

Gallbladder Cancer Discovered on Histological Specimen after Cholecystectomy: The Patients Whom do not Need Reoperation

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Abstract

A significant percentage of patients with a histological discovery of gallbladder cancer cannot benefit from resection of the tumor residue during complementary surgery. Despite the contribution of modern complementary examinations, the predictability of resection remains problematic. The objective of this work is to define a score that can predict the resectability of the residual tissue.

Material and Method: All patients with cancer discovered on the operating room and having a complete file were included. The patients were divided into 3 groups A: patients who underwent resection, group B is formed by patients who underwent monitoring after cholecystectomy and group C consists of patients who could not benefit tumor resection. A score consisting of several the score was established. It is made up of clinical signs (pain, jaundice, palpable mass, etc.) side 0 to 4, morphological signs in favor of the tumor residue (ultrasound and / or CT and / or MRI) side 0 to 1, and tumor markers (Ca19.9 and CEA) side from 0 to 4 points. Each criterion has an annotation from 0 to 1 and from 0 to 4 is noted between one to 4 points depending on its importance.

Results: one hundred and sixty-two were included. These are 138 women and 24 men with an average age of 67 years (26-85 years). The 3 groups A, B and C consist respectively of 79, 32 and 51 patients. The presence of a clinical symptom, an abnormal morphological examination and a high marker in the patient is significantly associated with the absence of tumor resection during additional surgery or at the time of recurrence for group B. The average time for complementary surgery was 103.8 days (30 - 387 days) for the 122 patients who underwent complementary surgery. The respective average times for group A and C are 102.2 and 109.6 (Not significant). The score increases from group A to group C. For patients of group A, 84,8% of them have a score of 0-2 while only 21,5% of group C have the same score. The resection rate goes respectively from 86,1% for the score 0 - 2 and fail to respectively to 18,5% and 07,1% for the score 3 - 7 and 8 - 13 (one resection for 68 patients). Survival goes from 41.7% to 01,25% and 00% respectively for the same scores, 0 - 2, 3 - 7 and equal or superior to more than 8 points. Thus, the majority of patients who benefit from resection and 5-year survival had a score between 0 - 2 (resection rate of 86.1% and 5-year survival of 41.5%), while at beyond 3 points, the resection rate and 5-year survival are only 18,5% and 07,1% and 00%.

Conclusion: This study shows that the established score allows a large proportion to predict resection and survival before additional surgery for gallbladder cancer discovered on resected specimen. It can bring means to better choice a new indication for the advanced stages and not operate systematically. The new direction could be neoadjuvant therapy

INTRODUCTION

The incidental gallbladder cancer is a form recognized as having a good prognosis compared to other locally advanced or metastatic forms of this malignant disease [1-]. A reoperation is necessary for tumors classified pT1b, pT2 and pT3 [2, 3, 4-, 5- 6-7] for resection of the tumor residue left in place after cholecystectomy. In a meta-analysis, 40.9% of patients undergo complementary surgery and 23% of them had an unresectable tumor residue [8]. The purpose of this additional surgery is to resect the tumor residue and give the patient a chance of recovery, which is the only alternative at present. Thus, both the delay of the second surgery and residual tumor will be important for the long-term prognosis [9]. But despite all the morphological exploration and histological data, around one in two patients will not benefit from resection, which is the key to long-term survival. Histological discovery of gallbladder cancer is a prime example of a tumor outbreak after manipulating a tumor. Thus, the primordial question is the following: is it possible to predict resectability and therefore survival before undertaking this complementary surgery, which consequently will make it possible to better choose the patients for this surgery and without performing unnecessary acts? Is this reoperation justified in all patients? On the other hand, and apart from the criterion of parietal infiltration (pT) [10,11]. On the other hand, and outside the criterion of parietal infiltration [12, 13, 14], Reported work including histological parameters primarily to predict the presence of residual tumor tissue before re-resection indication. A recent study demonstrated that the residual is an important factor [15]. But is it possible to predict the non resectability of this residual tumor? It is important to know with a great certainty that the residual tumor is not resectable in addition to its diagnosis. To answer this question, we conducted a retrospective study analyzing the results of our successive therapeutic attitudes with the objective of isolating criteria allowing better targeting of patients who will benefit from surgery and not operating on patients who do not.

