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Cynthia A Doerr, MD

**Misadministration of Sn-117m Colloid
During Radiosynoviorthesis Presents No
Safety Concerns**

Disclosure

Cynthia Doerr MD is an employee of Serene, LLC

Background and Objectives

Background: Radiosynoviorthesis is the intraarticular injection of a radionuclide for the therapy of osteoarthritis and rheumatoid arthritis in humans.

Objective: Demonstrate the safety of homogeneous Sn-117m colloid (HTC) when intentionally or unintentionally misadministered.

Three events:

1. Cutaneous, subcutaneous and oral exposure in rats
2. Intravenous administration in rats
3. Inadvertent misadministration in a client-owned dog

1) Cutaneous, Subcutaneous and Oral Exposure--Rat

12 Sprague Dawley rats administered 25uCi/0.925MBq HTC (equivalent to 7.5mCi/227MBq in a human)

- 4 administered subcutaneous injection (followed 4 weeks)
- 4 administered orally (followed 2 weeks)
- 4 administered topical (followed 2 weeks)
- Visual observation in all groups

Results:

- No signs of abnormality



2) Intravenous Exposure--Rat

20 Sprague Dawley rats administered 25 μ Ci/0.925MBq HTC (equivalent to 7.5mCi/227MBq in a human)

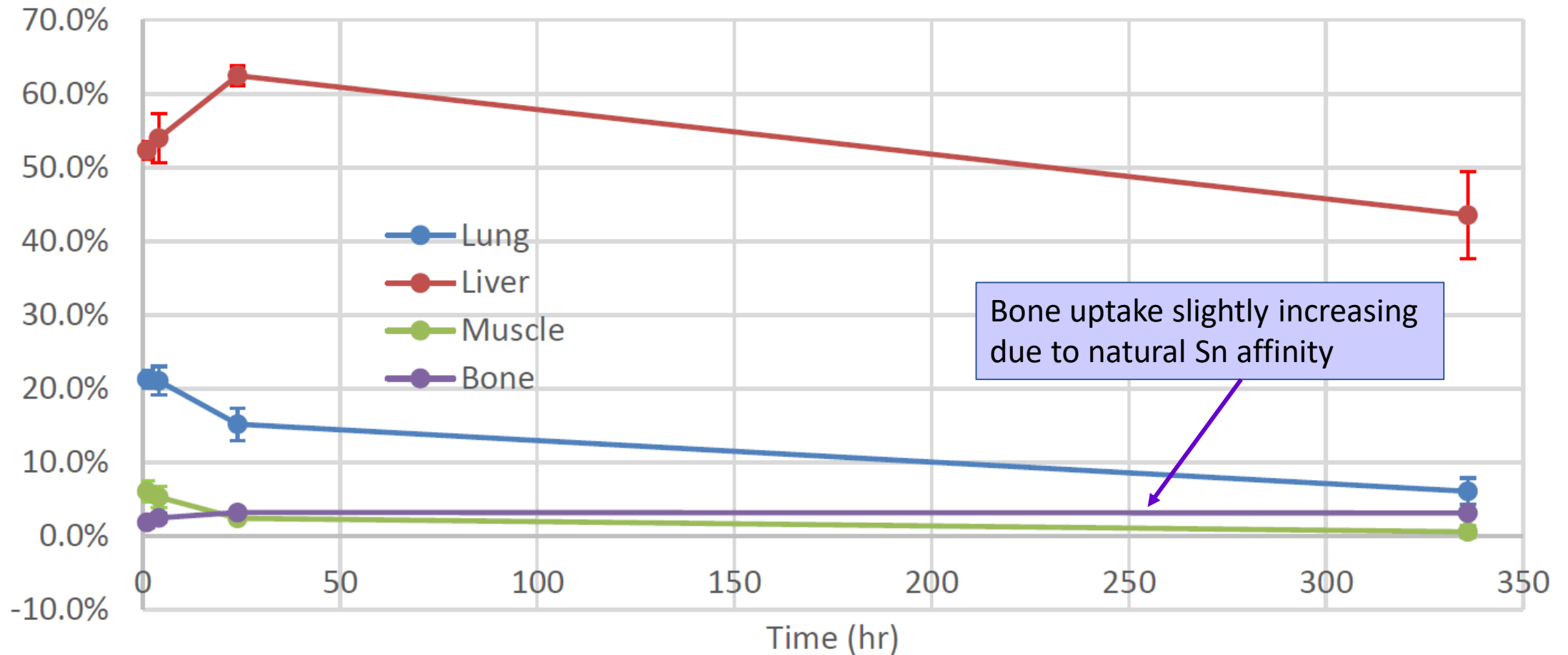
- 5 sacrificed at 1 hour
- 5 sacrificed at 4 hours
- 5 sacrificed at 24 hours
- 5 sacrificed at 14 days (1 half-life)
- Biodistribution in all groups

