Long-term Results of Observation vs Prophylactic Selective Level VI Neck Dissection for Papillary Thyroid Carcinoma at a Cancer Center

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**IMPORTANCE** The indication for prophylactic central neck dissection in papillary thyroid cancer (PTC) is controversial.

**OBJECTIVE** To compare long-term results of observation vs prophylactic selective level VI neck dissection for PTC.

**DESIGN, SETTING, AND PARTICIPANTS** We performed a retrospective cohort study of 812 patients with PTC who were treated from January 1, 1996, through January 1, 2007, at the Department of Head and Neck Surgery and Otorhinolaryngology of A. C. Camargo Cancer Center. A group of 580 consecutive patients with previously untreated PTCs and without lymph node metastasis were eligible for the study. We collected and analyzed retrospective data from February 1, 2012, through August 31, 2013.

**INTERVENTIONS** One hundred two patients (group A) underwent total thyroidectomy with elective central neck dissection; 478 patients (group B) underwent total thyroidectomy alone.

**MAIN OUTCOMES AND MEASURES** Absence of difference in rates of locoregional control and rates of major complications in group A.

**RESULTS** In group A, the rate of occult metastatic disease was 67.2%. Patients in group A exhibited higher rates of temporary hypocalcemia (46.1% vs 32.2%; *P* = .004) and permanent hypoparathyroidism (11.8% vs 2.3%; *P* < .001). We also found a significantly higher incidence of temporary (11.8% vs 6.1%; *P* = .04) and permanent (5.9% vs 1.5%; *P* = .02) recurrent laryngeal nerve dysfunction in group A. The overall recurrence rate at level VI was 1.9%.

**CONCLUSIONS AND RELEVANCE** Although the risk for occult lymph node metastasis reached 67.2% in a selected group of patients, elective central neck dissection for patients with PTC increased the risk for complications and did not contribute to a decrease in local recurrence rates.
Papillary carcinoma corresponds to more than 80% of malignant tumors of the thyroid gland. Despite the excellent prognosis associated with this carcinoma, as many as 30% of patients undergoing total thyroidectomy will develop recurrences, most often in the cervical lymph nodes. Lymph node metastases are common, occurring in 20% to 90% of patients. These metastases are located most often in the central compartment and are associated with a higher risk for recurrence. However, for a long time, nodal metastases were not identified among prognostic factors in patients with well-differentiated thyroid carcinomas. Recently, several studies have reported an association between lymph node metastasis and shorter survival, in particular in patients older than 45 years.

Central compartment lymph nodes of the neck (level VI) are considered the first step for lymph node metastasis in papillary thyroid carcinoma (PTC) and include the pretracheal, paratracheal, and delphian lymph nodes. A consensus exists that metastasis, as diagnosed by clinical or imaging examination, demands central compartment dissection. However, the role of prophylactic level VI dissection is a matter of debate. In theory, the advantages of routine lymph node dissection include better results of disease staging (pathologic stage); reduction of the risk for recurrence; reduction of the risk for complications associated with reoperation at level VI; a higher rate of patients with low serum levels of thyroglobulin and anti-thyroglobulin antibodies, which facilitate the tracking; and potentially improved rates of overall survival. Conversely, the disadvantages are related to the potential complications, especially hypoparathyroidism and recurrent laryngeal nerve injury. The present study aims to evaluate the effectiveness of selective indication for prophylactic level VI lymph node dissection in patients with PTC.

Methods

This retrospective cohort study was approved by the Ethics Committee on Research of the A. C. Camargo Cancer Center (agreement 1207/09). From January 1, 1996, through January 1, 2007, 812 patients with thyroid carcinoma were treated at the Department of Head and Neck Surgery and Otorhinolaryngology of A. C. Camargo Cancer Center. Patients eligible for this study included those with PTC that was histologically confirmed (classic or variants) of any T stage (including micro-papillary tumors) and no evidence of lymph node metastases as diagnosed by preoperative imaging or intraoperative findings (cN0). We included those patients who underwent completion thyroidectomy after the initial hemithyroidectomy. Patients undergoing therapeutic lymph node dissection beyond the central compartment were excluded. Based on information from patient medical records, we divided patients into group A, consisting of those who underwent total thyroidectomy associated with elective level VI lymph node dissection (unilateral or bilateral), and group B, including patients who underwent total thyroidectomy alone.

