CHAPTER IV

RESULTS

THE CONSORT E-FLOWCHART

(Fig 7)

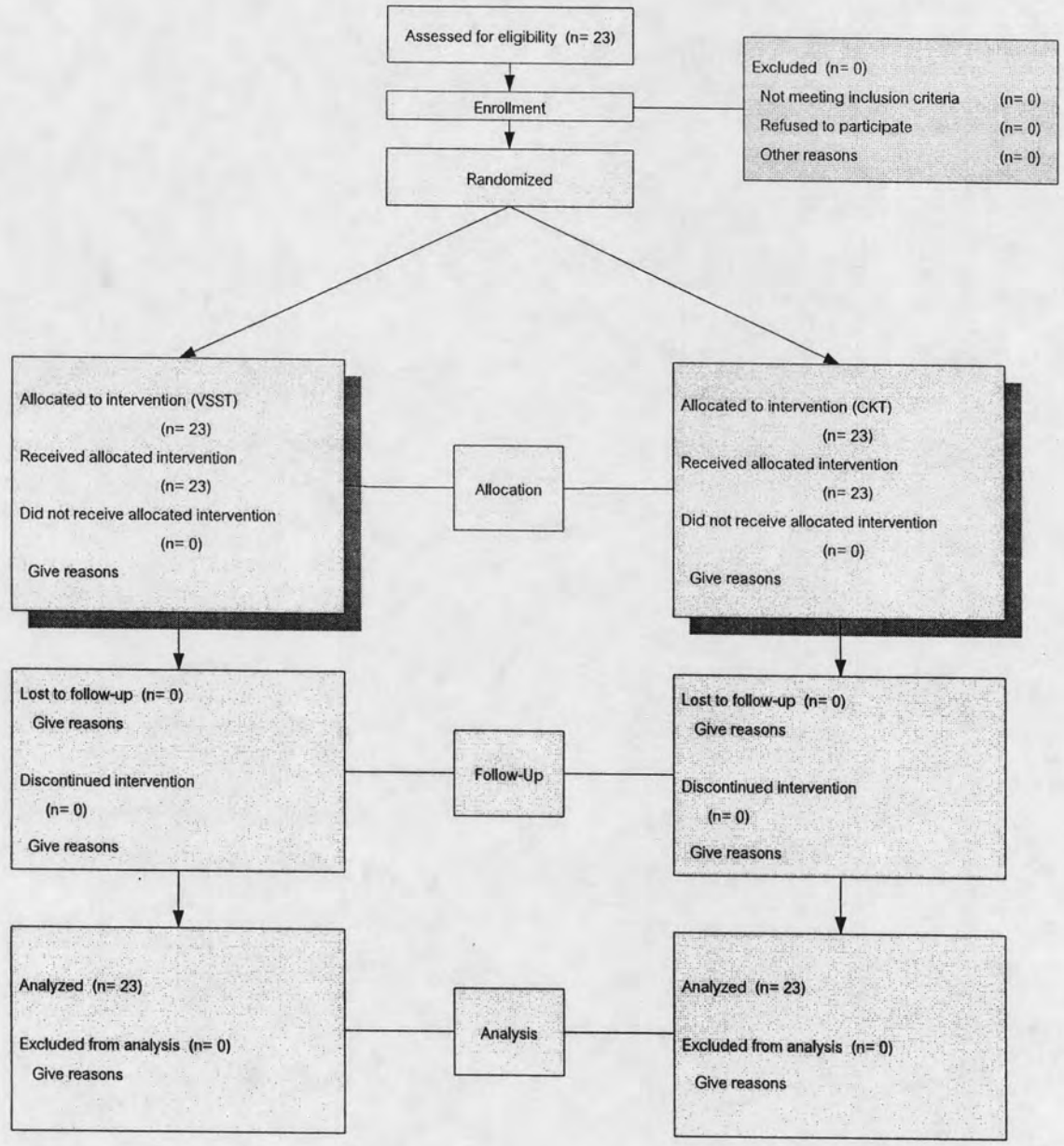

Figure 7: Flow chart of the Consort E-Flowchart

4.1 Characteristics of patients and baseline data

Twenty three subjects planned for tonsillectomy who were in eligible criteria were enrolled consecutively. Intervention was randomly allocated and performed by vessel sealing system tonsillectomy (VSST) on one side of tonsil and cold knife tonsillectomy (CKT) on the other side. Patients' demographic data were shown. (Table 1)

Table 1: Baseline data.

