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Original Article

Reduced incidence of postoperative symptoms following a novel bilateral supraclavicular approach to open thyroidectomy: a randomized clinical trial in a Chinese population

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Abstract: Transient postoperative symptoms, including pain, swelling, unnatural feelings during cervical movements, and incision adhesion formation are common in patients after open thyroidectomy, especially in those with bilateral lesions. Therefore, we proposed a new bilateral supraclavicular approach to reduce such complications, and compared it with the conventional transcervical approach to verify its safety and efficacy. Forty-four patients were recruited and randomized into either a conventional transcervical group (CT) or a bilateral supraclavicular (BS) group. Surgically-related variables, duration of postoperative symptoms, and incision adhesion formation status were recorded and evaluated. There were no statistically significance differences in sex, age, extent of surgery, pathological type, intraoperative blood loss, and operation duration between the two groups. The BS group had a slightly longer total incision length, but exhibited a significantly shorter period of postoperative symptoms (P=0.012) and lower risk for adhesion formation (P=0.035 in the 1st month, P=0.047 in the 10th month) compared to the CT group. In conclusion, the bilateral supraclavicular approach is a safe and effective method for reducing postoperative symptoms and adhesion formation in patients with bilateral thyroid lesions.

Keywords: Thyroidectomy, bilateral, supraclavicular, postoperative symptoms, adhesion formation, clinical trial

Introduction

Thyroid nodules are common clinical problems. While most nodules are benign, surgery is an important and effective method of treatment. Importantly, the incidence of severe surgery-associated complications, such as laryngeal nerve and parathyroid injury, has greatly decreased in recent years. However, transient postoperative symptoms including voice, swallowing, and sensory impairments are often inevitable, even after an uncomplicated thyroidectomy [1-3]. Additionally, most patients suffer from incision adhesion formation after conventional open thyroidectomy, which manifests as swallowing discomfort and a pulling sensation during neck extension [4]. These postoperative symptoms are often overlooked by clinicians, but they can greatly impair quality of life without effective prevention and treatment. Cosmetic considerations are another important concern associated with thyroid surgery. Patients often complain about the scar that is exposed on the neck following conventional surgery. Thus, developing a complication-free and cosmetically-satisfactory surgical method is of vital clinical value.

After reviewing published literature, three main surgical approaches were identified based on the location of the incision: (1) The transcervical approach is a generally adopted and effective traditional method for different kinds of thyroid surgeries, but results in a long and distinct scar lying on the central cervical region. Postoperative symptoms are ubiquitous and inevitable with this method [1-3]. (2) The lateral mini-incision approach, also known as Minimally Invasive Thyroid Surgery (MITS), accompanies the incision directly in front of the thyroid nod-

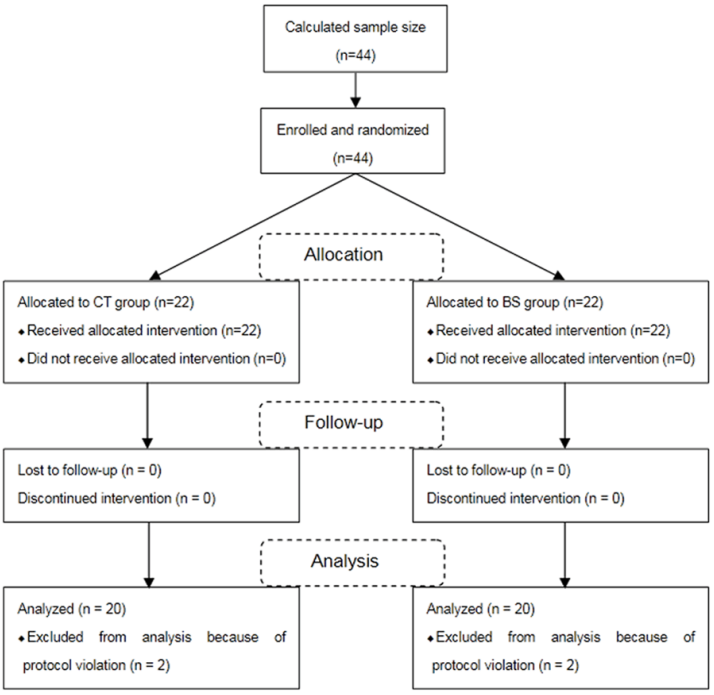

Figure 1. Flowchart of the study. CT, conventional transcervical group. BS, bilateral supraclavicular group.

