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Long-Acting Somatostatin Analogue Safety Monitoring Protocol for Outpatients with Neuroendocrine Tumors

Jordan Gabrielson1; Gianna Girone1; Bonita Bennett2; Anna Jung2

1 Jefferson College of Pharmacy; 2 Hospital of the University of Pennsylvania

BACKGROUND: Somatostatin analogues (SSAs) are widely used in the long-term treatment of neuroendocrine tumors (NETs) and have a relatively favorable safety profile. However, SSAs are associated with specific side effects that are important to monitor. Currently there is no standardized safety monitoring protocol for healthcare professionals to use as a reference when initiating patients on long-acting SSAs. The purpose of this study was to develop a comprehensive, practical SSA safety monitoring protocol for patients with NETs in the outpatient setting.

METHODS: A total of eight clinical studies were identified and selected for analysis through PubMed (1966-present) and Scopus (2004-present). Selected publications were searched for side effect frequency and monitoring parameters.

RESULTS: Side effect frequency analysis showed the most common side effects of interest, (CLARINET (Caplin et al., 2014), RADIANT-2 (M. E. Pavel et al., 2011), and others (Rubin et al., 1999; Wolin et al., 2015)), were hyperglycemia (0-28%), diarrhea (range 0-26%), fatigue (0-23%), nausea (3-16%), abdominal pain (0-14%), and cholelithiasis (0-10%). Safety monitoring analysis showed the most common baseline monitoring procedures performed prior to SSA initiation in all the clinical trials assessed were gallbladder ultrasounds, vital sign examinations, electrocardiograms, and clinical laboratory tests (including blood chemistry, hematology, fasting and postprandial blood glucose, and thyroid function). The most common follow-up monitoring procedures performed in these clinical
trials were physical examinations, vital sign examinations, clinical laboratory evaluations, gallbladder ultrasounds, and electrocardiograms.

**CONCLUSION:** Monitoring of patients’ safety during SSA treatment for NETs is an important component of patient management, particularly due to the widespread and chronic use of SSAs for this disease, and the similarity between disease symptoms and side effects associated with SSA use. We developed a thorough, practical safety monitoring protocol for use with patients initiating therapy with long-acting SSAs for NETs. Active monitoring and prompt identification of side effects can ensure long-term patient safety.