

**Title page**

**8 YEARS COHORT STUDY ON SHORT  
TERM OUTCOME OF SUTURELESS  
THYROIDECTOMY IN HOSPITAL RAJA  
PEREMPUAN ZAINAB II**

**By**

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**DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF  
THE REQUIREMENTS FOR THE DEGREE OF MASTERS OF  
MEDICINE (GENERAL SURGERY)**



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## ABSTRAK

**Latar Belakang:** Pembedahan thyroid merupakan salah satu pembedahan yang paling lazim dilakukan pada masa kini dengan kadar komplikasi yang rendah. Pengenalan teknologi penutupan saluran darah telah membantu pakar bedah dalam mengawal pendarahan di kawasan yang sukar dan memendekkan masa pembedahan. Walaubagaimanapun, ada yang masih ragu-ragu dengan keupayaan teknologi ini memandangkan banyak struktur yang penting berada berdekatan dengan kelenjar thyroid. Oleh sebab itu, kajian ini dilakukan bertujuan untuk menilai hasil pembedahan thyroid menggunakan teknologi penutupan saluran darah berbanding teknik konvensional iaitu dengan menggunakan kaedah ikatan benang.

**Kaedah:** Kajian ini merupakan kajian retrospektif terhadap pesakit yang menjalani pembedahan total thyroid dari 1hb Januari 2007 hingga 31hb Desember 2014 di Hospital Raja Perempuan Zainab II, Kota Bharu, Kelantan. Pesakit yang memenuhi kriteria dan syarat- syarat kajian akan dimasukkan di dalam kajian. Pesakit akan dibahagi kepada dua kumpulan iaitu kumpulan yang melalui pembedahan thyroid konvensional dan pembedahan thyroid tanpa menggunakan benang. Data pesakit akan dianalisis menggunakan program Statistical Package for the Social Sciences (SPSS).

**Keputusan:** Sejumlah 495 pesakit dimasukkan di dalam kajian ini berumur antara 8 hingga 76 tahun dengan purata umur 44.7 (13.29) tahun. Kajian ini mengandungi 70 lelaki dan 425 perempuan. Kebanyakannya Melayu (96.6%), diikuti Cina (2.2%) dan India (0.4%). Purata tempoh pembedahan thyroid tanpa menggunakan benang amat ketara lebih pendek (100.71 berbanding 121.73 minit,  $p < 0.01$ ). Tiada perbezaan ketara

dilihat diantara pembedahan thyroid tanpa menggunakan benang berbanding pembedahan konvensional dari segi hypocalcemia sementara (21.1% berbanding 25.7) atau hypocalcemia kekal (0% berbanding 3.1%), kecederaan saraf sementara (0% berbanding 2.8%) atau kecederaan kekal saraf recurrent laryngeal nerve (0% berbanding 1.4%), pendarahan dalaman (0% berbanding 1.2%), pembedahan kali kedua (0% berbanding 0.2%), jangkitan kuman pada luka pembedahan (0% berbanding 0.5%) dan tracheostomy (0% berbanding 0.2%). Tiada perbezaan ketara dilihat pada kedua-dua kumpulan dari segi tempoh berada di dalam wad selepas pembedahan.

**Rumusan:** Komplikasi pembedahan thyroid tanpa menggunakan benang adalah rendah dan setanding dengan pembedahan thyroid konvensional. Oleh sebab itu, pembedahan thyroid tanpa menggunakan benang boleh dilakukan dengan selamat dan ia memberi kelebihan dari segi memendekkan tempoh pembedahan. Secara tidak langsung, ia akan membuat penggunaan dewan bedah yang lebih efisien.

**Kata Kunci:** thyroid, pembedahan thyroid tanpa menggunakan benang

## ABSTRACT

**Background:** Thyroid surgery is one of the most common surgery performed now days with very low complication rates. The introduction of vessel sealing technology have assisted surgeon in securing hemostasis in limited operative field and shortened the operative time. However, surgeons are still skeptical in using this technology as there are many important structures in close proximity to the thyroid gland. Therefore, this study is performed to evaluate the outcome of sutureless thyroidectomy as compared to conventional knot tying technique.

**Methods:** This is a retrospective cohort study of case record of patients who underwent total thyroidectomy from 1st January 2007 to 31st December 2014 in Hospital Raja Perempuan Zainab II, Kota Bharu, Kelantan. Those who met the inclusion criteria will be recruited in the study. Patients were divided into two groups based on conventional or sutureless thyroidectomy. The short term outcome post thyroidectomy were studied. The data were analyzed using Statistical Package for the Social Sciences (SPSS).

