Medical Accidents and the Responsibility of the Medical Community

—A case in Japan and lessons learnt—

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Tatsuo KUROYANAGI*1

As detailed in the past issue of JMA Journal (Vol. 51, No. 4), the death of a woman in childbirth at Fukushima Prefectural Oono Hospital developed into a criminal case, in which the obstetrician/gynecologist who indicted caesarean section and removal of a placenta previa was arrested and prosecuted in Fukushima District Court (Criminal) for charges including professional negligence resulting in death, to the astonishment of not only obstetricians/gynecologists but also the whole medical society in Japan.

On August 20, 2008, shortly after the publication of that issue, Fukushima District Court declared the accused Dr. Y not guilty for professional negligence resulting in death and for violation of the Medical Act. The Fukushima District Public Prosecutors Office gave up without filing an appeal within the required period, thereby establishing the guiltlessness of the accused Dr. Y. The syllabus of court judgment was given on the day of judgment, and the formal judgment document, dated September 17, was later supplied to the parties involved. (In Japan, the judgment of a civil case must be given according to the judgment document on the judgment day, and therefore the judgment document is made available to the parties involved immediately after the rendition of judgment. On the other hand, the judgment document of a criminal case need not be prepared by the judgment day. It often takes a number of days before the judgment document in an important criminal trial is prepared and issued.)

The author lately obtained a reproduced copy of the judgment document. Based on this document, the following outlines the incident as described in the court's findings of fact and the judgment of the court regarding important points at issue.

Outline of the Incident

Patient A, the woman who was having a child in this incident, was born in 1975 and get married in 1997. In July 2001, she gave birth to her first child at the Department of Obstetrics and Gynecology, B Kosei Hospital by means of cesarean section. She conceived her second child in 2004. She visited early in May the Department of Obstetrics and Gynecology, Fukushima Prefectural Oono Hospital, and was diagnosed by the accused Dr. Y as being in the 5th week of pregnancy. Thereafter, she regularly attended the hospital and was examined by Dr. Y. On October 22, Dr. Y made a diagnosis of complete placenta previa. On November 22, patient A was admitted to Oono Hospital for treatment of threatened abortion and management of placenta previa. On December 6, Dr. Y explained to the patient that cesarean section would be performed and simple hysterectomy might become necessary depending on the circumstances. On December 14, Dr. Y gave explanation to patient A and her husband about the presence of a placenta previa, the possibility that the placenta might be on the scar of previous cesarean section, the possibility of blood transfusion, the possibility of thrombosis, and other facts, and obtained consent to surgical operation.

As of December 2004, Oono Hospital was a designated secondary emergency care hospital. It had the Departments of Internal Medicine, Surgery, Orthopedics, Obstetrics/Gynecology, and Anesthesiology, and was staffed with 12 full-time

*1 JMAJ Advisory Member, Legal Advisor, Japan Medical Association, Tokyo, Japan (jmaintl@po.med.or.jp).

Table 1 Timeline of medical procedures

Time	Remarks	Accumulate blood loss (ml)	BP (mmHg)	HR (bpm)	Events
	Five units of stored blood, ready in O.R.				
14:26	Operation started, under spinal anesthesia		80/40	120	Consciousness clear, could speak normally
:30			90–100/50–55		
:37	Delivered female infant Wt. 3,000 g, without problem			100–120	Oxytocin injection into uterine body
:40	Removal of placenta required manual explorations of uterus	2,000	100/50	110	Pumping I.V. crystalloid solution started
:45	Bleeding copiously		80/40	115	I.V. switched to Hespander
	Placenta removed by Cooper scissors				No haemostatic maneuver during this period
:50	Removed placenta finally			110	Oxytocin injection
:55		2,555	50/30		Noradrenalin I.V.
15:00	Blood transfusion started		70/30		
:05			40/20		Hysterectomy, considered due to continuous bleeding.
					Pt. complaint of discomfort, increased O2 inhalation from 2 to 6 L/min
:10	Another 5 unites of stored blood ordered	7,675	80/40		Noradrenalin I.V. infusion started
:25			60/30		
:27			60/20	120–140	Asked the blood donations to the hospital employees
:30	Next 5 units of blood ordered		60/30		
:35	Anesthesia switched over to general anesthesia, tracheal intubation performed			120–150	
:40		8,475			
:45	Radiated platelet, 20 unites ordered				
:50	Ten packs of fresh frozen plasma ordered				
:55					Miraclid 500,000 U I.V. drip started
:57		9,605			
16:00					Hospital employees fresh whole blood 3,000 ml, ready to use
:07		11,075			
:15		12,085			
:20	Stored 20 unites of blood brought into O.R.				
:25	Blood transfusion started again				
:30			60/30	120	
:35			100/50		
:40			120/60	140	
:45	Hysterectomy decided and started		110/60		
:50			100/60		
:55			90/40		
17:00			80–100/35–50	c. 140	
:18			〃	〃	
:22		17,055	〃	〃	
:30	Hysterectomy done		〃	〃	
:58			〃	〃	
18:00			60/30	〃	
:02		19,475			
:05	During restored bladder laceration, suddenly ECG showed ventricular tachycardia, blood pressure was not detectable, D.C. shock for 3 times applied				
19:01	Death confirmed	Total blood loss 20,445			

