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A LONG WAY TO A FATAL OUTCOME

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ДОВГИЙ ШЛЯХ ДО ФАТАЛЬНОГО РЕЗУЛЬТАТУ

Габріель М. Гурман

У статті описаний випадок смерті пацієнта через застосування седативних препаратів; висновок експерта та судове обговорення також включені в її текст. Стаття буде цікава практикуючим анестезіологам; працівникам охорони здоров'я неанестезіологического профілю, які використовують седацію в своїй повсякденній практиці; інтернам; людям, які цікавляться медичними та юридичними процедурами в Ізраїлі.

Ключові слова: седація, безпека пацієнтів, клінічний випадок, Ізраїль.

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The article describes the case of patient death due to the use of the sedative drugs; the expert opinion and court discussion are also included in its text. The article will be interesting to anesthesiology practitioners; non-anesthesiological medical personnel who use sedation in their daily practice; interns; people who interested in medical and legal procedures in Israel.

Keywords: sedation, patient safety, clinical case, Israel.

Sedation is a procedure which, in the vast majority of cases produces a significant decrease in patient's alertness and can be accompanied by cardio-respiratory instability. The first microgram of a sedative drug injected intravenously might, at least theoretically, jeopardizes the patient's homeostasis and in some cases even his/her life.

We present here a case, apparently banal and rather usual, with fatal outcome, and use this example to open for the readers a window towards the medicolegal aspects in Israel.

The case:

The patient was at the time of the event 70 years old. He was well known by his current physician since he had a significant co-morbidity: high blood pressure treated by enzyme inhibitors, insulin-dependent diabetes, sleep apnea, mild obesity (body mass index, BMI, of 32) and chronic renal insufficiency which necessitated renal transplantation some years before event. The anamnesis also included heavy smoking, 40 years of one pack/day.

One day his wife paid attention to the fact that her husband was slow in verbal response, confused and presented signs of muscle weakness. She brought him immediately to the emergency department of a university hospital in the center of the country.

The physical examination did not reveal any specific sign, except confusion and a decrease in response of peripheral reflexes. His temperature was 37.9 C, blood pressure (BP) 149/89, pulse 76, respiratory rate 23/minute.

A chest X ray demonstrated a slight pulmonary engorgement and an increase in the overall pulmonary structure.

The laboratory tests were normal, except blood creatinine level of 1.38 mg/100 ml and hemoglobin level of 10.3 g/100 ml.

The working diagnosis established by the emergency room physician was suspicion of brain abscess and the patient was immediately admitted to one of the Internal Medicine departments. An i-v infusion with Saline 0.9% was started, a blood sample was sent for culture, as well as urine sample.

The patient was re-hydrated for 24 hours but his general condition did not improve and he was scheduled for an emergency brain CT scan.

That evening, at 21.00 hours, the patient was transported to the Radiology, accompanied by the physician on duty at the medicine department.

Once at Radiology, the patient became agitated, his BP rose to 176/99 and the pulse to 88/minute.

His physician decided to sedate him and order administration of promethazine (Phenergan) 25 mg intramuscular, but no effect was noticed for the next 15 minutes, so 5 mg midazolam was injected intra- venously. Eventually the brain CT test was performed, the diagnostic of brain abscess infirmed and the patient was sent back to his department, accompanied this time by a hospital assistant (orderly). At the moment of discharge from Radiology, he was somnolent, did not answer to simple questions and his breathing was shallow and rapid (no precise data found in his chart).

Once back in the department of medicine he was checked by a nurse who discovered that the patient did not breath spontaneously and less than 2 minutes later no peripheral pulse was detected and heart beats not heard anymore.

The cardiopulmonary resuscitation (CPR) maneuvers started, the cardiac activity returned to normal, but the patient remained unconscious. A tracheal intubation was performed by an anesthesiologist, the patient was transferred to the General Intensive Care Unit, diagnosed as suffering from severe brain damage and he was mechanically ventilated for more than four months, up to his death.

During all this period of time he remained deeply unconscious, necessitated hemodialysis and periodical vasopressor support.

Family refused the postmortem examination.

The case in court:

The family brought the case to the attention of an attorney, who sent a complain to the municipal justice court and accused the hospital of malpractice in managing the case.

Simultaneously the lawyer asked an expert in the field to present the court his opinion in writing. The lawyer specifically asked the expert the following questions:

1. The practice of sedating a confusing patient with a combination of intramuscular and intravenously drugs;
2. What is the indicated monitoring in such a case;
3. What are the guidelines regarding physician supervision during patient sedation and transport;
4. What was expert's opinion about the patient chances to survive in case his management was flawless and his supervision correct and continuous.

A short description of the reality in the Israeli hospitals:

This case could be understood only in the framework of the current practice in Israel.

