

CHAPTER IV

RESULTS OF THE STUDY

Patients accounting

A Total of 124 patients were screened during July 1997 to January 1999. Forty-four was excluded according to exclusion criteria such as having diurnal enuresis , age less than 6 years , and living far from the hospital that they might prevent a regular contact with the physician.

Eighty patients (boys 24 , girls 56) were included in the study. These included the patients who had already been treated for 3 months duration (62 cases : boys 24 , girls 38) and on the process of treatment (18 cases : boy 1 , girls 17).

The 62 cases who had already been treated for 3 months period were divided into 2 groups of treatment , 31 cases (boys 12 , girls 19) were treated with pad and bell and the other 31 cases (boys 12 , girls 19) were treated with traditional one.

Two patients dropped out during the study , one patient was in pad and bell group , the other was in traditional one. The drop - out in the pad and bell group was because of rash at upper thigh and the drop out in the traditional group was because his father did not want the child to restrict fluid an hour before bed time. However their data were included in the analysis , based on intention - to - treat analysis.

Baseline data (Characters and distribution of Sample population)

Table 4.1 : Distribution of Sample Population Compared between Two Treatment Groups by Sex

Sex	Pad and bell	Traditional	Total
Male	12 (38.7%)	12 (38.7%)	24
Female	19 (61.3%)	19 (61.3%)	38
Total	31	31	62

From the total 62 sample population were male 38.7 percent (24 cases) and female 61.3 percent (38 cases).

Both treatment groups were equally distributed by sex.

Table 4.2 : Distribution of Sample Population Compared between Two Treatment

Groups by Father's Educational Levels

Educational levels	Pad and bell	Traditional	Total
Elementary	4 (13.8%)	10 (32.3%)	14
Secondary	13 (44.8%)	11 (35.5%)	24
High occupational	1 (3.4%)	6 (19.4%)	7
Bachelor	7 (24.1%)	3 (9.7%)	10
Higher than bachelor	4 (13.8%)	1 (3.2%)	5
Total	29 (2 cases unknown)	31	60

P - value = 0.069 (Mann - Whitney U test)

There was no statistical difference among the father's educational levels when compared between two treatment groups.

Table 4.3 : Distribution of Sample Population Compared between Two Treatment Groups by Mother's Educational Levels

Educational levels	Pad and bell	Traditional	Total
Elementary	4 (12.9%)	8 (25.8%)	12
Secondary	13 (41.9%)	9 (29.0%)	22
High occupational	4 (12.9%)	7 (22.6%)	11
Bachelor	9 (29.0%)	5 (16.1%)	14
Higher than bachelor	1 (3.2%)	2 (6.5%)	3
Total	31	31	62

P - value = 0.479 (Mann - Whitney U test)

There was no statistical difference among the mother's educational levels when compared between two treatment groups.

Table 4.4 : Distribution of Sample Population Compared between Two Treatment

Groups by Type of Wakening

Type of wakening	Pad and bell	Traditional	Total
consciously waken	15 (48.4%)	15 (48.4%)	30
Not consciously waken	16 (51.6%)	16 (51.6%)	32
Total	31	31	62

P-value = 1.0 (Chi-square test)

Both treatment groups were equally distributed by type of wakening.

Table 4.5 : Distribution of Sample Population Compared between Two Treatment Groups by Having or Not Having Parental Conflict

Parental conflict	Pad and bell	Traditional	Total
Parental conflict	8 (25.8%)	4 (12.9%)	12
No parental conflict	23 (74.2%)	27 (87.1%)	50
Total	31	31	62

P - value = 0.199 (Chi-square test)

There was no statistical difference on parental conflict (having or not having parental conflict) when compared between two treatment groups.

