



# Detailed Investigation of the Court Decisions against Neuroendovascular Therapy from the Disclosed Database by Courts in Japan

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**Objective:** Neurosurgeons are known as a high-risk group for malpractice litigation in western countries. Besides, based on our previously reported study, neurosurgeons are also in a high-risk group in Japan. Increasing risk of malpractice litigation is a big problem in Japanese healthcare system and several court decisions related to the neuroendovascular procedures are known. Herein, we reviewed the past court decisions regarding the neuroendovascular procedures and investigated the factors affected to the court decisions focusing on the prevention of allegations.

**Methods:** Court decisions related to neuroendovascular procedures between 2001 and 2015 were extracted from the database in Courts in Japan, and the reasons for the decisions were explored in each case.

**Results:** Ten cases regarding the neuroendovascular procedures were found among 446 retrieved healthcare-related court decisions. Five out of those 10 cases were attributed to the embolization of unruptured aneurysms, two were correlated with the embolization of arteriovenous malformations (AVMs), one was related to the carotid stenting, and two were associated with the diagnostic angiography. Negligence was identified in five out of the 10 cases, and dismissed in the other five cases. In the five court decisions in favor of plaintiffs, one identified negligence in clinical decisions, one in technical skills, and three in process of informed consent. In one case, defendants could not prove their contentions in technical skills for absence of intraprocedural video records and negligence was confirmed. In two out of five court decisions in favor of the defendant, the claim was dismissed based on the well-described clinical records or documents pertaining to the informed consent.

**Conclusion:** Neuroendovascular procedures are one of the high-risk groups for malpractice litigation. Sufficient informed consent, documentation, and storage of the clinical data are indispensable prerequisites to reduce the risk of malpractice litigation.

**Keywords** ► court decision, malpractice, lawsuit, litigation, neuroendovascular therapy

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## Introduction

Neurosurgeons are in a high-risk group for malpractice litigation in western countries, specifically while managing brain aneurysms that have a greater hazard to result in favor of the plaintiffs in neurosurgery.<sup>1,2)</sup> We investigated the court decisions for malpractice litigation in the neurosurgical field in Japan and reported that the Japanese neurosurgeons are also in a high-risk group for malpractice litigation.<sup>3)</sup> The risk of malpractice allegations in neuroendovascular procedures alone is not known; however, several judgments against the neuroendovascular procedures are recognized and affected to the latter court decisions in Japanese healthcare-related lawsuits.<sup>4)</sup> In this manuscript,

authors reviewed the past court decisions regarding the neuroendovascular procedures in Japan and described the factors affected to the decisions mainly for the risk prevention of malpractice litigation.

## Materials and Methods

Over 58000 of elected court decisions were provided in the website of Courts in Japan. Healthcare-related court decisions from January 2001 to December 2015 were retrieved from the database with the keywords of “healthcare” and “malpractice litigation.” All the regained court decisions, excluding the results out of the medical malpractice, were reviewed and court decisions regarding the neuroendovascular procedures (including diagnostic angiography) were included. All the texts of decisions extracted were investigated in detail and the factors affected to the court decisions were defined.

## Results

In 840 matched data retrieved from the database, 446 were found to be the healthcare-related court decisions. In total, 446 identified healthcare-related court decisions retrieved, 41 (38 cases) were decisions related to neurosurgery, and 11 among those 41 decisions were allegations against the neuroendovascular procedures including diagnostic angiography. All the 11 extracted court decisions are shown in **Table 1**. In the 11 court decisions, one decision in the Supreme Court (No. 7) was a result of retry for another decision in a District Court (No. 2) in the same case, subsequently, 10 cases were disclosed. Regarding those 10 cases, five were attributed to embolization for unruptured aneurysms, two were correlated with embolization for arteriovenous malformations (AVMs), one was related to carotid artery stenting (CAS), and two were associated with diagnostic angiography for subarachnoid hemorrhages. Additionally, negligence was identified in 5 of those 10 cases and dismissed in the other five cases. In the five court decisions where negligence was dismissed, claims of plaintiffs were terminated in two cases based on the well-described clinical records or documents pertaining to the informed consent. In contrast, among the five court decisions where negligence was identified, three cases disclosed negligence in process of informed consent due to the lack of information of the specific risks (including the past results, information regarding “off-label” use) or period for mature consideration.

## Discussion

In Japan, annual newly filed healthcare-related malpractice litigation is once decreased after 2004, it increased again from 2009 and exceeded over 800 cases in 2015.<sup>5)</sup> According to the disclosed data from Courts in Japan, among 13743 healthcare-related allegations tried from 2001 to 2015, 6790 (49%) were settled by settlement, and 5239 (38%) were decided (**Fig. 1**). Understanding the factors affecting the litigation and court decisions might support physicians to prevent the allegations; however, most of the cases were not disclosed and only 446 of them (8.5%) were provided during the selected period in the website of Courts in Japan.<sup>3)</sup>

Neurosurgeons are known as a high-risk group for malpractice litigation in western countries.<sup>1)</sup> In Japan, we reported that 41 (9.2%) of disclosed 446 healthcare-related court decisions disclosed in the website of Courts in Japan were related to the neurosurgery,<sup>3)</sup> and concluded that the Japanese neurosurgeons are also in a high-risk group. Among the 41 neurosurgery-related court decisions, 11 decisions were claims against neuroendovascular procedures including diagnostic angiography (which occupy a quarter of them). Accordingly, neuroendovascular procedures are considered to be in a high-risk group for malpractice litigation in neurosurgery.