The average Israeli physician is aware of the various aspects of cardio-respiratory emergencies. The explanation resides in the fact that most of the physicians serve in the army, and a large number of them have passed the ATLS and/or ACLS special courses during their residency years.

Another aspect of the Israeli health care situation nowadays is the continuous shortage of anesthesiologists. In the absence of once upon a time perennial immigration of physicians, Israel is faced today with lack of medical manpower in the field of anesthesia, radiology, neonatology and even pediatrics and internal medicine.

This is the reason why in many situations the tasks of sedating and supervising unstable patients belong to the internal medicine or pediatric resident on call.

This physician does not always possess the necessary knowledge and experience regarding sedation drugs pharmacology. Besides, during on calls he/she is overworked, being obliged to cover both his/her own department, as well as the emergency room and not only once the task of consulting problematic patients in other departments.

It can be said that during the night on calls the internal medicine resident fulfills the task of an expert for many patients admitted to various medical departments of the hospital.

During the last years we are witnessing a trend in improving the ability of the average physician on call in the hospital to manage difficult cases, but from time to time, and not seldom, he/she fails to efficiently cover the supervision and management needs of the unstable patient. In these cases, the intervention of the anesthesia or critical care resident might be too late and the result might be, like in the above case, catastrophic.

But the described situation cannot be used as an excuse for unexpected outcome of the patient management. The Israeli Law of Patients' Rights clearly expresses the universal right of every patient to get proper care in the proper time at the proper place.

This universally accepted demand guided the expert in this case in his answers to the plaintiff's attorney.

The expert opinion:

His opinion dealt with two main points egarding the deceased patient care: administration of sedation for performing the brain CT scan, and the immediate period after the end of the test till the patient's return to his department.

1.Sedation of the patient at the Radiology department.

The expert quoted a paragraph from a Hebrew manual of anesthesia [1] dealing with the problems of sedation outside the operation room.

The situation in this kind of cases might pose specific problems since the tests are done in a dark room, the patient is far from the person in charge with supervision and this is why a complex monitoring system is to be used. It has to include an ECG, a pulse oximeter and an automatic BP measurement device.

In this case nothing of the above has been used for monitoring the patient. The patient was not given oxygen by prongs or face mask and there was no sedation chart filled during the procedure.

Neither the physician in charge with administering sedation was fit for this job. The Israeli Ministry of Health's guidelines demand that the MD in charge with sedation is to be a person having the necessary theoretical knowledge and practical experience, both being obtained by attending a sedation course organized by a pertinent professional body.

Also, the American Society of Anesthesiologists (ASA) guidelines [2] strongly recommend that each sedated patient is to be connected to an oximeter, BP measured every 5 minutes, drugs are to be administered by a person understanding the principles of sedation and that person has to be a different one from that one who performs the imaging test.

The expert conclusion was that no request mentioned in the above protocols and guidelines has been respected by the physician in charge with the sedation of this patient.

The expert also mentioned the fact that the patient was a problematic one from the very beginning. He was a heavy smoker and most probably he had a certain degree of chronic obstructive lung disease (no test was performed in this direction before sending him for CT scan), he was also somnolent and confused, which means that the sedative drugs had to be titrated and by no means administrated intramuscularly, a way which does not permit dose adjustment. The fact that the patient suffered from chronic renal failure (in spite of renal transplantation which he had years before) demands special precautions and a cautious adjustment of sedative drugs administration, because in case of renal failure the central nervous system is very sensitive to sedation drugs [3]. Also selecting promethazine is considered an inappropriate decision. Promethazine is a long-acting hypnotic drug and this was one of the causes of prolonged somnolence of the patient at the end of the radiological procedure and during transport.

In summary, the expert opinion regarding the performance of sedation was that the physician in charge, by not respecting the specific indications and protocols, jeopardized patient's life and did not fulfilled his tasks as a professional.

2.Patient transport back to his department.

In his written opinion the expert summarized patient's condition at the moment the CT scan procedure ended: he was semi-comatose, did not react, nor to questions and (according to his son who was present during all the procedure) neither to verbal commends. There was no data about his vital signs, since nobody measured them and wrote down numbers in his chart. No member of the medical staff was near the patient at that very moment. The radiologist left the room immediately after the end of the scan procedure and the internal medicine physician left the patient minutes before.

The expert suggested that a more careful approach to the patient's condition just before transport would have lead the therapeutic team to the conclusion that the patient was in respiratory distress and most probably this situation would have indicated tracheal intubation and artificial ventilation, started by an anesthesia on call resident. In this case the presence of an anesthesiologist could solve the problem and avoid worsening patient's respiratory status.

