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Review

Sudden unexpected death in epilepsy (SUDEP): Development of a safety checklist

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ABSTRACT

Purpose: The incidence of sudden death appears to be 20 times higher in patients with epilepsy compared with the general population. Epilepsy-related death, particularly sudden unexpected death in epilepsy (SUDEP), is still underestimated by healthcare professionals and this may reflect the mistaken belief that epilepsy is a benign condition. The risk of death associated with epilepsy appeared rarely to have been discussed with patients or their families. It appears the decision to discuss SUDEP and also to peg SUDEP risk is arbitrary and clinical. Unfortunately there is no structured evidenced mechanism at present to represent person centered risk of SUDEP and there is currently no easy manner or template to have this discussion with the family and the patient.
Methods: We conducted a detailed literature review in Medline, Embase and Psychinfo databases to extract the common risk factors as evidenced from literature till date. Research into risk factors has identified a number of risk factors for SUDEP, some of which are potentially modifiable.
Results: Based on the literature review, we believe that the ascertained risk factors could be employed in clinical practice as a checklist to reduce an individual patient's risk of SUDEP. The SUDEP safety checklist may be of practical use in reducing risks in some individuals and is definitely of use in helping communication.
Conclusions: An evidence based checklist identifying the major risk factors can help both clinicians and patients to focus on minimizing certain risk factors and promote safety by focusing on the modifiable factors and guide treatment. It can be a tool to open a person centered discussion with patients and to outline how individual behaviors could impact on risk.

1. Introduction

Epilepsy is a major global health problem; it is the most common chronic disabling condition of the nervous system affecting an estimated 50 million people worldwide[1] and around 400,000 people in the UK.[2]

Epidemiological studies consistently report a standardized mortality rate (SMR) of 2–4 for epilepsy. In newly diagnosed epilepsy, death is largely attributable to the underlying disease (for example, vascular disease, and tumor). In chronic epilepsy, however, the main cause of excess mortality is death during a seizure: sudden unexpected death in epilepsy (SUDEP).

SUDEP is estimated to account for 500 deaths a year in the UK.[5] The incidence of sudden death appears to be 20 times higher in patients with epilepsy compared with the general population, and SUDEP is the most important directly epilepsy-related cause of death. However, the risk varies markedly between different epilepsy populations. SUDEP is uncommon in patients with new onset epilepsy and in patients in remission where the incidence has been estimated to 0.1–0.35 cases in 1000 person years in population-based cohorts of epilepsy patients. It is considerably higher in patients with chronic epilepsy, 1–2 per 1000 person years, and highest among those with severe, refractory seizures, 3–9 per 1000. SUDEP may occur at all ages, with highest rates between 20 and 40 years. In most cases SUDEP appears to be seizure-related.[6]

Epilepsy-related death, particularly SUDEP, is still under-estimated by healthcare professionals and this may reflect the mistaken belief that epilepsy is a benign condition. The risk of

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death associated with epilepsy appeared rarely to have been discussed with patients or their families. There was little documented evidence of contact with bereaved relatives after death;[2] leading to significant emotional trauma when SUDEP happens leaving families and clinicians searching for answers. It is important for people with epilepsy and their families to be aware of the risks associated with epilepsy. A small number of people have a risk of sudden death due to their epilepsy. Most people who know somebody who has died due to epilepsy say they wished they had known more about the risks before the person died.

The NICE and SIGN guidelines both advocate discussion of SUDEP with the patient at the earliest.[5,25] A fatal accidental enquiry into two epilepsy deaths concluded in 2011 that the risk of SUDEP should be advised to patients and carers unless in the case of a particular patient there is a risk of serious harm. It also advised that the information and advice about SUDEP should be provided directly by the consultant in charge of the patient's case or, where appropriate, by an epilepsy specialist nurse.[5] On the other hand clinicians working in epilepsy feel that bringing the issue of death into preliminarily consultations could have a stigmatizing effect while also having an impact on the therapeutic relationship. A survey among UK neurologists showed that only 4.7% of them discussed SUDEP with all patients and 25.6% with the majority. The rest discussed the risk of SUDEP with very few or no patients.[16] A recent retrospective case note series shows only 4% recorded a discussion of SUDEP.[17] It appears the decision to discuss SUDEP and also to peg SUDEP risk is arbitrary and clinical. Unfortunately there is no structured evidenced mechanism at present to represent person centered risk of SUDEP and there is currently no easy manner or template to have this discussion with the family and the patient.

