

Effects of Stroke Unit Care in Acute Ischemic Stroke Patient Ineligible for Thrombolytic Treatment

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Background: Several trials have verified the benefits of stroke unit (SU) in acute stroke care worldwide.

Objective: Compare clinical outcomes and costs of care in acute ischemic stroke patients who were ineligible for thrombolytic treatment (recombinant tissue plasminogen activator-rt PA) in a primary stroke center.

Material and Method: A prospective study was conducted in acute ischemic stroke patients, aged 15 years old and above, presenting within 72 hours of onset. At discharge, neurological and medical complications, mortality rate, National Institutes of Health Stroke Scale (NIHSS), Barthel Activities of Daily Living (Barthel ADLs Index), and modified Rankin Scale (mRS) for disability were measured, as well as the length of stay, and cost of hospital care.

Results: There were 1,110 acute ischemic stroke patients, 472 subjects (42.52%) in general medical ward (GMW), and 638 subjects (57.48%) in stroke unit (SU). The number of neurological (brain edema, hemorrhagic transformation, or recurrent stroke), and medical complications (gastrointestinal hemorrhage, pneumonia, or pressure sore) in GMW had highly statistical significance ($p < 0.001$, $p < 0.001$) more than those in SU, with adjusted OR (aOR) (95% CI) of 84.53 (31.14 to 229.46), 4.03 (1.99 to 8.17), respectively. Whereas, the death rate, NIHSS, and disability (Barthel Index of ADLs, and mRS) were statistically significant lower among SU cases ($p = 0.05$, $p < 0.001$, $p < 0.001$) respectively. The median length of stay was three days in both groups, while the median cost of in hospital care was 10,206 Thai Bahts in SU, which was 15.23% higher ($p < 0.001$).

Conclusion: The stroke unit increases the survival rate among stroke patient compared with the general medical ward and have less complication.

Keywords: Acute ischemic stroke, Stroke unit, Primary stroke center, Outcome, cost

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Stroke is a leading cause of death and serious long-term disability in the United States and in Thailand⁽¹⁻³⁾. Moreover, stroke was the first cause of Disability Adjusted Life Years (DALYs) in Thai women and the second in Thai men⁽³⁻⁶⁾. On the other hand, most acute ischemic stroke patients did not get appropriate care. In the United States, about 22% of all ischemic stroke patients presented at an emergency department within three hours, but only about 8% met all other eligibility criteria for thrombolytic treatment⁽⁷⁾. In Thailand, the National Health Security Office (NHSO) revealed that less than 10% of acute stroke patients received proper care. Under the Thai universal coverage scheme, the admission rate of cerebral infarction patients aged 15 and above was slowly increased to

124.04 cases per 100,000 of population in 2013 fiscal year. The rate of thrombolytic treatment in the same period of time was only 3.12%⁽⁸⁾. Hence, most of the cases did not receive the thrombolytic treatment. There were 873 hospitals in the networks (increasing from 843 hospitals in 2012 fiscal year) and included 38 principle hospitals (or mother nodes of the network), 98 smaller hospitals (or child nodes) that could provide thrombolytic treatment, and 737 hospitals that could only diagnose the stroke.

The American Heart Association gives strong evidence about the benefit of stroke unit care to acute patients⁽⁹⁾. However, in Thailand there were few studies regarding to the result of care in the acute ischemic stroke patients in stroke unit confine to tertiary care university medical centers in Bangkok^(10,11). Furthermore, there was no study focused on patient ineligible for thrombolytic treatment, comparing the stroke unit (SU) to general medical ward (GMW). Presently, the health care service load and limitation of resource are the main problems for the public health.

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Effect of SU care in most acute ischemic stroke patients, ineligible for thrombolytic treatment, would let us provide appropriate care among the constrain of resources. The present study was aimed to compare clinical outcomes and costs of care in acute ischemic stroke patients who were ineligible for thrombolytic treatment (recombinant tissue plasminogen activator-rt PA) between SU and GMW.

Material and Method

The authors prospectively collected data of acute ischemic stroke patients, presenting within 72 hours of onset, age of 15 and above admitted in 4-bedded SU, and GMW between February 26, 2014 and September 30, 2015. The stroke unit of Hat Yai Hospital has been certified as primary stroke center (PSC) since 2014, by healthcare accreditation institute (public organization), in terms of clinical practice guideline (treatment protocol, investigation, rehabilitation, and follow-up program), and full time staffing (one stroke specialized nurse, and one practical nurse). The GMW had an occupancy rate about 130%, without stroke specialized nurse, which is similar situation as the other provincial hospitals under Ministry of Public Health of Thailand.