ule. Thus, the lesion can be removed using the shortest route with minimal invasion of the surrounding tissues. Advantages of using lateral mini-incision have been further highlighted by Miccoli et al. who combined this approach with endoscopy and developed the Minimally Invasive Video-assisted Thyroidectomy (MIVAT) technique [5]. (3) Endoscopic extracervical approaches, such as the axilla, breast, chest wall or a combination of approaches have been used since 1997 [6]. Although the excellent cosmetic outcome with no scar on the neck is appealing, the strict indications, expensive equipment, and emerging complications restrict their application [7-10]. In reality, this is a cosmetic surgery rather than a minimally invasive surgery.

The lateral mini-incision approach is most suitable for benign nodules since it is easily adaptable and minimally invasive. To achieve a better esthetic result, Yang [11] and Chen et al [12] modified the location of the incision by moving it to the supraclavicular compartment, so it can be hidden under a collar or by neck ornaments. However, it is intractable to deal with contralateral lesions in the same incision. Therefore, we proposed a new bilateral supraclavicular approach to address bilateral lesions with two independent incisions. Intact central cervical compartment alleviated postoperative symptoms and incision adhesion formation. A prospective randomized open method was approved to evaluate the efficacy and safety of this approach compared to the conventional method.

Material and methods

Patient selection

Patients with bilateral thyroid nodules were included in this study. They were consecutively and randomly assigned to either the conventional transcervical group (CT) or the bilateral supraclavicular group (BS), according to a permuted-block randomization method. After considering the alpha and beta error, power of the test, and dropout rate, 22 patients were included in each group. This study was approved by the clinical ethical committee of 1st Affiliated Hospital of Wenzhou Medical University, Zhejiang, China, and written informed consent was obtained from each patient. **Figure 1** shows the flowchart of the study.

Inclusion criteria were: 1) patients aged 20-70 years with bilateral thyroid nodules <4 cm in diameter, requiring surgical intervention; and 2) benign diseases or nodules with indeterminate fine-needle aspiration cytology, but with esthetic impact, oppression symptoms, or heavy psychological burden. Exclusion criteria were: 1) malignant diseases; 2) patients with indications for isthmectomy; 3) history of neck surgery; or 4) pregnancy, severe chronic diseases, or laryngeal or vocal fold diseases.

Surgical procedure

For the CT group, a 4-6 cm long incision was made horizontally about one finger above the sternal notch. The platysmal muscle was transected, and a subplatysmal flap was created. The linea alba cervicalis was incised, and strap muscles were elevated and retracted bilaterally after blunt longitudinal division. As a result, the

