Survival and Long-term Outcomes Following in-hospital Cardiac Arrest in a Swiss University Hospital: a Prospective Observational Study

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Abstract

Background: Incidence of in-hospital cardiac arrest is reported to be 0.8 to 4.6 per 1,000 patient admissions. Patient survival to hospital discharge with favourable functional and neurological status is around 21%. The Bern University Hospital is a tertiary medical centre in Switzerland with a cardiac arrest team from the Department of Anaesthesiology and Pain Medicine that is available 24 h per day, 7 days per week. Due to lack of central documentation of cardiac arrest team interventions, the incidence, outcomes and survival rates of cardiac arrests are unknown. The aim was thus to record all cardiac arrest team interventions over 1 year, and to analyse the outcome and survival rates of adult patients after in-hospital cardiac arrests.

Methods: We conducted a prospective single-centre observational study that recorded all adult in-hospital cardiac arrest team interventions over 1 year, using an Utstein-style case report form. The primary outcome was 30-day survival after in-hospital cardiac arrest. Secondary outcomes were return of spontaneous circulation, neurological status (after return of spontaneous circulation, after 24 h, after 30 days and 1 year), according to the Glasgow Outcomes Scale, and functional status at 30 days and 1 year, according to the Short-form-12 Health Survey.

Results: The cardiac arrest team had 146 interventions over the study year, which included 60 non-life-threatening alarms (41.1%). The remaining 86 (58.9%) acute life-threatening situations included 68 (79.1%) as patients with cardiac arrest. The mean age of these cardiac arrest patients was 68 ±13 years, with a male predominance (51/68; 75.0%). Return of spontaneous circulation was recorded in 49 patients (72.1%). Over one-third of the cardiac arrest patients (27/68) were alive after 30 days with favourable neurological outcome. The patients who survived to 1 year after the event showed favourable neurological and functional status.

Conclusions: The in-hospital cardiac arrest incidence on a large tertiary Swiss university hospital was 1.56 per 1,000 patient admissions. After a cardiac arrest, about a third of the patients survived to 1 year with favourable neurological and functional status. Early recognition and high-quality cardiopulmonary resuscitation provided by a well-organised team is crucial for patient survival.

Trial Registration: The trial was registered in clinicaltrials.gov (NCT02746640).

Introduction

The incidence of in-hospital cardiac arrests (IHCAs) has been reported to be from 0.78 to 4.60 per 1,000 patient admissions [1–8]. Despite immediate treatment of IHCAs with high-quality cardiopulmonary resuscitation (CPR) [9, 10], mortality remains high [11]. Patient survival to hospital discharge after an IHCA has improved over recent years, and has been reported as 26% of patients, although only 21% had good functional and neurological status [12]. Long-term survival of these patients has also improved over the past 20 years, although good functional outcomes after 1 year remain at around 12% for these IHCA survivors [13].

Fast and competent interventions based on current resuscitation guidelines are essential for increased survival with good neuropsychological outcome after cardiac arrest [14, 15]. As well as local implementation of international resuscitation recommendations [16] and guidelines [14, 15], potential key factors that influence successful in-hospital resuscitation include: (1) a focus on prevention and early recognition of cardiac arrest, with immediate start of basic life support [17]; (2) immediate activation of emergency responses to IHCAs, to provide early high-quality advanced life support [18]; (3) a high-performing hospital-wide rapid response system consisting of a cardiac arrest team and/or medical emergency team that are organised, well trained, and available 24 hours per day, 7 days a week [19–23]; (4) state-of-the-art post-resuscitation care [24]; (5) performance-driven debriefings [25, 26]; and (6) recording of the institution resuscitation success, with reporting of the results. These measures contribute to further optimisation of local procedures and maintain adherence to current guidelines [5, 23].

The Bern University Hospital is one of the largest tertiary acute care hospitals in Switzerland, and it treats about 47,000 inpatients and over 520,000 outpatients annually [27]. It is also a certified referral cardiac arrest centre [28, 29]. Until recently, there was no central documentation of the cardiac arrest team interventions, and no indication of their efficiency within the hospital. This therefore allowed no analysis of the annual number of IHCAs, and the resuscitations, outcomes and survival rates of these patients.