**Results:** Total of 495 patients were included in this study aged between 8 and 76 years old with mean age of 44.7(13.29) years. It comprises 70 males and 425 female. Majority were Malays (96.6%), followed by Chinese (2.2%) and Indian (0.4%). From the total of 495 patients, 71 of them underwent sutureless thyroidectomy and 424 patients underwent conventional thyroidectomy. The mean operative time was significantly lower in the sutureless group (100.71 versus 121.73 min,  $p < 0.01$ ). There were no significant difference in the post-operative outcome of sutureless thyroidectomy compared to conventional thyroidectomy in term of transient hypocalcemia (21.1%

versus 25.7%), permanent hypocalcemia (0% versus 3.1%), transient recurrent laryngeal nerve injury (0% versus 2.8%), permanent recurrent laryngeal nerve injury (0% versus 1.4%), hematoma (0% versus 1.2%), reoperation (0% versus 0.2%), surgical site infection (0% versus 0.5%) and tracheostomy (0% versus 0.2%). There were no statistical significant comparing the post-operative length of stay between these 2 groups.

**Conclusion:** Post-operative complications in sutureless thyroidectomy were similar if not better than conventional thyroidectomy. Therefore, sutureless thyroidectomy can be safely practiced as it have the advantage of shorter operative time thus indirectly improving the operating room efficiency.

**Keywords:** thyroidectomy, sutureless

## ABSTRACT

### 8 YEARS COHORT STUDY ON SHORT TERM OUTCOME OF SUTURELESS THYROIDECTOMY IN HOSPITAL RAJA PEREMPUAN ZAINAB II

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**Introduction:** Thyroid surgery is one of the most common surgery performed now days with very low complication rates. The introduction of vessel sealing technology have assisted surgeon in securing hemostasis in limited operative field and shortened the operative time. However, surgeons are still skeptical in using this technology as there are many important structures in close proximity to the thyroid gland. Therefore, this study is performed to evaluate the outcome of sutureless thyroidectomy as compared to conventional knot tying technique.

**Objectives:** The aim of this study is to evaluate the feasibility and safety of using sutureless technique in performing thyroidectomy over conventional thyroidectomy.

**Methods:** This is a retrospective cohort study of case record of patients who underwent total thyroidectomy from 1st January 2007 to 31st December 2014 in Hospital Raja Perempuan Zainab II, Kota Bharu, Kelantan. Those who met the inclusion criteria will be recruited in the study. Patients were divided into two groups based on conventional or sutureless thyroidectomy. The



short term outcome post thyroidectomy were studied. The data were analyzed using Statistical Package for the Social Sciences (SPSS).

**Results:** Total of 495 patients were included in this study aged between 8 and 76 years old with mean age of 44.7(13.29) years. It comprises 70 males and 425 female. Majority were Malays (96.6%), followed by Chinese (2.2%) and Indian (0.4%). From the total of 495 patients, 71 of them underwent sutureless thyroidectomy and 424 patients underwent conventional thyroidectomy. The mean operative time was significantly lower in the sutureless group (100.71 versus 121.73 min,  $p < 0.01$ ). There were no significant difference in the post-operative outcome of sutureless thyroidectomy compared to conventional thyroidectomy in term of transient hypocalcemia (21.1% versus 25.7%), permanent hypocalcemia (0% versus 3.1%), transient recurrent laryngeal nerve injury (0% versus 2.8%), permanent recurrent laryngeal nerve injury (0% versus 1.4%), hematoma (0% versus 1.2%), reoperation (0% versus 0.2%), surgical site infection (0% versus 0.5%) and tracheostomy (0% versus 0.2%). There were no statistical significant comparing the post-operative length of stay between these 2 groups.

**Conclusion:** Post-operative complications in sutureless thyroidectomy were similar if not better than conventional thyroidectomy. Therefore, sutureless thyroidectomy can be safely practiced as it have the advantage of shorter operative time thus indirectly improving the operating room efficiency.

Miss Wan Zainira Bt Wan Zain : Supervisor

Mr. Imisairi Bin Ab Hadi : Co-Supervisor

Dr. Wan Nor Arifin Wan Mansor : Co-supervisor

# **CHAPTER 1**

## **INTRODUCTION**

### **1.1 LITERATURE REVIEW**

#### **1.1.1 CONVENTIONAL THYROIDECTOMY**

Post-operative period is very crucial in total thyroidectomy patient as life threatening complication may occur. Post-operative bleeding causes neck hematoma and this will compromise the airway. The incidence of post thyroidectomy hematoma reported varies between 0.1-2.5% (Agarwal and Mishra 1997). Recognizing neck hematoma early is very important. If bleeding into the wound is suspected, dressing should be removed, skin suture are to be taken out and blood clot to be evacuated. Wound should be reexplored in the operating room to secure any major bleeding vessel.

Other complications of total thyroidectomy results in severe implications to the patients. Vocal cord paresis or paralysis due to iatrogenic injury of the recurrent laryngeal nerve (RLN) is one of the main problems in thyroid surgery. Although many procedures have been introduced to prevent the nerve injury, the incidence of recurrent laryngeal nerve palsy is still significant with incidence of 0.3-14% (Martensson and Terins 1985). Bilateral RLN injury remains the most feared complication with very serious functional sequelae for the patient. It must be avoided as it will result in potentially life threatening airway obstruction and patient may need tracheostomy.