SEX (M,F)	15 (65.2%), 8 (34.8%)	
AGE (Yr)	24.9 +/- 13.1 (Range 6 - 46)	
CONCOMITANT OPERATION		
Tonsillectomy alone	18 (78.3%)	
Tonsillectomy + Adenoidectomy	4 (17.4%)	
Tonsillectomy + UPPP	1 (4.3%)	
INDICATION		
Chronic inflammation	16 (69.6%)	
Sleep-disordered breathing	7 (30.4%)	
	CKT	VSST
	n (%)	n (%)
TONSIL SIZE		
Grade 1	4 (17.4%)	3 (13.0%)
Grade 2	7 (30.4%)	8 (34.8%)
Grade 3	10 (43.5%)	10 (43.5%)
Grade 4	2 (8.7%)	2 (8.7%)
SIDE OF TONSILLECTOMY		
Left	12 (52.2%)	11 (47.8%)
Right	11 (47.8%)	12 (52.2%)

Of the 23 subjects, 15 (65.2%) were male and 8 (34.8%) were female. The mean age was 24.9 ± 13.1 years. Tonsillectomy alone was performed in 18 cases (78.3%),

Concomitant tonsillectomy and adenoidectomy was done in 4 cases (17.4%) and tonsillectomy combined with UPPP was done in 1 case (4.3%). For surgical indications of tonsillectomy, 16 cases (69.6%) were diagnosed as chronic inflammation of tonsils and 7 cases (30.4%) were sleep-disordered breathing patients. In VSST group, the size of tonsil were in Grade 1 / Grade 2 / Grade 3 / Grade 4 = 3 (13.0%) / 8 (34.8%) / 10 (43.5%) / 2 (8.7%) and in CKT group, they were in Grade 1 / Grade 2 / Grade 3 / Grade 4 = 4 (17.4%) / 7 (30.4%) / 10 (43.5%) / 2 (8.7%), respectively. From all performed by VSST, 11 cases (47.8%) were on the left side and 12 (52.2%) were on the right side.

Measured outcomes for efficacy and adverse effects are intraoperative blood loss, operative time, postoperative pain in Faces Pain Scale – Revised (FPS-R), postoperative bleeding and other adverse effects. Efficacy of VSST is significantly better than CKT in terms of intraoperative blood loss and operative time. Median (IQR) of intraoperative blood loss from VSST / CKT / paired difference = 25.00 (10.00 – 35.00) / 1.00 (0.00 – 1.00) / 20.00 (7.00 – 35.00) milliliters ($p < 0.01$). Mean ± SD of operative time from VSST / CKT / paired difference = 3.70 ± 2.27 / 8.52 ± 4.79 / 4.83 ± 4.60 minutes (95% CI of paired difference = 2.84 – 6.81, $p < 0.01$), However, no significant difference in daily (day0 – day14) postoperative pain ($p = 0.10 – 0.96$) and average (day0 – day14) postoperative pain ($p = 0.77$) from Faces Pain Scale – Revised (FPS-R) between both groups. No immediate (within 24 hours) postoperative bleeding was found but delayed (after 24 hours) postoperative bleeding was found in two cases from CKT side and not found in VSST side.

4.2 Analysis of the primary outcomes

4.2.1 Intraoperative blood loss (milliliters)

Unit of analysis of intraoperative blood loss (IBL) data is milliliters which are continuous data. Paired difference data of intraoperative blood loss between both techniques were skewed to the right. (Fig 8)

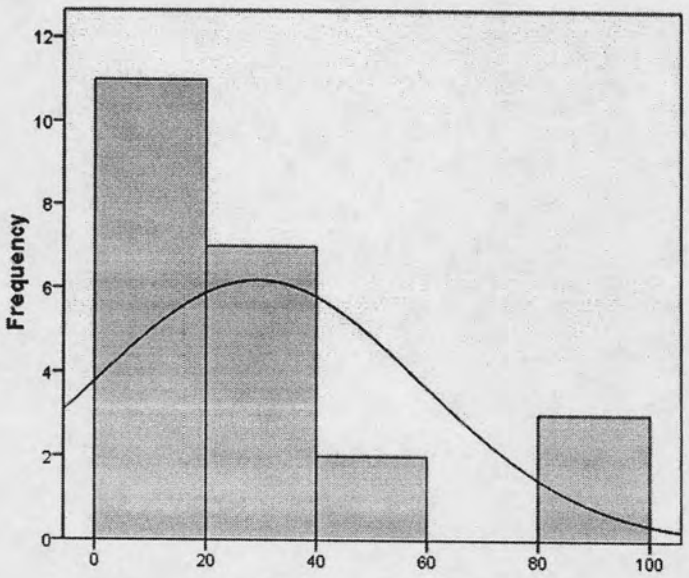

Figure 8: Histogram of intraoperative blood loss

Data of intraoperative blood loss between both techniques (CKT – VSST) were presented as "median (IQR)". Median (IQR) of intraoperative blood loss from CKT, VSST, and paired difference = 25.00 (10.00 – 35.00), 1.00 (0.00 – 1.00), and 20.00 (7.00 – 35.00) minutes, respectively. (Table 2)

