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DEVELOPMENT OF SYNTHESIS METHOD FOR THE AUTOMATED PRODUCTION OF 177LU-EDTMP WITH ML-EAZY and PHARMTRACER MODULES

Background

The symptomatic treatment of skeletal pain due to metastases is complex. Especially in patients with multiple skeletal lesions and osteoblastic lesions on skeletal scintigraphy, systemic radiotherapy with radionuclides linked to a bone-seeking agent is preferred because of its efficacy, low cost, and comparatively low toxicity. Various radiopharmaceuticals available for this radiotherapy including 32P, 89Sr, and 186Re labelled hydroxyethylidene diphosphonate and 153Sm and 177Lu labelled ethylene diamine tetramethylene phosphonate (EDTMP). Because of its use in many Nuclear Medicine protocols including peptide radionuclide therapy and radioimmunotherapy, the clinical experience is higher with 177Lu. Therefore, 177 Lu-EDTMP is most preferred among these radiopharmaceuticals. However, in contrast to other peptide radionuclide therapy agents (177Lu-PSMA, 177Lu-DOTATATE, 177Lu-DOTANOC) there is no standard and optimized method for the synthesis process in routine practice, and clinics use their own manual methods. The aim of this study was to develop the automated 177Lu-EDTMP synthesis for routine use.

Methodology

The study was conducted in 3 main groups: 1) to determine and optimize the synthesis conditions of EDTMP and 177 Lu to be complexed in maximum ratio 2) Development of automated standardized production method by transferring manually determined synthesis parameters to automatic synthesis device (ML-Eazy and Pharmtracer, EZAG GmBH, Germany) 3) Development of the radiochemical purity analysis of method 177Lu-EDTMP.

Results and Discussion

Determined synthesis conditions were: EDTMP: 40 mg, 177Lu: 10-100 mCi, buffer: NaHCO3 (1M), time15-30 dk, temperature: 80 C°

Synthesis parameters

1. Pre-heating of reaction vial at 50 ℃ (60 sec)
2. Transfer of 177Lu to reaction vial by elution with radiolabelling solution (90 sec)
3. Radiolabelling at 80 ℃ (1500 sec)
4. Cooling with 4 mL saline
5. Transfer by passing through Sep Pak CM cartridge
6. Filtration from 0.22 µm filter

Developed analysing method parameters were:
Device: Shimadzu LC-20A
Column: C18 perfectbond ODS-H 5µm (100x4 mm)
Mobile phase: A: water:ethanole (90:10); B: water:TFA (100:0.1)
Elution: Gradient 100% A (0-5min), 100% B (5-5.30min), 100% B (5.30-16 min), 100 % A (16-20min)
Sample chromatogram was presented in Figure 1.

Conclusion

In this study, the method for automated synthesis of 177Lu-EDTMP with PharmTracer and ML-Eazy synthesis modules was developed. Repeatable production of this agent in pharmaceutical grade can be achieved in hospital setting.

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