An evidence based checklist identifying the major risk factors can help both clinicians and patients to focus on minimizing certain risk factors and promote safety by focusing on the modifiable factors and guide treatment. It can be a tool to open a person centered discussion with patients and to outline how individual risk factors could impact on overall risk.

For patients it opens up discussion around a sensitive, complex and difficult topic. It gives better understanding of what risk factors lay in the locus control of the patient and which are not. It helps patients make informed choices. A recorded person centered discussion would help reduce corporate risk and potential complaints too.

We wished to review the available literature to inform the development of a safety checklist for sudden death in epilepsy (SUDEP). The SUDEP safety checklist may be of practical use in reducing risks in some individuals.

2. Methodology

We conducted a search in Medline, Psychinfo and Embase databases with the following keywords: Risk AND factors combined with SUDEP, sudden AND death AND in AND epilepsy, sudden death in epilepsy.

52 studies were initially identified using these criteria. These considered many putative risk factors for SUDEP from progressive deterioration in heart rate variability to thalamic nuclear abnormalities.[7–15] Many studies were seeking to elucidate potential mechanisms for SUDEP using a small number of cases from a specialist center. Relatively few studies involved a population based sample. We decided to restrict our review to population based studies where a control group was employed.

3. Results

Nilsson et al. conducted a retrospective nested case control study in Stockholm with the objective of investigating the association between several clinical variables and SUDEP.[18] The 6880 population studied was limited to those who had been admitted to hospital with a diagnosis of epilepsy in the study period. The authors estimated that 60% of the adult epilepsy population of Stockholm was included in the cohort. Case ascertainment was based on a national cause of death register and the authors' criteria for a SUDEP case. Each case was compared with 3 randomly selected controls. The authors excluded four cases from their analysis who had received AED treatment for less then one year.

The authors found the largest increase in relative risk for SUDEP associated with seizure frequency greater then 2 per year with escalating relative risk for higher frequencies (RR 10.16 for more than 50 seizures per year). The authors did not distinguish between seizure types. The risk of SUDEP increased with increasing number of antiepileptic drugs taken concomitantly – 9·89 for three antiepileptic drugs compared with monotherapy. When the authors statistically controlled for seizure frequency this association persisted. Among men the RR for SUDEP was 17.64 in those whose epilepsy had its onset prior to age 15 compared with onset after age 45 with a weaker trend in the same direction for females. Frequent changes of AED dose (3–5 dose changes) in the last year compared with no changes were associated with an RR of 6.08. A threefold increase in RR was seen in those taking anxiolytic medications, especially men.

In relation to seizure frequency the authors had a category of unknown. This group represented patients who were not seizure free, but in whom medical notes were not sufficiently detailed to allow further calculation. This group had the strongest association with SUDEP of all seizure frequency groups (RR = 15.04). The authors did not find an increase in RR for SUDEP in the following groups: patients with heart disease, cerebrovascular disease or alcoholism. They did find an increase in RR in patients with a history of injuries (non CNS).

Walczak et al. conducted a prospective cohort study in 3 centers in the Midwest of America of patients presenting to epilepsy centers.[19] In all they prospectively followed up 4578 patients for a total of 16,463 patient-years. The majority of patients underwent extensive evaluation including identification of epileptiform discharges on interictal EEG or electrographic seizures (90% of cohort), AED levels and seizure type. 111 deaths in the study period were reviewed against SUDEP criteria by a committee of investigators including a SUDEP expert. There was a cross checking mechanism permitting identification of unreported deaths.

Deaths were classified as definite or probable SUDEP, possible SUDEP and non SUDEP. The following risk factors were studied: age at enrolment, gender, number of seizures of any sort in 12 months prior to last visit, number of tonic–clonic seizures in the 12 months preceding the last visit and duration of epilepsy. The authors also examined the effect of mental retardation, epileptogenic structural lesions; number of AED used at last visit, psychotropic drug use and whether AEDs were at therapeutic levels. Ten risk factors were examined in total by the group where there were 20 cases of SUDEP (definite or probable).

The authors found a progressive increase in the risk for SUDEP with increased seizure frequency (any seizure type) which was significant only when there were more than 50 seizures per month (OR = 11.5). When Generalized Tonic Clonic Seizure (GTCS) were examined specifically as few as 1–3 per year were associated with an increased risk of SUDEP (OR = 2.4). Greater then 3 GTCS per year were associated with an OR of 8.1.