MATERIAL AND METHOD

This is a retrospective study encompassing all cases of histological discovery managed at the service level over the past twenty years. Our attitude of taking

charge of these histological discoveries went through 3 phases: During the first phase, resumption of surgery was not the rule and monitoring was offered to the patient. During the second phase, additional surgery was indicated for tumors classified as pT2 and pT3. Finally, the third phase added the tumor classified pT1b above to the previous ones. To be able to be included in this study, the patient file had to contain the following criteria: The degree of parietal infiltration divided into pT1a, pT1B, pT2 and pT3 (cancer pT3 with infiltration of a neighboring organ and pT4 were excluded from the study since they do not strictly speaking constitute a histological discovery). Upon receipt of the result of the histological study, a request for re-reading is requested from the pathologist in order to have the following elements in the report if they were omitted in the first report: the macroscopic aspect, the exact location of the tumor (bottom, body and collar), the degree of infiltration at the level of the wall (pT), the section section of the cystic duct, the presence of vascular emboli and / or perinervous sheaths and the degree of differentiation of the tumor. The patient is examined and any clinical sign suggestive of tumor recurrence (jaundice, palpable mass of the right hypochondrium, ascites, etc.) is noted. Biological examinations are systematically requested (formula blood count, urea and creatinine, blood crase, blood sugar and protein levels. In case of jaundice examinations of liver biological parameters at least alkaline phosphatases, transaminases and gamma-glutamyl transferases are also requested. An electrocardiogram, echocardiography and pulmonary radiology are also required, abdominal ultrasound and / or computed tomography and / or cholangio-MRI according to the results of the clinical examination are required. patient does not reveal a contraindication to complementary surgery and after explaining the reason for the reoperation. When the patient presents after a clinical, morphological and biological evaluation, a tumor spread contraindicating complementary surgery, palliative surgery is selected when there is obstructive jaundice and / or digestive stenosis, in order to remove the symptomatology. It is symptomatic and not complementary or radical surgery. To carry out this study, the following parameters were noted and studied retrospectively: Age, sex, pre-reintervention symptoms, Abdominal echotomography, CT scan, MRI and cholangio-MRI, the level of the carbohydrate antigen 19.9 (Ca19.9) and carcinoembryonic antigen

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(CEA), time for reoperation, tumor residue and its site and 5-year survival. For morphological examinations, any anomaly in favor of the existence of a residual tumor caused the morphological examination to be classified as abnormal examination. If no evidence of tumor recurrence was found, the examination was classified as normal. The Ca19.9 assay was also carried out and any elevation above the upper standard of the laboratory which carried out this examination, the result was noted as high. The same was true for the CEA with the difference that a threshold of 2 times normal from the laboratory was necessary to classify the result as high. All symptoms present before complementary surgery are listed (see appendix).

We classified the patients into 3 groups:

- **Group A:** patients resumed and having benefited from a radical resection of lesions.
- **Group B:** is formed by patients in whom the treatment consisted of a cholecystectomy alone without attempting a radical secondary surgery (choice of patient and / or the surgeon who performed the cholecystectomy) and who have been followed to date or until their tumor recurs. Secondary resection was performed at the time of recurrence after a resectability assessment identical to that of groups B and C.
- **Group C:** patients who underwent catch-up surgery and whose lesions could not be resected during this reoperation or patients who presented an advanced disease deemed unresectable (locally advanced and / or metastatic cancers). For groups A and C, the clinical examination, the morphological examinations and the markers were carried out just before this reintervention. For group B, the clinical examination, the morphological and biological examinations were regularly carried out to date or at the time of the recurrence. For patients alive to date, the score is counted during follow-up and if a recurrence occurs, the score is established at the time of the latter, regardless of the attitude towards the latter. Established a simple arithmetic score by giving a point annotation for each clinical, biological and morphological element when it was abnormal (see appendix: Post-cholecystectomy score). For morphological examinations, the annotation is taken for a single examination: Abdominal ultrasound scan (ECT) or computed tomography (CT) or magnetic resonance imaging (IRM).

