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Original Research

Intra-capsular total thyroid enucleation versus total thyroidectomy in treatment of benign multinodular goiter. A prospective randomized controlled clinical trial

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HIGHLIGHTS

- Intracapsular Total thyroid enucleation technique is safe with the least serious complications.
- No recurrence reported after this technique.
- The technique still not radical so couldn't be used in suspicious cases for malignancy.

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ABSTRACT

Background: Due to high recurrence rate after subtotal thyroidectomy, most of centers have shifted to total thyroidectomy as a surgical treatment for benign multinodular goiter (BMNG), but serious complications, as laryngeal nerve affection & hypocalcaemia, are still present. This study aimed to evaluate treatment of BMNG using intra-capsular total thyroid enucleation in comparison to standard total thyroidectomy.

Patients &methods: This is a prospective randomized controlled clinical trial conducted in a hospital in the period from December 2009 to December 2015. Of total 224 patients with clinically BMNG. 112 patients operated by intracapsular total thyroid enucleation (ITTE group) and the other 112 patients operated by standard total thyroidectomy (STT group). The minimal follow up period was 36 months.

Results: The mean operative time in ITTE group was (93.7 ± 9.6 min) compared to (86.9 ± 8.3 min) in STT group. Transient recurrent laryngeal nerve (RLN) palsy was 0% in ITTE group VS 7.1% in STT group. No cases (0%) developed permanent RLN palsy in ITTE group VS 0.9% in STT group. Symptomatic transient hypocalcaemia occurred in 1.8% in ITTE group VS 11.6% in STT group. No cases (0%) developed permanent hypocalcaemia in ITTE group VS 0.9% in STT group. No recurrence (0%) in both groups after minimal 3 years of follow up.

Conclusion: Intracapsular Total thyroid enucleation technique is safe with the least serious complications, especially RLN injury and hypoparathyroidism, with no recurrence, but this technique still not radical so couldn't be used in suspicious cases for malignancy.

1. Introduction

The goal of surgical management of benign multinodular goiter (BMNG) should be to remove the pathology with a low complication rate and to minimize the recurrence [1]. Recent meta-analysis of retrospective studies have shown that subtotal thyroidectomy for bilateral multinodular goiter has apparently high recurrence rates (30–50%), as usually there is no normal thyroid tissue in patients with BMNG. The recurrence requires redo surgery; with increased risk of recurrent laryngeal nerves (RLN) and parathyroid glands damage up to 20 folds [2,3]. In the 1970s the standard approach to the thyroid gland disease was to identify the RLN in the tracheo-oesophageal groove (lateral dissection), the nerve then dissected throughout its whole length to the cricopharyngeus removing all tissue medial to it with attempt to preserve the vascular supply to parathyroid glands, but parathyroid glands and

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RLN are at risk of injury, so the thyroid surgeons recently have shifted from lateral dissection to more medial dissection (capsular dissection) in total thyroidectomy especially for benign disease with ligation of tertiary branches of inferior thyroid artery on the surface of the thyroid capsule trying to minimize the injury to RLN or parathyroid [4]. In this study we aimed to evaluate the intracapsular total thyroid enucleation technique as a treatment for BMNG, where the dissection is shifted not only from lateral to medial but it kept within the thyroid capsule.

2. Material and methods

This study is a prospective randomized controlled trial (the flow chart of the clinical trial is shown in Fig. 4), conducted at an institute in Egypt between December 2009 and December 2015. From total 425 patients attended to our outpatients' clinics, we included patients that had clinical and ultrasound picture of benign multinodular goiter. Patients that had suspicious finding of malignancy, recurrent cases, unfit patients for surgery and patient that refuse to share in the study were excluded (but managed as consistent with each case but not included in the study). 224 patients with BMNG enrolled in the study, all of them underwent open total thyroidectomy by the same surgeon in the 1st 2 years of the study. Using computer generated numbers and sealed nontransparent envelops, patients were randomly assigned to 2 equal groups. Group 1: in which intracapsular total thyroid enucleation (ITTE) was done. Group 2: in which standard total thyroidectomy (STT) was done. All included patients underwent clinical examination, thyroid ultrasonography (US), thyroid hormonal profile and preoperative laryngoscopy. Data collected included gender, age, preoperative diagnosis (simple or toxic nodular goiter) preoperative total serum calcium level, operative time (from skin incision till the end of wound closure). The postoperative parameters included the serum calcium level (mg/dl), postoperative RLN status and recurrence state. All patients with toxic goiter were prepared for surgery by antithyroid drugs and beta-blockers. The protocol of this study approved by the ethical committee of our institution. All the patients gave their informed written consent to be included in this study.

