Special Feature
Should medical accidents be judged in criminal court?—Establishing a new patient safety system in Japan

The Case of Fukushima Prefectural Ono Hospital *From the standpoint of the defense counsel*

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Introduction

Today's symposium is subtitled "Towards Determining Causes and Preventing a Recurrence," but my comments are not directed towards investigating the causes of the patient's death in this particular case or preventing its reoccurrence. Rather, I regard today's theme as being determining the reasons why a physician who should not have been charged with criminal liability for his patient's death was arrested, detained, and indicted, and preventing this situation from recurring.

Problems that Were Highlighted by the Ono Hospital Case

There are two problems related to why the Ono Hospital case became a criminal incident: (1) the existence of a report by the prefectural medical accident investigation committee, and (2) the problem of expert opinion (both expert opinion on medical practice and expert opinion on pathology). These contents raise the question of the physician's negligence.

Furthermore, there are three problems related to the criminal procedures in this case: (3) problems regarding the physician's arrest and detention; (4) an indictment that ignored the written opinions of specialists; and (5) the charged facts that interpreted the physician's discretions as his negligence. I will examine all of these problems sequentially.

Problem 1: The Police Investigation Was Triggered by the Medical Accident Investigation Report

The prosecution claimed that in the Ono Hospital case trial, the police investigation was initiated by newspaper articles, and submitted two newspaper articles as evidence. These newspaper articles with photographs reported that the Fukushima prefectural medical accident investigation committee had released the findings that a medical malpractice had occurred and that the prefecture had acknowledged negligence and apologized.

At the first public trial, after the charging sheet had been read and the prosecution had made their opening statement, the defense counsel said the following about the medical accident investigation report in their opening statement: "This report was prepared from the viewpoint of preventing a recurrence and in consideration of eligibility for liability insurance, which is premised on medical negligence, and does not recognize any negligence in connection with the defendant's criminal liability."

I remember I initially became involved in this case when I was called to the University of Tokyo Hospital by the then Chairperson of the Executive Board of the Japan Society of Obstetrics and Gynecology (JSOG), who showed me this report saying, "This is the incident that happened, can anything be done about it?" Reading through the report I thought, "This is very difficult. Since three specialists in obstetrics prepared

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the written opinions, it will be very difficult to simply reverse what they have said."

However, after taking the case and quickly beginning my own investigations, I discovered that, in preparing this report, the prefectural officer responsible had asked three ob/gyns, who were the members of the medical accident investigation committee, to prepare written opinions that took eligibility for liability insurance into consideration. Thus, while the report acknowledged the negligence of the physician who performed the operation, the medical procedure that is described in the report was not conducted in actual clinical practice. I asked many physicians about this point, and this was the conclusion that was arrived at. Of course, I am sure that the prosecution also discovered this during the course of their investigation, but to the end they never filed this medical accident investigation report as evidence, which should was first and foremost filed as evidence.

In future, I am sure that many more medical accident investigation reports will be written, and I think that they need to be written with great thought given to how they will be used before they are prepared and made public. In the case that an accident occurs, of course the causes need to be identified and measures taken to prevent a recurrence. Medical accident investigations review the circumstances at the time of the accident, investigate in retrospect the causes, and determine what measures need to be taken in future to prevent a recurrence. However, it is difficult to bear for any physicians whose actions have been acknowledged as negligent in the way that at that time the physician should have used Method B instead of Method A or that this was the cause of the accident. I believe that the content of reports must sufficiently clarify what the physician was thinking and how they were making decisions during the medical procedure.

Problem 2: Written Expert Opinion by Non-Specialists in Perinatal Medicine that Formed an Important Premise for the Prosecution's Indictment

I will now talk about problems with written expert opinion. First of all is the written expert opinion on medical practice, which was dated October 6, 2005—before the indictment—and submitted to the court during the trial. The university professor whom the prosecution requested to provide an expert opinion testified during the trial that he had said to the police, "I am not a specialist in perinatal medicine, I am a specialist in general obstetrics and gynecology, and so I can only provide an expert opinion based on this knowledge; will that be sufficient?" To which the police had replied, "Please provide the opinion." In other words, the police were unaware of the difference between perinatal medicine and general obstetric and gynecological medicine. Especially since this incident involved a case of placenta accrete—a condition that occurs once in every 5,000 births and is so rare that many obstetricians never seen a case in their lifetimes—the specialization of expert witnesses needed to be carefully considered, but it seems that the police had no awareness of this. In other words, the police lacked specialist knowledge.

This medical expert witness was a physician specializing in gynecological tumors and had never operated on a patient with placenta accreta, nor had he even conducted an ultrasound of placenta accrete—facts that became clear during cross-examination. In contrast, the defense's two witnesses were the then Chairperson and former Chairperson of the JSOG Perinatal Committee, both of who were specialists of perinatal medicine in the country.

