A Randomized Controlled Trial for Perioperative Morbidity in Microdebrider Versus Cold Instrument Dissection Tonsillectomy

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Background: *Tonsillectomy is a common procedure in children. It could produce moderate to severe post operative pain and morbidity. Preserving tonsillar capsule attached to pharyngeal constrictor muscle by microdebrider technique may reduce pain when compared to conventional cold dissection technique.*
Objective: *To compare the postoperative pain, perioperative, and postoperative morbidity between the microdebrider-assisted intracapsular tonsillectomy (MT) and cold instrument dissection tonsillectomy (CT).*
Material and Method: *Forty children with ages between 3-14 years old in Songklanagarind Hospital with tonsillar hypertrophy were randomly assigned to have MT and CT in each group. Data of perioperative morbidity, time to start taking food, LOS, treatment satisfaction, post operative pain, and amount of analgesia were recorded for 7 days. Post operative complication was also followed-up.*
Results: *There were no statistical significantly differences between groups in operation time, time to start taking food, LOS, and amount of postoperative analgesia and treatment satisfaction score. The MT had significantly more blood loss during operation (54.3 $\pm$ 35.45mL) than the CT (14.78 $\pm$ 18.71mL) ($p < 0.001$). The MT had significantly less post operative pain score on postoperative day 2 (2.50 $\pm$ 1.15 and 1.05 $\pm$ 0.83) and 3 (1.70 $\pm$ 0.80 and 1.05 $\pm$ 0.76) ($p < 0.05$) but no difference on day 0, 1, 4, 5, 6. Pain score after analgesia was significantly better in the MT on day 0 (2.45 $\pm$ 0.94 and 3.40 $\pm$ 1.47) ($p = 0.024$) but no difference on day 1-6. There were no significant differences in fentanyl use for break through pain, immediate and delayed complications between the groups.*
Conclusion: *MT is an effective alternative procedure for children with tonsillar hypertrophy and results in improved postoperative pain but have more intraoperative blood loss.*

Keywords: *Cold dissection tonsillectomy, Microdebrider-assisted intracapsular tonsillectomy, Tonsillar hypertrophy, Postoperative pain*

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Tonsillectomy is one of the most commonly performed operations in the United States of America[1], and accounts for approximately 20% of ear nose and throat surgery[2]. Since antibiotics are widely used to treat infection effectively, an indication for tonsillectomy in acute tonsillitis or peritonsillar abscesses is not very common. Obstructive sleep disorder breathing (OSDB) is now the most common indication for tonsillectomy. The standard technique of removal of the tonsils in England, Wales, and Germany is cold dissection tonsillectomy (CT)[2,3]. A variety of techniques has been used to remove the tonsil tissue; although total tonsillectomy is effective, it is often associated with a difficult recovery with a poor oral intake and a difficult recovery with prolonged pain. Painless tonsillectomy was introduced with a combination of new surgical techniques and medications. A microdebrider instrument has been used for many years in rhinosurgery for the removal of polypoid mucosa and sinus obstruction. The new technology uses a microdebrider to cut and suck the tonsil tissue away from the surgical field leaving the posterior capsule. Maintaining the capsule is a natural biologic dressing to cover the pharyngeal muscles,

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preventing them from sustaining injury, inflammation, and infection, which results in less postoperative pain, a more rapid recovery, and perhaps fewer delayed complications[4]. Previous studies of intracapsular tonsillectomy for OSDB have used varying techniques such as guillotine, electrocautery, CO_2 laser, coblation, radiofrequency ablation, and harmonic scalpel. None of them can be performed faster or with less injury to the capsule of the tonsil compared to microdebrider[5,6]. Microdebrider intracapsular tonsillectomy (MT) will leave some of lymphoid tissue at the tonsillar capsule which results in the most common complication of this technique, tonsillar regrowth[6]. The tonsillar remnants can become reinfected and be a source of persistent disease in chronic infection. Chronic tonsillitis is considered to be a contraindication to intracapsular tonsillectomy[7]. The present study compared the treatment of OSDB by CO_2 laser intracapsular tonsillectomy and conventional tonsillectomy, that the clinical results in children with snoring and sleep apnea showed no statistically significant difference[8]. There were no previous controlled trial studies comparing these two most popular techniques, CT vs. MT. In the present study, the authors compared the intraoperative and postoperative outcome of two established techniques for removing tonsillar tissue in OSDB children.