2.1. Operative technique of intracapsular total thyroid enucleation

All steps of the procedure were done as usual standard way for thyroid surgery till the superior vessels were dissected and selectively ligated then the middle and inferior thyroid veins were ligated, leaving the inferior thyroid artery. Then fine vertical incision, with small scalpel (size 11), was done at the junction between the lateral one third and medial two thirds of the thyroid lobe, the capsule was clamped with small mosquito clamps and reflected laterally (Fig. 1).

Thyroid lobe was enucleated from the capsule and dissected from lateral to medial using bipolar diathermy for dissection and to control branches of inferior thyroid artery within the capsule without affection of parathyroid blood supply and away from recurrent laryngeal nerve. Dissection continued until separation of the lobe and isthmus from trachea. The other lobe then delivered and enucleated from the capsule in the same way. At the end, the complete gland was enucleated leaving only part of the capsule behind (Fig. 2). In some cases the capsule was torn with difficulty to separate it as one sheet but it was not a major problem and we continued dissection within its clamped remnant. Hemostasis was ensured and the remnant capsule and fascia (Fig. 3) closed together at the midline or to the pretraheal fascia by 4/0 vicryl continuous suture. A suction drain was inserted. Strap muscles, platysma and skin were closed with absorbable suture. The specimen sent for histopathological study.

2.2. Definitions and postoperative management

Serum calcium level measured on the same day of the surgery and then twice daily for 3 days. Temporary hypocalcaemia was defined as serum calcium level less than 8.0 mg/dL in at least 2 consecutive samples. If it was asymptomatic and resolved within days without vitamin D or calcium supplementation here it was described as mild temporary hypocalcaemia (not significant). While if symptoms of hypocalcaemia were present and the patient received vitamin D with or without calcium and the condition resolved in less than 6 months, hypocalcaemia here described as sever (significant) but still defined as temporary hypocalcaemia. If vitamin D and calcium supplementation required for more than six months to control symptoms; here hypocalcaemia was defined to be permanent. Temporary RLN palsy was defined as hoarseness of the voice, with or without dyspnea, and immobility of vocal cord at laryngoscopy that improved in less than 6 months postoperative. However, permanent RLN palsy was defined if the condition continued more than six months [3].

Before discharge, laryngoscopy and Otolaryngologist consultation for all patients was done. In all patients L-thyroxine was begun within five days postoperative. The 1st follow-up visit was one month postoperative then At 6 and 12 months. All patients evaluated as regard the motility of vocal cord, hormonal replacement, hypocalcaemia and recurrence. This was done by clinical examination, serum calcium level, neck US and thyroid hormones level. While in Patients with severe or permanent hypocalcaemia the

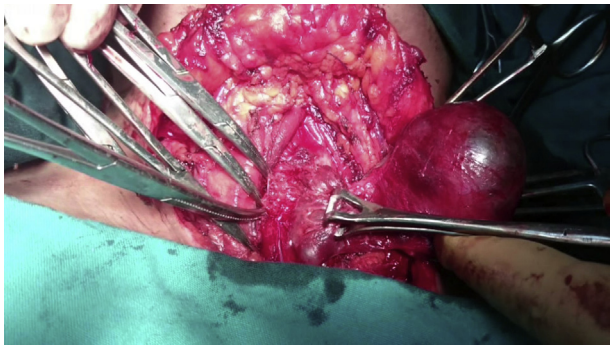

Fig. 1. The capsule of the gland is incised and clamped by mosquitos and retracted laterally to begin intracapsular thyroid enucleation.

Fig. 2. The thyroid specimen after intracapsular thyroidectomy.