



## CHAPTER V

### DISCUSSION AND CONCLUSION

#### *Discussion*

In this randomized, controlled study, vessel sealing system tonsillectomy (VSST) was compared with the standard cold knife tonsillectomy (CKT). The self-paired comparison between both sides of different surgical techniques reduced bias and increased precision of the study. The paired difference lies in the standard error usually being smaller than the standard error of the difference between the means. Factors influencing the outcomes may not be equal in unpaired groups, such as age, tonsil size, degree of infection, concomitant medication, hypertensive status and surgical indication. Randomization can not guarantee equality of bias between two groups.

Postoperative pain scale is subjective outcome. Self-paired comparison (left side versus right side) may be better to show the difference and more reliable than comparison among the subjects. Paired control study of postoperative pain using the Faces Pain Scale–Revised from different techniques of tonsillectomy was reported by Lister MT et al (2006) in a randomized, double-blind, paired control study of postoperative pain from microdebrider tonsillotomy (MT) compared with electrosurgical tonsillectomy (ET) [10]. Patients were randomized to have one tonsil removed by MT and the other by ET. Main outcome was postoperative pain as recorded by Faces Pain Scale–Revised. From this study, comparison of post-tonsillectomy pain could be done by paired control study. Patients including children (age over 5) are able to discriminate pain from either side of tonsillectomy. Data collection via daily telephone interview by masked assessor is such a good technique to prevent recall bias and missing data. However paired t test used in this study is not an appropriate statistical analysis because the FPS-R scores are ordinal data. Nonparametric test is more appropriate in this setting.

Using Faces Pain Scale–Revised for evaluation pain severity in Thai patients including adults and children was reported more appropriate than Visual Analogue Scale or VAS from the previous comparison of study pain scales in Thai children by

Newman CJ. et al (2005) [22]. Children had more difficulty understanding the use of the VAS than that of the FPS-R.

In this study, the method for the vessel sealing system and cold knife tonsillectomy were described in detail to enhance the reproducibility. The operative time in minutes was clearly defined as the duration of tonsillectomy operation on one side of tonsil starting at the time of incision and ending when complete hemostasis was done, not at the time of removal of tonsil. Intraoperative blood loss was estimated by measuring the amount in the suction bottle and by weighing the gauze before and after each procedure.

Randomization was performed by mixed block randomization. Intervention by vessel sealing system tonsillectomy was randomized to "Right or Left" side. VSST was performed first, and then CKT was done on the other side. There was one senior ENT surgeon involving in the study (the principal investigator) to make sure that the surgeon using well-practiced techniques. The allocation was concealed and blinded to physician, patients and personnel involved in the study. The allocation concealment was used by sequentially numbered opaque sealed envelopes with an enclosed card containing the assignment and the signature of the person preparing the sequence over envelope seals.

No loss of follow-up and no missing data found in this study are also a strong point of this study.

According to the mechanism of vessel sealing system providing excellent hemostasis, the amount of intraoperative blood loss and operative time from the tonsillectomy procedure using this technique was less in comparison with CKT group. Median (IQR) of intraoperative blood loss from VSST / CKT / paired difference = 1.00 (0.00 – 1.00) / 25.00 (10.00 – 35.00) / 20.00 (7.00 – 35.00) milliliters ( $p < 0.01$ ). Mean  $\pm$  SD of operative time from VSST / CKT / paired difference =  $3.70 \pm 2.27$  /  $8.52 \pm 4.79$  /  $4.83 \pm 4.60$  minutes (95% CI of paired difference = 2.84 – 6.81,  $p < 0.01$ ),

These results got along with the previous studies [18-20]. Lachanas VA. et al (2005) reported a randomized controlled trial of vessel sealing system tonsillectomy (VSST) versus cold knife tonsillectomy (CKT) procedure on adult patients [18]. The VSST and CKT groups consisted of 108 and 92 individuals, respectively. In the VSST group,

there was no measurable intraoperative bleeding, whereas mean bleeding for CKT group was 125 (range, 45–432) milliliters. The mean operative time was 15 +/-1.43 minutes for the VSST group and 21 +/- 1.09 minutes for the CKT group ( $p < 0.01$ ). The difference of mean operative time between both techniques was about 6 minutes less in the VSST group in comparison with CKT group. Therefore, VSST was proved to be a better technique for tonsillectomy in terms of better hemostasis and shortening of the operative time.

If at least 10 minutes of the total operative time of 20 minutes (50% of total time) can be saved, it will reduce the risk of anesthesia and the cost of operating room. In general, 10 minutes (or 5 minutes per each side) are more appropriate clinical significant level. The results from this study showed advantages of VSST in terms of bleeding control from surgery and shortening the operative time statistically significant but the magnitude of these benefits were not clinically significant.

