



CHAPTER I

INTRODUCTION

Diabetes mellitus is a state of having an excessive concentration of glucose in the blood, a state of chronic hyperglycemia, which may result from many environmental and genetic factors, often acting together. Hyperglycemia may be due to a lack of insulin or to an excess of factors that oppose its action. This imbalance leads to abnormalities of carbohydrate, protein, and lipid metabolisms. The major effects of diabetes include characteristic symptoms, ketoacidosis, the progressive development of disease of the capillaries of the kidney and retina, damage to the peripheral nerves, and excessive arteriosclerosis. Diabetes mellitus contributes significantly to premature death and prolonged ill health. Diabetes mellitus is a universal health problem affecting human societies at all stages of development. At least 30 million people are involved throughout the world, and the numbers of cases reported are increasing rapidly with the aging of populations, changes in lifestyle, and improvement in screening and diagnosis.

In western Europe and North America diabetic kidney disease is the leading cause of death in insulin-dependent diabetes mellitus, usually occurring 17-25 years after the onset of diabetes. After more than 25 years of diabetes, coronary disease predominates. In non-insulin-dependent diabetes mellitus (NIDDM) of Europe and North America the leading cause of death is coronary disease, responsible for about half the mortality. Ischemic heart disease, glomerulosclerosis, retinopathy, gangrene of a lower extremity, neuropathy, stroke, and cataract are major causes of

prolonged ill health. Rates of disability are in general about 2-3 times greater in diabetics than in non-diabetics, but blindness is about 10 times more common and gangrene 20-30 times. In all societies ketoacidosis is a significant cause of death in diabetics, and in some developing countries it is a leading cause of diabetes-related death. Table 1 summarizes the cost diabetes mellitus puts on patients in terms of health and economic costs (World Health Organization Expert Committee on Diabetes Mellitus. Second Report. Technical Report Series No. 546. World Health Organization, 1980).

Table 1. Costs of diabetes

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1. Mortality excessive by a factor of 2-3.
 2. Heart disease and stroke excessive by a factor of 2-3.
 3. Blindness 10 times more common than in the general population.
 4. Gangrene and amputation about 20 times more common than in the general population.
 5. Second leading cause of fatal kidney disease.
 6. Other chronic disabilities (e.g., neuropathy, infections, and sexual dysfunction).
 7. As compared to age-matched elements of the general population, hospitalization increases about twofold.
 8. Direct costs to medical care system include professional time, drugs, and rehabilitative services (e.g., services for the diabetic blind), other services and materials.
 9. Other costs to society include costs of medical services, pensions, and loss in productivity and earnings due to both disability and premature death.
 10. Lifetime risk of diabetes 2-12% (variation by country).
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Diabetes mellitus is one of the major non-communicable diseases that affect Thai people. Mortality rate from diabetes mellitus in Thailand was 3.1 per 100,000 populations in 1980. The trend in mortality rate due to diabetes mellitus increased from 1.8 per 100,000 populations in 1975. The trend ratio is 1.7. So the trend in mortality rate due to diabetes mellitus increases every year. In addition, mortality rate increases as age increases. The prevalence rate of diabetes mellitus in urban area in Thailand is 3.4 - 4 % in 1987. The trend for the prevalence rate of diabetes mellitus in Thailand is increasing.

Most of diabetic patients are non-insulin-dependent diabetes mellitus. It is estimated that at least 20-30% of NIDDM patients will benefit from oral hypoglycemic agents. All hypoglycemic agents are expensive, imported drugs. Other alternative hypoglycemic agents which cost less and are widely available in the country are desirable. Many medicinal plants have hypoglycemic effects and one of the most promising such medicinal plants is Aloe vera Linn. This plant grows easily throughout Thailand and costs little to keep and harvest. It has a great potential to be a low-cost, widely-available hypoglycemic agent for Thai diabetic patients and will help reduce the cost of treating many Thai diabetics. It needs proper evaluation for its pharmacological and therapeutic effects.

A few studies suggested that Aloe vera may have hypoglycemic and also hypolipidemic effects. Agarwal, O.P. (1985) reported the largest study on the effect of Aloe vera on blood glucose and blood lipid levels in 5,000 patients. Another preliminary clinical study at Siriraj Hospital, Bangkok showed that aloe vera juice reduce blood glucose level more in diabetic patients who received both aloe vera juice and regular diabetic treatment than in diabetic patients who received only regular diabetic treatment. The hypoglycemic effect appeared in the first week and persisted

through 6 weeks of treatment. Thus it appears that Aloe vera might have potentially useful hypoglycemic and hypolipidemic effects both at the individual patient level and at the public health level. However, we need to evaluate the efficacy of aloe vera juice in controlling diabetes mellitus in a randomized controlled clinical trial. This study intends to evaluate the efficacy of Aloe vera in lowering blood glucose level and blood lipid levels in Thai diabetic patients in a randomized double-blinded controlled clinical trial.

Objectives of the study

The objectives of the study are:

1. To evaluate the efficacy of the Aloe vera juice as hypoglycemic and hypolipidemic agent in Thai diabetic patients.
2. To evaluate the adequacy of glycemic control of the Aloe vera juice in Thai diabetic patients.
3. To evaluate compliance to the Aloe vera juice and its adverse effects.

Expected benefit of the study

The researcher expect that this study can provide information regarding the effect of Aloe vera on blood glucose level and blood lipid level in Thai diabetic patients, the adverse effects of Aloe vera and the patients' acceptance of the preparation of Aloe vera. This may lead to:

1. Further study to evaluate the clinical effectiveness of Aloe vera in diabetic patients.
2. Further study to evaluate a dose-response relationship of the Aloe vera preparation.
3. Recommendation and advocating for patients with diabetes mellitus in using Aloe vera for the control of diabetes mellitus.

Research Questions

Primary research question:

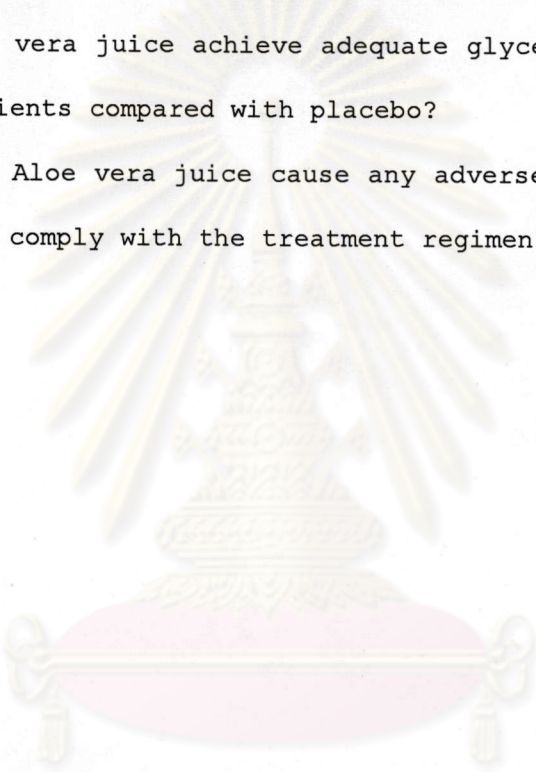
1. Can Aloe vera juice reduce blood glucose levels 30% in Thai diabetic patients compared with placebo?

Secondary research questions:

1. Can aloe vera juice reduce lipid levels 30% in Thai diabetic patients compared with placebo?

2. Can Aloe vera juice achieve adequate glycemic control in Thai diabetic patients compared with placebo?

3. Does the Aloe vera juice cause any adverse effects? Will diabetic patients comply with the treatment regimen?



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