

CHAPTER 4

RESULTS

4.1 Baseline variables

This study comprised 112 healthy volunteers. The age of the volunteers ranged between 21 to 25 years with a mean of 22.97 (± 0.83) years. The volunteers' age, gender, and N₂O concentration of each group were presented in Table 2. There were no statistically significant difference in age, gender, and concentration of N₂O in each group (Table 2).

There was no statistically significant difference in the pre-sedation anxiety level in each group ($p=0.416$) (Table 2). The length of procedure in this study was between 16-25 minutes. There was statistically significant difference in the length of procedure between the SO and RO groups ($p=0.015$) and the SR and RO groups ($p=0.008$) as presented in Table 2. The slow titration (SO and SR) group had longer procedure time than the rapid induction (RO and RR) group. Moreover, the graph showed frequency of pre-sedation anxiety level and length of procedure of each group were presented in Appendix D.

Table 2 Baseline variables

	Group				Mean or total	<i>p</i> -value	
	SO	SR	RO	RR			
Age (years) (mean± SD)	23.07 ±0.86	23.00 ±0.67	23.14 ±1.01	22.68 ±0.72	22.97 ±0.83	0.165 NS ¹	
NS ¹ : not significantly different by One-way ANOVA analysis, 0.05 level of significance							
Gender	Male	10/28 (35.71%)	8/28 (28.57%)	9/28 (32.14%)	12/28 (42.86%)	39/112 (34.82%)	0.711 NS ²
	Female	18/28 (64.29%)	20/28 (71.43%)	19/28 (67.86%)	16/28 (57.14%)	73/112 (65.18%)	
NS ² : not significantly different by Chi-square analysis, 0.05 level of significance							
N₂O/O₂ concentration (%)	30	1/28 (3.57%)	0/28 (0%)	1/28 (3.57%)	2/28 (7.14%)	4/112 (3.57%)	NS ³ 0.473 NS ²
	40	6/28 (21.43%)	9/28 (32.14%)	5/28 (17.86%)	4/28 (14.29%)	24/112 (21.43%)	
	50	21/28 (75.00%)	19/28 (67.86%)	22/28 (78.57%)	22/28 (78.57%)	84/112 (75%)	
NS ³ : not significantly different by Fisher Exact test, 0.05 level of significance NS ² : not significantly different by Chi-square analysis, 0.05 level of significance							
Pre-sedation anxiety level (mm.)	Median	8.50	18.00	16.00	8.25	0.416 NS ⁴	
	Minimum	0.00	0.00	0.00	0.00		
	Maximum	49.00	78.00	53.50	82.00		
Length of procedure (min)	Median	18.00†	18.00‡	17.00†‡	17.00	0.023*	
	Minimum	16.00	16.00	16.00	16.00		
	Maximum	24.00	23.00	21.00	25.00		
NS ⁴ : not significantly different by Kruskal wallis test, 0.05 level of significance *: The Kruskal wallis test significance level is 0.05, <i>p</i> -value = 0.023 significantly different †: The Mann-Whitney U test significance level is 0.05, <i>p</i> -value = 0.015 significantly different ‡: The Mann-Whitney U test significance level is 0.05, <i>p</i> -value = 0.008 significantly different							

4.2 Physiologic parameters

Physiologic parameters recorded in this study were blood pressure, heart rate and SaO₂ at different stage of sedation. Blood pressure and heart rate were recorded in the term of change from the baseline. The pre-oxygenation stage was the time that volunteers received 100% O₂ before N₂O administration. The N₂O termination stage was the time that N₂O was discontinued. The end of procedure stage was the fifth minutes after N₂O termination and volunteers received 100% O₂ or room air. The discharge stage was the time that volunteers were ready to be discharged.

4.2.1 Blood pressure

There were no statistically significant differences in change of systolic and diastolic blood pressure from the baseline in each group at all time point recorded (Table 3 and 4). However, there was statistically significant difference in change of systolic blood pressure from the baseline at the end of procedure between both groups ending with 100% O₂ (SO and RO) ($p=0.017$) and both groups beginning with rapid induction technique (RO and RR) ($p=0.044$) as presented in Table 3.