Most operations were performed by third- to fifth-year residents under the direct supervision of an experienced head and neck surgeon. Total thyroidectomy was established as the criterion standard treatment, especially in PTCs larger than 1.0 cm. Elective dissection of the central compartment with total thyroidectomy was not performed routinely but according to the surgeon's discretion, especially in tumors larger than 2.0 cm or in the presence of extrathyroidal extension. Lymphadenectomy was performed according to the standardized technique, which consisted of dissection and isolation of the recurrent laryngeal nerve from the cricothyroid membrane to the sternal notch and from the common carotid artery (lateral limit) to the trachea (medial limit). In the inferior direction, dissection could extend to the level of the innominate artery (level VII). In this procedure, the paratracheal, pretracheal, and delphian lymph nodes were removed. Autotransplant of parathyroid glands was performed if the surgical team deemed it necessary.

Postoperative laryngoscopy was performed within 30 days and repeated when necessary. The rates of recurrent laryngeal nerve dysfunction (temporary or permanent) were compared between the 2 groups. Calcium levels were measured during the first 24 hours and 1 week after surgery, and measurement was repeated if necessary. Supplementation of calcium and calcitriol was instituted only in patients with clinical (symptomatic) and/or hypocalcemia confirmed by laboratory test results and defined by a serum total calcium level of less than 8.0 mg/dL or an ionized calcium level of less than 1.0 mg/dL (to convert to millimoles per liter, multiply by 0.25). Hypoparathyroidism was considered to be established when the patient needed replacement of calcium and calcitriol 6 months after surgery. We recorded all information concerning patients who had a hematoma that required surgical intervention and all postoperative infections (defined by the need for antibiotic therapy).

Whole-body scintigraphy was performed approximately 4 weeks after surgery and in patients with indications for radiiodine ablation therapy. We also performed scintigraphy after ablation therapy. Scintigraphy was repeated in cases with suspected recurrence during follow-up. Basal serum levels of thyroglobulin and antithyroglobulin antibodies were recorded during follow-up and at least every 6 months. The measurement of stimulated thyroglobulin levels became routine at the 1-year follow-up for patients treated near the end of the study period.

Data were collected from February 1, 2012, through January 31, 2013, and analyzed from February 1 through August 31, 2013. We used a frequency distribution to describe categorical variables and used measures of central tendency and variability for numerical or continuous variables. The χ² test assessed the association between categorical variables and study groups (performance of level VI lymph node dissection). When at least 1 expected frequency was less than 5 in 2 × 2 tables, we used the Fisher exact test. When the normality of the data was not identified, we applied the Mann-Whitney test to compare the numerical variables. We adopted the significance level of 5% for all statistical tests and used commercially available software (Intercooled STATA, version 7.0; Stata Corporation) to perform the statistical analysis.
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Original Investigation Research

nodedissection(1.0%).Themead follow-up time was longer in group A (80.2 months) compared to group B (67.4 months; \( P < .001 \)). The overall rates of temporary hypocalcemia and permanent hypoparathyroidism were higher in group A (46.1% vs 32.2%; \( P = .004 \)) and permanent hypoparathyroidism (11.8% vs 2.3%; \( P < .001 \)) than those in group B. In our analysis of patients in group A, no differences in permanent hypoparathyroidism were found between bilateral paratracheal elective neck dissection (3 of 23 patients [13%]) compared with patients who underwent unilateral dissection (9 of 79 patients [11%]). We found a significantly higher incidence of temporary (11.8% vs 6.1%; \( P = .04 \)) and permanent (5.9% vs 1.5%; \( P = .02 \)) recurrent laryngeal nerve dysfunction in group A (Table 2).

