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Original Research Article

Total thyroidectomy: conventional suture ligation technique versus sutureless techniques

Mahmoud N. M. Ali*, Ahmed Abdelkahaar Aldardeer, Ayman M. A. Ali, Alaa A. Radwan

Department of General Surgery, Sohag Faculty of Medicine, Sohag University, Sohag, Egypt

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***Correspondence:**
Dr. Mahmoud N. M. Ali,
E-mail: nmahmoud624@yahoo.com

ABSTRACT

Background: Since the introduction of successful thyroidectomy no change occurred in the technique but with the innovation of sutureless surgery, sutureless thyroidectomy becomes a competitor for the conventional technique. In this study we tried to analyze the outcomes of each.
Methods: This was a prospective cross armed uncontrolled randomized study included 65 patients suffering from non-malignant goiter who underwent total thyroidectomy, admitted to Sohag University Hospital from September 2017 to October 2018. Patients were randomly allocated into two groups; Group (S) managed with sutureless thyroidectomy, and Group (C) managed with conventional knot tying technique. The data of the patients were gathered and analyzed considering the operative and post-operative outcomes. All patients were followed-up for 6 -12 months.
Results: We found a significantly shorter operative time (p=0.001), also the amount of intra-operative blood loss was highly significant less in Group S (p=0.001). There was higher incidence of post-operative pain in Group C (p<0.001), post-operative drainage volume was highly significantly less in Group S (p=0.001). Regarding post-operative complications; the incidence of recurrent laryngeal nerve paralysis (RLNP) was insignificant between both groups (p=0.38), in the same time the incidence post-operative transient hypocalcaemia was significantly more in Group C (P=0.025). The overall post-operative complication rate was significantly more in Group C (p=0.002). The duration of hospital stay was highly significant shorter in Group S (p=0.0001).
Conclusions: The use of Harmonic FOCUS® is beneficial for both patient and surgeon; it is efficient and a trustable safe substitute to the conventional knot tying technique.

Keywords: Thyroidectomy, Harmonic focus, Hemostasis

INTRODUCTION

Kocher and Billroth have founded the basics of successful thyroid surgery in the nineteenth century, while it was plagued with more than 40% mortality because of bleeding as it is the second highly vascular organ in the body and respiratory morbidities.[1] It consisted of identification and ligation of thyroid vessels and securing laryngeal nerves, and parathyroid glands.[2,3]

Thyroidectomy technique is the same till now, and the instruments are the same but the changes affect only the methods of hemostasis.[4]

Hemostasis during thyroidectomy is achieved classically with suture ligation, or electrocautery. Suture ligation is time taking, tedious and technically demanding especially in this small operative field close to important structures.[5,6] Also there is a risk of knot slippage

occurring in 0.3% to 2% of cases leading to fatal outcome and re-exploration prolonging hospital stay and overall cost.[7,8] Although electrocautery is fast yet it has the drawback of lateral thermal damage which limits its use.[9]

As the technology advanced, a new technique has been introduced; sutureless thyroidectomy using hemostatic devices like Harmonic Scalpel (HS) (Ethicon endo-surgery, Inc., USA) which provides bloodless field and low complication rates.[8,10] HS uses vibration rather than emitting heat at 55,000 Hz which disrupts hydrogen bonds of proteins leading to its rupture, and because the temperature induced is mild (80^{o}C) in comparison with electrocautery and water in tissue does not boil, the proteoglycans and collagen fibers in the tissue become denatured and mix with the intracellular and interstitial fluids to form a glue-like substance (coagulum), which seals the 5 mm vessels providing hemostasis, equivalent to electrocautery, and simultaneously cut tissues.[11]