Post-operative hypocalcemia is another important complications following total thyroidectomy. Therefore, it is also considered to be one of the main outcomes to be checked post operatively. It is due to parathyroid gland injury and has been reported in many studies ranging from less than 1% to 46% (van Zuidewijn, Songun et al. 1995, Bhattacharyya and Fried 2002, Mehanna, Jain et al. 2010). Majority of the post-operative hypocalcemia cases develop or manifest within 24 hours post operatively.

### **1.1.2 SUTURELESS THYROIDECTOMY**

Over the past few years, surgical techniques have greatly involved together with the advancement of other medical disciplines. However the principles of thyroid surgery had remained constant with regards to the importance of hemostatic control. The introduction of advanced vessel sealing technology replacing the conventional knot tying technique have greatly helped the surgeon to improve the efficiency in performing thyroidectomy and at the same time reduce the post-operative complication.

Conventionally, thyroidectomy involves multiple knot tying to control hemostasis as thyroid gland is rich in blood supply. However, knot tying technique is time consuming. The introduction of vessel clip have shortened the surgery time. The introduction of new advanced vessel sealing device also provide a safe alternative in controlling hemostasis.

Harmonic scalpel is an advanced energy device manufactured by Johnson and Johnson, Ethicon which produces high frequency ultrasonic energy to simultaneously coagulate and cut vessels. The active blade oscillates at 55 kHz produces temperature

nearly 80 degree celsius and will cause disruption in the protein hydrogen bonds and subsequently coagulate and cut vessels. It produce minimal thermal spread ( $2.54 \pm 0.48$  mm) with reliable vessel sealing up to 5mm (Ethicon 2016). Studies have shown that the collateral damage due to heat production was directly proportional to the power setting and the activation time (Emam and Cuschieri 2003).

Several studies have been conducted to look at the risk and benefit of using sutureless thyroidectomy compared to conventional knot tying technique. Ahmadreza Soroush, et al. had done a randomized clinical trial involving 68 patient in Iran in 2013. They found that application of Harmonic Scalpel (HS) in thyroidectomy significantly reduces operating time and intra-operative bleeding. Postoperative drainage, pain, hypocalcaemia, and length of hospitalization were also significantly lower in the HS group (Soroush, Pourbakhtyaran et al. 2013).

Comparable finding was attained by Theodosis and friends. They concluded that the use of the Harmonic Scalpel in total thyroidectomy is more effective than the clamp-and-tie technique: the duration of surgery, intraoperative difficulty, postoperative pain and hospitalization are reduced. Both techniques are equivalent concerning RLN injuries, postoperative vocal alterations and blood loss (Papavramidis, Sapalidis et al. 2010).

Based on a study by Emanuele Ferri, et al. they collected a total of 100 consecutive patient underwent thyroidectomy between January 2010 to May 2011. They found that the sutureless thyroidectomy group have significantly shorter mean operative time and lower total drainage volume. Post-operative recurrent laryngeal nerve injury and transient hypocalcaemia occur more frequently in conventional thyroidectomy group and sutureless

thyroidectomy group experience significantly less post-operative pain. Nevertheless there is no difference was found in mean hospital stay (Ferri, Armato et al. 2011).

A retrospective study by Shen, Wen et al. comparing electrothermal vessel sealing system versus standard vessel ligation in thyroidectomy done in California, USA. They reviewed 234 consecutive patients who underwent thyroidectomy by one surgeon. Standard vessel ligation was used from 1997 and 2000 on 99 patients, and the LigaSure™ was used from 2001 and 2003 on 135 patients. They concluded that the LigaSure™ group had significant lower operating times (2.9 vs 3.6 hours). (Shen, Baumbusch et al. 2005)

Similar finding was reported by Turkay Kirdak, et al. This study prospectively evaluated 58 consecutive patients who underwent thyroidectomy. Patients were allocated into two groups, 30 patients in the Ligasure group and 28 patients in the conventional surgery group. Complications, operating time, and hospital stay were compared between the two groups. The age, sex, and indications were similar in the two groups ( $p > 0.05$ ). Complication rates and hospital stays did not show any difference according to the techniques used. Operating time was shorter in the hemithyroidectomy and total thyroidectomy patients of the Ligasure group (mean – SD: 77.38 – 13.71 vs. 99.80 – 12.53 minutes,  $p = 0.005$ ; and 102.50 – 16.69 vs. 128.89 – 19.74 minutes,  $p = 0.010$ ) (Kirdak, Korun et al. 2005).

Between April 2003 and March 2005, a study have been conducted at Tartu University Hospital, Estonia, involving 403 consecutive patients who underwent primary thyroid surgery. A conventional suture-ligation technique was used in 199 patients (conventional group) and the Ligasure was used in 204 patients (Ligasure group). The mean operating time for was significantly shorter in the Ligasure group compared with the

conventional group with average saving in operating time was 25.8 minutes (95% ci 19.5–32.2;  $p < 0.0001$ ). Among all types of complications, only postoperative transient hypoparathyroidism demonstrated a significantly lower incidence in the Ligasure group (2.5% vs 7.0%;  $p = 0.022$ ) (Lepner and Vaasna 2007).