Ablative radioiodine treatment was performed in 270 patients, with a mean dose of 133.6 (range, 30-400) mCi (to convert to millibecquerels, multiply by 3.7 × 1010). All patients treated with iodine I 131 in this study underwent a single ablation. More patients in group A underwent this adjuvant treatment (56.9% vs 44.4%; \( P = .03 \)), and the doses were higher in group A (mean, 151.1 vs 129.3 mCi; \( P = .01 \)). In the Figure, the results were stratified between those who underwent radioiodine ablation and those who did not and the profile of recurrence in the respective groups. This analysis did not find any statistically significant differences between groups.

The proportion of cases with elevated thyroglobulin antibody levels during follow-up was equivalent in both groups (9.5% vs 7.7%; \( P = .58 \)). The number of patients with basal serum thyroglobulin levels less than 1.0 ng/mL (to convert to micrograms per liter, multiply by 1.0), measured at 6 months postoperatively, was also comparable (97.8% vs 96.6%; \( P = .75 \)). The percentage of patients with serum levels of stimulated thyroglobulin (using endogenous thyrotropin) less than 1.0 mg/L, measured 1 year after surgery, was similar in both groups (51.5% vs 48.6%; \( P = .82 \)).

After a mean follow-up of 69.7 months, no PTC-related deaths occurred. Recurrences were documented in 11 of the

### Table 1. Characteristics of Patients and Tumors

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Treatment Groupa</th>
<th>Group B (n = 478)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (range)</td>
<td>41.2 (13-75)</td>
<td>45.2 (17-84)</td>
<td>.004b</td>
</tr>
<tr>
<td>≥45</td>
<td>35 (34.3)</td>
<td>231 (48.3)</td>
<td>.01c</td>
</tr>
<tr>
<td>&lt;45</td>
<td>67 (65.7)</td>
<td>247 (51.7)</td>
<td></td>
</tr>
<tr>
<td>Distribution by sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>87</td>
<td>423</td>
<td>.37</td>
</tr>
<tr>
<td>Female</td>
<td>15</td>
<td>55</td>
<td></td>
</tr>
<tr>
<td>Tumor size, mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (range)</td>
<td>14.8 (4-40)</td>
<td>10.2 (1-125)</td>
<td>&lt;.001b</td>
</tr>
<tr>
<td>pT1a</td>
<td>38 (37.3)</td>
<td>290 (60.7)</td>
<td>.03</td>
</tr>
<tr>
<td>pT3-pT4a</td>
<td>19 (18.6)</td>
<td>73 (15.3)</td>
<td>.03</td>
</tr>
<tr>
<td>Adverse histologic variant</td>
<td>8 (7.8)</td>
<td>20 (4.2)</td>
<td>.12</td>
</tr>
<tr>
<td>Multifocality</td>
<td>35 (34.3)</td>
<td>136 (28.5)</td>
<td>.24</td>
</tr>
<tr>
<td>Bilaterality</td>
<td>23 (22.5)</td>
<td>78 (16.3)</td>
<td>.19</td>
</tr>
<tr>
<td>Positive margins</td>
<td>13 (12.7)</td>
<td>47 (9.8)</td>
<td>.38</td>
</tr>
<tr>
<td>Extracapsular extension, extranodal</td>
<td>35 (34.3)</td>
<td>118 (24.7)</td>
<td>.045</td>
</tr>
<tr>
<td>Extrathyroidal extension</td>
<td>20 (19.6)</td>
<td>74 (15.5)</td>
<td>.31</td>
</tr>
<tr>
<td>Associated thyroiditis</td>
<td>45 (44.1)</td>
<td>174 (36.4)</td>
<td>.14</td>
</tr>
<tr>
<td>Lymphatic and/or vascular invasion</td>
<td>11 (10.8)</td>
<td>15 (3.1)</td>
<td>.002c</td>
</tr>
<tr>
<td>Mean follow-up, mo</td>
<td>80.2</td>
<td>67.4</td>
<td>&lt;.001b</td>
</tr>
</tbody>
</table>

Abbreviation: p, pathologic.

a Group A included patients who underwent total thyroidectomy with elective central neck dissection (level VI); group B, patients who underwent total thyroidectomy only. Unless otherwise indicated, data are expressed as number (percentage) of patients.

b Calculated using the Mann-Whitney test.

c Calculated using the Fisher exact test.

