

Suture-less Thyroidectomy Using Harmonic Scalpel versus Conventional Thyroidectomy: A Randomized Controlled Trial

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ABSTRACT

BACKGROUND: The conventional thyroidectomy using knot and tie leads to increased operative time and bleeding but with the advent of harmonic scalpel (HS), which cuts and coagulates the tissues at the same time using a mechanical energy, has significantly decreased the operative time and bleeding. This study assessed to compare the mean operative time and mean post-operative bleeding time in sutureless thyroidectomy using harmonic scalpel with conventional thyroidectomy.

METHODS: We conducted a randomized controlled trial at the surgical unit of the Shifa International Hospital and Shifa College of Medicine, Islamabad. Both male and female patients with age of ≥ 18 years were enrolled in the study. During the period of 6 months, 160 patients were divided equally in HS group (n=80) and conventional thyroidectomy group (n=80) respectively. Patients were enrolled in the study after obtaining informed consent. Patients with re-do thyroidectomies, retrosternal goiter, concomitant neck dissections and known coagulopathies were

excluded from trial. The mean operative time and mean post-operative blood loss was recorded.

RESULTS: During the six months period (March to August 2014), 160 patients were randomized into two equal groups (n= 80). Of 160 patients with multinodular goiter, 134 (83.8%) were females and 22 (16.2%) were males. The age ranged from 18 to 61 years in both groups with mean age in group A of 42 years (SD=9) and group B of 43 years (SD =9.8). The mean operative time in HS thyroidectomy (Group A) was 76 minutes (SD=9) and conventional thyroidectomy was 116 minutes (SD=16); difference between two groups =40 minutes (P<0.001). The mean post-operative bleeding in HS thyroidectomy was significantly lower as compared to the conventional thyroidectomy group (18.2 ml vs.76.0 ml, P< 0.001).

CONCLUSION: Mean operative time and mean post-operative bleeding in thyroidectomy with HS was less as compared to conventional thyroidectomy.

Keywords: Conventional thyroidectomy; Harmonic scalpel; Knot and tie

INTRODUCTION

About 20 million Pakistanis live in endemic areas for thyroid disorders [1]. For thyroid disorders; one modality of treatment is surgery which is offered in the form of lobectomy, subtotal thyroidectomy, and total thyroidectomy. Surgery is often needed for toxic adenoma, endemic multinodular goiter with pressure symptoms, toxic diffuse or multinodular goiter not responding to medical therapy and for suspicious

or confirmed malignancy [2]. Subtotal and total thyroidectomy are time consuming tasks that require careful dissection and meticulous hemostasis to avoid per operative blood loss, recurrent laryngeal nerve injury, life threatening post-operative hematoma formation leading to air way obstruction and hypocalcemia [3]. Hemostasis is secured during conventional thyroidectomy by applying clips then dividing and ligating the vessels using a suture material which is time consuming [4]. In spite of

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meticulous dissection, good suturing technique and use of proper suture material, there is a risk of slippage of ligature leading to re-exploration of the operative field which in turn increases morbidity, hospital stay and total cost [3, 4].

With the advancement in technology, a new technique has been adopted world over, so called sutureless thyroidectomy. This technique uses modern hemostatic devices such as Harmonic Scalpel (Ethicon endo-surgery, Inc., USA) and Ligasure (Valleylab Inc., Colorado, USA) [4, 5]. The harmonic scalpel (HS) is a very useful device for the surgeon because it is hand friendly, safe and effective in terms of good hemostatic results, clean surgical field, greater capability of grasping delicate tissues, reduced operative time, and less post-operative bleeding and complications [6]. HS has two blades, one is static and the other vibrates at a high frequency of 55000 hertz and divides the tissue. This mechanical action, takes place at a lower temperature of 80°Celsius as compared to diathermy and also cause less collateral damage by heat dissipation [6].

One study found a significant difference in the mean operative time and the mean post-operative drainage at 24 hours between the HS group and the conventional group. The mean operative time was 44.9 minutes and 69.5 minutes in HS and conventional group respectively ($p < 0.001$) and mean post-operative drainage was 37.4 ml and 56.1 ml respectively ($p < 0.001$) [7]. With the use of HS the mean operative time was reduced by 15 % to 20%. In a similar study decreased mean operative time was evident in the smaller thyroid glands, a finding important in our regional context and questioning HS utility in our patients as most of the patients present late and with large sized thyroid glands [8]. HS has been recently introduced in Pakistan and is not used as frequently due to financial constraints, lack of regional studies and large-size thyroid glands. The studies have shown variable results in terms of operative time and post-operative drainage when both surgical techniques are compared. We aimed to compare sutureless thyroidectomy with conventional thyroidectomy.

For our study, we defined sutureless thyroidectomy as a surgery in which division of all the vascular pedicles were performed using a HS which cuts and coagulates the vessels at the same time. We defined conventional thyroidectomy as a thyroidectomy in which surgery is performed using conventional method of clip, cut and ligation using Vicryl 2.0 and Vicryl 3.0.