• One unite of blood: concentrated human red blood cells in M.A.P. solution from 200 ml of whole blood, not 400 ml.
• Infant: Female, 3000 g.
• Placenta: Elliptical shape (minor axis 11–12 cm, major axis 28 cm), thickness 2.5 cm, weight 766 g.

physicians. However, the Department of Obstetrics/Gynecology had no physician other than the accused Dr. Y, who had been working for the hospital since April of the same year and had an experience of 8 years and 7 months in obstetrics/gynecology.

The hospital was not keeping a stock of blood for transfusion. Whenever blood transfusion was necessary, blood was ordered from Fukushima Prefecture Iwaki Red Cross Blood Center, located more than 50 km from the hospital, and transported by car taking about one hour.

Medical Procedures on the Day of the Incident

On December 17, 2004, the operation of cesarean section was started at 2:26 p.m. by a team consisting of the accused physician performing as the operating surgeon, a surgeon as the assistant, an anesthesiologist, two midwives, and four nurses.

The judgment document contained a very long description of findings of fact. For the convenience of the readers, the author have summarized it in Table 1 showing the development of events from the beginning of operation to the death of the patient (including bleeding, vital signs, etc.)

Charged Facts

The facts that the prosecutor alleged as constituting the offense charged (charged facts) were described in the judgment document as quoted below.

"(Charged facts) The accused Dr. Y, acting as the operating surgeon, performed cesarean section on patient A (29 years old) at 14:26, December 17, 2004. Patient A had a history of cesarean section once in the past, and the accused had recognized, on preoperative examination, the adhesion of the placenta to the area of incision in the previous cesarean section. After the delivery of a female infant at about 14:37, the accused applied traction on the umbilical cord of patient A, but this failed to cause placental removal. He attempted manual removal of placenta by inserting the fingers of his right hand between the placenta and the uterus, but the placenta showed adhesion to the uterus and was not removed.

In such a case, a continued attempt at removing the placenta might cause massive bleeding from the uterine surface affected by placental removal, creating a risk to the life of the patient. Therefore, it was a professional duty of care to avoid, by immediately discontinuing placental removal and switching to hysterectomy, the vital risk for the patient resulting from massive bleeding associated with the removal of the placenta from the uterus.

Nevertheless, the accused Dr. Y neglected to exercise the above duty of care. Instead of immediately discontinuing placental removal and switching to hysterectomy, he performed removal at the site of placental attachment using Cooper scissors till about 14:50, and through this negligence, he caused massive bleeding from the surface affected by placental removal and caused the patient's death from blood loss at about 19:01 of the same day."

Judgment of the Court

"(A) The prosecutor alleges that the medical standard at the time of this incident demanded immediate discontinuation of placental removal and switching to other means such as hysterectomy once a placenta accreta was confirmed, and the accused had an obligation to discontinue placental removal. While this allegation is based on some medical literature and the expert opinion of Dr. T, it is clear from the above discussion that the expert opinion of Dr. T depends more on medical literature than on clinical experience, and therefore the allegation of the prosecutor may be considered based on the opinion in a limited range of medical literature.

(B) However, the allegation of the prosecutor may not be adopted because of the following reasons:

a. Any medical standard that imposes physicians engaged in clinical practice with the duty to conduct certain actions in medical treatment and serves as a criterion for incriminating the neglect of the duty must be the ones that have generality or commonness to an extent that most of the physicians engaged in the clinical practice in the relevant area, faced with the relevant situation, conduct the medical treatment according to the standard.

   This is because denial of the above notion would prevent clinical physicians from making practical and timely selection of treatment methods when there is discrepancy between the medical treatment used in clinical practice and the description in some medical literature,

causing confusion in clinical practice, obscuring the criteria for incrimination, and disrupting the principle of clarity.

In this respect, while the prosecutor alleges the medical standard based on some medical literature and the expert opinion of Dr. T, there is no proof that they are recognized widely by physicians and that there are many clinical cases complying with the medical standard, and there is no proof that the medical standard has generality and commonness to an extent as stated above.

b. In addition, as mentioned above, the prosecutor alleges that the accused had an obligation to discontinue placental removal, mentioning the high risk associated with the continuation of placental removal, the high probability of the patient's death, and the ease of switching to other means such as hysterectomy.

