Comparison of Bone Graft Storage Effectiveness Between Cryopreservation and Subcutaneous in Patients Conducted Craniectomy Decompression

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ABSTRACT

Decompression craniectomy is a surgical method used for immediate reduction of intracranial pressure. Repair of cranial bone defects to protect the brain and reconstruct the original cranial brain compartment is called a cranioplasty. In this study researchers will conduct research and compare storage of bone graft in the freezer with a temperature of -20 ° C and subcutaneous to the risk of infection. The research design used was paired clinical trials. Clinical tests were in open label form. The analysis of significance using the Mann Whitnay test showed that the value of p = 0.381. This means that there is no significant difference between the storage group in the subcutie and the storage group in the Cryopreservation (p > 0.05). The analysis of significance using the McNemar test showed that the p value = 0.003. This means that there is a significant relationship between the storage group in the subcutie and the storage group in the Cryopreservation (p <0.05).

Keywords: Decompression craniectomy, cranioplasty, bone graft, freezer, subcuties

Introduction

Decompression craniectomy is a surgical method used for immediate reduction of intracranial pressure¹, malignant cerebral edema and hernation of the brain due to cerebral infarction, intracranial hemorrhage, and severe traumatic brain injury². One of the complications
is postoperative neurologic deterioration due to decompression. One of the treatment is decompression craniectomy.

Repair cranial bone defects for brain protection and reconstruct the original cranial brain compartment. Those who survive are obliged to undergo a second procedure for cranial surgical reconstruction which is cranioplasty. Cranioplasty is a surgical intervention to correct cranial defects both cosmetically and functionally. The history of cranioplasty has already existed since 7000 B.C. There are four possible treatments for the bone flap after craniotomy, i.e.: the bone is placed under the subcutaneous abdominal tissue, the bone is preserved in the subgaleal space at the edge of the craniotomy, the bone flap is frozen and the flap is removed for delayed cranioplasty.

Subsequent cranioplasty with autologous skull bones had a bone resorption rate from 4% to 22.8% and an infection rate from 3.3% to 26%. Nowadays there is no standard method to treat craniectomy bone flap is explored. The traditional method is to place a bone flap in the subcutaneous pocket against the abdominal wall. Alternatively, craniectomy bone flaps can be stored in the freezer at -80°C (with an acceptable range of 70°C to 90°C) using the aseptic technique.

In this study, researcher will conduct a study and compare the storage of bone graft in the freezer with a temperature of –20°C and subcutaneous to the risk of infection in patients undergoing decompression craniectomy. The researcher will scrutinize which one is more effective against the risk of infection in patients undergoing decompression craniectomy. Researcher used a temperature of –20°C because the household freezer temperature was ± 20°C.

Method
Design of the study used was paired clinical trials. Clinical tests were conducted in open label form. The population in the study were all patients who underwent craniectomy at dr. Mohammad Hoesin Palembang General Hospital. The sampling was done by using Matching Formulas (gender and age) sums up 15 people per group.

If the gap between the bone graft and the skull increased by > 20% during the follow-up period, three cross sections were randomly selected and the Hounsfield unit (HU) of the graft and skull was measured at five different points. In cases where the mean HU measurement from bone
grafts decreased > 5 % compared to the remaining skull, contours were also compared. The damage of the bone is defined as a decrease in the surface area of the bone that is associated resorption and atrophy.

**Result**

This study is a paired clinical trial. Clinical tests are conducted in open label form. 30 people were performed with decompression craniectomy, which were divided into two groups which are the subcuties group and the Cryopreservation storage group. This chapter described the data normality test, difference test and relationship test.

**Tabel 1.** Frequency distribution between subcuties storage group (15) and Cryopreservation storage group (n=15)

| Variable        | Characteristic  | Total   | Subcuties | Cryopreservation |
|-----------------|-----------------|---------|-----------|-----------------|
| Age             | Year            | 39.73 ± 14.902 | 40.27 ± 12.657 |
|                 | Early Adolescent| 2       | 1 (50.0%) | 1 (50.0%)       |
|                 | Late Adolescent | 4       | 3 (75.0%) | 1 (25.0%)       |
|                 | Young Adult     | 3       | 1 (33.3%) | 2 (66.7%)       |
|                 | Adult           | 9       | 4 (44.4%) | 5 (55.6%)       |
|                 | Early Elderly   | 7       | 3 (42.9%) | 4 (57.2%)       |
|                 | Late seniors    | 5       | 3 (60.0%) | 2 (40.0%)       |
|                 | > 35 years old  | 21      | 10 (47.6%)| 11 (52.4%)      |
|                 | ≤ 35 years old  | 9       | 5 (55.6%) | 4 (44.4%)       |
| Gender          | Male            | 18      | 9 (50.0%) | 9 (50.0%)       |
|                 | Female          | 12      | 6 (50.0%) | 6 (50.0%)       |
| Occupation      | Housewife / Jobless | 12 | 6 (50.0%) | 6 (50.0%)       |
|                 | Trader          | 7       | 3 (42.9%) | 4 (57.1%)       |
|                 | Employee        | 6       | 3 (50.0%) | 3 (50.0%)       |
|                 | Farmer          | 5       | 3 (60.0%) | 2 (40.0%)       |
| Education       | Primary School  | 2       | 1 (50.0%) | 1 (50.0%)       |
|                 | Junior High School | 13 | 8 (61.5%) | 5 (38.5%)       |
|                 | Senior High School | 14 | 6 (42.9%) | 8 (57.1%)       |
|                 | University      | 1       | 0 (0%)    | 1 (100.0%)      |
| Socioeconomic   | Rupiah (Rp)     | 2.000.000 ± 1.732.051 | 2.366.667 ± 1.685.089 |
|                 | Under minimum wage | 16 | 9 (56.3%) | 7 (43.8%)       |
|                 | Above minimum wage | 14 | 6 (42.9%) | 8 (57.1%)       |
Based on the data above, it shows that the age of the respondents are 21 people with the mean in the storage group in the subcutie is 39.73 ± 14.902 and the storage group in the Cryopreservation is 40.27 ± 12.657. The dominant gender is man which is 60.0% . Most of the occupation were housewife / not working at 40.0% . Most education level is high school sum up to 46.7%. The socioeconomic dominance under the minimum wage is 53.3% with the mean in the storage group in the subcutie is 2.000.000 ± 1.732.051 and the storage group in the Cryopreservation is 2.366.667 ± 1.686.089. The dominant marital status is married with 80.0% people. The incidence of infection of the dominant respondent was non infected with the total of 26 people with the mean in the storage group in the subcutie was 9452.00 ± 5047.6 and the storage group in the Cryopreservation was 9204.67 ± 5933.75. All craniectomies were abnormal. The bone graft was dominant, amounting to 26 people. The dominant subcutie were 12 people and all bone grafts in the storage group in the Cryopreservation were stored at -20°C.

