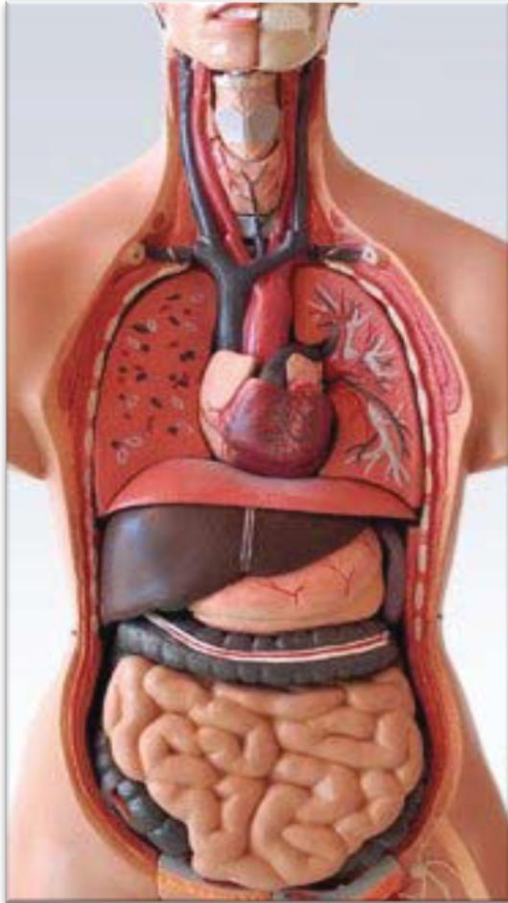


Gold Anchor enables safe reach to inner organs



Fine needles for cytology

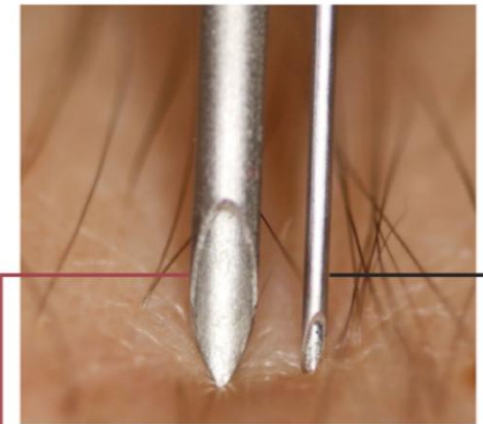
- have been used >50 years
- in all parts of the human body
- with no to very little harm

Gold Anchor comes pre-loaded in needles of the same size



Advantages:

- Reduced risk of pneumothorax
- Reduced patient discomfort
 - Less need for anesthesia
- Less risk of infection and bleeding
- Less risk of seeding of cancer cells



Regular gold marker needle:

- 17G needle, diameter of 1.47 mm



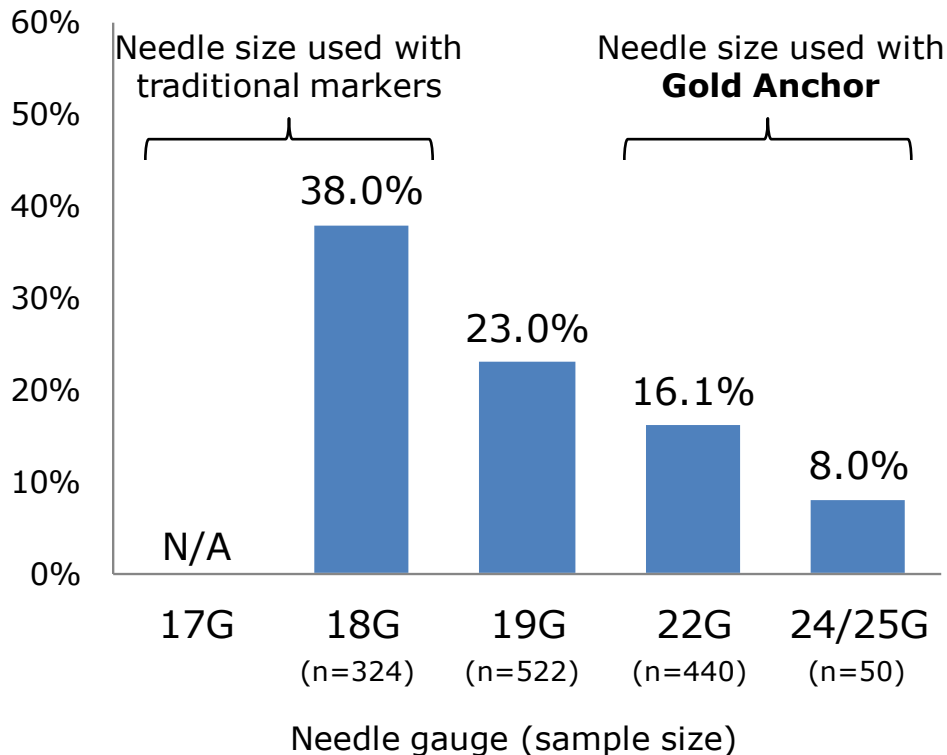
Gold Anchor fine needles:

