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Abstract

This study analyzed perinatal medical malpractice court cases in Japan between 1999 and 2021, especially those where midwives were found negligent in cases involving the use of labor-inducing medications. The aim was to identify the turning points where adverse events could have been avoided and examine the necessary measures to prevent missing these turning points. Two cases of successful plaintiff's verdicts where the midwife's fault was recognized during the use of labor-inducing medications were found. In both cases, the turning points where the adverse events could have been avoided were related to the midwife's failure to properly evaluate the situation and make critical judgments, such as deciding whether to increase the dose of labor-inducing medications, fitting an electronic fetal heart rate monitoring device and interpreting the results, and observing the delivery progress. To prevent medical errors, midwives must engage in ongoing education and training, practice effective communication and collaboration with healthcare providers, refer to guidelines to minimize the risk of medical errors, and accurately record patient information. The findings are deemed useful for modern medicine as they highlight the importance of midwives' responsibilities in preventing medical errors during labor and delivery.

Keywords: Malpractice, Midwife, Turning Points



Introduction

Medical malpractice during delivery can result in cerebral palsy (CP) and other lifelong disabilities, causing immense suffering on infants and families (Jonsson, 2007). Many legal challenges to labor management involve allegations regarding the misuse of labor-inducing medications (Berglund, et al.2008). For example, oxytocin is used for inducing and enhancing uterine contractions and treating uterine bleeding, but excessive stimulation may lead to reduced gas exchange to the placenta (Oscarsson, 2006). To prevent this, medications must be used judiciously and in accordance with institutional policies and procedures.

In Japan, cases where the dosage and administration of oxytocin preparations fell within the standard range of the "Guidelines for the Practice of Obstetrics and Gynecology–Obstetrics" have increased, and 70%–80% of cases involved continuous fetal heart rate monitoring using electronic fetal heart rate monitoring (cardiotocography, CTG) devices (The Japan obstetric compensation system for Cerebral Palsy, 2022) These improvements are considered to be the result of various measures taken to prevent accidents caused by inappropriate use, such as the establishment of obstetric care compensation and medical accident investigation systems, as well as the publication and revision of guidelines for obstetric and gynecological care. Moreover, cases where mothers and infants have experienced serious outcomes due to failure of using the product in accordance with standards have been repeatedly reported in Japan. In particular, the use of labor-inducing medications is an auxiliary service under the direction of physicians, and midwives must work together with physicians to safely carry out their duties. Thus, the necessary measures that midwives must take to prevent medical errors caused by inappropriate use or violation of their duty must be determined to improve the use of these drugs.

Medical accident cases have often been used to prevent recurrence, and learning from past cases has been demonstrated to be beneficial and important for ongoing midwifery education (Guidera, et al. 2012). In Japan, attempts have been made to utilize case studies as a means of emphasizing the potential for preventing medical accidents and developing the ability to avoid overlooking warning signs. However, previous studies on medical malpractice trials suggest that unfavorable outcomes could have been prevented if timely and appropriate measures had been taken (Jonsson M, 2007). We believe that this case study can contribute to future medical safety education for midwives by enhancing their ability to accurately identify critical moments that may develop into adverse events. Therefore, this study analyzed a perinatal medical malpractice trial that occurred at the time of the adverse event and identify the turning point where the adverse event could have been avoided based on the facts revealed during the trial. The study aims to examine the necessary measures to prevent missing this turning point and provide insights into the care needed to avoid medical errors.

Definition of Terms:

- 1. Perinatal medical malpractice refers to a legal determination of negligence by a healthcare provider in a lawsuit related to childbirth.
- 2. Turning point refers to a critical moment at which the occurrence of medical malpractice can be prevented. In this paper, the turning point is defined as the moment before the midwife's negligent act that was determined by the trial court, at which the midwife's actions and circumstances presented an opportunity to prevent negligence from occurring.

