A Model for Predicting Outcome Following Surgical Clipping in Patients with Aneurysmal Subarachnoid Hemorrhage

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Background: *Aneurysmal subarachnoid hemorrhage is one of the most serious neurosurgical conditions. There are a few studies in Thai population.*

Objective: *To investigate factors related to poor outcome after cerebral aneurysms clipping and establish a risk score model to predict unfavorable outcome.*

Material and Method: *A nested case-control study was conducted from cohort data between January 2010 to December 2016 at Her Royal Highness Princess Maha Chakri Sirindhorn Medical Center and Saraburi Hospital. One hundred and sixty-eight aneurysmal subarachnoid hemorrhage patients were enrolled in the study. Surgical outcome was assessed by Glasgow Outcome Scale (GOS). The number of the case per control was 1: 1. Factors associated with unfavorable outcome were analyzed. A risk score model was developed by backward stepwise binary logistic regression analysis, and the Receiver Operating Characteristic (ROC) curve was constructed.*

Results: *Factors associated with poor outcome were the Modified Fisher grading scale of grade 3 or 4 (OR 17.8; 95% CI 6.8 to 46.7), the best motor response of Glasgow Coma Scale M4 or M5 (OR 8.1; 95% CI 3.2 to 20.4), and age of patients over than 60 years (OR 3.2; 95% CI 1.2 to 8.4). The final risk score model = 1 (age over than 60) +2.5 (GCS M4 or M5) +5.5 (Modified Fisher grading scale 3 or 4). The corresponding ROC for the accuracy of predicting the unfavorable outcome was 0.91; 95% CI 0.86 to 0.95 (p<0.001).*

Conclusion: *The simple risk score model based on three independent factors (Modified Fisher grading scale of grade 3 or 4, the best motor response of GCS being M4 or M5, and the age of the patients >60 years) was created to predict unfavorable outcome.*

Keywords: *Cerebral aneurysm, Aneurysmal subarachnoid hemorrhage, Cerebral aneurysm clipping outcome, Outcome predictive model, Risk score model*

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Aneurysmal subarachnoid hemorrhage (SAH) is the second most common cause of hemorrhagic stroke, following hypertensive intracerebral hemorrhage[1]. There is a variation of the incidence and outcomes in different parts of the world[2,3]. The standard treatment is aneurysm clipping or coil embolization for prevention of rebleeding[4]. Although all modalities of treatment are achieved, devastating neurological outcomes with a relatively high mortality and morbidity rate still occur[5]. Fifteen percent of patients with aneurysmal SAH die before admission, 45 percent die within 30 days after treatment, 10 to 20 percent are dependent, and only 40 percent have excellent outcomes[5-8].

Several studies revealed factors associated with outcomes, such as level of consciousness and neurological status on admission, age of patients, and patterns of SAH on computed tomographic scan (CT)[9-13]. Nevertheless, there are few reports regarding aneurysmal SAH in Thailand[14,15].

For improving treatment outcome of aneurysmal SAH, the main objective of the present study was to investigate factors predicting surgical outcome in patients who underwent surgical clipping at two tertiary care centers in Thailand and to develop a risk model for predicting the surgical outcome.

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Material and Method

After the protocol of the study was ethically approved by the Institutional Review Board of Srinakharinwirot University and Research Center of Saraburi regional hospital, the authors conducted a nested case-control study from a retrospective cohort data. All patients with aneurysmal SAH who underwent surgical clipping between January 2010 to December 2016 at Her Royal Highness Princess Maha Chakri Sirindhorn Medical Center faculty of Medicine Srinakharinwirot University and Saraburi Regional Hospital were enrolled in the study. The exclusion criteria were ruptured traumatic aneurysms and ruptured arteriovenous malformation-associated aneurysms.