### Results

From January 1, 1996, through January 1, 2007, 812 patients underwent surgical treatment for PTC at A. C. Camargo Cancer Center. Of these patients, 580 met the established selection criteria. One hundred two patients underwent total thyroidectomy and elective lymph node dissection of the central compartment (group A). In 23 of these 102 patients (22.5%), the lymph node dissection of the central compartment was bilateral. Total thyroidectomy alone was performed in 478 patients (group B).

The characteristics of the patients and tumors were different between groups. Although patients in group A were younger (mean age, 41.2 vs 45.2 years; \( P = .004 \)), they had larger tumors (mean tumor size, 14.8 vs 10.2 mm; \( P < .001 \)) and more frequent lymphatic and/or vascular invasion (10.8% vs 3.1%; \( P < .001 \)) and extracapsular extension regarding the thyroid nodule (34.3% vs 24.7%; \( P = .04 \)). Patients in group A had a longer mean follow-up (80.2 vs 67.4 months; \( P < .001 \)), they had larger lymph nodes (mean number of lymph nodes removed in group A was 6.8 (range, 5-49). Results of the pathologic examination in group A showed metastasis in 64 cases (62.7%).

The rates of surgical site infection and postoperative hematoma that required surgical reexploration were comparable. Patients in group A had 1 or more parathyroid glands removed during thyroidectomy more frequently than those in group B (35.3% vs 13.4%; \( P < .001 \)). The overall rates of temporary hypocalcemia and permanent hypoparathyroidism were 34.7% and 4.0%, respectively. Patients in group A showed higher rates of temporary hypocalcemia (46.1% vs 32.2%; \( P = .004 \)) and permanent hypoparathyroidism (11.8% vs 2.3%; \( P < .001 \)) than those in group B. In our analysis of patients in group A, no differences in permanent hypoparathyroidism were found between bilateral paratracheal elective neck dissection (3 of 23 patients [13%]) compared with patients who underwent unilateral dissection (9 of 79 patients [11%]). We found a significantly higher incidence of temporary (11.8% vs 6.1%; \( P = .04 \)) and permanent (5.9% vs 1.5%; \( P = .02 \)) recurrent laryngeal nerve dysfunction in group A (Table 2).

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After a mean follow-up of 69.7 months, no PTC-related deaths occurred. Recurrences were documented in 11 of the
The central compartment of the neck (level VI) is bounded superiorly by the hyoid bone, inferiorly by the superior border of the sternal manubrium, and laterally by the common carotid arteries. This compartment consists of the parathyroid and the pretracheal, paratracheal, and delphian lymph nodes. The compartment continues inferiorly to the superior mediastinum (level VII) and to the level of the innominate artery. Elective lymph node dissection of the central compartment of the neck in patients with PTC is defined as a complete excision of the level VI lymph nodes in patients without evidence of regional metastasis after clinical and preoperative ultrasonography beyond the intraoperative evaluation.