In Japan, a study by Takeo Fujita et al, comparing electrothermal coagulation versus conventional hand tie technique involving 56 patients, showed no significant differences in operative duration, volume of intraoperative hemorrhage, postoperative course, or duration of postoperative drainage. However, the postoperative hospital stay was found to be significantly shorter with the electrothermal coagulation group. The postoperative hospital stay was 7.25 days (range, 3-13 days) in the conventional group and 6.0 days (range, 4-15 days) in the vessel sealing system group (Fujita, Doihara et al. 2006).

Lombardi and friends had performed a study in 2007 comprising 200 patients comparing the safety and cost-effectiveness of the harmonic scalpel (HS) during thyroidectomy versus knot tying thyroidectomy (CT). Results shows mean operative time was significantly shorter in the HS group ( $P < 0.001$ ), as well as the total operative room occupation time ( $P < 0.001$ ). However, no significant difference was found between the two groups concerning the complication rate and charges of the hospitalization (Lombardi, Raffaelli et al. 2008).

Another retrospective study from 382 consecutive total thyroidectomies done in Hippokrateion Hospital, Athens, Greece from September 2004 to August 2006. Patients were divided into 3 groups: those who underwent total thyroidectomy with the classic suture ligation technique, with the electrothermal bipolar vessel sealer and with the harmonic scalpel. Compared with the classic technique, surgical time was reduced

significantly by about 20% when the bipolar vessel sealer or harmonic scalpel was used. However, no differences were observed regarding these 2 devices. Therefore, the choice should be made based on the surgeon's preferences and experience (Manouras, Markogiannakis et al. 2008).

In Australia, Ling-Yun Chang, et al. had performed a case cohort from January 2006 to July 2009. 1935 patients were included in this study. Of these, 772 patient underwent conventional thyroidectomy and 1163 were performed using sutureless thyroidectomy. They found that the mean operative time was significantly lower in the sutureless group (71 versus 86 min,  $P = 0.02$ ). On top of that, there was an overall cost saving of AUD\$14 300 per 100 total thyroidectomy cases performed using the sutureless technique. However, there was no difference in the post-operative complications of hematoma (0.78% conventional versus 1.12% sutureless,  $P = 0.46$ ), permanent hypoparathyroidism (1.30% conventional versus 0.52% sutureless,  $P = 0.06$ ) or permanent RLN injury (0.26% conventional versus 0.52% sutureless,  $P = 0.39$ ) (Chang, O'Neill et al. 2011).

It was supported by a study done by Aleksander Konturek from Poland. He also found that sutureless thyroidectomy operations were shorter ( $45.4 \pm 8.7$  min vs.  $64.5 \pm 14.2$  min;  $p < 0.001$ ), a lower mean blood loss ( $29.9 \pm 9.8$  ml vs.  $56.8 \pm 11.0$  ml;  $p < 0.001$ ) and appeared to be more cost-effective ( $666.2 \pm 37.5$  EUR vs.  $718.0 \pm 69.2$  EUR;  $p < 0.01$ ) compared to conventional thyroidectomy (Konturek, Barczyński et al. 2012).

Another retrospective study done by Allan E. Siperstein et al, comprising one hundred seventy-one consecutive patients undergoing lobectomy or total thyroidectomy by a single surgeon. Patient were divided into 2 groups, 86 patients underwent thyroid surgery

with the conventional clamp-and-tie technique and 85 with the harmonic scalpel. Mean operative time was shorter in the harmonic scalpel group compared with the conventional technique group for both lobectomy ( $89\pm 20$  minutes vs  $115\pm 25$  minutes;  $P<0.01$ ) and total thyroidectomy ( $132\pm 39$  minutes vs  $161\pm 42$  minutes;  $P<0.01$ ) procedures. There was no difference between the 2 techniques regarding the amount of blood loss for different procedures (Siperstein, Berber et al. 2002).

On the other hand, a study by David S. Leonard from Department of Otolaryngology Head and Neck Surgery, Royal Victoria Eye and Ear Hospital, Dublin, Ireland did not find any quantifiable benefit in routine thyroid lobectomy when comparing ultrasonic dissector with conventional techniques (Leonard and Timon 2008).

Ahmet Pergel et al have conducted a study in Turkey between June 2009 and March 2011. A total of 456 patients having undergone a total thyroidectomy operation and they were divided into 2 groups. Group L comprised of 182 patients where only LigaSure was used, and group LT consisted of 274 patients where ligation was used in the vicinity of the recurrent laryngeal nerve and parathyroid glands, and LigaSure was used in all other parts of the surgery. They found that Pure LigaSure for total thyroidectomy may increase laboratory hypocalcemia rate, but not symptomatic hypocalcemia. Hemorrhage related complications were similar and low in the two groups. Ligations in the places close to delicate anatomic structures did not cause longer operative times and may be a safer option in total thyroidectomy (Pergel, Yucel et al. 2014).