Our policy in front these patients when we operate on is the remove at minimally the IV and V segments with extensive lymphadenectomy which interests hepatic pedicle, hepatic common artery, retroduopancreatic area, coeliac trunk and aorto-caval area. The explorative period check visually and manually the liver and liver bed, different node area, peritoneum and pelvis. All macroscopic lesion must be resected even with enlargement of the hepatectomy or resect neighboring visceral. The final diagnostic of residual tumor will be assessed by histological exam. If a few or localized hepatic metastasis are found they will be resected as minimal carcinomatosis.

Statistical analysis used Chi2 for qualitative variable and the student test for quantitative variable. Global survival and recurrence used Kaplan Meier. Only univariate analysis was used. For the statistical tests, p significance less than of 0.05 was used

RESULTS

Out of two hundred and forty-two patients, one hundred and sixty-two were included. These are 138 women and 24 men with an average age of 67 years (26-85 years). The 3 groups A, B and C consist respectively of 79, 32 and 51 patients. The characteristics of these three groups are reported in Table 1. The latter that for clinical, morphological and biological criteria the differences are clear and statistically significant ($p < 0.05$) (**Table 1**). The presence of a clinical symptom, an abnormal morphological examination and a high marker in the patient is significantly associated with the absence of tumor resection during additional surgery or at the time of recurrence for group B. Thus, with the presence of a clinical sign, a pathological morphological examination and a high marker is an indicator of an unresectable residual disease. Conversely, when none of these signs exists, the situation is opposite and radical resection is possible in the majority of cases (**Table 2**). The average time for complementary surgery was 103.8 days (30 - 387 days) for the 122 patients who underwent complementary surgery (eight were not operated because with a locally advanced and / or metastatic disease widely demonstrated by morphological examinations). The respective average times for group A and C are 102.2 and 109.6 (NS). The overall residual disease is 64.7% (79/122) for operated patients while it rises to 67% if we add 8 patients

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with a manifest residual tumor, but not operated on (Table 3). This residual disease rate rises to 65% if we include patients in the group that recurs. If the rates of resection and the rates of residual disease are not different, survival is paradoxically superior for the less or equal delay and superior period of 90 days but the difference does not reach the threshold of significance. The distribution of the three groups according to the score is reported in Table 4. The score increases from group A to group C. For patients of group A, 84,2% of them have a score of 0-2 while only 21,5% of group C have the same score. The patients of this last group are in 78,5% of the cases divided between a score 3 and more. The table 4 shows the trend of increasing score from group A to group C. When we report the resection rate to the score, we notice that the latter drops from score 0 to score 13. The resection rate goes respectively from 86,1% for the score 0 – 2 and fails to reach 18,5% and 07,1% for the score

3 – 7 and 8 - 13 (one resection for 68 patients) from three and beyond three points. Survival goes from 41.7% to 01,85% and 00% respectively for the same scores, 0 – 2, 3 -7 and equal or superior to more than 8 points (Table 4). Thus, the majority of patients who benefit from resection and 5-year survival had a score between 0 - 2 (resection rate of 86.1% and 5-year survival of 41.5%), while at beyond 3 points, the resection rate and 5-year survival are respectively only 18,5% and 07,1% and 01,85% and 00%. These obtained results followed both cholecystectomy alone and secondary surgery (Table 5). The only patient alive at 5 years, had a cholecystectomy associated with chemotherapy and who underwent a metastasectomy 40 months postoperatively after a hepatic recurrence. She died at 75 months from other disease (Diabetes). We must point out that no patients without infiltrated lymph nodes, showed recurrence regardless of the pT (pT1b, pT2 and pT3) (Data not shown).