Table 4.6 : Distribution of Sample Population Compared between Two Treatment Groups by Age , Number of Urinations per Night before Treatment and Number of Wetnights per Week before Treatment

	Pad and bell	Traditional	P – value
Age			
mean \pm SD	10.13 \pm 1.82	9.30 \pm 2.37	0.046
95% CI	9.46 – 10.80	8.16 - 9.90	
Urination - night			
mean \pm SD	1.69 \pm 0.76	1.60 \pm 0.49	0.554
95% CI	1.41 - 1.97	1.42 - 1.78	
Wetnight - week			
mean \pm SD	6.19 \pm 1.47	5.65 \pm 1.80	0.194
95% CI	5.65 - 6.73	4.99 - 6.31	

By using student t- test, there was only one baseline variable which was statistically significant between two groups of treatment ,i.e., age (P-value was 0.046)

Others such as sex , education of father , education of mother , type of wakening , parental conflict , number of urination per night and number of wetnights per week before study were not statistically significant between two treatment groups.

Therapeutic results

Primary outcome

Table 4.7 : Results of Two Treatment Groups

	Pad and bell				Traditional			
	male		female		male		female	
	W+	W-	W+	W-	W+	W-	W+	W-
Remission	4	4	7	7	1	1	4	-
Much improved	2	1	2	-	1	-	-	-
Improved	-	1	-	2	3	4	2	6
Not improved	-	-	-	-	-	1	3	4
Drop out	-	-	-	1	1	-	-	-
Total remission	22/31 = 70.97%				6/31 = 19.35%			

W+ = Consciously waken, W- = Not consciously waken

For 31 cases treated with pad and bell, 22 cases reached remission criterion (22/31 = 71%), 5 cases were much improved, (having less than 2 wetnights weekly), 3 cases were improved (reduction of wetnights per week more than half of the beginning) and one case dropped out (because of the rash at the upper thigh). Every case improved.

For 31 cases treated with traditional method ,6 cases reached remission criterion (6/31 = 19.35%) , 1 case was much improved , 15 cases were improved , 8 cases were not improved and one case dropped out (because his father did not want the child to restrict fluid).

Table 4.8 : Remission rate compared between two treatment groups

	Pad and bell	Traditional
Remission	(22/31) 71%	(6/31) 19.35%
95 % CI	(55.03 % , 86.97 %)	(5.44 % , 33.26 %)

From 2×2 table , we calculate the P-value by Z-test (with α error = 0.05 , and magnitude of difference = 0.3,one-tailed hypothesis).The P-value was 0.02333 (P-value < 0.05) with statistical significance.

$$Z = \frac{(\hat{P}_1 - \hat{P}_2) - d_0}{\sqrt{\frac{\hat{P}_1 \hat{Q}_1}{n_1} + \frac{\hat{P}_2 \hat{Q}_2}{n_2}}}$$

$$Z = \frac{(0.7097 - 0.1935) - 0.3}{\sqrt{\frac{(0.7097)(1 - 0.7097)}{31} + \frac{(0.1935)(1 - 0.1935)}{31}}}$$

$$= 1.999$$

$$\text{P-value} = 0.02333$$

Secondary outcomes

Table 4.9 : Relapse rate compared between two treatment groups

	Pad and bell		Traditional	
	male	female	male	female
Relapse	1	5	2	2
F / U	2	2	-	1
Still remission	5	7	-	1
Total Relapse	6/18 = 33.33%		4/5 = 80%	

$$Z = \frac{P_1 - P_2}{\sqrt{P(1-P) \left(\frac{1}{n_1} + \frac{1}{n_2} \right)}}$$

$$\text{when } P = \frac{X_1 + X_2}{n_1 + n_2}$$

$$Z = 1.86$$

$$p\text{-value} = 0.0314 \text{ (one-tailed)}$$

There was a statistical difference between two groups in relapse rate (P-value < 0.05)

Table 4.10 : Comparison between Two Groups of Treatment by Number of Days Taken to Reach Remission and Number of Wetnights before Reaching Remission