Table 3 Change of systolic blood pressure from the baseline at different stages of sedation

		Group				p-value
		SO	SR	RO	RR	
Change of systolic blood pressure from the baseline (mean±SD)	Pre-oxygenation	2.79 ±7.45	3.25 ±9.55	6.21 ±12.16	2.11 ±9.07	0.407NS
	N ₂ O termination	-1.14 ±9.24	1.36 ±8.99	6.57 ±12.72	0.75 ±10.16	0.052NS
	End of procedure	-1.93 ±8.27†	2.75 ±10.99	6.64 ±13.18†‡	-0.79 ±8.67‡	0.013*
	Discharge	-2.75 ±8.03	0.14 ±9.69	-0.04 ±12.40	-3.61 ±8.33	0.394NS
		0.067 NS	0.635 NS	0.139 NS	0.113 NS	
NS: not significantly different by the One-Way ANOVA analysis, 0.05 level of significance *: The One-Way ANOVA significance level is 0.05, p-value = 0.013 significantly different †: Post Hoc Multiple Comparison significance level is 0.05, p-value = 0.017 significantly different ‡: Post Hoc Multiple Comparison significance level is 0.05, p-value = 0.044 significantly different						

Table 4 Change of diastolic blood pressure from the baseline at different stages of sedation

		Group				<i>p</i> -value
		SO	SR	RO	RR	
Change of diastolic blood pressure from the baseline (mean±SD)	Pre-oxygenation	3.50 ±5.53	3.64 ±7.13	6.82 ±10.24	3.89 ±7.03	0.318NS
	N ₂ O termination	2.57 ±7.97	2.50 ±7.66	7.18 ±10.26	2.71 ±9.33	0.138NS
	End of procedure	2.61 ±6.71	5.29 ±9.09	7.21 ±9.48	5.96 ±7.26	0.201NS
	Discharge	-1.29 ±7.65	0.79 ±8.54	2.71 ±6.93	0.61 ±6.59	0.264NS
		0.058 NS	0.214 NS	0.209 NS	0.070 NS	
NS: not significantly different by the One-Way ANOVA analysis, 0.05 level of significance						

4.2.2 Heart rate

There were no statistically significant differences in change of heart rate from the baseline in each group at all time point recorded. However, there was statistically significant difference in change of heart rate from the baseline at the end of procedure in both groups beginning with rapid induction technique (RO and RR) ($p=0.043$) and the SR and RO groups ($p=0.008$) as presented in Table 5.

Table 5 Change of heart rate from the baseline at different stages of sedation

		Group				p-value
		SO	SR	RO	RR	
Change of heart rate from the baseline (mean±SD)	Pre-oxygenation	-2.64 ±9.02	-4.29 ±8.17	-7.04 ±8.94	-4.79 ±9.51	0.330NS
	N ₂ O termination	-5.71 ±8.32	-8.61 ±6.90	-9.29 ±8.75	-7.68 ±8.603	0.392NS
	End of procedure	-5.93 ±9.22	-3.29 ±6.18†	-10.07 ±7.75†‡	-4.54 ±7.60‡	0.009*
	Discharge	-0.50 ±8.00	-3.43 ±10.66	-5.82 ±9.49	-2.04 ±10.31	0.211NS
		0.060 NS	0.053 NS	0.243 NS	0.148 NS	

NS: not significantly different by the One-Way ANOVA, 0.05 level of significance
 *: The One-Way ANOVA significance level is 0.05, p -value = 0.009 significantly different
 †: Post Hoc Multiple Comparison significance level is 0.05, p -value = 0.008 significantly different
 ‡: Post Hoc Multiple Comparison significance level is 0.05, p -value = 0.043 significantly different

4.2.3 Oxygen saturation

Post-sedation oxygen saturation (SaO₂) dropped from the baseline in both groups ending with room air (SR and RR group). Nine from twenty-eight volunteer (32.14%) in the SR group and six from twenty-eight volunteer (21.43%) in the RR group were considered having SaO₂ drop while none of volunteer in both groups ending with 100% O₂ (SO and RO) had post-sedation SaO₂ drop from the baseline. Frequency of post-sedation SaO₂ drop from the SR and the RR group were compared.