Table 1. Characteristics of all patients

Paramètres	Groupe A: 79	Groupe B : 32	Groupe C: 51
Age	57years (45 – 77year)	59 (40 -79year)	58 (42 -79year)
Sex : 138femmes – 24hommes	65femeles 14males	26femeles 5males	44femeles 7males
Sex	69F 10H	27 F 05H	42F 09H
pT1a	01	02	00
pT1b	12	10	00
pT2	16	00	01
pT3	50	20	50
Global residual tumor	46,8% (37/79)	59,3% (19/35)	100% (51/51)
Symptoms	3/79 (03,8%)	09/32 (28,1%)	29/51 (49%)
Abnormal US	07/47 (14,9%)	17/27 (63%)	24/29(82,8%)
Abnormal CT Scan	09/57 (15,8%)	15/26(57,7%)	35/42(83,3%)
Ca 19.9: High	11/79 (14%)	15/32 (46,9%)	25/51(49%)
CEA: High	05/79 (06,3%)	06/31 (19,4%)	16/51 (31,4%)

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Table2. Résection according to the presence or absence of the preoperative criteria

Caracters	Resection rate	p
Symptoms		
Absent	90/118 (76,3%)	<0,001
Present	03/44 (06,8%)	
US		
Normal	50/56 (89,3%)	<0,001
Abnormal	08/47 (17%)	
CT Scan		
Normal	57/67 (85%)	<0,001
Abnormal	10/58 (17,3%)	
Ca19.9		
Normal	78/110 (71%)	<0,001
High	13/51 (25,5%)	
CEA		
Normal	86/134 (64,2%)	<0,05
High	05/27 (18,5%)	

Table3. Residual tumor and resection rate according to the delay of reoperation

Reintervention delay 122	Résection	Résidu	Vivant à 5ans
Less or equal to 90 days	40/64 (62,5%)	44/64 (68,7%)	13/64 (20,3%)
Superior to 90days	39/58 (67,2%)	35/58 (60,3%)	20/58 (34,5%)
Total	79/122 (64,7%)	79/122 (64,7%)	33/122 (27%)
P	0.9	0.9	0.1

The delay does not impact the presence of residual tumor nor resection rate.

Table4. The score according to the three groups

	A: 79	B: 32	C: 51	
0-2	67 (84,8%)	16 (50%)	11 (21,5%)	94
3 - 7	10 (12,6%)	13 (40,6%)	23 (45%)	46
8 - 13	02 (02,5%)	03 (09,3%)	17 (33,5%)	
Total	79	32	51	162

For the group A, 84,5% of patients have the score 0 - 2, in contrast 78,5% of patients of the group C have score beyond 3 points.

Table5. The resection rate and global 5 year survival according to the score

First level of score	Resection rate	Global 5year survival
0 - 2 : 94	81/94 (86,1%)	39/94 (41,5%)
Second level of the score		
3-7 : 54	10/54 (18,5%)	01/54 (1,85%)
Third level of the score		
8 - 13 : 14	01/14 (07,1%)	00/14 (00%)

Even if the resection rate is of 18,5%, the global 5 year survival is of 1,85% for the score of 3 - 7 and nil for the score of 8 - 13 points

DISCUSSION

Our series shows that the IGC is not always a favorable situation from a prognostic point of view. Thus, the overall residual tumor rate is 65% and only 35% are alive for the entire series. A meta-analysis carried out by KS Choi et al has shown that the rate of tumor residue deemed unresectable during complementary surgery is 23% [8]. F. Ausania et al insist on the delay of 3 months to perform the complementary surgery [16]. These authors justify this delay by the fact that the residual tumor will become obvious to the radiologist around 3 months on the CT scans. Some authors have located it around 2 months [17]. It is currently accepted that patients with a tumor classified as pT2 and pT3 must undergo additional surgery in order to precisely resect the residual tumor tissue. Whereas for tumors classified pT1b, the debate is not completely closed between the authors favoring simple cholecystectomy [18] and those for radical surgery. However, in our view, the sole criterion of the parietal invasion remains insufficient and cannot predict the resectability of the residual tumor. For 162 patients included, only 57 patients are alive and 105 others died, at a rate of 64.8%. The cause of death for the latter is cancerous disease. Thus, after a histological discovery, there is a need to better choose the patients for complementary surgery. The latter should only be used in whom with great probability to have their residual tumor resected. It is of course possible to carry out a thorough clinical and morphological assessment (abdominal ultrasound, computed tomography, magnetic resonance imaging, pet scan, laparoscopy, etc.) to properly select the patients and eliminate all those who have disseminated disease after cholecystectomy. In addition to a formal general contraindication or a manifestly advanced disease, the surgical teams continue to perform reoperations in patients with an unresectable residual disease for all authors even with use of all modern exam. For us, it is possible not to carry out a very detailed and expensive morphological assessment for each patient. We established this simple score in order to properly establish this selection. The parameters chosen after daily practice over several years (studies conducted on clinical parameters and markers - data not shown-), enabled us to establish this simple score. All the parameters chosen are discriminant taken one by one and their association in construction of the score, makes it possible to increase this

