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Randomized trial of a short course of preoperative potassium iodide in patients undergoing thyroidectomy for Graves' disease

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Abstract

BACKGROUND: A short course of potassium iodide (SSKI) has been traditionally used to prepare patients with Graves' disease for thyroidectomy. The rationale for this treatment has evolved over time; from control of hyperthyroidism to facilitating surgery by making the gland less friable and bloody.

METHODS: Randomized trial of preoperative SSKI vs no SSKI to test whether that is true.

RESULTS: Mean estimated blood loss in the SSKI group (62 mL) was less than in the control group (162 mL) as was the median estimated blood loss (50 vs 140 mL). Mean (142 vs 162 minutes) and median (138 vs 150 minutes) operative times were also less in the SSKI arm. Subjective difficulty of operation was similar. Multivariable comparisons of groups with analysis of covariance showed the SSKI group suffered a mean blood loss 35% of the no treatment group ($P = .036$), the 9.2% decrease in Operating Room (OR) time between the SSKI group and the no treatment group was not statistically different ($P = .464$).

CONCLUSIONS: SSKI given before operation in patients with Graves' disease reduces blood loss during thyroidectomy.

Thyroidectomy has been an accepted definitive treatment for hyperthyroidism caused by Graves' disease for more than a century. Over that time, however, other treatment strategies with radioactive iodine and antithyroid medications have been developed and have emerged as the primary treatment choice for this condition, especially in the United States. Thyroidectomy for Graves' is now generally reserved for patients who require definitive treatment for persistent or recurrent hyperthyroidism and cannot or will not take radioactive iodine.[1] Endocrinology practice at our institution historically had a more liberal and favorable view of the role of thyroidectomy for Graves' disease[2] which resulted in higher proportion of these patients being referred for operation.

Potassium iodide (short course of potassium iodide [SSKI]) or potassium iodine (Lugol's solution) have been used to prepare patients with Graves' disease for surgery for as long as thyroidectomy has been done for the condition.

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The authors declare no conflicts of interest.

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However, the rationale for its use has changed over time. Originally, a short course was used to control the patients' hyperthyroidism (the Wolff–Chaikoff effect) and decrease the likelihood and severity of an intraoperative or postoperative thyroid storm. With the advent of antithyroid drugs such as propylthiouracil and methimazole to control the patient's hyperthyroidism as well as beta blockade to inhibit the effects of excess thyroid hormone when necessary, these iodide-containing solutions are rarely required or used for this purpose now. Instead, the rationale for their use preoperatively is to decrease the vascularity and friability of the gland and make thyroidectomy easier. Aside from surgical tradition, there is some evidence that this might be true. Small studies using thyroid scans[3] or ultrasound[4,5] have demonstrated decreased thyroid blood flow and decreased blood loss[5] in Graves' disease patients treated with a short (7 to 10 days) course of Lugol's solution. Although an iodide preparation is often used and is recommended by the ATA guidelines for this purpose, it is by no means a modern standard of care.[6,7] Our surgical practice used SSKI sporadically for Graves' patients rendered euthyroid by modern medications and uniformly performed either total—or near total—thyroidectomy for this condition.

Because of this practice pattern and the treatment approach of our medical endocrinology colleagues, we thought that we might be in a peculiar enough position to evaluate whether preoperative preparation of Graves' disease patients with SSKI practically did result in less operative blood loss, less operative time, and an easier operation. This report presents the results of our small, single-institution, randomized trial of preoperative SSKI vs no SSKI, in patients rendered euthyroid by antithyroid drugs, and undergoing an elective thyroidectomy as definitive treatment of their Graves' disease.

Methods

Design

Eligible patients were consented on an institutional review board approved protocol and then randomized to treatment with a standard preparation dose of SSKI (8 drops in a glass of water daily for a week before operation) or to a no treatment arm. There was no further stratification. Adult patients were eligible for inclusion in this trial if they were referred by their endocrinologist for definitive management of their Graves' disease/hyperthyroidism by surgical resection, had already agreed to that treatment after surgical consultation, and had their condition of hyperthyroidism clinically and biochemically controlled with antithyroid medication. All patients continued on their previously prescribed antithyroid medication to the time of operation. Patients who were offered the trial but declined to participate were not logged or tracked. Randomization was accomplished by creating a table (for 50 patients at a time) from the website research randomizer (https://www.randomizer.org) and placing prescriptions for SSKI or a blank paper in envelopes numbered according the table. Patients were supplied with their prescription by the Advanced Nurse Practitioner (M.S.) when the patient consented and the envelope was pulled. The operating surgeons were blinded to the treatment arm but supervised the collection and entry of data on the data form in the operating room. Subjects were told not to inform their surgeon of the treatment arm and the nurse practitioner who supplied the patients with the envelopes did not inform the surgeons. Compliance with assigned treatment was not subsequently assessed. The trial was registered with NIH.gov (NCT00946296).

End points

The end points of this trial were between arm differences in estimated blood loss, operative time, and the subjective degree of difficulty of the thyroidectomy. The null hypothesis was that there was no between arm difference in any of these end points, and clinically meaningful differences in estimated blood loss and operative time were stipulated a priori as 100 mL and 20 minutes, respectively. No clinically meaningful between arm difference was stipulated a priori for the degree of operative difficulty.

Data collection

Thyroidectomies were performed by 3 experienced thyroid surgeons (A.L., R.Q., and G.W.) assisted by surgical residents ranging in level from post graduate year (PGY) 0 (medical student) to PGY 5. No particular operative protocol or style was prescribed for this study. Operative time was measured from neck incision to skin closed. Estimated blood loss was measured at the conclusion of the operation by the circulating nurse who counted the number of sponges, estimated the percentage of saturation for each one and totaled them up. Fully saturated Raytec sponges were counted as holding 20 mL of blood (http://www.manuelsweb.com/blood_loss.htm). The nurse also totaled up the amounts in the suction canister after subtracting the irrigation fluid. At the conclusion of the case, the attending surgeon characterized the difficulty of the procedure on a scale of 1 to 5, with 1 defined as "one of the easiest thyroidectomies I have done," and 5 defined as "one of the most demanding and difficult thyroidectomies I have done." Placement of a drain, which was not a practice habit of any of the surgeons, was noted on the data sheet as were any operative mishaps or immediate complications.

Patients

Between October 2005 and April 2013, 36 eligible patients were consented and randomized into each arm of the trial. Accrual was a third of the planned target and