They also found an association between long duration of epilepsy (>30 years) and SUDEP (OR = 13.9). Likewise mental retardation (IQ < 70, as measured by WAIS) was associated with SUDEP with an OR of 5. The number of AEDs used remained a risk

factor after adjusting for the number of all seizures (OR = 3.8) and GTCS (OR = 3).

The main strengths of this study were that it was a population based prospective cohort study in which epilepsy diagnoses were secure. In the majority of patients a range of clinical information was available e.g. AED levels. Weaknesses included the number of associations tested for when there were only 20 cases, some cases did not undergo post mortem examination and that the population was one attending epilepsy centers so that the severity of epilepsy may have been higher than in a purely geographically identified population.

Langan reported a retrospective case control study of SUDEP based on deaths identified through the coroner, neurologists or bereaved families.[20] Controls (4 per case) were taken from the MRC General Practice Research framework. 154 cases in which an autopsy was performed were identified. Odds ratios for fourteen putative risk factors were determined by backward stepwise conditional logistic regression analysis. Variables with more than 35% of the data missing were excluded from the analysis. The analysis controlled for frequency of convulsive seizures so that the effect of other variables could be assessed independently of their relationship to seizure frequency.

A history of generalized tonic–clonic seizures (OR = 13.8) and a high frequency of them in the recent past (OR > 10 for more than 10 GTCS in previous 3 months) were associated with a significant increase in the risk of SUDEP. The authors' findings suggested an association with Carbamazepine and SUDEP but the OR of 2 had a 95% confidence interval including 1. The authors did not find current polytherapy an independent risk factor for SUDEP, but did find that greater numbers of AEDs ever taken were associated with higher risk as was an unclear treatment history and no treatment.

The presence of supervision at night was found to be protective against SUDEP (OR = 0.4) when a supervising individual shared the same bedroom or when special precautions such as a listening device were employed (OR = 0.1).

Hesdorffer et al. pooled the data from four published case control studies which had live controls to increase power to determine risk factors.[24] They aggregated data from the Nilsson et al. (1999), Walczak et al. (2001), Langan et al. (2005) and Hitiris et al. (2007). We have described three of the four (excluding Hitiris et al., 2007) in detail above. The pooled data had a total of 289 cases and 958 controls. Chief risk factors which were prominent included increase in frequency of generalized seizures, duration of epilepsy, young age of onset, gender, symptomatic etiology and Lamotrigine therapy. The pooled data results were largely consistent with the findings of the results of the individual studies though the analysis revealed certain significant variances. In particular they identified hitherto unassociated factors such as Lamotrigine therapy, male gender and symptomatic etiology. As with any combined analysis this work is vulnerable to the heterogeneous nature of the study population and methodology employed in the individual studies.

Hughes et al. attempted to provide up-to-date quantitative data from published reports on sudden unexpected death in epilepsy (SUDEP) appearing on Medline and, especially, to provide a means to predict the probability of SUDEP in a given patient.[12] The mean incidence of SUDEP was 1.8/1000, similar to the median of 1.5. The mean standardized mortality ratio was 6.8, and the mean percentage of SUDEP cases among deaths from epilepsy was 16.6. Seventeen risk factors were identified, each given a value according to the number of studies in the literature that specified that condition as a significant risk. The addition of these 17 values then indicated the risk for a given patient. The author calculated these for a group of 91 patients who died of SUDEP and also for 91 live control patients with epilepsy. Many of the values for the SUDEP cases were significantly different. The sensitivity of the risk factor analysis was 71.3%, the specificity 81.8%, and the positive predictive value 84.6%. A discussion includes the question of whether the death in SUDEP is primarily due to cardiac or pulmonary mechanisms and a suggestion that it may be either or both in a given patient. The most important risk factor in this study was non-compliance with antiepileptic medication, and the main message of this study to caregivers is that therapeutic drug levels are crucial to avoid SUDEP.

Monte et al. aimed to review systematically risk factors for SUDEP and also to determine their relevance for SUDEP by calculating relative risk factor ratios.[13] The authors performed a literature-search on "SUDEP". Studies with unknown number of SUDEP cases or those with less than five SUDEP cases and reviews were excluded from further analysis. The value of each paper was assessed, based on the quality of the study and the reliability of the diagnosis of SUDEP. This value ranged from 1 (low quality) to 10 (high quality). Papers with a value below 7 were eliminated for further analysis. For each analyzed factor, a risk factor ratio was determined, with a higher ratio for a stronger risk factor.