In Malaysia, limited study have been done comparing the short term outcome between the conventional knot-tying thyroidectomy and sutureless thyroidectomy. Only 1 prospective observational study including 35 patients who underwent sutureless total



thyroidectomy in University Kebangsaan Malaysia Medical Center (UKMMC) between January 2007 till May 2008 have been found (Suhaimi, Yaakub et al. 2012).

## **1.2 RATIONALE FOR THE STUDY**

Many study have been done abroad showing the advantages of sutureless thyroidectomy. However, sutureless thyroidectomy is still new in this region and most of the surgeons still sceptical about its effectiveness and safety. This study will provide local data regarding thyroidectomies done in Hospital Raja Perempuan Zainab II from 2007 to 2014. This study will also provide local data on sutureless thyroidectomy and its short term outcome. Hence this study hopefully will change the current conventional knot tying thyroidectomy technique to sutureless technique.

**CHAPTER 2**  
**STUDY PROTOCOL**

**RESEARCH PROPOSAL FOR MASTER OF MEDICINE**

**PARTIAL REQUIREMENT FOR MASTER OF MEDICINE (SURGERY) PROGRAMME**

**UNIVERSITI SAINS MALAYSIA**

**TITLE:**

**8 YEARS COHORT STUDY ON SHORT TERM OUTCOME OF  
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## **1. INTRODUCTION**

### **1.1. OVERVIEW**

Thyroid is a very vascular organ and situated close to delicate structure such as parathyroid gland, recurrent laryngeal nerve and oesophagus. Injury to these structure is really unwanted due to its complication. Thus, meticulous dissection must be done to reduce post-operative complication.

In the early years, thyroidectomy is associated with a very high morbidity and mortality. The main complications encountered are bleeding, asphyxia, hospital gangrene and air embolism. Up to 1849, the mortality rate was as high as 40% <sup>1</sup>. Not till the advancement of antisepsis and anaesthesia, Theodor Kocher was able to greatly reduce the mortality rate <sup>1</sup>.

Thyroidectomy has well evolved since then. Conventional thyroidectomy, require numerous knot tying and thus carry the risk of knot slipping. With the advancement of medical technology, multiple devices had been introduced to help surgeons in securing haemostasis in limited operative field and shortened the operative time.

### **1.2. LITERATURE REVIEW**

A lot of studies have been done abroad to compare the outcome between conventional and sutureless thyroidectomy. Ahmadreza Soroush , et al.<sup>2</sup> had done a randomized clinical trial involving 68 patient in Iran in 2013. They found that application of Harmonic Scalpel (HS) in thyroidectomy significantly reduces operating time and Intra-operative bleeding. Postoperative drainage, pain, hypocalcaemia, and length of hospitalization were also significantly lower in HS group.

Based on a study by Emanuele Ferri, et al. <sup>3</sup> they collected a total number of 100 consecutive patients who underwent thyroidectomy between January 2010 to May 2011. They found that the sutureless thyroidectomy group have

significantly shorter mean operative time and lower total drainage volume. Post-operative recurrent laryngeal nerve injury and transient hypocalcaemia occur more frequently in conventional thyroidectomy group and sutureless thyroidectomy group experience significantly less post-operative pain. Nevertheless there is no difference was found in mean hospital stay.

In Australia, Ling-Yun Chang, et al.<sup>3</sup> had performed a case cohort from January 2006 to July 2009. 1935 patients were included in this study. Of these, 772 patient underwent conventional thyroidectomy and 1163 were performed using sutureless thyroidectomy. They found that the mean operative time was significantly lower in the sutureless group (71 versus 86 min,  $P = 0.02$ ). However, in contrast to journal by Ahmadreza Soroush , et al.<sup>2</sup> there were no difference found in the post-operative complications of haematoma (0.78% conventional versus 1.12% sutureless,  $P = 0.46$ ), permanent hypoparathyroidism (1.30% conventional versus 0.52% sutureless,  $P = 0.06$ ) or permanent RLN injury (0.26% conventional versus 0.52% sutureless,  $P = 0.39$ ).

It was supported by few other studies done by Turkay Kirdak, et al.<sup>4</sup>, Qingqing He. Et al. <sup>5</sup> and Andreas Manouras. Et al. <sup>6</sup>. They also found that there were no difference in term of complication rates and hospital stay but significantly lower operating time was achieved in patient of the sutureless thyroidectomy group.

In Malaysia, limited study have been done comparing the short outcome between the conventional knot-tying thyroidectomy and sutureless thyroidectomy. Only 1 prospective observational study including 35 patients who underwent sutureless total thyroidectomy in University Kebangsaan Malaysia Medical Center (UKMMC) between January 2007 till May 2008 have been found (Suhaimi, Yaakub et al. 2012).

