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A Comparative Study of Harmonic Scalpel and Conventional Ligature in Open Thyroid Surgeries: Randomised Control Study

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Abstract: ***Introduction: Thyroidectomy is a surgical procedure that requires meticulous dissection, safe anatomical exposure and effective homeostasis. This study aims at comparing harmonic scalpel in enabling efficient haemostatic coagulation and division of small vessels with conventional suture ligation in open thyroid surgeries. Methodology: Randomised control study. A total of 50 patients underwent various open thyroid surgeries in the department of general surgery in S N Medical college, Bagalkot. They were randomly allocated into control group who underwent open thyroid surgeries with conventional ligation and cases group who underwent open thyroid surgeries with harmonic scalpel. Both groups were compared with respect to operating time, amount of blood lost, amount of drainage fluid, recurrent laryngeal nerve injury and number of hospital stay. Results: The operative time was significantly greater in control group with mean operating time of 113 mins compared to cases group with a mean operating time of 94 mins. Intra - operative blood loss was almost the same in both control and cases. Volume of drainage fluid was significantly greater in control group with mean volume of 49ml compared to cases group with mean volume of 34ml. Recurrent laryngeal nerve injury was same compared to both cases and control group. Hospital stay was significantly greater in control group compared to cases group. Conclusion: This study shows that Open thyroid surgeries with harmonic scalpel for dissection and vessel ligation was significantly better than conventional ligature with sutures with respect to operating time, volume of drainage fluid and days of hospital stay and showed no changes compared to blood loss and recurrent laryngeal nerve injury.***

Keywords: Thyroid surgery, harmanic scalpel

1. Introduction

Thyroid surgeries have a very interesting and illustrated history. Dating back to 952 AD since Albucasis first performed the surgery, the course of thyroid surgeries has gone through its peaks and valleys. It was not until surgeons like theodore kocher and theodore billroth, who gave this surgery a new breath of life, did it become popular and undergo numerous modifications to where it stands. From being considered one of the dreadful surgeries, thyroid surgeries have crossed a long path of time, to the present time when new techniques are being employed to make the surgery minimally invasive and the incisions even smaller [1]. Thyroid gland has a very extensive vascular network.

A very meticulous and exhaustive hemostasis needs to be achieved to ensure a successful thyroidectomy. The operation requires a dry surgical field to avoid inadvertant damage to the adjacent structures such as the recurrent laryngeal nerve and the parathyroid glands, as the two most significant common complications with incidence regarding permanent recurrent laryngeal nerve palsy and hypoparathyroidism of up to 14% and 4% respectively. [2] Many methods have been employed to achieve succesful hemostasis during the surgery. Hemostasis is achieved by means of clamp and tie maneuvers for ligation of small and numerous thyroid vessels. Other methods include clips and electrocautery. Suture ligations are time consuming and carry the risk of knot slippage. Clips carry the risk of dislodgement. Electrocautery produces remarkable thermal spread to the adjacent tissue [3].

The successful introduction of Harmonic scalpel, a newly developed alternative to conventional vessel sealing techniques, has led to further research to compare this new technique with conventional methods of hemostasis. Harmonic scalpel is a device that cuts and coagulates simultaneously using high frequency mechanical sounds of 55.53 kHz. It offers adequate hemostasis with minimal thermal spread and minimal adjacent tissue destruction. Furthermore no foreign bodies like ligatures or clips are left behind. They are used in abdominal surgery [4, 5], thoracic surgery [6], parotid surgery [7], and thyroid surgery [8, 9]. So, the aim of our study is to compare the harmonic scalpel and the convention ligature method in open thyroid surgeries in terms of operative time, blood loss and post operative complications, volume of drainage fluid and days of hospital stay.

2. Methodology

A total of 50 patients were selected for the study from patients admitted in the department of general surgery in S Nijalingappa medical college, Bagalkot. They were randomly divided imto standard and intervention group.

Intervention group: patients undergoing open thyroid surgery with harmonic scalpel

Standard group: patients undergoing open thyroid surgery with conventional ligature

Inclusion criteria

1) Patients with benign or malignant diseases of the thyroid gland undergoing open thyroid surgeries.
2) Patients giving informed consent for the procedure.

