

Definitive Improvement in the Approach to the Treated Patient as a Radioactive Source

Many patients treated with ^{131}I , mainly for thyroid cancer, have been subjected to inpatient isolation for no medical reason. Protection of the environment from a radioactive source (which the patient is believed to be), including protection of the closest voluntary caretaker and other family members, has been the main justification for this attitude.

In 1997, the Nuclear Regulatory Commission amended the regulations for the release of patients receiving treatment with radioactive materials. The maximally exposed individual could now be exposed to a limiting effective dose equivalent of 5 mSv (500 mrem), whereas children and pregnant women should not be exposed to >1 mSv (>100 mrem). This created the possibility that patients receiving $>1,110$ MBq (>30 mCi) ^{131}I could be treated as outpatients. In this issue of *The Journal of Nuclear Medicine*, Siegel et al. (1) describe a practical methodology for this change in policy.

Eligibility for treatment as an outpatient would depend on a patient-specific dose calculation based on serial total-body activity measured after the injection of a low dose of the ^{131}I -labeled antibody to calculate total-body residence time and on dose rate measured at 1-m distance with an ionization chamber after the administration of the high-activity therapy dose. Look-up tables were generated on the

basis of those measurements to facilitate the decision of releasability and the duration of contact restriction specific for the different members of the patient's human environment. Field measurements of the family members of patients treated on an outpatient basis proved to be below calculated exposures following the precise oral and written instructions that they received. Applying the situation described in this article to the patients whose thyroid disease was treated with ^{131}I needs modification because of the differences in body clearance that are biexponential in many thyroid patients. However, the release criteria are the same.

Today, where the previous regulations are still mandatory, patients and hospital systems pay a heavy and unnecessary price for inpatient treatment. Patient isolation is a unique and depressing situation with which these patients are confronted. The very cautious individuals in their surroundings relate to them as a living and moving radiation source. This apprehension, which exists among all medical personnel on whom the patient is dependent, is clearly recognized by the patient. The more stringent the protective measures, the greater is the feeling of isolation. The traumatic consequences are made evident when, as is frequently the case, they need a second or third treatment.

Traditional regulations have frequently influenced the medical decision concerning the treatment dose by indicating lower radioactivity to avoid a hospital stay. Furthermore, patients after total thyroidectomy, already in deep hypothyroidism where an initial high dose of ^{131}I was indicated and of which the patients were informed,

have been called back when no appropriate hospital room was available. They are then faced with alternatives: to start treatment with thyroid hormones for a limited time until an appropriate hospital room becomes available or, on other occasions, to reduce the ^{131}I treatment dose to 1,110 MBq and receive it with no greater delay as an outpatient. The decision on further treatment would then be considered in the future. These situations are real, are not infrequent, and are on the boundary of mismanagement, while attempting to comply with the previously existing regulations. The acceptance of the amended regulations will be very helpful by significantly reducing the number of inpatient treatments.

A point that has not been discussed is the Nuclear Regulatory Commission's limit of 5 mSv to the closest caretaker. This limit should be seen as a guideline when planning exposure. The risk of stochastic effect (carcinogenesis) to an adult exposed to effective doses of 5 mSv is virtual and is based on extrapolations from high-dose exposures following the linear nonthreshold principle. When seen in the light of epidemiologic studies from adult populations, there is still no statistically significant evidence of an increase in cancer mortality after exposures of <0.1 Sv, or 20 times the limit set by the Nuclear Regulatory Commission. To further perceive the significance of this effective dose, we should know that it is equal to or lower than the exposure of many diagnostic procedures. True, the latter exposures are justified by medical indications. Nevertheless, the voluntary exposure of a knowledgeable caretaker to a treated patient (most frequently a close family

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member) is, in my view, also perfectly justified. If the occupancy time is longer than expected and the dose exposure is slightly higher, this should not be considered prohibitive, as long as the patient and the caretaker comply with the “as low as reasonably achievable” principle.

The new regulation should be adopted in other countries, too, because it is of

benefit for the patient and the hospital system, whereas the risk to the human environment following the pertinent instructions is extremely low, not demonstrable, or nonexistent.

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REFERENCE

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