However, so long as any medical action is invasive to the body, the presence of a risk to the life and body of the patient is self-evident, and it is difficult to predict the outcome of a medical action precisely. Therefore, in order to assert the obligation to discontinue a medical action, the prosecutor must give concrete demonstration of the risk that might occur if the said medical action was not discontinued, and thereafter must prove the presence of a better alternative method. In the context of this case, the prosecutor must give concrete demonstration of the high probability of a failure in uterine contraction, the high probability of a failure in hemostasis once uterine contraction is achieved, the volume of bleeding expected in this case, and the availability and effectiveness of other practical methods of hemostasis, and thereafter must prove the high probability of the patient's death. To make such proof in a concrete way, it is at least necessary to present a considerable number of clinical cases supporting the allegation or comparable similar clinical cases.

Nevertheless, the prosecutor based the proof solely on some medical literature and the expert opinion of Dr. T, without submitting any clinical cases supporting the allegation, and the medical standard mentioned by the prosecutor is not considered to have generality and commonness as stated in 'a' above. Therefore, there is no proof of the concrete risk associated with the fact that the accused did not discontinue placental removal.

(C) According to the above findings, the court finds that, contrary to the prosecutor's allegation, the standard medical treatment for placenta accreta in actual clinical practice was exactly working as the medical standard, so long as this case is concerned.

(D) According to the above, the court does not approve the prosecutor's allegation that the medical standard at the time of this incident demanded immediate discontinuation of placental removal and switching to other means such as hysterectomy once a placenta accreta was confirmed, and also does not approve the allegation that the accused had an obligation to discontinue placental removal because of concrete high risk and other reasons. Therefore, the acknowledged fact of the continuation of placental removal by the accused does not constitute the negligence of a duty of care.

(E) According to the result of the above examination, the court finds that the charged fact No. 1 lacks proof because there is no proof of the duty of care that the accused had to exercise."

Comment

(1) The judgment confirmed that a physician's duty of care (negligence) is delimited by whether or not the act of the physician was against the standard (level) of medical practice at the time of the act even in a criminal case. Then it stated that "while the prosecutor alleges the medical standard based on some medical literature and the expert opinion of Dr. T, there is no proof that they are recognized widely by physicians and that there are many clinical cases complying with the medical standard" and "there is no proof that the medical standard has generality and commonness to an extent as stated above."

On this basis, the court made the judgment that "in order to assert the obligation to discontinue a medical action, the prosecutor must give concrete demonstration of the risk that might occur if the said medical action was not discontinued, and thereafter must prove the presence of a better alternative method." Remarking that "the prosecutor based the proof solely on some medical literature and the expert opinion of Dr. T, without submitting any clinical cases supporting the allegation, and the medical standard mentioned by the prosecutor is not considered to

have generality and commonness as stated in 'a' above," it proceeded "therefore, there is no proof of the concrete risk associated with the fact that the accused did not discontinue placental removal." As the final conclusion, the court declared the accused not guilty, stating, "According to the result of the above examination, the court finds that the charged fact lacks proof because there is no proof of the duty of care that the accused had to exercise."

Although the conclusion of this trial was not guilty as quoted above, it should be remarked that the judgment was based on the prosecutor's failure to fulfill the burden of proof and the innocence was not positively demonstrated.

(2) In the trial of a civil damage case involving death from bleeding (blood loss), it is usual that the primary issue is the appropriateness of the physician's response and action in preparing for or addressing to the need for blood transfusion. The second issue, though it partly overlaps with the first, is whether the patient should have been transferred or admitted early to a higher-level medical institution, considering the blood transfusion system, the physician's skills, and the hospital's medical care capabilities.

The problem of blood transfusion is closely associated with the development of a country's system for the supply of blood for transfusion. In Japan, a nation-wide blood supply system centered on Japanese Red Cross Society was established in the years around 1980, triggered by the proposal of Dr. Kaoru Matsuura, then Vice-president of Japan Medical Association (JMA) and promoted by a widespread movement. By the latter half of the 80s, the system enabled hospitals in many regions to receive blood from regional blood centers generally within 1 hour after ordering.

As a result, physicians in Japan are procuring blood for transfusion in advance and placing additional orders during operations assuming the presence of this blood supply system. In emergencies, it is also common that physicians ask for a supply of blood from the stockpiles at other hospitals in the vicinity.