Next is the problem of expert opinion on pathology, and here too the written expert opinion was prepared before the indictment. In the prosecution's record of pretrial investigation, this medical expert witness stated that "You can see by looking at the pictures that the placenta was also cut during the cesarian section." However, during the investigation stage, the investigators did not know that photographs of the placenta existed, and naturally neither did the medical expert witness. In other words, the photographs that the medical expert witness stated were photographs of a specimen with a dissected uterus soaked in formalin and not photographs of the patient's placenta in the Ono Hospital case. This prosecution's pathologist was a physician specializing in tumor pathology; this case was only the witness's second pathological diagnosis of placenta accreta, and he had no experience conducting specialist research on placenta pathology. In contrast, the defense's pathologist was a spcialist with abundant experience of placental pathology, having made pathological diagnoses in 60 excised

whole uterus cases, 280 uterine corpus cases, and 370 uterine cervix cases, and was acknowledged as such in the court's decision. Of course, this pathologist also writes specialized books.

In the pathological expert opinion, the existence of placental villi on the anterior wall of the uterus became a problem. The reason this was a problem was that the patient in this case had had a history of cesarian section, and placental villi can easily adhere to scarring from a previous incision. Thus, if there were placental villi on the anterior wall of the uterus, it is possible to consider that they may adhere to scarring on the anterior uterine wall. However, according to the defense's medical expert witness, these villi were necrotic and atrophic, while the prosecution's medical expert witness did not make this distinction and also paid any attention to artifacts. Although it is possible for various foreign substances to enter in the examination process, this was not considered either. The prosecution's witness had not heard any clinical information, nor could he recall seeing any pictures of the placenta. After the trial began, extremely clear photographs of the detached placenta, both front and back, were submitted as evidence by the defense counsel, and these photographs showed absolutely none of the cuts to the placenta mentioned above. The defense's medical expert witness explained that the villi remaining on the anterior uterine wall were necrotic and atrophic villi, and that they broke apart easily; he also said that there were artifacts in several places as well. Furthermore, clinical information is also very important, and the opinion of the defense's pathological expert witness was consistent with the clinical information provided by the operating physician and surgeons who said that the placenta was easily detached from the anterior uterine wall. The photographs of the placenta show deciduous membrane remaining on the anterior uterine wall. This deciduous membrane was not used in the court's decision, but was included in expert evidence.

I believe that it is imperative for medical expert witnesses with specialized experiences to provide expert opinion regarding medical procedure and pathology in cases involving rare conditions such as placenta accreta.

Problem 3: Unjustified Arrest Aimed at Obtaining a Confession

Dr. Kato was arrested on February 18, 2006. The Code of Criminal Procedure states that "In cases where a judge deems that there exists sufficient probable cause to suspect that the suspect has committed an offense, he/she shall issue the arrest warrant…upon the request of a public prosecutor or a judicial police officer," but it also states that "…this shall not apply in cases where the judge deems that there is clearly no necessity to arrest the suspect." We believe that this case is clearly one of those in which there was no necessity to make an arrest. That is to say, for more than one year after the death of the patient in this case, Dr. Kato continued to treat many patients both hospitalized patients and out-patients, as the only physician and chief of the obstetrics and gynecology department of the prefectural Ono Hospital. He was married and his first child was about to be born; in fact, I am sure the baby was born while he was in detention. Moreover, Dr. Kato had no awareness that the patient had died for negligence. In addition, during the nearly year-long investigation, the police gathered all of the material evidence, such as the patient's medical chart; the police's questioning of important witnesses had been completed and a record of statements had been prepared. After all that, why was there a need to arrest and detain Dr. Kato?

I think that Article 60 of the Code of Criminal Procedure makes it clear that there was no need for detention in this case. Naturally, Dr. Kato had a fixed residence and, even if he had wanted to destroy any material evidence or witness statements, he could not have done so as they had all been taken by the police already. There was absolutely no reason to be suspected that Dr. Kato would try to flee.

However, as Dr. Sato also mentioned, under the Japanese criminal justice system, detaining someone in order to obtain a letter of confession is a normal investigation method, and so the police arrested and detained Dr. Kato in order to get him to confess.

Question 4: Indictment that Ignored Specialists' Written Opinions

This case involved a patient with placenta accreta, a rare condition in perinatal medicine. Between

the time of Dr. Kato's detention and his indictment, the defense counsel submitted written opinions by five specialists to the prosecutor, two of whom were the above-mentioned then Chairperson and former Chairperson of the JSOG Perinatal Committee. However, the prosecutor completely ignored these written opinions and went ahead with the indictment. As you can see by reading these written opinions, the opinions they expressed are extremely close in thinking to the court ruling, yet they were still ignored by the prosecution.