Methods

This study collected and analyzed perinatal medical malpractice court cases between 1999 and 2021, wherein midwives were found negligent in cases involving the use of labor-inducing medications. A legal database (TKC Law Library, 2020) was used for this purpose, and the study falls under the category of literature review. The reason for focusing on court cases from the past 20 years is that this was a period during which Japan's medical safety measures were being promoted based on the history of similar repeated accidents. The issues for medical malpractice prevention derived from this study are deemed to be useful in modern medicine. Keywords including "medical accidents" and/or "childbirth" were used to search for cases from April to December 2020. Two cases of successful plaintiff's verdicts where the midwife's fault was recognized during the use of labor-inducing medications were selected. After organizing the issues, arguments of the parties, and background information based on the chronological medical history chart (Supreme Court of Japan, 2017), the turning point was examined. During the analysis of the turning point, objectivity was ensured by making a comprehensive assessment of (1) the scientific basis, (2) evidence presented at the trial, and (3) statements of the witnesses and parties. The assessment also considered the foreseeability of serious outcomes for the mother and child. In addition, three medical professionals experienced in medical malpractice lawsuits provided oversight to ensure objectivity in the case.

Results

The following is a summary of the two selected court cases and their respective turning points.

Case 1: LEX/BD Document No. 28060137, Fukuoka District Court, July 29, 1999.

1) Outline of the case

Ms. A, a woman with a history of multiple childbirths, was induced with an oxytocin preparation for delivery at Hospital C. Midwives monitored her progress. About 3 h after the start of the infusion, a midwife reported to Dr. D that the baby's heartbeat had decreased. Dr. D attempted suction delivery and Kristeller maneuver, but was unsuccessful in delivering the baby, which led to a Cesarean section. As a result, Baby B was left with residual cerebral palsy.

2) Negligence of certified midwives established by court

Midwife E was found to be negligent for overlooking the appearance of late deceleration or suspected bradycardia that occurred after 11:56 a.m. Midwife F was found to be negligent for not taking appropriate measures after taking over from midwife E.

3) Turning point

Midwife E increased the dose of oxytocin at 10:40 a.m., approximately 3 h before the delivery of Baby B.

Fetal distress, including 12 episodes of late deceleration, was suspected, but the midwife was unaware of it. The midwife should have considered reducing or discontinuing the use of oxytocin. In addition, fetal heart rate monitoring should have been performed to assess fetal well-being.

4) Verification of the turning point

(1) Timeline

9:57 a.m.: Late deceleration occurred, followed by mild sustained tachycardia of 160 to 180 bpm. Midwife E noticed the sustained tachycardia, but she did not consider it abnormal and decided to observe carefully, without reporting to Dr. D.

10:10 a.m.: Oxytocin dosage increased.

10:16 a.m.: Contractions occurred intermittently every 2.5–3 min.

10:18–10:53 a.m.: Fetal distress, including 12 episodes of late deceleration, was suspected.

10:40 a.m. (turning point): Midwife E increased the dose of oxytocin preparation.

11:45 a.m.: Midwife E noticed that the fetal heart rate had dropped to about 80 bpm.

11:50 a.m.: Midwife E began administering 3 L of oxygen per minute, which resulted in a recovery of the fetal heart rate to about 160 bpm. Due to the rapid recovery of the fetal heart rate, it was decided to monitor the patient and report to Dr. D if the drops in fetal heart rate became more frequent. From the witness examination of Midwife E, it was found that "it is difficult to find that Midwife E was actually aware of the variable deceleration."

12:00 p.m.: Midwife E informed Midwife F that the fetal heart rate had decreased at approximately 11:45 a.m. but recovered with the administration of oxygen, and Midwife F took over. The fetal heart rate began to show late deceleration, but Midwife F did not notice.

12:15 p.m.: Midwife F noticed that the fetal heart rate had dropped to 70 bpm and reported this to Dr. D. Among other interventions, she stopped the oxytocin infusion and increased the oxygen dosage.