However, from time to time, local hospitals are faced with patients requiring difficult operations that may result in massive bleeding. A physician seeing such a patient usually makes a reference and transfers the patient to a large medical institution, where advanced medical care is conducted routinely and sufficient human and material resources are maintained (typically located in central cities such as prefectural capitals, provided with a stockpile of blood, and capable of quick procurement of blood from a blood center).

(3) The author gave a lecture entitled "Issues around Medical Disputes—A Discussion of Court Decisions in the Field of Obstetrics/Gynecology" at a seminar for family planning and eugenic protection instructors co-sponsored by the Ministry of Health and Welfare and JMA in 1994 (later published in Journal of the Japan Medical Association Vol. 113, No. 12). This lecture provided an exhaustive review of the civil court decisions (district courts) regarding 371 cases in the field of obstetrics/gynecology published in the 41 years from 1952 to 1993. Considering the launch of the JMA Professional Medical Liability Insurance System in 1973, this lecture divided the entire period into phase I from 1952 to 72, phase II from 73 to 83, and phase III from 84 to 93, and focused on the comparison between phase II (125 cases) and phase III (105 cases). Maternal death occurred in 20 cases in phase II (including 9 cases of death from bleeding) and 22 cases in phase III (including 11 cases of death from bleeding). Seven of the 9 cases in phase II turned out against physicians on the ground that the timing of blood transfusion was too late. Of the 11 cases in phase III, physicians lost in 5 cases, and 2 of these cases were judged on the ground that physicians had obligation to transfer patients to higher-level medical institutions earlier and at appropriate timing.

Fifteen years has passed since the above-mentioned seminar. We have seen various developments in this period, including the amendment of the Code of Civil Procedures, the improvement of the expert opinion system, and the establishment of medical cases divisions in courts in large cities, and the ability of Japanese courts in examination and judgment has improved remarkably so long as civil cases are concerned. The framework for judging negligence in a case of death from bleeding in obstetrics/gynecology remains the same. The main point is that "the physician should procure blood for transfusion at appropriate timing, and a failure to procure when procurement is possible" is considered negligence. Complementary to this point, there is another point that "a patient who exceeds or has exceeded the capability of a physician or a medical institution should

be referred and transferred to a higher-level medical institution at early and appropriate timing, and a failure to conduct this when it is possible" is considered negligence. These are the bases for the current established practice.

(4) However, in the present case, Fukushima District Public Prosecutors Office asserted that "In such a case, a continued attempt at removing the placenta might cause massive bleeding from the uterine surface affected by placental removal, creating a risk to the life of the patient. Therefore, it was a professional duty of care to avoid, by immediately discontinuing placental removal and switching to hysterectomy, the vital risk for the patient resulting from massive bleeding associated with the removal of the placenta from the uterus," and alleged that the failure to fulfill this duty was negligence. This assertion translates into burdening physicians with the affirmative duty to perform hysterectomy at early timing. This assertion, if it were right, is straightforward and apparently comprehensible. It is true that hysterectomy is a possible option as a thoroughgoing method to stop obstetric bleeding, but hysterectomy itself causes bleeding. Simply obliging physicians to perform hysterectomy without considering the response to such bleeding—the preparation for blood transfusion—seems misguided. At least, the proper approach to cases like this, which has developed through civil trials, is first to define the duty of care (affirmative duty) to procure blood for transfusion at appropriate timing and then to accuse the non-fulfillment (nonfeasance) of this duty. Even in a criminal case, this approach should have been considerably effective in supporting the allegation, if the prosecutor side had made painstaking efforts in preparation.

(5) A question, however, remains as to whether a case like this should have been judged in a criminal trial, and whether the arrest was justifiable. It seems as if the prosecutor side chose the easy way of extracting a confession. Needless to say, the right way of criminal investigation is the painstaking efforts to collect objective evidence and establish a case. The court judgment in this case shed light on the danger associated with the attempt to elicit a confession to fit the simple story in the head of the investigator. As seen from civil law specialists like the author, this case should have been judged relying upon the outcome of the corresponding civil trial, and the needless or erroneous intervention of the police and administration did nothing more than complicating the situations.

However, in retrospect, what has this case left for the medical care in the future? It would be too fruitless and too cruel, if the only thing it left were the criticism of the wrongs of investigating agencies. A woman in childbirth died of a potentially avoidable cause. What the medical circle must immediately begin, triggered by this case, is to consider seriously where the problem of this case lay and what better approaches could have been taken, to develop concrete measures to keep similar incidents from happening again, and to propose them not only to the medical circle but also to society at large. In this sense, this case left all medical professionals under the burden of tremendous responsibility.

For physicians to remain the true advocator of patients, it is necessary that they examine every individual case, find problems, and consider means to prevent future incidents. The author believes that physicians must always abide by this fundamental principle.