The SU is the first priority for admission of acute ischemic stroke patient, unless it is full. The SU subjects were categorized according to the initial type of care. All patients were enrolled, except if treating for thrombolytic drugs within 4.5 hours of onset.

Baseline characteristics of two groups included age, sex, risk factors, level of consciousness by Glasgow Coma Scale (GCS), etiology of ischemic stroke by TOAST criteria⁽¹²⁾, stroke severity by the National Institutes of Health Stroke Scale (NIHSS), Barthel Index of Activities of Daily Living (ADLs), and modified Rankin Scale (mRS) for disability. At discharge, the performance indicators were assessed.

There were two outcome measurements, clinical outcomes, and performance indicators. Clinical outcomes included immediate neurological and medical complications, mortality rate, Barthel index of ADLs, and mRS at discharge time.

The neurological complications were defined as brain edema, hemorrhagic transformation, and recurrent stroke. The brain edema was defined as deterioration of consciousness confirmed by imaging, and excluded other cause of conscious change such as sepsis and electrolyte imbalance. Hemorrhagic transformation of cerebral infarction was defined as neurological worsening causing from hemorrhagic

transformation confirmed by repeated CT scan brain. A recurrent stroke was diagnosed when patient developed a new onset of focal neurological deficit lasting more than 24 hours during admission which was not the complication of presenting stroke.

The medical complications were defined as gastrointestinal hemorrhage, nosocomial infection (pneumonia or urinary tract infection), deep venous thrombosis, and pressure sore. Regarding to the systemic complications' definitions, gastrointestinal hemorrhage was diagnosed by visible bleeding or positive occult blood in feces with dropped hematocrit. Nosocomial pneumonia was diagnosed when the patient had fever plus dyspnea three days after admission with lung crepitation, positive sputum culture, or compatible, radiologic finding. Urinary tract infection was diagnosed when having fever with leukocyte in urine or positive urine culture. Deep venous thrombosis was diagnosed by clinical symptom/sign with compatible laboratory investigation and specific radiological finding. Performance indicators included length of stay and hospital cost of treatment.

The neurological outcome evaluation was performed in three measurements. The NIHSS⁽¹³⁾, a serial measure of neurologic deficit, in a 42-point scale was divided into four levels, 4 or below (mild), 5 to 14 (moderate), 15 to 24 (moderately severe), 25 or above (severe). The Barthel Activities of Daily Living (Barthel ADLs Index)⁽¹⁴⁾ is a reliable and valid measure of the ability to perform activities of daily living such as eating, bathing, walking, and using the toilet. Patients able to perform all activities with complete independence are given a score of 100. The Barthel Index was divided into three levels: 95 to 100 (near independence to complete independence), 55 to 90 (partial dependence), 0 to 50 (near dependence to complete dependence). The mRS⁽¹⁵⁾ is a simplified overall assessment of function in which a score of 0 indicates the absence of symptoms and a score of 5 indicates severe disability. The mRS was divided into three levels: 0 or 1 (nearly normal), 2 or 3 (moderate disability), 4 or 5 (severe disability). All measurements were done at initial admission and at discharge time. The evaluators were well trained stroke nurses for all patients with the same parameters. All data for analysis were collected in the stroke registry program.

Because there were no prior studies, all 1,110 acute ischemic stroke patients who admitted since launching of the stroke unit (February 26, 2014) were counted in this study.

This study was conducted under permission of Hat Yai Hospital ethic committee. The protocol number was 03/2016.

Descriptive statistics were used for describing baseline characteristics, neurological outcomes, and complications at discharge using mean/median standard deviation and percentages. Unpaired t-test, Chi-square test, and Wilcoxon rank sum test were used for comparing two continuous data, categorical data, and non-parametric data respectively. Univariate logistic regression analysis and multiple logistic regression analysis were used for comparing outcomes between GMW and SU. A *p*-value less than 0.05 was

considered statistically significant. Stata software version 14 was used in all analyses.