Sutureless thyroidectomy avoids leaving foreign bodies in the patient's body thus eliminating its complications, decreases the incidence of knot slippage, reduces the operative time by using one instrument in dissection, hemostasis, and cutting of tissues thus reducing patient's exposure to anesthesia, efficient in hemostasis decreasing intra-operative blood loss and safe, reducing post-operative drainage volume, provide a clean surgical field, and showed greater capability of grasping delicate tissues,[1,11-13] provides precise and safer dissection near vital structures due to minimal lateral thermal tissue injury, a smaller incision can be used in thyroid surgery using HS, provides smoke-less surgery, no electrical energy to or through patient, less charring, desiccation, and tissue sticking and no neuromuscular stimulation when compared to electrocautery, increases the utility of the operating rooms, means that more patients can be managed, decreases post-operative use of analgesics in comparison to conventional technique, decreases the incidence of post-operative hypocalcemia, decreases the incidence of lymphorrea caused by dissection and ligations allowing shortening of the hospital stay, and decreases the costs collectively.[13-19] In the meantime, post-operative thyroid specimens excised by HS are easily evaluated histopathologically.[20]

But it has its own disadvantages including the cost of device and availability limitations in some areas.[21] Also, their effectiveness in achieving hemostasis remains limited by the vessel size, and the risk of damage to adjacent structures cannot be completely eliminated.[22]

A number of researchers reported the superiority of HS in comparison to the conventional knot tying method in thyroid surgery through randomized controlled trials.[23] Still any new technology should be subjected to trial to ascertain its efficacy and safety before its publicization.

Aim of the work

Our study aimed to compare sutureless thyroidectomy technique by Harmonic FOCUS® versus knot tying technique in total thyroidectomy regarding efficacy and safety.

METHODS

This was a prospective cross arm uncontrolled randomized study analyzing outcomes of conventional knot tying versus sutureless technique for total thyroidectomy at Sohag University Hospital, from September 2017 to October 2018 with follow-up till April 2019 on 65 patients admitted electively with a diagnosis of non-malignant goiter. Only patients who were treated with total thyroidectomy were included in the study. We excluded patients <25 years, patients with retrosternal extension, patients with previous neck irradiation, patients with vocal cord dysfunction, patients with hypocalcemia, patients with recurrent goiter, patients received hemithyoidectomy or subtotal thyroidectomy, and patients with coagulopathies.

This study was performed after approval granted by the Institutional Medical and Ethics Committee. Written and informed consent was taken from all patients enrolled into the study. Patients were subjected to complete pre-operative clinical evaluation to assess the nature of goiter. Pre-operative investigations concentrating on thyroid hormones when indicated and serum calcium. Pre-operative radiological assessment included neck ultrasound, chest plain x-ray and abdominal ultrasound. In addition vocal cord examination was routinely done. Finally pre-operative fine needle aspiration cytology was conducted.

The included patients were divided randomly by the closed envelop method into two groups; Group S (Sutureless thyroidectomy group) and Group C (Conventional knot tying thyroidectomy group).

Both techniques were conducted under endotracheal general anesthesia. Patients were placed in supine position with adducted upper limbs, supported by a small pillow placed between the scapulae and the neck was hyperextended. A small low collar skin crease incision was made. Platysmal flaps were raised and dissected using electrocautery. Superior flap sutured to the chin.

Cautery was then used to dissect the strap muscles till trachea or isthmus through the linea alba of the neck then they were retracted laterally. Hemostasis was done as following; firstly the middle thyroid vein was clamped with Harmonic FOCUS® (Harmonic Focus, Ethicon Endo-Surgery, Inc, Cincinnati, OH, USA) or ligated by "clip, cut and tie" technique according to the study protocol. Then the same process was applied for the superior and inferior thyroid poles. The superior thyroid vessels were divided close to the gland to avoid damage to the external laryngeal nerve (Figure 1). The thyroid lobe was then rotated medially and the vessels in the ligament of Berry were then sealed and divided. In both techniques the RLN was identified and preserved bilaterally and the same was applied for the parathyroid

glands (Figure 2). If there was a question about the blood supply of glands they were autotransplanted in the sternocleidomastoid muscle during the same secession. Similar steps were applied also for the other lobe.

Only vessels with diameter of 5mm or smaller were divided using Harmonic FOCUS®. Harmonic FOCUS® was not used if important structures lie at close proximity i.e. 3 mm or nearer to the site, but we applied knots instead. For closure of and division of superior and inferior thyroid arteries and veins we set the instrument at a power 2 i.e. more coagulation. And when smaller vessels like capsular veins we set it to the level 5 i.e. more cutting.

