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H. Manabe, T. Kato, K. Haraguchi, T. Ito

TREATMENT CHOICE FOR UNRUPTURED CEREBRAL ANEURYSMS

Hakodate Shintoshi Hospital (Japan)

Key words: choice of treatment method, cerebral aneurysm, hospital stay, complication.

The incidence and mortality of aneurysmal subarachnoid haemorrhage is both well documented and well known. Among 100 thousand population per year, 20–28 patients have been reported to suffer from aneurysmal subarachnoid haemorrhage and about half of them died. Among a population older than 40 year, according to a study by Kiyohara et al., the ratio of SAH patients / 100 thousand population was 96.1, and 35% of the patients died within 8 hours after the onset [8]. Because of this devastating outcome, many neurosurgeons have recommended the treatment of unruptured aneurysm (UrAn).

Although surgical clipping has been established as the standard treatment of cerebral aneurysms, coil embolization has become an alternative treatment since the clinical introduction of Guglielmi's detachable coil (GDC). The great merit of GDC embolization is its non-invasive characteristic, so that it has become the first choice of treatment for ruptured aneurysms having difficulty in surgical access such as aneurysms on posterior circulation or on paraclinoid portion of internal carotid artery. Moreover, a recent randomized control study on ruptured aneurysms, which were thought to be geometrically or anatomically suitable for both methods, revealed a better outcome one year after treatment in patients treated by GDC embolization than by direct surgery [5]. However, the role of GDC embolization for the treatment of UrAn is still being investigated.

Recent systemic review revealed that the treatment-related permanent complication rate in GDC embolization for cerebral aneurysm was calculated as 3.7% (95% CI 2.7–4.9%) [5], which seems much better than the mortality and morbidity of surgical treatment for unruptured aneurysms by meta-analysis as 2.6% mortality (95% CI 2.0–3.3%) and 10.9% morbidity (95% CI 9.6–12.2%) [12]. In the systemic review, permanent occlusion with GDC was reported in only 54% of the cases [3]. Other studies suggested that GDC embolization for UrAns would cost significantly less than surgical treatment for UrAns, but in these reports, the occurrence of adverse outcome of surgical treatment (18.5–25%) was much higher than those of the above mentioned meta-analysis [12]. Therefore, further comparison of the two treatment methods for UrAn from both clinical and economical point of view is needed, especially by analyzing data from Japanese institute, in order to provide useful information for management of Japanese hospital.

On March 1997, the clinical use of GDC started in Japan. After having clinical experience of GDC use in several cases, we designed a protocol for treatment of unruptured cerebral aneurysms. In this paper, the preliminary results with use of the protocol are analyzed, and a choice of treatment methods for UrAns from clinical and economical point of view in current Japanese situation is investigated (table).

Protocol for treatment. On September 1997, we designed a protocol for treatment of UrAn. The basic conception of this protocol was followings; 1) Non-giant saccular aneurysms were included into this protocol. Giant aneurysm and dissecting aneurysm were excluded because proximal occlusion or trapping plays an important role in treatment for such type of aneurysms. 2) The first choice of treatment was direct surgery. The "direct surgery" includes aneurysm neck clipping and aneurysm wrapping. Of course, the first choice of the surgical treatment was clipping, but wrapping was performed when an aneurysm was thought to be unclippable due to atherosclerotic change around aneurysm neck. 3) GDC embolization was performed for aneurysms which were difficult to access surgically, but seemed to be a good candidate for GDC intra-aneurysm packing judging from angiograms of at least four different projections. If the embolization failed, no other surgical treatment was done. 4) If the aneurysm was thought to be too difficult for either treatments due to geometrical or anatomical reasons, or if the patient refused any surgical or endovascular intervention, the aneurysms received no treatment.

The judgments about whether the shape of an aneurysm was suitable for GDC packing and whether an aneurysm was a good candidate for direct surgery were made after discussion among 2 neurosurgeons and one interventional neuroradiologist.

