13 Endoscopic Ultrasound-Guided Fiducial Marker Placement for Stereotactic Body Radiotherapy (SBRT) of Pancreatic Cancer

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13.1 Introduction

Pancreatic cancer presents with surgically unresectable (locally advanced or metastatic) disease in 80% of patients [1]. In this group of patients, the standard of care is chemotherapy either with FOLFIRINOX or gemcitabine with nab-paclitaxel which provides a median survival of 6–8 months [2]. There is conflicting evidence on the benefit of radiotherapy in the treatment of pancreatic ductal adenocarcinoma (PDAC). Two initial randomised trials combined conventional external beam radiotherapy (EBRT) with 5-fluorouracil chemotherapy and demonstrated a survival advantage for resectable PDAC [3, 4]. However, the larger ESPAC-1 trial (2004) revealed a worse survival outcome in patients receiving combination therapy (10% vs. 20% 5-year survival rate, $P = 0.05$) [5]. It was hypothesised that the reason for this reduced survival was that EBRT caused toxicity to surrounding organs along with forcing the interruption of chemotherapy.

One approach to overcome this problem is to use marker-guided stereotactic body radiotherapy (SBRT), which has been recently applied in the field of radiation oncology. SBRT is a technique that requires image guidance to track motion of the tumour during inspiratory and expiratory respiratory cycles [6]. This is best achieved with the implantation of devices called fiducial markers. The potential advantage over conventional EBRT is the delivery of high doses of targeted radiation to the tumour with rapid dose falloff at the tumour periphery. Furthermore, since SRT can be delivered over a shorter duration, there is minimal interruption to chemotherapy.

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In order to minimize toxicity, SBRT has been used in combination with chemotherapy and early experience confirmed a survival benefit (median 11.15 months) with a comparatively low rate of adverse effects (22.3%) [7]. Recently, the use of neoadjuvant SBRT with chemotherapy in 159 patients with BRPC and LAPC downstaged the disease and allowed resection in 51% of patients, of which 91% had R0 resection margins. More importantly, grade 3 or greater toxicity occurred in only 7% of cases [8]. These recent studies have revived the interest in the use of combined chemoradiotherapy for the treatment of pancreatic cancer, especially with SRT as the preferred modality.

In summary, radiotherapy is undergoing a resurgence as an effective treatment strategy in patients with LAPC and BRPC. There is evidence for its advantage in a neoadjuvant and palliative setting due to good local control and low incidence of side effects. With many centres increasingly adopting SBRT, referrals for fiducial implantation are becoming commonplace. The aim of this chapter is to outline the benefits, methods, and outcomes of EUS-guided fiducial placement to assist treatment planning for SBRT in surgically unresectable, non-metastatic pancreatic cancer.

13.2 Role of Fiducial Placement in SBRT for Pancreatic Lesions

The main problems with treatment planning in SBRT are that (a) soft tissue is poorly visible on traditional computed tomography, (b) pancreatic lesions move together with the respiratory cycle, and (c) variation in the location of the tumour depending on the degree of distension of the GI lumen [9, 10]. Taken together, this makes a "moving, poorly visible target" without any fix bony landmarks to determine an accurate tumour margin to allow precise delivery of focus radiation.

In order to outline the margin of the targeted lesion, fiducial placement has been widely adopted in many tertiary centres. Fiducials are radiopaque markers of variable materials and sizes, which can be implanted into solid tumours either via the percutaneous (CT or US guided) route or via EUS [11]. Gold is the most commonly used fiducial as it is inert and has superior visibility compared to hydrogel and lipiodol. Using three-dimensional or four-dimensional CT software, the tumour margin and its surrounding organs can be delineated and tracked in real time, which allows variable doses of radiation to be delivered to different parts of the cancer (Fig. 13.1).

Another use for fiducial placement is in the marking of neuroendocrine tumours smaller than 2 cm in size prior to surgical resection. This has been reported in a few cases whereby intraoperative localisation of small NETs is challenging, and fiducial markers (or tattooing which will not be described here) allow intraoperative localisation to enable R0 resection margins to be achieved [12].

