CHAPTER 4

RESULTS

4.1 Demographic and baseline data

A total of one hundred and eight patients who underwent lower extremity surgery under spinal anesthesia with intrathecal morphine were enrolled in the study. Fifty-eight patients were randomly allocated to each group (ginger group and placebo group).

The baseline characteristics of the patients in both groups were comparable regarding age, sex, body weight, height, ASA physical status, incidence of intraoperative hypotension and duration of surgery (Table 1)

Table 1 The demographic characteristics and baseline data

	Ginger group(n = 54)		Placebo group(n = 54)	
	Mean(SD)	Min , Max	Mean(SD)	Min , Max
Age (yrs)	37.6 (14.8)	17, 64	35.1 (13.6)	16, 64
Sex : male#	30 (56%)		33 (61 %)	
Weight (kg)	61.2 (12.1)	43, 91	61.1 (10.7)	42, 100
Height (cm)	163.9 (8.7)	145, 182	163.8(7.3)	150, 180
ASA status : I #	45 (83%)		42 (78%)	
Intraoperative hypotension#	4 (7%)		9 (17%)	
Duration of surgery (min)	100.0 (41.6)	15, 205	114.81(51.2)	15, 270

number (%)

4.2 Primary outcome analysis

The proportion of PONV in ginger group was significantly lower than that in the placebo group (38.9% vs. 61.1% , p-value = 0.021). Absolute risk reduction for PONV by premedication with ginger was 22%, with 95% confidence of interval from 3.6 % to 40.4%. So the number needed to treat was 5, with 95% confidence of interval from 2 to 28 (Table 2).

Table 2 The incidence of PONV in the first 24 hr postoperatively

	Ginger group	Placebo group	ARR(95%CI)	NNT(95%CI)	p-value
PONV					
24 h postop.	21 (39%)	33 (61%)	22% (4, 40)	5 (2, 28)	0.021
Intraop.	4 (7%)	4 (7%)	0% (-10, 10)		1.000
0-6 h postop.	19 (35%)	25 (46%)	11% (-7, 30)		0.24
6-24 h postop.	8 (15%)	13 (24%)	9% (-6, 24)		0.224

4.3 Secondary outcome analysis

4.3.1 Nausea and vomiting

Since no patient vomited without experiencing nausea, the incidence of nausea as well as the absolute risk reduction and number needed to treat were then the same as those of PONV (Table 3) .

Table 3 The incidence of nausea , nausea score and requirement of anti-emetic

	Ginger	Placebo	ARR(95%CI)	NNT(95%CI)	p-value
Nausea 24 h postop.					
No	33 (61%)	21 (39%)	22% (4, 40)	5 (2, 28)	0.021
Yes	21 (39%)	33 (61%)			
Nausea score					
0	33 (61%)	21 (39%)			0.037[a]
1	10 (18%)	13 (24%)			
2	8 (15%)	17 (31%)			
3	3 (6%)	3 (6%)			
Anti-emetic rescue					
No	4 (76%)	33 (66%)	15% (-2, 32)		0.097
Yes	13 (24%)	21 (39%)			

a. Chi-square for trend

The incidence of vomiting at the first 24 hours after the operation in ginger group was lower than in placeco group (27.8% vs. 44.4%). However, this difference was not statistically significant (95% CI from –1.22% to 34.4% and p-value = 0.07) as shown in table 4.

Table 4 The incidence of vomiting in the first 24 hr postoperatively

	Ginger group	Placebo group	ARR (95% CI)	p-value
Vomiting				
24 h postop.	15 (28%)	24 (44%)	16.% (-1%, 34%)	0.07
Intraop.	3 (6%)	2 (4%)	-2% (-10, 6)	0.647
0-6 h postop.	12 (22%)	19 (35%)	13% (-4, 30)	0.136
6-24 h postop	3 (6%)	7 (13%)	7% (-4, 18)	0.184

There were no statistically significant differences between two groups, according to the incidence of PONV when we observed at different period, that is intraopeative, 0-6 hour, and 6-24 hour postoperatively (Table 2). The incidences of nausea at different period equaled to those of PONV. The incidences of vomiting at different period had also not statistically significant differences (Table 4).

