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ORIGINAL ARTICLE

The application of carbon nanoparticles in the lymph node biopsy of cN0 papillary thyroid carcinoma: A randomized controlled clinical trial

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KEYWORDS

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Summary Objective: We applied carbon nanoparticle suspensions to the papillary thyroid carcinoma cases with no clinical regional lymph node metastasis (cN0) to show the lymph flow from primary tumors, and evaluated its value in the lymph node biopsy of cN0 papillary thyroid carcinoma and protection of parathyroid.

Patients and methods: One hundred and fourteen patients with cN0 papillary thyroid carcinoma were randomly assigned to experimental and control groups. The experimental group received carbon nanoparticles injection around the primary tumor, while the control group received no injection. Both groups subsequently received standard lateral thyroid gland resection, isthmus resection, subtotal thyroidectomy, or clearance of lymph nodes (LNs) of the central compartment.

Results: A total of 342 LNs of the central compartment were dissected in the experimental group (6.00 ± 0.98 per patient) with 81 LNs confirmed to be positive (0.95 ± 0.77 per patient), whereas 261 LNs of the same area were dissected in the control group (4.58 ± 0.60 per patient) with 27 confirmed to be positive (0.47 ± 0.50 per patient). There is a significant difference between experimental and control groups in the average number of LNs dissected per patient (6.00 ± 0.98 vs. 4.58 ± 0.60 , $p < 0.001$) but not the positive LNs per patient (0.95 ± 0.77 vs. 0.47 ± 0.50 , $p = 0.11$). Parathyroid was found in two patients from the experimental group and in seven patients in the control group ($p = 0.29$). Three patients in the experimental group and seven patients in the control group had hypocalcemia ($p = 0.21$), and four patients in each

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group had hoarseness ($p = 0.58$).

Conclusions: Carbon nanoparticle suspensions can be used to stain central lymph nodes of cN0 papillary thyroid carcinoma without staining of parathyroid and leakage, and improve the resection of LNs.

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1. Introduction

Thyroid cancer is a common type of malignant cancer in the head and neck area. Most thyroid cancer cases are differentiated thyroid carcinoma, including papillary thyroid carcinoma (PTC) and follicular thyroid carcinoma, with PTC accounting for 60–70% of cases. With improved health status and detection technology, PTC with no clinical regional lymph node metastasis (cN0) becomes increasingly common, making it important to improve the treatment of this disease.

Surgery is the most popular treatment choice of PTC, with complete resection of the lateral thyroid gland, isthmus, and subtotal thyroidectomy. The current consensus treatment for patients with positive cervical lymph node (LN) and LN metastasis is complete resection of the tumor and cervical LNs. However, whether this treatment is necessary for cN0 PTC is still disputable.¹ It was reported that 40% to 60% of LNs resected could be positive, supporting the need for complete removal of all cervical LNs to prevent the risk of cancer recurrence and treatment failure.^{2,3}

With technical improvements, the focus of thyroid surgery is gradually changing from the protection of recurrent laryngeal nerve injury to protection of the parathyroid. Parathyroid is located on the inside lobes of the thyroid, and its number is variable. The position of the superior parathyroid is relatively stable and easy to preserve *in situ* during surgery. On the contrary, the location of the inferior parathyroid can be varied and accidentally removed as LNs during central LNs dissection. It was reported that 6.9% to 46% of thyroid surgery resulted in parathyroid damage.⁴ In light of this, the best practice is to preserve the parathyroid during thyroid surgery to avoid damage to parathyroid functions.⁵

Carbon nanoparticles suspensions (CNS) injection has been applied as a new LN biopsy tracer with high specificity for the lymph system. Compared with traditional dye, carbon nanoparticles (CNs) have the advantages of a long retention time in the lymph system, low toxicity, and exclusion from blood circulation. Moreover, CNs usually do not stain the parathyroid, providing better demarcation of the parathyroid. The CNs in tissue can be subsequently removed together with the thyroid tissue and LNs, while the remaining CNs are captured by macrophages and excreted through the lungs, kidneys, and intestines after a few months.⁶ Further, CNs do not interfere with pathological examination of stained tissue because they can not be detected with optical microscopy due to their small size.

Here we carried out a random controlled study of the application of CNS to cN0 papillary thyroid carcinoma surgery. Patients with cN0 papillary thyroid carcinoma treated at our hospital were randomly assigned to control and experimental groups. Patients in the experimental group were injected with CNS while patients in the control group received no injection. The amount of LNs, positive LNs, parathyroid, pre- and post-operative serum parathyroid hormone, pre- and post-operative serum calcium, and the number of patients with hypocalcemia and postoperative hoarseness were statistically analyzed between experimental and control groups. The value of CNS in sentinel LN biopsy and protection of the parathyroid in cN0 papillary thyroid carcinoma surgery was evaluated.

2. Patients and methods

2.1. Patients

One hundred fourteen patients with cN0 papillary thyroid carcinoma who sought treatment at our hospital between September 1, 2013 and August 31, 2014 were included in this study, including nine men and 105 women (16–60 years of age). This study was approved by the Institutional Review Board of Jinling Hospital. All patients were informed of the approach and risk of this treatment and signed the consent. Patients were randomly assigned into experimental and control groups.

Patients who met the following criteria were recruited: (1) diagnosis of papillary thyroid carcinoma by ultrasound guided fine needle aspiration; (2) meet cN0 stage standard (no clinical regional LN metastasis and no LNs larger than 1 cm detected using imaging); (3) no history of thyroid surgery or neck irradiation; (4) no hypocalcemia or numbness or spasms of limbs; (5) surgery was performed by the same group of surgeons; and (6) no sign of blood coagulation dysfunction.

2.2. Imaging agents

CNS was purchased from Chongqing Lummy Pharmaceutical Co. Ltd. (China) under the name Carbon Nanoparticle Suspension Injection.

2.3. Surgical procedure

All patients received the same surgical procedure. An incision was made through the skin and the platysma. Flap separation was performed before making an incision in the

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