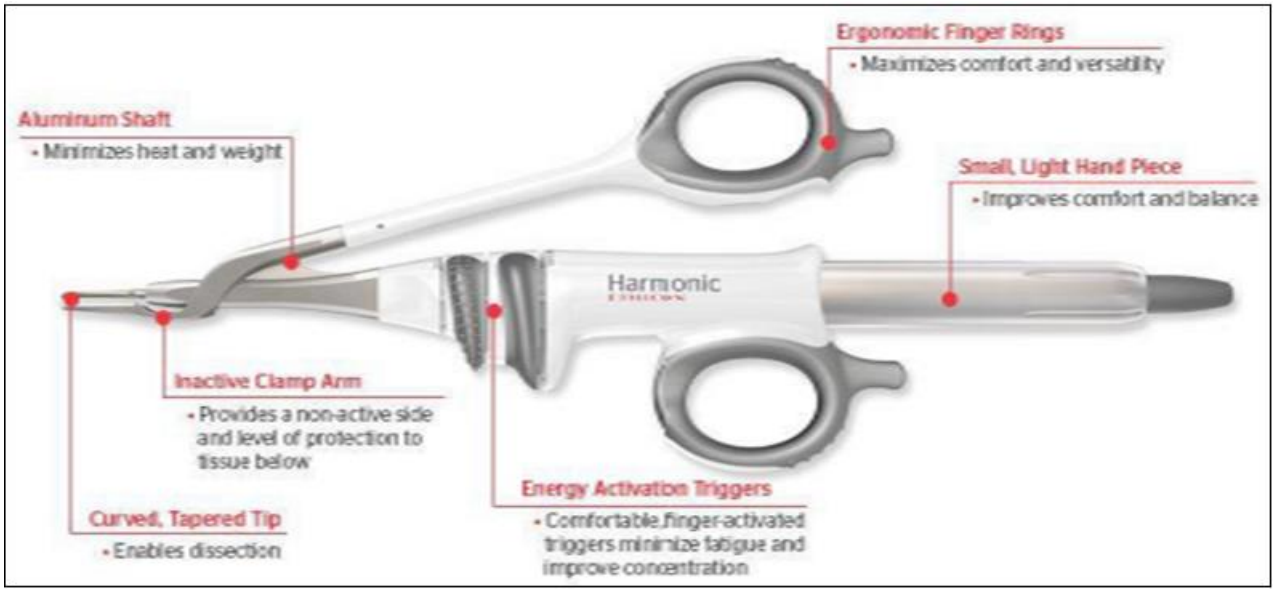
Exclusion criteria

1) Patients with age less than 18yrs
2) Patients with previous neck surgery or irradiation
3) Patients with pre existing RLN palsy

4) Patients with fixation of tumor to RLN requiring transection of RLN.
5) Patients with bleeding disorders.
6) Patients treated with anticoagulants 7 days before operation

Techniques to be employed

1) Patients requiring open thyroid surgery and satisfy the inclusion criteria are selected for the study.
2) Randomization done by using a computer generated software and subjects divided into intervention group and standard group.
3) Detailed history is obtained and thorough clinical examination done.
4) Appropriate investigations performed over the patients.
5) In intervention group, patients open thyroidectomy is done using harmonic scalpel
6) In standard group, patients open thyroidectomy is done using conventional ligatures.
7) A specific structural proforma will be used to collect information of individual cases
8) Operating time was recorded as the time from first incision to the last skin suture.
9) Gauzes were weighed before and after use to estimate amount of intraoperative bleeding. (1gm=1mlblood)
10) Patients are observed for post operative complications such as recurrent laryngeal nerve injury and post operative bleeding.
11) Patients are followed up till their hospital stay.



