Study Protocol

Comparison Between the Axillary Bilateral-breast Approach (ABBA) and Bilateral Axillo-breast Approach (BABA) for Robotic Thyroidectomy (NCT02768753) April 30,2017

Objective

To compare the therapeuic effcts between the axillary bilateral-breast approach (ABBA) and bilateral axillo-breast approach (BABA) for robotic thyroidectom. To explore the efficacy, safety, cosmetic results and clinical value by the two approaches

Criteria

Inclusion Criteria: The initial surgery;preoperative needle aspiration biopsy of thyroid cancer, and the diameter of no more than 1cm, no lateral neck lymph node metastasis;the tumor is confined to the thyroid membrane, not invading trachea and recurrent laryngeal nerve;intraoperative frozen section diagnosis of thyroid cancer;the patient informed consent.

Exclusion Criteria : High-frequency ultrasound preoperative tumor diameter greater than 1cm, or lateral neck lymph node metastasis in patients;there had been a history of thyroid surgery or neck radiation therapy;pregnant or lactating women;with severe Hashimoto's thyroiditis, thyroid volume greater than II°;coagulation disorders,hyperthyroidism or hypothyroidism patients;sternal goiter.

Methods

All patients were dived into two groups randomly. According to the standard of surgey, the 60 patients who have been diagnosed with thyroid cancer are numbered. The random number is even assigned ABBA group(n = 30) and the random number is odd assigned BABA (n = 30). All patients were operated on by the same surgical team through the da Vinci robotic surgical system use method of circular mobilization. After the operation, the number of resected lymph nodes, intraoperative blood loss, postoperative pain scores 24h, catheterization time, the time of drainage, Swallowing Evaluation , Subjective Voice , operative time, postoperative hospital stay, cosmetic results satisfaction, recurrent laryngeal nerve injury and hypoparathyroidism and other related complications were compared between groups. The patients were

followed up for 3~22 months.

Data management and statistical analysis:

SPSS 22.0.0 software was used for statistics. The measurement data were used to describe the average number of standard deviation; the ratio / rate of counting data was calculated; the measured data between the two groups were compared with the paired t test; the rate of the two groups was compared with the chi square test. The difference was statistically significant in p<0.05.