The question is why was Dr. Kato indicted? The reasons were the existence of the medical accident investigation committee report, the existence of written expert opinion that the Ono Hospital case had been a medical malpractice, and the fact that the police completely ignored the opinions of specialists in perinatal medicine. In other words, throughout the entire period of investigation for this trial, and even during the trial, the prosecution never once submitted the opinion of an appropriate specialist in this case.

Question 5: An Indictment that Interpreted the Physician's Discretion as Negligence

The charged facts stated in the charging sheet were that the defendant did not immediately stop the placental detachment and switched to hysterectomy, and by negligence in detaching the section of the placenta attached to the uterine wall, the patient's death due to loss of blood was caused." This incident was not a clear case of medical negligence in which the patient was administered the wrong type or amount of medicine, or in which an organ or blood vessel was mistakenly cut, or in which a medical instrument was mistakenly left inside the patient's body. The indictment was based on the physicians discretion in performing a normal medical procedure as an obstetrician as to whether or not to continue with the placental detachment or to stop the detachment and immediately remove the uterus. I could still somehow understand making such an indictment if the prosecution were making the indictment based on a clear understanding of the standard medical procedures performed in clinical practice.

However, during the trial the following testimony was given about medical procedures in obstetric clinical practice with regard to placenta accreta. First of all, the prosecutor's witness had been performed more than 10,000 deliveries, of which three were cases of placenta accreta; in these three cases, although there was not a lot of bleeding, the witness testified that he had completed placental detachment. Next, Professor Okamura of Tohoku University—who at the time was the Chairperson of the JSOG Perinatal Committee—testified that he had also performed more than 10,000 deliveries, of which between 100 and 200 were cases of placenta previa, of which 8 to 10 were cases on placenta accreta; in all of these cases—regardless of the amount of bleeding—he had completed placental detachment. Furthermore, Professor Ikenoue of Miyazaki University—the former Chairperson of the JSOG Perinatal Committee—testified that at the university hospital he has overseen 12 cases of placenta accreta and in all cases where placental detachment had been started, it was completed. In addition, the Obstetrics and Gynecology Department of an undisclosed university—the department of the professor who wrote the prosecution's expert opinion—had three cases of placenta accreta out of 34 cases of placenta previa in 2006, and in all of these cases placental detachment was completed.

In other words, the prosecution was unable to submit even one example of a placenta accreta case in which placental detachment was immediately stopped and the uterus removed when it became apparent to the operating physician that the placenta was adhering to the uterine wall. I believe this means that Dr. Kato was indicted without a shred of evidence.

Consequently, with regard to the physician's obligation to stop the medical procedure and his obligation to stop the placental detachment, a judgment stated that "As long as any medical procedure is physically invasive, it is obvious that there are risks to the patient's life and body, and it is inherently difficult to accurately predict the outcome of any medical procedure. Accordingly, in order to establish that the physician had an obligation to stop the medical procedure, the prosecution must clarify in concrete terms not only the risk of the medical procedure in question, but also the risk of the medical procedure not being discontinued and prove the existence of a better alternative method. In order to concretely establish this proof, the prosecution must,

at the very least, submit a substantial number of evidential clinical cases or similar clinical cases for comparison." However, as mentioned above, the prosecution was unable to show even one such example.

Conclusion

In this case, Dr. Kato was also indicted under Article 21 of the Medical Practitioners Act, which requires that unnatural deaths be reported to the police. If such deaths are reported, the physician becomes a suspect in the following investigation. However, as mentioned above, medical specialists cannot intervene with the police investigation. No matter how many times Dr. Kato explained what had happened to the police and prosecutor, they were unable to understand specialist matters.

In order to prevent the unjustified arrest of a physician from recurring, Article 21 of the Medical Practitioners Act should promptly be revised and the obligation to report an unnatural death to the police be abolished. In other words, the current system has definitive problems: even if an unnatural death is reported, the police have neither the knowledge nor the ability to make decisions about specialized medical procedures. A judgment in the Ono Hospital case determines that there is no obligation for physicians to report patient deaths resulting from medical practices such as in the Ono Hospital case to the police, that in such cases the death is not "abnormality"; either way, since Article 21 has clearly problems in the system, it should be revised swiftly.

Moreover, as this case is showed, erroneous indictments such as this case occur because there are no specialists to intervene. For this reason, I believe that it is crucial that a medical accident investigation committee of medical professionals be established by a fair and impartial third-party organization to determine the causes of medical accidents and formulate measures for preventing a recurrence.

In the Ono Hospital case, the Japan Medical Association also recommended that medical accident investigation committee be established by all hospitals and clinics, but experience tells me that in some cases impartiality and fairness can be difficult to maintain. I believe that it is imperative that a path be created that enables hospitals and clinics to request a specialist organization—one in each prefecture, for example—to conduct an investigation in difficult medical cases or when a patient or their family requests an investigation.