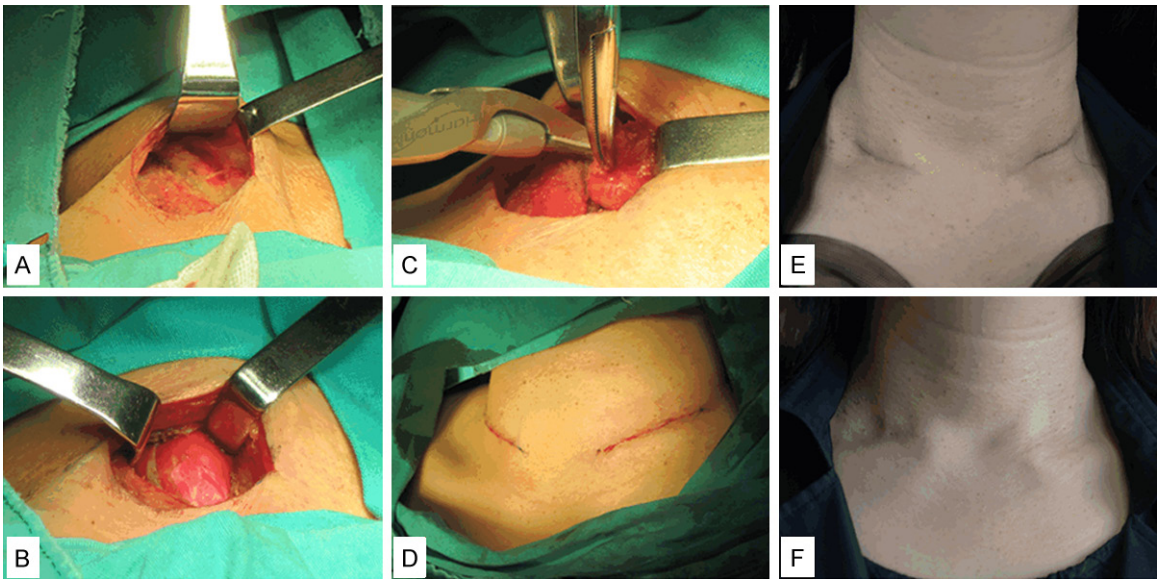

Figure 2. The supraclavicular approach and postoperative skin changes. Two symmetrical incisions were designed. On each side, the incision was about 2 cm away from the sternoclavicular joint, 3-4 cm long, and parallel with the clavicle at the outer edge of the sternocleidomastoid (D). A subplatysmal flap was created (A). The strap muscles were cut longitudinally and retracted, thereby exposing the lower outer side of the thyroid (B). The ipsilateral lesions were manipulated after slightly blunt division to reveal the whole lobe or isthmus, as necessary (C). Postoperative skin changes in the cervical area were assessed and recorded at the 1 month (E) and 10 months (F).

Table 1. Questionnaire used to evaluate transient postoperative symptoms

items	scores
1. How much discomfort do you have in anterior neck at rest?	( )
2. How much discomfort do you have in swallowing saliva or speaking?	( )
3. How much discomfort do you have in neck extension?	( )

Each item was scored from 0 to 5 with increasing uncomfortable feelings.

whole thyroid gland was exposed, and subsequent partial, subtotal, or total lobectomy was conducted.

For the BS group, we performed two symmetrical incisions. On each side, the incision was about 2 cm away from the sternoclavicular joint, 3-4 cm long, and parallel with the clavicle at the outer edge of the sternocleidomastoid. A subplatysmal flap was created. The strap muscles were cut longitudinally and retracted, thereby exposing the lower outer side of the thyroid. The ipsilateral lesions were manipulated after slightly blunt division to reveal the whole lobe or isthmus, as necessary (**Figure 2A-D**).

All surgical procedures were performed under general anesthesia by the same group of surgeons. The recurrent laryngeal nerve was routinely identified and protected. An ultrasonic scalpel was used to excise the thyroid gland.

Follow-up and assessment

Incision length, intraoperative blood loss, extent of surgery, and operation duration were recorded. Intraoperative blood loss was roughly estimated by the quantity of gauze soaked with blood. The extent of surgery was evaluated from a total score calculated by considering partial lobectomy as 1 point, subtotal lobectomy as 2 points, and total lobectomy as 3 points, on each side.

Transient postoperative symptoms were assessed by a three-item questionnaire with a visual analog scale (0, no discomfort; 5, worst discomfort) (**Table 1**). Patients were asked to fill in their scores every day before breakfast for

Table 2. Neck Adhesion Score for postoperative adhesion formation

Items	Scores		
	1	2	4
Symptoms	No discomfort	Uncomfortable feelings	Difficulty in swallowing*
Signs	No skin retraction	Skin retraction only	Skin retraction and pulling**

Symptoms and signs were assessed in the anterior neck around the incision. *Difficulty in swallowing was defined as an obvious pulling or blocked sensation in swallowing saliva, water, or food. **Pulling was defined as an unnatural movement of the skin when swallowing, speaking, or during neck extension.

