



Professional Liability in Anaphylactic Shock Cases: Case Report

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Case Report

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Abstract

Drug-induced fatal anaphylaxis is a common challenge in the last period because of the claim of medical malpractice in these cases. Medical malpractice emerges usually during drug administration by the healthcare provider because of the failure to recognize the allergic condition or failure to apply precautions regarding preventive measures or failure to apply appropriate resuscitation measures at a suitable time for saving the patient's life. So, the current presentation of case reports aims to show the professional liability of healthcare providers during dealing with anaphylactic shock in two different situations. Therefore, the job description of every involved healthcare provider should be outlined based on the determination of the legal and professional rules to identify any healthcare provider who breached the duty. In addition, the pillars of professional liability should be recognized while dealing with these medical malpractice issues and different medical errors in cases of anaphylactic shock. Thus, the role of the forensic expert is an application of the mentioned rules to identify shortcomings aspects that lead to medical malpractice wherein medical errors may be caused by a shortage of medical knowledge, lack of care, workplace disorganization, or miscommunication among healthcare providers or with the patient besides an unsuitable workplace environment.

Keywords: Anaphylaxis; Malpractice; Professional Liability

Introduction

An allergy (hypersensitivity) is a reaction of the body to something that may be inhaled, ingested, injected, or in contact with the skin. Drug hypersensitivity is considered one of the common allergic reactions in clinical practice. A severe allergic reaction may be life-threatening, which is called anaphylaxis. Diagnosis of anaphylaxis is a challenge in medical practice because it depends mainly on history and clinical manifestations that may appear rapidly within

minutes of allergic exposure or be delayed up to 12 to 24 hours in some cases [1].

According to the American Academy of Allergy & Immunology, anaphylaxis is a collection of symptoms affecting multiple body systems such as breathing difficulties and hypotension or shock, but it may be fatal in the absence of respiratory affection. Drug-induced hypersensitivity reactions are classified into IgE-mediated immediate hypersensitivity and non-IgE-mediated hypersensitivity.

IgE-mediated immediate hypersensitivity reactions may manifest within 72 hours of the drug exposure that include anaphylaxis, bronchospasm, angioedema, and urticaria. Non-IgE-mediated delayed reactions are manifested by serum sickness, Steven Johnson syndrome, and interstitial nephritis within several days [2].

Drug-induced fatal hypersensitivity (anaphylaxis) is increasing in frequency in the last period wherein it represents one case for 4000 emergency cases wherein its incidence is 3 % [3]. Iatrogenic anaphylaxis due to drug administration is considered a common cause of fatal hypersensitivity, especially the patients with a history of allergic reactions or due to radiocontrast media. Antibiotics and nonsteroidal anti-inflammatory drugs are the most common drugs that induce iatrogenic anaphylaxis. So, there is a challenge for physicians to select appropriate drugs for patients who have a history of allergies. Moreover, it is also a challenge for health care providers' teams such as nurses who should be aware of the practical steps of intradermal skin test that should be done to detect drug hypersensitivity of the patient before giving him any drug injection [4].

Recently, there are many medicolegal issues that are related to professional liability in cases of anaphylaxis. The claim of medical malpractice is usually done because of the failure to recognize the allergic condition or failure to apply precautions regarding preventive measures or failure to apply appropriate resuscitations measures at a suitable time for saving the patient's life. So, medical malpractice issues in anaphylactic cases emerge during drug administration by the healthcare provider or during a skin test performance [5].

Apart from the identity of the responsible health care provider about the medical error, there are pillars for medical liability that should be recognized during dealing with medical malpractice issues. The first pillar is the act (error) wherein the health care provider or physician performs a procedure or prescribes medication for the patient while the second pillar is the result (harm) that results from the act that may be death, permanent infirmity, or injury. The third pillar is the causative connection (link) between the act (error) and the result (harm) [6].

Noteworthy, medical errors divide usually into two major types, the first type of medical error is an omission that results from action not taken such as the use of non-sterilizing surgical instruments while the second type is a commission that results from the wrong action taken such as the administration of medication to a patient who has a known allergy [7]. Therefore, this article aimed to discuss the professional liability of healthcare providers during dealing with anaphylactic shock cases through a presentation of two different cases in two different situations.