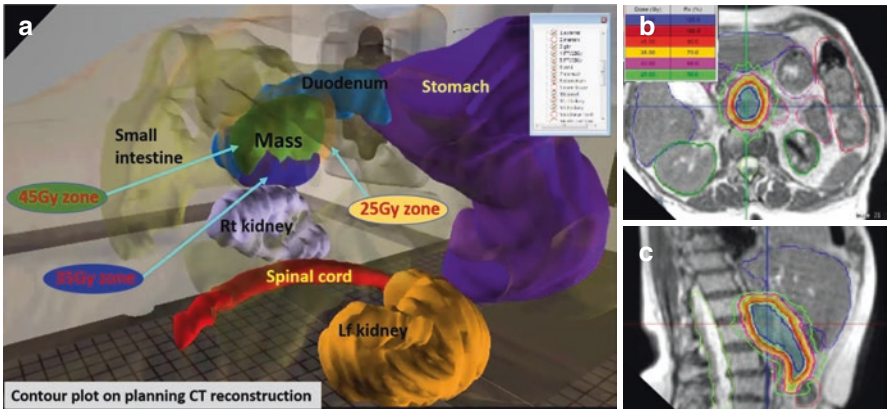

Fig. 13.1 Contour mapping and dosage delivery to the targeted cancer on 3D CT scan during preparation for SBRT. Simulated three-dimensional image on various angles and intensities of radiation beams targeting the tumour (**a**). Axial (**b**) and coronal (**c**) images of CT treatment planning. The colour borders around the lesion demonstrate the reduction of intensity from the centre of the lesion to the periphery reducing the potential damage to surrounding organs

13.3 Methods of Fiducial Placement

Laparoscopic: This method is infrequently adopted when the lesion is discovered as "unresectable" at the time of surgery. Before the closure of the abdominal wound, the tumour margin is marked by attaching fiducials to the surgical suture site intraoperatively. This approach has been shown to be superior in achieving ideal fiducial geometry (IFG) where the distance between two fiducials is 2 cm with a minimum fiducial angle of 15° to one another. However, IFG has not been shown to be important in the delivery of SRT and this will be described further below [13].

Percutaneous: Prior to the EUS-guided approach, percutaneous-guided approach via either US or CT was the most frequently used technique. In addition to the pancreatic lesion, this approach is also ideal for SBRT treatment of cancer locates in right liver lobe. For lesions in the retroperitoneal position of the pancreatic head and uncinate process, percutaneous approach can be technically challenging or impossible due to the overlying gas, which obscured the visualisation of the lesions. The complication is high with a 3.3% risk of bleeding and a 0.005% risk of tumour seeding along the needle path [11].

EUS-guided: Given the ability of EUS to access the pancreatic lesions, this approach is now the most widely used method for deploying fiducials in the pancreas and biliary tract. Not only it allows visualisation of the lesion in high resolution, EUS also provides a shorter distance from the needle puncture site to the lesion. These properties allow EUS to precisely define the margin of the cancer for marking, which is most relevant for small lesions that are not seen by conventional

imaging. Another advantage of EUS is that the Doppler function avoids major vascular structures and minimises the risk of bleeding and related complications. As a result, the risk of bleeding (1.8%) and tumour seeding along the needle track (only three cases reported thus far) are lower than those by percutaneous route [14].

