

Lateral neck sentinel lymph node biopsy in papillary thyroid carcinoma, is it really necessary? A randomized, controlled study

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Background. Although occult metastasis to lymph node in the lateral neck compartment is common in papillary thyroid carcinoma (PTC), the clinical impact of these metastasis is unknown. We hypothesized that sentinel lymph node biopsy (SLNB) of the lateral neck compartment with radioisotopes may detect occult metastasis, which could prevent recurrence.

Methods. This randomized, controlled study was conducted from June 2009 to January 2011 and included 283 patients with PTC who were receiving treatment at the Samsung Medical Center.

Results. Of the 283 patients enrolled in the study, 141 were randomized to a lateral SLNB (LSLNB) group and 142 patients were to the control group. Lateral sentinel lymph nodes (LSLNs) were identified in 80 of the 127 patients (63.0%) for whom stimulated thyroglobulin (sTg) levels were available.

Among the 80 patients with LSLNs, 24 (30.0%) had metastases and underwent an ipsilateral modified radical neck dissection. Among the 191 patients for whom repeated sTg test results were available, the first median level of sTg in the LSLNB study group was less compared with the control group ($P = .012$, adjusted for duration). However, the second sTg level (after the first radioactive iodine ablation) was not different between the 2 groups. Moreover, the sTg levels were not significantly different between the LSLN-positive ($n = 23$) and other patients ($n = 168$) after the first and second ablations. During patient follow-up (median, 39 months; range, 7–55), 3 cases of recurrence were observed in the control group and 1 case in the study group (a LSLN had not been detected in this case).

Conclusion. Although LSLNB was able to remove occult metastasis in PTC, this procedure had no effect on either sTg levels or on recurrence rates at a mean follow-up of 39 months. Additional long-term studies are needed to explore fully the clinical usefulness of LSLNB in the prevention of PTC recurrence. (Surgery 2015;157:518-25.)

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ALTHOUGH LATERAL NECK NODE METASTASES in papillary thyroid cancer (PTC) are common,¹⁻³ the prognostic importance of lateral neck occult lymph node metastasis in thyroid carcinoma remains controversial. As suggested by the revised 2009 guidelines of the American Thyroid Association,^{3,4}

functional compartmental resection approaches such as modified radical neck dissection (MRND) can be useful for decreasing recurrence and possibly death in patients with clinically evident nodal disease; in contrast, prophylactic MRND may cause unexpected complications and is of no proven benefit.

Sentinel lymph node biopsy (SLNB) in thyroid cancer was first introduced in 1998.⁵ Most studies of SLNB have focused on the central neck nodes; reports describing SLNB of the lateral neck node are rare.^{6,7} We first reported a prospective study demonstrating that lateral SLNB (LSLNB) using a radioisotope was useful for detecting occult metastases.⁷ In our previous report, we focused on the incidence of occult metastases, the feasibility of LSLNB, and the potential indications of LSLNB.

Conflict of interest: The authors declare no conflicts of interest.

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Because PTC is indolent and responds well to radioactive iodine (RAI) ablation, the more important perspective for the clinical application of LSLNB is its impact on patient outcomes, such as recurrence and survival. This report presents a short-term follow-up study (mean, 30 months) focusing on the usefulness of LSLNB. The level of preablative stimulated thyroglobulin (sTg), which is considered to be a predictor of residual and recurrent disease, was used as a surrogate measure to predict the benefit of LSLNB.^{4,8,9}

In this study, we tested the hypothesis that LSLNB could detect and remove occult metastases, and eventually decrease recurrence in the lateral compartment.

PATIENTS AND METHODS

Study design and patient selection. This prospective study was conducted on patients with PTC, with the aim of evaluating the efficacy of SLNB in LSLNB. Approval was granted by the Institutional Review Board of Samsung Medical Center (ClinicalTrials.gov ID, NCT01137097). Patients with tumors >1 cm in size or with clinically suspicious preoperative central neck node metastasis were enrolled in this study. Patients with lateral neck lymph node metastases that had been confirmed by a fine-needle aspiration biopsy were excluded. All patients included in this study underwent a CT preoperative of the neck. We used CT rather than cervical ultrasonography, as used by other groups, to investigate the presence of cervical node disease.

