

Efficacy and safety of needle- knife fistulotomy in treatment inoperable periampullary carcinoma.

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ABSTRACT

Background Ampullary carcinoma is the third most common tumor causing obstructive jaundice ,and they are potentially curable lesion if the correct diagnosis is made at an early stage. In patients for whom surgery is not appropriate, endoscopic implantation of biliary endoprosthesis is a palliative therapy and often improve the quality of life . Endoscopic sphincterotomy is needed in most therapeutic biliary procedures but is not always possible . When selective (deep) common bile duct (CBD) cannulation and consequent endoscopic sphincterotomy are not possible ,a precutting needle-knife fistulotomy is used. This procedure is indicated when papilla is obstructed ,usually by an inoperable ampullary carcinoma .4 This study identifies for the first time our limited experience in such procedure. Setting: Gastroenterology Teaching Hospital ,Medical City- Baghdad.

Methods: Between June 2003 and January 2006 ,14 consecutive patients (10 male, 4 female; mean age 70 years) with inoperable ampullary carcinoma underwent biliary needle- knife fistulotomy with metal stent placement had been studied. With the needle-knife fistulotomy procedure, a small incision (3 to 5 mm above the papillary orifice) was made on bulging intraduodenal segment of common bile duct. If attempt was successful, the opening was extended cephalad with sphincterotome, followed by metal stent placement.

Result: Successful needle-knife fistulotomy during the first attempt was 85.7% (12 out of 14) .One out of the remaining two patients successful second attempt was achieved. Successful drainage rate with metal placement was reported in 92.9% and jaundice disappear in all patients within 3 weeks.

Neither hospital mortality nor 30-days mortality was recorded. Early complications including perforation, pancreatitis, cholecystitis, early clogging were not reported. Only single case of bleeding required injection therapy was reported. Late complications including metal stent dysfunction owing to biliary sludge formation was seen in one case after 7 months, clogging of prosthesis by tumor ingrowth or overgrowth occurred in up 21.3%, clogging occurred from 5 to over 22 months with mean of about 13.5% months.

Conclusions: Needle-knife fistulotomy is an effective and safe procedure for treating inoperable ampullary carcinoma when cannulation of CBD by standard method is not possible . The 2- year survival in this technique is comparable to surgical bypass.

Introduction:

Ampullary carcinoma is the third most common tumor causing obstructive jaundice after carcinoma of pancreatic head and of the common bile duct. As this tumor is often resectable, endoscopic diagnosis and therapy are steps in the preparation for surgery, the definitive treatment that should be the goal.¹

Pylorus-preserving pancreaticoduodenectomy is reported to be an easier and less time-consuming operation with less blood loss, a shorter hospital stay, and better weight gain during follow-up with no difference in recurrence rate and patient survival compared with the standard Whipple procedure.² In patients for whom surgery is not appropriate, endoscopic implantation of biliary endoprosthesis is a palliative therapy and often improve the quality of their remaining life . Endoscopic sphincterotomy is needed in most therapeutic biliary procedures but is not always possible. The success rate for the procedure ranges from 80% to 95%, even among experienced endoscopists. When selective (deep) common bile duct (CBD) cannulation and consequent endoscopic sphincterotomy are not possible ,a precutting technique is used .Among various techniques, precutting with a needle knife is the most popular.³ Biliary

fistulotomy is an incision into the suprapapillary portion of a dilated bile duct. This procedure is indicated when papilla is obstructed , usually by an inoperable ampullary carcinoma .4 This study identifies for the first time our limited experience in such procedure.

Patients and Methods: Between June 2003 and January 2006, 14 consecutive patients with inoperable ampullary carcinoma underwent biliary needle-knife fistulotomy (NKF) with metal stent placement had been studied at Gastroenterology teaching hospital ,medical city -Baghdad. They were 10 men and 4 women (mean age, 70 years; range, 55-85 years). The initial diagnosis of ampullary tumor was suggested by clinical , laboratory ,and radiologic data (diagnostic ultrasound and MRI) , whereas the final diagnosis was documented by endoscopic biopsy (100% adenocarcinoma).