13.4 Types of Fiducials for SBRT

Traditional gold (TG) fiducials are shorter and larger (5 mm in length × 1.2 mm in diameter) whereas flexible coiled (FC) fiducials are longer and smaller (10 mm in length × 0.35 mm in diameter) (Fig. 13.2a, b) [15]. The main advantages of smaller FC fiducials are increased flexibility and ease to load a 22G needle allowing easier extrusion of the needle when using a transduodenal approach. However, FC

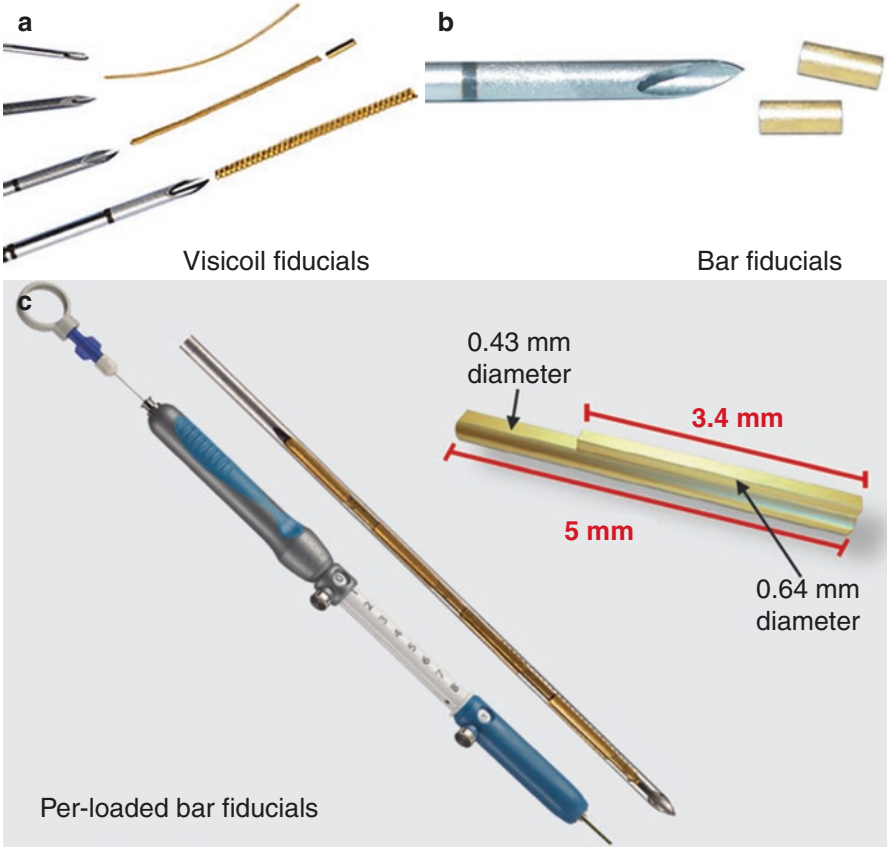

Fig. 13.2 Images of the available fiducials that are currently used in clinical practice, including coiled fiducials (**a**), bar fiducial (**b**), and a pre-loading bar-fiducial needle (**c**)

fiducials have a higher reported migration rate of up to 9% and reduced visibility compared to TG fiducials [16]. As such, the newer preloaded devices preferentially use smaller TG fiducials (5 mm × 0.43 mm) which can be loaded into a 22-gauge needle (Fig. 13.2c) [17]. The properties, advantages, and disadvantages of different types of fiducials are summarised in Table 13.1

13.5 Methods of Loading the Fiducial Needle

Whether the fiducials are inserted via percutaneous or EUS approach, the loading method of fiducials for insertion is similar. Each fiducial marker can be either front or back loaded into the needle prior to insertion.

1. *Back Loading:* The back-loading technique is most commonly used as it avoids pushing the fiducial through the entire length of needle, which can be difficult at times due to resistance. This involves preparing a fine-needle aspiration (FNA) delivery device prior to insertion into the accessory channel. This is done by withdrawing the stylet by 3 cm, pushing out the needle and inserting the fiducials in a retrograde manner using a catheter. Following insertion of the fiducials, the needle is pierced into bone wax to plug it and prevent loss of the fiducial while it is being advanced down the accessory channel (Fig. 13.3). The FNA needle is then injected into the tumour, and the stylet is inserted deploying the fiducial.