Patient population. From September 1997 to December 2007, one hundred-fifty-four consecutive patients were diagnosed as having unruptured cerebral aneurysms (total 185 aneurysms) by cerebral angiography. Of them, 51 patients were male. Age distribution ranged from 30 to 80 years (mean 60.9). Aneurysms were found by the following reasons: concomitant intracranial disease, 90 aneurysms; incidental, 90 aneurysms; and symptomatic, 5 aneurysms. Seventy-two aneurysms were located on the middle cerebral artery (MCA), 10 were on the anterior cerebral artery (ACA), 27 were on the anterior communicating artery (AcoA), 62 were on the internal carotid artery (ICA), and 14 were in posterior circulation. One-hundred sixty one aneurysms were small (<10mm), 21 were large.

Technical procedure. The coil embolization was usually performed under local anesthesia. However, general anesthesia was also performed according to the patient's request. After bolus injection of 5000 IU heparin, the guiding catheter was inserted into the carotid or vertebral artery. During the procedure, the ACT was kept at twice the baseline value by additional bolus injection of heparin. The post-embolization systemic heparinization was maintained for 24 hours and then discontinued without intravenous administration of protamin sulfate. The two-dimensional or three-dimensional GDC was used as first coil. In addition to the usual microcatheter technique, a double catheter technique was used for irregular shaped or wide-necked aneurysms [4]. Neither balloon remodeling technique nor stent-assist technique was used in this series. The direct surgery was performed using standard microsurgical technique. The following two points were kept in mind for microsurgery: limited use of brain retractor and careful preservation of the veins. After clipping, good flow within the parent artery and its branches was confirmed by the intraoperative Doppler sonography. As for the anterior cerebral artery aneurysms and anterior communicating artery aneurysms of high location, the inter-hemispheric approach was chosen. The other aneurysms in the anterior circulation and basilar tip aneurysm were approached by pterional route, and aneurysms in the vertebral artery and its branch aneurysm were approached by retromastoid or suboccipital route.

Complications and angiographical results. Complications were defined as temporary when the deficit resolved within one month and returned to the baseline condition, and as permanent when present even after one month. Obliteration of the aneurysm was assessed by angiograms of different four projections or three-dimensional CT angiography. The postoperative clinical and the postoperative angiographical assessments were made by 2 neurosurgeons and one interventional neuroradiologist.

Cost of treatment and postoperative hospital stay. The cost of treatment was defined as the sum of charges of hospitalization from the day of operation or embolization to the day of discharge, and was calculated from the bill for health insurance. This included the cost of operation or embolization, material for operation or embolization, imaging, ward and ICU bed, hospital meal, drugs, laboratory or radiological examination, and rehabilitation. Postoperative hospital stay was defined as duration from the day of operation or embolization to the day of discharge, including stay for the rehabilitation if patient has a postoperative deficit. For precise comparisons, cost of treatment and postoperative or post-embolization hospital stay were investigated on 82 surgical or endovascular procedures in 79 patients whose aim of hospitalization was only treatment for their UrAns.

Statistical analysis. Statistical analysis was performed using commercially available statistical software (Microsoft Exel 98). Unpaired t-test, Chi square test, Fisher's exact test, Mann-Whitney U test were used when appropriate. Statistical significant was set at a probability value less than 0.05.

Result. Direct surgery was performed for 120 aneurysms in 99 patients with 103 procedures (Surgical group). Of them, 116 aneurysms were treated by neck clipping, 4 by wrapping. Endovascular treatment using GDC was performed for 26 aneurysms in 25 patients with 25 procedures (Endovascular group), in which the embolization failed in two IC paraclinoid aneurysms. Of them, in one IC paraclinoid aneurysm, attempted embolization was followed by emergent aneurysm neck clipping because of intra-procedure rupture. In the other, attempted embolization of the small IC paraclinoid aneurysm (diameter < 3mm) was not followed by any surgical or endovascular treatment because of difficulty in both catheter insertion and surgical approach. Thirty-nine aneurysms in 30 patients were not treated at all, and their course was followed by observation (Non-treatment group). The age distribution and male/female ratio were 30-78 years (mean 59.2) and 34/65 in Surgical group, 44-78 years (mean 59.3) and 8/17 in Endovascular group, and 53–80 years (mean 68.2) and 8/22 in Non-treatment group, respectively (table).