With this methodology the authors identified a number of strong risk factors for SUDEP: young age, early onset of seizures, the presence of generalized tonic clonic seizures, male sex and being in bed. Weak risk factors for SUDEP included prone position, one or more subtherapeutic blood levels, being in the bedroom, a structural brain lesion and sleeping. The authors used a transparent methodology for identifying risk factors and rating the quality of studies. They acknowledge that their risk factor value method has not been validated previously. Excluding studies with less than 5 SUDEP cases may have failed to identify risk factors of small effect.

Tellez-Zenteno et al. did a systematic review to provide an evidence-based analysis of the risk factors and incidence of SUDEP, and to assess methodological aspects and sources of variation in studies dealing with SUDEP.[21]

They searched Medline, Index Medicus, and the Cochrane library and included case-control or cohort studies focusing on SUDEP in children or adults, published in the English language. They found 404 citations, 83 potentially eligible articles were reviewed in full text and 36 studies fulfilled eligibility criteria (29 cohort and 8 case-control studies). They drew a distinction between the findings in studies using non-SUDEP deaths as controls and studies using living patients with epilepsy. For the first category the most consistent risk factors were a seizure preceding death, and subtherapeutic antiepileptic drug levels. In studies that used persons living with epilepsy as controls the main risk factors for SUDEP were youth, high seizure frequency, high number of antiepileptic drugs and long duration of epilepsy. They found an annual incidence of SUDEP ranging from 0 to 10/1000. It was highest in studies of candidates for epilepsy surgery and epilepsy referral centers (2.2 to 10/1000), intermediate in studies including patients with intellectual disability (3.4 to 3.6/1000), and lowest in children (0 to 0.2/1000). The incidence was similar in autopsy series (0.35 to 2.5/1000–) and in studies of epilepsy patients in the general population (0 to 1.35/1000). The median proportion of SUDEP in relation to overall mortality in epilepsy was 40 and 4% in high- and low-risk groups, respectively.

The authors concluded that although studies on SUDEP are heterogeneous in methodology, consistent patterns in incidence and risk factors emerge. Low- and high-risk patient groups are identified, which determine the relative contribution of SUDEP to overall mortality in epilepsy. In addition to patient population, risk factors for SUDEP depend on the type of controls used for comparison (dead versus live patients with epilepsy). Risk factors found in different studies are not necessarily contradictory, but are often complementary.

Table 1
Statistics of salient findings of relevant studies.

Risk factor	Range	Cases *n*	Controls *n*	OR (95% CI)	Authors
Early onset of epilepsy in men	>45 yrs	4	25	1.00 (reference)	[18]
	<15 yrs	11	10	17.64 (2.65–117.60)	
Full scale IQ (WAIS)	>79	5	36	1.00 (reference)	[19]
	<70	7	10	5.0 (1.3–19.3)	
Presence of supervision at night	None	109	169	1.00 (reference)	[20]
	Same room	34	156	0.4 (0.2–0.8)	
Number of concomitant AEDs	1	22	115	1.00 (reference)	[18]
	3	12	7	9.89 (3.20–30.60)	
Time since last anticonvulsant prescription	<90 days	8250	10847	1.00 (reference)	[22]
	≥365 days	908	5019	0.24 (0.22–0.26)	

Ridsdale et al. did not look at SUDEP exclusively, but considered epilepsy mortality rates in a UK general practice database.[22] We included their study in our review because of the large population followed up and the finding of 3 risk factors for general mortality in epilepsy coinciding with risk factors identified in SUDEP specific studies. A nested case control study design was used and 434 GP practices were included involving 3.3 million patients in 2007. The study time frame was 1993–2006 and patients with epilepsy dying of any cause were included in the analysis. Over the period the prevalence of epilepsy in the study population increased from 9/1000 in 1993 to 12/1000 in 2007. Epilepsy deaths also increased in this period. The authors found mortality to be associated with:

1. Recorded alcohol problems, OR = 2.96.
2. Collection of AED 3–6 months ago, OR = 1.83.
3. Having an injury in the previous year, OR = 1.41.
4. Treatment for depression, OR = 1.39.

By contrast the authors found being recorded seizure free in previous 12 months (2004 data onwards) was associated with lower mortality, OR = 0.78. It is important to recognize that this study looked at epilepsy mortality in general and not SUDEP in particular.