Cohort data were collected from a computer base system. Pre-operative clinical assessments were performed by using Hunt and Hess grading scale[16], Glasgow Coma Scale (GCS), and World Federation of Neurosurgeons (WFNS) Scale[16,17]. Subarachnoid blood patterns on CT scan was evaluated by using Fisher Grading Scale[16,18] and Modified Fisher Grading Scale[11,19] (Fig. 1). All patients were operated with standard microsurgical clipping technique[15], Triple-H therapy for prevention of cerebral vasospasm was done, and nimodipine was used as a cerebral protective agent[20].

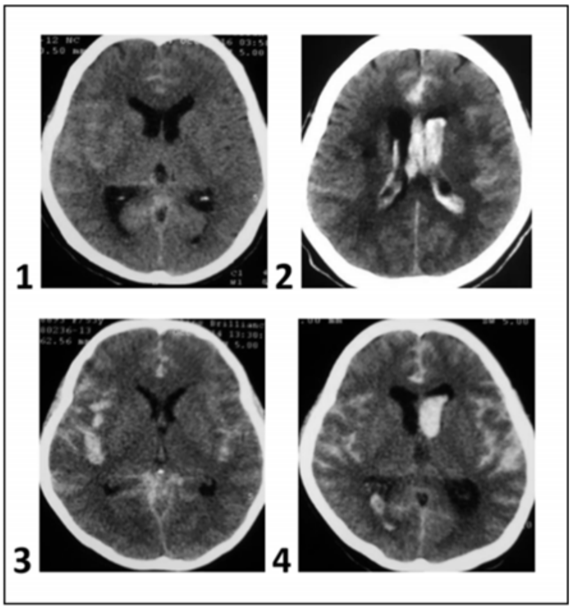

Fig. 1 Modified Fisher subarachnoid hemorrhage CT grading: (1) grade 1 minimal SAH and no intraventricular hemorrhage (IVH); (2) grade 2 minimal SAH with bilateral IVH; (3) grade 3 thick SAH without bilateral IVH; (4) grade 4 thick SAH with bilateral IVH[11,19].

Surgical outcome was evaluated by Glasgow Outcome Scale (GOS)[21] at 180 days after surgery. Patients with severe disability, persistent vegetative status, and death were classified as unfavorable outcome group (case), whereas patients with good recovery and moderate disability were classified as favorable outcome group (control).

Sample size calculation based on predictive factors of the unfavorable outcome at Saraburi Regional Hospital obtained from a previous pilot study[22]. The authors found that age of patients over than 60 years was a predictive factor for unfavorable outcome that provided the largest sample size. Therefore, at least 42 patients in each group were needed to reveal the statistical significance [alpha = 0.05, beta = 0.1, p (exposure/control) = 0.3, p (exposure/case) = 0.67]. In the present study, there were 84 patients in the case and 84 patients in control.

In univariate analysis, factors associated with the unfavorable outcome was analyzed by using Chi-square or t-test. Backward stepwise binary logistic regression analysis was used in multivariate analysis. Statistically significant variables were those with p <0.05.

An equation obtained from binary logistic regression analysis for calculating the probability of an unfavorable outcome is:

P (unfavorable outcome) = $1/1+\exp^{-(Z)}$

$Z = B_0 + B_1X_1 + B_2X_2+B_3X_3+\ldots.B_pX_p$

Z = linear combination of the independent variables

B = B coefficient in the logistic regression

X = variables in the logistic regression

P = number of variables

The suitability of the equation was calculated by Hosmer and Lemeshow test. This equation was an exponential form which was difficult to use. Therefore, A simple predictive model was developed from these variables with p<0.05 in logistic regression equation, the corresponding Exp (B) coefficients were used to assign the specific value as the risk score. An area under the curve of Receiver Operating Characteristic (ROC) was calculated to demonstrate discriminatory power of the model. The statistical analysis was performed using SPSS software (version 23.0; SPSS Inc., Business Applications, Thailand).

Results

During the period of study, there were 84 patients with unfavorable outcome (case) and 84 patients with favorable outcome (control). Mortality was found in 31 cases (36.9%) of the unfavorable outcome group. Demographic characteristics of both groups are shown in Table 1. The unfavorable outcome group had age significantly older than that of the control group.