Material and Method

The protocol for the present study was reviewed and approved by the ethics committee of the Faculty of Medicine, Prince of Songkla University. The study population consisted of 40 patients aged 3 to 14 years, scheduled to undergo tonsillectomy with or without adenoidectomy and myringotomy with PE tube insertion at the Department of Otolaryngology. The data were collected between January 2003 and December 2005. Inclusion criteria were tonsillar enlargement $\geq$ 3+ associated with any of the following symptoms: excessive snoring, chronic mouth-breathing, failure to thrive, restless sleep, enuresis, daytime somnolence, hyperactive, cor pulmonale, dysphagia, or speech abnormalities. The exclusion criteria were acute suppurative tonsillitis, recurrent acute tonsillitis, and hematological disorder. Informed consent was given by the patients and their families regarding the study protocol. The willing participants were randomized to either CT or MT. The patients and their families or guardians were blinded as to the technique utilized, and the surgeon would notify the group status after finishing the follow-up on the sixth postoperative day.

Randomization

Randomization was performed using blocks of four. In the microdebrider group, the procedures were performed by the first author. In the cold instrument group, the procedures were performed by the attending surgeon or by a senior resident surgeon under the supervision of an attending surgeon and followed the standard service of Songklanagarind Hospital.

Sample size

The sample size was estimated on hypothesis testing of two population proportion, at an a level of 0.05 with power of test 80%, according to the previous study, in which moderate to severe pain was 13% in the MT group and by 63% in the tonsillectomy group[8].

Surgical techniques

After anesthetic induction and intubation, myringotomy with PE tube was performed in case of serous otitis media. The patient was set in Rose's position. The Crowe-Davis mouth gag was inserted and red rubber catheter was used to retract the soft palate. Prior to surgery of the tonsils, 0.25% bupivacaine with 0.5% lidocaine with adrenaline 1:200,000 ratio of 1:1 was infiltrated into the anterior pillar and tonsillar base bilaterally. The tonsils were removed with microdebrider using Stryker TPS system (Stryker instruments, Kalamazoo, MI, USA 49001) and hand piece hummer II, setting at 1,500 rpm in oscillating mode with aggressive cut, blade size 4 mm. The resection began with the left side tonsil with the microdebrider held in the opposite hand, and moved from the inferior to the superior pole, medially and proceeding laterally. When the plane of the pillars had been reached, a Hurd elevator was used to retract the anterior pillar, medialize the remaining tonsil, and allow a thin rim of lymphoid tissue on the tonsillar capsule to remain. Hemostasis of the tonsillar bed was achieved using bipolar electrocautery. The right side tonsil was removed in the same fashion. CT was performed with a sickle knife incision at the superior pole and blunt dissection at the plain of posterior capsule of the tonsils. Hemostasis of the tonsillar bed was achieved with monopolar or bipolar electrocautery. The times to perform tonsillectomy alone were recorded starting from making the incision at the superior pole in the CT group and beginning debridement in the MT group. The ending time was recorded when bleeding was totally stopped. Each side of the tonsils was recorded separately. The bleeding was estimated by weighting

gauze sponges and conversion to milliliter (mL) by using the value of density of blood of 1.053 mg/mL and adding the blood lost in a suction bottle, collected by urine volume control set. In the MT group, the bleeding was estimated by the total amount of fluid subtracted by volume of tonsils and the irrigated saline in the use of microdebrider.

Postoperatively, all patients received amoxicillin (40 mg/kg/day) or erythromycin (40 mg/kg/day) in the case of allergy to penicillin for five days, and acetaminophen (15 mg/kg/dose) orally every four hours. Fentanyl (0.5 microgram/kg/dose) was given intravenously whenever the pain score > 4 every two hours. First dietary intake was recorded. Pain was scored by the same research assistant at 7.30-9.00 am everyday for six days while awake with a self-rating scale 0-10, the Wong-Baker FACES pain rating scale[9] and the CHIPPS (Children and Infant Postoperative Pain Scale)[10] scored by the research assistant using 15 seconds for each question. After discharge from the hospital, caregivers were asked to record the Wong-Baker FACES pain rating scale and responded to the research assistant's phone call everyday. An office visit was performed 1 week after surgery to the attending physician the satisfaction of the treatment with a visual analog scale of 1-10 was assessed before telling which technique group they were in and recording any surgery-related complications.