22G needle, diameter of 0.71 mm

25G needle, diameter of 0.53 mm

Reduced risk of pneumothorax

Incidence of pneumothorax during percutaneous transthoracic needle aspiration biopsy of the lung



Possibly higher risk for cancer patients
"In our experience, ~50% of these patients developed pneumothorax, as might be expected in patients with severe lung disease. This is similar to the rate typically described for transcutaneous needle biopsies of lung lesions... Pneumothorax developing after transcutaneous placement of fiducial markers frequently necessitated hospitalization with chest tube placement. This may be explained by the rapid progression to tension pneumothorax or an increased likelihood of symptomatic stable pneumothorax in a population with poor pulmonary reserve."

Source: Kupelian PA, Forbes A, Willoughby TR, et al. Implantation and stability of metallic fiducials within pulmonary lesions. *Int J Radiat Oncol Biol Phys* 2007;69:777-785

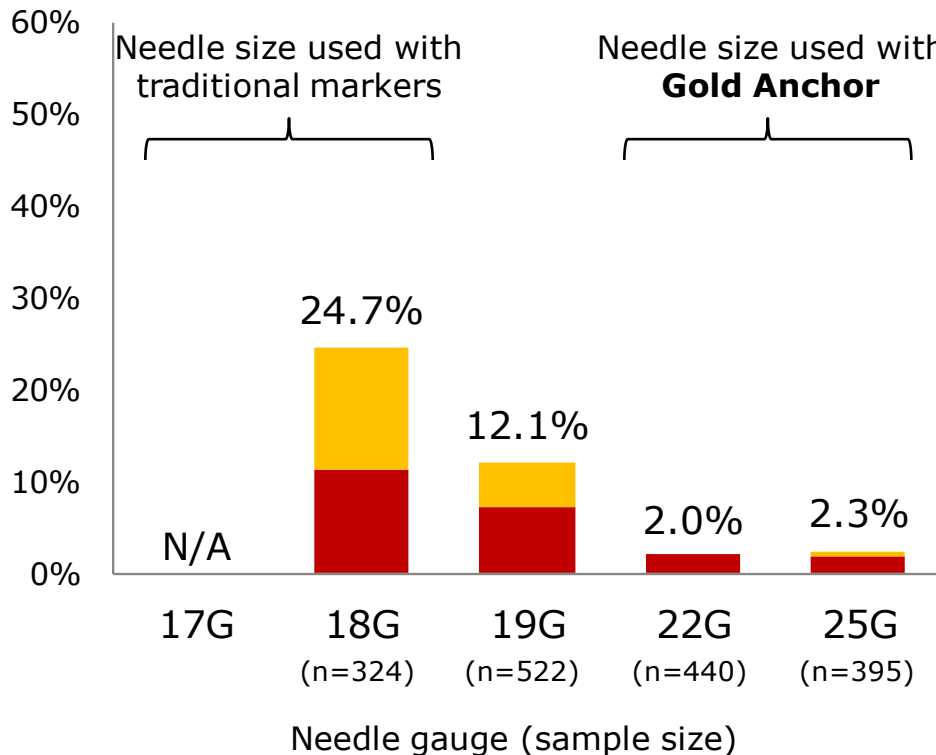
Source (18G and 19G): Geraghty, PR, Kee, ST, McFarlane, G, et al. CT-guided transthoracic needle aspiration biopsy of pulmonary nodules: needle size and pneumothorax rate. *Radiology* 2003;229:475-481

Source (22G): W S Chin, I Sng. The Chiba needle for percutaneous lung biopsy. *Sing Med J*. 1988; 29: 371-373

Source (24/25G): Zavala DC, Schoell JE. Ultrathin needle aspiration of the lung in infectious and malignant disease. *Am Rev Respir Dis*. 1981;123(1):125-31