Table 3. Clinical characteristics and perioperative variables of enrolled patients

Characteristics	CT (n=20)	BS (n=20)	*p*-value
Gender (Male/Female)	2/18	3/17	0.500
Age (yr), mean ± SD (range)	52.0±11.77 (26-66)	50.6±10.18 (32-65)	0.690
Extent of surgery (Scores)			0.236
2	9	6	-
3-5	8	10	-
6	3	4	-
Pathological type			0.774
Nodular goiter	9	7	-
Hashimoto disease	2	2	-
Follicular adenoma	2	1	-
Mixture of benign lesions	7	10	-
Total incision length (cm)	5.3±0.52	7.7±0.62	<0.001*
Intraoperative blood loss (piece)	1.6±0.35	1.5±0.39	0.643
Operation duration (min)	56.8±11.27	59.6±7.38	0.361

*P<0.05. CT, conventional transcervical group. BS, bilateral supraclavicular group.

two weeks after surgery. No symptoms were present when all the scores were <2. The outcomes were used to calculate the duration of cervical discomfort.

Incision adhesion formation was measured at 1 month and 10 months after surgery, according to a Neck Adhesion Score (NAS) (**Table 2**) that assesses symptoms and signs on a scale of 2 (minimum) to 8 (maximum), a method similar to previous publications [4, 13, 14]. To improve the accuracy of the classification, each score was converted to one of three levels: no adhesion (<3), potential adhesion (3), and obvious adhesion (>3). All the variables were assessed by one experienced surgeon.

Statistical analyses

Statistical analyses were performed with the per-protocol population using IBM SPSS Statistic v19.0 (IBM Co., Armonk, NY, USA). Continuous variables were expressed as the mean ± standard deviation, and compared using the independent t-test or the Mann-Whitney U-test. Unordered categorical variables were tested using the Pearson Chi-Square test, and ordinal categorical variables were tested using the Mann-Whitney U-test. The Kaplan-Meier method was used to compare transient postoperative symptoms between the two groups. The Mann-Whitney U-test was used to compare postoperative adhesion formation at each time point. Reported *P* values are 2-tailed, and P<0.05 were considered statistically significant.

Results

44 patients were recruited for this study; 4 patients were excluded because they required isthmus removal. A total 20 patients were assigned to each group in the per-protocol population. No laryngeal nerve injury or other severe complications were observed postoperatively. Clinical characteristics, including sex, age, extent of surgery, and pathological type were not statistically different between the two

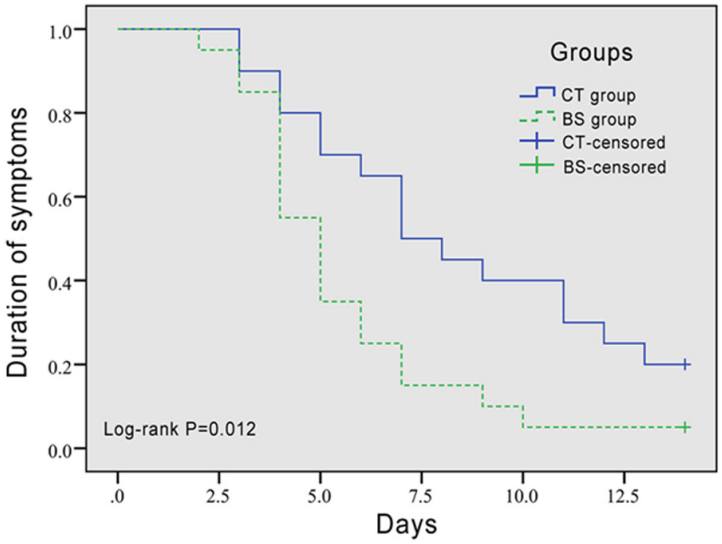

Figure 3. Kaplan-Meier analysis of transient postoperative symptoms. Postoperative symptoms persisted for approximately one week in most subjects. The bilateral supraclavicular group (BS) exhibited a decreased duration of postoperative symptoms compared to the conventional transcervical group (CT) within two weeks after operation (Log-rank, *P*=0.012).

