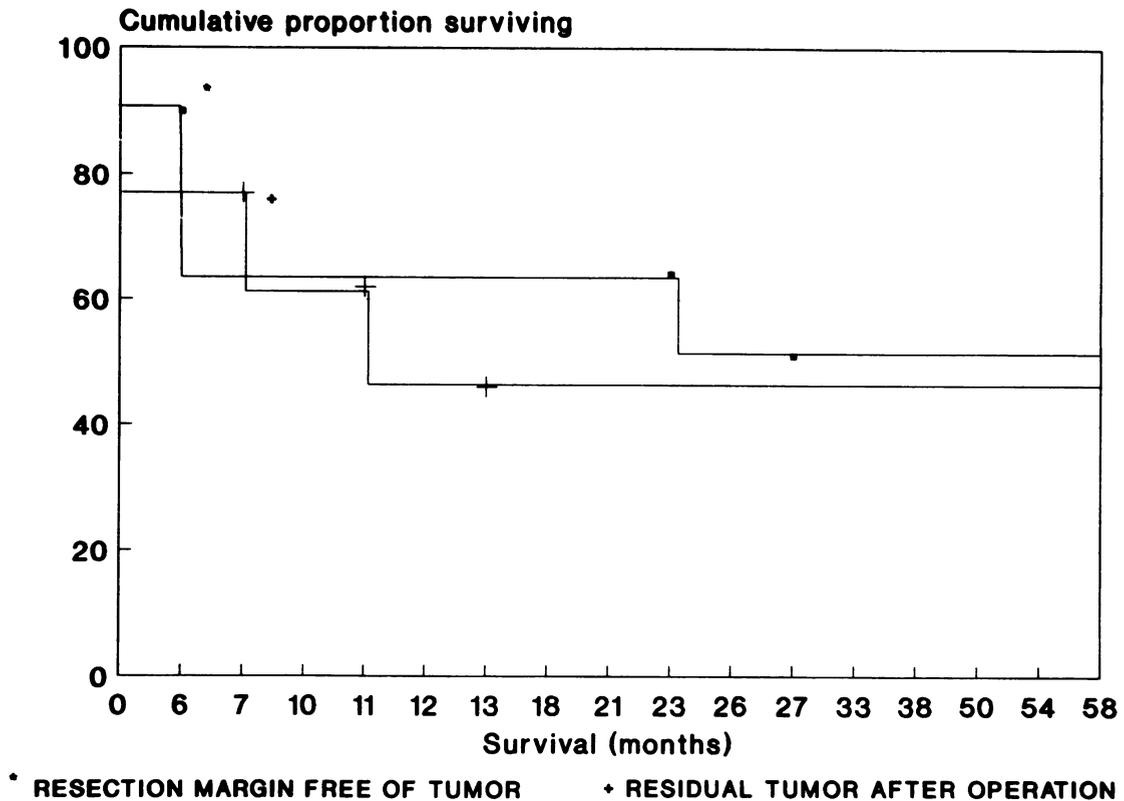


Figure 5. Actuarial survival (disease-free vs. residual tumor).

condition. The proximal dissection always should be extended as far from the tumor as possible and still allow a safe biliary enteric anastomosis. This is more easily achieved on the left duct, with its longer extrahepatic segment. If the dissection is pursued to this limit, a positive frozen section becomes irrelevant because further dissection is impossible. Frozen sections may be inaccurate, and if any doubt exists regarding the unilateral ductal extension of tumor, then a hepatic resection is indicated if the patient can tolerate the more extensive procedure. Larger caudate ducts should be anastomosed, but the smaller ducts can simply be oversewn, with eventual caudate atrophy. Only one of six patients so managed developed biliary fistula.

Nine of our patients had residual tumor after operation, but this figure is misleading because, in five of the nine, a palliative local resection through gross tumor was chosen because the patients were not considered fit to tolerate the more extensive procedure. Two other patients had local metastases, and the only two patients with tumor at the resection margin after an attempt at curative resection were the two hepatic resections performed after initial local excision.

In the current series, the mean actuarial survival after local excision of 36 months was comparable to the 32 months achieved with hepatic resection, and far longer

than that possible by nonresectional methods. There was a trend toward longer survival after a tumor-free margin (40 months), when compared with the patients with residual disease (21 months), but the short follow-up does not allow statistical significance. Boerma<sup>48</sup> recently reviewed the 40 series published during the 1980s of resections for hilar bile duct cancer. The operative mortality rate in 499 resections was 12%.<sup>48</sup> Data were available for follow-up of 295 patients and the 2-, 3-, and 5-year survival percentages were 30%, 24%, and 13% respectively. Local resection had an 8% operative mortality rate and a 7% 5-year survival rate. After hepatic resection, the mortality rate was 15%. Comparisons of the mortality and survival rates were each statistically significant. It would seem that the possible increase in survival after hepatic resection is bought at the cost of higher operative mortality rate. The results in our series, however, demonstrate that a combination of careful patient selection, complete radiologic assessment, and diligent perioperative care will allow hepatic resection in suitably fit patients without an increase in operative mortality rate when compared with local procedures. The medical condition of the patient and the limit of tumor extension should dictate the type of resection.