Lymph node metastases of PTC can be diagnosed in rare cases by clinical examination or preoperative ultrasonography. Most metastases are diagnosed during surgical exploration and are treated using a therapeutic indication for lymph node dissection. In such cases, lymph node dissection is associated with lower recurrence rates and better survival. However, the role of elective lymph node dissection of the central compartment remains a controversial topic. Despite the growing interest in prophylactic lymph node dissection of the central compartment, a routine indication remains questionable owing to the lack of demonstrated benefit in terms of reduced rates of tumor recurrence and mortality. Zetoune et al examined 1264 patients, and results of a meta-analysis showed no significant decrease in the rate of local recurrence after prophylactic lymph node dissection of the central compartment. No randomized prospective studies have analyzed the impact of prophylactic lymph node dissection on recurrence and survival rates in patients with PTC.
dissection of the central compartment in terms of the overall and recurrence-free survival rates. The best evidence in support of this phenomenon comes from a population-based prospective study that demonstrated a reduction in cancer-specific mortality of 8.4% to 11.1% in controls and 1.6% in the group undergoing an elective lymph node dissection of the central compartment.19 However, most studies and retrospective cohorts,6,33-38 including a meta-analysis,37 suggest no benefit. In our series, after a mean follow-up of 69.7 months, the rate of recurrence in the central compartment in patients who did not undergo an elective lymph node dissection was only 0.4%.

Lower levels of thyroglobulin before and after radioiodine ablation have been considered excellent markers of disease remission and predictors of disease-free survival.39-40 Sywak et al41 postulate that prophylactic lymph node dissection of the central compartment provides greater clearance of thyroid tissue and metastatic lymph nodes, which reduces postoperative levels of thyroglobulin. This effect could simplify the monitoring of these patients, thereby reducing the need for adjuvant radioiodine therapy and complementary examinations during follow-up. However, according to other authors,42 at 6 months after ablation, levels of thyroglobulin become comparable between patients who do and do not undergo the prophylactic dissection, which can be explained by the destruction of residual thyroid and micrometastases by radioiodine treatment. In the present study, we found no difference in the levels of nonstimulated thyroglobulin before or 6 months after radioiodine treatment. The levels of antithyroglobulin antibodies were also comparable between the groups.

Lymph node metastases in the central compartment are frequent, even in micropapillary carcinomas (tumors <1.0 cm), and are found in as many as 46.5% of patients.43-46 Knowledge of lymph node status and accuracy of staging are important in the choice of adjuvant treatment and follow-up of these patients, especially those who are older than 45 years. Patients with histologically proved lymph node metastases may experience migration from stages I and II to stage III disease according to the TNM classification,47 assuming an intermediate risk for recurrence according to the American Thyroid Association.21 Several authors20-33,48-49 postulate that elective dissection of the central compartment could provide an upstaging of disease, with important implications for treatment planning. These patients are classified as a group at high risk for recurrence and are treated with greater doses of radioiodine and undergo more frequent reevaluations during follow-up. Moreover, according to Shinoda et al,26 patients older than 45 years have larger tumors, with a greater propensity for regional metastasis and poorer response to radioiodine therapy, justifying the more aggressive treatment in this group. So et al50 examined 551 patients with papillary microcarcinoma who underwent total thyroidectomy and prophylactic lymph node dissection of the central compartment and showed that male sex, multifocality, and extrathyroidal extension are the main predictors of regional lymph node spread in a multivariate analysis. In the present study, the decision whether to perform the central compartment dissection was based on the risk for lymph node metastases, and no increased risk for recurrence was associated with age. This fact should be emphasized because more patients in group A underwent radioiodine ablation (56.9% vs 44.4%; P = .03) and received a higher mean dose (151.1 vs 129.3 mCi; P = .01).

Elective lymph node dissection of the central compartment is the best staging procedure for the detection of micrometastatic disease, but the relevance of subclinical lymph node disease, in terms of recurrence and survival, has been questioned in retrospective studies.35 Moreover, other authors51,52 suggest that prophylactic lymph node dissection of level VI may be waived in patients with indications for postthyroidectomy radioiodine ablation. The results of the present study tend to support this proposal in view of the low risk for recurrence observed in patients who did not undergo elective lymph node dissection.

When the central compartment dissection is performed as salvage surgery after lymph node recurrence, rates of permanent hypoparathyroidism and nerve damage are increased (≤25% of patients).53-59 Such findings may suggest a more aggressive approach in the first surgery to avoid surgical reexploration of level VI. In our series, all 4 cases of recurrence observed in patients undergoing total thyroidectomy and elective level VI dissection occurred exclusively in the lateral lymph node chains (levels II to V) of the neck.