Clinical outcome and postoperative complications. In Surgical group, temporary deficits were seen after nine operations (8.8%); one nasoliquarrhea after craniotomy with drilling of anterior clinoid process for clipping of ICA aneurysm, eventually treated by direct repair, 2 transient mild aphasia after MCA aneurysm clipping, one transient quadrantoanopsia after clipping of basilar tip aneurysm, one transient memory disturbance after AcoA aneurysm clipping, one consciousness disturbance in 78 year-old woman after bilateral craniotomy for clipping of 6 aneurysms in one procedure, one epilepsy occurring 6 days after clipping of MCA aneurysm, and two transient oculomotor palsy after clipping for ICA aneurysm. Of them, fresh small low density area on CT scan was recognized in 2 cases. These symptoms fully recovered and these patients retured to their baseline neurological condition within one month after their operation. The permanent deficits were seen after 2 operations (1.9%): a hemiparesis due to temporary occlusion of patrent artery during intraoperative rupture of MCA aneurysm, and a unilateral blindness after clipping of aneurysm on paraclinoid portion of ICA. No death was occurred in the surgery group. The other 87 patients fully recovered to their baseline neurological condition within 24 hours after their operations. In the endovascular group, one patient developed a temporary deficit (4.0%), after intraoperative rupture of aneurysm on paraclinoid portion of ICA followed by emergency aneurysm neck clipping. This patient recovered fully and eventually returned home without any neurological deficit 32 days after the clipping. No permanent deficit and no death were seen in the endovascular group. Therefore, although the temporary/permanent morbidity and mortality rate in the surgery group was higher (10.8%) than that in the endovascular group (4.0%), the difference was not statistical significant (Fisher's exact test).

Aneurysm size and angiographical results. The mean size of the aneurysms was rather larger in the endovascular group (mean±S.D.: surgical group 6.6±2.7 mm; endovascular group 6.9±3.4 mm), but there was no statistical significant between them (unpaired-t test). As for the dome-neck ratio and neck size of aneurysms treated by GDC embolization, fourteen aneurysms showed more than 2 dome-neck ratio, ten aneurysms showed 1.5–2.0, and two aneurysms had neck size of more than 5 mm and twenty-two aneurysms had less than 5 mm, respectively. Postoperative angiography or three-dimensional CT angiography was performed for all aneurysms. In surgical group, complete obliteration

Table

Comparison between direct surgery and GDC embolization

Index	Direct surgery	GDC embolization	Probability value
Patients	99	25	–
age	59.2 (30–78)	59.3 (44–78)	N.S.***
sex (F : M)	65 : 34	17:8	N.S.**
Aneurysms	120	26	–
cavernous ICA	0	1	–
IC ophthalmic	0	12	–
supraclinoid IC	34	3	–
AcoA, ACA	23	3	–
MCA	60	0	–
vertebrobasilar	3	7	–
size (mean±SD)	6.6±2.7	6.9±3.7	N.S.*
Treatment	120 Ans / 103 procedures	26 Ans / 25procedures	–
	Clipping: 116	Intra-aneurysm occlusion: 26	–
	Wrapping: 4		–
Operative complication	after 103 procedures	after 25 procedures	N.S.****
temporary deficit	9 (8.8%)	1 (4.0%)	–
permanent deficit	2 (1.9%)	0 (0.0%)	–
death	0 (0.0%)	0 (0.0%)	–
Angiographical result	120 Ans	26Ans	0.00012**
complete occlusion	105 (88%)	14 (54%)	–
incomplete occlusion	15 (12%)	12 (46%)	
Postoperative hospital stay	67 pt	18 pt	0.000003***
(days)	16.2 (9–80)	6.2 (3–32)	
Cost for treatment (yen)	67 pt	18 pt	N.S.***
	1 680 142	2 224 524	–
	(1 006 040–4 731 780)	(1 487 700–4 040 590)	–