Therefore, this prospective single-centre observational study aimed to systematically record and analyse all of the cardiac arrest team interventions at the Bern University Hospital over 1 year.

Methods

Ethics Commission approval and registration

The study protocol was approved by the Ethics Commission of the Canton of Bern (KEK Nr: 108/15), and was prospectively registered with ClinicalTrials.gov (NCT02746640). The need for informed consent was waived by the Ethics Committee.

Setting

For the Bern University Hospital, in cases of cardiac arrest or acute life-threatening events the cardiac arrest teams are activated, for adults from the Department of Anaesthesia and Pain Medicine, and for children under 16 years from the Paediatric Intensive Care Unit. Both teams are available 24 h per day, 7 days a week.

The cardiac arrest team for adults is composed of a board-certified anaesthesiologist and a certified anaesthesia nurse, to provide guideline-conforming high-quality advanced life support for all persons within the hospital campus. The cardiac arrest team is summoned via a centralised hospital-wide phone number, and they bring with them a resuscitation cart that is equipped with all that is necessary for advanced life support monitoring and treatment at the scene. All of the hospital staff are trained to deliver high-quality basic life support and are instructed on how to use an automated external defibrillator

(AED). These AEDs are placed at various locations within the hospital campus, and can be used until the cardiac arrest team arrives on the scene to take over.

Cardiac arrests that occur in adult and paediatric Intensive Care Units, or the Cardiac Catheterisation Laboratory, Emergency Rooms or Operating Rooms are treated primarily by the professionals working in these settings. However, the cardiac arrest team can be summoned to these areas as well. Ward patients with non-life-threatening, rapidly deteriorating clinical situations are primarily referred to the medical emergency team activated from the Adult Intensive Care Unit, which is also available 24 h per day, 7 days a week [21].

Participants

We included all adult IHCA team interventions from 1 March, 2015, to 28 February, 2016. We excluded paediatric patients (< 16 years), patients with out-of-hospital cardiac arrests (OHCAs) admitted to the Emergency Room under ongoing CPR, and cardiac arrests in the paediatric and adult Intensive Care Units.

Procedures and measures

During the day, the data were collected by an observer who accompanied the cardiac arrest team, but who was not involved in the treatment. This member of the research team prospectively recorded all of the research-related data on an Utstein-style case report form [30, 31], as adapted for IHCAs (Digital Supplemental Content 1). The observer could report more than on reason per case for an alarm. For IHCAs during the night, the case report form was filled in by the cardiac arrest team, and the medical team leader was interviewed about the event the following day. The observer recorded the 'Return Of Spontaneous Circulation' (ROSC) during resuscitation when it occurred for at least 1 min, and 'sustained ROSC' was defined as no further chest compressions needed for at least 20 minutes [32]. All of the patients with IHCA who were treated by the cardiac arrest team were assessed neurologically immediately after resuscitation on scene or at the arrival on Intensive Care Unit, and 24 h after the cardiac arrest, according to the Glasgow Outcome Scale (GOS) [33–35]. At 30 days and 1 year from the cardiac arrest, the patients were contacted by telephone for a 30-min interview to assess their neurologic status, according to the GOS, and their functional status, according to the Short-form-12 Health Survey (SF-12) [36, 37]. All of the patient data were recorded separate from the hospital information system, and stored coded in a password-protected departmental electronic research database, according to the Swiss Act on Human Research.

Instruments

The GOS was used to categorise the neurological outcomes. In brief, the GOS has five categories, where the higher values define better neurological outcomes, as: 'Death' (score 1), 'persistent vegetative state' (score 2), 'severe disability' (score 3), 'moderate disability' (score 4) and 'low disability' (score 5). For the purpose of this study, GOS 2 and 3 were considered as 'poor neurological outcome', while GOS 4 and 5 were considered as 'favourable neurological outcome'. Sedated patients during post-resuscitation care were not assessed with GOS.