Reduced risk of pneumothorax

Incidence of pneumothoraces needing treatment after percutaneous transthoracic needle aspiration biopsy of the lung



Treatment

- = Aspiration
- = Chest tube

Nominal outer diameter

Gauge	mm	inches
17G	1.473	0.058
18G	1.270	0.050
19G	1.067	0.042
22G	0.718	0.028
25G	0.514	0.020

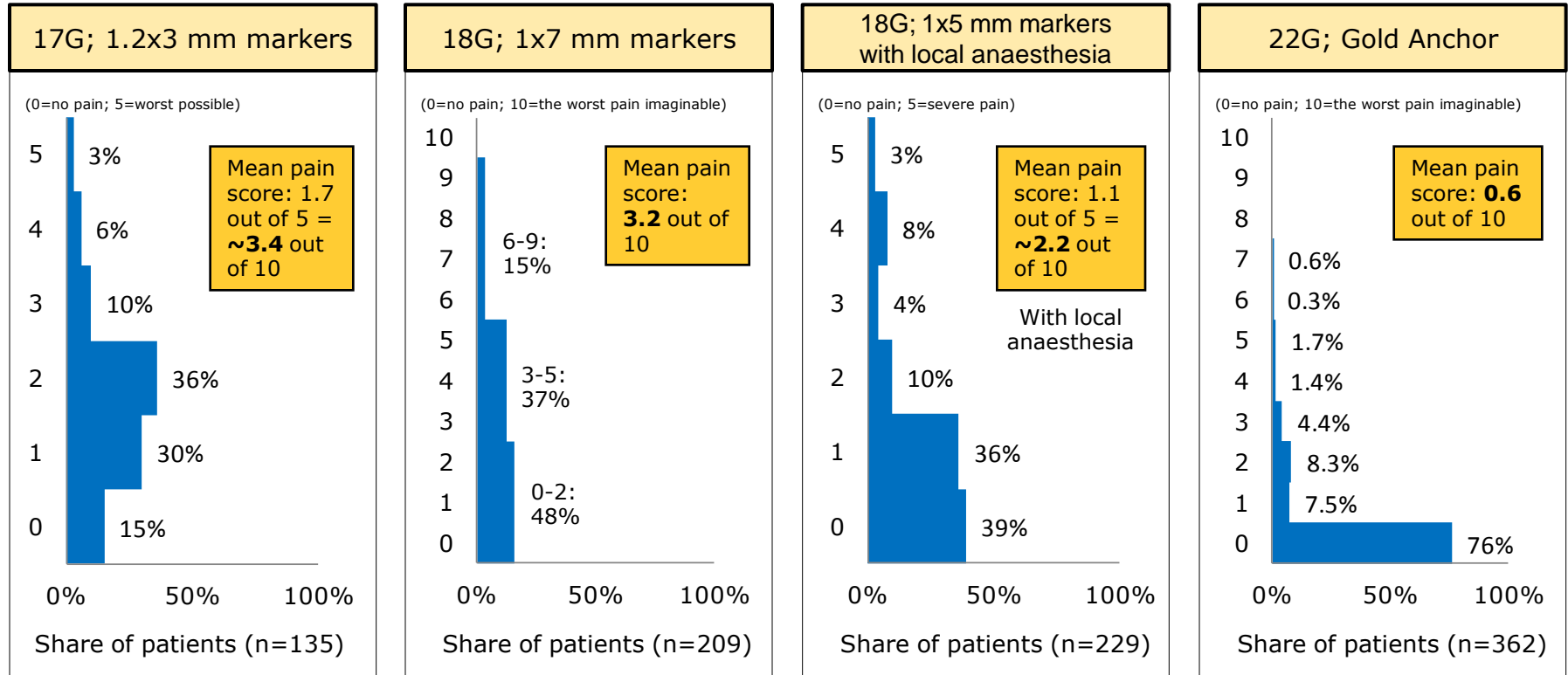
Source (18G and 19G): Geraghty, PR, Kee, ST, McFarlane, G, *et al.* CT-guided transthoracic needle aspiration biopsy of pulmonary nodules: needle size and pneumothorax rate. *Radiology* 2003;229:475-481

Source (22G): W S Chin, I Sng. The Chiba needle for percutaneous lung biopsy. *Sing Med J.* 1988; 29: 371-373

