Case-controlled Comparison of a Percutaneous Collagen Arteriotomy Closure Device versus Manual Compression after Liver Chemoembolization

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PURPOSE: To compare complications and outcomes between the use of the Duett collagen closure device after one or multiple deployments and manual compression in patients treated with transcatheter arterial chemoembolization (TACE) for primary or metastatic liver cancer.

MATERIALS AND METHODS: A database of 214 patients who underwent a total of 426 TACE procedures between July 2001 and July 2003 was retrospectively analyzed with regard to the use of the Duett closure device to obtain hemostasis. The Duett device was used in 211 cases (121 patients), whereas manual compression was performed in 215 cases (93 patients). Primary endpoints included complications related to hemostasis, time to hemostasis (TTH), time to ambulation (TTA), and time to discharge (TTD). Risk factors were tested for correlation with complications ($P < .05$). Other endpoints included descriptive data regarding the Duett treatment group.

RESULTS: Only minor complications were observed in both groups, without a statistically significant difference ($P = .16$). The mean TTH and TTA were significantly shorter ($P < .0001$) in the Duett group, whereas there was no difference in TTD between groups ($P = .59$). Reaccessing the same arterial site for separate procedures was not a significant risk factor for complications in the Duett group ($P < .0001$).

CONCLUSION: The Duett closure device achieves similar safety and efficacy as manual compression in this distinct group of patients. In addition, this device can be safely and repetitively deployed at the arteriotomy site after each TACE procedure.

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Abbreviations: CFA = common femoral artery, TACE = transcatheter arterial chemoembolization, TTA = time to ambulation, TTD = time to discharge, TTH = time to hemostasis

TRANSCATHETER arterial chemoembolization (TACE) is currently considered as a major palliative interventional oncology option for patients with unresectable primary or metastatic liver cancer (1–4). In these patients, the percutaneous arteriotomy site may be frequently reaccessed for multiple treatments. In posttreatment sheath removal, hemostasis is achieved conventionally with manual compression of the access site, but this technique is associated with prolonged immobilization and significant patient discomfort. One of the alternative options to manual compression is the use of collagen hemostasis devices, the efficacy of which has been widely investigated in diagnostic and therapeutic coronary procedures in the current literature. However, there is a paucity of reports of its use after therapeutic oncology interventions in the radiology literature. Our study was designed to evaluate the efficacy and safety of a percutaneous collagen hemostasis device for arteriotomy closure versus traditional manual compression in a prospectively collected database of patients who underwent TACE, and to demonstrate the safety of serial use of a collagen hemostatic device after each TACE procedure at the same arterial site, as the majority of patients with liver cancer undergo more than one TACE session. These parameters have been evaluated rarely in the oncology group of patients treated with TACE for primary or metastatic liver cancer.

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Table 1
Comparison of Risk Factors between the Duett and Manual Compression Groups

Risk Factor	Duett Group (n = 211)	Manual Compression Group (n = 215)	P Value
Age (y)	63.7 ± 10.1	61.7 ± 14.2	.34
Male/female (%)	78.5/21.5	65.6/34.4	.32
Diabetes mellitus (%)	20.7	14.3	.37
Hypertension (%)	6.3	3.6	.06
History of smoking (%)	28.7	21.7	.26
Warfarin (%)	2.8	2.9	.8
History of MI (%)	3.4	1.8	.74
History of CAD (%)	11.2	8.0	.23
History of CVA (%)	3.5	2.2	.8
PVD (%)	2.1	6.9	.8
Time between procedures (d)	58.5 ± 84.2	65.1 ± 93	.7
Mean hemoglobin level (g/dL)	12 ± 1.8	12.8 ± 1.8	.27
Mean platelet count (per mm^3)	212,190 ± 121,419	232,740 ± 135,264	.07
Mean INR for prothrombin time	1.08 ± 0.3	1.13 ± 0.4	.07

Note.—MI = myocardial infarction; CAD = coronary artery disease; CVA = cerebrovascular accident; PVD = peripheral vascular disease.