Table 2 reveals factors associated with surgical outcome. Age >60 years, Hunt and Hess grade 3 or 4, the best motor response of GCS being M4 or M5, WFNS scale grade 4 or 5, Fisher grade 3 or 4, and Modified Fisher grade 3 or 4 were statistically significant associated with unfavorable outcome. All

Table 1. Demographic characteristics

Characteristics	Unfavorable outcome (n = 84), n (%)	Favorable outcome (n = 84), n (%)	*p*-value
Mean age ± SD (years)	60.0±12.7	52.2±12.4	<0.001
Gender			
Female	62 (73.8)	59 (76.2)	0.606
Underlying disease			
Hypertension	45 (53.6)	38 (45.2)	0.280
Diabetes mellitus	8 (9.5)	7 (8.3)	0.787
Behavioral status			
Smoking	10 (11.9)	8 (9.5)	0.618
Alcoholic drinking	10 (11.9)	8 (9.5)	0.618
Signs and symptoms			
Headache	22 (26.2)	64 (76.2)	-
Alteration of consciousness	46 (54.8)	14 (16.7)	-
Focal neurological deficit	6 (7.1)	1 (1.2)	-
Cranial nerve III palsy	0 (0)	2 (2.4)	-
Seizure	9 (10.7)	3 (3.6)	-
Locations of aneurysm			
A-com	33 (39.3)	36 (42.9)	-
P-com	11 (13.1)	23 (27.4)	-
MCA	22 (26.2)	15 (17.9)	-
Distal ACA	1 (1.2)	1 (1.2)	-
Anterior choroidal	1 (1.2)	0 (0)	-
Clinoid ICA	2 (2.4)	1 (1.2)	-
Distal ICA	8 (9.5)	5 (6.0)	-
PICA	4 (4.8)	2 (2.4)	-
Vertebral	0 (0)	1 (1.2)	-
Aneurysm > 1 location	4 (4.8)	3 (3.6)	-

A-com = anterior communicating artery; ACA = anterior cerebral artery; ICA = internal carotid artery; MCA = middle cerebral artery; P-com = posterior communicating artery; PICA = posterior inferior cerebellar artery

Table 2. Factors associated with treatment outcome in univariate analysis

Factors	Unfavorable outcome n = 84, n (%)	Favorable outcome n = 84, n (%)	*p*-value
Age >60 (years)	44 (52.4)	21 (25.0)	<0.001
Hunt and Hess grade 3 or 4	69 (82.1)	20 (23.8)	<0.001
GCS with motor response of M4 or M5	61 (72.6)	13 (15.5)	<0.001
WFNS Scale grade 4 or 5	55 (66.7)	16 (19.0)	<0.001
Fisher grade 3 or 4	82 (97.6)	43 (51.2)	<0.001
Modified Fisher grade 3 or 4	74 (88.1)	21 (25.0)	<0.001

Table 3. Factors related to unfavorable outcome in multivariate analysis

Factors	Crude OR	95% CI	*p*-value	Adjusted OR	95% CI	*p*-value
Modified fisher grade 3 or 4	22.2	9.7 to 50.6	<0.001	17.8	6.8-46.7	<0.001
GCS M4 or M5	14.2	6.7 to 30.6	<0.001	8.1	3.3-20.4	<0.001
Age >60 years	3.3	1.7 to 6.3	<0.001	3.2	1.2-8.4	0.018

Table 4. Variables in the binary logistic regression equation

Variables	B	Exp (B)	95% CI	*p*-value
Age over than 60 (years)	1.162	3.198	1.218 to 8.396	0.018
GCS M4 or M5	2.097	8.141	3.246 to 20.417	<0.001
Modified fisher 3 or 4	2.877	17.761	6.761 to 46.661	<0.001
Constant	-3.030	0.048		

these factors were analyzed in multivariate analysis.

