Comparison of Sonographically Guided Percutaneous Sodium Tetradecyl Sulfate Injection with Ethanol Injection in the Treatment of Benign Nonfunctioning Thyroid Nodules

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ABSTRACT

Purpose: To compare the efficacy of percutaneous sodium tetradecyl sulfate (STS) injection with ethanol injection in the treatment of benign nonfunctioning thyroid nodules.

Materials and Methods: This prospective study included 47 patients with 50 benign thyroid nodules. The lesions were randomly assigned into two groups: 20 in the ethanol arm and 30 in the STS arm. The mean lesion volume was 25.6 mL ± 28.5 (range, 4–122.1 mL) in the ethanol arm and 25.4 mL ± 27 (range, 0.72–129 mL) in the STS arm. One sitting of sclerosant injection was done in 20 lesions, and two injections, three injections, four injections, five injections, six injections, seven injections, and eight sittings of injections were done in 9 lesions, 4 lesions, 8 lesions, 4 lesions, 2 lesions, 2 lesions, and 1 lesion. The mean volumes of the instilled ethanol and STS were 5.3 mL and 7.8 mL, respectively, per sitting. Follow-up sonography was performed at 1, 3, 6, and 12 months after the procedure.

Results: The final 12-month follow-up lesion volumes were 4.1 mL ± 3.7 (range, 0.3–15.2 mL) in the ethanol group and 4.4 mL ± 5.8 (range, 0.01–29.6 mL) in the STS group ($P = .85$). The mean volume reduction was 84% and 82.8% in the two groups. No significant adverse effects were seen in either of the two groups.

Conclusions: Sonographically guided percutaneous ethanol and STS injections are not significantly different from each other in terms of the volume reduction achieved in benign nonfunctioning thyroid nodules.

ABBREVIATION

STS = sodium tetradecyl sulfate

Benign nodules account for most thyroid lesions that manifest with features of hyperthyroidism or recognizable neck swelling. Surgery and radioiodine ablation, previously considered the standard forms of treatment, are being replaced by less invasive percutaneous ablation techniques in a select group of patients because of wider acceptance by patients and fewer adverse effects. However, percutaneous ablation of nodules is not the standard of care for benign nodules and should definitely not be used in patients with malignancies or suspicion of malignancy.

Percutaneous ethanol injection has proven to be of significant benefit in treating benign functioning as well as nonfunctioning thyroid nodules such as cysts or solid nodules (1–3). Although widely used for this indication, there are significant side effects associated with this drug, including local pain in almost all patients, transient vocal cord palsy, and venous thrombosis in sporadic cases (1). Other drawbacks that may prove hazardous in a shelf drug include high degree of flammability, a burning sensation on contact with eyes and skin, and airway irritation on inhalation. Poor response rates in

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solid lesions are also a cause of concern with ethanol (4). Many other sclerosants, such as tetracycline (5), OK-432 (6), and sodium tetradecyl sulfate (STS) (7), and other techniques, including radiofrequency (8), laser (9), and microwave (10) ablation techniques, also have been used to treat thyroid nodules. Of all these, STS has shown the most remarkable results in the treatment of vascular malformations in more recently (11,12), although its application has not been widely described in thyroid nodules (13). Based on its widespread availability, ease of use, and safety profile, STS may be an attractive alternative to ethanol for the treatment of benign thyroid nodules. The purpose of this study is to compare the efficacy of percutaneous ethanol injection with STS injection in this setting.