MATERIALS AND METHODS

Study Design and Eligibility Criteria

After approval was obtained from our institutional review board, a database of patients who underwent TACE in our department for primary or metastatic liver cancer between July 2001 and July 2003 was retrospectively analyzed. Informed consent was obtained in all patients before each procedure. Criteria for inclusion in our study were treatment with TACE for primary or metastatic liver cancer and manual compression or application of the Duett closure device (Vascular Solutions, Minneapolis, MN) for arteriotomy closure after one or multiple TACE procedures. The method of arteriotomy closure in each patient was dependent on individual operator preference. Depending on the method used to achieve hemostasis after sheath removal, patients were assigned to the Duett group or the manual compression group for the purposes of the study. The Duett group consisted of 121 patients treated with TACE (78.5% men, 22.5% women; mean age, 63.6 years ± 10.1) in whom the Duett collagen hemostasis device was deployed at the arteriotomy site after each procedure. In this group, the Duett device was used in 211 cases. The control group comprised 93 patients (65.6% men, 34.4% women; mean age, 61.7 years ± 14.2) in whom manual compression was applied at the arteriotomy site. These patients underwent a total of 215 procedures. There were no significant differences between the Duett and manual compression groups in any of the parameters measured (**Table 1**).

The exclusion criteria for the use of the Duett system applied to both groups. Patients who received any combinations of closure methods were also excluded. Laboratory tests including a hematologic and biochemical profile were available for each patient before each TACE procedure. At the end of each chemoembolization procedure, a routine angiographic evaluation at the site of the sheath insertion, which included ipsilateral oblique projection of each puncture site, was performed to document the location of the common femoral artery (CFA) puncture in relation to the CFA bifurcation, the diameter of the CFA, and the presence or absence of puncture site vascular abnormalities.

Procedure reports and clinical charts were reviewed for the presence of puncture site complications, time to hemostasis (TTH), time to ambulation (TTA), time to discharge (TTD), and presence of risk factors for complications for all patients.

Chemoembolization Procedure

TACE involves local delivery of chemotherapeutic agents, iodized oil, and embolic agents to tumor tissue. By embolizing the arteries that feed a given tumor, these drugs remain in contact with tumor tissue for a prolonged period (1). No anticoagulation is usually necessary for this therapeutic interventional procedure. According to our department's guidelines, a chemoembolization procedure may be repeated depending on tumor response to treatment based on imaging, biochemical, and performance status criteria. A period of 6 weeks is the mean interval between treatment cycles if indicated. Arterial access at the groin is routinely obtained with the single-wall Seldinger technique and a 5-F vascular sheath. In this study, patients were treated with TACE for hepatocellular carcinoma (55.6%), metastatic neuroendocrine tumors (18.69%), and other tumors (25.71%; colon, breast, gastric stromal tumor metastases, metastatic leiomyosarcoma and melanoma, and cholangiocarcinoma).

Closure of the Arterial Puncture

The patients in the Duett group received one or more Duett vascular hemostasis devices for an equivalent number of chemoembolization procedures. This device consists of a balloon-positioning 3-F catheter and an injectable procoagulant. The inflated balloon is elliptical, 3 mm long, and as wide as 7 mm. The balloon is inflated and withdrawn to the arteriotomy, where it seals the puncture site from within the lumen. Optimal positioning of the balloon is ensured by checking for the absence of bleeding from the puncture site and resistance to further retraction of the catheter. The negative aspiration confirms the apposition of the balloon to the arterial wall. A procoagulant mixture of 250 mg bovine microfibrillar collagen (Avitene; Davil, Woburn, MA) and 10,000 U bovine thrombin (Jones Medical, St. Louis, MO) reconstituted in phosphate buffered saline solution is then injected as the sheath is slowly withdrawn to fill in the tract created by the sheath (**Figure**). In this way, hemostasis is achieved by facilitating extravascular thrombosis in the perivascular tissue (5). Absolute contraindication for its