Table 3 provides the results of multivariate binary logistic regression analysis. Factors related to unfavorable outcome were Modified Fisher grade 3 or 4, the best motor response of GCS being M4 or M5, and age over 60 years.

Table 4 reveals the results of binary logistic regression analysis, which were used to develop the risk score model for unfavorable outcome prediction. All three variables with a *p*-value <0.05 were included in the model. The probability of unfavorable outcome is shown as follow:

$$P\text{ (unfavorable outcome)} = 1/1 + \exp^{-[-3.03 + 1.162\text{ (age > 60 years)} + 2.097\text{ (GCS M4 or M5)} + 2.877\text{ (Modified Fisher grade 3 or 4)}]}$$

The following Exp(B) coefficient (Table 4) was used to assign a specific value as the risk score. The Exp(B) coefficient ratio of variables are 3.2: 8.1: 17.8 (1: 2.5: 5.5). The final equation of predictive model (Risk score) was constructed by using the transformation and computation of the variables in SPSS. Therefore, the risk score is:

Risk score = 1 (age over than 60 years) + 2.5 (GCS M4 or M5) + 5.5 (Modified Fisher 3 or 4)

Regarding score in this equation, age of patients is categorized as equal or over than 60 years old = 1 and less than 60 years old = 0; the best motor response of GCS is categorized as M4 or M5 = 1 and M6 = 0; Modified Fisher Grading Scale is categorized as score of 3 or 4 = 1 and score of 0-2 = 0.

The association between risk score and unfavorable outcome were analyzed by using ROC curve. The area under the ROC curve for predicting the significant unfavorable outcome of SAH by predictive score model is shown in Fig. 2. The area under ROC curve is 0.91; 95% CI 0.86 to 0.95.

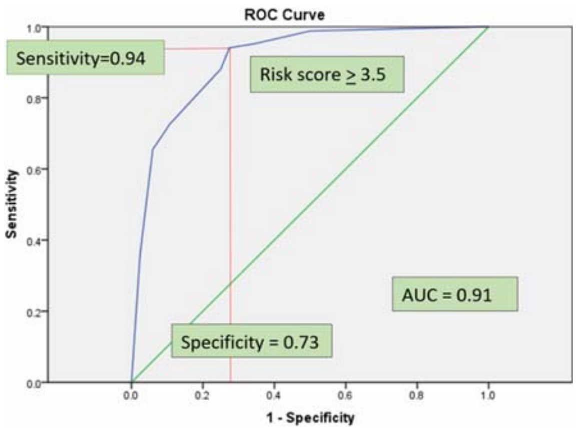

Fig. 2 The ROC curve of the risk score for predicting unfavorable outcome in patients with aneurysmal SAH treated by surgical clipping, area under the curve = 0.91; 95% CI = 0.86 to 0.95. Risk score ≥3.5 is the cutoff point; sensitivity = 0.94, specificity = 0.73.

The present study demonstrates that a value of risk score ≥3.5 is the cutoff point to predict the unfavorable outcome; 94% sensitivity, 73% specificity, 77.5% positive predictive value (PPV), 92.4% negative predictive value (NPV), and 83.3% accuracy, 95% CI 76.8 to 89.9. Risk score value and parameter estimation by the risk score equation model are shown in Table 5.

Discussion

According to previous studies, many clinical and radiographic grading systems have been

Table 5. Risk score value and parameter estimation by the risk score equation model

Risk score	Sensitivity	specificity	PPV (%)	NPV (%)	LL+	LL-	Accuracy (%)
0	0.01	0.50	2.3	33.6	0.024	1.98	25.6
1.0	0.99	0.50	66.4	97.7	1.98	0.02	74.4
2.5	0.95	0.65	73.4	93.2	2.71	0.08	80.4
3.5	0.94	0.73	77.5	92.4	3.48	0.08	83.3
5.5	0.88	0.75	77.9	86.3	3.52	0.16	81.5
6.5	0.73	0.89	87.1	76.5	6.64	0.30	81.0
8.0	0.65	0.94	91.7	73.1	10.83	0.37	79.8
9.0	0.36	0.98	93.8	60.3	18.00	0.65	66.7

