To determine whether Feraheme has diagnostic utility.

Purpose:
To determine whether Feraheme has diagnostic utility.

Background:
Ultrasmall superparamagnetic iron oxide (USPIO) nanoparticle coated with a low molecular weight semi-synthetic carbohydrate. Intravenously (IV) administered and marketed for treatment of anemia in adult patients. Lymphotrophic agent absorbed by macrophages in the lymph nodes and reticuloendothelial system.

Normal Lymph Node Suppression with MRI

Results

- Group 1
  - 90 (96%) had metastatic prostate cancer
  - 4 (%) were normal
  - 68 (76%) of Group 1 patients had malignant nodes not fulfilling the usual MRI criteria (lower limits of resolution 2-3 mm)
  - Sensitivity 70%
  - Specificity 92%
  - Positive Predictive Value 96%
  - Negative Predictive Value 54%
  - Accuracy 76%

Methods

- Non-randomized prospective
- 178 consecutive patients (2/13 – 3/15)
- High risk for lymph node dissemination
- Analyses of only those with positive findings on MRI
- All received Feraheme
  - 177 at 6 mg/kg
  - 1 with 3 mg/kg
- All patients underwent MRI with MEDIC/T2* sequencing 24 hours after infusion.
- Images were independently reviewed by two board certified diagnostic radiologist with consensus interpretation
- Readers were blinded to clinical and histopathology

Conclusion

- With MEDIC/T2* sequences, lack of suppression of signal in lymph nodes after infusion of Feraheme highly suggests lymphatic dissemination in prostate cancer patients. Our findings suggest a lower limit of resolution of 2-3 mm.
- Combining Feraheme Imaging with additional MRI sequences improves sensitivity and specificity.
- Toxicity was acceptable at 6 mg/kg

Methods

- Group 1 (94 patients): Abnormal lymph nodes if no suppression after Feraheme infusion (i.e., hyperintense on T2*/MEDIC sequence)
  - 83 (86%) had CT guided biopsies and 11 (14%) an open PLND
- Group 2 (85 patients): Suspicious lymph nodes by MRI if suppressed by Feraheme but with high intensity on DWI, decreased ADC map values, typical morphologic and/or size criteria
  - 76 (89%) had CT guided biopsy and 9 (11%) an open PLND
- Resected lymph nodes were stained and reviewed by a single pathologist with no knowledge of the MRI findings
- The histopathology results for each lymph node were catalogued for comparison with MRI findings

Efficacy of Ferumoxytol (Feraheme) as a Lymphatic Contrast Agent in Prostate Cancer
ASCO 2018 Genitourinary Cancer Symposium
February 8-10, 2018

Feraheme Background

Post-contrast T1 demonstrates heterogeneous enhancement of external iliac lymph node.

Normal Lymph Node Suppression with MRI

Abnormal Lymph Node

Post-contrast T1 demonstrates homogeneous enhancement of external iliac lymph node.

Normal Lymph Node Suppression with MRI

Demonstrates a homogeneously suppressing all external iliac lymph node.

Demonstrates a T2* sequence after Feraheme administration. There is complete and homogeneous suppression of signal consistent with normal uptake of Feraheme by the lymph node.

Demonstrates a homogeneously suppressing all external iliac lymph node.

Demonstrates complete and homogeneous suppression of the lymph node on T2* sequencing after Feraheme administration. This corresponds to normal uptake of the Feraheme by the lymph node.

Demonstrates a homogeneously suppressing all external iliac lymph node.

This corresponds to normal uptake of the Feraheme by the lymph node.

Background

There are about 180,000 newly diagnosed cases of prostate cancer in the United States each year, with 26,000 deaths per year. Due to the marked variability and aggressiveness of this cancer, evaluation for both osseous and lymphatic metastatic disease is important to determine prognostic implications.

Results

- Group 2
  - 39 (46%) had metastatic prostate cancer
  - 46 (54%) were normal
  - Overall combining Groups 1 and 2
    - Sensitivity 100%
    - Specificity ~ 92%
    - Positive Predictive Value 92%
    - Negative Predictive Value 96%
    - Accuracy 97%

Conclusion

- Toxicity was acceptable at 6 mg/kg
- With MEDIC/T2* sequences, lack of suppression of signal in lymph nodes after infusion of Feraheme highly suggests lymphatic dissemination in prostate cancer patients. Our findings suggest a lower limit of resolution of 2-3 mm.
- Combining Feraheme Imaging with additional MRI sequences improves sensitivity and specificity.
- Toxicity was acceptable at 6 mg/kg

Normal Lymph Node Suppression with MRI

Post-contrast T1 weighted image demonstrates enhancement of the left axillary lymph node.

Demonstrates complete and homogeneous suppression of the lymph node on T2* sequencing after Feraheme administration. This corresponds to normal uptake of the Feraheme by the lymph node.