Comparison between Modified Neuroendoscopy and Craniotomy Evacuation of Spontaneous Intra-Cerebral Hemorrhages: Study of Clinical Outcome and Glasgow Outcome Score

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Comparison between modified neuroendoscopy and craniotomy evacuation of spontaneous intra-cerebral hemorrhages: study of clinical outcome and glasgow outcome score

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ABSTRACT

Background: Stroke is still one of a leading health-care problem in industrial country and developing country. Spontaneous Intra-Cerebral Hemorrhage accounts for 30–60% of all stroke admissions and considered to be a poor prognostic factor. While the craniotomy procedure failed to show benefits over functional outcome, a less invasive and quicker surgical decompression might improve the outcome. Neuroendoscopy is one of promising optional on minimal invasive treatment for spontaneous intra-cerebral hemorrhage.

Material and Methods: Randomized control trial was conducted to evaluate Glasgow Outcome Score and clinical outcome of patients with Spontaneous Intra-Cerebral Hemorrhage who underwent modified neuroendoscopic surgery and craniotomy. The removal of intra-cerebral hemorrhage was done by a modified neuroendoscopic transparent sheath made of silastic material, derived from pieces of thoracic tube No. 21F as a conduit working channel.

Results: 43 patients were enrolled which 25 patients treated with neuroendoscopy surgery and 18 patients with craniotomy. The mortality rate was significantly higher, in craniotomy group n=12 (63.2%) compared with neuroendoscopy group, n=7 (36.8%) (p<.005). Patients with Glasgow Outcome Scale score 3–5 was higher in neuroendoscopy group, n=18 (75%) compared with craniotomy group n=6 (25%). The survival rate analyzed by Kaplan Meier methods, found that patients in the neuroendoscopy group were a significantly longer survival rate compare with the craniotomy group during 6 months post operative follow-up period.

Condusions: Treatment of spontaneous intra-cerebral hemorrhage with modified neuroendoscopy procedure was faster in action, safer and had significantly higher survival rate compared with conventional one.

Keywords: spontaneous intra-cerebral hemorrhage, modified endoscopic transparent sheath, 21 F thoracic tube.
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INTRODUCTION

Stroke is one of a leading health-care problem in industrial country and developing country, including Indonesia.[1,2,3] Stroke is the second most common cause of death after ischemic heart disease in the low to medium income countries.[3,4,5,6,7] The incidence of hemorrhagic stroke, also known as Spontaneous Intra-cerebral Hemorrhage (ICH), is 10-60 cases per 100,000 populations and 15% - 22% mortality of all patients with stroke caused by Spontaneous ICH.[8,9]

In addition, almost half of the patients had a permanent disability.[10,11,12] In Indonesia, Riset Kesehatan Dasar (National Basic Health Research) 2013 provided by Indonesian Ministry of Health reported that the prevalence of spontaneous ICH patients in Indonesia is 7/1000 population.[13] The incidence of Spontaneous ICH in Indonesia is considerably high compared with other ASEAN countries which is 39% compared to 17.2% in Malaysia.[14,15]

The trigger of Spontaneous ICH is a rupture of intra-parenchymal small capillaries which usually caused by chronic hypertension[16,17] and found in 60% of cases of Spontaneous ICH.[18] Other 10% cause of Spontaneous ICH are cerebral amyloid.[18] The resulting hematoma will cause an inflammatory process, ischemia and edema surrounding the lesion, penumbra area. Furthermore, there will be an increase in intra-cranial pressure, which would release of free radicals and damage surrounding neurons and neuroglia.[19] Shortly, irreversible tissue injury follows in surrounding tissue follow by progressive cascade of increased local pressure, edema and excito-toxicity caused by an additional secondary lesion surrounding brain parenchym.

Secondary injury is associated with the mass effect of new bleeding, also the toxicity related with hematoma decomposition and release of pro-inflammatory mediators and free radicals.[20,21,22] Initial treatments to

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reduce high intra-cranial pressure is to evacuate the hematoma which usually lead to clinical improvement in 6 months.[23,24] Surgery with neuroendoscopy was performed if hematoma reside in deeper location. In addition, quick and precise cauterization can be used to stop bleeding process as well as prevent additional hematoma formation.[25,26,27,28,29] The purpose of this study to determine the clinical outcome evaluated by the Glasgow Outcome Scale at 6-month follow-up period.