Results:

- No toxicity noted

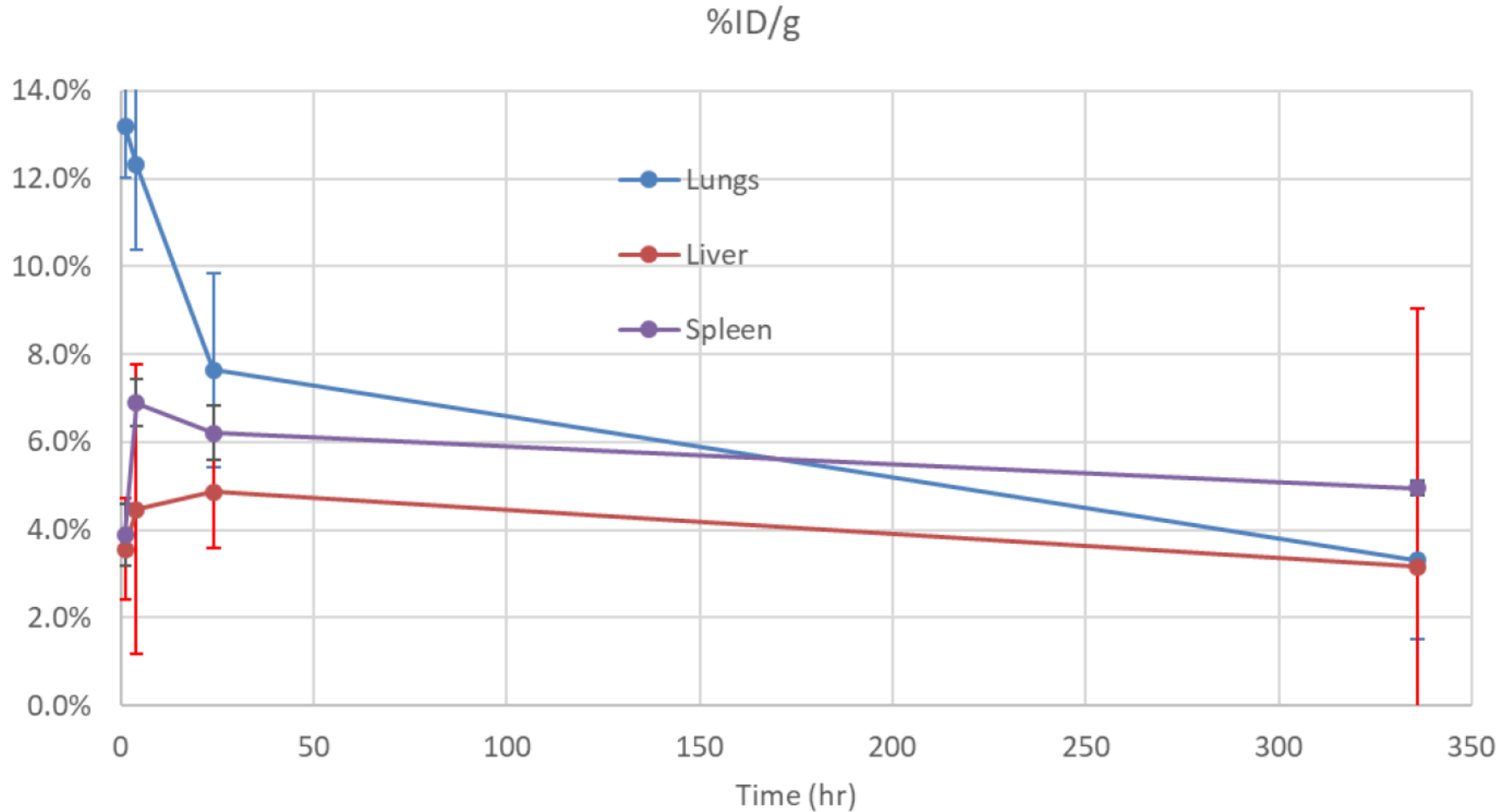
Intravenous Exposure--Biodistribution

Percent injected dose at major sites of accumulation



Intravenous Exposure—Biodistribution cont.