PPV = Positive predictive value; NPV = Negative predictive value; LL+ = Positive likelihood ratio; LL- = Negative likelihood ratio

established(16-19), such as Hunt and Hess grading scale, WFNS grading scale, Fisher grading scale, and Modified Fisher grading scale which were used as outcome predictor of aneurysmal SAH. However, it remains unclear about independent factors for predicting the outcomes because there was a variation in the study population and research methodology(9,12,14,23).

In the present study, the significant risk factors associated with unfavorable outcome are Modified Fisher grading scale 3 or 4, the best motor response of GCS of M4 or M5; and age of patients >60 years. In contrast, there is no statistically significant association between high-grade of Fisher scale 3 or 4, high-grade of Hunt and Hess scale 3 or 4, and high- grade of WFNS Scale 4 or 5 and poor outcome. From these results reveal the outcome of the patients depended on the base line amount of subarachnoid blood on CT scan, neurological status, and the age of patients at the time of admission.

The Fisher grading scale has been widely used to predict cerebral vasospasm(18,23). Thick subarachnoid blood (grade III) is a potential risk factor for cerebral vasospasm, but patients with significant intracerebral hemorrhage or intraventricular hemorrhage (grade IV) patients may have excellent or worse outcome, depending on the amount of thickness of subarachnoid blood. In recent studies, the Modified Fisher grading scale(11,19) (Fig. 1) has been a new grading system revised from Fisher grading scale, that considers the thickness of subarachnoid blood and intraventricular hemorrhage. Grade III and IV are an intermediate and a high risk of symptomatic vasospasm, respectively. The present study, consideration on the particular subarachnoid blood on CT scan; the results corresponded to the Modified Fisher scale. Therefore, the Modified Fisher grading scale is a more efficient tool for predicting the outcome of aneurysmal SAH than the Fisher grading scale. Recent studies indicate that cerebral vasospasm is a major complication of aneurysmal SAH. Many patients with this complication will have poor outcome(16,18,20,23). The severity of cerebral ischemia depends on the thickness and the amount of subarachnoid blood in the basal cistern(16,18,23). In some patients with grade IV of Fisher grading scale, if there is no thick subarachnoid blood, they may have a favorable outcome. On the other hand, patients with grade IV of Modified Fisher grading scale must have thick subarachnoid blood and IVH. Therefore, most of the patients with this grade will have a poor outcome.

Clinical grading of patients on admission was assessed by GCS, Hunt and Hess scale, and WFNS scale. In contrast, with previous studies(10,14,16), the present study shows that only the best motor response of GCS was statistically significant factor associated with unfavorable outcome, while the high-grade of Hunt and Hess scale and high-grade of WFNS were not associated with unfavorable outcomes. These results might be due to a small sample size of the study and the variability of clinical assessment may have occurred. In such cases, clinicians cannot assess WFNS scale in patients with endotracheal intubation or cannot classify patients between grade II and III of Hunt and Hess grading scale. Whereas, there is minimal variability of assessment by using GCS because the definition of the best motor response of GCS is easy to interpret.

From the present study, old age was a major factor for predicting poor outcomes, which correspond to the results of previous studies(13,14,22). Old patients may have many medical problems and perioperative complications. In the present study, old age was defined as age of the patients >60 years, along with a previous pilot study[22].

In the present study, the authors established a new risk score model to predict unfavorable outcome of patients with aneurysmal SAH who had treated with surgical clipping. The risk model was based on the three independent risk factors associated with unfavorable outcome. It is simplified to use because each factor in the equation is the categorical variable (1, 0), is easy to interpret, and the definition of each variable is clear which can decrease interobserver variability.

