Introduction

Wire localization has been successfully used since its development in 1970s and is the standard method to guide surgical excision of nonpalpable lesions. Although reliable, wire localization has notable disadvantages including patient discomfort, risk of wire displacement, and limiting the surgical dissection and protruding routes. In addition, wire placement should be performed on the day of surgery and in the same building by the radiologist. This requires the patient and the radiologist to be available early before the surgery and this may cause logistical problems between the surgeon and the radiologist leading to OR delays. As of 2017, three additional localizers have been US Food and Drug Administration cleared: a radar reflector using micro-impulse radar (SAVI SCOUT, Cianna Medical Inc, Aliso Viejo, California), a magnetic seed (Magseed, Endomagnetics Inc, Austin, Texas), and a radiofrequency tag (Faxitron’s LOCalizer, Faxitron Inc, Tucson, Arizona). The flexibility in implementation of these localizers before the day of surgery has improved efficiency in scheduling and eliminated the OR delays. Additionally, the time slots scheduled for the same day wire replacements can be used for biopsies and decrease biopsy waiting times. Our goal here is to review the advantages and disadvantages of these non-wire localization technologies.

SAVI SCOUT

SAVI SCOUT is the first non-radioactive, non-wire localizer that was cleared by FDA in 2014. It uses a radar reflector that is 12 mm in length with a 4 mm body. Reflectors are activated by receiving infrared lights emitted from the handpiece and reflects electromagnetic waves. The electromagnetic waves are then detected through the handpiece-and-console system. The reflector is inserted through a preloaded 16-gauge introducer needle.

Magseed

Magseed is the second non-radioactive, non-wire localizer that received FDA approval in 2016. It contains a 5 mm × 1 mm paramagnetic steel and iron oxide seed. The seed is preloaded and deployed by an 18-gauge needle. Sentinel probe generates alternating magnetic field within the seed that is detected by probe. 5, 4, 7

Faxitron LOCalizer

Faxitron LOCalizer was FDA-cleared in 2017. It uses a miniature Radiofrequency Identification (RFID) tag deployed with a preloaded 12-gauge needle. The radio waves emitted from the Tag (9x2.2 mm) are detected with either a handheld Reader that has an integrated loop probe through the skin surface to determine the surgical path or with a sterile pencil probe during the operation. 2, 4

Advantages

• Can be placed up to 30 days before surgery, decoupling the localization procedure from surgery 3, 7
• Flexibility in scheduling for the radiologist, surgeon, and the patient 5
• Significant reduction in surgery schedule delays 3
• Minimal migration or displacement 3

Disadvantages

• Ferromagnetic surgical instruments interfere with the signal, so special non-ferromagnetic instruments should be used 3, 5
• Need for frequent calibration during the surgery
• Not FDA-cleared for neoadjuvant therapies
• Second most expensive device in the market
• Electrocautery or other metallic instruments also interfere with the signal 5, 7
• Few available studies evaluating its efficacy 3, 7
• Signal not detectable more than 4-cm depth 4

Future Directions

Cost appears to be a potential limitation of the non-wire localization devices compared to the standard wire localization. Although they are substantially more expensive than wire localization, simple cost level, reducing the wire localization related OR delays may provide the financial compensation. Previous studies have already reported a significant reduction in OR delays and better scheduling with SAVI SCOUT and Sentimag. Although the same result can safely be expected with Faxitron, no study has reported the efficiency of this device in terms of costs and patient satisfaction to this day.

We are going to demonstrate that OR delays can be reduced by at least 30% by using Faxitron compared to wire localization in a 6-month trial. We will next use a multi-factorial economic analysis considering purchase price, reimbursement, OR delays, and institutional cost of operation delays and cancellations to draw a comparison between the final costs of wire and non-wire Faxitron device.

References

2. Dauphine, C.; Reicher, J.J.; Reicher, M.A.; Goudsouz; C.; Khalkhali, I.; Kim, M. A prospective clinical study to evaluate the safety and performance of wireless localization of nonpalpable breast lesions using radiofrequency identification technology. AJR Am J Roentgenol. 2015, 204(6), W720-W723