Results

There were 1,110 acute ischemic stroke patients, 472 patients (42.52%) in GMW, and 638 patients (57.48%) in SU. The baseline characteristics in the two studied groups were shown in Table 1. There was no statistically significant difference in baseline age, sex, common risk factors, initial Barthel index, and mRS, as well as no obvious difference in common risk factors such as dyslipidemia, hypertension, diabetes, smoking, alcohol drinking, or previous stroke. On the

Table 1. Baseline characteristics of patients admitted in GMW and SU

| Item | GMW (n = 472) No. (%) | SU (n = 638) No. (%) | <i>p</i> -value |
|------------------------------------|--------------------------|-------------------------|-----------------|
| Mean age (SD) | 64.75±14.34 | 63.26±14.59 | 0.091 |
| Male | 266 (56.36) | 394 (61.76) | 0.070 |
| GCS at admission | | | <0.001** |
| Less than 11 | 52 (11.02) | 33 (5.17) | |
| 11 to 13 | 28 (5.93) | 62 (9.72) | |
| 14 to 15 | 392 (83.05) | 543 (85.11) | |
| Risk factors | | | |
| Dyslipidemia | 123 (26.06) | 132 (20.69) | 0.109 |
| Hypertension | 288 (61.02) | 354 (55.49) | 0.179 |
| Diabetes | 112 (23.73) | 132 (20.69) | 0.414 |
| Smoking | 239 (50.64) | 309 (48.43) | 0.468 |
| Alcohol drinking | 286 (60.59) | 377 (59.09) | 0.614 |
| Atrial fibrillation | 6 (1.27) | 11 (1.72) | 0.783 |
| Previous stroke | 35 (7.42) | 45 (7.05) | 0.818 |
| Stroke etiology by TOAST criteria | | | 0.004* |
| Large vessel atherosclerosis | 71 (15.04) | 130 (20.38) | |
| Cardiac embolism | 13 (2.75) | 10 (1.57) | |
| Small vessel disease | 329 (69.7) | 453 (71) | |
| Other determined etiology | 39 (8.26) | 26 (4.08) | |
| Other undetermined etiology | 20 (4.24) | 19 (2.98) | |
| NIHSS at admission | | | 0.020* |
| ≤4 | 219 (46.4) | 311 (48.75) | |
| 5 to 14 | 175 (37.08) | 260 (40.75) | |
| 15 to 24 | 60 (12.71) | 56 (8.78) | |
| ≥25 | 18 (3.81) | 11 (1.72) | |
| Barthel Index at admission | | | 0.134 |
| 95 to 100 | 122 (25.85) | 172 (26.96) | |
| 55 to 90 | 215 (45.55) | 317 (49.69) | |
| 0 to 50 | 135 (28.60) | 149 (23.35) | |
| Modified Rankin Scale at admission | | | 0.149 |
| 0 to 1 | 196 (41.53) | 296 (46.39) | |
| 2 to 3 | 142 (30.08) | 191 (29.94) | |
| 4 to 5 | 134 (28.39) | 151 (23.67) | |

* Statistical significance (*p*<0.05), highly statistical significance (*p*<0.001)

other hand, stroke etiology by Trial of Org 10172 in acute stroke treatment (TOAST) criteria indicated large vessels was 20.38% in SU as compared to 15.04% in GMW group ($p = 0.004$). Initial GCS and NIHSS revealed significant more neurological severity at admission in GMW as compared to SU ($p < 0.001$ and $p = 0.02$ respectively), (Table 1).

In term of neurological outcome, NIHSS, Barthel index, and mRS were highly statistically significant in SU compared to GMW ($p < 0.001$ in all items).

Brain edema/hemorrhagic transformation/recurrent stroke decreased among SU compared to GMW (0.94/0.16/0 versus 12.29/2.33/3/18%, all $p < 0.001$). In addition, the gastrointestinal bleeding/urinary tract infection/pneumonia/pressure sore decreased among SU compared to GMW (0.31/0.16/1.57/0.16 versus 4.87/0.21/3.60/2.12%, $p < 0.001$, $p = 0.830$, $p = 0.030$, and $p = 0.001$, respectively). In both groups, no deep vein thrombosis was reported, and the urinary tract infection was not significantly different. The death rate was significantly lower in SU compared to GMW (2.82% and 6.57% in GMW ($p = 0.003$)).

The median length of stay in both groups was three days, without significant difference ($p = 0.609$). Median cost of hospital care in SU was 10,206 Thai Baht compared to 8,857 in GMW, 15.23% lower cost ($p < 0.001$), (Table 2).