MATERIALS AND METHODS

Institute review board approval was obtained for this prospective randomized study. The study spanned a 5-year period and initially enrolled all patients consecutively who presented to the endocrinology outpatient services of a tertiary care teaching hospital with a primary complaint of neck swelling (n = 143). A detailed clinical examination with routine baseline investigations (hemoglobin, platelet, and total/differential leukocyte counts) and neck ultrasound examination was performed on all 143 patients. The swelling in 87 patients was attributed to an enlarged thyroid based on clinicoradiologic parameters, and these patients underwent a detailed clinical work-up that included thorough general physical and systemic examinations, serum electrolytes, renal and thyroid function tests, abdominal ultrasound, chest radiograph, and thyroid nuclear scintigraphy followed by fine-needle aspiration biopsy. The inclusion criteria for enrollment in the study were (*a*) the presence of symptoms related to thyroid swelling, (*b*) a biochemically euthyroid state, (*c*) cytologic confirmation of the benignancy of the thyroid nodule, (*d*) the absence of tracer uptake on nuclear scintigraphy, and (*e*) availability of written informed consent. The following patients were excluded: (*a*) patients with the suspicion of malignancy on an ultrasound examination and (*b*) patients undergoing thyroid-related therapy. The trial ultimately included 47 patients with 50 nodules (44 patients had one nodule each, and 3 patients had two nodules each) (**Fig 1**). The 50 nodules were randomly assigned based on computer-generated methods into the ethanol (n = 20) and STS (n = 30) arms. The primary outcome of the study was the percentage reduction in lesion volume with at least 50% overall reduction at the final follow-up examination at 12 months. Secondary outcomes were subjective patient satisfaction and symptom relief.

The study group consisted of 47 patients (2 males and 45 females) with a total of 50 lesions. The mean patient

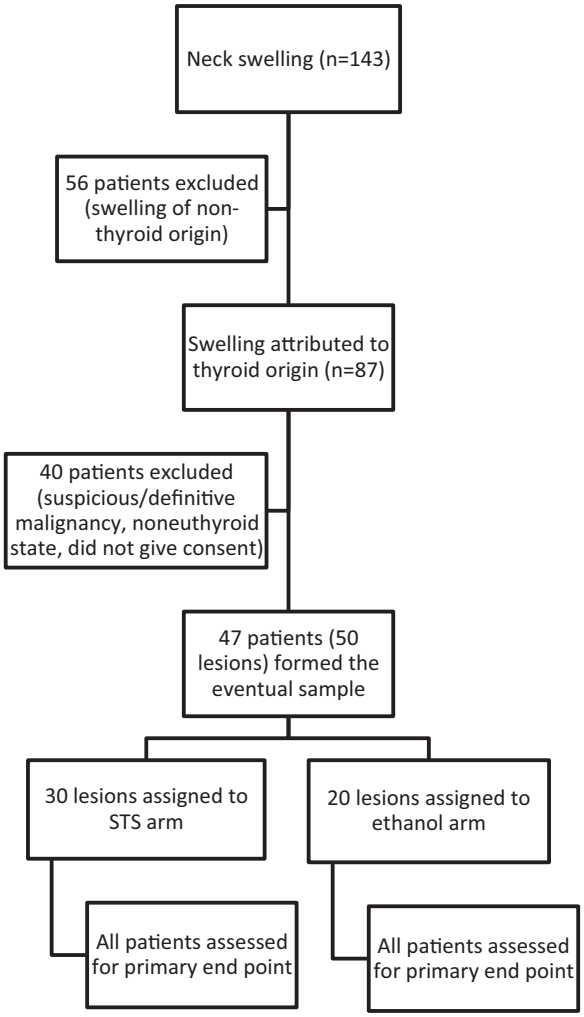

Figure 1. Flow chart of enrollment, randomization, and follow-up of patients with neck swelling.

age was 35.9 years (range, 10–57 y). There were 29 solid nodules and 21 cystic nodules. The details of patients grouped into ethanol and STS categories are provided in **Table 1**.

The chief complaint was neck swelling in all patients (47 of 47); > 50% (29 of 47) of patients attributed significant cosmetic implications to the mass. Other presenting complaints were local discomfort (n = 4) and dysphagia (n = 2). All patients were clinically and biochemically euthyroid and had no other significant comorbidities that were likely to change the course of the disease or treatment.

Based on the ultrasound appearance of the thyroid lesion, the patients were classified into two groups. Group I was composed of patients having solid or predominantly solid nodules (> 60% volume), and group II was composed of patients having cystic or predominantly cystic nodules (> 60% volume). The total volume (V) of the nodule and the predominant component of the nodule (solid or cystic) were calculated with the formula V = lxbxhxΠ/6 with l, b, and h representing the length, breadth, and height (vertical