CHAPTER V

DISCUSSION CONCLUSION AND SUGGESTION

DISCUSSION

Remission rate

This was a randomized controlled study evaluating the effectiveness of pad and bell which is the new method used at the first plan in Siriraj hospital and the first time in Thailand , compared to the traditional method which is the home-spun technique still used for most of physicians even we did not know its efficacy for enuresis treatment.

There have been two major modalities for enuresis treatment , i.e., medication and behavior therapeutic method in which both pad and bell and traditional one are classified. One of the important disadvantage of medication is its side effects that the physician should be aware of and it is the reason for some physicians to choose the behavior method as the first choice.

Traditional method (fluid restriction and night lifting) is the common sense treatment technique that if it is not really effective enough , it may cause the negligence attitude of parent towards the treatment that could magnify the other further problem of the child.

As reported , the remission rate of traditional method was only about 20 percent which was not far different from spontaneous remission rate (10-15% per year by DSM-IV) that might be the effect from the nature of this study. Because this study was

hospital based , tertiary care and most patients had ever used one or both techniques of traditional method (night lifting and fluid restriction) at some period of time before enrolling in this study , it might be the reason , why treatment with traditional method was not effective because the patients who had good response to this home-spun techniques didn't seek for the professional treatment.

On the other hand , since both treatment methods in this study mostly relied on the patient and his parent , and we tried very hard to prevent drop-out and improved compliance by keeping weekly regular contact to ensure , encourage and monitor whether the patients could follow the instruction properly (that was unusual in clinical practice) which could improve the results of both treatment methods especially for pad and bell because from the other studies we had found more drop-out and premature termination of treatment because of its procedure which was more difficult and time consuming , particularly for Thai patient to whom it seemed as the new and unfamiliar method.

The remission rate of pad and bell was about 71% (Table 4.8) , nearly the same as most other studies which reported the remission rate around 75-80%[12-13,25-33] The difference of this result may arise from the difference in the duration of treatment ,the sample population studied , the definition of remission and the research methodology.

However , we could state that the pad and bell was one of the effective and curative treatment for enuresis and should be considered in all patients who had failed from the traditional method especially in the well-compliant patients.

Relapse rate

As in this study , the relapse rate of pad and bell was 33.33% (Table 4.9) , the traditional method had the relapse rate of 80% (Table 4.9). The result was statistically significant (P-value = 0.0314). The relapse rate in this study was little different from

some of the other studies which reported the relapse rate of pad and bell at about 10-30%.[17, 34-37] The difference might be due to the difference in the duration of following-up period , the definition of relapse , the research methodology and the number of patients studied.

Eventhough the pad and bell treatment method had a much less relapse rate than the traditional method , its relapse rate was still rather high. So the attempts to identify the predictors of relapse and to find the techniques to reduce this problems should be the important and interesting issues for the further studies.

Number of wetnights before reaching remission

The traditional method had a mean of wetnights of 7.50 $\pm$ 5.96 , while the pad and bell had a mean of wetnights of 17.36 $\pm$ 10.33 (Table 4.10). The traditional treatment was statistically different in fewer wetnights than the pad and bell (P-value = 0.035). This may be caused by the conditions of method in traditional treatment itself which reguired both fluid restriction and night lifting (had waken the child up to urinate before he had bedwetting). These could make the child to have less urine and more advantage to be dry than the pad and bell technique.

Eventhough the traditional method was associated with fewer wetnights but it could not indeed cure him from enuresis.

Number of days taken to reach remission

The duration from the start of treatment and remission were 42.67 $\pm$ 26.33 and 50.86 $\pm$ 15.36 for the traditional and the pad and bell method respectively (Table 4.10). There were no statistical difference between two groups of treatment (P-value = 0.345) as well as between sexes among those who had remission (P-value = 0.737). This may be due to

the fact that the difference between two groups of treatment was not big enough and the number of subjects was too small (number of patients who reached remission in traditional method was only 6 cases).

We could conclude from this study that eventhough the traditional method had the advantage of having less wetnights before reaching remission than the pad and bell , it did not have any other advantages and could not really cure more enuresis.

Co-variate analysis

In this study , we had planned to evaluate two important prognostic factors which might affect the main outcome (remission) .i.e.,sex and type of wakening by using Mantel-Haenszel method because both factors were discrete variables. The analysis showed no statistical differences by both strata of sexes and types of wakening (P-value = 0.313). This might be related to the small number of subjects in each arm of stratum. Anyway, we could state from this study at this moment that the results of treatment were not different or affected by sexes and types of wakening.

Parent's satisfaction for the method of treatment received

The pad and bell method was associated with more parent's satisfaction score than the traditional method with statistical significance (Table 4.18).

Eventhough the pad and bell method was more complicated and more difficult to follow the instructions , the parent still had more satisfaction score than the traditional method. This might be due to the fact that the parents were more interested in the new method and had more successful treatments in the pad and bell method.