Harmonic scalpel used for hemostasis in thyrid surgery

3. Results

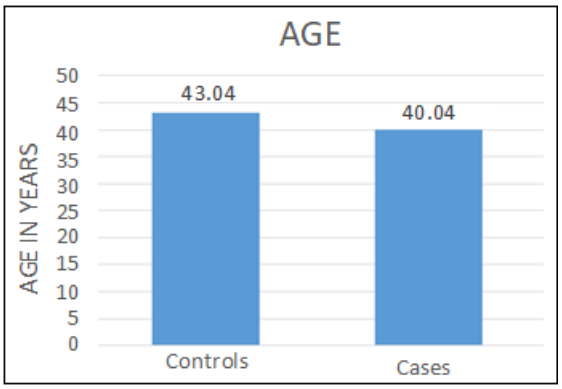
Analysis summary

The data were analysed using IBM SPSS version 25. Continuous and categorical variables were presented as mean ± standard deviation and percentages and compared between the two groups using unpaired t - test and chi square analysis respectively. A p value of <.05 was considered significant for all analyses.

Table 1: Inter - group comparison of age.

Group	N	Mean	Standard deviation	T statistic (p value)
Controls	25	43.04	18.070	T=.631
Cases	25	40.04	14.945	P =.531

Age was not significantly different between the two groups.

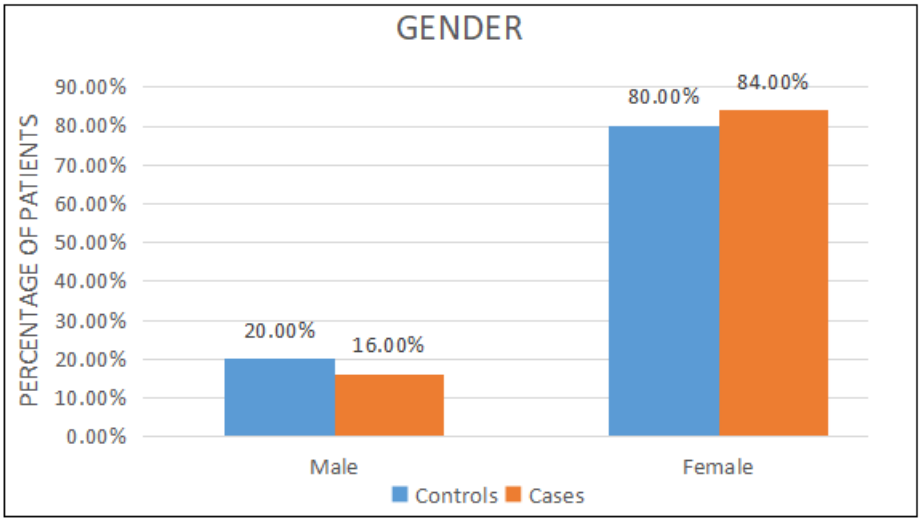


Graph 1: Inter - group comparison of age

Table 2: Inter - group comparison of gender.

Group	N/%	Male	Female	Chi square (p value)
Controls	N	5	20	.136 (.713)
	%	20.0%	80.0%	
Cases	N	4	21	
	%	16.0%	84.0%	

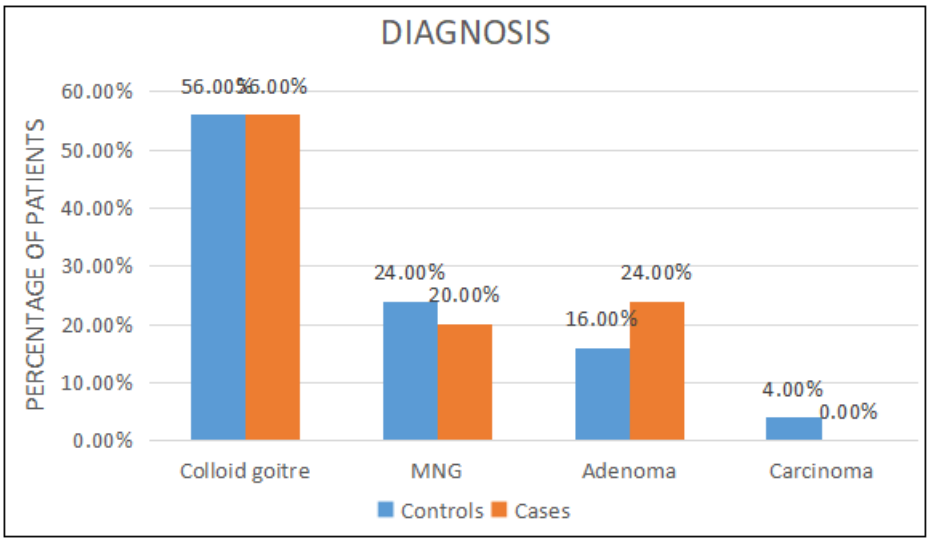
Gender was not significantly different between the two groups.