For example of a calculation by the risk model, if age of patient was 65 years old, the best motor response of GCS on admission was M6, and the modified fisher grading scale was grade 3.

Risk score = 1 (1) + 2.5 (0) + 5.5 (1) = 6.5

The interpretation of risk score 6.5 was shown in Table 5; the probability of unfavorable outcome in this patient is 87.1% (PPV), 73% sensitivity, and 89% specificity (+LL = 6.64, -LL = 0.3).

According to the present study, a cutoff value for predict poor outcomes was 3.5, it means that patients must have age >60 years, and the best motor response of GCS being M4 or M5. From this clinical data, the authors assign age of patients >60 years, and the best motor response of GCS being M4 or M5 are the minor criteria for risk score model.

From Table 5, if the risk score is 5.5, it means that patients must have only the Modified Fisher scale of grade 3 or 4 (age must be less than 60 years, and the best motor response of GOS must be M6). From this clinical data, the authors assign the Modified Fisher grade 3 or 4 is the major criteria for risk score model.

From the present study, if the patients have two minor criteria or have only one major criterion for risk score model, these patients may have a high probability to have unfavorable outcome (77.5% to 77.9% of PPV).

The authors demonstrated that high-grade of the Modified Fisher Scale (3 or 4) is the most major factor for predict unfavorable outcome. Therefore, the next question in future research study may be what is the best effective way to rapidly clear diffuse subarachnoid blood from the basal cistern and ventricles to improve clinical outcome of patients. Although all variables in the equation are unchangeable factors, this may help the attending physicians to concern about their patients and doing the best way for them. This risk score model may be a reliable tool for identifying patients with a high probability of unfavorable outcome, that may assist in more efficient planning of intensive treatment in high-risk group of patients.

The strength of the present study is that cohort data were collected from computer database system at the two tertiary care centers, the data collection was completed. However, the limitation of the present study was a small sample size, and there was no sampling of the control group because the number of the favorable outcome (control) group was equal to that of the unfavorable outcome (case) group. Because the risk score model was developed from the two tertiary care centers, it may not be compatible with the other regions of the world. Therefore, further research studies are required.

Conclusion

High-grade Modified Fisher grading scale of grade 3 or 4, the best motor response of GCS being M4 or M5, and age of patients >60 years are associated with unfavorable outcome in patients with aneurysmal SAH after surgery. A risk score model was created by these three independent factors. Further studies are required to identify other preventable risk factors associated with poor outcome.

What is already known on this topic?

Aneurysmal SAH is a burden of neurovascular disease that produces an adverse neurological outcome. Recently, there are several grading systems used for predicting the surgical outcome, such as Hunt and Hess scale, WFNS scale, Fisher grading scale, Modified Fisher grading scale and age of patients.

What this study adds?

The present study shows that subarachnoid hemorrhage characteristic from a CT scan used the Modified Fisher grading scale, the Glasgow Coma Scale, and patient's age are factors used for predicting outcome. The authors developed a simple risk score model based on these three independent factors for predicting the unfavorable outcome.

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Potential conflicts of interest

None.

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โมเดลสำหรับทำนายผลการรักษาหลังการผ่าตัดหนีบหลอดเลือดสมองโป่งพองในผู้ป่วยที่มีเลือดออกใต้เยื่อหุ้มสมองชั้นอะแรคนอยด์ซึ่งมีสาเหตุจากหลอดเลือดสมองโป่งพองแตก

สุรเชษฐ์ ศรีแก้ว, อภินันท์ แก้วประดิษฐ์, กฤตพล คงเกษม, ดลฤดี สองทิศ

ภูมิหลัง: *ภาวะเลือดออกใต้เยื่อหุ้มสมองชั้นอะแรคนอยด์ที่มีสาเหตุจากหลอดเลือดสมองโป่งพองแตกเป็นโรคที่ร้ายแรงทางศัลยกรรมระบบประสาท ซึ่งยังมีการศึกษาเพียงเล็กน้อยในประเทศไทย*