Health-related quality of life was assessed with the SF-12, which comprises 12 questions that define two core dimensions, as the ‘Mental component summary’, and the ‘Physical component summary’, with each calculated on a scale of 0 to 100. These scores are age dependent, and they describe better health-related quality of life as the values increase [32, 36, 37]

Statistical analysis

Statistical analysis was performed using Stata version 14 (StrataCorp, Texas, USA) and SPSS 27 (IBM Corp., New York, USA). Categorical variables were described as absolute numbers, and relative frequencies as percentages. Continuous variables were described as means ± standard deviation (SD), or median and interquartile range (IQR) for non-normally distributed data. Student’s t-tests were used to compare continuous parametric data, and Mann–Whitney or Kruskal–Wallis tests for non-parametric data. Categorical variables were compared with chi-squared tests or Fisher’s exact tests. The significance level of probability was defined as ≤ 0.05.

Results

In all, 146 cardiac arrest team alarms were recorded for the 1-year study period (Table 1, Fig. 1). Of these, 86 (58.9%) were considered acute life-threatening alarms. For 23 patients (15.8%), the alarms were triggered before they went into cardiac arrest. A total of 100 reasons for the alarms were recorded on the Utstein-style case-report forms (Table 1).

Table 1
Indications, locations and reasons for the 146 cardiac arrest team alarms.

Indication/ location/ reason	Patients [n (%)]
With life threatening conditions	**86 (58.9)**
Cardiac arrest	68 (46.6)
Acute airway problem	6 (4.1)
Other life-threatening conditions	12 (8.2)
With non-life-threatening conditions	**60 (41.1)**
Syncope	25 (17.1)
Unspecific deterioration of clinical status	14 (9.6)
Suspected seizure	8 (5.5)
Do not attempt resuscitation order	2 (1.4)
Unintentional activation	11 (7.5)
Locations	
Central campus building	107 (73.3)
Wards	66 (45.2)
Cardiac Catheterisation Laboratory	28 (19.2)
Emergency Room	11 (7.5)
Operating Room	2 (1.4)
Peripheral campus pavilions	31 (21.2)
Not documented	8 (5.5)
Reason for cardiac arrest team alarms[a]	**100 (100)**
Ongoing cardiopulmonary resuscitation	49 (49.0)
Heart rate < 40 bpm or > 140 bpm	16 (16.0)
Glasgow Coma Scale decrease ≥ 2 points	8 (8.0)
Blood pressure < 90 mmHg or rise from baseline > 40 mmHg	8 (8.0)
Respiration rate < 6 bpm or > 35 bpm	8 (8.0)
Peripheral oxygen saturation (SpO_2) < 90%	4 (4.0)

[a]cases can accumulate multiple reasons, [‡]only if no objective reason could be defined

Indication/ location/ reason	Patients [n (%)]
Seizure	1 (1.0)
Seriously worried about patient‡	3 (3.0)
[a]cases can accumulate multiple reasons, ‡only if no objective reason could be defined	

Sixty of the resuscitation alarms (41.1%) were not related to life-threatening conditions. Eleven of the alarms (7.5%) were triggered unintentionally (by children, facility personnel, or during construction work). Ten of the alarms (6.9%) were considered as miscommunication, as the medical emergency team should have been called.

Most of the alarms came from the central campus building (n = 107; 73.3%), while 31 (21.2%) came from peripheral campus pavilions. The locations of eight alarms (5.5%) were not recorded. In the central campus building, the alarms came from wards (n = 66; 45.2%), the Cardiac Catheterisation Laboratory (n = 28; 19.2%), the Emergency Room (n = 11; 7.5%), and the Operating Room (n = 2; 1.4%).

Of the 60 alarms that were not related to life-threatening situations, significantly more came from peripheral campus pavilions (n = 20/31; 64.5%) compared to the central campus building (n = 40/107; 37.4%; p = 0.002). Overall, for all of the alarms, the mean time between an alarm and the arrival of the cardiac arrest team was 3.0 ± 1.6 min.

In-hospital cardiac arrests

With 68 IHCAs recorded, this corresponded to an incidence of 1.56 in 1,000 admissions (admissions during the study year: 43,697). The descriptive characteristics of the patients who experienced these 68 IHCAs are summarised in Table 2.