Abbreviations: F, female; M, male; ICA, internal carotid artery; IC, internal carotid; AcoA, anterior communicating artery; ACA, anterior cerebral artery; MCA, middle cerebral artery; pt, patients; * unpaired t-test, ** Chi square test, *** Mann-Whitney U test, **** Fisher's exact test, P: p value, N.S.: not significant.

was seen in 104 aneurysms (88%). In endovascular group, 14 aneurysms (54%) were judged as complete occlusion (more than 95% occlusion), and the other 12 aneurysms as incomplete occlusion (90-95% occlusion in 9, less than 90% in 1, and two failure). The rate of obliteration of the aneurysm after the treatment was significantly higher in the surgery group (Chi square test; P=0.00012). No aneurysm rupture was seen during postoperative period of 6–88 (mean 33.8) months in surgical treated 120 aneurysms, during 5–79 (mean 41.2) months in 24 embolized aneurysms, and during 9–81 months (mean 40.8) in 39 non-treated aneurysms.

Cost for treatment and postoperative hospital stay. The postoperative hospital stay was significantly longer (Mann-Whitney U test; P=0.000003) in surgical treatment (67 procedures in 64 patients. 9–80 days, mean 16.2) than in GDC embolization (18 procedures in 18 patients. 3–32 days, mean 6.2). The cost for treatment was rather higher in GDC treatment (18 procedures, 1 487 700–4 040 590 yen, mean 2 224 524 yen) than in surgical treatment (67 procedures, 1 006 040–4 731 780 yen, mean 1680142 yen), but the difference was not statistically significant (Mann-Whitney U test).

Discussion

The characteristics of the aneurysms in this study. The selection of the treatment method for each UrAn in this series was based on the following policy: 1) the surgical clipping is the first choice of treatment for the aneurysms. 2) Embolization is performed for aneurysms which are thought to be hardly accessible by direct surgery but have good shape and good access route for GDC treatment. 3) The additional techniques in GDC packing other than double catheter technique are not used.

The reason why we took direct surgery as first choice of treatment was the difficulty in coil embolization for wide-necked aneurysms. On September 1997, when this protocol was designed, the following specific techniques or device in GDC embolization had not been widely accepted in Japan: balloon remodeling techniques [14], double catheters technique [2, 14], stent-assisted embolization [5, 14], and three-dimensional GDC [14]. Moreover, we could not judge by conventional DSA image if we could get satisfactory embolization in "rather" wide-necked aneurysms. Therefore, at that time, a wide-necked aneurysm was thought to be too difficult to treat by GDC embolization. During the following 7 years, above mentioned endovasucular technique, device and three-dimensional DSA have been developed. Indeed, such technique and the three-dimensional DAS image are effective for embolization in wide-necked aneurysms [2, 5, 14]. But some of these techniques have drawbacks. Balloon remodeling technique includes the higher risk of embolic complication than usual GDC embolization [9], and the navigation of balloon-expandable coronary stent into intracranial artery could be achieved in only selected cases due to its stiffness [5]. Innovation in neuro-endovascular treatment has not reached in Japanese market. The Japanese government has not permitted to use self-expandable intracranial stent and bioactive coils. Therefore, we useed the double catheter technique as an additional technique and three-dimensional GDC as a new device in several cases, because low procedure-related complication rate would be expected. In this situation, it was difficult to design the randomized controlled trial (RCT) in selection of the treatment method for UrAn. If we designed the RCT, we would have a significant number of aneurysms which were eventually treated by direct surgery after failure of embolization.

The aneurysms treated by direct surgery in this study were mainly located on the anterior circulation, and most of them were small-sized aneurysm (less than 10 mm). Aneurysms located on the posterior circulation and on paraclinoid portion of ICA would be more difficult to treat by direct surgery than by endovascular treatment [13]. The aneurysms of either dome/neck ratio of more than 2 or neck size of less than 5 mm are believed to be good candidates for GDC intra-aneurysmal embolization.