วัตถุประสงค์: *เพื่อหาปัจจัยที่สัมพันธ์กับผลการรักษาโรคที่ไม่ดีในผู้ป่วยโรคหลอดเลือดโป่งพองในสมองแตก ที่ได้รับการรักษาด้วยการผ่าตัด Aneurysm clipping และสร้างสมการทางคณิตศาสตร์เพื่อทำนายโอกาสของผลการรักษาโรคที่ไม่ดี*

วัสดุและวิธีการ: *คณะผู้นิพนธ์ได้ทำการศึกษาแบบ nested case-control study จากข้อมูลผู้ป่วยที่มีการเก็บข้อมูลไปข้างหน้าระหว่างเดือนมกราคม พ.ศ. 2553 ถึงเดือนธันวาคม พ.ศ. 2559 พบผู้ป่วยโรคหลอดเลือดโป่งพองในสมองแตก 168 ราย ที่ได้รับการรักษาด้วยการผ่าตัด Aneurysm clipping ที่ศูนย์การแพทย์สมเด็จพระเทพรัตนราชสุดาฯ สยามบรมราชกุมารี และโรงพยาบาลสระบุรี ประเมินผลการรักษาด้วย Glasgow Outcome Scale (GOS) โดยผู้ป่วยที่มีผลการรักษาที่ไม่ดีจัดเป็นกลุ่มศึกษา ในขณะที่กลุ่มที่มีผลการรักษาที่ดีจัดเป็นกลุ่มควบคุม ด้วยอัตราส่วนหนึ่งต่อหนึ่ง วิเคราะห์ปัจจัยเสี่ยง แล้วนำปัจจัยดังกล่าวมาสร้างแบบจำลองเป็นสมการทางคณิตศาสตร์ เพื่อทำนายการเกิดผลการรักษาโรคที่ไม่ดี ด้วยวิธีการวิเคราะห์ backward stepwise binary logistic regression และตรวจสอบความสามารถในการทำนายของสมการโดยการใช้ Receiver Operating Characteristic (ROC) curve*

ผลการศึกษา: *ปัจจัยที่มีความสัมพันธ์กับผลการรักษาโรคที่ไม่ดีได้แก่ ลักษณะของเลือดที่ออกใต้เยื่อหุ้มสมองประเมินจากการตรวจ CT scan สมองโดยใช้ Modified Fisher grading scale ระดับ 3 หรือ 4 (OR 17.8; 95% CI 6.8 ถึง 46.7), คะแนนการสั่งการของ Glasgow Coma Scale (GCS) เท่ากับ M4 หรือ M5 (OR 8.1; 95% CI 3.2 ถึง 20.4) และอายุของผู้ป่วยที่มากกว่า 60 ปี (OR 3.2; 95% CI 1.2 ถึง 8.4) สมการในการทำนายโอกาสการเกิดผลการรักษาโรคที่ไม่ดีเท่ากับ 1 (อายุมากกว่า 60 ปี) +2.5 (GCS M4 หรือ M5) +5.5 (Modified Fisher grading scale 3 หรือ 4) ทำการทดสอบค่าความถูกต้องในการทำนายของสมการโดยใช้ ROC curve ได้พื้นที่ใต้ curve เท่ากับ 0.91; 95% CI 0.86 ถึง 0.95 (p-value <0.001)*

สรุป: *สมการทางคณิตศาสตร์ อย่างง่ายในการทำนายผลการรักษาโรคหลอดเลือดสมองโป่งพองแตกที่ได้รับการรักษา ด้วยการผ่าตัดถูกสร้างขึ้นโดยอาศัย 3 ปัจจัยที่สัมพันธ์กับผลการรักษาโรคที่ไม่ดี (Modified Fisher grading scale 3 หรือ 4, GCS M4 หรือ M5, และอายุมากกว่า 60 ปี) โดยแต่ละปัจจัยมีความเป็นอิสระต่อกัน*