Before the data analysis were conducted, normality and homogeneity of the data must be tested to determine the use of parametric or alternative tests. The data normality was tested using the Shapiro- Wilk test, the result of the data normality test between groups showed that all data were p < 0.05 , meaning that the data was not normally distributed, so an alternative test was used which was Mann Whitnay test and continued with the McNemar test. Data analysis used a 95% confidence level or stated differently if p < 0.05.
Table 2. The difference between subcuties dan Cryopreservation (n=30)

| Group            | N  | mean ± SD (mm³) | p   |
|------------------|----|-----------------|-----|
| Subcuties        | 15 | 9452.00 ± 5057.58 | 0.903 |
| Cryopreservation | 15 | 9204.67 ± 5933.75 |     |

The data above shows that the mean number of leukocytes in the storage group in the subcutie was 9452.00 ± 5057.58 and the mean number of leukocytes in the storage group in the Cryopreservation was 9204.67 ± 5933.75. The analysis of significance using the Mann Whitnay test showed that the value of p = 0.903. This means that there is no significant difference between the storage group in the subcutie and the storage group in the Cryopreservation (p > 0.05).

Table 3. Relation between Bone Graft storage and infection incidence (n=30)

| Variable                | Bone Graft Storage | Total | p   |
|-------------------------|--------------------|-------|-----|
|                         | Subcuties          | Cryopreservation |     |
| Infection               | 3 (75.0%)          | 1 (25.0%) | 4   | 0.003 |
| Non Infection           | 12 (46.2%)         | 14 (53.8%) | 26  |     |

The table above shows that the storage group in the subcutie that was not infected was 46.2%, while the infected group was 75.0% and the storage group in the Cryopreservation who was not infected was 53.8%, while the infected were 4 people. The analysis of significance using the McNemar test showed that the p value = 0.003. This means that there is a significant relationship between the storage group in the subcutie and the storage group in the Cryopreservation (p > 0.05).

Discussion

Recently, the indications for cranioplasty have changed from only being cosmetic and protective to being therapeutic. One indication of cranioplasty is a large cranium defect. In daily practice, this procedure is generally performed 3-6 months after craniectomy because of the risk of infection of brain swelling that has not yet healed.

Infection graft cranioplasty was not associated with indication of craniectomy, time or interval of cranioplasty, graft material, or bone defect size but was significantly associated with
previous temporal muscle resection, preoperative sub galeal fluid accumulation, and the interference with postoperative wounds.\textsuperscript{12}

The basic principle of cranioplasty is: choosing a material that is suitable for the type and size of the defect, the material must have a low infection rate, low heat conduction, non magnetic, radiolucent tissue- acceptable, strong, can be formed easily and inexpensive. Before reaching bone closure, clear bony boundaries must be obtained, the SCALP must be separated from the dura. Dura tears must be closed immediately in an impermeable manner (water tight). The bone and cranioplasty material should be maximally attached to each other. To prevent the cranioplasty from shifting, the material must be fixed to the bone with the appropriate plates.

Overall it can be said that storage in the subcutie and storage in the Cryopreservation is acceptable but each patient still has an infection. This can be caused by other factors such as poor storage and maintenance of bone graft. In addition, the bones stored in the subcuties undergo lysis, when the bones are re-assembled they look less tidy because the distance between the bones is far away, while the storage in the Cryopreservation does not undergo lysis.

**Conclusion**

The analysis of significance using the Mann Whitnay test showed that the value of \( p = 0.381 \). This means that there is no significant difference between the storage group in the subcutie and the storage group in the Cryopreservation ( \( p > 0.05 \)).

The analysis of significance using the McNemar test showed that the \( p \) value = 0.003. This means that there is a significant relationship between the storage group in the subcutie and the storage group in the Cryopreservation ( \( p < 0.05 \)).

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