Figure 5 The incidence of PONV at different period

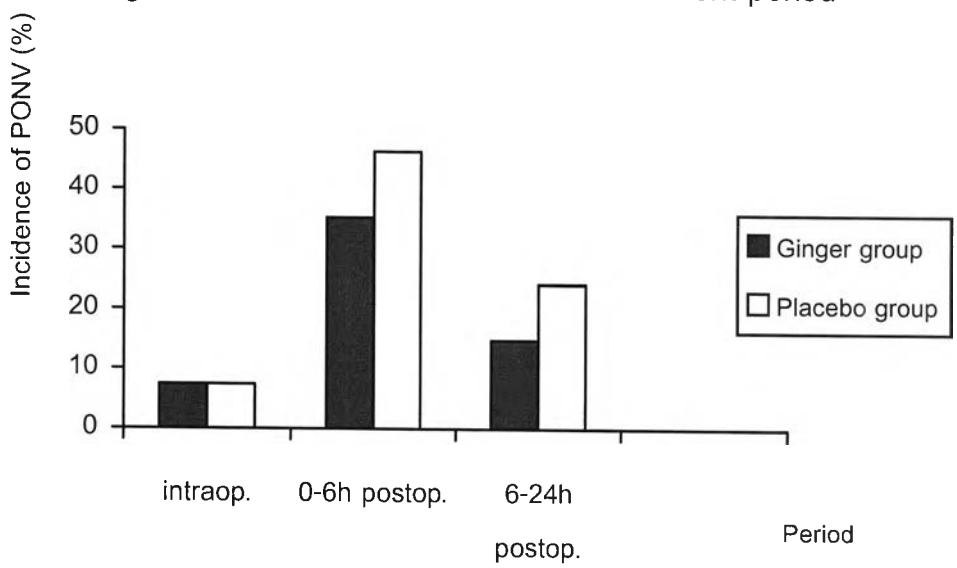
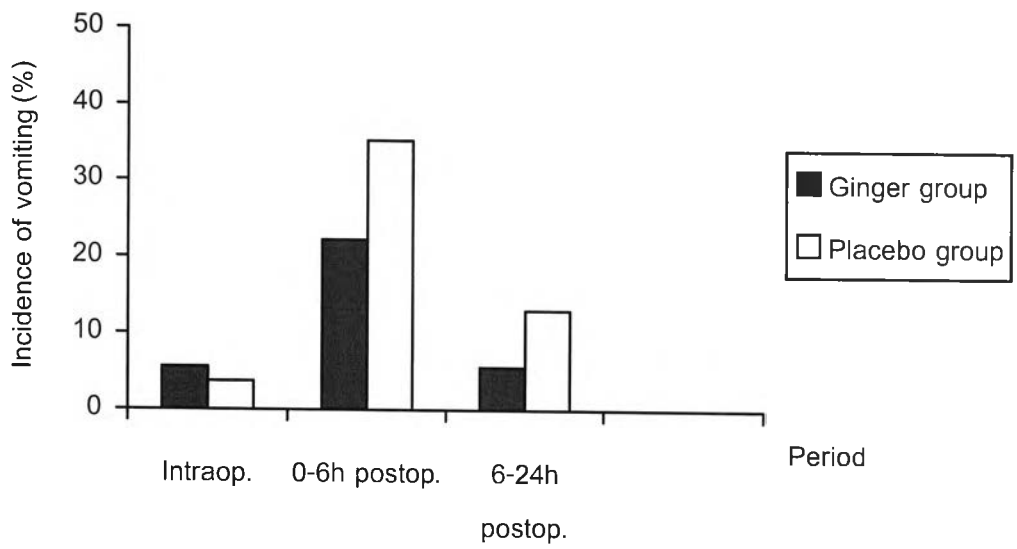


Figure 6 The incidence of vomiting at different period



Considering the severity of nausea, the percentage of no nausea was as high as 61.1% (33 in 54) for ginger group compared to only 38.9% (21 in 54) for placebo group. Ginger group also had less mild and moderate nausea compared to placebo (18.5% vs.24.1% and 14.8% vs. 31.5% , respectively), but had equal severe nausea of 5.6 % (Table 3). In summary, the severity of nausea was less in the ginger group than in the placebo(p-value = 0.037).