Table 2
Demographic features and characteristics of the 68 patients with in-hospital cardiac arrests.

Demographic	**Location**		***p***
	Wards	**Cardiac Catheterisation Laboratory/ Emergency Room/ Operating Room**	
Total patients(n)	40	28	
Male [n (%)]	25 (62.5)	24 (85.7)	NS
Mean age (years)	63.0 ± 15.8	71.9 ± 12.3	**0.014**
Arrest witnessed [n (%)]	26 (65.0)	28 (100)	
Time to cardiac arrest team arrival (min)	3.4 ± 2.0	2.2 ± 0.8	**0.005**
Initial rhythm [n (%)]			
Shockable	24 (60.0)	19 (67.9)	NS
Non-shockable	6 (15.0)	8 (28.6)	NS
Reason for cardiac arrest [n (%)]			
Cardiac	21 (52.5)	23 (82.1)	**0.012**
Pulmonary	5 (12.5)	1 (3.6)	NS
Neurological/stroke	1 (2.5)	0	NS
Bleeding	2 (5.0)	2 (7.1)	NS
Unknown	11 (27.5)	2 (7.1)	NS
STEMI diagnosed [n (%)]	2 (5.0)	8 (28.6)	NS
Time to ROSC (min)	7.2 ± 8.4	9.6 ± 7.0	NS
Survival [n (%)]			
Immediate	20 (50.0)	23 (82.1)	**0.04**

STEMI, ST elevation myocardial infarction; ROSC, return of spontaneous circulation

Demographic	Location		*p*
At 24 h	17 (42.5)	15 (53.6)	NS
At 30 days	12 (30.0)	15 (53.6)	NS
At 1 year	9 (22.5)	13 (46.4)	**0.037**

STEMI, ST elevation myocardial infarction; ROSC, return of spontaneous circulation

For 55 of these IHCA alarms (80.9%), the cardiac arrest was directly witnessed by a bystander. In 46 of all IHCA alarms (67.6%), chest compressions and bag-mask ventilation were already being performed on arrival of the cardiac arrest team, and in 24 of these 46 patients (52.2%), the self-adhesive pads of an AED had already been attached, and in 13 of these 24 patients (54.2%) a shock has been delivered by the basic life support team prior the arrival of the cardiac arrest team. For 5 of all IHCAs (7.4%), only chest compressions were being delivered, and in another 5 (7.4%), no CPR had been attempted.

For the 40 patients (58.8%) where IHCAs occurred on wards, the cardiac arrest team took 3.4 ± 2.0 min to reach them, which was significantly longer than for the 28 patients (41.2%) who were in the Cardiac Catheterisation Laboratory, Emergency Room or Operating Room (2.2 ± 0.8 min; $p = 0.005$). Comparing these two patient groups further, although those with IHCAs on wards were significantly younger (63.0 ± 15.8 years vs. 71.9 ± 12.3 years; $p = 0.014$), it was the patients where the IHCAs occurred in the Cardiac Catheterisation Laboratory, Emergency Room or Operating Room who had sustained ROSC more frequently (20/40 vs. 23/28; 50.0% vs. 82.1%; $p = 0.040$) and who showed greater survival after 1 year (9/40 vs. 13/28; 22.5% vs. 46.4%; $p = 0.037$), although this was not accompanied by better neurologic or functional outcomes.

The patient neurological outcomes for the various recorded periods after resuscitation are summarised in Table 3. Overall, almost three quarters of these patients (n = 49/68; 72.1%) had return of spontaneous circulation during CPR, and overall, 43 patients (63.2%) initially survived (GOS > 1). Twenty-three patients (33.8%) treated by the onsite basic life support team before the cardiac arrest team arrived, showed already sustained ROSC with favourable neurological status (moderate to low disability: GOS 4, 4/68 [5.9%]; GOS 5, 19/68 [27.9%]). The remaining immediate surviving patients (n = 20/68; 29.4%) treated by the cardiac arrest team with sustained ROSC showed on arrival at the Intensive Care Unit neurological outcomes of persistent vegetative state (GOS 2: n = 3/68 [4.4%]), severe neurological status (GOS 3: n = 6/68 [8.8%]) or were sedated (n = 11/68 [16.2%]).