Therefore, although the selection was not based on randomized way, we recognize that the comparison in this study was made between aneurysms suitable for and treated by direct surgery and those suitable for and treated by GDC embolization.

Clinical outcome of direct surgery and endovascular treatment for unruptured cerebral aneurysms. Although many studies have reported mortality and morbidity associated with direct surgery for UrAns, the range of the mortality and morbidity rate is wide (0.0 to 16.7% for morbidity and 0.0 to 7.7% for mortality) [7]. This may depend on the proportion of posterior circulation aneurysms or the proportion of large- and giant-sized aneurysms included in each study. Clinical outcome of direct surgery in this study should be compared to other studies which had similar characteristics to our own, such as majority of the aneurysms that were located on anterior circulation and small-sized. In the meta-analysis by King et al. containing 733 asymptomatic aneurysms from 28 studies published from 1966 to 1992, the majority of the aneurysms were small-sized and located on the anterior circulation; 94% were on the anterior circulation and 72% were small (less than 10 mm) [7]. According to this analysis, the surgical treatment of asymptomatic cerebral aneurysms would be associated with a mortality rate of 1.0% (95%CI, 0.4 to 2.0%) and morbidity rate of 4.1% (95%CI, 2.8 to 5.8%). This value is compatible with our surgical results (0% mortality, 2.0% morbidity).

Endovascular occlusion with GDC for UrAn has been reported as relative safe treatment. Murayama et al reported a morbidity rate of 4.3% and no procedure-related mortality in treatment of 109 aneurysms [11]. Other studies also estimated a morbidity and mortality rate as similar value to Murayama's study; 4.8–5.2% as morbidity and no mortality in treatment of 39–116 aneurysms. Although a number of GDC-treated aneurysms in our study were small, the mortality/morbidity rate after GDC treatment in this study was close to the results in these other studies.

Angiographical results after direct surgery and endovascular treatment. Although complete occlusion of the aneurysm is ideal result after treatment, all aneurysms could not be occluded completely by either GDC embolization or neck clipping. Mizoi et al reported the operative outcome of elective surgical treatment for 119 incidental aneurysms, 92% of which were treated by neck clipping and the rest were by wrapping [10]. In other study by David et al, 160 aneurysms were surgically treated, 147 (91.8%) of which were treated by clipping and 8 (5%) by wrapping and 12 (8.2%) of 147 clipped aneurysms showed residual neck on postoperative angiography [4]. The incidence of residual neck after neck clipping was estimated as 4–18% [8]. In our study, 3.4% of surgically treated aneurysms were wrapped, and 9.6% of clipped aneurysms showed residual neck on postoperative DSA or CT angiography. As for GDC embolization, several studies reported that 5-9% of aneurysms could not be embolized because of their geometrical shape or difficulty of catheter insertion, and complete occlusion was seen in only 46-63.3% of GDC embolized aneurysms [11]. Brilstra et al performed a review of 25 studies on embolization with retrievable detachable coils, and found that only 400 of 744 embolized aneurysms showed complete occlusion [3]. Therefore, these studies suggested that the incidence of incomplete occlusion after usual GDC embolization would be higher than after direct surgery.

A higher occlusion rate after GDC embolization would have been gained if several cases in these studies had been treated with balloon-assisted technique [9]. But this technique has a risk of transient ischemic complication, varying between 8.9% to 13.6%, and the permanent morbidity rate due to ischemic event was up to 3.3% [9, 13]. In addition to the ischemic complications, other complications such as aneurysm perforation and delayed coil migration into the parent artery were reported [9]. The procedure-related morbidity and mortality rate was reported as 1-5.1% and 0-3.8%, respectively. Considering the mortality/morbidity rate from meta-analysis on surgical treatment of UrAn, with the mortality rate as 1.0% (95%CI, 0.4 to 2.0%) and morbidity rate as 4.1% (95%CI, 2.8 to 5.8%) [7], balloon-assisted GDC embolization is thought to be risky treatment for UrAns. The stent-assisted embolization would also increase the occlusion rate; however, we are sure that this technique can be used only in selected patients because of a difficulty of intracranial navigation of balloon-expandable coronary stent [15], which is only the system we can use for intracranial lesion. I believe that such techniques have not reached a sufficiently safe level to be used in embolization for UrAns. This was the reason why we did not use these remodeling techniques in conjunction with GDC packing in this study.