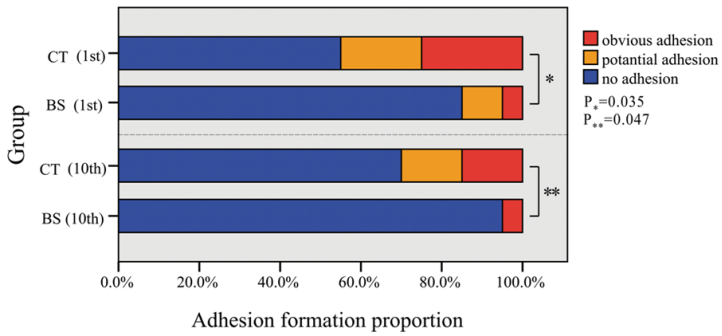

Figure 4. Postoperative adhesion formation at the 1 month and 10 months after surgery. The bilateral supraclavicular group (BS) had a lower risk for adhesion formation at each time point compared to the conventional transcervical group (CT) (*P*=0.035 and *P*=0.047).

groups. The BS group had a longer total incision length as compared to the CT group, but there were no statistically significant differences in intraoperative blood loss and operation duration between the two groups (**Table 3**). All the patients left the hospital on the 3rd or 4th day after surgery.

Transient postoperative symptoms

Postoperative symptoms persisted for approximately one week in most subjects, with a median of 7 days in the CT group and 5.5 days in the BS group. 4 patients (20%) in the CT group and 1 patient (5%) in the BS group complained of discomfort associated with postoperative symptoms when they submitted their questionnaires. Using the Kaplan-Meier analysis, we found that the BS group exhibited a decreased duration of postoperative symptoms compared to the CT group (Log-Rank, *P*=0.012) (**Figure 3**).

Incision adhesion formation

At the end of first month, 45% of patients in the CT group experienced postoperative adhesion formation; 25% exhibited obvious adhesions and 20% exhibited potential adhesions. 5% of patients in the BS group experienced obvious postoperative adhesion formation and 10% of patients experienced potential postoperative adhesion formation. Obvious and potential postoperative adhesion formation decreased by 10% and 5% at 10 months in the CT group and 0% and 10% in the BS group, respectively. The BS group showed a lower risk for adhesion formation at each time point as compared to the CT group (*P*=0.035 and *P*=0.047) (**Figure 4**).

Discussion

The unilateral supraclavicular approach provides satisfactory cosmetic outcomes after open thyroidectomy [11]. However, this supraclavicular approach is not suitable for bilateral lesions, as further dissection and rough retraction is required to access the contralateral lobe. Therefore, we introduced a novel bilateral supraclavicular approach for bilateral lesions. Two incisions were made, and each was designed only for manipulating the ipsilateral lesion.

Transient postoperative symptoms and incision adhesion formation after thyroid surgery are the most common short-term and long-term complications, respectively. The incidence of these complications was significantly reduced