The crude odds of having neurological complications, medical complications, and death were significantly higher in GMW compared to SU (crude OR 19.52, 4.70, 2.42 respectively).

After adjusted for baseline characteristics such as GCS, TOAST etiology, and NIHSS at admission, the odds of having any neurological complications increased from 19.52 (8.93 to 42.63) to 84.53 (31.14 to 229.46: $p < 0.001$) in GMW compared to SU group. After adjustment, the odds of having any medical complications in GMW compared to SU group, decreased from 4.70 (1.52 to 4.78) to 4.03 (1.99 to 8.17: $p < 0.001$). Moreover, after adjustment, the OR of death decreased from 2.42 (1.34 to 4.38) to 1.94 (1.00 to 3.78: $p = 0.050$).

The three horizontal bar graphs, divided into levels of severity showed the results of all three outcome measures at discharge time (Fig. 1). By comparing both SU and GMW groups for each neurological outcome, most outcomes favored treatment in SU group. The greater proportion of patients left with minimal or less deficit and surviving in SU compared with GMW at discharge time. The positive effect of SU on all outcome measures at discharge time was seen consistently with statistical significance ($p < 0.001$).

Discussion

Although thrombolytic treatment in acute ischemic stroke patients revealed beneficial effect, a

Table 2. Complications, death, LOS, and cost of hospital care between patients admitted in GMW and SU

| | GMW (n = 472) | | SU (n = 638) | | p-value |
|---|-----------------------|-------|------------------------|------|---------|
| | No. | % | No. | % | |
| Neurological complications | | | | | <0.001 |
| None | 388 | 82.2 | 631 | 98.9 | |
| Brain edema | 58 | 12.29 | 6 | 0.94 | |
| Hemorrhagic transformation | 11 | 2.33 | 1 | 0.16 | |
| Recurrent stroke | 15 | 3.18 | 0 | 0 | |
| Medical complications | | | | | |
| Gastrointestinal bleeding | 23 | 4.87 | 2 | 0.31 | <0.001 |
| Urinary tract infection | 1 | 0.21 | 1 | 0.16 | 0.830 |
| Pneumonia | 17 | 3.6 | 10 | 1.57 | 0.030 |
| Pressure sore | 10 | 2.12 | 1 | 0.16 | 0.001 |
| Deep venous thrombosis | 0 | 0 | 0 | 0 | |
| Death | 31 | 6.57 | 18 | 2.82 | 0.003 |
| Length of stay (days)(median)(min/max) | 3 (0/63) | | 3 (0/41) | | 0.609* |
| Cost of hospital care (median)(min/max) | 8,857 (1,520/302,244) | | 10,206 (2,904/231,785) | | <0.001* |

* Two-sample wilcoxon rank-sum (Mann-Whitney) test

Table 3. Crude OR and adjusted OR of complications and death compared between patients admitted in GMW and SU

| | Incidence of complication | | Crude OR | 95% CI | Adjusted OR* | 95% CI | p-value |
|------------------------------|---------------------------|-------|----------|---------------|--------------|-----------------|---------|
| | No. (%) | Total | | | | | |
| Neurological complications** | | | | | | | <0.001 |
| SU | 7 (1.1) | 638 | 1 | | 1 | | |
| GMW | 84 (17.8) | 472 | 19.52 | 8.93 to 42.63 | 84.53 | 31.14 to 229.46 | |
| Medical complications** | | | | | | | <0.001 |
| SU | 13 (2.04) | 638 | 1 | | 1 | | |
| GMW | 42 (8.9) | 472 | 4.70 | 1.52 to 4.78 | 4.03 | 1.99 to 8.17 | |
| Death | | | | | | | 0.050 |
| SU | 18 (2.82) | 638 | 1 | | 1 | | |
| GMW | 31 (6.57) | 472 | 2.42 | 1.34 to 4.38 | 1.94 | 1.00 to 3.78 | |

* Adjusted for categories of GCS, TOAST etiology and NIHSS at admission except in neurological complication adjusted using ordinary data