Source (25G): I. Naslund, P. Wersall, E. Castellanos, *et al.* Gold Anchor™ marker for IGRT, a new fiducial for high-precision radiotherapy *Int J Radiat Oncol Biol Phys* 2009;75:S608-S609

Reduced patient discomfort

Intensity of pain during transrectal implantation in prostate without local anaesthesia



Source (22G): Wioletta Mista, Leszek Miszczyk. An evaluation of side effects after gold markers (Gold Anchor™) implantation to prostate gland in patients with prostate cancer. *Onkologia Info* 2011;8;2:110-111

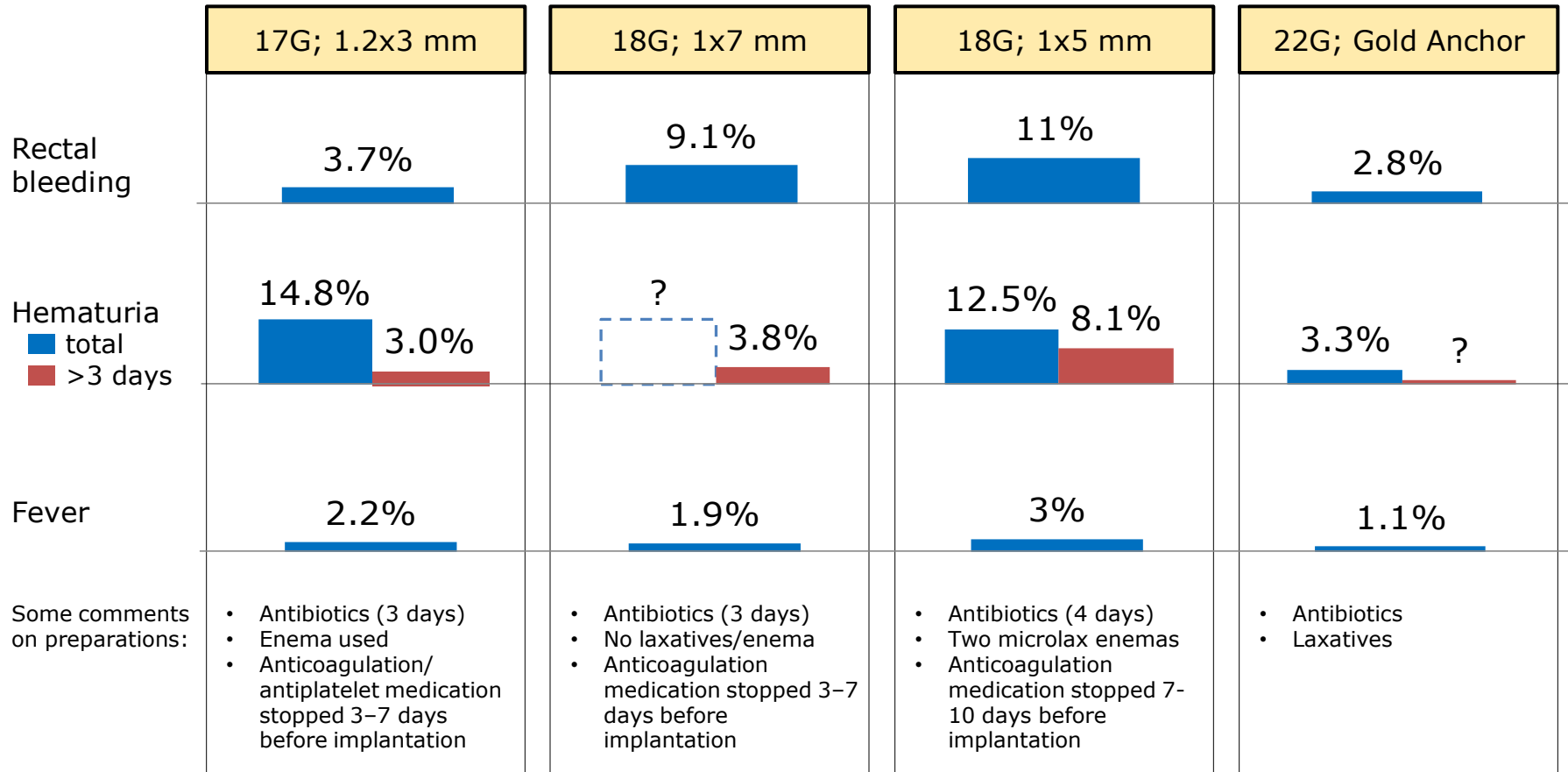
Source (18G; 1x5 mm): S Gill, J Li, J Thomas, et al. Patient-reported complications from fiducial marker implantation for prostate image-guided radiotherapy. *Br J Radiol.* 2012 Jul;85(1015):1011-7