There was no statistically significant difference between both groups ($p=0.547$) (Table 6).

Table 6 Frequency of post-sedation oxygen saturation drop compared to the baseline in each group

	group			
	SO	SR	RO	RR
Frequency of post-sedation oxygen saturation drop compared to the baseline	0/28 (0%)	9/28NS (32.14%)	0/28 (0%)	6/28NS (21.43%)
NS: The Fisher Exact Test significance level is 0.05, p -value = 0.547 not significantly different				

SaO₂ drop in this study was detected since the first minute after N₂O termination in both groups ending with room air. There were statistically significant differences of SaO₂ drop at the fourth minute after N₂O termination between the SO and SR groups and between the RO and RR groups. Similarly, there were statistically significant differences of SaO₂ drop at the fifth minute after N₂O termination between the SO and SR groups (Table 7). However, SaO₂ returned to the baseline within 0.50-3.50 minutes with a mean of 1.25 (± 0.96) minutes after the drop of SaO₂. None of the

volunteers had post-sedation SaO₂ below 95% so true O₂ desaturation or diffusion hypoxia did not present in any groups of this study.

Table 7 Post-sedation oxygen saturation at different time point

Post-sedation oxygen saturation		group				<i>p</i> -value
		SO	SR	RO	RR	
Baseline (%)	median	99	99	99	99	
	minimum	99	99	99	99	
	maximum	99	99	99	99	
1 min after N ₂ O termination (%)	median	99	99	99	99	0.059NS
	minimum	99	98	99	98	
	maximum	99	99	99	99	
2 min after N ₂ O termination (%)	median	99	99	99	99	0.109NS
	minimum	99	99	99	98	
	maximum	99	99	99	99	
3 min after N ₂ O termination (%)	median	99	99	99	99	0.053NS
	minimum	99	98	99	98	
	maximum	99	99	99	99	
4 min after N ₂ O termination (%)	median	99	99	99	99	0.012*
	minimum	99 [†]	97 [†]	99 [‡]	98 [‡]	
	maximum	99	99	99	99	
5 min after N ₂ O termination (%)	median	99	99	99	99	0.005*
	minimum	99 ^γ	97 ^γ	99	98	
	maximum	99	99	99	99	

NS: not significantly different by Kruskal wallis test , 0.05 level of significance
 *: Significantly different by The Kruskal wallis test, 0.05 level of significance
 †: Mann –Whitney U test significance level is 0.05, *p*-value = 0.020 significantly different
 ‡: Mann –Whitney U test significance level is 0.05, *p*-value = 0.020 significantly different
 γ: Mann –Whitney U test significance level is 0.05, *p*-value = 0.010 significantly different

4.3 Psychomotor performance

In the recovery period, the Trieger test was used to assess psychomotor performance of volunteers who obtained different administrative and ending techniques of N₂O. The range of time that psychomotor performance returned to the baseline after N₂O termination was 5-25 minutes and the median of every group were between 5-8 minutes. There were no statistically significant differences of time that psychomotor performance returned to the baseline after N₂O termination between groups as shown in Table 8. Moreover, there was no psychomotor impairment in each group. The graph showed frequency of time that psychomotor performance returned to the baseline after N₂O termination of each group were presented in Appendix D.

Table 8 Time that psychomotor performance returned to the baseline after N₂O termination

		Group				<i>p</i> -value
		SO	SR	RO	RR	
Time that psychomotor performance returned to the baseline after N ₂ O termination (min)	median	6.50	5.00	8.00	5.00	0.529NS
	minimum	5.00	5.00	5.00	5.00	
	maximum	25.00	25.00	17.00	22.00	

NS: not significantly different by The Kruskal wallis test, 0.05 level of significance

4.4 Post-sedation complications

Post-sedation complications that volunteers had complained were only minor complications such as nausea, headache, dizziness, confusion, lethargy, drowsiness and prolonged numbness as shown in Table 9. The most common complication found in this study was dizziness. There was no incidence of vomiting. None of volunteers had post-sedation SaO₂ below 95% so true O₂ desaturation or diffusion hypoxia did not present in any groups. There were no statistically significant differences in post-sedation complications in each group.