Thus this study, hopefully will provide local data on the advantages of sutureless thyroidectomy and change the current knot-tying thyroidectomy technique to sutureless thyroidectomy.

### 1.3. RESEARCH JUSTIFICATION AND BENEFITS

Many studies have been done abroad showing the advantages of sutureless thyroidectomy. However, sutureless thyroidectomy is still new in this region and most of the surgeons are still sceptical about its effectiveness and safety. This study will provide local data on sutureless thyroidectomy and its short term outcome. Hence this study hopefully will change the current conventional knot tying thyroidectomy technique to sutureless technique.

### 1.4. OBJECTIVES

#### a) GENERAL OBJECTIVES

Comparing the complications, operative time and post-operative hospital stay of sutureless and conventional thyroidectomy.

#### b) SPECIFIC OBJECTIVES

a) To compare percentage of RLN injury, hypocalcaemia and post-operative hematoma between sutureless and conventional thyroidectomy

b) To compare the mean operative time and post-operative hospital stay between sutureless and conventional thyroidectomy

### 1.5. RESEARCH QUESTION

a) What is the prevalence of conventional and sutureless thyroidectomy in HRPZII?

b) What is the rate of complications (hematoma, transient hypocalcaemia, permanent hypocalcaemia, transient recurrent laryngeal nerve injury and permanent recurrent laryngeal nerve injury) following thyroidectomy in HRPZII?

- c) Is there any difference in term of post-operative outcome between conventional and sutureless thyroidectomy.
- d) Is there any difference in term of operative time and post-operative hospital stay between conventional and sutureless thyroidectomy.

#### 1.6. HYPOTHESIS

- a) The percentage of RLN injury, hypocalcaemia and post-operative hematoma is different between the sutureless and conventional thyroidectomy group.
- b) There are differences in operative time and post-operative hospital stay between sutureless and conventional thyroidectomy group.

## 2. **METHODS**

### 2.1. RESEARCH DESIGN

This is a retrospective cohort study

### 2.2. STUDY VENUE

This study will be conducted in Hospital Raja Perempuan Zainab II, Kota Bharu, Kelantan

### 2.3. STUDY DURATION

This study will be conducted from January 2007 to December 2014

### 2.4. STUDY POPULATION

The study includes all patients who have undergone total thyroidectomy from 1st January 2007 to 31st December 2014. The data collection will be started after ethical approval.

## 2.5. SELECTION CRITERIA

### a) INCLUSION CRITERIA

All patient undergone total thyroidectomy in HRPZII from January 2007 to Dec 2014

### b) EXCLUSION CRITERIA

Previous neck dissection, surgical procedure adjunct to thyroidectomy, extra thyroidal invasion, coagulopathy, hypocalcaemia, recurrent laryngeal nerve palsy, goiter with retrosternal extension

## 2.6. ETHICAL APPROVAL

Data will be collected after gaining ethical approval from National Medical Research Registry (NMRR). NMRR ID : 24483

## 2.7. SAMPLE SIZE

Sample size calculation using PS software.

### a) Objective 1 : Pearson's Chi Square

<b>Variables</b>	<b>P<sub>0</sub> (%)</b>	<b>P<sub>1</sub> (%)</b>	<b>n</b>	<b>n + 10%</b>
Hematoma	2.5 <sup>a</sup>	0.5	427	470
Transient Recurrent Laryngeal Nerve Injury	13.4 <sup>b</sup>	3.0	79	87
Permanent Recurrent Laryngeal Nerve Injury	4.5 <sup>b</sup>	0.5	117	129
Transient Hypocalcemia	16.8 <sup>c</sup>	4.0	64	70
Permanent Hypocalcemia	4.0 <sup>c</sup>	1.0	310	341

With  $\alpha = 0.05$ . Power = 80%. M = 3

**P<sub>0</sub>** = Proportion of patient who developed post-operative complication in conventional thyroidectomy group

**P<sub>1</sub>** = Proportion of patient who developed post-operative complication in sutureless thyroidectomy group based on expert opinion

#### References

- a) Agrawal A, et al. Post-thyroidectomy hemorrhage ; An analysis of critical factors in successful management. J Indian Med Assoc 1997; 95(7): 418-419, 433.
- b) Dutta H et al. Recurrent laryngeal nerve palsy after thyroid surgery and literature review. Nepalese Journal of ENT Head and Neck Surgery 2011; 2(2): 27-28.
- c) Jay K Harness, et al. Total thyroidectomy: complication and technique. World J. Surg. 1986; 10: 781-786.

b) Objective 2: independent t-test.

<b>Variables</b>	<b>SD</b>	<b>mean</b>	<b>n</b>	<b>N + 10%</b>
OperativeTime	15 min	43 min	130	143
Post operative hospital stay	1 day	2.67 day	113	124

\*Reference based of breast and endocrine unit audit statistic from 2007 to 2010



The largest sample size from calculation is 470 patients.