Statistical analysis

The demographics data of CT and MT were presented as mean and standard deviation and compared using unpaired t-test or Chi-square test. The differences of operative time, intraoperative blood loss, time to resume first diet, admission day, and rescue analgesic medication between groups were compared using unpaired t-test. Individual pain score was compared between groups using the Mann-Whitney test. Statistical significance was set at ($p < 0.05$).

Table 1. Demographic data

Characteristic	Cold technique n = 20	Microdebrider n = 20	p-value
Sex (girl:boy)	5:15	8:12	0.025
Age			
Mean ± SD	6.35 ± 3.25	6.30 ± 3.15	0.96
Range (years)	3-12	3-11	
Body weight (kg)	24.37 ± 10.58	25.65 ± 9.05	0.68
Size (scale 0-4)	3.15 ± 0.37	3.30 ± 0.47	0.26
Type of surgery			
T	7	2	0.05
T+A	13	15	
T+A+M	0	3	

T = tonsillectomy; A = adenoidectomy; M = myringotomy and PE tube insertion

Role of the funding source

The Faculty of Medicine, Prince of Songkla University, had no role in the study design, collection, analysis, interpretation of data, writing of the report or the decision to submit the paper.

Results

Fourty patients between the ages of 3 and 14 years undergoing tonsillectomy with or without adenoidectomy were randomly assigned to CT (n = 20) and MT (n = 20). There were 23 girls and 17 boys in the study. There were significantly more girls in the MT group but age, body weight, and size of tonsils were well balanced in the two groups. The MT group had greater number of patients undergoing adenoidectomy and myringotomy (Table 1).

Intraoperative blood loss in the MT group (54.3 ± 35.45 mL) was significantly greater than in the CT group (14.8 ± 18.77 mL) ($p < 0.001$), but operative time (CT = 21.13 ± 9.18 min and MT = 15.5 ± 8.42 min; $p < 0.07$), time to start first diet (CT = 6.37 ± 6.37 min

Table 2. Intraoperative and postoperative data

Intraoperative and postoperative data	Cold technique n = 20 (mean ± SD)	Microdebrider n = 20 (mean ± SD)	p-value
Operative time (min:sec)	21:13 ± 9:18	15:53 ± 8:42	0.07
Intraoperative blood loss (mL)	14.78 ± 18.77	54.30 ± 35.45	<0.001
Time to resume first diet (hour)	6.37 ± 6.37	3.55 ± 2.48	0.07
Admission (day)	1.75 ± 0.79	1.70 ± 0.66	0.83
Therapy preference	9.55 ± 0.69	9.35 ± 0.81	0.44

Table 3. Post operative pain

Postoperative day	Cold technique			Microdebrider			p-value		
	Wong-baker FACES pain rating scale		CHIPPS Mean ± SD	Wong-baker FACES pain rating scale		CHIPPS Mean ± SD	Pain score during swallow	Pain score after medication	CHIPPS
	During swallow Mean ± SD	After medication Mean ± SD		During swallow Mean ± SD	After medication Mean ± SD				
Day 0	4.50 □ 1.54	3.40 ± 1.47	3.25 ± 2.02	3.55 ± 1.05	2.45 ± 0.94	1.80 ± 1.06	0.41	0.024	0.007
Day 1	3.20 ± 1.47	2.10 ± 1.21	2.10 ± 1.65	2.55 ± 1.10	1.55 ± 0.94	1.10 ± 0.64	0.10	0.18	0.05
Day 2	2.50 ± 1.15	1.50 ± 1.19	-	1.65 ± 0.81	1.05 ± 0.83	-	0.005	0.23	-
Day 3	1.70 ± 0.80	0.95 ± 0.76	-	1.05 ± 0.76	0.50 ± 0.69	-	0.018	0.05	-
Day 4	1.00 ± 0.79	0.50 ± 0.69	-	0.70 ± 0.73	0.30 ± 0.57	-	0.22	0.31	-
Day 5	0.50 ± 0.76	0.20 ± 0.52	-	0.60 ± 0.60	0.20 ± 0.41	-	0.41	0.74	-
Day 6	0.20 ± 0.41	0.00 ± 0.00	-	0.50 ± 0.61	0.20 ± 0.41	-	0.08	0.037	-

