The sudden unexpected death in epilepsy (SUDEP)

SUDEP (sudden unexpected death in epilepsy) is a sudden event in a person suffering from epilepsy that is associated with the death of the patient.[1] In a SUDEP, 90% of people suffer a fatal cardio-respiratory or cerebral dysfunction.[2]

The incidence of SUDEP is on average 3 cases per 1000 patient years.[2,3,4,5] In people with difficult-to-treat epilepsies, the incidence increases to up to 9 cases per 1000 patient years.[6,7] The lifetime risk of SUDEP is particularly high in people who have had epilepsy since childhood or adolescence: it is about 7 to 8%.[8] Overall, SUDEP is the causative cause of 5% to 20% of premature deaths in epilepsy patients.[9]

20%

SUDEP is the cause of 20% premature death from epilepsy

There are different risk factors for a SUDEP[9]:

- Male sex
- Beginning of epilepsy at a young age (<16 Years)
- Symptomatic cause of epilepsy (pathological changes in the brain, e.g. due to acute brain diseases, craniocerebral traumas, intracerebral haemorrhages, cerebral infarctions, brain abscesses)
- Longer epilepsy duration
- Nightly epileptic seizures
- Prone position during sleep
- Polytherapy
- Irregular medication use

The risk of SUDEP increases with the number of epileptic seizures per year. However, the most relevant and strongest risk factor is the occurrence of bilateral tonic-clonic seizures.[10]

What are tonic-clonic epilepsy seizures?

Epileptic seizures can be primarily generalized or focal in onset. The spread of epileptic activity over the entire brain in a bilateral tonic-clonic seizure (also known as a “grand mal”), represents the most dangerous form of epileptic seizures.

Tonic-clonic epileptic seizures occur in three phases:

1. Tonic phase
Unconsciousness, fall, stiffening of the entire body, short respiratory arrest (>1 minute) and pupils stiff as light.

2. Clonic phase
Rough twitching in the face and arms, legs and trunk.

3. Post-phase:
Return of consciousness, resumption of breathing and state of exhaustion.

„Generalized tonic-clonic seizures occur in two phases: In the first phase the affected person loses consciousness, his extremities, but also his breathing becomes tense. In the second phase, rhythmic twitching occurs, which is also associated with a high risk of injury. However, it is critical that in both phases breathing does not function normally, which can lead to a lack of oxygen - especially in the brain".

Prof. Dr. med. Andreas Schulze-Bonhage
Head of Department at the Epilepsy Center of the University Medical Center Freiburg (European Reference Center)

In general, a tonic-clonic seizure can also develop from a focal seizure. Generalized tonic-clonic seizures can lead to suppression of cardiorespiratory functions in the early post-ictal phase and are therefore considered a relevant risk factor for SUDEP, as they can lead to death within about 10 minutes after the end of the seizure.

The role of cardiac dysfunction in epileptic seizures

In connection with epileptic seizures, a large number of different cardiac dysfunctions of varying severity occur very frequently.[11] In most cases (in 80-90% of all seizures) an increase in heart rate is already measurable at an early stage.[12] In generalized tonic-clonic seizures, the heart rate increases to 150 beats per minute on average.[13]

„Tonic-clonic seizures usually last 80 to 120 seconds. However, breathing and heart rate can still be severely disturbed afterwards, which can result in a SUDEP. Therefore, rapid assistance - preferably within 3 minutes - is important in the case of a nocturnal tonic-clonic seizure".

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Recommendations[2,8] to avoid a SUDEP

Frequently, a generalized tonic-clonic seizure - and thus also a SUDEP - can be prevented by drug control. In this context, comprehensive education of the epilepsy patient about the risks is an important instrument that can contribute to improving patient adherence. If drug therapy is not an effective option, successful epilepsy surgery or vagus nerve stimulation can reduce the risk of SUDEP. An additional measure is the nocturnal monitoring (supervision) of epilepsy patients. This can be done either by having another person sleep in the patient‘s room or by using electronic warning devices (e.g. NightWatch). In addition, relatives as well as nursing staff should be trained in performing cardiopulmonary resuscitation.