The follow up time for adverse effects including postoperative pain, bleeding and others was decided to be 14 days in this study. There was no significant difference in daily (day0 – day14) postoperative pain ( $p = 0.10 - 0.96$ ) from Faces Pain Scale – Revised (FPS-R) between both groups. These results were different from the previous studies [18-20]. Lachanas VA. et al (2005) reported the overall mean pain score for the VSST group was significantly lower than the CKT group ( $p < 0.01$ ). From the  $p$  value of 0.10 – 0.96, comparison of change from day0 to day14 between two treatment groups had no tendency to have significant difference even though more sample size might be increased. Although postoperative pain relief was postulated by the advantage of VSST in terms of less tissue trauma, patients in this study had got the same pain scale level in both groups. This might be due to some insensitivity of 6 levels of Faces Pain Scale–Revised to discriminate the pain sensation perceived by the patients in this study. In the other way, VAS in the previous study of Lachanas VA. et al (2005) might be the overestimated result.

For postoperative bleeding, no immediate (within 24 hours) hemorrhage was found in both groups but delayed (after 24 hours) bleeding was found in two cases from CKT group and not found in VSST group. These results were different from the previous studies [18-20]. Lachanas VA. et al (2005) reported postoperative hemorrhage occurred

in 2 out of 108 subjects of the VSST group and 2 out of 92 subjects of the CKT group, respectively. This was not tested by statistical analysis because much more factors than only different surgical techniques should be considered. In experienced ENT surgeon, incidence of postoperative bleeding needed for hemostasis is low. If the primary aim of study was to prove this, it would have needed a large number of sample sizes. Postoperative bleeding from tonsillectomy resulted from many factors such as surgeon factors including surgeon's experience, surgeon's carefulness in hemostasis, degree of tissue trauma from his dissection skill. Patient factors such as bleeding tendency, habit of coughing, phlegm spitting or throat clearing, may aggravate bleeding from tonsillectomy area postoperatively. Surgical technique factors which produce too much tissue trauma, intraoperative bleeding control from different techniques or wound infection may be other causes of postoperative hemorrhage.

There were some limitations of this study. Firstly, Amount of blood loss was defined by amount of fluid in milliliters including blood and saliva measured from container and gauze. The saliva in the fluid was too difficult to be separated from blood. In this study, amount of total fluid collected from each tonsillectomy was assumed to be amount of blood loss. Secondly, operative time of either technique may be skewed by the biased surgeon. The surgeon involving in the study (the principal investigator) tried to perform both techniques without bias. Thirdly, operative time of bilateral CKT might be less than 2 times of unilateral CKT duration. During packing for homeostasis on one side of tonsil, ENT surgeons usually do the other side CKT until the second tonsil is removed, then go back to stop bleeding on the first side. Fourthly, postoperative pain is the subjective symptom and the outcome measurement in this study is the Faces Pain Scale – Revised (FPS-R), so the patients may feel uncertain to evaluate. Pain medication (Paracetamol qid) may also have some dilutional effect on pain scale. The most effort was used to make the patients understand and follow the protocol correctly. Finally, vessel sealing system tonsillectomy is a new technique, and there is always a learning curve in all new techniques, whereas cold knife tonsillectomy, as described previously, has been the gold standard technique in our department for the last 15 years. Undeniably, our senior surgeon (the principal investigator) is at least as practiced and familiar with cold knife tonsillectomy.

There were many strong points in this study. Firstly, research design, operational definition, data management and analysis were planned prior to recruitment. Secondly, if co-intervention (e.g. concomitant medications) occurs, it will affect both sides of tonsillectomy equally. Thirdly, there was no contamination of both groups, so intention-to-treat basis was not needed. Finally, consistent, standardized protocol of preoperative, intraoperative and postoperative care including every medication was used to minimize co-intervention.

The information of efficacy and adverse effects of vessel sealing system tonsillectomy from this study may provide information to choose better choice for tonsillectomy in order to reduce operative time, intraoperative blood loss, postoperative pain, postoperative bleeding and adverse effects.

Considering the comparable result of the VSST and CKT group in reducing Intraoperative blood loss and operative time, the cost of VSS should be taken into account. The cost of VSS machine is about one million baht and the cost of biclamp is 60,000 baht (more than 200 times of reusage) while CKT is 6,000 baht which is much cheaper. This should be considered in treatment planning for each individual. (Table 7)

	CKT	VSST
	baht	baht
Operation room (per case)	400, 1000, 3000, 4000	400, 1000, 3000, 4000
General anesthesia (per case)	3000	3000
Special machine (per case)	0	2000 (VSS machine)
Instrument (per case)	0	300 (VSS biclamp)
Medicine (per case)	1000	1000
Admission room cost : ordinary, special 2, 3, 5	500, 900, 1000, 1300	500, 900, 1000, 1300
- Hospital ward (per case/day)	100, 300, 400, 700	100, 300, 400, 700
- Food (per case/day)	100, 300, 300, 300	100, 300, 300, 300
- Nursing care (per case/day)	300, 300, 300, 300	300, 300, 300, 300

***Conclusion***

Vessel sealing system tonsillectomy (VSST) had a significant beneficial effect in reducing intraoperative bleeding and operative time in tonsillectomy over cold knife tonsillectomy (CKT). Although no advantage of VSST in reducing postoperative pain was observed. Delayed postoperative bleeding was found only in 2 cases of CKT in this study. The cost-effectiveness should be considered.

***Disclosure***

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