Postoperative hospital stay and cost for treatment. Jonston et al reported that the hospital stay after GDC treatment is significantly shorter than that after direct surgery. The result in our study is similar to these studies. The noninvasive characteristic of GDC treatment makes the duration of postoperative hospital stay dramatically short. The duration of hospital stay seems to be longer in Japan than in United states. It may be due to that, in Japan, the patients who receive direct surgery usually return home after healing of the scalp incision, and even after the healing, many patients want to return home on superstitious good day, “Taian”, as good luck.

We also compared the cost of treatment between direct surgery and GDC treatment, and concluded that the GDC treatment would be performed with significantly less expense than direct surgery. Another study from United States showed similar results [28]. This is contrary to our results, which showed that the cost was rather higher for GDC treatment than for surgical treatment. The cost for treatment would be higher of course in cases with postoperative complications than with no complications. The adverse outcome in Jonston’s study was defined as a change in Rankin scale of 2 or more, and occurred in 25% of surgical treated patients and in 8% of GDC treated patients [2]. In Barker’s study, when discharge to short-term rehabilitation was counted as an adverse event, patients treated by GDC had significantly better outcome than those treated by clipping at the time of hospital discharge [1]. Our study revealed a similar tendency that postoperative complication occurred more commonly in surgical treatment than in endovascular treatment; however, the cost paid for surgical treatment was lower than that paid for GDC embolization in our study. This suggested that the discrepancy may be due to the difference of cost system between United States and Japan.

The choice of treatment method for unruptured cerebral aneurysms in current Japanese situation. The results of this study led to the following conclusions: 1) Although the selection of the treatment method was not based on the randomized way, each aneurysm in this study seemed to be treated by suitable method in terms of aneurysm shape or location. 2) The temporary and permanent morbidity and mortality rate in the surgery group was higher than that in the GDC group, but the difference was not statistical significant. 3) Significantly higher incidence of complete aneurysm occlusion occurred after treatment by direct surgery than by GDC embolization. 4) Mortality/morbidity rates and angiographical obliteration rate after both direct surgery and GDC treatment in our study were acceptable in comparison with those reported in other studies. 5) Significantly longer postoperative hospital stay was needed after direct surgery than after GDC embolization. 6) Less expensive cost was paid for direct surgery than for GDC embolization, but the difference was not significant.

Considering these results, in current Japan, recommendation for choice of treatment method for UrAn could not be gained. However, as device and technique in neuro-endovascular treatement are rapidly developing, so this conclusion will change in near future

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АНАЛИЗ ЭФФЕКТИВНОСТИ МЕТОДОВ ЛЕЧЕНИЯ МОЗГОВЫХ АНЕВРИЗМ

Х. Манабэ, Т. Като, К. Харагучи, Т. Ито
Больница Shintoshi г. Хакодате (Япония)

Представлены результаты оперативного лечения неосложненных аневризм сосудов головного мозга у 124 пациентов нейрохирургического отделения. В 99 случаях (120 аневризм) проведена открытая операция, в 25 случаях (26 аневризм) – эндоваскулярная эмболизация нитью Guglielmi. После открытого вмешательства преходящие нарушения мозговой гемодинамики наблюдали у 9 (8,8%) и стойкие – у 2 (1,9%) человек. После эндоваскулярной окклюзии в 1 наблюдении зарегистрированы только преходящие нарушения мозгового кровообращения (4%). В первой группе была достигнута полная окклюзия 88% аневризм, во второй – в 54%. Средняя длительность пребывания в стационаре после открытых вмешательств составила 16,2 дня, после эндоваскулярных окклюзий – 6,2 дня. Разница в стоимости лечения была статистически несущественна. Делается вывод, что эндоваскулярная окклюзия аневризм сосудов головного мозга не имеет значительных преимуществ перед открытым вмешательством.

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