   A variation in the back-loading technique is the wet-fill technique in which the needle is immersed in saline, and a negative pressure is generated by withdrawing the stylet by 10 cm. The fiducials are then loaded retrograde into the needle without the use of bone wax seal and remain in place due to the surface tension of the saline. Deployment of the fiducial is achieved by full insertion of the stylet as above. The major drawback of this loading method is the risk of needle stick injury.
2. *Front Loading:* This technique involves inserting the FNA needle into the tumour using EUS guidance, removing the stylet completely then placing fiducial markers at the stylet opening. The stylet is then reinserted pushing the fiducial along until it is deployed in the tumour bed. Alternatively, instead of reinserting the stylet, small quantities of saline can be injected into the stylet port and used to flush the fiducial out into the tumour. The advantages and disadvantages between the two methods of fiducial loading are summarised in Table 13.2.
3. *Pre-loaded Fiducial Needles:* To eliminate the need for scope withdrawal and reloading a needle during the procedure, Cook™ and Medtronic™ currently manufacture preloaded fiducial delivery systems (Table 13.1). The Cook Echotip preloaded delivery system uses a 22G needle to deliver four gold bars (Fig. 13.2c) whereas the Medtronic Beacon system provides a 19-gauge or 22-gauge option preloaded with two gold bars to deliver fiducials of varying thickness [18].

Table 13.1 Comparison of the properties, method of deployment, advantages, and disadvantages between different types of fiducials

Fiducial type	Dimensions (mm)	Manufacturer	Method of deployment	Cost per fiducial unit (USD)	Advantages	Disadvantages
Cylindrical Gold Seeds	3–5 × 0.8–1.2	CIVCO Radiotherapy™	FL or BL using 19G needle	$43.60	Most experience, good visibility, low migration rate, cheap	Difficulty in deployment using 19G via transduodenal approach
Gold Anchor	10 × 0.28	Innomedicus Gold Anchor™	FL or BL using 22G needle	$130	Low migration rate	Difficulty deploying using FL approach (31.3% failure rate), expensive
Flexible coil	10 × 0.35	IZI Medical Visicoil™	FL or BL using 22G needle	$200	Transduodenal approach	Increased migration risk, less visibility
Gold Bar	5 × 0.43 5 × 0.43 5 × 0.75	Cook Echotip™ Ultra Medtronic Beacon™ Medtronic Beacon™	Preloaded 22G (4 fiducials) Preloaded 22G (2 fiducials) Preloaded 19G (2 fiducials)	$82.50/ fiducial $149/fiducial	No need to load needles thus reduced procedure time	Limitation to the number of fiducials per needle

