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Feasibility and safety of percutaneous transhepatic endobiliary radiofrequency ablation as an adjunct to biliary stenting in malignant biliary obstruction

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KEYWORDS
Malignant biliary obstruction;
Percutaneous;
Endobiliary radiofrequency ablation;
Stent patency

Abstract
Purpose: The purpose of this study was to investigate the feasibility and safety of percutaneous transhepatic endobiliary radiofrequency ablation (RFA) combined with biliary stenting in palliative treatment of malignant biliary obstructions.
Materials and methods: Twenty-one patients who had undergone percutaneous transhepatic endobiliary RFA as an adjunct to biliary stenting were included. There were 12 men and nine women with a mean age of 67 ± 13.6 (SD) years (range: 34—86 years). Demographic data, procedure details and follow-up data including complications, survival time and stent patency time were documented. The median stent patency time and survival time, as well as the 30- day and 180-day cumulative survival and stent patency rates were estimated using the Kaplan-Meier method.
Results: Twenty-four percutaneous transhepatic endobiliary RFA procedures were performed. There were no procedure-related major complications or death. Three patients who had developed stent reocclusion underwent a second endobiliary RFA, without insertion of a new stent. The most common complications were post-procedural pain and cholangitis. Overall survival and stent

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patency times ranged between 5—542 days and 5—251 days, respectively. The median survival time was 76 days (95%CI: 0—233 days) and stent patency time was 133 days (95% CI: 25—240 days). The 30- and 180- day cumulative stent patency rates were 75% and 34%, respectively.
Conclusion: Percutaneous transhepatic endobiliary RFA is a feasible, safe and cost-effective method in restoration of biliary drainage in patients with malignant biliary obstruction.

Malignant biliary obstruction may result from primary tumor of bile duct epithelium, as well as from primary or metastatic tumors involving the bile ducts. Percutaneous transhepatic biliary drainage (PTBD) with biliary stenting is a safe and effective alternative technique for palliation of malignant biliary obstructions in which endoscopic treatment fails or is unavailable, as in patients with hilar obstruction or surgically altered anatomy [1—3]. The major limitation and complication of biliary stenting is stent occlusion due to tumoral growth [4,5]. To prevent stent occlusion, various techniques, such as the use of new metallic stent models, photodynamic therapy and intraluminal brachytherapy, have been proposed. Of these, photodynamic therapy has not proved to be of any survival benefit and has been found to be more prone to complications, including photosensitivity, cholangitis and hemobilia [6—8]. The use of intraluminal brachytherapy is limited to few centers and its value as an adjunct to biliary stenting is unproven [7,9,10].

Endobiliary radiofrequency ablation (RFA) has emerged as a new technique as an adjunctive tool for the palliation of malignant biliary obstructions. This technique, which uses radiofrequency energy to generate irreversible cellular damage by thermal affect, can be performed using either an endoscopic or a transhepatic approach, and may have the potential to delay stent occlusion by reducing tumor load along the obstructed bile duct [7,9,11].

The purpose of this study was to investigate the feasibility and safety of percutaneous transhepatic endobiliary RFA combined with biliary stenting in palliative treatment of malignant biliary obstructions.

Materials and methods

Study design and patient selection

The approval of the ethics board for non-pharmacological clinical trials was obtained to conduct this retrospective study (24 November 2015, 80558721/283). Between June 2014 and October 2015, patients with malignant biliary obstruction secondary to unresectable tumor were recruited. The decision on inoperability was made by a multidisciplinary team including surgeons, medical and radiation oncologists and radiologists. All patients had specific biliary obstruction symptoms and hyperbilirubinemia at the time of their referral. Of these, a total of 21 patients with a life expectancy greater than three months who had accepted to undergo transhepatic endobiliary RFA combined with biliary stenting for palliative treatment of biliary obstruction were included in the study. All patients were informed about the details and the potential complications of the procedure and informed consent was obtained from all. None of the patients were clinically instable for a percutaneous transhepatic approach, and none of them had uncorrectable coagulopathy, systemic infection-sepsis, or pregnancy, all of which were the accepted contraindications for the procedure.

Patient demographics

Twenty-one patients underwent a total of twenty-four percutaneous endobiliary RFA procedures for malignant biliary obstruction. There were 12 men (57.1%) and 9 women (42.9%) with a mean of mean age of 67 ± 13.6 (SD) SD years (median age 71years; range: 34—86 years). Ten patients (47.6%) had pancreatic carcinoma, seven patients (19.1%) had cholangiocarcinoma. Five patients (23.8%) had distal malignant biliary obstruction due to distal gastric carcinoma, one patient (4.8%) had gallbladder carcinoma and one (4.8%) had malignant biliary obstruction due to metastatic spread of larynx carcinoma. Ten patients had stage III and 11 patients had stage IV disease according to tumor-node-metastasis (TNM) classification of American Joint Committee on Cancer (AJCC). Of the four patients with cholangiocarcinoma, three had Bismuth-Corlette type II carcinoma and one patient had a type IIIA carcinoma. Biliary obstruction was in distal biliary segment in 15 patients (71.4%), and 6 patients (28.6%) had proximal segment involvement. Patient demographics and tumor characteristics are shown in Table 1.

Technique

Preoperative evaluation

Prior to each procedure, a complete blood count was performed, biochemical and blood coagulation parameters were evaluated. Patients were fastened for at least 8—12 hours before the procedure. Pre-procedural broad spectrum antibiotic prophylaxis (second generation (cephazol) or third generation (ceftriaxone, cephaperazone) cephalosporines, 1 g) was administered intravenously to prevent transient bacteremia during the procedure.

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