Case Report 1

A mother went with her two girls to a physician at a private outpatient clinic for consultation because her two daughters had a common cold. After that, the mother went to the pharmacy to buy the prescribed drugs that the physician decided for her daughters. The medical prescription included cephalosporin (Cefotaxime) antibiotic in an injection form. The pharmacist suggested an alternative drug to what was written in the prescription (cephalosporin) without consultation with the physician. A worker in the pharmacy (A Student in the College of Nursing) gave two injections to the two sisters wherein she has sufficient experience to do it. Two sisters felt very ill immediately and were taken to the hospital, where they died. The pharmacist said that the two injections were dispensed based on the physician's prescription and according to the dose mentioned in this prescription. Moreover, the pharmacist goes on his talk that the required antibiotic was not available and that there was a similar one with the same active substance wherein the mother of the two girls went to look for it in other pharmacies, then returned to the pharmacy and asked the pharmacist to give her the alternative medication. The pharmacist informed the prosecution authority that the antibiotic injection which was given at his pharmacy was the second dose wherein the two sisters received the first dose of the same antibiotic injection a day before in another place after confirming the negative result of the hypersensitivity test.

Discussion

Initially, the discussion of the first case report should be based on the determination of the legal and professional rules that outline the job description of every involved healthcare provider in this case starting from the prescriber of the drug (physician) to the pharmacist and the nurse beside the pharmaceutical manufacturer to identify any healthcare provider who breached the duty. Thus, the role of the forensic expert, in this case, is an application of the mentioned rules to identify shortcomings aspects that led to medical malpractice and the death of the two sisters if these aspects already come true in this issue besides the determination of the professional liability.

The administration of any drug may have a potential risk for a hypersensitivity reaction. So, healthcare providers should be cautious, especially with medication that has a known higher risk of hypersensitivity reaction. The physician should select the suitable drug for the suitable patient during writing the medical prescription and instruct the guidelines to the patient according to his condition based on history and investigations [8]. Moreover, the pharmacist should give the prescribed medications without any change or substitution because giving the drug substitution should be

after the consultation of the physician while the nurse should carry out the prescribing treatment applying the written instructions of the physician's prescription either the dose or other instructions such as skin test before the administration of some drugs [9].

The role of forensic experts in these medicolegal issues is to determine the aspects of medical malpractice and the cause of death. So, the forensic expert should have answers to many questions such as what are the malpractice aspects of the issue? Who is the responsible person for the act that led to the medical error? What is the cause of death if it is the result of the harm that occurred? [10].

According to the foundations of the physician-patient relationship, there are three basic requirements that should come true to achieve a sound legal relationship. It is competency, consent, and care. Competency means the presence of a medical certificate leading to acquiring a professional license from a specialized national authority. In addition, the consent of the patient and duty of care for the intention of recovery are considered complementing requirements for the physician-patient relationship [11].

Therefore, the physician should do his best to keep the patient safe according to the latest medical knowledge and available facilities. Secondly, there is no sure guarantee for the result in medical practice wherein a bad result or unsuccessful treatment doesn't always mean negligence or incompetence (lack of skill). Furthermore, the physician is responsible for the acts of his assistants such as the nurse [12].

Medical (clinical) malpractice may be due to incompetence (lack of reasonable skill) wherein a healthcare provider does not apply authorized scientific medical principles in a medical situation leading to medical error. So medical malpractice is judged by the standards of the specialty and the act of other professionals in the same situation [13]. Negligence (lack of reasonable care) is another aspect of malpractice wherein there are breached standards of the provided care, the rights of the patient, and physicians' duties. Therefore, an omission from a healthcare provider leads to a risk to the patient's safety. So, healthcare providers deserve medical negligence charges, if providing care to patients is unacceptable for the standards of medical practice such as an overdose or missed towel [14].

A nurse is one of the health care providers who has a professional liability in the correct clinical administration of medication to the patient. So, there are five rights that should come true during medication administration to uphold the patient's safety. These rights include the right patient, the

right drug, the right route, the right time, and the right dose [15].

The right patient means that it should ascertain that this patient is the correct recipient for the prescribed medication while the right drug means confirming that the administered medication is the same prescribed drug name. Noteworthy, the nurse should also check the expiration date of any medication before administration to the patient besides affirming that the patient has not had any allergic response to the administered medication by asking him about the known history of an allergic response or by performing skin test to exclude hypersensitivity reaction [16].

The right route of the administered medication is another right wherein intravenous administration of medication has a higher bioavailability and faster onset of action than oral medication. So, the nurse should be aware of the right administration route for any prescribed drug. Moreover, the right time of drug administration should be applied according to the prescription of a physician to maintain specific intervals and therapeutic efficacy. The right dose is the last right in medication administration to avoid an incorrect dosage via the application of physician instructions and consultation with other professional personnel to reduce medical errors as much possible as. Worthwhile, the nurse can administer the drugs with valid permission (professional license), but the nurse cannot legally prescribe any drug [17].