METHODS

We conducted a randomized controlled trial at the surgical unit of the Shifa International Hospital and Shifa College of Medicine, Islamabad. Male and female patients above the age of 18 years were enrolled in the study. Approximately 80 patients in HS and 80 patients in conventional thyroidectomy were randomized. Patients with re-do thyroidectomies, retrosternal goiter, concomitant neck dissections and known coagulopathies were excluded from trial. During the period of 6 months, one hundred and sixty patients who met the selection criteria were enrolled in the study after obtaining informed consent. The procedure was performed by the consultant surgeon and the mean operative time and mean post-operative blood loss was recorded.

Data Collection Procedure: The operation was performed by a consultant surgeon and operative time was measured from the start of skin incision to the skin closure in both groups. Two graduated suction drains were placed in the thyroid bed in both groups to measure post-operative bleeding.

Data Analysis Plan: Software SPSS version 16 was used to analyze the data. The demographic characteristics were expressed in frequencies and percentages. Quantitative variables such as operative time and post-operative bleeding were expressed as mean \pm standard deviation. Independent sample t-test was used to compare the operative time and post-operative bleeding in both groups. P value of < 0.05 was considered statistically significant.

RESULTS

During the six months period (March to August 2014), 160 patients were randomized into two equal groups ($n=80$). Of 160 patients with multinodular goiter, 134 (83.8%) were females and 22 (16.2%) were males. The age ranged from 18 to 61 years in both groups with mean age in group A of 42 years ($SD=9$) and group B of 43 years ($SD=9.8$).

The mean operative time in HS thyroidectomy (Group A) was 76 minutes ($SD=9$) and conventional thyroidectomy was 116 minutes ($SD=16$); difference between two groups =40 minutes ($P < 0.001$) (Table 1). The mean post-operative bleeding in HS thyroidectomy was significantly lower in the conventional thyroidectomy group (18.2 ml vs.

Table 1: Operative time and postoperative bleeding in the conventional and harmonic scalpel thyroidectomy groups (data is presented as mean (standard deviation))

Variable	Conventional (N=80)	Harmonic scalpel (N=80)	P-value
Operative time (minutes)	117.0 (16.9)	76.7 (9.8)	<0.001
Postoperative bleeding (ml)	76.0 (31.7)	18.2 (7.4)	<0.001

76.0 ml, $P < 0.001$).

DISCUSSION

We found that in our patient population, the HS thyroidectomy had statistically significantly lower operative time and lower blood loss than conventional thyroidectomy. Thus we showed that benefits of HS extend to our patient population as well. Cirocchi and colleagues allocated 321 patients into two groups; ultrasonic dissector (UAS) and conventional thyroidectomy [9]. All patients underwent total thyroidectomy. The mean operative time in the conventional group was 113 min and was 75 min in the UAS group ($P < 0.001$). In our study mean post-operative bleeding in both groups was lower than Cirocchi et al although we also found a significant difference between the two groups.

Soroush et al conducted a single blinded randomized clinical trial that included 68 patients randomized to conventional and HS group [10]. Patients in both groups underwent total thyroidectomy and were evaluated in terms of operative time and post-operative bleeding. The operative time in HS group was 60.0 ± 9.2 versus 121.9 ± 30.9 in conventional group. A significant difference was observed in terms of operative time ($p < 0.001$) and the results were consistent with our findings. Another study performed by Asker et al randomized 130 patients in two groups [11]. The use of HS resulted in significantly shorter operative time as compared to conventional method (50.3 vs. 102.4 minutes). Kilic et al randomized 80 patients to two groups [12]. Equal number of patients were operated using HS and conventional knot and tie and significant differences were observed between the two groups in terms of operative time, incision length amount of bleeding and post-operative drainage. Another study published in 2008 by Kang et al established the efficacy of HS in terms of operative time and thyroid tissue weight and concluded that HS was efficient while operating on smaller thyroid glands [6]. Kowalski et al compared the two techniques using a larger sample size to eliminate the flaws in the previous small sample size studies [13]. They found a mean difference of 17% of

operative time in favor of HS and also a cost effective difference of 14%.

HS is advantageous in cases with primary thyrotoxicosis and thyroid cancer, significantly reducing ($p < 0.05$) operative time as concluded by Micolli et al and Saleh et al. However, another study conducted by Leonard and Timon found that routine thyroid lobectomies with HS did not had any quantifiable benefit as compared to conventional surgery and that there was no significant difference in operative time and incision [14-16].

A meta-analysis by Ecker et al [17] including 1153 patients compared both techniques for operative time, blood loss, post-operative drainage and pain. The mean operative time was reduced by 22 minutes ($p < 0.001$) and blood loss was reduced significantly by 20 ml ($p < 0.001$). They concluded that HS significantly reduced the mean operative time and blood loss but the post-operative drainage volume difference was not statistically significant.

CONCLUSION

Mean operative time and mean post-operative bleeding in thyroidectomy with HS was less as compared to conventional thyroidectomy and the difference was statistically significant.

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