Comparative analysis of traditional and coiled fiducials implanted during EUS for pancreatic cancer patients receiving stereotactic body radiation therapy

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Background: EUS-guided fiducial placement facilitates image-guided radiation therapy (IGRT).

Objective: To compare 2 types of commercially available fiducials for technical success, complications, visibility, and migration.

Design: Retrospective, single-center, comparative study.

Setting: Tertiary-care medical center.

Interventions: Traditional fiducials (TFs) (5-mm length, 0.8-mm diameter) and Visicoil fiducials (VFs) (10-mm length, 0.35-mm diameter) were compared. Fiducials were placed using linear 19-gauge (for TFs) or 22-gauge (for VFs) needles. A subjective visualization scoring system (0-2; 0 = not visible, 1 = barely visible, 2 = clearly visible) was used to assess visibility on CT. Fiducial migration was calculated as a change in interfiducial distance.

Main Outcome Measurements: Technical success, complications, visibility, and migration of 2 types of fiducials.

Results: Thirty-nine patients with locally advanced pancreatic cancer underwent EUS-guided placement of 103 fiducials (77 TFs, 26 VFs). The mean number of fiducials placed per patient was 2.66 (standard deviation 0.67) for the 19-gauge needle and 2.60 (standard deviation 0.70) for the 22-gauge needle ($P = .83$). No intra- or postprocedural complications were encountered. The median visibility score for TFs was significantly better than that for VFs, both when scores of 0 were and were not included (2.00, interquartile range [IQR] 2.00-2.00 vs 1.75, IQR 1.50-2.00, $P = .009$ and 2.00, IQR 2.00-2.00 vs 2.00, IQR 1.50-2.00, $P < .0001$, respectively). The mean migration was not significantly different between the 2 types of fiducials (0.8 mm [IQR 0.4-1.6 mm] for TFs vs 1.3 mm [IQR 0.6-1.5 mm] for VFs; $P = .72$).

Limitations: Retrospective, nonrandomized design.

Conclusions: Visibility was significantly better for TFs compared with VFs. The degree of fiducial migration was not significantly different for TFs and VFs. There was no significant difference in the mean number of fiducials placed, indicating a similar degree of technical difficulty for TF and VF deployment. (Gastrointest Endosc 2012; 76:962-71.)

Abbreviations: CBCT, conebeam CT; IGRT, image-guided radiation therapy; IQR, interquartile range; RT, radiation therapy; SBRT, body radiation therapy; SD, standard deviation; TF, traditional fiducial; VF, Visicoil fiducial.

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Pancreatic cancer is the second most common GI malignancy and the fourth leading cause of cancer deaths in the United States.[1] Pancreatic cancer has a poor prognosis with postoperative 5-year survival rates of 3% to 25%.[2,3] In two thirds of patients with resectable tumors, local recurrence develops within 2 years of surgery.[4] The disease is often advanced at presentation, and nearly 90% of patients have inoperable disease at the time of diagnosis, with a median survival of approximately 4 months without treatment.[3] Patients with locally advanced pancreatic adenocarcinoma most often have tumor involvement of celiac axis or superior mesenteric artery. In these patients, chemotherapy, conventional radiation therapy (RT), or a combination of both may positively influence overall survival and quality of life.[5-8] The goal is to attempt to downstage the tumor, improve local control, and offer palliation.[9] However, these treatment modalities have had a modest impact on the overall prognosis.[5-8] In recent years, improvements in RT, namely, stereotactic body RT (SBRT), were possible because of advances in CT, magnetic resonance imaging, and positron emission tomography. SBRT delivers multiple beams of radiation with extreme accuracy, allowing the safe and effective delivery of RT to target sites.[10,11] However, treatment of extracranial lesions with SBRT requires placement of intratumoral radiographic markers (fiducials) to allow image-guided RT (IGRT). With IGRT, it is possible to deliver high doses of RT with submillimeter accuracy, sparing surrounding organs at risk.[9]

Percutaneous radiographic marker placement is an established technique for the deployment of fiducials in pancreatic tumors.[12] However, this approach is invasive and carries a nontrivial morbidity risk with a relatively high rate of fiducial migration.[12] EUS-guided fiducial placement has been reported in recent years to be a less invasive and effective means for fiducial placement in patients with inoperable pancreatic cancer.[13-19] EUS-guided fiducial placement is traditionally performed by using 19-gauge FNA needles because of the wide diameter (0.8 mm) of traditional fiducials.[13,14,17-19] This has created technical difficulties in fiducial placement because of the stiffness of 19-gauge needles, especially in cases of cancers of the head of the pancreas. Recently, new, smaller fiducial markers, which can fit into 22-gauge FNA needles, were introduced.[15,16] These may circumvent intricacies with fiducial placement because of the flexibility of the smaller needles.

Poor fiducial visualization and/or fiducial migration during IGRT can lead to insufficient dose coverage of the targeted tumor volume, excessive irradiation of adjacent normal structures, and compromised clinical outcomes.[20] The aims of the current study were to compare 2 types of commercially available fiducials for technical success, complications, visibility, and migration.

Take-home Message

- Progress in fiducial design and custom-made FNA needles is needed to allow easy fiducial deployment, optimal visualization, limited migration, and multiple fiducial placement with 1 pass.

METHODS

Patients

A prospectively collected radiation oncology database at the Johns Hopkins Hospital was searched for patients who underwent EUS-guided fiducial placement followed by IGRT between June 2010 and September 2011. The study was approved by the Institutional Review Board for Human Research and complied with Health Insurance Portability and Accountability Act regulations. Only patients with malignant pancreatic tumors were included. All tumors were locally unresectable because of vascular invasion. A retrospective analysis of institutional medical records was done to collect relevant data: demographic (age, sex), clinical (tumor location, tumor size), procedural (type of FNA needles used, type of fiducials used, number of fiducials placed, technical success, technical difficulty, technical failures and reasons for failure, use of fluoroscopy, complications).

Materials

Two kinds of commercially available fiducials were compared: traditional fiducials (TFs) (5-mm length, 0.8-mm diameter) and Visicoil fiducials (Core Oncology, Santa Barbara, Calif) (VFs) (10-mm length, 0.35-mm diameter). Unlike TFs, the VFs are flexible and have a coiled design, which theoretically reduces the incidence of fiducial migration. In addition, VFs are preloaded on a needle carrier delivery device that allows direct insertion of the fiducial into the EUS needle. The system used by our radiation oncologists for IGRT is the Synergy-S or Infinity platform (Elekta AB, Stockholm, Sweden). Both systems incorporate kilovoltage conebeam CT (CBCT) and planar x-ray imaging for initial positioning and monitoring during therapy.

EUS-guided fiducial placement and periprocedural care

If a tissue diagnosis had not been previously established, FNA with a 22- or 25-gauge Echotip needle (Cook Endoscopy, Winston-Salem, NC) was performed by using intraprocedural evaluation by an experienced cytopathologist to confirm malignancy. After FNA, fiducials were placed by 6 endosonographers using linear echoendoscopes (FG36-UA; Pentax Medical Corp, Montvale, NJ, or GF-UC140P-AL5; Olympus America, Center Valley, Pa) and 19-gauge (for TFs) or 22-gauge (for VFs) needles by using standard techniques under propofol-based sedation