However, the high professional competency of nurses is measured via clinical experience, pharmacological knowledge, and the ability to perform assessments of the patient before any medication administration despite the professional license based on the certificate is considered the measure of competency in most countries. Thus, the application of the previous five rights is the responsibility of the whole healthcare organization that should improve the work environment. Therefore, avoiding medical errors requires ensuring the safety of medication administration according to the five rights wherein all healthcare workers should uphold their responsibilities in the healthcare system. However, the nurse has the first responsibility to protect the patient via inquiring from either pharmacist or the physician if there are any questions related to the medication itself, the dose, or the route of administration [18].

On the other side, the role of pharmaceutical manufacturers should not be ignored in the healthcare system and in medicolegal-related issues. Therefore, the pharmaceutical manufacturer should show pharmacological instructions such as written warnings and side effects of the drug in the internal pamphlet or on the drug package including any probable hypersensitivity to

the active substance of the drug or any additives such as a vehicle [19].

Furthermore, the hypersensitivity of any person to any drug is detected by performing an intradermal skin test that is more sensitive. Medicolegally, this test should be carried out in a well-equipped place with facilities including an intensive care unit that can deal with any probable severe allergic reaction besides an obtained written informed consent from the patient before performing the test [20]. However, the intradermal skin test has higher false positive and negative results. Regarding Cephalosporin, the intradermal skin test is performed using native molecules, but Cephalosporin undergoes degradation and generates haptens or neo-antigens when it is administered intravenously. Therefore, the intradermal skin test for Cephalosporin may be false negative [21].

In addition, there is no standardization for hypersensitivity test in clinical practice, especially intradermal skin test according to some studies. However, it should remind that the most recorded medical malpractice issues emerged from performing this test by unqualified nurses. So, there are many mistakes that occur during performing the intradermic test such as the use of an undiluted drug, insufficient skin penetration that leads to a false negative result, a large volume to be injected, or performing the test subcutaneously [22]. However, the negative result of the hypersensitivity test does not guarantee the safe administration of the drug if there is a convincing history related to the patient and the allergy because the testing may be negative even in the patient who has already an allergy [23].

In the related context, there are some cases of ceftriaxone-induced anaphylaxis that were recorded despite its negative intradermal skin testing [24]. Therefore, skin testing for cephalosporin is not useful for predicting immediate hypersensitivity because it has low sensitivity and less positive predictive value [25]. Noteworthy, anaphylaxis usually develops within a few minutes of exposure, but it may occur later than 72 hours after the exposure. Moreover, there are biphasic reactions that may occur within one hour to 72 hours after the initial attack with an asymptomatic period of one to eight hours in between [26].

Last but not least, postmortem diagnosis of anaphylaxis is a very sophisticated task in forensic medicine because there are no specific findings that may confirm postmortem diagnosis of anaphylactic shock wherein it is diagnosed based on exclusion criteria [27]. However, some studies referred that postmortem diagnosis of fatal anaphylaxis may be diagnosed depending on multi-factorial criteria that include biochemical, immunological, and histological

findings. Multi-factorial criteria include a significant increase in the levels of total tryptase, histamine, and immunoglobulin E (IgE) besides histological changes in the larynx, trachea, lung, heart, and spleen that vary its severity according to the anaphylaxis cause [28].

Finally, and based on the above mentioned, medical errors are multifaceted because of the shared responsibility of the health care providers and the complex process of medication administration. Furthermore, the healthcare provider is a human being prone to act the error, so medical errors will occur inevitably. Medical errors may be caused by a shortage of medical knowledge, lack of care, workplace disorganization, or miscommunication with a patient or among healthcare providers besides an unsuitable workplace environment [29].