FL front loading, *BL* back loading

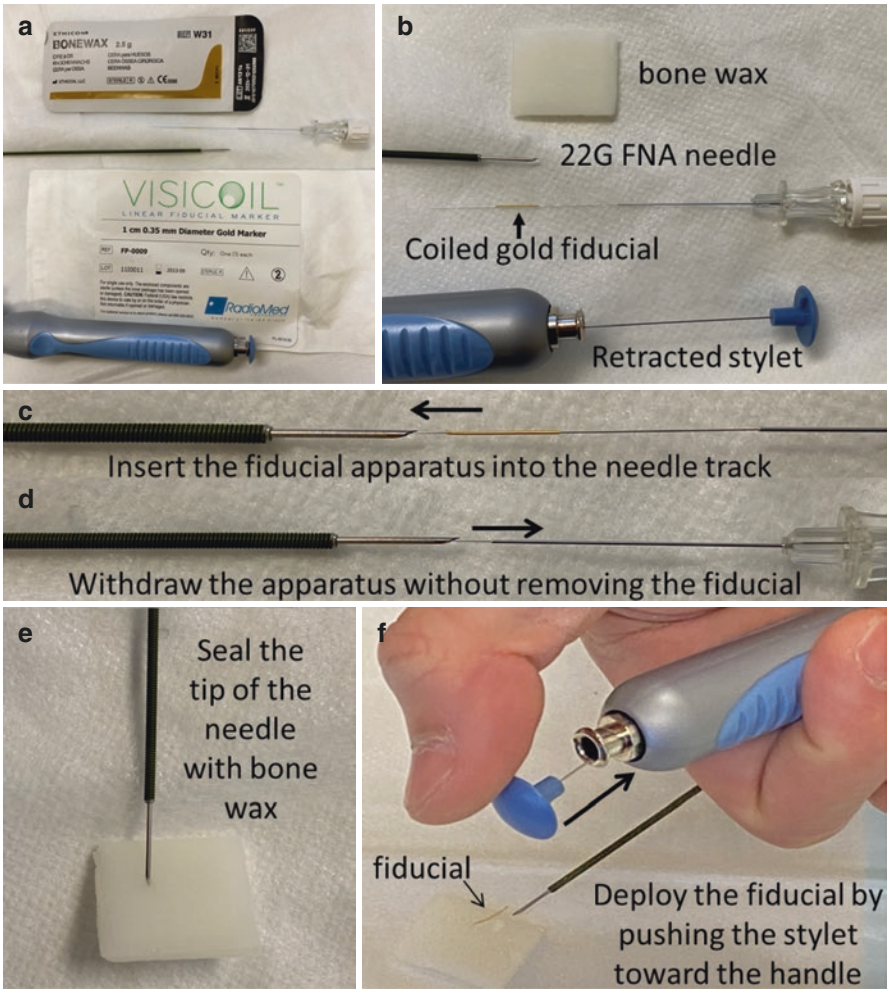

Fig. 13.3 Equipment and technique used in back-loading Visicoil fiducials for insertion of fiducial by EUS. The procedure requires a 22G FNA needle, a 1 cm 0.35 mm gold Visicoil and sterile bone wax (**a**, **b**). With the needle tip exposed for 1 cm and the stylet retracted for 5 cm, the gold Visicoil is loaded into the tip of the 22G needle by inserted the apparatus into the needle track with the tip of the needle face up (**b**, **c**). Once the gold Visicoil is completely inside the needle, the apparatus should be gently removed without pulling the gold Visicoil out (**d**). The tip of the needle is then sealed with steril bone wax (**e**). The needle tip is then retracted into the sheath, ready for the use by the EUS endoscopist. Once the needle tip is placed in the correct position within the lesion, the gold Visicoil can be deployed by pushing the stylet toward the handle (**f**). The expulsion of the fiducial into the lesion can be directly visualised under EUS

Table 13.2 Comparison of advantages and disadvantages of different loading methods of fiducial for insertion

Technique	Advantages	Disadvantages
Front loading	1. Does not need bone wax 2. Do not need to remove the needle to reload 3. Reduces the risk of needlestick injury	1. More technically challenging
Back loading (either bone wax seal or wet saline)	1. Relatively easy to use	1. Needle stick injury 2. Need to remove the needle from the accessory channel to reload 3. Needs bone wax which can lead to granuloma formation or cause failure of deployment due to plugging

13.6 Optimal Location to Place Fiducials for SBRT

The optimal placement of fiducials in relation to a pancreatic mass remains uncertain. The superiority of laparoscopically placed fiducials in achieving ideal fiducial geometry was previously described; however, this was not shown to lead to improved tracking and delivery of SRT [13]. In general, it is best to outline the main borders (medial and lateral) of the lesion, and if possible, its superior and inferior borders by fiducial placement (Fig. 13.4). Thus, at least two fiducials should be placed per lesion. For lesions larger than 4 cm, more fiducials may be required to delineate the extent of the lesion (Fig. 13.5). Our preference is to deploy fiducials within the lesion as opposed to along the outer edge to avoid the risk of migration, pancreatitis, or injury to adjacent organs.

