

there must be pharmacologic data available from studies in *human* subjects that would form the basis of the committee's action. If no data are available, even the smallest amount of the drug must be assumed to produce pharmacologic activity, and an IND should be sought.

Once approved, the study should be the subject of continuing review at the committee's quarterly meetings so that it does not evolve into a research project that no longer satisfies the criteria for RDRC approval. Reports of the progress of approved studies are made to us yearly, but there is a requirement for immediate reporting if the study involves exposure of more than 30 research subjects or of any research subject under 18 yr of age. This requirement has not been complied with in some cases, and we consider it important to our overview responsibility.

There are several other issues that have been the source of some confusion in the past:

1. The RDRC, as defined in 21 CFR 361.1 has no oversight responsibility or authority over an investigation carried out under an IND exemption. This authority is retained by the FDA. Title 21 CFR 361.1 however, does not in any way prohibit an institution from involving the RDRC in other policy matters, including the use of radioactive drugs, if it so chooses.

2. The RDRC is distinct from all other investigational drug review committees within an institution such as the radiation safety committee and the Institutional Review Board (IRB). The approval of both of these committees in addition to RDRC approval, is required before an RDRC investigation can be permitted to start.

3. The RDRC is established and chartered by the FDA under 21 CFR 361.1. It is not related to any specific type of license granted by the NRC or State-Regulatory bodies. These licensing authorities, of course, make their own regulations, rules, and requirements. For their own purposes, they may make an RDRC a requirement for a specific type of license, but these are not requirements under 21 CFR 361.1.

In sharing these observations with you, I also invite your comments. My intent is to preserve and improve the implementation of the RDRC regulations.

Questions and comments should be directed to Mr. Neil Abel, a Reviewing Pharmacist and the Executive Secretary of the Radiopharmaceutical Drugs Advisory Committee to the FDA. His address is the Division of Oncology and Radiopharmaceutical Drug Products, Office of Drug Research and Review (HFN-150), Food and Drug Administration, Center for Drugs and Biologics, 5600 Fishers Lane, Rockville, Maryland 20857.

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### Sialadenitis Following Iodine-131 Therapy for Thyroid Carcinoma

**TO THE EDITOR:** Allweis et al. (1) recently demonstrated ten cases of radiation sialadenitis following radioiodine therapy for thyroid carcinoma. Our team inaugurated salivary gland

scintigraphy in 1965 (2) and is also interested in salivary gland alterations in the follow-up of thyroid-carcinoma. In 1980 we conducted a prospective quantitative study using dynamic salivary gland scintigraphy to evaluate radiation risk of iodine-131 (<sup>131</sup>I) therapy (3), as proposed by Dr. Allweis.

We examined 20 thyroid carcinoma patients (16 female, 4 male; age range 25 to 82 yr) three times each, applying 2 mCi technetium-99m pertechnetate and analyzing time-activity curves from regions of interest over parotids and submandibular glands (before <sup>131</sup>I therapy, after cumulative doses of 170 mCi and 270 mCi <sup>131</sup>I). All tests ran under full thyroid hormone substitution. Salivary secretion was quantified by pertechnetate uptake before and after stimulation (2 ml plain lemon-juice by mouth).

Our data demonstrated a dose-dependent reduction of salivary gland function due to high dosage <sup>131</sup>I therapy. Parotid alterations were more frequent and more distinct than submandibular gland lesions.

For parotid glands, pertechnetate uptake after 270 mCi <sup>131</sup>I is reduced on an average of 40% compared to 30% for submandibular glands (4).

A general survey of our <sup>131</sup>I-treated thyroid carcinoma patients showed alterations of at least one salivary gland in about 30% (5). According to our data, in some cases complete loss of salivary gland secretion threatens after a cumulative dose of 500 mCi <sup>131</sup>I.

In conclusion, we agree with Dr. Allweis that actual salivary gland function should be taken into consideration planning <sup>131</sup>I therapy for thyroid carcinoma. Patients undergoing radioiodine treatment should consequently stimulate salivation during the days following <sup>131</sup>I application. We feel that this, besides sufficient fluid intake, is one of the quite rare medical indications for lemon candies and chewing gum.

### REFERENCES

1. Allweis P, Braunstein GD, Katz A, et al: Sialadenitis following I-131 therapy for thyroid carcinoma: Concise communication. *J Nucl Med* 25: 755-758, 1984
2. Börner W, Grünberg H, Moll E: Die szintigraphische darstellung der kopfspeicheldrüsen mit technetium-99m. *Med Welt* 2378-2380, 1965
3. Reiners C, Eilles C, Eichner R, et al: Speicheldrüsenfunktionsszintigraphie zur verlaufskontrolle bei der therapie des schilddrüsen-karzinoms mit radiojod. *Nuklearmedizin* 3: 281-286, 1980
4. Reiners C, Eichner R, Eilles C, et al: Kamera-funktionsszintigraphie der kopfspeicheldrüsen nach hochdosierter radiojodtherapie bei schilddrüsenkarzinompatienten. In *Nuklearmedizin*, Schmidt HAE, Riccabona G, eds. Stuttgart, New York, Schattauer, 477-481, 1980
5. Reiners C, Börner W, Eilles C, et al: Functional scintigraphy of the human salivary glands. *IAEA-SM* 247: 152-153, 1980

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