However it is not feasible to collect such amount of patient as total number of patient undergone sutureless thyroidectomy for the past 8 years in HRPZII is about 100 patient. So we take all available patients, keeping in mind that the study might be underpowered.

## 2.8. RESEARCH TOOLS AND DATA COLLECTION

Data collection form (Performa) is design to obtain the information from patient's case record. After ethical approval, a list of patients who underwent total thyroidectomy in between January 2007 to December 2014 will be obtained from the record in the operation theater. Patients who fulfil the inclusion and exclusion criteria will be recruited in the study. The data of patients will be obtained by retrospective study of patient's medical records. The data will be entered in a data collection form (Appendix 1). Patients will be divided into two groups based on conventional or sutureless thyroidectomy.

## 2.9. DEFINITIONS

- a) Sutureless thyroid surgery in this study was defined as mobilizing the thyroid gland and securing haemostasis during thyroidectomy using clips and Harmonic Scalpel Focus device (Johnson & Johnson).
- b) Transient hypoparathyroidism – having post-operative serum calcium < 2.0 mmol/L or symptoms of hypocalcaemia requiring medication
- c) Hypoparathyroidism were considered permanent when no evidence of recovery was seen within 6 months postoperatively.
- d) Vocal cord palsy were confirmed by doing indirect laryngoscope by the ENT team and were considered permanent when no evidence of recovery was seen within 6 months postoperatively.

#### 2.10. STATISTICAL ANALYSIS

The data will be analysed using Statistical Package for the Social Sciences (SPSS) software version 20. Pearson's Chi Square and independent T-test will be used to determine the difference. *P* value of less than 0.05 is considered statistically significant.

#### 2.11. ETHICAL ISSUE

This is a retrospective data review and analysis. The patients with missing case notes or incomplete data collection involving the important information (5 variables of analysis) will be excluded from the study. No telephone call for further information retrieval. Permission from the Director of HRPZ II for retrieving the patients' medical records from record office will be obtained before the data collection (Appendix 2). The personal medical information will be kept confidential. Only the final analysis result will be presented or published. The personal medical information may be reviewed by the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying the clinical data.

### 3. FLOW CHART

List of patients underwent thyroidectomy from January 2007 to December 2014 is obtained from the operation theater.



Recruitment of patients who fulfilled the inclusion and exclusion criteria



Review of medical records of patients that recruited in the study



Data from medical records entered in the data collection form



Data collection and statistical analysis



Report and manuscript write up

### 4. GANTT CHART

PROJECT ACTIVITIES	2015							2016					
	JUN	JUL	AUG	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN
RESEARCH ACTIVITIES													
DATA COLLECTION	→												
DATA ANALYSIS / INTERPRETATION						→							
REPORT WRITING								→					
SUBMISSION OF REPORT											→		
SUBMISSION OF RESEARCH PAPER												→	

## 5. PLANNED MILESTONE

- a. OCTOBER 2015 : COMPLETION OF DATA COLLECTION
- b. DECEMBER 2015 : COMPLETION OF DATA ANALYSIS
- c. MARCH 2016 : REPORT WRITING
- d. JUNE 2016 : SUBMISSION OF RESEARCH PAPER

## 6. REFERENCES

1. A E B Giddings. The history of thyroidectomy. Journal of the royal society of medicine. 1998; 33 (91): 2-6
2. Ahmadreza Soroush , et al. Harmonic Scalpel is more Secure than Conventional Methods in Total Thyroidectomy: A Randomized Clinical Trial. J Minim Invasive Surg Sci. 2013;2(1): 1-5.
3. Emanuele Ferri, et al. Focus Harmonic Scalpel Compared to Conventional Haemostasis in Open Total Thyroidectomy: A Prospective Randomized Trial. International Journal of Otolaryngology. 2011;2011: 1-7
4. Ling-Yun Chang, et al. Sutureless total thyroidectomy: a safe and cost-effective alternative. ANZ J Surg. 2011; 81: 510–514
5. Turkey Kirdak, et al. Use of Ligasure in Thyroidectomy Procedures: Results of a Prospective Comparative Study. World J. Surg. 2005;29: 771-774
6. Qingqing He. Et al. Harmonic focus in total thyroidectomy plus level III-IV and VI dissection: a prospective randomized Study. World Journal of Surgical Oncology. 2011; 9(141): 1-5.
7. Andreas Manouras. Et al. Thyroid surgery: comparison between the electrothermal bipolar vessel sealing system, harmonic scalpel, and classic suture ligation. The American Journal of Surgery. 2008; 195: 48–52.

## 7. APPENDICES

### 7.1. APPENDIX 1

#### THYROID PERFOMA

##### PATIENT'S PARTICULAR

1. **Reference number : .....**

2. Age : ..... yrs

3. Birth date : .....

4. Sex : M / F

5. Race : M / C / I / Others

##### PREOPERATIVE INFORMATION

6. Thyroid status

Euthyroid

Free T4 : .....