and MT = 3.55 ± 2.48 min; p = 0.07), time of admission (CT = 1.75 ± 0.79 days and MT = 1.7 ± 0.66 days; p = 0.83), and the satisfaction with the treatment (CT = 9.55 ± 0.69 and MT = 9.35 ± 0.81; p = 0.44) did not differ significantly (Table 2).

Postoperative pain was scored six hours postoperatively and daily up to the sixth postoperative day using the Wong-Baker FACES pain rating scale and using the CHIPPS six hours postoperative and daily up to the second postoperative day. The pain was scored in two periods: during swallowing, which represents the most severe pain, and after taking medication, which represents the mildest pain. At the immediate postoperative time, during swallowing pain in CT (4.50 ± 1.54) and in MT (3.55 ± 1.05) did not differ significantly (p = 0.41) while the MT group had less post-medication pain than the CT group (2.45 ± 0.94 and 3.40 ± 1.47, respectively, p = 0.024). On the second postoperative day, during swallowing and post-medication pain scores in the MT group were significantly less than in the CT group (p = 0.005 and 0.23, respectively) (Table 3). The patients in both groups received acetaminophen every four hours and intravenous fentanyl for break-through pain every two hours. There were no differences between the groups in the requirement for rescue analgesia (Table 4).

One patient in the MT group had to be readmitted for observing postoperative bleeding from residual adenoid tissue. It was stopped by nasal packing with mixture of 4% lidocaine with ephedrine in the ratio of 1:1.

Discussion

New approaches to tonsillectomy have been recently introduced with the goal of minimizing discomfort and the risk of complications from the procedure. However, none of the variations of tonsillectomy techniques has been able to achieve this goal. Retrospective studies by Koltai et al[6,11] have suggested a clinical advantage of the microdebrider over conventional tonsillectomy. The data from the

Table 4. Postoperative rescue analgesia medication (fentanyl)

Postoperative day	Cold technique Mean ± SD	Microdebrider Mean ± SD	p-value
Day 0	1.80 ± 1.36	1.4 ± 0.88	0.28
Day 1	1.00 ± 1.45	0.3 ± 0.73	0.06
Day 2	0.15 ± 0.49	0.0 ± 0.00	0.18

current prospective study also support the efficacy of microdebrider-assisted intracapsular tonsillectomy. The present results clearly demonstrated that patients had less postoperative pain in MT. Pain score in the MT group was significantly less than in the CT group at the earlier postoperative time, even though by the fourth post operative day, the pain score was not significantly different. Lister et al[12] found the microdebrider group had significantly less post-operative pain score on postoperative days 1 to 9. Sobol et al[13] also noted that the microdebrider group had near normal diet intake 1.7 days earlier than electrocautery tonsillectomy and Derkay et al[14] found the microdebrider group had near normal activity and stopped medication for pain earlier.

Sorin et al[5] explained that the capsule of the tonsil acted as a protective sheet covering the deeper neurovascular structure, which has made intraoperative bleeding less than in the total tonsillectomy technique. On the other hand, the authors found intraoperative blood loss in the microdebrider group had greater than in the cold instrument dissection as in others studies (Table 5). However, another study of Koltai et al[11] found that intraoperative blood loss in the microdebrider and the cold instrument dissection was not significantly different. The MT needs normal saline facilitating suction of resected tissue away from the surgical field, which may interfere with the measurement of intraoperative blood loss. It created more exposed raw surface of tonsil than the cold technique that resects at the plain of the capsule, and bleeding was more difficult to stop by electro cauterization. The unique technique in the present study was the collected intraoperative blood loss using a urine volume control set, which precisely collected and weighed the gauze sponge to calculate back to volume using a blood density of 1.053 mg/mL and subtracted the volume of suction fluid.