After completion of thyroidectomy in both techniques, 2 suction drains were inserted into the thyroid bed and skin sutured. Drains removed if the drainage was less than 30 ml.

All patients received NSAID injection for pain relief. All the excised specimens were subjected to histopathologic examination.

The main outcome measures were recorded and analyzed in both groups; the operative time, intra-operative blood loss, post-operative pain, post-operative drainage volume, post-operative wound infection, seroma, serum calcium, transient or permanent hypocalcaemia, post-operative RLNP and length of hospital stay.

Serum Calcium level was measured at first post-operative day (to detect asymptomatic hypocalcaemia), and 48 hours post-operative and discontinued if normal. If necessary an oral calcium supplement was prescribed.

Patients were discharged after removal of the drains, in patients without post-operative complication. Oral antibiotic coverage was recommended after discharge.

Follow-up was scheduled on post-operative day 7, and then at 1 month, 3 months, 6 months and 1 year in outpatient clinic. At follow-up, thyroid hormones and serum calcium levels were measured, and post-operative laryngoscopy was performed within 4 weeks after surgery in all patients to evaluate vocal cord function.

Statistical analysis of the data was performed using the SPSS (IBM SPSS version 18 program for Windows (SPSS Inc, Chicago, IL)). Qualitative data were expressed as number and percentages, and quantitative data were expressed as mean and SD. Categorical variables were described using frequency distributions. For comparison of means in quantitative variables, a Student *t*-test was used. Survival time was calculated from the time of operation and estimated by using the Kaplan-Meier method. The cutoff for significance of all used statistical analyses was rated as $p \leq 0.05$, $p=0.001$ was rated as highly significant, and $p>0.05$ was rated as not significant.

RESULTS

This study included 65 patients experienced total thyroidectomy for non-malignant goiters. Patients were classified into two groups; Sutureless total thyroidectomy group (Group S); included 30 patients (46.2%) and Conventional knot tying total thyroidectomy group (Group C) comprised 35 patients (53.8%). Both groups were comparable regarding the preoperative variables. Patient demographics are listed in Table 1.

Regarding the operative outcomes; operative time was shorter in Group S; this difference was highly significant (p=0.001). In the same time, the amount of intraoperative blood loss was highly significant less in Group S (p=0.001) (Table 2).

Table 1: Patients' demographics and preoperative data in both groups.

	Group S	Group C	P value
	N (%)	N (%)	
	30 (46.2)	35 (53.8)	
Gender			
Female	26 (86.66)	30 (85.7)	0.582
Male	4 (13.34)	5 (14.3)	
Occupation			
Employee	4 (13.3)	4 (11.4)	0.582
House wives	14 (46.7)	14 (40)	0.879
Manual workers	1 (3.3)	0 (0)	0.534
Not working	9 (30)	14 (40)	0.667
Students	2 (6.7)	3 (8.6)	0.321
Co-morbidities			
Diabetes Mellitus	3 (10)	5 (14.2)	0.874
Hypertension	7 (23.33)	8 (22.9)	0.756
Cardiac	3 (10)	3 (8.57)	0.987
Renal	1 (3.33)	1 (2.85)	0.832

Continued.

	Group S	Group C	P value
	N (%)	N (%)	
	30 (46.2)	35 (53.8)	
Indications for surgery			
Multinodular goiter	25 (83)	30 (85.7)	0.087
Secondary toxic goiter	3 (10)	2 (5.7)	0.709
Primary toxic goiter	2 (7)	3 (8.6)	0.764
Preoperative thyroid function			
Euthyroid	24 (80)	30 (85.7)	0.362
Hyperthyroid	5 (16.66)	5 (14.28)	0.257
Hypothyroid	1 (3.33)	0 (0.0)	0.624

Table 2: Operative and post-operative outcomes in both groups.