Table 3
Outcomes for the 68 patients following their in-hospital cardiac arrests.

Outcome	Time from post cardiac arrest			
	Immediate	**24 h**	**30 days**	**1 year**
ROSC at least 1 min during CPR [n (%)]	49 (72.1)	-	-	-
Sustained ROSC/ overall survival [n (%)]	43 (63.2)	32 (47.1)	27 (39.7)	22 (32.4)
Glasgow Outcome Scale Scores [n (%)]				
1 (dead)	25 (36.8)	11 (16.2)	5 (7.4)	5 (7.4)
2–3 (poor outcome)	9 (13.2)	5 (7.4)	2 (2.9)	0
4–5 (favourable outcome)	23 (33.8)	24 (35.3)	23 (33.8)	20 (29.4)
Not assessable (sedated)	11 (16.2)	3 (4.4)		
Not assessable (language barriers)			2 (2.9)	2 (2.9)
Short-form-12 Health Survey (mean ± SD)				
Physical Component Summary	-	-	42.8 ± 7.7	47.0 ± 8.6
Mental Component Summary	-	-	47.0 ± 13.1	53.4 ± 7.4
ROSC, return of spontaneous circulation; CPR, cardiopulmonary resuscitation				

Data on follow-up

Twenty-four hours after the IHCAs, nearly half of these 68 patients were still alive (n = 32; 47.1%). Favourable neurological outcomes (i.e., GOS 4, 5) were recorded for the majority of these patients (n = 24/32; 75.0%), although some had severe disability (GOS 3: n = 4/32; 12.5%) or were sedated (n = 3/32; 9.4%), and one patient was in a vegetative state (GOS 2: 3.1%). Eleven of the patients (16.2%) who showed immediate post-IHCA survival then died within the first 24 h.

At 30 days, over one-third of the patients were still alive (n = 27/68; 39.7%). Excluding two patients who were alive at follow up (at both 30 days and 1 year) where their neurological and functional status could not be evaluated due to language barriers (n = 2/68; 2.9%), almost all of the patients who remained alive (n = 23/27; 85.2%) showed favourable neurological status (GOS 4: n = 3/27, 11.1%; GOS 5: n = 20/27, 74.1%), with only two of these 27 (7.4%) in a severe state (GOS 3). Five of the patients who had survived to 24 hours died within the first 30 days (n = 5/68; 7.4%).

At 1-year from these IHCAs, again with two patients with GOS unknown due to language barriers (2.9%), there were 20 patients (29.4%) still alive, who also showed favourable neurological outcomes (GOS 4, n =

3, 4%, GOS 5, n = 17, 25%); none of these alive patients were recorded with GOS 2 or 3. Five patients (7.4%) had died from 30 days to the end of the first year from these IHCAs.

For the SF-12 assessments of the alive and assessable patients after 30 days (n = 23/27), comparison with the Physical Component Summary score of a healthy sample of the Swiss population (49.8 ± 8.6) [38] showed a lower mean value (42.8 ± 7.7) (Table 3). However, this difference was not seen 1 year after their IHCAs (47.0 ± 8.6). For the Mental Component Summary score after 30 days, comparing here to healthy volunteers (46.3 ± 10.1), no significant difference was seen for these surviving patients (47.0 ± 13.1). These patients also showed a small, but not significant, increase in their Mental Component Summary score after 1 year (53.4 ± 7.4).

Discussion

This study analysed all of the adult cardiac arrest team interventions at a large Swiss university hospital over 1 year. Perhaps surprising, 41.1% of all of these cardiac arrest team alarms were unrelated to life-threatening events, with only about half of all of the alarms actually activated for a cardiac arrest. The incidence and neurologic outcomes of this trial have provided data that are in agreement with similar reports from other countries [1–7, 39]. Additionally, the 30-day and 1-year survivals, and their neurological and functional outcomes, were a little higher than reported in other studies [2–4, 6, 7, 39, 40].