MATERIAL AND METHODS

Study Design

We conducted a prospective study using a randomized controlled clinical trial with reference of CONSORT 2010.[30] The study was approved by the Ethical Committees of the Abdul Wahab Syahranie Hospital - Samarinda; East Kalimantan. The study was performed according to the Good Clinical Practice standards and written informed consent was obtained from the patient's main family or healthy relatives.

To be eligible for the study, patients with spontaneous ICH need to meet the following inclusion criteria: 1) Aged 30-70 years; 2) CT-confirmed intra-cerebral sub-cortical, supra tentorial hemorrhage; 3) Hematoma volume ≥30ml; 4) Surgery to be instituted within 72 hours of the onset of clinical symptoms. Cases of deep coma with Glasgow Coma Scale (GCS) score of 3 and 4 were excluded. We also excluded patients with post-traumatic intra-cerebral hematomas, tumor bleeding, aneurysma or arteriovenous hemorrhage, and bleeding tendencies caused by uremia, liver cirrhosis, or anti-coagulation therapy.

Patients

Forty-three spontaneous ICH patients admitted to our Department of Neurosurgery AW Syahranie Teaching Hospital, Samarinda, East Kalimantan between March 2012 to July 2014 were eligible. Forty-three patients were included and randomly divided by block randomization into two groups using the random number generator in Microsoft Excel®. Twenty-five patients were done with Neuroendoscopy (58.1%) and 18 patients was done with craniotomy (41.9%). All patients underwent head CT scan before surgery and 4th day post-operative. Hemorrhage volume was calculated by the software program volumetric CT scanning (CT scan - Hitachi W 450 Single Slices, third generation).

Surgical Procedures

The surgical procedure was performed under general anesthesia with supine position for all patients. A 4-cm coronal linear skin incision was made 2 cm lateral to the mid-line over the frontal area ipsilateral to the hematoma for putaminal hemorrhage (frontal approach) or ipsilateral approach to the hematoma for all subcortical hemorrhage patients. The hematoma evacuation rate (%) was defined as (preoperative volume - postoperative volume)/ (preoperative volume) × 100 (%). Prognosis was assessed by the Glasgow Outcome Score (GOS) at 6 months follow up period.

In craniotomy group, we made a burr hole with a diameter of 3 cm as an access for evacuation of hematoma. Hematoma was evacuated with vacuum (suction) equipment, the source of bleeding was stopped by the bipolar cautery tool. Required two small pieces spatula to clarify the operation field.[27]

In neuroendoscopy group, the surgery was performed by making a burr hole, closest to the vertical trajectory from the cranium; 3 cm in diameter. A 2.7-mm, 0-degree rod-lens endoscope (Karl Storz GmbH & Co, KG, Tuttlingen, Germany) was inserted into the tube for visualization and magnification. A 2.5-mm rigid straight suction tube was also inserted and manipulated through the remaining space within the tube a 7 mm modified transparent working channel sheath (red arrow). Suction tip was 2.5 mm outer diameter (OD) and 2.1 mm inner diameter (ID) can also function as a mono-polar cautery, which can simultaneously inserted by lenscope. This transparent sheath made by researcher with modification which is made by cutting a sterile thoracic tube 21 F, 12 cm in length and 7 mm in outer diameter (OD), made of *silastic*, a mixture of silicone (polydimethylsiloxane) and inert plastic[27] (Fig 1) (Table 1). Hematoma evacuation was performed through a transparent sheath as described previously.[25,26,27,28,29] The price of silastic material is much cheaper than ceramic or steel[27] (Table 1). Direct hemostasis with a rigid suction canal was performed as a combination irrigation-coagulation method. When an intraoperative hemorrhage occurred, the surgical field

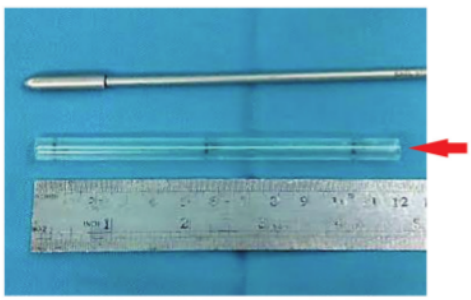

Figure 1 Modified transparent sheath cannula

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was kept clear with balanced normal saline irrigation and suction simultaneously. The surgeon performed endoscopic surgery free-handed and could saw clearly the operating field by LCD monitor (Storz).

