CHAPTER III

RESEARCH METHODOLOGY

Target population

Adult patients with twenty to seventy percent burn. We choose this group of patients because they have a high rate of infection(>60%) and the normal skins are adequate for the donor of split thickness skin graft in covering the burn wounds .

Sample population

This study enrolls the burn patients admitted in the burn unit Bhumibol Adulyadej Hospital with eligible criteria.

Inclusion criteria:

1. Newly diagnosed 20-70% burn patients evaluated by burn-staff at Bhumibol Adulyadej Hospital according to burn chart (appendix I). These patients were included in the study when there were signs of burn wound infection (appendix II).

2. Age 13-70 years (The patients with age under 13 years will be admitted in the Pediatric department).

3. The degree of burn must be deep second degree or third degree according to the standard classification of the degree of burn.

4. Patients' consent (sign in the informed consent).

Exclusion criteria:

1. Patients with associated diseases which can affect infection such as:- DM.

2. Patients who are immunocompromised hosts such as who receive chemotherapy or steroid, including those who have immune deficiency diseases.

3. The patients with first or superficial second degree burn.

4. The patients who do not receive initial treatment at Bhumibol Adulyadej Hospital (referred cases).

All of patients who fulfill the eligible criteria will be included in the study and randomized into two groups when there is a sign of burn wound infection(appendix II).

Sample size calculation

Because this study will compare the difference of mean duration from culture to successful skin graft between two independent groups, so for the calculation of the sample size we will use formula :-

$$N = 2[(Z_{\alpha/2} + Z_\beta)SD]^2 / (Mc - Mt)^2$$

$Z_{\alpha/2}$= Type I error 5%(two-tailed test) = 1.96

Z_β = Type II error 20% = 0.84

SD^2 = Variance = $(2.61)^2$

Mc = Mean of outcome in control group

Mt = Mean of outcome in treatment group

$$N/ group = 2[(1.96+0.84)2.61]^2 / (2)^2$$

$$= 26.7 = 27$$

This study will include 54 patients.
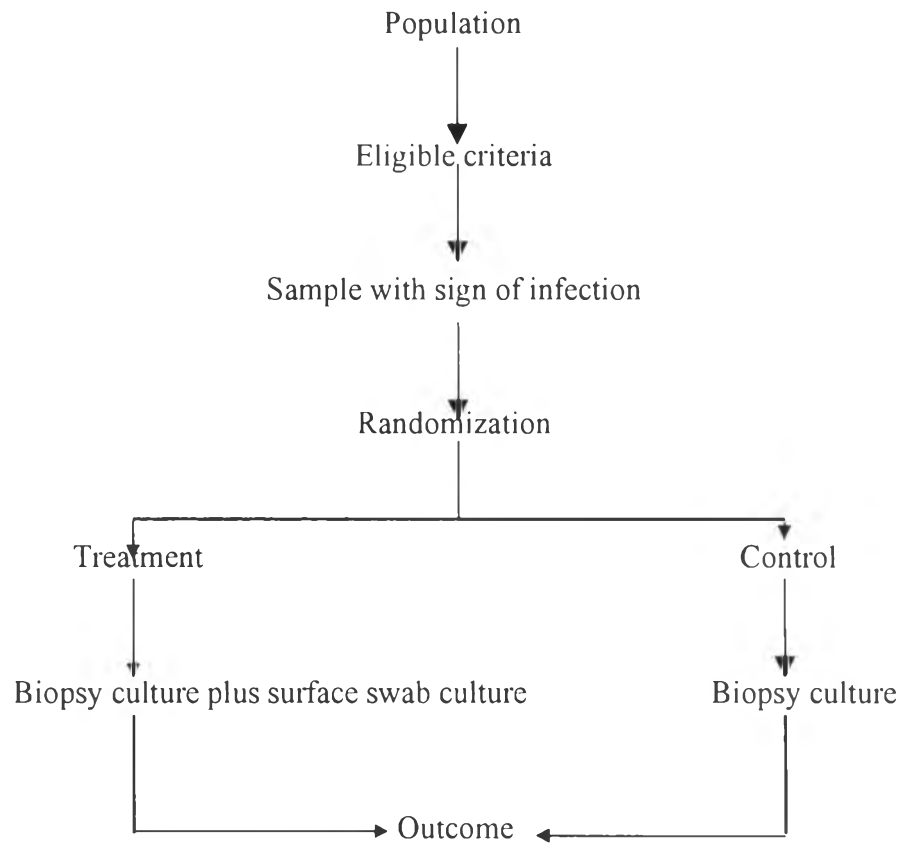
Methods of the study

After the patients were admitted in burn unit, they are treated by standard fluid resuscitation, nutritional therapy and wound dressing. When there was a sign of burn wound infection (appendix II), they were randomized into two groups by block randomization to get equal number of patients. The patients were stratified by age (13-40 and 41-70 years) and percent burn (20-45% and 46-70%). In the treatment group we took surface swab culture and cut the tissue for quantitative burn wound biopsy culture at the same time. Both specimens were sent to the laboratory and continued procedures were done by a microbiologist. The results were reported in 2-3 days for surface swab culture and 3-5 days for quantitative burn wound biopsy culture. In the control group we cut the tissue for quantitative burn wound biopsy culture. Attending physician prescribed 3rd generation cephalosporin (Ceftriazone) on the day of culture, but he adjusted the antibiotics according to results of the cultures. In the treatment group, antibiotics follow the result of surface swab culture until the result of burn wound biopsy culture came back, and were changed if biopsy culture suggested differently. The burn wound were observed every day. If its appearance was good (meeting all criteria in appendix III), the patients underwent the operation for skin graft, decision were made by a physician who doesn't know the group of patients. After 5 days the graft were evaluated, if the result of skin graft was more than 80% taking, we considered the patient a successful skin graft and used the duration from culture to the day of successful skin graft for comparing between the two groups. We also recorded the number of cases with the changing of antibiotics, the duration of hospital stay, the type of microorganism found, complications and mortality in both groups.

In this study we have two microbilogists, the first one continued in the process of surface swab culture and the in the process of quantitative burn wound biopsy culture.

Both microbiologists stayed in the different rooms or we can say that they were blinded for the result of each other.

The personnel in the burn unit also didn't know the group of the patients for reducing the bias and prevention of cointervention.

In the real situation we took both methods of culture in both groups of the patients for answering the question about the accuracy of surface swab culture. In the control group we didn't consider the result of surface swab culture for changing the antibiotics just only the result of quantitative burn wound biopsy culture.

Research frame work

Population

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Eligible criteria

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Sample with sign of infection

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Randomization

Treatment   Control

↓   ↓

Biopsy culture plus surface swab culture   Biopsy culture

→ Outcome ←

Duration from culture to skin graft

Accuracy of surface swab culture

Most common microorganism

Mortality rates and complications

Data collection

1. Administrative variables : name, address, identification number

2. Zero state variables :

   - age, sex, percent and degree of burn area

   - time from the burn injury to the hospital

3. Outcome variables :

   - duration from culture to successful skin graft

   - mortality rate, complication, and hospital stay in both group

   - antibiotics usage, antibiotics change

   - type of microorganism

   - for surface swab culture

    positive = the result of culture is microorganism presented

    negative = the result of culture is no growth

   - for quantitative burn wound biopsy culture

    positive = microorganism $> 10^5$ / gram of tissue

    negative = microorganism $< 10^5$ / gram or no growth