Parameter	Group S	Group C	P value
	N (%)	N (%)	
	30 (46.2)	35 (53.8)	
Operative time (min) Mean±SD	55.40±7.894	108.14±11.186	0.001
Intraoperative blood loss (ml) Mean±SD	33.07±5.753	75.09±15.417	0.001
Post-operative pain in the 1st post-operative day			
Need for 1 ampoule of NSAIDS	30 (100)	35 (100)	0.879
Need for 2 ampoules NSAIDS	15 (50)	30 (85.7)	0.001
Need > 2 ampoules	2 (6.7)	10 (28.6)	0.039
Reactionary hemorrhage			
Yes	0	1 (2.85)	0.876
No	30	34 (97.14)	0.743
Post-operative seroma			
Yes	1 (3.33)	3 (8.57)	0.745
No	29 (96.6)	32 (9142)	0.653
Wound infection			
Yes	0 (0)	3 (8.57)	0.335
No	30	32 (91.42)	0.765
Post-operative drainage volume (ml) Mean±SD	19.30±4.442	47.49±12.125	0.001
RLNP			
Yes			
Unilateral	0 (0)	2 (5.72)	0.38
Bilateral	0 (0)	1 (2.85)	0.543
No	30 (100)	32 (91.43)	0.812
Post-operative hypocalcaemia			
Yes			
Transient	1 (3.33)	6 (17.14)	0.025
Permanent	0 (0)	2 (5.72)	0.485
No	29 (96.67)	27 (77.14)	0.213
Reoperation rate			
Yes	0 (0)	1 (2.85)	0.078
No	30 (100)	34 (97.14)	0.654
Overall complication rate	2 (6.7)	18 (51.4)	0.002
Duration of hospital stay (days) Mean±SD	1.97±0.183	4.31±1.795	0.001

Post-operative wound pain during the first day which was reflected as a need for analgesics; non-steroidal anti-inflammatory drugs (NSAIDs), it showed an equal need for one ampule NSAIDs administration in all patients of each group and was non-significant (p=0.879). While there was highly significant more need for two ampoules

during the first day in Group C in 30 patients (85.79%) than in Group S in 15 patients (50%) (p=0.001). In the same time there was a need for >2 ampules administration in Group C; 10 patients (28.6%) than in Group S; 2 patients (6.7%) (p=0.039) (Table 2).

Regarding early post-operative complications, although reactionary hemorrhage did not occur in any patient of Group S, it occurred in only one patient (2.85%) in Group C. This parameter was non-significant, p=0.876 (Table 2). Post-operative seroma, developed in 3 patients (8.57%) of Group C compared to one patient (3.33%) in Group S, p=0.745 (Table 2). Although superficial wound infection happened in 3 patients (4.61%) from Group C, and none in Group S, it was non-significant, p=0.335 (Table 2). Post-operative drainage volume was highly significantly less in favor of Group S compared to Group C, p=0.001 (Table 2). RLNP was only seen in 3 patients (8.57%) of Group C; 2 patients (5.72%) with unilateral RLNP, and one patient (2.85%) with bilateral RLNP, while it was not seen in Group S, this parameter was non-significant, p=0.38 (Table 2).

Meanwhile post-operative transient hypocalcaemia developed in 7 patients, one patient (3.33%) in Group S, and 6 patients (17.14%) in Group C, p value was significant (p=0.025). And only 2 patients (5.72%) from Group C developed post-operative permanent hypocalcaemia, while there was not any in Group S (0%), p value was not significant (p=0.485) (Table 2). Regarding the reoperation rate, only one patient (2.85%) in group C was re-operated who developed post-operative reactionary hemorrhage and there was not any of Group S, p=0.078 (Table 2).

So, the overall post-operative complication rate was 2 patients (6.7%) in Group S, and 18 patients (51.4%) in Group C, this difference was significantly more in Group C, p=0.002.

