PRESS RELEASE

SPL Medical is welcoming a powerful open-access publication in European Radiology highlighting the useability of Ferrotran® (Ferumoxtran) for pre-operative metastatic lymph node detection in pancreatic, duodenal, or periampullary adenocarcinoma.

Nijmegen, The Netherlands, 03.07.2024 – SPL Medical announced today the publication and online availability of the full paper in European Radiology (https://doi.org/10.1007/s00330-024-10838-w) about the use of Ferrotran® for lymph node detection in pancreatic and other adenocarcinoma. A prospective study involving 453 lymph nodes in 18 patients with histopathology as ground truth revealed strong conclusions.

Conclusions
"USPIO-enhanced MRI is a promising technique to preoperatively detect and localize LN metastases in patients with pancreatic, duodenal, or periampullary adenocarcinoma."

Clinical relevance statement
"Detection of (distant) LN metastases with USPIO-enhanced MRI could be used to determine a personalized treatment strategy that could involve neoadjuvant or palliative chemotherapy, guided resection of distant LNs, or targeted radiotherapy."

Sensitivity / specificity
"For 55 LNs node-to-node matching was possible. Analysis of these 55 matched LNs, resulted in a sensitivity and specificity of 83% (95% CI: 36–100%) and 92% (95% CI: 80–98%), respectively."

Relevance and current status
"Lymph node (LN) metastases are associated with decreased overall survival (OS) for pancreatic ductal adenocarcinoma (PDAC, 11% vs 4% 5-year OS), duodenal, and periampullary tumours (cholangiocarcinoma 47% vs 24% 5-year OS, duodenal cancer 65% vs 21% 5-year OS, and ampulla of Vater cancer 61 vs 25 months median survival).
Especially para-aortic LN metastases, classified as distant metastases by the TNM criteria of the Union for International Cancer Control (UICC), are associated with lower survival. Therefore, adequate LN assessment is critical in managing these cancers.
Conventional diagnostic imaging for pancreatic, duodenal, and periampullary cancer, including contrast enhanced computed tomography (CECT), magnetic resonance imaging (MRI), fluorine-18-fluorodeoxyglucose positron emission tomography-computed tomography ([18F]FDG-PET-CT), and endoscopic ultrasound (EUS), demonstrate limited sensitivity and specificity for detecting LN metastases."
Currently the diagnostic cutoff for metastatic LN detection is at about 10 mm and size is the most common criterium in MRI so far.

Ferumoxtran
Up to now no prospective study evaluated on a node-to-node level the power of USPIO enhanced MRI for pancreatic cancer. With this study, the power of Ferumoxtran (Ferumoxtran-10, Ferrotran®) for efficient lymph node detection in pancreatic cancer could be clearly demonstrated.
Sensitivity and specificity are in the (high) range of studies involving Ferrotran® in other cancers.

Of special importance is the fact that most LNs detected by Ferrotran® were <10 mm and about 20% of these LNs were qualified as positive by histopathology, "supporting that size is not an adequate tool to detect LN metastases".

The authors conclude that "The results show that USPIO-enhanced MRI is a promising technique to preoperatively detect LN metastases in patients with pancreatic, duodenal, or periampullary adenocarcinoma, with a high sensitivity and specificity. This holds promise for early detection and localisation of both local and distant LN metastases, which can be used to improve staging and guide neoadjuvant and adjuvant therapy, such as targeted radiotherapy."

"Enabling for an efficient early lymph node diagnosis and staging in various relevant cancer types is an essential step forward in the development of Ferrotran® and crucial for the patients suffering from these dreadful diseases", stated Dr. Jürgen Feuerstein, Chief Executive Officer of SPL medical.

About Ferrotran®:

Ferrotran® belongs to the group of USPIO's (Ultrasmall Superparamagnetic Particles of Iron Oxide). Ferrotran® can be applied in MRI as a safe bloodpool agent for angiography and for functional diagnostics in detection of even the smallest lymph node metastases. Ferrotran® is available already now to patients within the running phase III trial PROSTAPROGRESS, but as well in a named-patient-use program in Nijmegen, Netherlands and in a compassionate use programme in Zurich, Switzerland.

About SPL Medical:

SPL medical is a spin-off of the Radboud university medical center and is funded additionally by Oost NL, a Dutch regional venture capital company, and b.e.imaging GmbH, a German company specialized in the development and commercialization of contrast agents.

For more information about Ferrotran®, the clinical trials or SPL Medical:

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