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Translatable human SSTR2-based reporters for imaging gene expression

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Clinical trials of gene therapy have been hampered by a lack of clinically relevant methods for *in vivo* detection of gene transfer. Currently in the clinic, evaluating success of gene transfer is primarily limited to analyses of biopsy samples, which provides limited assessment of *in vivo* gene delivery, is prone to sampling error, has associated morbidity and mortality, and can have problems with patient compliance especially when repeated evaluation or monitoring of multiple sites is needed. Instead, monitoring of exogenous gene expression should be non-invasive and easily repeatable over time in the same patient. This would inform regarding the location, magnitude, and kinetics of gene expression, and, could prove instrumental towards the rational development of innovative formulations designed to selectively target particular tissues, organs, or disease sites. To approach these needs, reporter genes may be used. These often encode enzymes, transport proteins, and receptors that most frequently bind and/or entrap an imaging agent. These may be limited for percutaneous imaging of humans because of scatter, such as light based agents; size; immunogenicity, particularly if not of human origin; quantification; and availability of clinically approved imaging agents. A desirable feature of the reporter is that it does not affect the intracellular milieu by signaling or pump action so that it does not cause untoward effects in expressing cells. We find that human somatostatin receptor type 2 gene-based reporters (SSTR2-based) reporters have desirable features for imaging in animals and for translation to humans. The SSTR2-based systems enable in vitro, in vivo, and ex vivo assessment of the reporter. They can be imaged using clinically approved radiopharmaceuticals and can be designed to be signaling deficient. Using small animal cognates of clinical machines as well as machines designed for patients, we have used a combination of functional and anatomic imaging to quantify *in vivo* expression of SSTR2-based reporters. We have used these to evaluate methods for improving expression. Imaging and quantification of such reporters has been performed in small animals and as a bridge to translation, in large animals.

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