The statistics for some of the major studies in this paper are shown in Table 1. The available data seems to suggest that the following are well-recognized risk factors for SUDEP:[13,15]

- Having uncontrolled generalized tonic–clonic seizures.
- Not taking anti-epileptic drugs (AEDs) as prescribed.
- Having tonic clonic seizures that are not controlled by AEDs.
- Having sudden and frequent changes to AEDs.
- Being a young adult (in particular male).
- Having sleep seizures.
- Having seizures when alone.
- Drinking large amounts of alcohol.

4. Discussion

Our literature review identifies certain factors which appear to have a higher risk potential contributing to SUDEP than others. We could not find any papers where this research has been transferred into a communication tool or a risk safety list to engage patients in as we propose to do.

While it is not yet known how to prevent SUDEP, one needs to see if we can minimize the risk factors which might lead to SUDEP. An evidence based risk checklist (Appendix 1) can help both clinicians and patients to focus on minimizing certain risk factors and promote safety.

For clinicians it would be an objective and quick way of looking at risk factors of SUDEP, especially the modifiable factors. It could help guide treatment by being a potential reflector of change in status in risk and help justify their actions. It would also help as a tool which can be used as a medium to open discussion with patients who have risk factors and to outline how individual behaviors could impact on risk (for example – lack of compliance seen in association with types of seizures happening could be highlighted on the checklist and shown during discussion which might then bring about insight in the patient).

For patients it opens up discussion around a sensitive, complex and difficult topic. It gives better understanding of what risk factors lay in the locus control of the patient and which are not. It helps patients make informed life style choices.

From a corporate perspective[23] there is clarity in recording of discussion in a structured evidence manner and evidence of change. No attempt has been made to rank these risk factors. The tool can be used in daily clinical practice as it is simple and quick to use. A copy of the checklist could be placed in the patient's medical notes as evidence. Where an overall SUDEP risk rating is increasing in relation to the individual the clinical team can intervene to mitigate the risks or use it to evidence the difficulty in changing the risks inspite of attempts to reduce risk.

Therefore it would help quantify certain risk issues linked to SUDEP and to raise awareness of them in partnership with the patient and carer with a view to promoting safety in a structured manner.

Our thanks to SUDEP Action for the educational Grant and support we received to develop the checklist.

Conflict of interest

None declared.

Appendix A

SUDEP safety checklist

Static factors	evidence	present /absent
Male sex	Descriptive studies commonly found, but not replicated in controlled studies.	
Duration of epilepsy (15-30years)	Suggested by several studies, but not after multiple logistical regression analysis for seizure frequency	
Unclear treatment history	Reported finding	
Primary generalised epilepsy (in men only)	Few studies small numbers	
Intellectual disability	Limited evidence	

Modifiable factors

Severity of seizures	Not quantified in studies	
Number of AEDs	Has been reported (not universally)as an independent risk factor (after correction for seizure frequency)	
Compliance issues	Implied by finding of variable AED hair strand levels in SUDEP group of controls. Not collected AED last 3 months (Ridsdale et al 2011).	
Frequent AED prescribing changes	Implied by finding of variable AED hair strand levels in SUDEP vs. group cf controls	
Sub therapeutic AED levels	Not found to be a factor in most studies	
Lamotrigine	Hesdorffer et al study on combining the data of the 4 case control studies in SUDEP	
Carbamazepine	Small number of studies have implicated as independent risk factor	
Reported alcohol problem	Ridsdale et al 2011: associated with overall increase in mortality	
Treatment for depression	Ridsdale et al 2011: associated with overall increase in mortality	
Anxiolytic medication	Nilsson et al 1999	

Moderate risk-static factors

Younger age	Commonly found in descriptive studies, but biases exist. In controlled studies 70-80% less than 45 yrs old.	

Moderate risk-modifiable factors

No surveillance at night	Several studies independent risk factor	
Prone position	Several studies independent risk factor	
Failed assessment for epilepsy surgery	Higher SUDEP incidence if no surgery cf successful VNS	

Established risk-static factor

Early onset of epilepsy	Several controlled studies suggest increased risk. 8 fold increased risk age 0-15 reported in one controlled study (cf >45yrs)	

Established risk-modifiable factor

High seizure frequency esp. convulsive seizures	Several descriptive and large case control studies, but not all found increased risk	

SUDEP Safety Checklist Version 1.0 dated 11th September 2012

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