



CHAPTER III

RESEARCH DESIGN AND METHODOLOGY

3.1 Research questions

Can postoperative knee immobilization reduce blood loss in patients having cemented total knee arthroplasty?

3.2 Research objectives

- **Primary research objective**

To measure postoperative blood loss from Hemovac drain between the patient with postoperative knee immobilization with A-P splint group and knee without splint.

- **Secondary research objectives**

To compare the wound complications and knee motion at 8 week postoperation in both groups.

3.3 Hypothesis

Research Hypothesis : There is the difference in mean blood loss between non-cast and in cast group.

$$H_1 : \mu A \neq \mu B$$

Statistical Hypothesis : The mean blood loss in non-cast group is equal to cast group

$$H_0 : \mu A = \mu B$$

μA = mean of blood loss from Hemovac drain in 24 hour postoperative knee elevation without splint.

μB = mean of blood loss from Hemovac drain in 24 hour postoperative knee elevation with A-P splint.

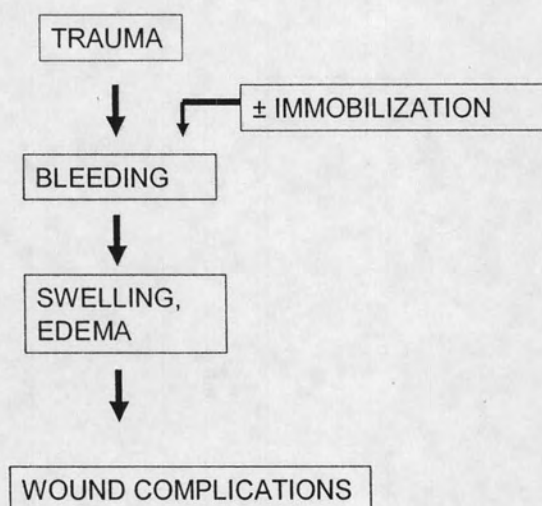
Significant level 5%

Power of the test 90%

Hypothesis testing : unpaired t-test in 2 independent group

Reject H_0 , if p value <0.05

3.4 Conceptual framework



3.5 Assumption

The surgeons have at least 10 years experience of performing TKA and they operate anteromedial approach to the knee. The wound length is between 14 to 16 centimeters.

The Hemovac drain is working during 24 hour postoperatively which we can detect by the marker of function whether the drain is leaked at the top of the bottle.

3.6 Operational definition

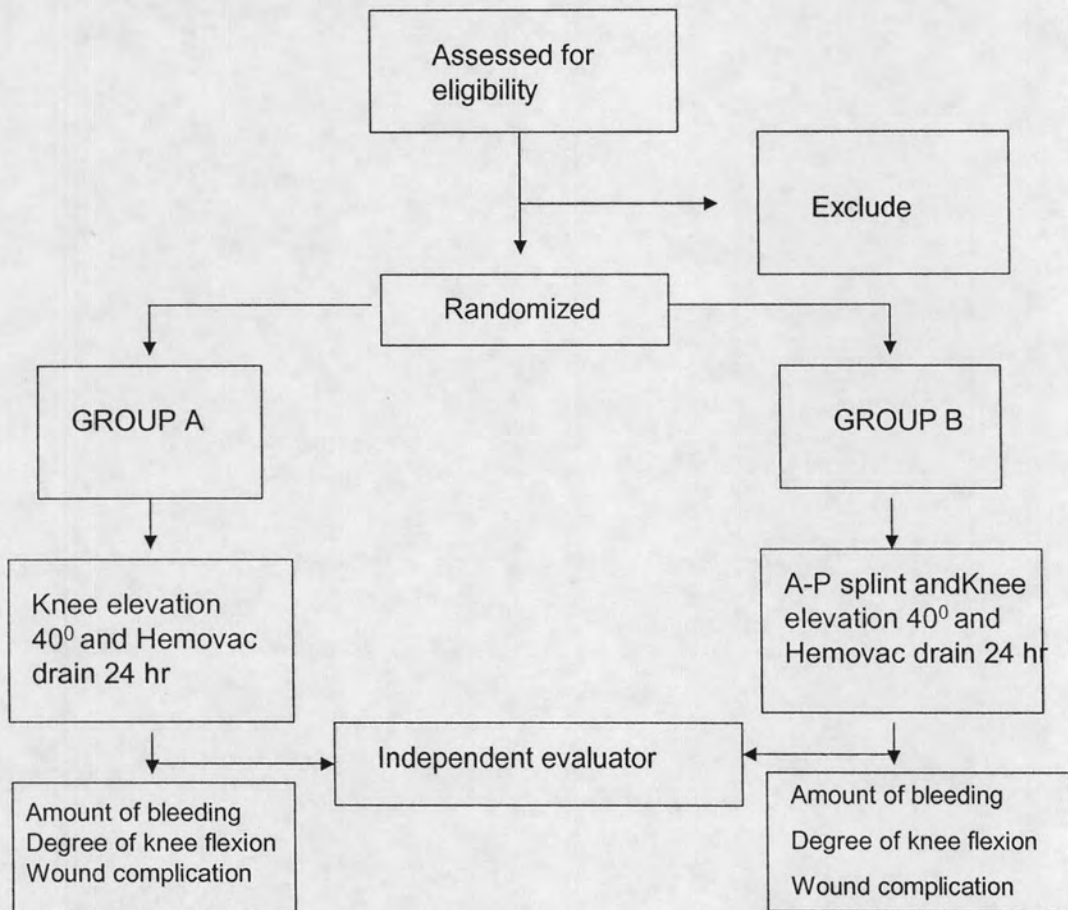
Total knee arthroplasty (TKA) is defined as an operation that changing the articular surface of tibia , femur and patellar of knee joint.