13.7 Technical Outcomes of Fiducial Insertion in Pancreatic Lesions

Depending on the type of fiducial and size of the delivery needle, the technical success of EUS-guided fiducial insertion varies between 88% and 100% (Table 13.3). An initial experience with fiducial insertion using a 19G needle was 100% successful in nine patients by using a saline flush through the stylet port [19]. However, a subsequent larger study in 57 patients reported difficulties despite using this approach with success rates only reaching 88% [20]. This success rate, however, would reflect the real-life results as targeting lesions in the head, and uncinate process of the pancreas can be technically challenging when using a stiff 19G needle. By using a 22G needle and narrower traditional gold (TG) or flexible coil (FC) fiducials, the success rates in fiducial deployment transduodenally reached 100% [21]. Sealing the needle tip with bone wax reduced the problem of air bubble extrusion during fiducial placement obscuring

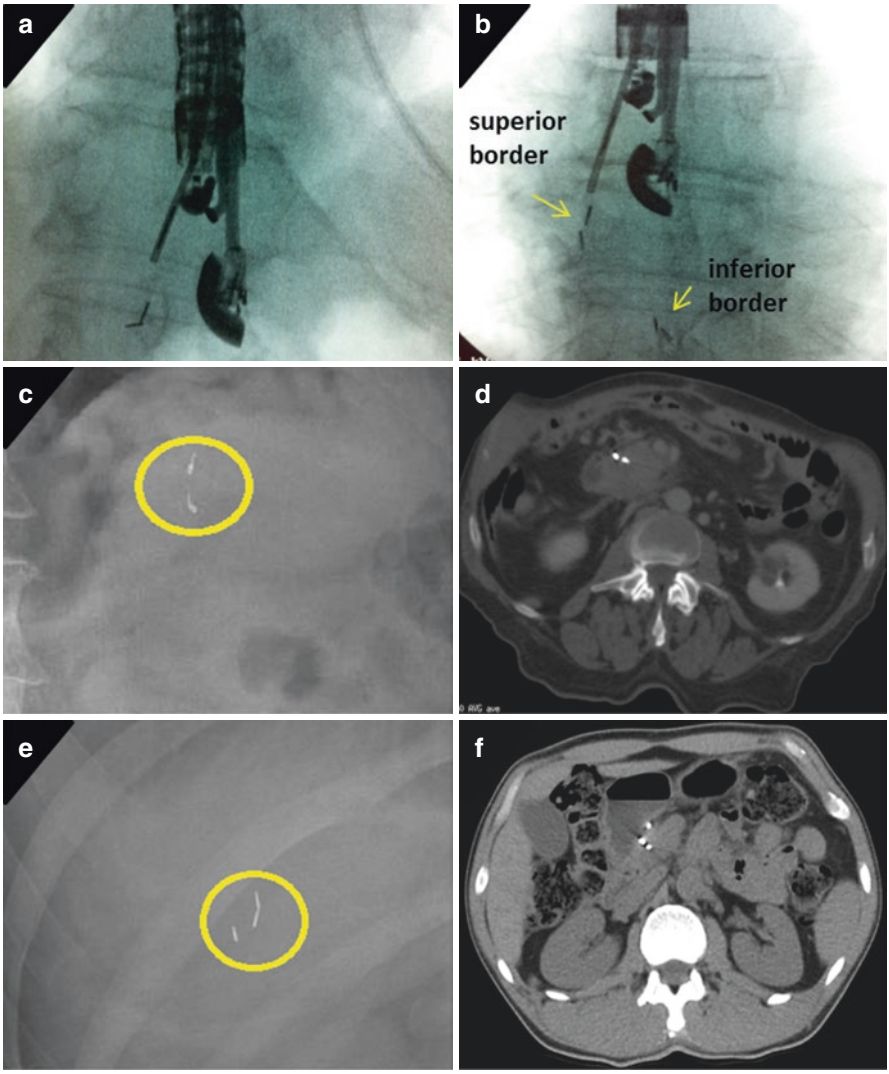

Fig. 13.4 Fluoroscopic appearance outlining the inferior and superior border of a pancreatic cancer using the pre-loaded bar fiducial 22G needle (**a**, **b**). Comparison of visibility of different types of fiducial marker, Visicoil (**c**, **d**) versus bar (**e**, **f**) fiducials, based on fluoroscopic (**a**, **b**) and tomographic assessments

the EUS view [22]. Although flexible coil fiducials have increased flexibility, there have been concerns regarding migration (up to 9% migration rate) and reduced visibility compared to TG fiducials [16, 17]. With greater experience, there was no longer a need for fluoroscopy, and multiple procedures were able to be performed in a single setting (FNB and coeliac plexus neurolysis) [22].