The primary objective in this prospective study was to assess the protective role of LSLNB against PTC recurrence. The secondary purpose was to investigate the feasibility of LSLNB. Patient sample size was calculated assuming an enrollment duration of 3 years and an average follow-up of 13 years, an estimated 3-year recurrence rate of 5% in the control group and 2% in the study group, and a type I error of $\alpha = 0.05$ with 80% power. Using these parameters, we calculated that 133 patients in each group were required to support our primary purpose.

From June 2009 to January 2011, 283 patients with PTC were enrolled for this study in the Department of Surgery at the Samsung Medical Center. Patients were assigned randomly to 1 of the 2 groups using a computer-generated randomization code. In total, 141 patients were injected with radioisotope in the LSLNB study group and 142 patients underwent total thyroidectomy or lobectomy and central neck node dissection as a control group. The CONSORT (Consolidated Standards

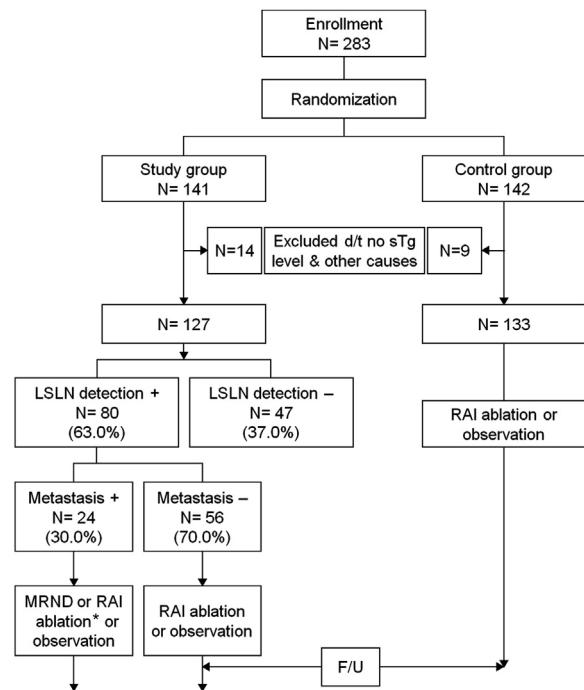


Fig 1. CONSORT diagram showing participant flow through the study. *Patients who had frozen negative and permanent positive metastases in the sentinel; only radioactive iodine (RAI) ablation was performed, without additional modified radical neck dissection (MRND). F/U, Follow-up; LSLN, lateral sentinel lymph node; sTg, stimulated thyroglobulin.

of Reporting Trials) diagram, which describes the patients flow through each step of this preliminary study, is shown in Fig 1. To determine the effect of LSLNB on postoperative sTg levels, we selected patients who had undergone ≥ 2 RAI ablation therapies and had undergone a total thyroidectomy; lobectomy patients were excluded. Among the 283 patients who were enrolled for this randomized, controlled trial, the effects of RAI ablation were only analyzed in 191 patients.

Procedure. On the day of the operation, patients underwent preoperative lymphoscintigraphy after the intratumoral injection of a Tc-99m phytate 1 mCi in 0.1–0.2 mL 0.9% NaCl under ultrasonographic guidance. Total thyroidectomy or lobectomy with central neck dissection preceded SLN detection to avoid interference by primary tumor radioactivity. After total thyroidectomy or lobectomy, the dissections were performed toward the internal jugular chain beneath the sternocleidomastoid muscle. A handheld, collimated gamma probe and lymphoscintigraphy were used to scan the lateral compartments (through skin and under the SCM) for “radioactive” lymph nodes (Fig 2). Removed SLNs were submitted immediately for

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