The principal argument against elective lymph node dissection of the central compartment is the increased risk for complications, even when the operation has been performed by experienced surgeons. The high risk for complications observed in this study and in a previous publication60 was also confirmed by other authors.29,37,64-69 Again, no prospective randomized trials have addressed this issue. Most studies, including a meta-analysis with 1132 patients,64 suggest a higher rate of transient hypocalcemia in patients undergoing elective neck dissection but similar rates of permanent hypoparathyroidism and recurrent laryngeal nerve injury.17,18,29,41,64-69 Giordano et al61 reviewed data from 1087 patients treated for papillary carcinoma and demonstrated a higher rate of permanent hypoparathyroidism associated with bilateral, paratracheal, elective neck dissection compared with patients who underwent unilateral dissection or thyroidectomy alone (46.2%, 7.0%, and 6.3%, respectively; P < .001). In the present study, 23 of the 102 patients in group A (22.5%) underwent bilateral level VI lymph node dissection. Infection rates and postoperative hematoma requiring surgical reexplanation were comparable to those of the group undergoing total thyroidectomy alone, in agreement with the published data of other authors.39,37,64 However, rates of permanent hypoparathyroidism, temporary hypocalcemia, and permanent damage to and temporary dysfunction of the recurrent laryngeal nerve were significantly higher in group A. Further evaluation compared the complications among those who underwent unilateral vs bilateral central neck dissection. The only variable that showed statistically significant differences was the rate of transient hypocalcemia, which was higher in the group undergoing bilateral central neck dissection (P = .02). Regarding definitive hypocalcemia, this study demonstrated a higher rate of permanent hypoparathyroidism associated with bilateral, paratracheal, elective neck dissection compared with patients who underwent unilateral dissection or thyroidectomy alone (13.0%, 11.0%, and 2.6%; P = .04). Recently, Viola et al70 performed a pro-
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Despite the high risk for regional metastases, papillary carcinoma remains a disease with an excellent prognosis. Even with the finding of micrometastases in 61% of cases, several authors have reported very low rates of recurrence in patients undergoing elective lymph node dissection of the central compartment (0%-0.43%) and in those undergoing isolated thyroidectomy (0%-0.65%). After a mean follow-up of 69.7 months, we observed no deaths related to the disease, and only 11 of 580 patients (1.9%) developed tumor recurrence; most of these recurrences (10 of 11) were in the neck. We must highlight the possibility that selection bias (specifically, the disproportionate numbers of patients with T1a tumors in the group that did not undergo neck dissection) might play a role in this sample.

**Conclusions**

The evidence-based guidelines from the National Comprehensive Cancer Network do not support the routine use of lymph node dissection of the central compartment in patients treated for PTC. In its latest review, the American Thyroid Association recommends dissection selectively in patients with tumors larger than 4.0 cm or with extrathyroidal extension. Although the present study has a number of limitations, such as the retrospective nature and the bias of the therapeutic decision of each surgeon, our results support these guidelines and do not confirm the need for elective dissection in most cases. Therefore, a good assessment with preoperative ultrasonography is highly recommended, especially in patients at low risk, to ensure that gross disease is not left behind. The real impact of elective lymph node dissection of the central compartment in the management of PTC must be evaluated by a randomized prospective study with patients at higher risk for lymph node recurrence.

**ARTICLE INFORMATION**

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Author Contributions: Drs de Carvalho and Chulam had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: de Carvalho, Kowalski.

Acquisition, analysis, or interpretation of data: de Carvalho, Chulam.

Drafting of the manuscript: de Carvalho, Kowalski.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: de Carvalho, Chulam.

Obtained funding: de Carvalho.

Administrative, technical, or material support: All authors.

Study supervision: de Carvalho, Kowalski.

Conflict of Interest Disclosures: None reported.

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REFERENCES


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