discrimination. This simple score allows not only to predict the resection but also the possible benefit of it. Thus, a score between 0 and 2 is the one that allows us to choose the patients who will benefit from radical resection during complementary surgery. Beyond this score, the chances of resection are minimal and even more survival. The advantages of our series are its simplicity, its availability and its cost compared to the use of multiple morphological examinations. In addition, these morphological examinations can miss small lesions that are discovered intraoperatively. The practice of Pet Scan alone is still insufficient and its association with computed tomography is promising but expensive. [21, 22]. Performing diagnostic laparoscopy can have a definite contribution to the preoperative evaluation of a histological discovery [23]. For our score, the clinical examination does not pose any problems, carrying out the dosage of markers (Ca19.9 and CEA) are systematically used during cancer of the gallbladder cancer whereas a computed tomography remains for us an examination to be carried out preoperatively associated with the realization of magnetic resonance imaging in the event of insufficiency of or presence of jaundice.

In the last few years, CG Ethunet al [24] published a retrospective study about a score called gallbladder cancer predictive score risk score (GCPRS) which established tree levels of risk: low (3 - 4 points), intermediate (5 - 7 points) and high risk (8-10 points). This score uses the T stage (pT1a, pT1b, pT2 and pT3/T4 with respectively 0, 1, 2 and 3 points), the grading of tumor (well, moderately and poor differentiated with respectively 1, 2 and 3 points), presence of lymphovascular and perineural invasion (negative 1 point and positive 2 points). The residual tumor was found in 129 patients (49%). This score predicts the residual tumor and survival. Moreover, the lymphovascular and perineural invasive were not established for all the patients with only 43,1% and 44,6%. It was one of the limitations of their study. The second point which we want to ask, is the fact that the GCPRS is established only to predict the residual tumoral. In contrary, our parameters are suitable in all patients and simple and our score is established to choose the patients with advanced and not resectable disease. We have showed that residual tumor is more important than the delay both for the resection and the 5 survival [25]. It is essential to highlight the residual tumor before deciding the reoperation and our score allows us to predict it.

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We must not lose sight of the fact that our study may present biases. First, it is a retrospective study and the patients included were included over a long period of course with changes in the choice of therapeutic methods. However, it should be noted that it is impossible for ethical reasons to conduct a prospective study for this type of patients. Secondly, certain choices were inherent to the patients insofar as certain indications for cholecystectomy alone were chosen by the patients themselves after having received the explanations inherent in the disease and in the complementary surgery.

Overall, we think that this score is simple and reproducible by all surgical teams. It is not accompanied by any addition of exams since they are all which are routinely already requested in the management of this disease. In addition, if in some patients the disease can be diagnosed as unresectable in the face of evidence of residual tumor lesions on morphological examinations, others can be excluded from the additional operating indication with this score while the morphological examinations are reassuring. Thus, this simple score allows us to predict the presence of residual tumor tissue, even when it is not visible (millimeter-peritoneal carcinomatosis nodules are the typical example), resection and long-term survival. The results of our study allow us to go towards a prospective study which evaluates this score by including other simple and available parameters (histological criteria in particular in addition to that described in this study) for each patient presenting a histological discovery. Conclusion: We were able, on simple parameters, available and reproducible preoperatively, to show that it is possible to predict the resectability of the tumor residue after histological discovery of gallbladder cancer. Once our prospective study is complete (we are at the end of the inclusions) and if it confirms the results of this retrospective study, we think that patients not to be selected for complementary surgery must have another neoadjuvant therapeutic approach in order to offer them the possibility of secondary surgical resection.

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