SUDEP – Key Facts

- Unexpected death in epilepsy
- Especially high risk for patients with generalized tonic-clonic seizures
- Risk reduction through seizure control, patient education and monitoring

> *„Un-controlled patients who continue to suffer many seizures are particularly at risk. This can be caused by a lack of adherence, but patients who have to take many drugs at the same time are also at risk. If these patients suffer many nocturnal tonic-clonic seizures and are poorly monitored, there is a high risk of a fatal event“.*
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> **Prof. Dr. med. Andreas Schulze-Bonhage**

Opportunities for patients and relatives to reduce SUDEP risk

Successful drug therapy is crucial for seizure control. Although this is prescribed by the treating physician, patients and relatives make an important contribution by ensuring that the medication is taken regularly (compliance).
In addition, comprehensive education about epilepsy and SUDEP is important. Furthermore, relatives and also nursing staff can enable the rapid initiation of life-sustaining measures in the case of SUDEP by monitoring the endangered epilepsy patient at night (e.g. using warning devices). This is because 86% of SUDEP cases occur when those affected are unobserved[14], 90% of them at night, in the period between 10 p.m. and 6 a.m.[4]

The risk of SUDEP can be reduced by 69%[15] by not allowing epilepsy patients to sleep unattended.

Examples of technical monitoring methods for seizure control

Bed sensors: To monitor the nightly sleep of people with epilepsy, mattresses are equipped with a so-called bed sensor as standard. These sensors detect movements of the person concerned during sleep and can trigger an alarm if necessary via a special control unit. However, since tonic-clonic seizures in particular often begin initially with a stiffening of the body, such critical events are often registered by the bed sensors too late or not at all.

Surveillance wearables: The novel wearables (e.g. NightWatch) are attached to the upper arm of the affected person before falling asleep. NightWatch not only registers the nightly movements during sleep, but also controls the heart rate. Thus it detects 9 out of 10 clinically relevant seizures - in particular tonic-clonic seizures - at an early stage. Compared to bed sensors, NightWatch detects clinically relevant nocturnal seizures 3 times more frequently.[16]

> *„Recently, there have been good, new developments in the field of night-time surveillance. Particularly noteworthy here are devices that the patient can wear while sleeping. These are similar to a Smartwatch and measure movements as well as heart rate. If a nocturnal tonic-clonic seizure is registered, the devices immediately trigger an alarm and inform caregivers. Compared to conventional bed sensors, these wearables are much more sensitive. The sensitivity is very high with an average of 90% detected tonic-clonic seizures".*
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> **Prof. Dr. med. Andreas Schulze-Bonhage**

> *„My son's attending physician had recommended NightWatch to us because my son repeatedly has tonic-clonic as well as static seizures, which the bed sensor used until then did not reliably register. Thanks to NightWatch this has now changed. The detection rate is many times better - finally almost every seizure is detected. Not only we, but also the nursing staff is enthusiastic about the device. It is easy to use, so that my son can also handle it. I would advise every affected person to apply for such a device".*

Katja B.
Mother of a 30-year-old son suffering from generalized epilepsy

NightWatch - safe and effective seizure detection system

Since 2018, NightWatch has been an effective monitoring device that alerts patients, parents/carers and nursing staff in the event of an epileptic seizure occurring during sleep. NightWatch was developed by the epilepsy centers Kempenhaeghe and SEIN (Netherlands) and was created in cooperation with the University Hospital Utrecht and the Technical University Eindhoven as well as patient organizations.

NightWatch consists of a wireless, comfortable arm module that precisely detects the heart rate and movements of the wearer while he or she is lying in bed. As soon as NightWatch suspects a severe epileptic seizure, a wireless alarm signal is transmitted to the caregiver in the other room via the associated base station.

NightWatch is suitable for professional care facilities and for private use.

