

## CHAPTER VI

### DISCUSSION

Diabetes mellitus is a chronic illness that requires continuing medical care and education to prevent acute complications and to reduce the risk of long-term complications. Persistent hyperglycemia is the hallmark of all forms of diabetes. Treatment aimed at lowering blood glucose levels to or near normal in all patients has been proven to benefit patients. Treatment of non-insulin-dependent diabetes mellitus should emphasize diabetes management through dietary modification and exercise and weight reduction, supplemented when indicated by glucose lowering agent and/or insulin. Many diabetic patients need hypoglycemic agents to remain symptom-free or to lower blood glucose to near normal level. The choice of pharmacological agents is limited to insulin, sulfonylureas, the biguanide metformin, and the  $\alpha$ -glucosidase inhibitor acarbose. Although these agents have been effective in many patients, the difficulty of achieving near-normal glycemia in the majority of non-insulin-dependent diabetes mellitus patients emphasizes the need for additional therapeutic options. Many medicinal plants have been categorized as having hypoglycemic effect and used to treat diabetes. Aloe vera is another potentially useful such medicinal plant which has been shown in a few studies to have substances that lower blood glucose. This study evaluate the efficacy of Aloe vera juice in lowering blood glucose to examine the potential of using it as a hypoglycemic agent.

Subjects were patients who were newly-diagnosed as having diabetes mellitus. They did not receive any modalities of treatment for diabetes mellitus. The subjects were not having classic symptoms of diabetes mellitus which might raise ethical problems in including

them in the study. The subjects received patient education regarding dietary control, weight control and exercise. Plasma glucose levels during the run-in period helped decide whether subjects were able to take care of the possible co-intervention, that is, diet, exercise, and weight gain or weight loss. These factors are important co-intervention that may easily change glycemic control. Subjects who satisfied eligibility criteria were informed and asked for consent to participate in the study. Agreeing and signing formed consent, subjects entered the study receiving either Placebo juice or Aloe vera juice which were identical physically.

The study was designed to reduce biases as much as possible. Various methods were incorporated to ensure minimum biases in the study. They were randomization, double masking or blindness, placebo- and controlled design. The effect of randomization showed in the rather similarness of the baseline characteristics of the two treatment groups, even though the number of patients in each group was small( $n=8$ ). The researcher and subjects never knew the identity of juice being taken at any time until the randomization schedule was revealed at the end of the trial. Thus, there seemed to be minimal biases in this study.

Another characteristic of the study design is cross-over design. This design offered advantage in that the treatments are compared "within subjects". It is assumed that between subject variations are not present in this design. This advantage strengthens internal validity of the study result.

The researcher conducted the study strictly as designed. Blindness were maintained throughout the study period. Subject cooperation were excellent reflecting the selection process and the subjects' willingness to participate without dropping out. Patient compliance and drug compliances were very good.

The laboratory were the Chulalongkorn Hospital Central Laboratory with good quality control. Laboratory personnels did not know the subjects and what kind of treatments they received.

The result of the analysis of the main outcome variable, fasting plasma glucose level, was that Aloe vera juice had the same hypoglycemic effect as Placebo juice. In other words, Aloe vera juice did not have any hypoglycemic effect. The analytic procedures had shown that the carry-over effect and the period effect, if ever existed, did not cause the difference or indifference of the fasting plasma glucose levels between subjects taking Aloe vera juice and subjects taking Placebo juice. The possible explanation for the result were the following:

1) Subjects changed dietary habits and exercise temporarily. These changes could happen seasonally or periodically owing to seasonal fruits, festivals.

2) Some subjects shown markedly changes in fasting plasma glucose levels in opposite directions as shown in Fig.3. These "outliers" could have dramatic effect on the precision of analysis.

From this study, we showed that with a well-designed trial, Aloe vera extract in liquid form did not exert hypoglycemic and hypolipidemic effects in non-insulin-dependent diabetic patients. However, It is still possible that Aloe vera has hypoglycemic effect but the effect may not be as strong as we expected.

## CONCLUSION

Aloe vera is a medicinal plant that has the potential to be developed into widespread use for treatment of diabetes. However, this study did not demonstrate the hypoglycemic and hypolipidemic effects of Aloe vera extract when compared with Placebo. The inability of the study to demonstrate favorable effects of Aloe vera may be due to optimistic sample size based on poorly designed previous trial, co-interventions, and the real absence of hypoglycemic effect of Aloe vera. Further study on Aloe vera in the treatment of diabetes mellitus need to take the result of this study, the skin rash in one subject into account before planning another study.



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