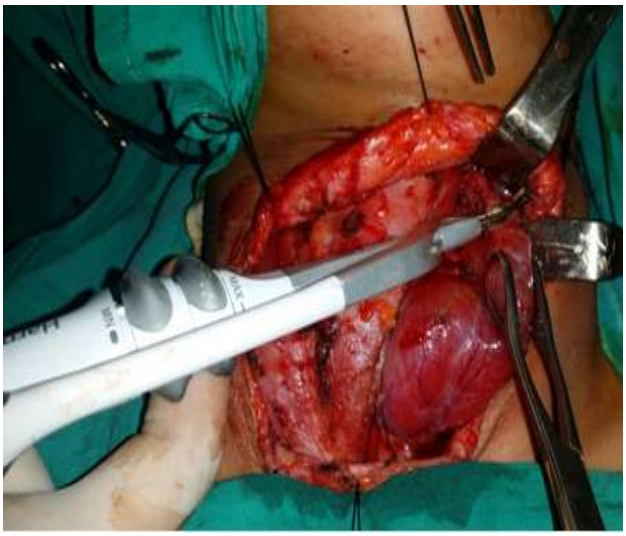

Figure 1: Total thyroidectomy with Harmonic FOCUS®.

Figure 2: Sutureless thyroidectomy with harmonic FOCUS® with preservation of parathyroid gland.

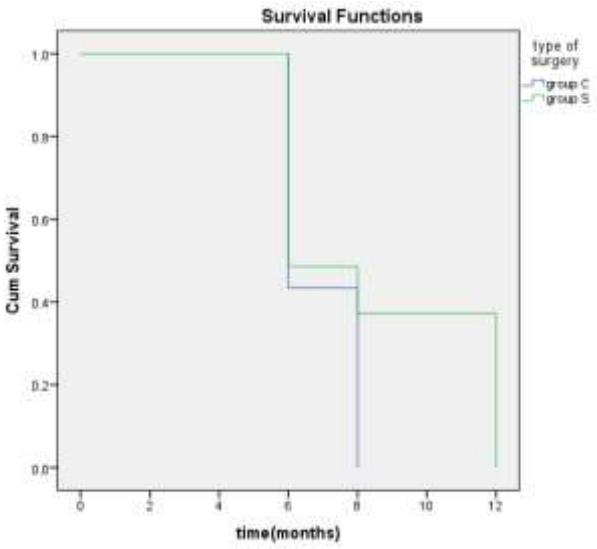

Figure 3: Kaplan- Meier' estimates curves (survival rate) type 1 (Group C), type 2 (Group S). It shows that there was no mortality in our study in the period of post-operative follow up (from 6 to 12 months).

The mean duration of hospital stay was shorter in Group S (1.97±0.183 days) than Group C (1.97±0.183 days); this difference was highly significant (p=0.001) (Table 2).

During follow-up there was not any mortality in-between both groups (Table 2). For overall survival rate, Kaplan-Meier' estimates curves are represented in Figure 3.

DISCUSSION

Since the evolution of sutureless surgery, era of bloodless surgery, the use of HS constitutes a major advance in hemostasis. Sutureless thyroidectomy has been practiced widely and proved its efficacy; providing good hemostasis in a rather highly vascular surgical field and better safety than the conventional knot tying technique.[11]

There is a saturation of evidences that suggest the superiority of sutureless thyroidectomy compared to the conventional knot tying technique.[11,12,22]

In the conventional knot tying thyroidectomy technique, much time is expended in many knots add to this the question of safety when these knots slip. Also, time is lost in the change of instruments; about 50 instruments. Shorter operative time with the use of Harmonic FOCUS® is taken as it is used for dissection, hemostasis, and cutting. So, saves time of suturing, clipping, and cutting in conventional knot tying thyroidectomy. In our study, the use of Harmonic FOCUS® significantly decreased the operative time compared with conventional knot tying technique in a matter of 50% less, ($p<0.001$), which was also reported by other studies.[24] In the same time, there was a significant decrease in blood loss with the use of Harmonic FOCUS® equals to 44%. This comes in accordance with the others who proved significantly less blood loss with the use of HS.[1]