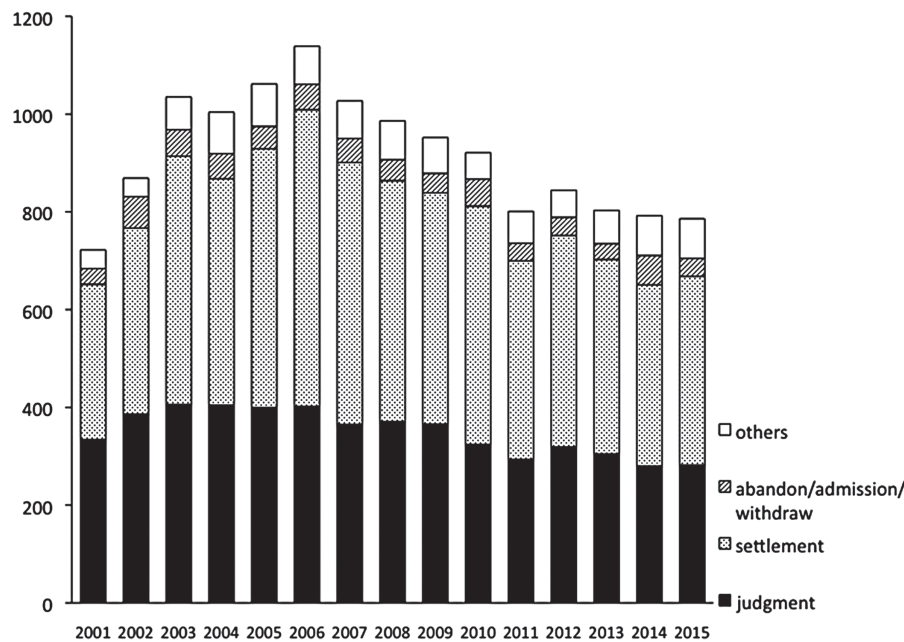
In this series, half of the 10 cases were allegations against the embolization of unruptured aneurysms. Gupta et al.<sup>2)</sup> reported 66 malpractice litigations related to the brain aneurysms in United States and concluded that a majority of the verdicts were not in the defendant's favor. In Japan, we stated the trend of malpractice litigation against neurosurgeons; besides, we found that 11 of 38 (29%) cases (including five cases in this series) were attributed to unruptured aneurysms.<sup>3)</sup> Kuwabata et al.<sup>4)</sup> reported that litigations against the neuroendovascular procedures for aneurysms or AVMs are increasing in number. Embolization of the unruptured aneurysms might be a higher-risk group of malpractice allegations.

Herein, 5 of 10 cases (including three cases with unruptured aneurysms, one case with AVM, and one case with carotid stenosis) were identified as negligence and resulted in favor of the plaintiffs. In those five cases, the court identified negligence in the clinical decisions during the procedure in one historical case of unruptured aneurysm and malpractice in technical skills in another case with AVM. In the remaining three cases, negligence in the process of informed consent was identified, but negligence in the clinical decisions or technical skills and correlation to