Source (18G; 1x7 mm): Langenhuijsen JF, van Lin EN, Kiemeny LA, et al. Ultrasound-guided transrectal implantation of gold markers for prostate localization during external beam radiotherapy: complication rate and risk factors. *Int J Radiat Oncol Biol Phys* 2007;69:671-676

Source (17G): Igdem S, Akpınar H, Alço G, et al. Implantation of fiducial markers for image guidance in prostate radiotherapy: patient-reported toxicity. *Br J Radiol* 2009;82:941-945

Less risk of infection and bleeding

Some* complications after transrectal implantation in prostate



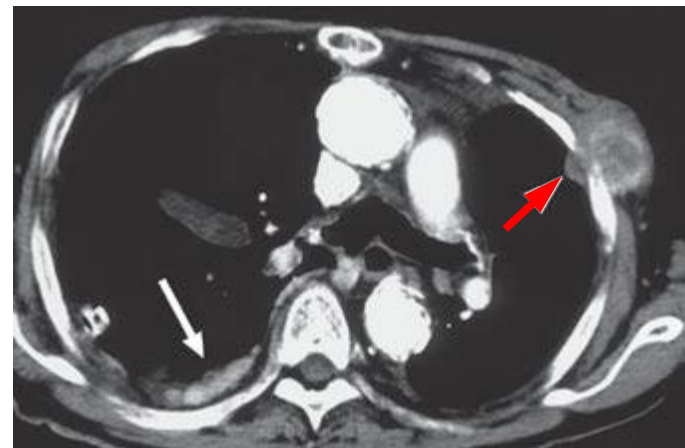
Note: *All complications are not shown. The complications above are those that were mentioned in all four articles.
 Source: See previous page.

Less risk of seeding of cancer cells

What is tumor seeding?

- Targeting lesions using a percutaneous approach requires the needle to be introduced across a number of tissue planes; initially through skin, and thereafter through intervening tissues, which often include subcutaneous fat, fascial layers, pleura, and muscle, depending on anatomical location
- Tumor seeding occurs when malignant cells are deposited along the needle tract during the biopsy procedure. This can occur within the organ harbouring the abnormality or within overlying tissues

Example of implantation metastasis (in lung)



Less risk of seeding of cancer cells

Risk of seeding varies with organ...

Low risk in general

"Needle tract seeding is a potential risk [of percutaneous needle biopsy], yet has been demonstrated to be an extremely unlikely outcome of these procedures."

Low risk in lung and kidney

"Needle tract seeding following biopsy of intra-pulmonary lesions and renal lesions is extremely rare..."

Somewhat higher risk in primary liver tumors

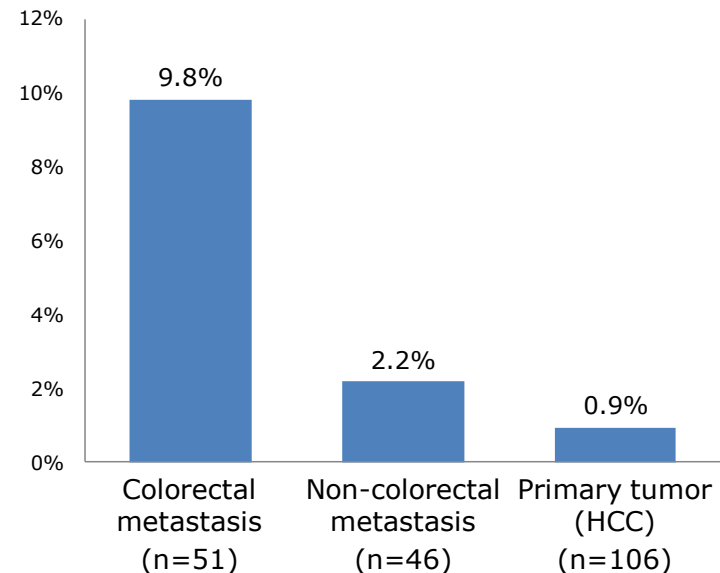
"The likelihood of needle tract seeding following biopsy of HCC [hepatocellular carcinoma] may previously have been exaggerated; in most circumstances, the benefit of accurate diagnosis will outweigh the perceived risks of biopsy..."