Selective cannulation of the CBD was attempted with either a standard catheter or a standard wire-guided sphincterotomy (hydrophilic 0.035-inch guidewire). If the attempts were unsuccessful, cannulation was attempted by needle- knife fistulotomy procedure. With the NKF procedure, a small incision was made on the bulging orifice.

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Results :

Fourteen patients had inoperable ampullary tumor underwent ERCP with needle-knife fistulotomy (NKF) procedure. They were ten men and four women. The age range of the patients at the time of diagnosis is 55 to 85 years with a peak in the seventh decade of life (mean age, 70 years). Diabetes and ischaemic heart disease was the major cause of inoperability in seven patients, while chronic obstructive pulmonary disease with forced expiratory volume in one second less than one liter in four patients, two patients with cholangitis and renal impairment and one patient with hepatitis C liver cirrhosis Child Pugh C. Successful NKF during the first attempt was achieved in 12 of 14 patients, during the second attempt successful cannulation was achieved in one patient, NKF did not result in selective CBD cannulation in second patient.

All patients who underwent successful NKF had a dilated bile duct; the diameter was more than 10 mm in eight patients without cholecystectomy and more than 12 mm in patients (6) who underwent cholecystectomy. Successful drainage rate with metal stent placement was reported in 92.85% (i.e. 13 out of 14). No hospital mortality was recorded as well as 30-day mortality. Jaundice disappear in all patients with successful drainage within three weeks. Only one case of bleeding required injection therapy with 1:10,000 epinephrine; no further treatment was required, was reported as an early complication of NKF and stent placement (Table 3). The remaining early complications (perforation, pancreatitis, cholecystitis, early clogging) were not reported.

Late dysfunction owing to biliary sludge formation was seen in one case after 7 months. Clinically, patient presented with malaise, low grade fever, deterioration of

liver function test. Frank cholangitis and jaundice were not recognized, flushing and irrigation of clogging prosthesis were technically possible.

Clogging of prosthesis by tumor ingrowth or overgrowth occurred in up to 21.42% of cases (Table 2). In our experience, clogging occurred from 5 months to over 22 months after prosthesis placement with a mean of about 13.5 months. Jaundice and frank cholangitis with hypotension and mental confusion were the main clinical manifestations of those patients. Such problem resolved by inserting another metal stent, through the blocked metal stent.

Discussion:

Tumors of papilla are unusual entities, comprising less than 9% of all digestive tract neoplasms in Iraq. The role of endoscopy in the management of tumors of the main duodenal papilla continues to evolve. In this study, needle-knife fistulotomy were performed for fourteen patients. The group of our patients selected for this procedure had more risk factors (old age, mean age; 70 years, 7 patients with ischaemic heart disease and diabetes, 4 patients had advanced chronic pulmonary disease, azotemia and cholangitis in 2 patients, and one patient with Child Pugh C hepatitis C liver cirrhosis). Mean age was 70 years, with a peak incidence (71.42%) between 60-69 years, comparable to that reported by Iraqi and western studies.^{4,6,7} They were ten men and four women (M/F 2.5:1). There is slightly more male predominance in our study, comparable to most western series.^{5,6} This is explained on the basis that our study included a limited number of patients (only 14 patients).

Needle-knife fistulotomy in our study was found well effective in gaining access to biliary tree after the first attempt (85.7%). For the remaining 2 patients, second attempt of NKF resulted in selective CBD in one patient (50%). Second attempt 7 days later when local conditions were more favorable (absence of edema, bleeding). The overall success rate for this technique (92.85%), was comparable with that success rate in first attempt or second attempt 75.67%, 99.54% respectively reported by Christos Marvogiannis et al. in his study using NKF in treatment of bile duct stones.³ Recchia et al.⁸ reported a success rate of 96%, whereas O'Connor et al.⁹ reported a success rate of 89% with use of the same technique. Following successful cannulation and passage of a guidewire through the NKF incision, a placement of metal covered stent (SHIM-HANAROSTENT) was straightforward. The goal of endoscopic palliative treatment is to relieve pruritus, treat cholangitis and lessen the impact of cholestasis. In our experience, the overall successful drainage rate was 92.3%, 100% disappearance of jaundice within 3 weeks and no 30-day mortality was recorded. Use of this (NKF) technique is recommended only for therapeutic reason by most experts, NKF differs

from needle-knife papillotomy in that incision starts above the papillary orifice in an attempt to minimize the possibility of pancreatic duct injury and consequently to reduce the risk of pancreatitis.