** Any of complications

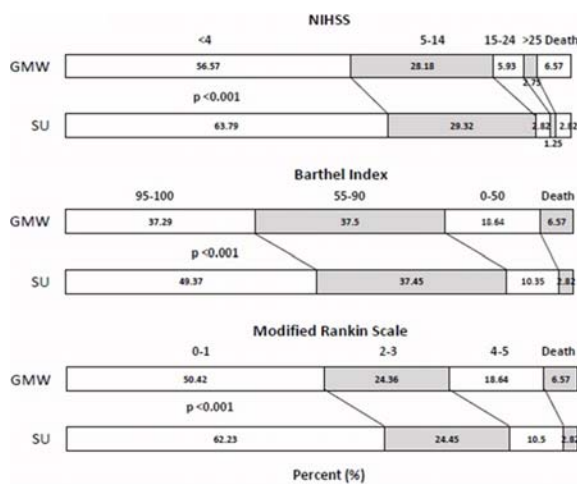


Fig. 1 Neurological outcome in percentage between general medical ward (GMW, n = 472) and stroke unit (SU, n = 638) at discharge time grouped by range of NIHSS, Barthel Index and Modified Rankin Scale.

relative small number of patient was eligible for this treatment. To increase thrombolytic treatment in acute ischemic stroke patients was quite difficult due to limit time window after stroke onset, investigation, and imaging. The organized stroke unit has been widely accepted as a standard approach of acute stroke care. The AHA/ASA guideline and European Stroke Organization strongly recommended comprehensive stroke unit in acute stroke care^(16,17). Organized stroke unit benefit was confirmed by The Cochrane

Collaboration⁽¹⁸⁾. The authors designed this study to prove the beneficial effect of organized stroke unit in both clinical outcome and cost of hospital care as compared to conventional medical ward care on the acute ischemic stroke patients that are ineligible for thrombolytic treatment. The results of care from SU showed less common medical complications during admission. Dramatic and significant decrease of severe neurological complication especially brain edema, the leading cause of death in acute phase of stroke, was also found in SU care. Overall effects related to decrease mortality and morbidity of cases were admitted in SU. Standard and simple measurements used in the present study could be applied for any hospital. Even though the hospital care cost in SU is about 15% higher, the overall consideration for patients outcome is necessary. The cost included in the present study represented only direct cost in the hospital and may be misleading. In the GMW group, 18.6% of patients were severely disabled and were likely to require full time nursing care (mRS of 4 to 5 at discharge), whereas only 10.5% in the SU were severely disabled. If the total cost of health care, which include rehabilitation, long term nursing, and care for late complications were calculated, the overall cost effectiveness of SU care will overcome the higher hospital cost.

Conclusion

The result of the present study favors stroke unit as an appropriate care for acute ischemic stroke patients although not all patients get thrombolytic treatment. The early admission of these patients within

72 hours of stroke onset in stroke unit promotes the patient recovery with significant decrease in mortality and morbidity. An equal length of stay and a 15% higher cost of hospital care in stroke unit was shown. It is quite difficult to increase the thrombolytic treatment use in acute ischemic stroke patients due to limit of time after onset and necessary investigation. The stroke unit showed significant benefit and is quite easier to establish in most provincial hospitals under the Ministry of Public Health of Thailand.

What is already known on this topic?

Stroke unit management is the standard treatment of acute stroke. Admission in the stroke unit is shown to be associated with better neurological outcome and less complications when compared to general medical ward. Therefore, it is strongly recommended in many international and Thai guidelines.

Few studies of the benefit of stroke unit in Thailand were performed in tertiary care centers. The result may not be applied to primary stroke center under the Ministry of Public Health of Thailand outside metropolitan areas.

What this study adds?

The benefit of stroke unit care in patients who were ineligible for intravenous thrombolysis was demonstrated in Hat Yai Hospital, which is a primary stroke center under the Ministry of Public Health of Thailand outside Bangkok.

This is the first study comparing the cost of stroke care in stroke unit and general medical ward in primary stroke center under the Ministry of Public Health of Thailand. Although, the cost is 15% higher in patients admitted in the stroke unit, significant benefit on reduction of mortality, disability, and acute complications could overcome the cost.

Potential conflicts of interest

None.