	Pad and bell	Traditional	P - value
Days taken			
N	22	6	
mean \pm SD	50.86 \pm 15.36	42.67 \pm 26.33	0.493
95% CI	(44.05 , 57.67)	(15.03 , 70.30)	
Wetnights			
N	22	6	
mean \pm SD	17.36 \pm 10.33	7.50 \pm 5.96	0.035
95% CI	(12.79 , 21.94)	(1.25 , 13.75)	

By unpaired t-test , there was a statistical difference in number of wetnights before reaching remission compared between two groups of treatment (P-value = 0.035) but there was not any statistical difference in number of days taken to reach remission compared between two groups of treatment (P-value = 0.493)

The number of sample in the traditional group was too small to make any meaningful comparison .

Table 4.11 : Comparison between Two Groups of Treatment and Sexes by Number of Days Taken to Reach Remission and Number of Wetnights before Reaching Remission

Number of days taken to reach remission	Sum of Squares	Df	Mean Square	F	Sig.
Combined	355.405	2	177.702	.530	.595
Group	310.826	1	310.826	.927	.345
Sex	38.651	1	38.651	.115	.737

Number of wetnights before reaching remission	Sum of Squares	df	Mean Square	F	Sig.
Combined	629.108	2	314.554	3.501	.046
Group	443.958	1	443.958	4.941	.035
Sex	170.449	1	170.449	1.897	.181

There was only one statistical difference in number of wetnights before reaching remission compared between two types of treatment (P-value = 0.035) , but there were no differences when we compared by sexes.

We also tried to evaluate the other factors such as age , education of father and mother, parental conflict, compliance, number of urination per night and number of wetnights per week before treatment compared between one who reached remission and the other who did not to see whether there were any factors that could affect the outcome of treatment. We had excluded the 2 drop-out patients at this step of analysis because we couldn't know the results of treatment if they had received the full treatment duration.

1. By univariate analysis

Table 4.12 : Correlation between Sex Characteristics and Results of Treatment

Sex	Pad and bell			Traditional		
	Remission	No remission	P-value	Remission	No remission	P-value
male	8 (36.4%)	4 (50.0%)	0.678	2 (33.3%)	9 (37.5%)	1.0
female	14 (63.6%)	4 (50.0%)		4 (66.7%)	15 (62.5%)	
	▼	P-value = 1.0		▼		

By chi-square test, in each group of treatment , the results of treatment were not statistically different when compared between sexes.

In addition, among those who had remission, there was no statistical difference in sexes.

Table 4.13 : Correlation between Father's Educational Levels and Results of Treatment

Educational level	Pad and bell			Traditional		
	Remission	No remission	P-value	Remission	No remission	P-value
Elementary	3 (13.6%)	1 (16.7%)		2 (33.3%)	7 (29.2%)	
Secondary	10 (45.5%)	3 (50.0%)		3 (50.0%)	8 (33.3%)	
High occupational	-	-	0.849	1 (16.7%)	5 (20.8%)	0.462
Bachelor	6 (27.3%)	1 (16.7%)		-	3 (12.5%)	
Higher than	3 (13.6%)	1 (16.7%)		-	1 (4.2%)	
Total	22	6		6	24	
	▼	P-value = 0.157		▼		

By Mann-Whitney U test, there was no statistical difference on the results of each treatment group when compared among different educational levels of father. Among those who had remission, there was no statistical difference on the levels of education of father.

Table 4.14 : Correlation between Mother's Educational Levels and Results of Treatment

Educational level	Pad and bell			Traditional		
	Remission	No remission	P-value	Remission	No remission	P-value
Elementary	2 (9.1%)	2 (25.0%)		2 (33.3%)	5 (20.8%)	
Secondary	11 (50.0%)	2 (25.0%)		2 (33.3%)	7 (29.2%)	
High occupational	2 (9.1%)	1 (12.5%)	0.909	2 (33.3%)	5 (20.8%)	0.296
Bachelor	6 (27.3%)	3 (37.5%)		-	5 (20.8%)	
Higher than	1 (4.5%)	-		-	2 (8.3%)	
Total	22	8		6	24	
	▼	P-value = 0.259		▼		

By Mann-Whitney U test, there was no statistical difference on the results of each treatment group when compared among different educational levels of mother. In addition, among those who had remission, there was no statistical difference in the levels of education of mother.