In this study, for both treatment methods, the parent particularly the mother was the person who had to wake her child up.

But in the real practice, the alarm (pad and bell) itself wakes the child while the traditional method still has the mother to wake the child.

So the parents might be more satisfied for not being the one who have to wake the child as well as the child might be happier for not being forced by his/her parents.

We did not plan to evaluate the satisfaction score of the child since we thought that the child might be unable to understand and answer correctly for the questions and explanations about the visual analoque scale.

In fact, the parent's satisfaction score might be different from the satisfaction score of the child.

Factors correlated to the results

We had tried to evaluate and to find the factors which were correlated to the main outcome (remission). Those factors we evaluated were sex , age , education of father , education of mother , type of wakening , compliance , parental conflict , number of urination per night before treatment and number of wetnights per week before treatment.

We used univariate analysis to evaluate each of those factors to see whether it had any significant correlations with the main outcome. As reported , there were no factors which had a significant correlation with the main outcome (P-value > 0.05).

By stepwise logistic regression , the factor which had the highest correlation order with the main outcome was type of treatment and it also had a statistical significance (P-value < 0.001). The next order of correlation with the main outcome was compliance but it did not achieve a statistical significance (P-value > 0.05). This might be due to the too small number of patients (there were only 4 cases of non-compliant patients in this study).

The principal result of a clinical trial is a description of the most important outcome in each of the major treatment group. But it is tempting to examine the results in more detail than the overall conclusions afford.

We look at subgroups of patients with special characteristics or with particular outcomes. In doing so, however, there are some risks of being misled that are not present when examining the principal conclusions alone , and these should be taken into account when interpreting information from subgroups.

One danger in examining subgroups is the increased chance of finding effects in a particular subgroup that are not present in nature. This arises because multiple comparisons lead to a greater chance of a false positive finding than is estimated by the individual p-value for that comparison alone.

A second danger is of a false-negative conclusion. Examining subgroups in a clinical trial involves a great reduction in the data available, so it is frequently impossible to come to firm conclusion. Nevertheless, some tentative informations can be gathered. Table 4.19 lists some guidelines for deciding whether a finding in a subgroup is real[50].

Table 4.19 : Guidelines for Deciding Whether Apparent Differences in Effects within Subgroups Are Real

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From the study itself

- Is the magnitude of the observed difference clinically important ?
- How likely is the effect to have arisen by chance , taking into account
  - The number of subgroups examined ?
  - The magnitude of the p-value ?
- Was a hypothesis that the effect would be observed

Made before its discovery (or was justification for the effect argued for after it was found) ?

One of a small number of hypothesis ?

From other informations

- Was the difference suggested by comparison within rather than between studies ?
- Has the effect been observed in the other studies ?
- Is there indirect evidence that supports the existence of the effect ?

CONCLUSION

Nocturnal enuresis is a chronic condition which we can find quite common not only in daily life but also in clinical practical , but few of the patients receive an adequate and appropriate treatment. Eventhough enuresis itself is not a serious illness , it causes many direct and indirect complications and distresses to the child and his/her family.

Until now , there are two major modalities for enuresis treatment , i.e., medication and behavior therapeutic method in which both the pad and bell and the traditional one are classified. The important disadvantages of medication are its side effects and recurrence after discontinuation and most parents do not prefer to use medication for their children and always refuse to prolong medication. It is the reason that almost all of parents had already tried home-spun technique of behavior method (traditional method). So if traditional method is not really effective enough , it may cause the negligence attitude of parents towards the treatment that could magnify the other further problems of the child and his family.

On the other hand , most physicians themselves prefer to use medication and traditional method because they are easy and familiar to them . But both methods are not very effective and have a high relapse rate. If both methods do not work , it seems helpless for both physicians and patients.

We can conclude from this study that the pad and bell treatment was associated with high remission rate of about 71% and less relapse rate of 33.3% while the traditional method was associated with about 20% and 80% for remission rate and relapse rate respectively.

The traditional method had only one advantage of having fewer wetnights ,however, the number of days consuming of two methods were not different.

Since most of patients who come to see the physician had ever used traditional method for some period of time , and medications can cause many side effects for the child , pad and bell may be the other appropriate treatment of choice especially in the compliant child because it is effective and safe.

In Thailand , pad and bell is the new method used at the first place in Siriraj hospital , even it is not familiar to Thai physicians and patients. But from this study , we also reported its efficacy for enuresis treatment as other studies. The pad and bell method should provide us with the other helpful curative treatment of choice for enuresis treatment for Thai patients. It can give a new effective technique for Thai physicians and an improvement for enuresis treatment in Thailand comparable to the Western Countries.

SUGGESTION

Since the traditional method is not effective and most of patients have ever used this common-sense, home-spun technique before coming to see the physicians. The disadvantages of medication are its side effects and high relapse rate.

Pad and bell is the other treatment which is effective and safe. So it should be recommended to be the first choice of treatment especially in compliant patients or patients who failed from other treatments.