The hospital assistant, accompanied by the patient's son, moved the stretcher from the Radiology department to the ward, some 300-400 meters distance, and most probably the trip took at least 8-10 minutes.

No monitor was connected to the patient during transport and nobody could witness when exactly the respiratory arrest happened. The only exact data we have are the ward nurse notes, specifying that immediately after she discovered apnea the patient developed cardiac arrest.

It is clear that a chain of mistakes is responsible for this very serious development: the patient was discharged from Radiology without being examined by an MD, and without making sure that he was stable enough for transport. No MD accompanied him during the transport, no oxygen was given and no monitor was connected to the patient during all those long minutes. All these important points are parts of the recommendations included in the textbook of Longnecker and collab., from the year of 1998 [4]. Miller et al were even more specific and they repeated exactly the same recommendations referring to the patient transport from the Radiology department [5].

The conclusions of the expert opinion stated that the patient fate was seriously endangered by a wrong decision-making process during all the stages of the radiologic examination. No monitor was used during all the procedure and transport, no oxygen added to improve pulmonary gas exchange, sedation drugs have been inappropriately selected and administered and the medical supervision was close to nothing.

The expert concluded that patient's death was a result of malpractice and that the outcome could be avoided if the medical staff would have taken correct decisions regarding patient care.

The defense brought to court its own expert:

This expert was also an experienced anesthesiologist, employed in a well-known anesthesia department in a tertiary referral medical center in Israel.

His written expert opinion referred to the main points of the plaintiff's expert:

1. Patient condition in the medical department was stable during the 36 hours which preceded the CT scan. True, he was somnolent, did not control his sphincters, but was easily arousable and could answer correctly to simple questions. This was the reason why the department staff did not decide to have a physician present during the radiological procedure and during patient transport back to his ward.
2. The resident on call accompanied the patient to the Radiology department, administered the sedation drugs, made sure that the patient is calm, stable and comfortable and left him because his presence was badly needed in his own department.
3. There was no need for the presence of an anesthesiologist during the procedure and immediately after this since the patient condition was stable. True, he was still somnolent, but this could be explained by the residual effects of the sedative drugs administered during the procedure.

4. Even if an anesthesiologist intervention was needed in this case, the penury of specialists in Anesthesiology in the Israeli hospitals, especially during on calls, weekends or holidays, made his availability very problematic. This is why the Israeli Ministry of Health permits the performance of sedation by non-anesthesiologists.
5. All over the procedure and immediately after it, the clinical judgment of the internal medicine physician and the radiologist in charge with the procedure was correct and based on patient's assessment and his stable condition.
6. Promethazine is a valuable sedative drug. It is used for premedication surgical patients before anesthesia and has also antihistaminic effects. One cannot forget the fact that even a patient premedicated with promethazine is led to the operating room without a physician presence, since in such a moderate dose as it used (same dose as that injected to the patient in discussion) it does not have untoward effects.
7. The cause of death in this case is not clear (autopsy was not permitted), since the patient survived in the Intensive Care Unit more than four months after the cardio-respiratory arrest and his immediate cause of death was generalized sepsis. It would be completely illogical to link the patient death to an event which took place four months before.

The defense expert conclusions expressed his opinion that no malpractice can be demonstrated in this very case. The ASA guidelines do not represent an official document in Israel, so its recommendations cannot be taken and accepted word by word. The clinical judgment of the therapeutic team was correct all over all stage, the sedation drugs well selected and dosage appropriate to patient's condition.

The CPR maneuvers have been started on the spot, at the moment cardiac arrest was diagnosed and the fact that the patient survived four more months proved that the resuscitation was successful.

How can one conclude the case?

Fortunately, in order to conclude this case, we do not need the judge verdict.

The idea behind the decision to publish this case was to bring to the attention of the practitioner a situation which can be easily encountered any time in any hospital which admits and takes care of patients who might need sedation for various situations, mostly outside the operating room.

It is an obvious fact that sedating a patient in a radiology or gastroenterology department, away of usual facilities existing in the operating room, creates a special situation and specific preventive measures are to be taken to assure patient's stability.

So, one can easily learn from the above case and draw the necessary conclusions to be applied in his/her own place of work.

Needless to say, the presented case rises some important questions, for which the answers are to be found in every single hospital, since the situation on the field is different from one country to another and from one hospital to another.

Here are the pertinent questions:

a. Was the selection of sedative drugs appropriate?
b. What had to be the list of vital signs to be instrumentally monitored during the ct procedure and transport?
c. What can be considered the cause of death in this case?
d. Could the presence of an anesthesiologist or of any other competent and experienced physician change the outcome?

It is crucial, for the sake of our future patients, to try and find the answers to the above questions, and check in what way the care for this kind of patient could be improved and fatal outcome prevented.

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