The present study demonstrated that microdebrider took an average of five minutes shorter than cold instrument dissection, but the difference was not statistically significant. Compared to the study of Sobol et al[13] and Derkay et al[14], those previous studies showed a longer operation time for MT than the electrocautery dissection tonsillectomy. In the present study, the cold instrument dissection was used instead of electrocautery dissection tonsillectomy, which took more time to perform.

There was no significant difference in the started time to resuming first diet postoperatively because most patients started to take clear liquid diet, which was easy to swallow at about the same time.

The search for the painless tonsillectomy continues. Finding a technique that works best, *e.g.* corticosteroids has the effect of decreasing the inflammatory process of the healing tonsillar fossas[12,13,15,16], antibiotics as a pain adjuvant for tonsillectomy. Burkart et al[17] conducted a meta-analysis of antibiotics (amoxy/augmentin) and the postoperative complication and showed that there was no reduction of postoperative pain but there was a one-day earlier return to normal diet and normal activity. Dhiwaker et al[18] found that antibiotics had no effect in reducing pain scores but decreased fever and halitosis and improved time to normal activity. Other adjuvant techniques for controlling pain after

Table 5. Previous prospective studies[17-19]

Reference (country)	Age (year)	Type of surgery	Operative time (min:sec)			Postoperative pain or result	Intraoperative bleeding (ml)		
			MT	ET/CT	p-value		MT	ET/CT	p-value
Lister MT et al[17] (USA) 2006	5-15	MT/ET	-	-	-	MT<ET (p<0.01)	-	-	-
Sobol SE et al[18] (USA) 2006	3-7	MT/ET	20:54	16:36	<0.001	MT near normal diet intake 1.7 days earlier than ET	45	30	<0.0001
Derkay CS et al[19] (USA) 2006	>2	MT/ET	10	8	<0.0001	MT near normal activity and stop medication for pain earlier	99% >25 mL	4% >25 mL	<0.001
This paper	3-14	MT/CT	16:53	21:13	0.067	MT<CT (p<0.05)	54.3	14.78	<0.05

MT = microdebrider intracapsular tonsillectomy; ET = electrosurgical tonsillectomy; CT = cold dissection tonsillectomy

tonsillectomy include the use of ice packs for the neck, stretching the neck, swallowing iced drinks, and other comfort measures supplied by parents and caregivers[19].

The only complication seen in the present study was a delayed postoperative bleeding from residual adenoid tissue but no complication was seen in tonsillar fossa. Delayed hemorrhage is one of the most common major complications after tonsillectomy. A recent multicenter retrospective review reported a 0.7% rate of delayed postoperative hemorrhage after performing MT in 870 patient, while Sorin et al[5] reported tonsillar regrowth in 3.2% of patients Recently, Solares et al[20] reviewed rate of about 0.46%. The authors recommend further study of the extension rate of overall regrowth and the recurrence rate of OSDB.

A limitation of the present study was the different surgeons in the two groups. A tertiary care hospital for training residents as well as performing research, some cases needed to be performed by senior residents under supervision of senior staff. With a larger number of cases, it is expected that the decreased post operative pain in the MT group would have been statistically significant.

In conclusion, this randomized study demonstrated that MT in children with adenotonsillar hypertrophy results in improved postoperative morbidity but more intraoperative blood loss.

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การศึกษาเปรียบเทียบความเจ็บปวด และพยาธิภาวะระหว่าง และหลังการผ่าตัดต่อมทอนซิลโดยใช้ microdebrider และ cold instrument dissection

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ภูมิหลัง: *การผ่าตัดทอนซิลเป็นหัตถการที่ทำบ่อยในผู้ป่วยเด็ก ก่อให้เกิดความเจ็บปวดในระดับปานกลางถึงมาก การผ่าตัดโดยวิธีอนุรักษ์เปลือกหุ้มของทอนซิลที่ติดกับผนังคอหอยด้วย microdebrider น่าจะลดความเจ็บปวดหลังผ่าตัดได้มากกว่าวิธี cold dissection ซึ่งเป็นวิธีดั้งเดิมโดยการผ่าตัดทอนซิลออกทั้งหมด*