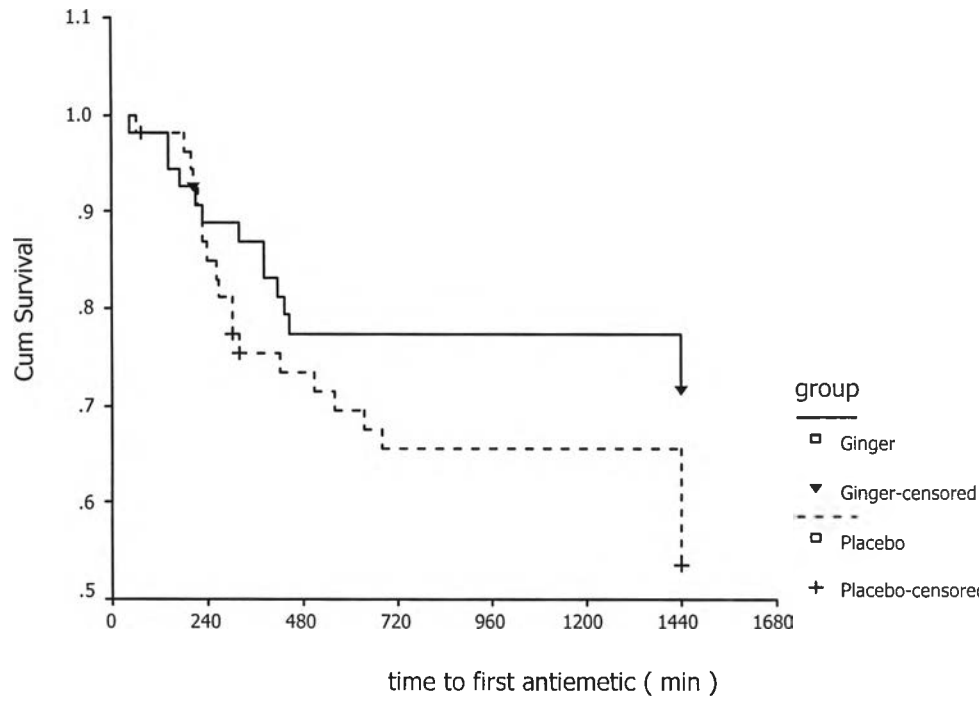
Patients in the ginger group seemed to require less anti-emetic than placebo (24.1% vs. 38.9%), however the difference was not statistically significant (p-value = 0.097). Among patients suffering from vomiting , the median emetic episode per patient were 3 (range = 1 – 13) in ginger group and 2 (range = 1 – 12) in placebo group and there was no statistically significant difference as shown in figure 5.

Figure 7 Emetic episode per patient

a Mann-Whitney U test

Survival curve of time to first anti-emetic was shown in figure 6. Since less than 50% of the subjects needed anti-emetic, the median survival time could not be estimated. Survival curve of Ginger group was over that of Placebo group; for example, at the time of 720 min, the cumulative survival were 0.75 and 0.65 in ginger group and placebo group, respectively. Again, it did not differ between ginger group and placebo group (p= 0.075).

Figure 8 Survival analysis of time to first antiemetic



4.3.2 Pruritus

Since there was no patient in placebo group who rated moderate pruritus (pruritus score = 2), the data in pruritus score 2 and 3 were combined (Table 5). The need for anti-pruritus were 11.1%, and 9.3% in ginger group and placebo group respectively, which was not statistically significant (p-value = 0.517).

Table 5 Pruritus score and requirement of anti-pruritus

	Ginger group	Placebo group	ARR (95% CI)	p-value
Pruritus score				
0	36 (67%)	36 (67%)		0.517[a]
1	13 (24%)	17 (32%)		
2, 3	5 (9%)	1 (2%)		
Anti-pruritus				
rescue	48 (89%)	49 (91%)	2% (-13, 9)	1.000
No	6 (11%)	5 (9%)		
Yes				

a. Chi-square for trend

4.3.3 Pain intensity

The VAS pain scores varied from 0 to 10 in both groups. The distribution of VAS pain scores in each group seemed to be normal, therefore unpaired t-test was employed. There was no statistically significance difference in mean VAS pain scores between the ginger group and placebo (3.7 ± 2.6 vs. 3.6 ± 2.3, p-value = 0.88).
In addition, the requirement rates of analgesics were 59.3% , and 55.6% in ginger group and placebo group respectively, which was not statistically significant (p-value = 0.697).

4.3.4 Adverse effect

There were seven patients, one in ginger group and six in placebo group , had urinary retention and were treated by single urine catheterization. No patient in both group complainted pungent smell or felt heartburn. No other side effect was noted.