Enabling anticoagulated patients for a better compliance and medication adherence

**Doctor's responsibility to inform and instruct anticoagulated patients**
Presented by Alexander P. F. Ehlers, Lawyer, MD, Munich, Germany:

**Overview Anticoagulation**
About 6% of all over 60 years old patients are taking anticoagulants.

Main legal challenges:
- Medical malpractice if anticoagulants are given too late/ not prescribed in spite of risk factors.
- Influence of anticoagulation on accidents and damages.
- Choice of individual therapy and preparation.

**Legal situation of medical treatment**
- According to German law, every medical treatment is a personal injury according to §§ 223 ff of the German Penal Code (STGB), §823 of the German Civil Code (BGB).
- However, if the patient has declared consent, the doctor is justified.
- Required: informed consent.
- The lack of informed consent injures the right of self-determination of the patient (Art. 1 II, 2 I of the Constitution).
- The doctor has to respect the health status of the patient as well as his autonomy.
  ➔ „salus et voluntas aegroti suprema lex“
Informed consent is also professional duty according to §8 of the rules of professional practice and out of the treatment contract.

**Law on patient rights**
- Judicially defined principles regarding the requirements of the informed consent codified.
- §630c,e BGB: Explanation of all facts that are important for the medical treatment, especially:
  - diagnosis;
  - predictable health development;
  - therapy and medical treatment options;
  - alternative therapy options;
  - pharmaceuticals’ side effects.
- No obligation to inform and explain ordinary risk!
- §630d BGB: Doctor is required to have patients’ informed consent before any medical action is taking place.

**Doctors’ challenges**

**Medical malpractice**
The German Medical Service of the Health Funds (MDK) defines the medical malpractice basically broader than civil courts.
According to that, a case of medical malpractice encompasses:
- the omission of the required medical treatment;
- a medically not necessary intervention or
- a treatment that does not fulfill current standards.
Anticoagulated patients and informed consent

- Extend of the patient’s education depends on how dangerous pharmaceuticals can be.
  → The more risks are related to a drug, the more details must be discussed with the patient.
- Explanation about side effects of the respective preparation and required patient’s behaviour.
- Doctor depends on communicated symptoms. However: If patient seems to have losses in sensory perception, the doctor needs to foresee special risks.
- Clear documentation of medical treatment!

Doctor’s liability

Consequences of a lack of patient’s education:

- If the medical malpractice or lack of education are proven to be causal of the damage, the doctor is liable and needs to pay compensation.
- Criminal prosecution with respect to negligent physical injury or homicide.
- Crucial: Documentation of informed consent.

Cases of medical malpractice associated with anticoagulants

Higher Regional Court of Hamm (Germany), Decision of 32.20.3007 (3 U 47/07) and Decision of 12.08.2013 (3U 122/12)

- Accumulation of risk factors indicate the need for anticoagulation.
- If the patient already had a myocardial infarction, the doctor is liable due to medical malpractice if no prescription of anticoagulation.
- Only in case patients had lone atrial fibrillation and no other risk factors, doctors can prescribe ASS.
- If stroke occurs anyway, doctor is not liable if the stroke has occurred also under anticoagulant therapy.
- Medical malpractice, if a radiologist does not involve a neurologist in case of a suspected stroke.

Cases of medical malpractice associated with anticoagulants

Higher Social Court of Schleswig-Holstein, Germany, Decision of 18.01.2007 /L1 U 48/06

- Anticoagulation in connection with a stem cell donation can lead to increased tendency to bleed. This can cause a subdural haematoma.

If this leads to a brain damage, the accident insurance of the clinic needs to cover the damage.
- Any pre-existing disease is irrelevant in that case.

Choice of anticoagulation

Efficiency principle, §§2, 12 SGB V: The most effective preparation for the individual patient to the lowest costs has to be prescribed.

Guidelines of the Drug Commission of the German Medical Association:

- Standard Therapy: Vitamin-K antagonists
- New preparations:
  → Doctors need to justify the need because of 20x higher costs,
  → doctors need to explain possible adverse events in advance (no antagonism in case of an acute bleeding, lower possibility of lysis treatment in case of a stroke).

Take home messages

- Detailed patient’s education and documentation of the medical treatment as well as the informed consent.
- Analyze patient’s risk factors carefully.
- Chose preparation individually.

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Following the lecture of Alexander Ehlers a round of talks took place. „Five minute medicine: What can be done to improve the anticoagulation therapy?“ Moderator Alexander P. F. Ehlers, Lawyer, MD, (right) discussed with (from left to right) Ron van’t Land, MD, The Netherlands; Benjamin Dieplinger, MD, Austria; Hannelore Rott, MD, Germany; Gentian Denas, MD, Italy; Preben Mandrup Johansen, Denmark and Ludovic Drouet, MD, France.