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Stability and efficacy of a therapeutic dose of Lu-Dotatate prepared at a remote centralized radiopharmacy: The initial clinical results

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Background: Lu Dotatate therapy has established its role in the management of patients with inoperable or metastasized neuroendocrine tumours. To our knowledge the clinical stability of Lu Dotatate therapy doses prepared at a centralized radiopharmacy and transported to a remote therapy centre has never been analysed or reported.

Aim & Objectives: To assess the stability in using Lu Dotatate prepared from a centralized radiopharmacy then transported to a remote therapy centre. This may create therapy opportunities for many remote centres in different countries with no direct access to onsite production.

Methods: The current radiopharmacy, NTP Radioisotopes, is situated in Pelindaba, 634.5 km (approximately 394 miles) from the Therapy Centre (Umhlanga, Kwa-Zulu Natal). Pelindaba receives the Lu-177 on a Wednesday morning (from ITG in Germany), labels it with Dotatate using protocols obtained from two sources in Germany. The protocols are adapted to suit our conditions and the product is then suitably stabilised. This process is usually completed by 09h00. Standard doses of 7400 MBq are prepared. The doses are then taken by NTP Logistics to the airport (OR Tambo International Airport) for clearance for the scheduled flight (duration of flight one hour). In Durban (King Shaka International airport), NTP logistics wait on site for the labelled product to be cleared and it is taken directly to the practice for administration. We analysed 19 therapies to determine the stability of the product from preparation to injection. The following were used for analysis: biodistribution of post therapy imaging vs diagnostic scan lesion uptake, and clinical therapeutic response. Injection, therapy and imaging protocols were standardized.

Results: The mean time from production to injection was 4.93 hours (+/- 1.07 SD). The mode was 4.5 hours. The longest time between preparation and injection was 7.33 hours. The interim clinical evaluation of 6 patients who received Lu Dotatate therapy: 16% complete response (CR), 33% partial response (PR), 50% stable disease (SD).

Conclusion: Our Centre experience with Lu Dotatate received from a central radiopharmacy suggests that the labelled compound remains stable both *in vivo* and *in vitro* with good target delivery and effective clinical outcomes.

Biography

Maharaj Masha did her MBBCh through Wits University, in Johannesburg. She was specialized at Tygerberg Hospital in Cape Town where she obtained qualifications through the College of Nuclear Physicians of SA (FCNP), thereafter obtaining her Master's in Nuclear Medicine (MMED) through Stellenbosch University. In May 2015, she participated in the 1st World Theranostics Academy (WTA) held in Innsbruck, Austria. She is the only South African with this certification.

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