RESULTS

Laboratory and basic characteristic of from March 2012 to July 2014, 43 patients were enrolled and met the inclusion criteria. Baseline characteristics are summarized in Table 2.

All patients had altered level of consciousness with or without focal neurological deficit. More than half of the group was male and the mean patient age was 56.5 years in the endoscopic group and 51.4 years in the craniotomy group. The median hematoma volume before surgery was 56.8 ml in the endoscopy group and 64.83 ml in the craniotomy group. The between-group difference in hematoma volume and age were statistically significant ($P<0.05$). The median evacuation rate in the endoscopy group was 79.7%%, while the median evacuation rate of the craniotomy group was 68.2%. The evacuation rate was statistically significant in the endoscopy group compared with craniotomy group (p = 0.014). Surgical time was significantly shorter in modified neuroendoscopic procedure compared with craniotomy (89.3 minute: 161.1 minute/p< 0.01).

Surgery was done in patients with spontaneous ICH, 25 treated by neuroendoscopy (58.1%) and 18 patients treated by craniotomy (41.9%). There were 19 cases of death among the 43 patients. Seven patients in the endoscopy group and 8 patients from craniotomy group died from respiratory failure due to pneumonia. Three deaths were due to primary hemorrhagic damage and 1 death caused by re-bleeding. We observed that mortality rates were 36,8% for the endoscopy group and 63,2% for the craniotomy group which was statistically significant (p<0.05) (Table 3).

We assess hemiplegic and hemiparesis state as clinical outcome in both procedures. We obtained statistically significant differences in clinical outcome between endoscopic and craniotomy group (p = 0.022). Risk assessment was also resulted in statistically significant OR and HR (OR: 4.333 (1.197-15.693); HR: 3.018 (1.185- 7.686))

Survival analysis indicated that endoscopy group survives 2 times longer than craniotomy group. The Kaplan-Meier analysis on 6 months follow up period is described in Table 5 and Figure 2.

Table 1 Specification of working channel sheath

	Specification	Ibrahim 2007 (Fig 1)	Nishihara, 2000	Cho, 2006
1	Material	*Silastic*	*acrylic resin*	*stainless steel*
2	Flexibility	Flexible	Rigid	Rigid
3	Price (USD)	±5	±45	±12
4	Transparency	Yes	Yes	No
5	Inert	Yes	Yes	Yes
6	Diameter (OD)	7 mm	8 mm	8 mm
7	Length	12 cm	12 cm	15 cm
8	Usage	Disposable	Recycle	Recycle

Table 2 Patients Baseline Characteristics

Variable	Endoscopic	Craniotomy	p
Number of patient	25	18	
Male/Female (n)	15/10	8/10	
Mean ages (range)	51.4	56.5	0.195
Mean GCS pre-op (range)	8.28	7.17	0.092
Median hematom (vol cc)	56.8	64.83	0.231
Median operative time (minute)	89.38	161.17	<0.01
Median hematoma evacuation rate (%)	79.07	68.02	0.014
Hematoma site (n)			
Ganglia Basal	3	6	
Putamen	1	4	
Parietal lobes	13	11	
Thalamus	1	4	
GOS			
Dead	7	12	
Severe Disability - Good Recovery	18	6	<0.01

DISCUSSION

Surgical evacuation of intra-cerebral hematoma is still a controversial issue in spontaneous ICH therapy. There is growing evidence that secondary injury of the surrounding brain tissue is not only by a simple

Table 3 Glasgow Outcome Score between the 2 groups at 6 months' post-operative

GOS	Endoscopic	Craniotomy	p
Good recovery	7	1	
Moderate Disability	10	4	
Severe Disability	1	1	
Vegetative state	0	0	
Dead*	7 (36,8%)	12 (63,2%)	0.012

* OR (95% CI): 5,14 (1,384-19,107)

Table 4 Clinical outcome between the 2 groups at 6 months' post-operative

Outcome*	Endoscopic	Craniotomy	p
Hemiplegic	(12) 57,1%	(9) 42,9%	0.022
Hemiparetic	(13) 59,1%	(9) 40,9%	

*OR=4.333 (1.197-15.693), HR = 3.018(1.185 - 7.686)

Table 5 Survival Time method (day)

