



Publication Abstract

Title:	Covered versus uncovered self-expandable nitinol stents in the palliative treatment of malignant distal biliary obstruction: results from a randomized, multicenter study
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Background:	Covered biliary metal stents have been developed to prevent tumor ingrowth. Previous comparative studies are limited and often include few patients.
Objective:	To compare differences in stent patency, patient survival, and complication rates between covered and uncovered nitinol stents in patients with malignant biliary obstruction.
Design:	Randomized, multicenter trial conducted between January 2006 and October 2008.
Setting:	Ten sites serving a total catchment area of approximately 2.8 million inhabitants.
Patient(s):	A total of 400 patients with unresectable distal malignant biliary obstruction.
Interventions:	ERCP with insertion of covered or uncovered metal stent. Follow-up conducted monthly for symptoms indicating stent obstruction.
Main Outcome Measures:	Time to stent failure, survival time, and complication rate.
Results:	The patient survival times were 116 days (interquartile range 242 days) and 174 days (interquartile range 284 days) in the covered and uncovered stent groups, respectively (P = .320). The first quartile stent patency time was 154 days in the covered stent group and 199 days in the uncovered stent group (P = .326). There was no difference in the incidence of pancreatitis or cholecystitis between the 2 groups. Stent migration occurred in 6 patients (3%) in the covered group and in no patients in the uncovered group (P = .030).
Conclusions:	There were no significant differences in stent patency time, patient survival time, or complication rates between covered and uncovered nitinol metal stents in the palliative treatment of malignant distal biliary obstruction. However, covered stents migrated significantly more often compared with uncovered stents, and tumor ingrowth was more frequent in uncovered stents. (Clinical trial registration number: NCT00280709.)
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