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Impact of hospital production vs commercial kits purchase of 68Ga-DOTA peptides.

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Introduction.

68Ga-DOTA peptides, somatostatin analogs, are used for neuroendocrine tumors diagnosis. Commercial kits of 68Ga-DOTATATE are available for this indication with an expansive supplying. The aim of this study is to evaluate the impact of a switch from commercial kits to an hospital production of 68Ga-DOTATOC.

Methodology.

To synthetize this radiopharmaceutical in our laboratory, a quality dossier has to be submitted to our local authority, Swissmedic. In this dossier, we have to describe the synthesis and quality control (QC) methods and validate them on three batches. Synthesis was done with Mini AiO® synthesis module (TRASIS, Belgium). For each batch, all QC required by European Pharmacopeia (8th edition) were performed. Moreover, an additional filter integrity test was done with Mini AiO® to assess the sterility of the synthesis process. Then, the synthesis of 68Ga-DOTATOC was compared to 68Ga-DOTATATE kits in regards to costs and time of production.

Results and discussion.

On validation batches, activity yields was 84.4% ± 6.31%. All QC parameters were in conformity with the limits prescribed by Pharmacopeia monography. Calculated radiochemical purity was 99.36% ± 0.15% and residual ethanol measured was 7.77% ± 0.83%. Microbiological analyses (sterility and endotoxin) showed that the entire synthesis process allows sterility conditions. Futhermore, filter integrity test was successful for all batches.
Synthesis module is located in a hotcell with a microbiological class A with a regular microbiological monitoring. Sedimentation plate and filter integrity test are also performed before pharmaceutical release. Based on these parameters, sterility and endotoxin analyses will be performed only on validation batches and every 6 months.
On one hand, synthesis and QC control of 68Ga-DOTATOC are longer than 68Ga-DOTATATE kits respectively 60 minutes vs 30 minutes and 130 minutes vs 15 minutes. Indeed, more QC are needed for 68Ga-DOTATOC (HPLC, GC) whereas only PRC determination by TLC and pH measurement are required for 68Ga-DOTATATE kits. Thus, additional human resources and materials are necessary for hospital production.
But, on the other hand products for 68Ga-DOTATOC synthesis are cheaper than 68Ga-DOTATATE kits. Based on a number of 130 synthesis per year scheduled by nuclear medicine department, hospital production allows to obtain human resources and an important saving for the institution.

Conclusion.

68Ga-DOTATOC is conveniently prepared in sterile conditions by using Mini AiO® synthesis module with high radiochemical purity (> 99.3%) and enough final activity for 2-3 patients in a single batch. The advantageous costs saving compared to the commercial kits available in Switzerland prompt to extend this work to other 68Ga radiotracers.
Moreover, radioprotection benefits of automatized synthesis vs manual preparation of commercial kits could be assessed in a future study.

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