Non-parametric test (Wilcoxon signed-rank test) of difference of intraoperative blood loss between both techniques (CKT – VSST) was used for analysis. The result showed statistically significant difference ($p < 0.01$). (Table 2)

Table 2: Comparison between CKT and VSST in terms of intraoperative blood loss (IBL), and difference of IBL between both techniques (CKT – VSST) by using non-parametric test (Wilcoxon signed-rank test).

	CKT	VSST	CKT – VSST	
	Median (IQR)	Median (IQR)	Median (IQR)	p-value
Amount of blood loss (millilitre)	25.00 (10.00 – 35.00)	1.00 (0.00 – 1.00)	20.00 (7.00 – 35.00)	< 0.01

4.2.2 Operative time (minutes)

Unit of analysis of operative time (OT) data is minutes which are continuous data. Paired difference data of operative time between both techniques were approximately in normal distribution. (Fig 9)

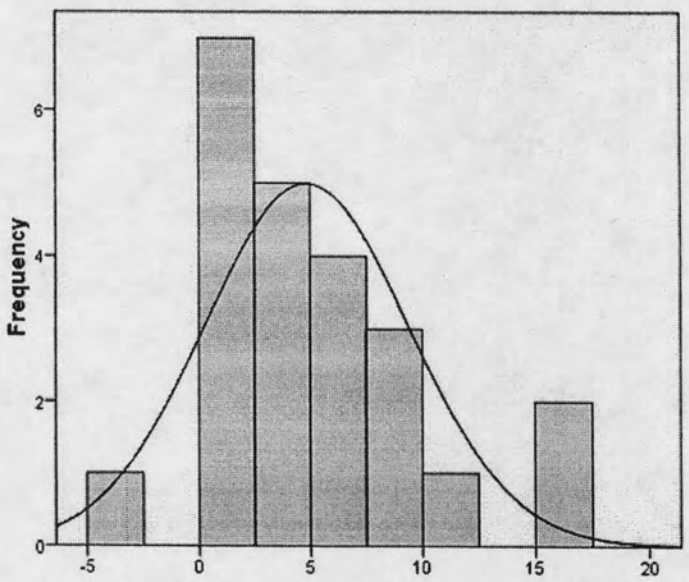

Figure 9: Histogram of operative time

Data of operative time between both techniques (CKT – VSST) were presented as "mean +/- standard deviation". Mean ± SD of operative time from CKT, VSST, and paired difference = 8.52 ± 4.79, 3.70 ± 2.27, and 4.83 ± 4.60 minutes, respectively. (Table 3)

Paired t-test of difference of operative time between both techniques (CKT – VSST) showed statistically significant difference (95% CI of paired difference = 2.84 – 6.81, $p < 0.01$). (Table 3)

Table 3: Comparison between CKT and VSST in terms of operative time (OT) and difference of OT between both techniques (CKT – VSST) by using paired t-test.

	CKT	VSST	CKT – VSST		
	Mean +/- SD	Mean +/- SD	Mean +/- SD	95% CI	p-value
Operative time (minutes)	8.52 +/- 4.79	3.70 +/- 2.27	4.83 +/- 4.60	2.84 – 6.81	< 0.01

4.2.3 Postoperative pain (Faces Pain Scale – Revised or FRS-R, Scores of 0, 2, 4, 6, 8, 10)

Unit of analysis of postoperative pain (Faces Pain Scale – Revised or FPS-R) data is score (0, 2, 4, 6, 8, 10) which are ordinal data.

Data of Faces Pain Scale – Revised (FPS-R) of the same technique (from both sides) were summed and presented as "median of each day (postoperative day 0-14)".