Graph 2: Inter - group comparison of gender

Table 3: Inter - group comparison of diagnosis.

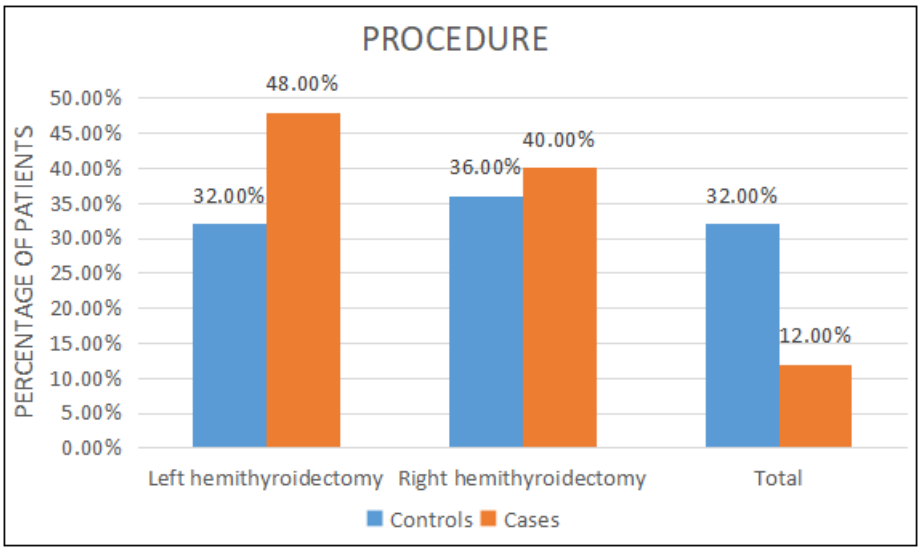
Group	N/%	Colloid goitre	MNG	Adenoma	Carcinoma	Chi square (p value)
Controls	N	14	6	4	1	1.49 (.684)
	%	56.0%	24.0%	16.0%	4.0%	
Cases	N	14	5	6	0	
	%	56.0%	20.0%	24.0%	0.0%	



Graph 3: Inter - group comparison of diagnosis

Table 4: Inter - group comparison of procedure.

Group	N/%	Left hemithyroidectomy	Right hemithyroidectomy	Total	Chi square (p value)
Controls	N	8	9	8	3.125 (.210)
	%	32.0%	36.0%	32.0%	
Cases	N	12	10	3	
	%	48.0%	40.0%	12.0%	

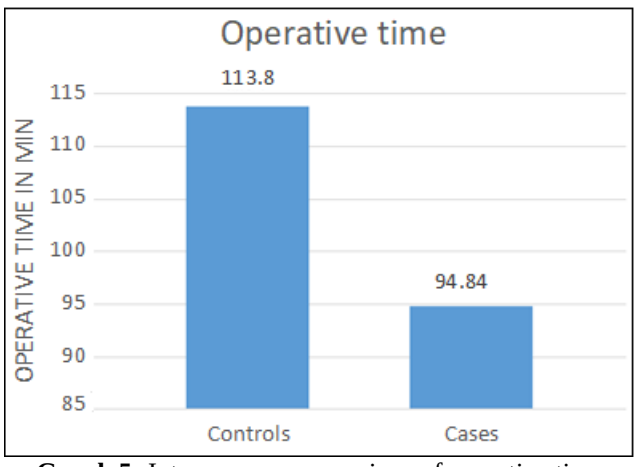


Graph 4: Inter - group comparison of procedure

Table 5: Inter - group comparison of operative time (minutes).

Group	N	Mean	Standard deviation	T statistic (p value)
Controls	25	113.80	16.220	T= 5.011
Cases	25	94.84	9.737	P =.000

Operative time was significantly greater in the controls.