	Mean (CI 95%)	Median (CI 95%)
Endoscopy	131,60 (101,23 -162,04)	-
Craniotomy	65,77 (28,42 - 103,12)	10.00 (3,76- 16,23)

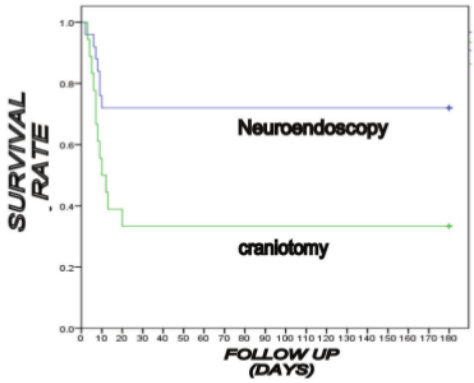

Figure 2 Survival time Kaplan Meier (6 months)

mass effect. In penumbra area, cytotoxic edema may develop as secondary effect from ischemia, which has been proposed to result from compression of microcirculation or vasoconstriction due to blood degradation products.[20,21,22,24] If surgery successfully evacuates most of the hematoma with minimal additional brain tissue damage, secondary injury due to mass effect and edema can be reduced.[23,24] Our study result showed statistically significant differences of the median evacuation rate in the endoscopy group was 79.7%%, while the median evacuation rate of the craniotomy group was 68.2%% (p= 0.014).

Spontaneous ICH in Indonesia

Currently, there were no comprehensive statistics about the incidence of spontaneous ICH in Indonesia. Based on *Riskesdas* (Basic Health Research) of the Indonesia Ministry of Health in 2013, the prevalence of spontaneous ICH patients in Indonesia is approximately 7 of 1000 population.[13] Spontaneous ICH in the capital city of East Java – Surabaya, Indonesia was 39% and if compared with Malaysia ranged from 17.2%.[14,15]

It should be noted that today's Indonesia facing an aging decade. The number of high-risk people older than 50 years will gradually increase and the annual spontaneous ICH incidence is predicted to rise in the upcoming decades.[13, 14, 27]

Surgical Treatment of ICH

The role of surgery in treating ICH is not fully established. Results from the STICH trial have greatly influenced the clinical management of ICH.[24] Surgical evacuation of the intra-cerebral hematoma is based on the concept of reducing mass effect due to hematoma. The procedure decreases ICP, improving regional blood flow and restricting release of toxic breakdown blood component products.[31] Traditional craniotomy arises the operative side effect because of its long operation time, large wound and more postoperative complications.[26] Possible negative side effects include the additional trauma caused by the procedure itself, possibly an increased risk of re-bleeding due to removal of the tampon effect provided by the hematoma.[1] Our study showed that mortality rates were 36,8% for the endoscopy group and 63,2% for the craniotomy group. Meanwhile, mortality rates between both groups show a statistically significant differences (p<0.05) (Table 3).

Neuroendoscopic Surgery

Evacuation of ICH by the endoscope was first reported by Auer in 1985.[25] It is arguable that early and complete removal of ICH by an endoscopy can reduce the secondary injury associated with ICH.[23,24,26] The last decade has brought significant advances in endoscopic surgical instruments and techniques that have improved patient outcomes.[25, 26,27,28,29] Recent reports on the rate of hematoma evacuation through endoscopic surgery have reached evacuation rates of 83,4% to 99% and no re-bleeding cases.[26,28,29] Our study showed that the rate of hematoma evacuation through endoscopic surgery have reached 79.7% and no re-bleeding as well. The results obtained was statistically significant (p=0.022). We found also found that mortality tendency of hemiplegic patients was greater than hemiparesis patients which clearly described in Kaplan-Meier survival curve. We believe that as long as the positioning is accurate, keyhole endoscopic surgery can accomplish the effect of large craniotomy surgery.

RESEARCH LIMITATION

The number of subjects in this research is considerably small. This was due to the limited number of hemorrhagic stroke patients who met the criteria, family rejection even though informed consent form had already signed. However, the sampling procedure was conducted randomly by block randomization and we controlled the confounding both statistically as well as by design.

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CONCLUSION

From this study, we conclude that the modified neuro-endoscopy technique is a safe, have faster in operating time and more practical technique for treatment of spontaneous ICH, especially in country hospitals or lower to middle-class hospitals in Indonesia. It can improve the independent survival of patients with spontaneous intra cerebral hemorrhage after triage of ICH patients according to strict criteria.

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