Median (IQR) of FPS-R in each day from CKT, VSST, and paired difference were = 25.00 (10.00 – 35.00) / 1.00 (0.00 – 1.00) / 20.00 (7.00 – 35.00) milliliters. (Table 4) (Fig 10)

No significant difference in each day (day0 – day14) postoperative pain (p = 0.10 – 0.96) from Faces Pain Scale – Revised (FPS-R) between both groups. (Table 4) (Fig 10)

Generalized estimating equation (GEE) was used for prediction of pain scale by considering treatment group and postoperative day as independent variables. Postoperative day was statistically significant (95% CI = -0.33 to -0.18; p < 0.01) but treatment group was not significant (95% CI = -0.73 to 0.54; p = 0.77). (Table 5)

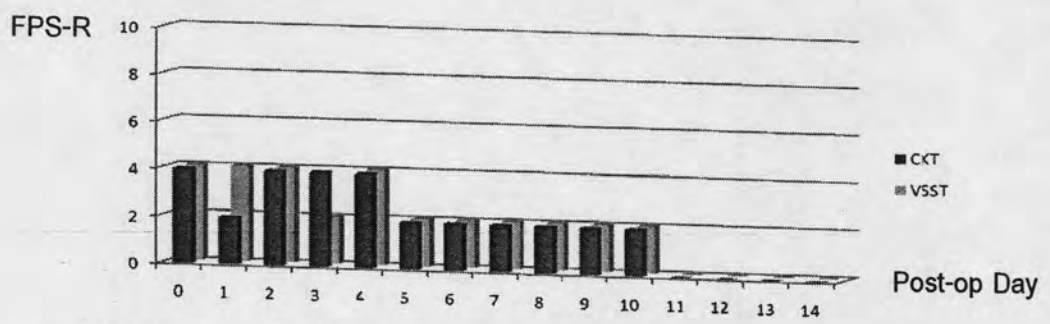

Figure 10: Comparison between CKT and VSST of Faces Pain Scale – Revised (FPS-R) from postoperative day0 to day14

Table 4: Comparison between CKT and VSST in terms of Faces Pain Scale – Revised (FPS-R) by using non-parametric test (Wilcoxon signed-rank test).

Pain Scales at Post-op Day	CKT	VSST	p-value
	Median (IQR)	Median (IQR)	
Day 0	4 (2-6)	4 (2-6)	0.60
Day 1	2 (2-4)	4 (2-6)	0.87
Day 2	4 (2-6)	4 (2-6)	0.54
Day 3	4 (2-6)	2 (2-6)	0.85
Day 4	4 (2-4)	4 (2-4)	0.79
Day 5	2 (2-4)	2 (2-6)	0.80
Day 6	2 (2-4)	2 (0-4)	0.41
Day 7	2 (2-4)	2 (0-4)	0.10
Day 8	2 (0-4)	2 (0-2)	0.48
Day 9	2 (0-4)	2 (0-2)	0.42
Day 10	2 (0-2)	2 (0-2)	0.82
Day 11	0 (0-2)	0 (0-2)	0.96
Day 12	0 (0-0)	0 (0-2)	0.43
Day 13	0 (0-0)	0 (0-2)	0.57
Day 14	0 (0-0)	0 (0-2)	0.47

Table 5: Hypothesis testing of Pain Scale by day and treatment using Generalized Estimating Equation (GEE).

Parameter	B	95% Wald Confidence Interval	p-value
(Intercept)	4.18	3.29 to 5.07	<0.01*
day	-0.26	-0.33 to -0.18	<0.01*
treatment	-0.09	-0.73 to 0.54	0.77
Dependent Variable = pain; Within-Subject Effect = day, treatment; Working Correlation Matrix Structure = AR(1)			

4.3 Analysis of the secondary outcomes

4.3.1 Postoperative bleeding

Unit of analysis of postoperative bleeding data is presence or absence of the event which are binary data. Data of postoperative bleeding of the same technique were summed and presented as "n (%)".

No immediate (within 24 hours) postoperative bleeding was found was found in both groups but delayed (after 24 hours) postoperative bleeding was found in two cases (8.7%) from CKT side and not found in VSST side. (Table 6) However, statistical test was not used for analysis of difference.

4.3.2 Other postoperative adverse effects

Unit of analysis of other postoperative adverse effects data is presence or absence of the event which are binary data. Data of other postoperative adverse effects of the same technique were summed and presented as "n (%)".

No other postoperative adverse effects were found in both groups. (Table 6) However, statistical test was not used for analysis of difference.

Table 6: Comparison between CKT and VSST in terms of postoperative adverse effects.

	CKT	VSST
	n (%)	n (%)
Immediate postoperative bleeding (within 24 hr) 0 = None or no need for hemostasis by physician 1 = Need for hemostasis by physician	0 (0)	0 (0)
Delayed postoperative bleeding (after 24 hr) 0 = None or no need for hemostasis by physician 1 = Need for hemostasis by physician	2 (8.7%)	0 (0)
Immediate other postoperative adverse effects (within 24 hr) 0 = None 1 = Yes (specified)	0 (0)	0 (0)
Delayed other postoperative adverse effects (after 24 hr) 0 = None 1 = Yes (specified)	0 (0)	0 (0)