TRANSLATION OF EXPERIENCE AND KNOWLEDGE FOR FORMULATION OF CONJUGATED MONOCLONAL ANTIBODIES FOR RADIOLABELING

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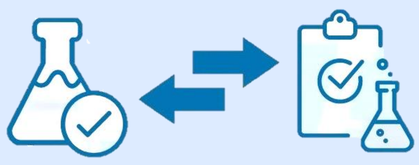
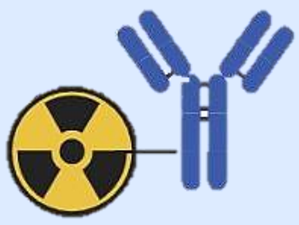
The aim of the study



- to take advantage of previous research-based experiences from our laboratory on the formulation of conjugated antibodies as potential radiopharmaceuticals radiolabeled with beta emitters,
- and to apply this knowledge to the development of stable immunoconjugates for labeling with positron or alpha emitters.

Material and methods



Monoclonal antibodies were chosen as the primary molecules for labeling due to their well-established pharmacokinetic and pharmacodynamic characteristics, as well as their targeted receptors for specific diseases.
The process of formulating antibody immunoconjugate complexes involved:

- purification of the antibodies,
- preparing concentrated antibody solutions,
- conjugating with chelators, and,
- freeze-drying to increase the stability of the complexes if suitable.

Results

After the formulation of the immunoconjugates and radioisotope labeling, our experience has shown that the following parameters are crucial to observe:

- the stability of the used ligands and obtained radiolabeled complex;
- appropriate validated analytical methods used for quality control of radiolabeled immunoconjugates;
- in vivo stability and pharmacokinetics of radiolabeled immunoconjugates;
- in vitro determination of degradation products of radiolabeled immunoconjugates;
- in vitro cell studies for determination of immunoreactivity and binding radiolabeled immunoconjugates.

Conclusion

Future studies should primarily focus on obtaining formulations with high chemical and radiochemical stability through standardized labeling procedures appropriate for the radioactive isotopes used, primarily using specific ligands.
Based on our previous research, in vivo receptor binding studies using cell cultures, biodistribution studies in animal models, pharmacokinetics in critical organs, the toxicity of radioactive immunoconjugates, and dose prediction through PK/PD ratio simulation, should be critical indicators for translation into clinical trials.

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