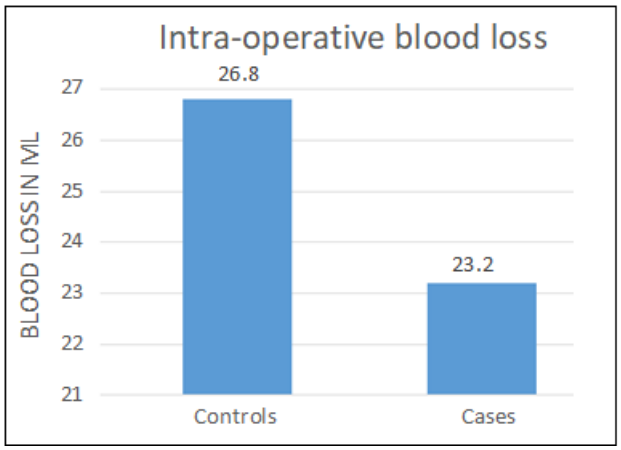


Graph 5: Inter - group comparison of operative time

Table 6: Inter - group comparison of intra - operative blood loss (ml).

Group	N	Mean	Standard deviation	T statistic (p value)
Controls	25	26.80	6.752	T= 1.793
Cases	25	23.20	7.427	P =.079

Intra - operative blood loss was almost the same in both cases and controls.

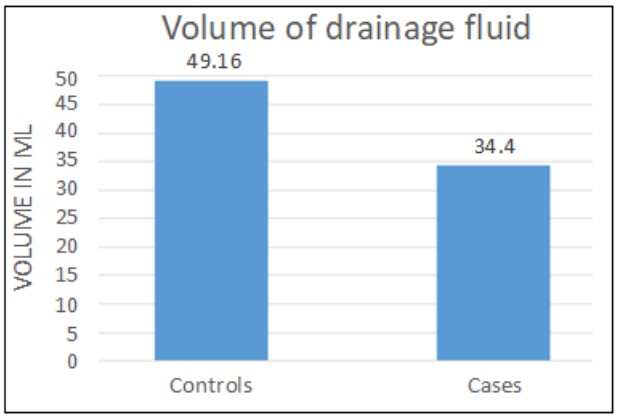


Graph 6: Inter - group comparison of intra - operative blood loss

Table 7: Inter - group comparison of volume of drainage fluid (ml).

Group	N	Mean	Standard deviation	T statistic (p value)
Controls	25	49.16	15.179	T= 3.374
Cases	25	34.40	15.745	P =.001

Amount of drainage fluid was significantly greater in the controls.

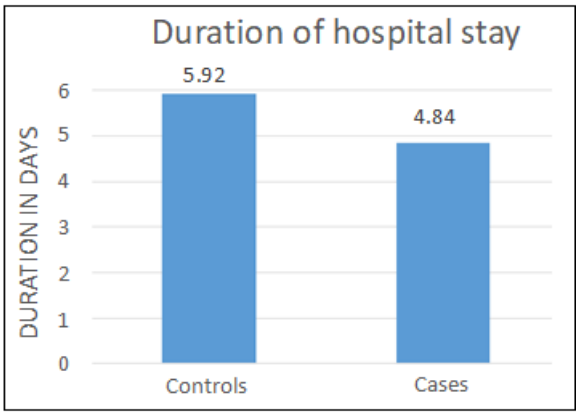


Graph 7: Inter - group comparison of volume of drainage fluid

Table 8: Inter - group comparison of duration of hospital stay (days).

Group	N	Mean	Standard deviation	T statistic (p value)
Controls	25	5.92	1.115	T= 4.121
Cases	25	4.84	.688	P =.000

The duration of hospital stay was significantly greater in the controls.

