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Stability and efficacy of a therapeutic dose of Lu-Dotatate prepared at a remote centralized Radiopharmacy: The initial clinical results [Work in progress]

Maharaj Masha
Netcare Umhlanga Hospital, South Africa

Background: Lu Dotatate therapy has established its role in the management of patients with inoperable or metastasized neuroendocrine tumors. 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 analyzed or reported.

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

Methods: The current radiopharmacy, NTP Radioisotopes, is situated in Pelindaba, 634.5km (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 stabilized. This process is usually completed by 9 hours. Standard doses of 7400MBq 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 labeled product to be cleared and it is taken directly to the practice for administration. We analyzed 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 labeled compound remains stable both in vivo and invitro with good target delivery and effective clinical outcomes..

drmasha@yahoo.co.uk