CHAPTER III

RESEARCH DESIGN OVERVIEW

Conceptual Framework.

ICH accounts for 12 percent of the cerebrovascular diseases and the mortality is as high as 50 percent. Risk factors of intracerebral hemorrhage include hypertension, AVM, aneurysm, drug abuse, anticoagulant therapy, etc. The grave prognosis of infratentorial intracerebral hemorrhage is well recognized, but in supratentorial intracerebral hemorrhage, the mortality rates depend on a number of factors. So we wished to develop a prognostic model that would predict the probability of death in hospital, as a tool for the clinician to assess these patients (FIGURE 3.1).

Research Question.

A. What is the prognostic model that best predicts death in hospital after spontaneous supratentorial ICH ?

B. What are the sensitivity and specificity of this model to predict death in hospital after spontaneous supratentorial ICH?

A DIAGRAM OF CONCEPTUAL FRAMEWORK

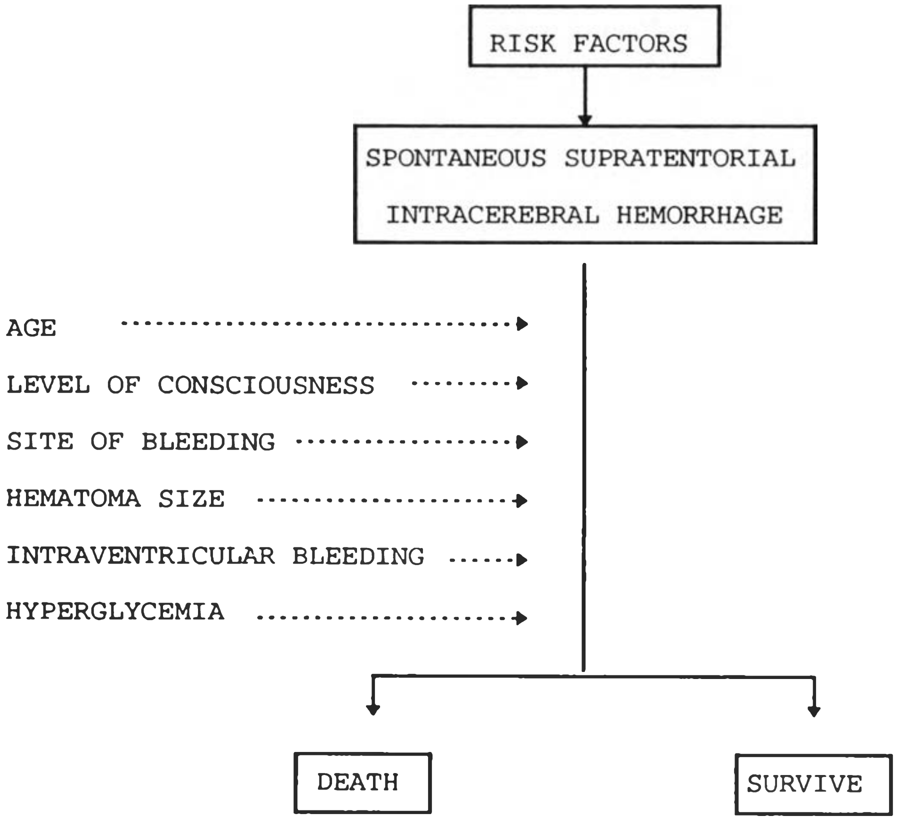

FIGURE 3.1

Research Objectives.

The following are the objectives of the proposed study :

A. Using a multiple logistic regression model, we will attempt to identify a prognostic model that can best predict the outcome (survival or death), after spontaneous supratentorial ICH.

B. To calculate the sensitivity and specificity of the prognostic model to predict in-hospital death after spontaneous supratentorial ICH.

Hypothesis.

The prcgnostic model that will be developed from the combination of prognostic factors by using a multiple logistic regression can best predict outcome of patients with spontaneous supratentorial intracerebral hemorrhage .

Research Design.

Prospective descriptive study.

Research Methodclogy.

A. Population and Sample.

1. Eligible Criteria. All patients between the ages of 40 and 90 years with a diagnosis of primary supratentorial intracerebral hemorrhage confirmed by computerized tomography admitted to Pramongkutklao Hospital during March 1994-December 1994.

2. Exclusion Criteria.

a) Head injury.

b) Ruptured aneurysm and arteriovenous malformations.

c) Bleeding tumor.

d) Bleeding disorders or anticoagulant therapy.

In addition, cerebral angiography was performed in all patients in whom aneurysm or arteriovenous malformations were suspected or an unusual site of bleeding was found.

B. Sample Size.

Hsieh (1989) presented a sample size table for logistic regression which extend the use of Whittemore's formula. Because the mortality rate of ICH in day 21^{th} is 50 percent and the estimated relative risk of death during the first week in patients over 70 years old is 2 (TABLE 3). From the sample size table, when alpha = 5 percent (one-tailed) and 1- beta = 80 percent, the sample sizes are 70 cases.

This sample size is calculated for bivariate analysis but when there is more than one covariate in the model, multiple logistic regression may be used to estimate the relationship of a covariate to the outcome. So the sample size will required more than 70 cases to detect such a relationship of covariate to outcome, which is adjusted by a multiple correlation coefficient (p) of the variables of interest. From the literature review, the correlation coefficient of age and level of consciousness is 0.4 .

RELATIVE RISK ESTIMATES OF THE STRENGTH OF ASSOCIATION OF PREDICTOR WITH EARLY MORTALITY AFTER STROKE.

Factor	*Early mortality*
Alert vs. not alert	2.3 - 15
Hemorrhagic vs. thrombotic stroke	2 - 5.5
Dysphasia	5
Pupil abnormality	1.6 - 3
Gaze paresis	1.8
Extensor plantars	2.2 - 2.6
Pyrexia	1.9
Abnormal breathing	2.2 - 2.9
Hematocrit over 50 %	2
Meningeal irritation	1.4
Systolic blood pressure (over 240 mmHg)	2
Age over 70	***2***
Atrial fibrillation	1.3 - 3

TABLE 3.1

If p = multiple correlation coefficient relating age to level of consciousness,

The adjusted sample size for multiple logistic regression is

$$= N\frac{1}{(1-p^2)}$$

$$= 70\frac{1}{(1-0.4^2)} = 83.33 \approx 84 \text{ cases.}$$