LUTATHERA®
EXTRAVASATION

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FOX CHASE CANCER CENTER
TOPICS TO BE COVERED

SETTING SCENE
WHAT IS AN EXTRAVASATION ANYWAY?
LUTATHERA EXTRAVASATION
MEDICAL EVENT? YES/NO/MAYBE
GOING FORWARD
CONCLUSION
PETITION FOR RULEMAKING: REPORTING NUCLEAR MEDICINE INJECTION EXTRAVASATIONS AS MEDICAL EVENTS

• DOCKET NUMBER: NRC-2020-0141
• SEPTEMBER 15, 2020
• PUBLIC MEETING 12/8/2020 (ML21005A436)
• 21 PARAGRAPHS DETAILING STRONG PRACTICE AND SCIENTIFIC BASED OPPOSITION FROM THE REGULATED COMMUNITY
• 3 PARAGRAPHS OF EMOTIONAL ARGUMENTS IN FAVOR OR THE PETITION
WIDESPREAD OPPOSITION TO THE PETITION

• ASTRO – AMERICAN SOCIETY FOR RADIATION ONCOLOGY
• HPS – HEALTH PHYSICS SOCIETY
• SNMMI - THE SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING
• ASNC - AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY
• ACNM - AMERICAN COLLEGE OF NUCLEAR MEDICINE
• NORTH CAROLINA RADIATION PROTECTION COMMISSION
WHAT IS AN EXTRAVASATION?

- **Intravenous site infiltration**
  - Pallor
  - Coldness
  - Edema
  - Fluid leak

- **Dislodged IV catheter leading to infiltration**

- **Safe administration**

- **Complete extravasation**

- **Total displacement of cannula tip into adjacent tissue**

- **Partial/slow extravasation**

- With increased flow and decreased resistance in the tissues, extravasation occurs without detection
EXTRAVASATION OR INFILTRATION?

- **INFILTRATION** is the accidental leakage of non-vesicant solutions out of the vein into the surrounding tissue.

- **WHEN THE LEAKED SOLUTION FROM AN INFILTRATION IS A VESICANT DRUG—one that causes tissue injury blisters or severe tissue damage—it is referred to as an extravasation.
NOVEMBER 12, 2020

• PETITION FOR RULE RESULTING IN LIVELY DISCUSSIONS IN MEDICAL CIRCLES

• NRC’S PUBLIC HEARING IN 18 DAYS

• SHORT STAFFED

• LUTATHERA NURSE CALLS

• LUTATHERA THERAPY EVERY 8 WEEKS
  • LU-177, 7.4 GBq (200 mCi)
  • 6.7 DAY HALF-LIFE
  • 490 keV BETA
  • 113 keV (3%) & 210 keV (11%) GAMMA
  • 30 MINUTE INFUSION OF LUTATHERA AND CONCURRENT 4 HOUR INFUSION OF AMINO ACIDS
FIRST THINGS FIRST - WHAT DO WE KNOW?

- PAIN AND SWELLING
- BUMP AT IV SITE
- 30 MINUTES AFTER THE LU-177 INFUSION FINISHED
- 2.5 HOURS OF AMINO ACID INFUSION LEFT
- 7.66 GBq (206.7 mCi)
- DIFFICULT VEINS
IMMEDIATE ACTIONS

• WITHIN 1.5 HOURS OF THE CONCLUSION OF THE Lu-177 INFUSION:
  • COMPRESSION
  • ELEVATED
  • WARM COMPRESS

• CHEMOTHERAPY EXTRAVASATION RATE:
  • "RANGES FROM 0.1% TO 6% WORLDWIDE" ¹
  • FCCC LUTATHERA EXTRAVASATION RATE: 0.5%
DATA COLLECTION

• EXPOSURE RATE MEASUREMENTS
  • LEFT ARM: CONTACT AT IV SITE AND 30 cm AWAY
  • RIGHT ARM: CONTACT AND 30 cm AWAY
  • MEASURED AT ~2, 3.5, 23, AND 120 HOURS
  • RESIDUAL LUTATHERA VIAL READINGS
  • 451P IONIZATION CHAMBER
  • GAMMA CAMERA IMAGING

• OBSERVED A 47% EXPOSURE RATE DROP BETWEEN MEASUREMENTS TAKEN AT 2 HOURS AND 3.5 HOURS.
ACTIVITY PRESENT

• 0.12 GBq Lu-177 = 0.134 mSv/hr
  (3.3 mCi Lu-177 = 13.4 mR/hr)

<table>
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<th>Date</th>
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<th>Activity (MBq)</th>
<th>Activity (mCi)</th>
<th>Decrease in Activity Present</th>
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DOSE?

• SNM ARTICLE: “EXTRAVASATION OF A THERAPEUTIC DOSE OF $^{131}$I-METAIODOBENZYLGUIANIDINE”

\[ \text{Dose} = \frac{1}{2} \times \frac{E_{av} \times A}{\rho \times V} \]

• $E_{av}$ IS THE AVERAGE $\beta$-ENERGY PER DECAY, 163 keV
• A IS FOR ACTIVITY, 7.66 GBq (207 mCi)
• V IS THE VOLUME DISTRIBUTION, 150 cm$^3$
• $\rho$ IS THE BASAL LAYER’S MASS DENSITY, ASSUMED TO BE 1 g/cm$^3$
DOSE

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TOTAL DOSE = 17 Gy
WHAT DID WE SEE?

- IMAGES WERE OBTAINED AT APPROXIMATELY 4 HOURS, 24 HOURS AND 120 HOURS POST INFUSION.
- AU EXAMINED THE IV SITE PRIOR TO IMAGING.
WATCHFUL WAITING

• IV SITE EXAMINATIONS
• SELF REPORTING EFFECTS
• PICC LINES
  • PERIPHERALLY INSERTED CENTRAL CATHETER
• PATIENT EXPIRED
MEDICAL EVENT?

• EXTRAVASATION SPECIFICALLY EXCLUDED
• WRONG ROUTE & DOSE?
• VARSKIN >>> 50 rem
• 24 HOUR REPORTING WINDOW
• POSSIBLE MEDICAL EVENT
MEDICAL EVENT RETRACTION

• IMMEDIATE ACTIONS TAKEN
• FUTURE ACTIONS PLANNED
• RETRACTION WAS ACCEPTED
WHAT NOW?

• STRICTLY CANCER PATIENT POPULATION

• EARLIER DETECTION?
  • IV SITE EXPOSURE RATE
    • 5 min POST LU-177 INFUSION

• ACTION LEVEL >> 40 mR/hr
  • NOTIFICATIONS
  • ELEVATE ARM
  • APPLY COMPRESSION AND HEAT
ACTION LEVEL

IV Site Contact Exposure Rates (mR/hr) per Patient per Infusion

Exposure Rate (mR/hr)

Action Level

Patients

A A B B C C C D D D E E F F F G G G H H I I J J K

0 5 10 15 20 25 30 35 40
CONCLUSION

- ANTICIPATED EVENTS
- READILY IDENTIFIABLE
- QUICK RESPONSE KEY
  - ELEVATION, COMPRESSION & HEAT
- GAMMA CAMERA IMAGING
- CONTINUOUS SKIN MONITORING
- DERMATOLOGY CONSULT IF NEEDED
REFERENCES

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THANK YOU

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