*Annotation: The normal fetal heart rate is 110–160 bpm.

(2) Based on the scientific evidence, trial evidence, and witness and party statements, we have determined that the medical malpractice in this case could have been prevented if the midwife had responded with a sense of urgency to the increased dose of oxytocin, predicted the subsequent progression, or considered the possibility of the fetal heart rate deviating from normal values and promptly reported it to the physician.

Case 2: LEX/BD Document No. 28091003, Kobe District Court, September 30, 2003.

1) Outline of the case

Ms. H, a first-time mother, was admitted to Hospital J in her hometown after her water broke in the first trimester. The next day, she was given a dinoprostone preparation due to weak labor pains. About 7 h later, she was diagnosed with fetal dysfunction and underwent a Cesarean section to deliver Baby I. Unfortunately, Baby I died shortly after birth. During the delivery induction at Hospital J, doctors and midwives visited the room at intervals to monitor the delivery progress by interweaving Doppler fetal heart rate checks, interviews, observations, and attachment of CTG as appropriate. On the day of delivery, there were four scheduled deliveries and three actual deliveries (including two using labor-inducing medications). Sixteen patients were admitted to the obstetrics and gynecology department, and outpatient care was provided in the morning and part of the afternoon.

2) Negligence of certified midwives established by court

From the time when six doses of dinoprostone, a labor-inducing agent, were administered at 1:15 p.m., high-grade bradycardia persisted until 3:00 p.m. Between 1:15 p.m. and 3:00 p.m., the midwife did not attach the fetal monitor and did not visit A's room, leaving her unattended.

The midwife had a duty to monitor the progress of labor in conjunction with the physician, and her failure to perform the monitoring duty constitutes negligence.

3) Turning point

Midwife M instructed Ms. A to take the fifth dinoprostone tablet at 12:15 a.m., approximately 3 h before the delivery of Baby I.

Due to the sudden increase in pain and the deviation of fetal heart rate from normal values, continuous monitoring using CTG should have been performed.

4) Verification of the turning point

(1) Timeline

11:15 a.m.: Ms. H took the fourth dinoprostone tablet.

11:30 a.m.: Ms. H was unable to eat lunch and endured each contraction by placing a towel over her mouth to stifle her voice and using breathing exercises to manage the pain.

Before taking the fifth dinoprostone tablet: Midwife L obtained information from Doppler auscultation, indicating a fetal heart rate of 150–170 bpm, a labor cycle of 2 min (as reported by Ms. H), and seizure time of 10–20 s.

12:15 p.m. (turning point): Midwife M ordered and confirmed the administration of the fifth tablet. She explained that she would consult with Dr. K on whether to administer the sixth tablet 1 h later, which also influenced the physician's decision to order the sixth tablet. Midwife M did not attach CTG to Ms. H.

1:00 p.m.: Ms. H, who was unable to walk unassisted due to the intensity of her contractions, went to the examination room with her husband for an internal examination by Dr. K. Dr. K noted an opening of the uterus of 3–4 cm and 50% retraction. Dr. K administered the sixth dose to Ms. H. Midwife N was present and provided a back massage to Ms. H.

3:00 p.m.: Midwife O fitted Ms. H with CTG (CTG was not available until 3:00 p.m. due to other patients).

*Annotation: The normal fetal heart rate is 110–160 bpm.

(2) Based on the scientific evidence, trial evidence, and witness and party statements, we have determined that the medical malpractice could have been avoided if the midwife had followed standard procedures by considering the possibility of complications and performing continuous monitoring with CTG. This was particularly necessary in the situation where the fetal heart rate deviated from normal values and the woman was experiencing a sudden increase in pain.

Discussion

We will examine the necessary measures and provide insights into the care needed to avoid medical errors.