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ผลการดูแลผู้ป่วยโรคหลอดเลือดสมองขาดเลือดเฉียบพลันซึ่งไม่สามารถให้ยาละลายลิ่มเลือดได้ในหอภิบาลโรคหลอดเลือดสมอง

เกียรติศักดิ์ ราชบริรักษ์, ทักษิพย์ ธรรมวิริยะกุล, จุก สุวรรณโณ

ภูมิหลัง: การทดลองจำนวนหนึ่งยืนยันผลประโยชน์ของหอภิบาลโรคหลอดเลือดสมอง ในการดูแลผู้ป่วยโรคหลอดเลือดสมองขาดเลือดเฉียบพลันทั่วโลก
วัตถุประสงค์: การศึกษามุ่งหมายเปรียบเทียบผลที่ได้รับทางคลินิกและต้นทุนในการดูแลผู้ป่วยโรคหลอดเลือดสมองขาดเลือดเฉียบพลัน ผู้ขาดคุณสมบัติสำหรับรักษาด้วยยาละลายลิ่มเลือดในศูนย์โรคหลอดเลือดสมองปฐมภูมิ

วัตถุประสงค์และวิธีการ: ศึกษาแบบมุ่งหน้าในผู้ป่วยโรคหลอดเลือดสมองขาดเลือดเฉียบพลัน อายุ 15 ปีหรือมากกว่า มาด้วยเริ่มต้นอาการภายใน 72 ชั่วโมงเมื่อออกจากโรงพยาบาล โดยตรวจวัดภาวะแทรกซ้อนทางประสาทวิทยาและการแพทย์ อัตราการตาย คะแนนตามแบบประเมินคะแนนโรคหลอดเลือดสมองเฉียบพลันของสถาบันสุขภาพแห่งชาติสหรัฐอเมริกา กิจกรรมการใช้ชีวิตประจำวันของบาร์เชล และระบบวัดแรงคืนประยุคต์สำหรับทุพพลภาพ เช่นเดียวกับระยะเวลาอยู่โรงพยาบาลและค่าใช้จ่ายของการดูแลในโรงพยาบาล

ผลการศึกษา: มีผู้ป่วยโรคหลอดเลือดสมองเฉียบพลัน 1,111 คน จำนวนนี้ 427 คน (ร้อยละ 42.52) อยู่หอผู้ป่วยอายุรศาสตร์ทั่วไป และ 638 คน (ร้อยละ 57.48) อยู่หอภิบาลโรคหลอดเลือดสมอง จำนวนภาวะแทรกซ้อนทางประสาทวิทยา (สมองบวม แปลงรูปเลือดออก โรคหลอดเลือดสมองเป็นซ้ำ) และอายุรศาสตร์ (เลือดออกจากกระเพาะอาหารและลำไส้ ปอดอักเสบ แผลกดทับ) ในหอผู้ป่วยอายุรศาสตร์ทั่วไปสูงกว่าหอภิบาลโรคหลอดเลือดสมองอย่างมีนัยสำคัญสูง ($p < 0.001$, $p < 0.001$) ด้วยอัตราเป็นต่อปรับแล้วเท่ากับ 84.53 (ร้อยละ 95 ช่วงความเชื่อมั่น 31.14 ถึง 229.46) และ 4.03 (ร้อยละ 95 ช่วงความเชื่อมั่น 1.99 ถึง 8.17) ตามลำดับ ขณะที่ในหอภิบาลโรคหลอดเลือดสมอง อัตราตายคะแนนตามแบบประเมินคะแนนโรคหลอดเลือดสมองเฉียบพลันของสถาบันสุขภาพแห่งชาติสหรัฐอเมริกา กิจกรรมการใช้ชีวิตประจำวันของบาร์เชล และระบบวัดแรงคืนประยุคต์ สำหรับทุพพลภาพค่ากว่าอย่างมีนัยสำคัญและนัยสำคัญสูง ($p = 0.05$, $p < 0.001$, $p < 0.001$) ค่ามัธยฐานของระยะเวลาอยู่โรงพยาบาลเท่ากับ 3 วัน ขณะที่ค่าใช้จ่ายของการดูแลในโรงพยาบาลเท่ากับ 10,206 บาทในหอภิบาลโรคหลอดเลือดสมองสูงกว่าหอผู้ป่วยอายุรศาสตร์ทั่วไปร้อยละ 15.23 อย่างมีนัยสำคัญ ($p < 0.001$)

สรุป: หอภิบาลโรคหลอดเลือดสมองเพิ่มอัตราอยู่รอดของผู้ป่วยโรคหลอดเลือดสมองเปรียบเทียบกับหอผู้ป่วยอายุรศาสตร์ทั่วไป เช่นเดียวกับภาวะแทรกซ้อน