The closed suction drain (Hemovac drain) is defined as the suction drainage system that use for removing blood from the closed space by negative pressure.

Anterior and posterior splint (A-P splint) is defined as the long leg anterior and posterior splint that made from plaster cast which it was molded along the anterior and posterior surface of the leg from mid thigh to mid foot.

3.7 Research design

Prospective randomized controlled trial using closed sealed envelope.



3.8. Population and sample

- Target population

All patients with knee disease that required treatment by TKA

- Study population

Patient with knee disease that required treatment by TKA at King Chulalongkorn Memorial Hospital who meet the following criteria

3.9 Eligibility criteria

- Inclusion criteria
 1. Age 60-80 yrs
 2. Primary and secondary osteoarthritis
 3. Pre-operative planning for TKA
 4. Agree to participate in this study and sign consent form
- Exclusion criteria
 1. Pre-operative planning for knee osteotomy
 2. Current use of medications that may cause bleeding problems that include anticoagulant (Heparin, Wafarin, Coumadin etc.) and anti platelet groups (aspirin etc.)
 3. Patient that has bleeding or coagulation disorder such as hemophilia, prothrombin time more than 15 seconds, partial thromboplastin time more than 40 second and platelet count less than 45,000 cell/mm³
 4. Any patient unable to cooperate for post operative A-P splint
 5. Inflammatory joint disease (rheumatoid arthritis)
 6. Pre operative planning for revision TKA

3.10 Sample size calculation

Sample size is calculated using the formula for comparison 2 independent means as follows :

$$n/\text{group} = 2(Z_{\alpha/2} + Z_{\beta})^2 \sigma^2 / (\mu_1 - \mu_2)^2$$

where :

α = Probability of type I error = 0.05(2-sided)

β = Probability of type II error = 0.10

- $Z_{\alpha/2} = 1.96$
- $Z_{\beta} = 1.28$

- μ_1 = mean postoperative blood loss in group 1
- μ_2 = mean postoperative blood loss in group 2
- σ^2 = pooled variance of postoperative blood loss

From the study of Kim YH et al.(10) , they used postoperative knee splint in 69 knees and the mean wound drainage was 436 ml with SD = 210 ml. the reason why we choose this paper because they used the knee splint almost the same as we plan to do. The study of Ishii et al.(20) about wound drainage in 30 non splint knees ,the mean of blood volume was 600 ml. and SD = 293 ml. The postoperative blood drainage from this paper was average blood loss as we had in the past records.