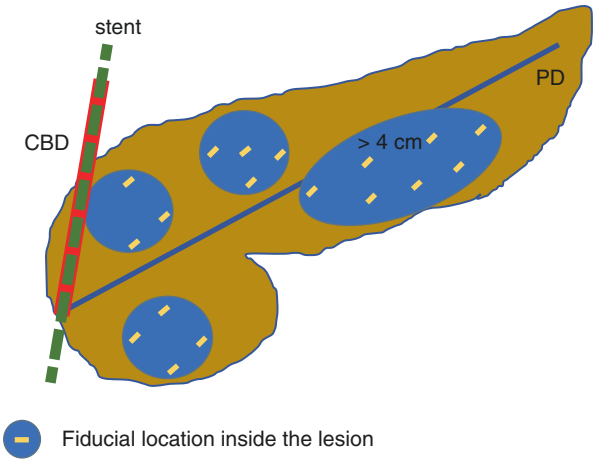

Fig. 13.5 Ideal configuration of fiducial placement within the pancreatic lesion for SBRT. The goal is to place 2–4 fiducials within the lesion to outline the borders of lesion on planning CT scan, providing a good mapping of the lesion for SBRT. Stent, either plastic or metal type, in the biliary tree can also be used a reference. For lesion in the body and tail of the pancreas, fiducials should be placed toward the posterior border of lesion to avoid outward migration. Avoid placement of fiducial within the pancreatic duct and inside the blood vessel. For lesions larger than 4 cm, more fiducials may be required to delineate the extent of the lesion

The development of preloaded fiducial needles has eliminated prior issues associated with back loading (time consuming, needle stick injury). These needles are preloaded with TG fiducials as opposed to FC due to superior visibility in patients with pancreatic cancer [17]. Our recent study [23] showed that a preloaded 22G fiducial needle (Cook Medical, USA) was associated with a shorter deployment time (0.94 vs. 5.5 min; P= 0.0001), greater fiducial number deployed (3.9 vs. 2.14; P = 0.0001), and was cheaper (USD$481 vs. USD$683; P = 0.001), compared to the use of a back-loaded 19G or 22G Echotip Ultra. In this study, the technical success was 100% in both groups.

In pancreatic neuroendocrine tumours smaller than 2 cm in size where surgical resection is indicated, the laparoscopic approach reduces the tactile feedback obtained by the surgeon intraoperatively. As such, localisation of a small lesion can be extremely challenging and EUS-guided fiducial placement is an option to aid enucleation of the lesion. Law et al. described two patients with a 7.4 mm uncinate lesion and a 9 mm neck of pancreas lesion whereby two FC fiducials were back-loaded onto a 22-gauge needle and injected into each patient successfully. Subsequent enucleation was successful with R0 resection margins [24]. Another case was described by Ramesh et al. whereby a 19-gauge needle was back-loaded with a single TG fiducial and successfully deployed into an insulinoma. This was easily identified in subsequent laparoscopic resection, and the patient had an excellent clinical outcome [12].