with our novel bilateral supraclavicular approach compared to the traditional transcervical approach, and patients maintained normal voice and swallowing functions. We used the Kaplan-Meier method to evaluate transient postoperative symptoms based on duration rather than using a direct comparison of scores between subjects; therefore, individual differences were reduced through a latent self-control. Similarly, we converted incision adhesion formation data to three levels to eliminate measurement inaccuracy. Transient postoperative symptoms following thyroid surgery are mainly caused by surgical trauma and are usually nonspecific, but the movement of the larynx and pharynx make them overt and afflictive. The bilateral supraclavicular approach resulted in a more comfortable postoperative state compared to the traditional transcervical approach, which greatly contributed to therapy compliance and postoperative recovery. Incision adhesion formation is a dynamic process. A peak was expected to occur between 1 month and 10 months following surgery, and in most patients, adhesion formation related symptoms began to dissipate after 10 months. In our analysis, the differences between patients treated with the bilateral supraclavicular approach and the traditional transcervical approach were more obvious in the early stage when adhesion formation was severe. This indicated that our new approach might provide a great benefit to patients with higher risk for adhesion.

The protective effects of the bilateral supraclavicular approach are as follows: First, cervical movements in the lateral part above the clavicle are much gentler and less frequent than the middle region. Naturally, patients treated with the supraclavicular approach have less discomfort when speaking or swallowing compared to those treated with the traditional transcervical approach, although they experience similar surgical trauma. Second, it appears to be important to keep the linea alba cervicalis, consisting of the investing fascia and pretracheal fascia, and the potential tissue spaces between them undisturbed. Different layers of fascia tend to knit together after surgical separation [15]. Meanwhile, swelling in the anterior neck is greatly alleviated when the local superficial jugular vein and lymph vessels are well preserved. Third, sensory nerves can be better protected during the bilateral supraclavicular approach compared to the traditional transcervical approach, a factor that may be attributed to innervation by the cervical plexus. Fourth, the supraclavicular approach is safer than the traditional transcervical approach, since the trachea cannot be directly compressed if a hematoma occurs.

We analyzed the disadvantages of our novel method. Although an additional incision and a slightly longer total incision were introduced, internal surgical trauma was not increased with the bilateral supraclavicular approach compared to the traditional transcervical approach. On the contrary, there were fewer complications associated with surgery, and subjects were satisfied with the cosmetic result. The incisions were flatter with less adhesion formation and could be well hidden. Another potential disadvantage was the operation time, which may increase with the need for two incisions; however, no significant difference between the bilateral supraclavicular approach and the traditional transcervical approach was revealed in this study. Of note, no drain was used in both groups, since the drainage of foreign matter may facilitate adhesion formation, and it seemed unnecessary to provide a drain after uncomplicated thyroid surgery with scrupulous hemostasis [16-18].

The bilateral supraclavicular approach was initially designed for benign diseases without isthmus removal or neck dissection, both of which increase risk for adhesion formation because the central cervical compartment is destroyed. Therefore, a per-protocol population was used in our primary analysis, and 4 patients that underwent isthmus removal were excluded. Considering the potential bias in population selection, we also analyzed the intention-to-treat population. No significant changes were observed between the two populations, indicating that isthmus removal may not be a restriction. Of note, our method would provide successful completion of a total thyroidectomy or neck dissection. As the bilateral supraclavicular approach involves definite exposure of the lower part of the thyroid, this approach is not suitable for the treatment of large tumors on the upper side of the thyroid due to the narrow surgical view.

This study was associated with some limitations. First, no blinding method could be applied because both the surgeons and patients can

distinguish which surgical approach is conducted through the external incisions. Second, the study included a relatively small sample size and potentially, a larger sample size may provide more detailed information. We justified the size using a formula that estimated an adhesion formation rate of 0.25 and 0.70 in the experimental and control groups, respectively. Finally, endpoint measurements were affected by subjective perception. Although we used the scoring system to make our assessment more objective and quantifiable, confounders, such as variations in individual sensitivity and endurance of postoperative symptoms, were unavoidable.

Conclusion

Our study revealed that the bilateral supraclavicular approach is a safe and practical method for thyroidectomy. Compared with conventional methods, it is a better choice for patients with bilateral benign nodules. The bilateral supraclavicular approach has efficacy in reducing the transient postoperative symptoms and incision adhesion formation associated with thyroid surgery and provides satisfactory cosmetic results.

Disclosure of conflict of interest

None.

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