Percent injected dose/gram for lungs, liver, spleen



3) Inadvertent Misadministration—Client-owned Dog

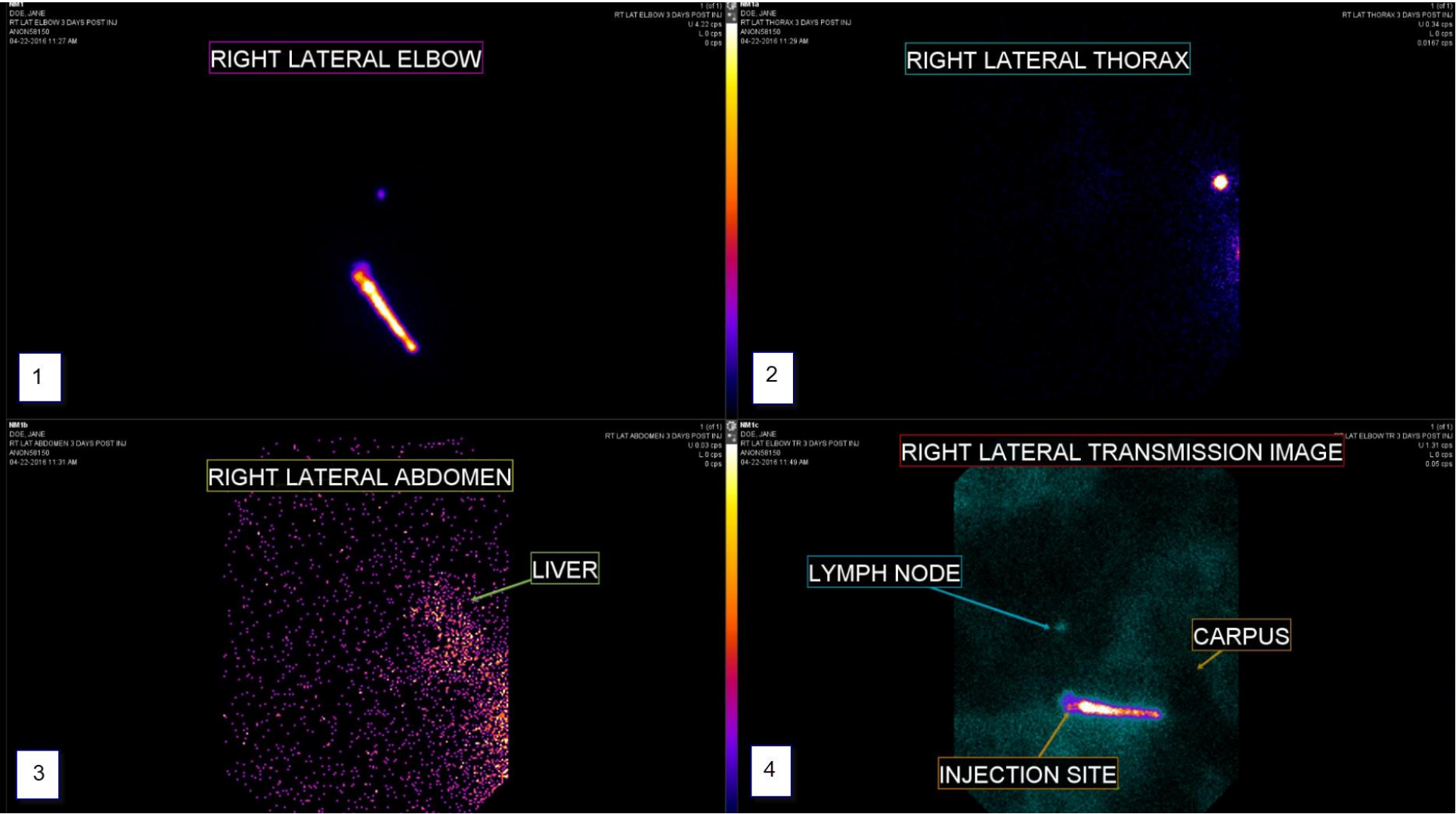
Client-owned pet dog participated in a clinical trial of elbow OA and received 1.61m Ci/59.6 MBq HTC. The needle bevel moved during administration and the entire dose was administered into the periarticular tissues, discovered 3 days after administration at the time of scintigraphy.

Results:

- No toxicity noted by clinical staff or owner
- No medical intervention was warranted
- Returned for an additional Sn-117m treatment



Inadvertent Misadministration—Client-owned Dog cont.



Conclusion

Sn-117m homogeneous colloid therapy is safe even when misadministered outside the intended treatment area.