Table 13.3 Summary of published studies that evaluated the outcomes of different types of fiducials marking using EUS-guided approach

Article	*N*	Cancer	Needle	Fiducial	Technique	Fluoroscopy	Antibiotics	Technical success	Complications
Pishvaian et al. [26] (2006)	13	Pancreas, colon, oesophagus	19G	TG	FL	Yes	No	85% (11/13)	Cholangitis ($n = 1$)
Varadarajulu et al. [19] (2010)	9	Pancreas	19G	TG	BL	Yes	No	100% (9/9)	None
Park et al. [20] (2010)	57	Pancreas	19G	TG	BL—stylet push and hydrostatic	No	No	88% (50/57)	Minor bleeding ($n = 1$)
Dimaio et al. [27] (2010)	30	Oesophagus (18), pancreas (9), gastric (1), ovarian (1), cholangio (1)	22G	FC	BL	No	Not routine	97% (29/30)	Fever with elevated LFT ($n = 1$)
Sanders et al. [25] (2010)	51	Pancreas	19G	GS	BL	No		90% (46/51)	2% pancreatitis, 7% migration
Ammar et al. [21] (2010)	13	Pancreas (7), node (3), adrenal (1), cholangio (1), liver (1)	22G	FC	FL	No	No	100% (13/13)	None
Khasab et al. [17] (2012)	39	Pancreas	19G (29) 22G (10)	TG (29) FC (10)	BL	Mostly not	Yes	100%	None
Majumder et al. [13] (2013)	39	Pancreas	19G	TG	BL	No	Yes	90% (4 failed due to fiducial migration)	13% (5 patients); (3 abdominal pain, 1 vomiting, 1 mild pancreatitis)

(continued)

Table 13.3 (continued)

Article	*N*	Cancer	Needle	Fiducial	Technique	Fluoroscopy	Antibiotics	Technical success	Complications
Choi et al. [22] (2014)	32	Pancreas (29), liver (3)	19G	TG	BL	No	Yes	100%	3.1% (1 patient) migration, 3.1% pancreatitis
Davila Fajardo et al. [16] (2014)	23	Pancreas	22G	FC GA	BL	Not routine	Not routine	100%	9.5% migration, 4.3% (1 patient) bleeding, 4.3% cholangitis
Dhadham et al. [14] (2016)	514	Oesophageal (207), gastric (33), pancreas (188), rectal (103), others (32)	19G, 22G	TG, FC	BL	No	Not mentioned	99.8% (513/514)	1.4% migration (7 pts), 1.8% minor bleeding (9 pts)
Phan et al. [23] (2019)	60	Oesophago-gastric (27), pancreas (28), hepatic (5)	19G, 22G	FC, TG	BL, preloaded	No	Yes	100%	Cholangitis ($n = 1$)

13.8 Complications of Fiducial Insertion

Pancreatitis and bleeding are rare occurring in 2% and 1% of patients, respectively. Reported cases are mild requiring conservative inpatient management, and most patients were able to be discharged after 24–48 h [22, 25]. Cholangitis occurs in up to 4% of patients in two early studies where there was no routine administration of prophylactic antibiotics [26, 27]. Subsequent studies which implemented routine prophylactic antibiotic use reported no rates of cholangitis. As such, it is recommended that antibiotics be administered prior to fiducial implantation [28]. Our choice of antibiotics is either ciprofloxacin (400 mg IV stat) or ceftriaxone (1 g IV stat).

The accepted fiducial migration rate is between 1% and 4%; however, two studies reported high rates of 7% and 9.5% and will be discussed in greater detail. The rate of 9.5% was reported in a study that utilised Gold Anchor and Flexible Coil fiducials. Interestingly, the GA was more difficult to deploy (31.3% failure rate) whereas the FC fiducial was successful in all attempts. However, the high rate of migration happened exclusively with the FC fiducial in this study [16]. The risk of fiducial migration can be minimized by increasing the number of fiducials deployed to 3–4, allowing sufficient tracking during SBRT [25].

13.9 Conclusion

As SBRT is increasingly utilised for treatment of locally advanced pancreatic cancer, there is a greater demand for accurate outlining of the cancer by fiducial marking. Of the available modalities, EUS-guided fiducial insertion is the least invasive technique that is associated with very high technical success and a low complication rate. The advances in preloaded fiducial needle technology have further improved the safety, efficacy, cost, duration, and outcomes of the procedure.

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