Several prominent authors have questioned the merit of an aggressive approach to tumor removal and of some-

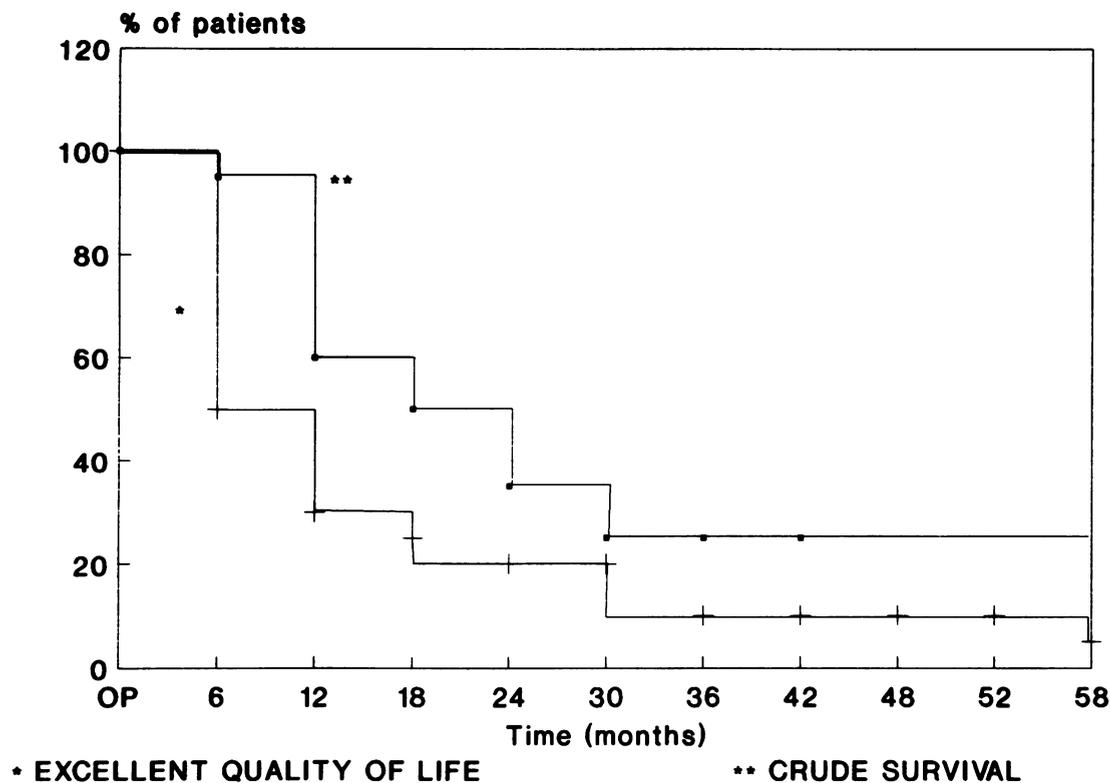


Figure 6. Palliation (crude survival with excellent palliation).

times accepting minimal or microscopically involved resection margins.<sup>2,49,50</sup> Long-term survivors may manifest recurrence as late as 5 or 10 years after resection. Does this marked improvement in survival justify a radical tumor excision if most are destined to recur?

Although there is an undeniably prolonged survival rate after resection, an equally important goal is the improvement in the quality of that survival. We believe a good quality of survival should not be complicated by repeated hospitalizations, or frequent stent replacement or reinterventions for occlusion. Determination of the quality of survival is always difficult because of the essentially subjective nature of the assessment process. The estimate of the quality of survival in this series shows that the palliation during most of the patient's survival was excellent (Fig. 6). Subjectively, the patients seemed to have derived psychological benefit from the combination of tumor removal and the lack of external apparatus. This contributed significantly to a rapid return to premorbid levels of activity. This was almost equally true for the patients in whom a palliative resection was performed through known tumor.

Late recurrences still may occur after a prolonged disease-free interval, and interventional radiologic stent placement then can be employed if late jaundice develops. All treatment methods for hilar cholangiocarcinoma, including operative removal, can be regarded as

palliative, and the issue becomes which modality provides the best palliation. Resection provides relief of jaundice, prolonged survival, improved quality of life, and the possibility of cure. If resection can be performed with acceptably low operative mortality and morbidity rates, then the risk/benefit ratio favors resection.

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