Pancreatitis was not reported among our study group, this finding was similarly reported by Christos et al study. Kasmin et al .10 and O, Connor et al 9 reported low rate of pancreatitis (2.4%) after use of a similar technique . Madhukar Kaw et al. 10 and Christos et al. 3 concluded in their studies that needle-knife sphincterotomy is associated with significant risk of pancreatitis (4.7% ,7.59% respectively) and this technique should be preserved only when therapeutic intervention is suspected . Only one case of perforation (NKF group) required an operation had been reported in Christos et al. study in comparison with no case of perforation recorded in our study. Bleeding as a result of precutting with a needle knife occurred among 7.1% of our patients. Effective endoscopic injection therapy with 1:10000 epinephrine was performed and no further treatment was required .Significantly lower rates of bleeding have been reported by several investigators, such Kasmin et al. 10 (4%) , O,Connor et al. 9 (1.2%), and Huibergets et al.12 (1.5%). Bickerstaff et al.13 studied seventeen patients with ampullary adenocarcinoma deemed unfit for surgical resection because comorbid disease (10 patients), hepatic metastases (1 patients) or dementia (6 patients) underwent sphincterotomy with or without stent insertion. They reported fatal hemorrhage in 1 (6%) as an early complications, and cholangitis in 2 patients (12%) ,both of whom had received an endoprosthesis. Cholangitis resolved in 1 of these 2 patients after endoprosthesis removal. Jaundice resolved in a median of 3 weeks ,and the median stay in hospital after sphincterotomy was 3 days . Recurrent jaundice developed between 4 and 11 months after sphincterotomy in 8 of 16 (50%) patients. In our study,

stent clogging occurred from 9 months to 22 months after first stent placement. The average symptoms-free interval after NKF and stent placement was 13.5 months ; 2 patients underwent a second successful stent placement through the blocked previous metal stent for recurrent jaundice and cholangitis. One patient needed a third stent placement (after 5 months) through second blocked stent because of tumor overgrowth the stent with sever attach of cholangitis . In 1980, Safrany 14 first reported endoscopic tumor sphincterotomy to be efficacious in a series of 21 patients with ampullary carcinoma who were deemed inoperable. The average symptoms-free interval after sphincterotomy was 5.5 months ; 5 patients underwent a second successful sphincterotomy for recurrent jaundice . The 2 years survival in our study was 28.57% in comparison to 12 months median survival after sphincterotomy in Bickerstaff et al. study. 12 Huibergetse K et al.15,16,17 calculated median survival in patients with ampullary carcinoma treated with endoprosthesis placement was 13 months. Al-Bahrani et al.7 in his study reported 37.5% 2-year survival in patients with ampullary carcinoma after bypass surgery compared to 64% in resected group, while 5- years survival was 42% in resected group and nil in bypass group, with post-operative mortality of 4%.

. Our results suggest that NKF is an effective and safe technique for treating inoperable ampullary carcinoma when cannulation of CBD by standard method is not possible . The 2- year survival in this technique is comparable to surgical bypass.

Complication	Rate (%)
A-Fistulotomy -related	
Bleeding	7.1
Pancreatitis	0
Perforation	0
B-Endoprosthesis related	
Cholecystitis	0
Early clogging (blood clots	0
Mortality	0

Table (1) Clinical results of endoprosthesis placement

Complications	Rate (%)
Clogging (cholangitis, jaundice, tumor ingrowth)	7.1 (mean 18.month)
Migration, duodenal or biliary	0
Perforation	0
Duodenal stenosis (tumor related)	0
Mortality (30-day)	0

Table (2) Early complications of doprosthesis placement

No of patients	14
Success rate %	92.85
Disappearance of jaundice %	100
Hospital mortality %	0
Early complications rate %	7.1
Recurrent jaundice %	21.42
2 year survival %	28.57

Table (3) Late complications of endoprosthesis placement

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