**Table 1** Detailed description of 11 court decisions

| No. | Year | Age (years) | Diagnosis                     | Case description                          | Primary issue                   | Result | Court    | Negligence identified                      | Cause of court decision (evidence)                                                           | Payment (million JPY) |
|-----|------|-------------|-------------------------------|-------------------------------------------|---------------------------------|--------|----------|--------------------------------------------|----------------------------------------------------------------------------------------------|-----------------------|
| 1   | 2001 | 52          | Unruptured An (VA dissecting) | Intraprocedural bleeding                  | Technical skills (balloon)      | P      | District | Technical skills (arterial occlusion site) | Occluded at inadequate site (descriptions in the clinical records)                           | 80                    |
| 2   | 2002 | 61          | Unruptured An (ICA)           | Cerebral infarction due to unraveled coil | Technical skills (coiling)      | P      | District | Informed consent (violation of rights)     | Process for informed consent is not adequate and unsatisfactory period affected the decision | (66)*                 |
| 3   | 2003 | 74          | SAH                           | Intraprocedural cerebral infarction       | Technical skills (angiogram)    | D      | High     | -                                          | Indications, skills, and clinical decisions were adequate                                    | -                     |
| 4   | 2004 | 53          | SAH                           | Hand paralysis after transbrachial AG     | Technical skills (angiogram)    | D      | High     | -                                          | Indications and skills were adequate, informed consent was not sufficient                    | -                     |
| 5   | 2004 | 43          | Unruptured AVM                | Postprocedural bleeding                   | Technical skills (embolization) | D      | District | -                                          | Indications and skills were adequate (clinical records were well described)                  | -                     |
| 6   | 2005 | 77          | Unruptured An (IC-PComA)      | Intraprocedural cerebral infarction       | Technical skills (coiling)      | D      | District | -                                          | Skills and clinical decisions were adequate                                                  | -                     |
| 7** | 2006 | 61          | Unruptured An (ICA)           | Cerebral infarction due to unraveled coil | Technical skills (coiling)      | P      | Supreme  | Informed consent (violation of rights)     | Unsatisfactory period after informed consent did not affect the decision                     | 8                     |
| 8   | 2006 | 16          | Ruptured AVM                  | Intraprocedural bleeding                  | Technical skills (embolization) | P      | District | Technical skills (catheter manipulation)   | Could not prove the arguments (video recordings were not exist)                              | 72                    |
| 9   | 2006 | 63          | Ischemic (ICA stenosis)       | Intraprocedural device trouble            | Technical skills (stenting)     | P      | District | Informed consent (violation of rights)     | Information was not sufficient (documents for informed consent was not sufficient)           | 2                     |
| 10  | 2007 | 56          | Unruptured An (ICA)           | Intraprocedural bleeding                  | Technical skills (coiling)      | D      | District | -                                          | Indications, skills, and clinical decisions were adequate (documents were well described)    | -                     |
| 11  | 2013 | 53          | Unruptured An (not described) | Postprocedural bleeding                   | Technical skills (coiling)      | P      | District | Informed consent (violation of rights)     | Information was not sufficient (documents for informed consent was not sufficient)           | 4                     |

AG: angiography; An: aneurysm; AVM: arteriovenous malformation; D: favor of the defendant; ICA: internal carotid artery; IC-PComA: internal carotid posterior communicating artery; P: favor of the plaintiffs; JPY: Japanese-yen; SAH: subarachnoid hemorrhage; VA: vertebral artery; \*: changed by retry; \*\*: retry of No. 2; -: No



**Fig. 1** Ultimate result of healthcare-related malpractice allegations in Japan. A half of the cases was settled by settlement and one-third of the cases were decided in courts. (X-axis: years, Y-axis: numbers of cases) (created from disclosed data by Courts in Japan; [http://www.courts.go.jp/saikosai/vcms\\_lf/2016053102ijikankei.pdf](http://www.courts.go.jp/saikosai/vcms_lf/2016053102ijikankei.pdf)).

the result was dismissed. In these three cases, the decided payout was as solatium for the emotional distress and estimated to be less than 10 million Japanese-yen (JPY). In contrast, two cases where negligence identified in clinical decision or technical skills, the estimated payout were over 70 million JPY as compensation for damages. Negligence in the process of informed consent and self-determination were identified in three of four court decisions after 2006. Payout tends to be lower in cases with identified negligence in the informed consent process; however, such cases are frequent in number. Based on our results, in two of five cases where negligence was dismissed, negligence in process of informed consent was discarded based on the clinical records or the well-described document. However, negligence was identified in the process of informed consent in three cases due to insufficient information of the specific risks (including past results and “off-label” use), and unsatisfactory period for mature consideration. Process of informed consent is described as an important process to exercise of the right to self-determination in these court decisions.<sup>7,8)</sup> Inadequate information or insufficient period before the decision is considered to deprive the chance to exercise of that right and likely to identify as negligence. Creating the documents and describing the process for informed

consent and giving a few days for self-determination might be an important process to reduce the risk of litigation.

In this series, the court accepted the complaints of plaintiffs and identified negligence of defendants in technical skills during the embolization in one case with AVM. In this case, defendants could not prove their contentions against the plaintiffs’ allegation in their procedure due to absence of video records during the embolization. Appropriate data storage such as movie records or photos is paramount as evidences supporting the contentions of defendants.

We are aware that this study might have some limitations. Understanding the affecting factors to the court decisions are important to prevent the outbreak of conflict; however, only selected 8.5% of court decisions are disclosed. Also, half of the filed allegations were resolved with settlement and details of the cases are not disclosed. Systemic analysis of the settlements based on the data in the insurance companies might be essential.

## Conclusion

Neuroendovascular procedures are in a high-risk group for malpractice litigation in neurosurgery. Sufficient information, creating the documents for informed consent and storing the clinical data such as movie records or photos

are vital indispensable prerequisites to reduce the risk on malpractice litigation.

## Disclosure Statement

Authors have no conflicts of interest with regard to submit the manuscript and authors who are member of the Japan Neurosurgical Society (HN, KH, and AN) completed the registration of online self-reported COI Disclosure Statement Forums through the website for the Japan Neurosurgical Society.

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