Thyrotoxicosis

Se T3 : .....

Hypothyroid

TSH : .....

7. Goiter

Duration : ..... month

Diffuse

Single nodule                      Right / Left

Multinodular goiter

8. ENT assessment (IDL) :

Vocal cord normal

Vocal cord paresis : right / left

9. Fine needle biopsy :

Not done

Inadequate / unsatisfactory smear

Benign

Follicular

Atypical

Malignant : .....

Others : .....

10. Preoperative diagnosis :

.....

11. Operation information

- Date of surgery : .....
- Performed by : .....
- Duration of surgery : .....min
- Procedure :
  - Total thyroidectomy
  - Hemithyroidectomy
  - Others : .....
- Type of thyroidectomy
  - Conventional
  - Sutureless
- Size of thyroid: .....cm
- Weight of thyroid gland resected : ..... gram

12. Complication

- Hematoma (re-open)
- Transient recurrent laryngeal nerve injury
- Transient hypocalcemia

13. Post operative hospital stay : ..... Day

14. Follow up at 6 month

- Permanent RLN injury
- Permanent hypocalcemia

15. HPE : .....

## 7.2. APPENDIX 2

### Approval letter to director of HRPZ II

Dr Am Basheer Bin Alias,  
Jabatan Pembedahan,  
Hospital Raja Perempuan Zainab II,  
Kota Bharu.  
2014

Tarikh: 3 Februari

Melalui:

Dr Imisairi Ab. Hadi,  
Pakar Perunding Unit Pembedahan Breast Endocrine,  
Hospital Raja Perempuan Zainab II.

Kepada:

Dato' Dr. Haji Ghazali Hasni B. Md. Hassan  
Pengarah Hospital Raja Perempuan Zainab II.

Yang berbahagia,

#### PERMOHONAN MENJALANKAN PENYELIDIKAN DAN MENDAPATKAN REKOD PESAKIT BAGI MENJALANI DISERTASI SARJANA PERUBATAN

Merujuk kepada perkara di atas, saya merupakan pelajar Sarjana Perubatan (Pembedahan Am) Universiti Sains Malaysia yang sedang menjalani latihan di Hospital Raja Perempuan Zainab II, Kota Bharu. Saya ingin memohon kebenaran untuk menjalankan penyelidikan dan mendapatkan rekod pesakit di hospital ini bagi tujuan menyiapkan disertasi program sarjana saya yang bertajuk: '8 YEARS

COHORT STUDY ON SHORT TERM OUTCOME OF SUTURELESS THYROIDECTOMY IN HRPZ II'.

2. Disertasi sarjana saya ini merupakan sebahagian daripada syarat dalam pengajian Sarjana Perubatan Pembedahan Am. Maklumat pesakit akan dirahsiakan. Hanya pihak Lembaga Etika kajian ini dan pihak berkuasa regulatori yang berkaitan berkuasa untuk membuat rujukan pada rekod pesakit.

3. Kebenaran daripada pihak tuan amatlah dihargai.

Sekian, terima kasih.

Yang Benar,

---

(DR AM BASHEER BIN ALIAS)

Pegawai Perubatan

Jabatan Pembedahan

Hospital Raja Perempuan Zainab II



## 2.1 DOCUMENT SUBMITTED TO FOR ETHICAL APPROVAL

Am Basheer Bin Alias (Research ID: 24483)  
Surgical Department,  
Hospital Raja Perempuan Zainab II,  
Kota Bharu, Kelantan

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Medical Research and Ethics Committee (MREC)  
Ministry of Health, Malaysia  
NIH Secretariat  
d/a Institut Pengurusan Kesihatan  
Jalan Rumah Sakit, Bangsar  
59000 Kuala Lumpur

8 June 2015

Dear Chairman

**SUBMISSION FOR APPROVAL: 8 YEARS COHORT STUDY ON SHORT TERM  
OUTCOME OF SUTURELESS THYROIDECTOMY IN HRPZ II**

We are pleased to inform that we are planning to conduct the above-mentioned study in Hospital Raja Perempuan Zainab II, Kota Bharu, Kelantan .  
Therefore, we would like to seek ethics approval for this study.  
This study is estimated to begin in July 2015 and be carried out for 6 months.  
We would like to apply for waiver as this is a retrospective study and we will be only going through patients records.

2. Kindly find attached the following documents for your perusal:

1. Research Proposal
2. Data Collection Form

Thank you for your kind consideration and looking forward to a favourable reply soon.

Yours faithfully



DR AM BASHEER ALIAS  
No MPM 47323  
Pegawai Perubatan UD46.....

Am Basheer Bin Alias (Research ID: 24483)  
Principal Investigator  
Medical Officer/Post Graduate Student  
Masters in General Surgery  
Surgical Department,  
Hospital Raja Perempuan Zainab II,  
Kota Bharu, Kelantan.