Table 9 Occurrence of post-sedation complications in each group

	SO	SR	RO	RR	Total	<i>p</i> -value
Dizziness	15/28 (53.57%)	14/28 (50%)	12/28 (42.86%)	12/28 (42.86%)	53/112 (47.32%)	NS
Drowsiness	8/28 (28.57%)	6/28 (21.43%)	3/28 (10.71%)	2/28 (7.14%)	19/112 (16.96%)	NS
Headache	3/28 (10.71%)	2/28 (7.14%)	1/28 (3.57%)	5/28 (17.86%)	11/112 (9.82%)	NS
Lethargy	1/28 (3.57%)	3/28 (10.71%)	2/28 (7.14%)	2/28 (7.14%)	8/112 (7.14%)	NS
Prolonged numbness						
-feet	1/28 (3.57%)	3/28 (10.76%)	3/28 (10.71%)	1/28 (3.57%)	8/112 (7.14%)	NS
-perioral soft tissue	1/28 (3.57%)	0/28 (0%)	2/28 (7.14%)	3/28 (10.71%)	6/112 (5.36%)	NS
-hands	0/28 (0%)	2/28 (7.14%)	3/28 (10.71%)	1/28 (3.57%)	6/112 (5.36%)	NS
Nausea	3/28 (10.71%)	0/28 (0%)	1/28 (3.57%)	2/28 (7.14%)	6/112 (5.36%)	NS
Confusion	1/28 (3.57%)	0/28 (0%)	1/28 (3.57%)	1/28 (3.57%)	3/112 (2.68%)	NS
Vomiting	0/28 (0%)	0/28 (0%)	0/28 (0%)	0/28 (0%)	0/112 (0%)	NS
Diffusion hypoxia	0/28 (0%)	0/28 (0%)	0/28 (0%)	0/28 (0%)	0/112 (0%)	NS
NS: not significantly different by The Fisher Exact Test, 0.05 level of significance						

4.5 Recovery time

The results of this study showed that the ranges of time that all subjective symptoms disappeared were between 1-56 minutes with the median between 4.50-6.50 minutes. The mean of time required for the patient to be discharged were between 16.18-18.75 minutes as presented in Table 10. Although the least recovery time of this study was in the SO group, there were no statistically significant differences of recovery time between each group. Moreover, the graph showed frequency of disappearance of subjective symptoms from sedation in each group was presented in Appendix D.

Table 10 Recovery time in each group

		Group				p-value
		SO	SR	RO	RR	
Disappearance of all subjective symptoms from sedation(min)	median	4.50	4.65	4.70	6.50	0.970NS ¹
	Minimum	1.25	1.14	1.00	1.00	
	maximum	30.00	38.00	20.00	56.00	
Time required for the patient to be discharged (min)	Mean ± SD	16.18 ± 7.27	18.75 ± 7.84	18.07 ± 6.83	16.25 ± 10.97	0.571NS ²
NS ¹ : not significantly different by The Kruskal wallis test, 0.05 level of significance NS ² : not significantly different by the One-Way ANOVA analysis, 0.05 level of significance						

4.6 Level of satisfaction of sedation method

There was the highest level of satisfaction in the SO group with a mean of 68.48 (± 2.48) mm. The mean of the level of satisfaction of the groups that beginning with slow titration (SO and SR) were more than the groups that beginning with rapid induction (RO and RR). Moreover, the mean of the level of satisfaction of the groups that ending with 100% O₂ (SO and RO) were more than the groups that ending with room air (SR and RR). However, there were no statistically significant differences of satisfaction of sedation method in each group (Table 11).

Table 11 Level of satisfaction of each sedation method

	Group				p-value
	SO	SR	RO	RR	
Level of satisfaction (mm.) (mean \pm SD)	68.48 ± 2.48	66.78 ± 2.37	67.69 ± 2.58	62.52 ± 2.88	0.828NS
NS: not significantly different by the One-Way ANOVA , 0.05 level of significance					