Advantages of NightWatch:

- Reduces the risk of medical complications by detecting critical seizures at an early stage and informing caregivers
- Provides additional security
- Easy to use
- Can be linked to existing nurse call systems
- Can improve the quality of care and relieve caregivers/nurses

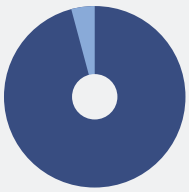
Clinical study proves: NightWatch detects clinically relevant nocturnal seizures better than bed sensors

In a multicenter, prospective, video-controlled cohort study[16] in the home environment, the sensitivity of two different technical monitoring methods (NightWatch arm module and bed sensor) was investigated. Over a period of three months, a group of 28 patients, each of whom suffered more than one nocturnal, clinically relevant seizure per month, were fitted with a NightWatch arm module attached to their upper arm. Tonic-clonic seizures, tonic seizures lasting more than 30 seconds, hyperkinetic and clustered myoclonic seizures were classified as clinically relevant seizures. The control group consisted of 14 subjects from the original group. These were additionally monitored by a bed sensor in the mattress, which is considered the monitoring standard.

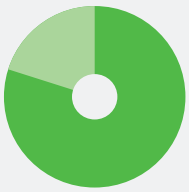
When used while sleeping, the NightWatch arm module registered movements (measured by 3D accelerometry) and controlled the heart rhythm (by photoplethysmography). In addition, all nocturnal seizures were confirmed by video and audio. A total of 1826 nights were monitored and 809 clinically relevant seizures were observed.[16]

The sensitivity of NightWatch was significantly higher. Compared to the control NightWatch detected nightly seizures much better: While the bed sensor detected only 3 of 10 seizures, 9 of 10 cases were registered with NightWatch. The improved control due to the high sensitivity was also appreciated by the caregivers involved: In an evaluation questionnaire, the majority stated that NightWatch is easy to use, provides more peace and freedom and reacts earlier when urgent help is needed.[16]

NightWatch detects:



96%
all tonic clonic seizures



80%
all other clinically urgent seizures including generalized tonic, hyperkinetic, and clustered myoclonic seizures

Conclusion: To avoid a SUDEP, clinically relevant epilepsy seizures must be detected quickly and better

Clinically relevant seizures such as tonic-clonic are associated with a high risk of SUDEP. Due to the short duration of such seizures, rapid detection is very important so that relatives/caregivers or nursing staff can quickly provide help to prevent a fatal event. Usually only 3 to 10 minutes remain. New monitoring systems such as NightWatch can help to quickly register 90% of the nightly clinically relevant seizures and immediately alert caregivers.

NightWatch detects different types of epileptic seizures with a high degree of accuracy, for example:

- Tonic seizures
- Tonic-clonic seizures
- Hypermotoric seizures
- Grouped myoclonic seizures

How does the NightWatch system work?

NightWatch Arm Module

Sensors in the arm module measure change in heart rhythm and movements

- Reliably and accurately measures heart rate and movement at night
- Individually adaptable
- Easy to operate
- Immediate signal transmission to base station if danger is detected

NightWatch Base Module

Possible clinically urgent seizures are detected and transmitted to the base station.

- Reliable seizure detection for every caregiving system
- Safe and stable wireless connection
- Monitors and gives insight

The base station is prepared as standard for connection to all common nurse call systems in order to transmit clinically relevant seizures directly to the nursing staff.

Optional GSM module

If the wearer of the NightWatch lives independently, a special GSM module optionally offers the possibility to call up to 5 phone numbers of selected caregivers in case of clinically relevant seizures. In addition, this module is equipped with an emergency call button which the wearer can press for immediate help if necessary.

NightWatch Portal

The NightWatch records all movements and heart rate during the night. The recorded data can be retrieved and stored via the NightWatch portal. To do so, the NightWatch only needs to be connected to the Internet and linked to the portal. The readout and storage of the data enables long-term seizure control and also allows statements about the intensity of individual seizures.

You can find more information about NightWatch and ordering options on the Internet at www.nightwatchepilepsy.com

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