Table 4.15 : Correlation between Type of Wakening and Results of Treatment

Type of wakening	Pad and bell			Traditional		
	Remission	No remission	P-value	Remission	No remission	P-value
consciously	11 (50.0%)	4 (50.0%)	1.0	5 (83.3%)	9 (37.5%)	0.072
not consciously	11 (50.0%)	4 (50.0%)		1 (16.7%)	15 (62.5%)	
Total	22	8		6	24	
	▼	P-value = 0.196		▼		

By chi-square test, there was no statistical difference on the results of each treatment group when compared between types of wakening. In addition, among those who had remission, there was no statistical difference in the types of wakening.

Table 4.16 : Correlation between Parental Conflict and Results of Treatment

Parental conflict	Pad and bell			Traditional		
	Remission	No remission	P-value	Remission	No remission	P-value
With	5 (22.7%)	3 (37.5%)	0.43	-	3 (12.5%)	1.0
Without	17 (77.3%)	5 (62.5%)		6 (100%)	21 (87.5%)	
Total	22	8		6	24	
	↓ P-value = 0.553 ↓					

By chi-square test, there was no statistical difference on the results of each treatment group when compared between having or not having parental conflict.

In addition, among those who had remission, there was no statistical difference in the reported parental conflicts.

Table 4.17 : Correlation between Compliance and Results of Treatment

Compliance	Pad and bell			Traditional		
	Remission	No remission	P-value	Remission	No remission	P-value
Good	22 (100%)	6 (75.0%)	0.064	6 (100%)	22 (91.7%)	1.0
No	-	2 (25.0%)		-	2 (8.3%)	
Total	22	8		6	24	

P-value =*

No compliance = could follow the instructions properly
less than half of the treatment days of 3 months

Good Compliance = could follow the instructions properly
more than half of the treatment days of 3 months

* = cannot do statistical test

By chi-square test, in each group of treatment, there was no statistical difference on the results of treatment when compared between good compliance and no compliance.

2. By multi-variate analysis (Stepwise logistic regression) :

To evaluate the influences (associations) of all of the factors .i.e., sex , education of father / mother , age , type of wakening , parental conflict , compliance , number of urination per night and number of wetnights per week before treatment silmutaneously in order to prevent or eliminate the confounding effects which might exist when we evaluate each factor one by one.

By stepwise logistic regression, there was one factor correlated with the result of treatment , i.e., type of treatment with statistical significance (P-value < 0.001). So by now we can state that type of treatment was the only factor that affect the difference of treatment result (remission).

Table 4.18 : Parent's Satisfaction Score for Method of Treatment Compared between Two Groups of Treatment by A Visual Analogue Scale

VAS	Pad and bell	Traditional	P-value
mean \pm SD	8.74 \pm 1.46	7.72 \pm 1.94	
95% CI	8.17 , 9.30	6.97 , 8.48	0.031
95% CI of mean difference	-1.94 , -0.09		

By the visual analogue scale, we asked the parent for his/her satisfaction for the method of treatment which his/her child had received, rating from zero (0) to ten (10) :

Zero = Parent was not satisfied at all

Ten = Parent was extremely satisfied

By the unpaired t test, the pad and bell method was associated with more parent's satisfaction score compared to the traditional treatment with statistical significance.

Co-variate analysis : Stratified analysis for two prognostic factors , i.e., sex and type of wakening

P – value = 0.31313737

As well as stratified analysis for two prognostic factor , i.e., sex and type of wakening by Mantel-Haenszel method , the results of treatment are not different or were not affected by sex and type of wakening (P-value = 0.313)