In Case 1, from 10:18 a.m. to 10:53 a.m., 12 episodes of late deceleration occurred, but the midwife was unaware of this fact. The midwife should have considered reducing or discontinuing the administration of oxytocin to the patient. Furthermore, an accurate interpretation of CTG should have been conducted to assess fetal health. The trial court concluded that the risks of administering oxytocin products should be comprehended, and any abnormal signs in the mother or fetus should be appropriately monitored to avoid preventable harm. In this regard, it was also determined that avoiding harm was warranted. In addition, if

the midwife had considered the possibility of fetal heart rate deviation from normal values, the situation could have been communicated to the physician approximately 2 h earlier than it was in the case, potentially leading to an altered outcome. According to the Japan Obstetric Compensation System for Cerebral Palsy, in situations where fetal dysfunction is suspected, it is recommended to promptly report to a physician or request his/her presence, as well as consider reducing or discontinuing uterotonic medications (Murakami, 2018). However, previous research speculated that midwives do not encounter obstetric emergencies or highrisk deliveries frequently and that it is impossible to acquire the necessary skills to manage such events solely in clinical practice. Therefore, supplementary training is deemed necessary (Hogh, 2021). Eggermont (Eggermont, 2015) analyzed cases of medical malpractice by midwives providing delivery care over the past 40 years and reported that many cases were related to the interpretation of fetal monitoring, with the most common responsibility lying with midwives who failed to identify fetal distress through fetal monitoring. The author also emphasized the importance of continuous monitoring, acquisition of accurate interpretation skills, need for good communication and organizational structure among healthcare professionals to facilitate support requests, and sharing of all relevant information with colleagues and obstetricians without hesitation, even when abnormalities are suspected. From these considerations, it becomes clear that there is a need for ongoing education and training, as well as effective communication and collaboration between healthcare providers, so that midwives can avoid medical errors and not miss turning points.

In Case 2, we conclude that medical malpractice could have been prevented if the midwife had accurately assessed the situation where the woman was experiencing sudden and severe pain and the fetal heart rate deviated from normal values. Continuous monitoring with CTG should have been performed. The package for labor-inducing medications in Japan was revised in 2020 to include a requirement for continuous monitoring with CTG when using oxytocin. This update was made in response to reports of severe cases of excessive labor and fetal dysfunction associated with the use of this drug. It is crucial that we adhere to these guidelines (Ministry of Health, Labor and Welfare, 2020). In cases where continuous monitoring is not possible, a clear rationale should be provided, and the patient should be monitored using an appropriate alternative method. If the alternative method is using a handheld Doppler to listen to the fetal heartbeat, then the labor stage, location of the heartbeat, appropriate timing and measurement interval of 60 s immediately following uterine contractions, and any additional findings should be described (Murakami, 2018). Based on the above cases, it becomes clear that midwives need to make important decisions at turning points regarding the assessment of whether to increase oxytocin, the attachment and interpretation of CTG during oxytocin use, and the observation of labor progress. In order not to miss the turning points, midwives should refer to guidelines and accurately record patient information to minimize the risk of medical errors.

In both cases, we identified a turning point, which was a critical point that could have altered the course of events toward prevention, several hours before the court's finding of negligence. However, there are limitations to examining "why the midwife missed the turning point" based solely on the facts stated in the court's decision. Further examination of the necessary care to avoid missing the turning point is needed. Another limitation of this study is that it only includes cases listed in the legal database (TKC Law Library,2022), which does not provide a comprehensive understanding of court cases involving labor-inducing medications.

Conclusion

Through these case studies, it becomes clear that turning points are situations that could lead to a shift in the direction toward avoiding medical errors, such as deciding whether to increase the dose of labor-inducing medications, fitting CTG and interpreting the findings, using labor-inducing medications, and observing the delivery progress. Midwives must make critical judgment during these turning points. Therefore, midwives should engage in ongoing education and training, practice effective communication and collaboration between healthcare providers, refer to guidelines to minimize the risk of medical errors, and accurately record patient information.

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