Case Report 2

A woman who did not exceed 29 years of age, married, came to a specialized hospital suffering from an eye complaint. A medical examination was performed by a consultant who diagnosed the patient's condition as autoimmune uveitis. Appropriate drops were prescribed to treat the symptoms, and the necessary investigations were requested to show the extent to which the retina was affected by the inflammation, which is a scan of the retina using fluorescein dye. The medical routine procedures were followed to prepare the patient, which consisted in asking questions to the patient about the presence of a previous history of any allergy to food, drugs, or dyes, and she answered in the negative in the presence of her husband. An installation of a cannula was performed for the injection of hydrocortisone ampoule as an anti-allergic drug as a usual precaution procedure with half an ampoule of fluorescein 2.5 cm. But the woman died within hours in the hospital after undergoing radiography on the retina using a fluorescein dye and all cardiopulmonary resuscitation procedures failed to save her life. The hospital disclaimed responsibility for the death of this young woman, explaining that a hypersensitivity test for fluorescein was not done before this intervention because there is no internationally recognized hypersensitivity test for fluorescein according to medical scientific rules.

Discussion

Regarding the second case report and based on the above-mentioned rules, there are requirements that should be fulfilled during the administration of any intravenous contrast media via the radiologist to avoid medical practice. So, the duty of forensic experts in these related medicolegal issues is verification of the application of these requirements determining the professional liability. Therefore, the forensic expert should investigate the issue systematically according

to chronological events. The forensic expert should begin to follow up the story from the starting point which is the referrer practitioner who has an answer to the first question, is there a medical necessity for performing this medical invasive intervention for the patient? [30].

So, it should verify that there is a necessity for performing this invasive maneuver or procedure (fluorescein angiography) taking into consideration the probable complications with assessing the benefits and the risk for the patient such as the possibility of an allergic reaction, especially if the alternative is not available. In addition, there is a second question about the responsible person who performed the procedure for the patient to identify the qualifications of this responsible person, is the radiologist or technician in presence of the radiologist? [31].

In addition, is there informed consent from the patient indicating that the patient gave permission for this medical procedure? This consent should include the possible complications and adverse reactions that may occur to enable the patient to decide regarding this medical procedure. Therefore, the radiologist is considered guilty and responsible for the patient's death if there is not obtaining informed consent wherein an anaphylactic reaction to the intravenous contrast media is considered one of the common probable complications [32].

Furthermore, there are principles of standard radiological care that should be applied before, during, and after performing the medical procedure to ensure the patient's safety to protect him against medical malpractice. Application of the standard medical care should be judged by the standards of the specialty and the act of other professionals in the same situation based on a scientific base and clinical experiences. Radiologists should apply authorized scientific medical rules in this medical situation to prevent medical errors such as medical history taking about the allergy to the used substance, drug, food, or insect sting or previous performing of hypersensitivity test if it was done. The selection of the suitable type and determining the accurate dose of intravenous contrast media is also the responsibility of the radiologist, not the radiographer depending on the condition of the patient [33].

However, a hypersensitivity test should be done if it is recommended scientifically besides some precautions that should be applied during the procedure such as giving the patient prophylactic antihistaminic and corticosteroid even if the test is negative to avoid any adverse effects because of the possibility of false results for the hypersensitivity test. Furthermore, the site of administration should be well equipped with the required facilities for performing the medical procedure and dealing with any probable adverse

effects or complications during or after the administration of intravenous contrast media such as anaphylactic shock [34].

Noteworthy, the first-time intravenous administration of radiocontrast media (primary exposure) may lead to a life-threatening anaphylactoid reaction that mimics anaphylaxis in clinical presentation and treatment, but it is not IgE-mediated [35]. However, skin testing for predicting hypersensitivity reactions for radiocontrast media is no clinical utility until now [36]. Although skin testing is not standardized and has a limited value as a screening tool for serious hypersensitivity to fluorescein angiography, it is considered the method of choice for diagnosing hypersensitivity to fluorescein. So, skin testing must be performed in patients with positive risk factors in their previous medical history [37].

Conclusion

Healthcare providers should be cautious during dealing with medication administration or any invasive intervention such as intravenous administration of contrast media that has a high risk of hypersensitivity reaction. There are many emerging medicolegal issues because of the medical errors that are related to the professional liability of health care providers in the cases of anaphylaxis which may be omission or commission. However, medical errors are considered multifaceted because of the shared responsibility of the health care providers and the complex process of medication administration. So, the role of forensic experts should be based on the identification of the medical liability pillars in these cases determining the error, harm, and causative link. Medical malpractice in these cases may be due to a lack of reasonable skill wherein a healthcare provider does not apply authorized scientific medical rules in this medical situation leading to a medical error. Medical malpractice is usually judged by the ideal standards of the specialty and the act of other health professionals in the same situation. Therefore, the health care provider should do his best to keep the patient safe according to the latest medical knowledge and available facilities.

Declaration of Conflicting Interests

The author declares that there is no conflict of interest.

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