Higher risk in certain cases

"Percutaneous needle biopsy of primary malignant pleural disease and of colorectal liver metastasis confers similar tumour seeding risk; the decision to perform biopsies should be considered on a case by case basis but biopsy is likely to be contraindicated in candidates for hepatic metastasectomy."

...and with type of tumor (liver example)

Share of patients with implantation metastases after fine-needle aspiration cytology (FNAC) of liver tumors

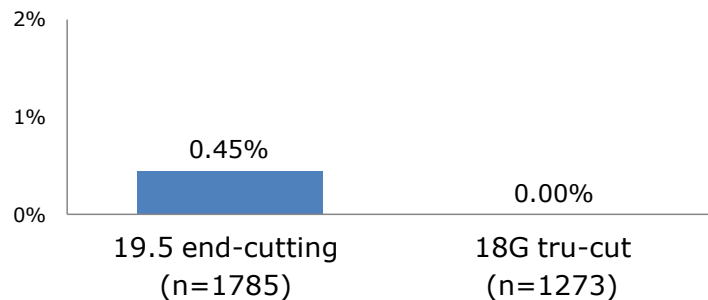


n = number of patients with malignant diagnosis
FNAC was carried out with 20- or 22-G needles

Less risk of seeding of cancer cells

Risk seems to vary with needle type...

Share of needle passes resulting in implantation metastases after biopsy of liver tumors



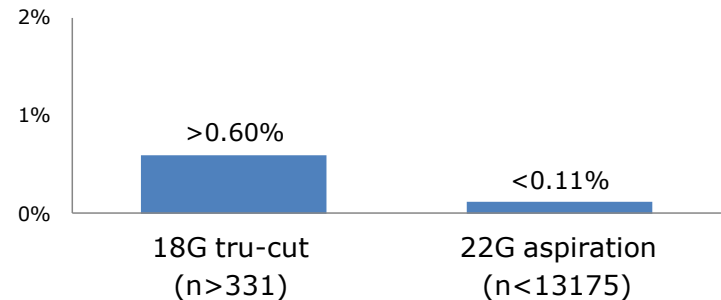
n = number of needle passes in patients with hepatocellular carcinoma (HCC)



Less risk of seeding with tru-cut
(insertion of fiducial marker resembles tru-cut more than end-cutting)

...and with needle size

Share of invasive procedures resulting in implantation metastases after biopsy and PEI of liver tumors



n = number of invasive procedures in patients with HCC
PEI = percutaneous ethanol injection



Less risk of seeding with fine needle

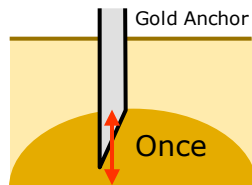
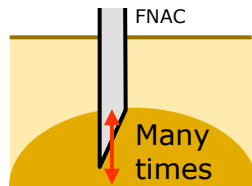
Source: Chang S, Kim SH, Lim HK, *et al.* Needle Tract Implantation After Sonographically Guided Percutaneous Biopsy of Hepatocellular Carcinoma: Evaluation of Doubling Time, Frequency, and Features on CT. *AJR Am J Roentgenol.* 2005;185(2):400-5.

Source: Tung WC, Huang YJ, Leung SW, *et al.* "Incidence of needle tract seeding and responses of soft tissue metastasis by hepatocellular carcinoma postradiotherapy. *Liver International, vol. 27, no. 2, pp. 192-200, 2007.*

Less risk of seeding of cancer cells – lower risk than with FNAC

Insertion of marker

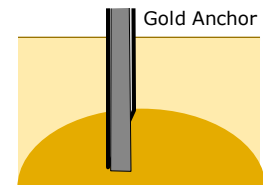
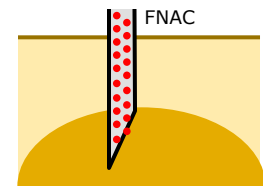
- During fine-needle aspiration cytology (FNAC) the needle is moved back and forth in the lesion several times
- Insertion of Gold Anchor involves only one insertion and withdrawal of the needle



Gold Anchor insertion is less traumatic than FNAC

Withdrawal of needle

- The FNAC needle contains malignant cells that may leak out during withdrawal of the needle
- The stylet that pushes out the Gold Anchor marker fills the needle during withdrawal



Gold Anchor needle withdrawal gives lower risk of seeding than FNAC