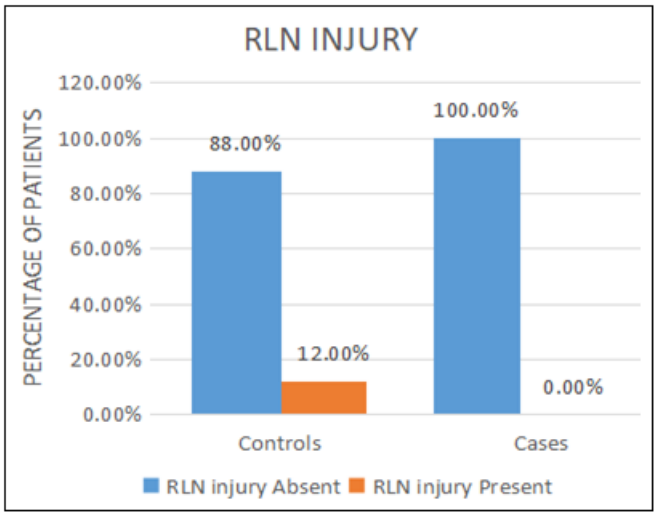


Graph 8: Inter - group comparison of duration of hospital stay

Table 9: Inter - group comparison of RLN injury

Group	N/%	Absent	Present	Chi square (p value)
Controls	N	22	3	3.19 (.074)
	%	88.0%	12.0%	
Cases	N	25	0	
	%	100.0%	0.0%	

The number of patients with RLN injury was not significantly different in the two groups.



Graph 9: Inter - group comparison of RLN injury

4. Discussion

Thyroid is a highly vascular organ, and therefore it is important to achieve good haemostasis during thyroid surgery. Using ligatures are probably the most common way to accomplish a good haemostasis. The use of clips and mono and bipolar diathermy is also common, but they are regularly not efficient for larger vessels like the superior thyroid arteries. Influenced by its favorable use in other surgical fields, the harmonic scalpel has, since the 1990's, become more frequently used in thyroid surgeries. Several publications have suggested that the harmonic scalpel shortens the operative time without any increase in complications and cost. [48 - 50] The aim of the present study was to compare the use of harmonic scalpel with conventional techniques in patients undergoing open thyroid surgeries. In our study, the use of harmonic scalpel was associated with a 30% reduction in operating time compared to use of the conventional hemostatic techniques. No

significant difference was seen in intraoperative bleeding between the two groups. Our results are in accordance with previous studies. [10 - 12] Shemen [10] found an advantage of 40mins reduction in operating time in total thyroidectomies performed with the help of the harmonic scalpel compared to conventional techniques. Voutilainen [12, 13] has observed a gain in operating time when using harmonic scalpel. In the literature, the rate of a permanent paresis of the recurrent laryngeal nerve after thyroidectomy is reported to be between 0.5% - 5%. [13 - 15] In the present study, 3 patients experienced transient paresis of RLN, all 3 patients in conventional group. A previous study reported an increased risk for transient paresis associated with harmonic scalpel compared to conventional group [9.7% vs 1.4%]. However, with increased experience with harmonic scalpel, difference was shown to disappear. In our study, significant difference was seen in volume of drainage fluid collected in suction drain. Cases observed a mean volume of 35ml compared to mean volume of 50 ml in harmonic scalpel group. In previous study by Lombardi also showed no difference in volume of drainage fluid.

In our study, significant difference was seen hospital stay, with a mean hospital stay of 6 days in conventional group and 5 days in harmonic scalpel group.

In the future, new instruments specifically adapted for thyroid surgery may even further increase the difference in operating time between these two hemostatic techniques. Furthermore, new technologies may also make it safer to operate closer to the nerves without risk of transient nerve damage.

5. Conclusion

Thyroid surgery has evolved in the last century. Many methods have been evolved to maintain homeostasis. In the present study, harmonic scalpel was compared with conventional ligature for open thyroid surgeries with respect to operative time, intraoperative bleeding, volume of drainage fluid, RLN injury and number of days of hospital stay. Harmonic scalpel was significantly better compared to conventional ligature in reducing the operative time by 30%, reduced collection of fluid in drain and less number of days of hospital stay and showed similar results with conventional group regarding intraoperative bleeding and risk of injury to RLN.

This study demonstrated the effectiveness of using harmonic scalpel in thyroid surgeries compared to conventional haemostatic methods. Therefore harmonic scalpel is a reliable and safe tool in thyroid surgeries.

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