- $\sigma^2 = ((n_1 - 1) S_1^2 + (n_2 - 1) S_2^2) / (n_1 + n_2 - 2)$
- $\sigma^2 = 74319.58$
- $n/\text{group} = 57.9 \Rightarrow 58$

We consider 10% drop out for non – compliance patient who has swollen knee after splint and impending compartment syndrome.

- $n^* = n / (1 - R)$
- $n^* = 58 / (1 - .9) = 68$

We operate one knee for one person and the number of patient in each group are 68 .

3.11 Sampling allocation:

The patients are randomly allocated into 2 groups by sealed envelopes opened immediately after the operation. For group A is operated TKA and used non splint knee and group B is operated TKA and used A-P splint postoperatively.

3.12 Intervention

The patients are operated by the surgeons who have more than 10 years experience in TKA. The surgical technique for TKA is standard anteromedial approach under tourniquet 350 mmHg and the wound length is approximately 14 -16 cm.

- Group A : Under general anesthesia, TKAs were performed using a medial parapatella arthrotomy extending 4 cm. into the quadriceps tendon with patella eversion. The length of the incision was averaged 14 – 16 centimeters. All prostheses were fixed with cement, and all patellas were resurfaced. A tourniquet was used and was not deflate until after wound closure. The knees were fitted with the Hemovac drain and kept the drain clamped for 1 hour postoperatively. A soft dressing was applied on knees. The legs were elevated at 40⁰ and the knee were extended. The amount of blood in Hemovac drain during 24 hours postoperation period was recorded.
- Group B : Under general anesthesia, TKAs were performed using a medial parapatella arthrotomy extending 4 cm. into the quadriceps tendon with patella eversion. The length of the incision was averaged 14- 16 centimeters. All prostheses were fixed with cement, and all patellas were resurfaced. A tourniquet was used and was not deflate until after wound closure. The knees were fitted with the Hemovac drain and kept the drain clamped for 1 hour postoperatively. An A-P splint was applied on the leg with the knee extension. The legs were elevated at 40⁰ and The amount of blood in Hemovac drain during 24 hours

postoperation period was recorded. The antero- posterior splint was used for three days.

3.13 Outcome measurement

Outcome variables

Primary outcome :The volume of blood drained over 24 hour post operatively.

Secondary outcome :

Knee motion : Arc of knee flexion at 8 weeks postoperatively

Wound complication : separation of the skin margins with drainage necessitating an alteration in the normal postoperative course.

3.14 Data collection

1. Demographic data of the patients :
 - Age (yrs)
 - Sex (male/female)
 - Weight (kgs)
 - Height (cms)
 - BMI (kg/cm^2)
2. the type of pathology (osteoarthritis)
3. side of the knee (right , left)
4. volume of blood drained over 24 hour postoperatively
5. Post operative angle of knee flexion at 8 week after surgery.
6. wound complication (yes/ no)

3.15 Data analyses

1. The demographic and baseline data will be presented as mean(SD) and frequency as appropriate
2. To compare mean of volume of blood drained over 24 hour postoperatively, unpaired student t-test or Mann-Whitney test will be used as well as 95% confidence interval.

3. For arc of knee flexion at 8 weeks postoperatively, unpaired t-test will be used for comparison between 2 groups.
4. To compare wound complication between 2 groups, a chi-square test will be used.

Type of variable	Scale	Statistical analysis
volume of blood drain over 24 hours	Continuous	Unpaired student t- test or Mann-Whitney test
Arc of knee flexion at 8 weeks postoperatively	Continuous	Unpaired student t- test
Wound complication	Binary	Chi- square test , Fisher's Exact test if necessary

3.16 Limitation

There will be about 100cases/year of patient who can afford TKA in King Chulalongkorn memorial hospital, For this study , it took about 1-2 year for gathering the case.

3.17 Ethical consideration

All patients have to be informed about the aims, methods, the benefits and potential hazards from this study and free to withdraw their consent to participate at any time without jeopardising their medical care. This project is conducted in accordance with the Helsinki Declaration(21) and approved by institutional research committee.

3.18 Expected benefits

If the study results show the benefit of this postoperative knee immobilization to prevent the bleeding and subsequently need for transfusion, we would recommend the surgeon to use knee immobilization for the patient who has rare blood group and the patient who could not stand for hemodynamic instability.