More than reduction of the operative time, many literatures confirm that the use of HS is associated with less post-operative drainage volume, our study showed a significant reduction equal to 60% in favor of the Harmonic FOCUS® group, which reflects better homeostasis, and this was in line with other studies.[8,25] Meanwhile the incidence of post-operative pain was significantly less in the Harmonic FOCUS® group similar to previous studies, which can be explained by less muscle traction due to less operative time and the smaller incision used.[22]

Seroma is an annoying sequel for both surgeon and patient with multiple visits and causes great patient's discomfort with increased possibility of post-operative infection.[26] In comparison to electrocautery, HS showed that it produces smaller volumes of pro-inflammatory cytokines; which evoke seroma formation, and accordingly significant reduction of post-operative seroma formation.[27] Also the simultaneous cut and hemostasis mechanism of HS decreases the incidence of lymphorrea occurring with electrocautery.[19]

Total thyroidectomy requires consideration of the proximity of the recurrent laryngeal nerve and the parathyroid glands to the thyroid gland to avoid their injury either directly or by thermal spread of hemostatic devices which mandates good exposure of these structures and bloodless field.[6] An important advantage of the Harmonic FOCUS® is the limited thermal injury to 2 mm beyond the tissue grasped by the forceps of the instrument.[28] The rate of transient and permanent RLN injury after thyroid surgery is 4% to 7% and 1% to 4%.[29] Also, the incidence of nerve paralysis is 3 to 4 times greater in patients where the nerve was not exposed than in patients where was routinely exposed, so the importance of identification during thyroidectomy.[30] Although some studies reported an increased risk of transient vocal cord paresis with the use of Harmonic FOCUS® compared with conventional techniques,[31] in our study we did not meet any patient with post-operative RLNP as we adopted the policy of applying knots in dealing with bleeding near RLN or the parathyroid glands.[32] Also we used the Harmonic FOCUS® at a maximal power 3 in dissection near these important structures to render it completely safe.[33] Our study showed that the incidence of post-operative RLN injury is not significant ($p=0.38$).

One of the important complications of total thyroidectomy is hypoparathyroidism with an incidence of transient hypoparathyroidism varying from 5-15% and permanent hypoparathyroidism incidence of 5%.[34] Temporary asymptomatic hypoparathyroidism can be as frequent as 63%.[35] Hypoparathyroidism during thyroidectomy may occur due to impairment of its circulation, direct injury, or inadvertent excision of the parathyroid gland.[36] Following the hypothesis of Emam et al seems that the less heat produced by the HS lead to decreased risk of impaired vascularity in the parathyroid glands and accordingly significantly less incidence of post-operative hypoparathyroidism ($p=0.025$) which is in line with other studies.[22,23,33] This indicates that HS reduce the risk of inadvertently damaging blood vessels when identifying in situ parathyroid glands for preservation during total thyroidectomy making it superior to other conventional hemostatic techniques regarding post-operative complications especially post-operative hypoparathyroidism.[37] This makes the use of HS safe in thyroid surgery with no increase in complication rates.[23,38]

One of the disadvantages of the use of Harmonic FOCUS® is the high expense of the device but it can be reused, furtherly this should be weighed with the reduction of the operative time, operating team time, operating room occupancy with more surgeries can be performed in the same operative session with better utilization of health resources and reduction of the waiting list, reduction of the anesthesia costs, pain medication, nursing time, morbidity treatment, redo surgeries, hospital stay, and eliminates the cost of sutures, accordingly decreasing the overall hospital costs which are evident with the use of Harmonic FOCUS®.[8,12,39,40] In our study the Harmonic FOCUS® group had significantly shorter hospital stay, $p=0.002$, which was due to the reduction in overall complications in this group, a similar result to that got by others.[8,14] The pitfall of a shortened length of hospital stay in the HS group was that there was a possibility of overlooking cases of symptomatic hypocalcaemia which may develop within 48 hours post-thyroidectomy.[41]

We can conclude that the use of Harmonic FOCUS® is beneficial for the surgeon and patient; reducing both intra and post-operative morbidities, reducing the operative time, hospital stay in a better significant parameters and can be a trustable safe substitute to the conventional knot tying technique.

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