วัตถุประสงค์: *เพื่อศึกษาระดับความเจ็บปวด และพยาธิภาวะระหว่างและหลังผ่าตัดทอนซิล ในการผ่าตัดโดยวิธี microdebrider-assisted intracapsular tonsillectomy เปรียบเทียบกับวิธี conventional cold dissection tonsillectomy*

วัสดุและวิธีการ: *เป็นการศึกษาแบบ randomized controlled trial ในผู้ป่วยเด็กที่มีทอนซิลโต อายุ 3-14 ปี จำนวน 40 คน ในโรงพยาบาลสงขลานครินทร์ ตั้งแต่วันที่ 1 มีนาคม พ.ศ. 2549 ถึง 1 เมษายน พ.ศ. 2550 โดยถูกสุ่มแบ่งเป็นข้างละ 20 คน ได้รับการผ่าตัดด้วยวิธี microdebrider-assisted intracapsular tonsillectomy เป็นกลุ่มศึกษากับวิธี conventional cold dissection tonsillectomy เป็นกลุ่มควบคุม เก็บข้อมูลระยะเวลาการผ่าตัด การเสียเลือดระหว่างผ่าตัด ระยะเวลาที่เริ่มรับประทานอาหารได้ ระยะเวลานอนโรงพยาบาล ความพึงพอใจต่อ วิธีการผ่าตัด และคะแนนด้านความเจ็บปวดหลังผ่าตัดขณะกลืนน้ำลาย และหลังได้รับยาแก้ปวดเป็นระยะเวลา 7 วัน และติดตามภาวะแทรกซ้อนหลังผ่าตัด*

ผลการศึกษา: *เวลาที่ใช้ในการผ่าตัด ระยะเวลาที่เริ่มรับประทานอาหารได้ ปริมาณยาแก้ปวดที่ได้รับระยะเวลานอนโรงพยาบาล ความพึงพอใจต่อวิธีการผ่าตัดทั้ง 2 วิธีนี้ไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ในขณะที่ปริมาณเลือดที่ออกระหว่างการผ่าตัดในกลุ่มศึกษา (54.3 $\pm$ 35.45 mL) มากกว่ากลุ่มควบคุม (14.78 $\pm$ 18.71 mL) อย่างมีนัยสำคัญทางสถิติ ($p < 0.001$) คะแนนความเจ็บปวดหลังผ่าตัดขณะกลืนน้ำลายของทั้ง 2 กลุ่ม ที่วันที่ 0, 1, 4, 5 และ 6 ไม่มีความแตกต่างกันอย่างมีนัยสำคัญ แต่กลุ่มศึกษามีคะแนนความเจ็บปวดน้อยกว่ากลุ่มควบคุมในวันที่ 2 (2.50 $\pm$ 1.15 และ 1.05 $\pm$ 0.83) และ 3 (1.70 $\pm$ 0.80 และ 1.05 $\pm$ 0.76) อย่างมีนัยสำคัญทางสถิติ ($p = 0.005$ และ $p = 0.018$ ตามลำดับ) คะแนนความเจ็บปวดหลังได้ยาแก้ปวดในกลุ่มศึกษา (2.45 $\pm$ 0.94) มีน้อยกว่ากลุ่มควบคุม (3.40 $\pm$ 1.47) อย่างมีนัยสำคัญทางสถิติ ($p = 0.024$) ในวันที่ 0 แต่ไม่แตกต่างกันในวันที่ 1-6 สำหรับยาแก้ปวด fentanyl ทั้งสองกลุ่มได้รับไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ ไม่พบภาวะเลือดออกหลังผ่าตัด และไม่มีผู้ป่วยหายไประหว่างการติดตามการรักษา*

สรุป: *การผ่าตัดทอนซิลในถุงหุ้มด้วย microdebrider เป็นวิธีการปฏิบัติทางเลือกที่มีประสิทธิภาพ สำหรับเด็กที่มีการโตเกินของทอนซิลและผลลัพธ์เกี่ยวกับความเจ็บปวดหลังผ่าตัดดีขึ้น แต่มีการสูญเสียเลือดระหว่างผ่าตัดมากกว่า*