A 2018 systematic review that analysed more than one million IHCAs from 1992 to 2016 reported an overall pooled 1-year survival of 13%, with a range of 6–28%, and large between-study variability [13]. In contrast to the Swiss national data [41] and data from international registries [42] on incidence and outcomes of OHCAs, data for IHCAs still remain underreported, with a general paucity of national Swiss and European data registries.

Life-threatening situations like cardiac arrest or respiratory failure due to acute airway obstruction need immediate and competent help for better survival. Therefore, the use of a low-threshold alarm system [43] that can be activated by any healthcare worker in a hospital, or even by a visitor to the hospital, allows for rapid rescue interventions. The downside of such a low-threshold alarm system is that alarms unrelated to life-threatening events (i.e., 'false alarms') can also be triggered. Dukes et al. [20] underlined that such a low-threshold alarm system is important for top performing hospitals in terms of IHCAs. Indeed, the low-threshold alarm system in this large Swiss university hospital might explain the high proportion of purported cardiac arrest alarms that were unrelated to life-threatening events.

Unsurprisingly, when larger distances need to be covered by the cardiac arrest team, this results in longer times to reach the patients, although here this did not have any significant influence on patient survival. For hospitals that cover large areas of land or are spread over several floors, reaching patients can pose a problem. One way to overcome this is the constant teaching and training of the resuscitation competence of ward personnel, with the aim being to provide early high-quality basic life support. Although in most cases, the ward staff correctly applied the basic life support algorithm – which resulted in sustained ROSC by the time the cardiac arrest team arrived for about one-third of these patients – some reports of incomplete or absent basic life support prior to arrival of the cardiac arrest team are of concern. Our findings imply that hospitals should promote continuous efforts to educate the ward staff, focusing specifically on overcoming the barriers to performing basic life support. Basic life support skills decrease over time from 3 to 12 months after training, and therefore brief and frequent re-training is recommended [44]. While the best timing for re-training is still under debate, a recent study showed that monthly training of CPR skills is a highly effective method to improve performance [45], although this can be difficult to implement due to time constraints. Therefore, mandatory yearly short competence refresher courses might be an easy way to better ensure the delivery of this early high-quality basic life support [25, 44].

For telephone alarm systems, the contact person might also be instructed to give advice to the person calling, on how best to deliver basic life support until the cardiac arrest team arrives. In the OHCA setting, CPR instructions delivered by telecommunicating dispatchers have been show to be independently associated with improved survival and improved functional outcome [46], and these are highly recommended by international resuscitation guidelines [14–16]. This might also be a suitable option to ensure correct and effective IHCA treatment. Specific and adapted education [47] will be needed for these in-hospital telephone dispatchers to be able to confirm a cardiac arrest situation [48, 49], to provide instructions for basic life support via the telephone, and to encourage the first arrivals to consider early use of an AED [50, 51] while the cardiac arrest team is on its way. The potential influence of such telephone dispatcher of CPR instructions on IHCA survival and favourable neurological long-term outcomes should be investigated in future studies.

Limitations

The major study limitations here were the overall low reported numbers of cardiac arrest team alarms over the 1-year observation period, and the loss of some patients during follow-up, mostly because further assessment was not possible due to language barriers. Some cases had missing values in the Utstein-style case report form. This and the relatively low numbers might have influenced the results of the statistical analysis of these data. Also, as the paediatric and adult intensive care units were not included in these observations, we cannot report outcome data for these patients. All in all, these limitations might have resulted in an underestimation of the overall incidence of IHCA at Bern University Hospital. This underlines the importance to report and integrate also such small numbers of local data into international registries and databases, with the aim to further explore the incidence, survival and long-term outcomes of IHCAs, and to define national and regional differences.

Conclusions

This 1-year prospective observational study in one of the largest Swiss tertiary centres and university hospitals showed an incidence of IHCAs of 1.56 in 1,000 hospital admissions. The 30-day survival rate was 40%, with 34% with good neurological outcomes. One year later, 32% of these patients with IHCAs remained alive, with 29% with favourable neurological outcomes. To improve patient outcome further, enhanced annual resuscitation competence refresher courses are needed, especially in large campus areas where the time needed by the cardiac arrest team to reach the patient is crucial.

Abbreviations

AED, automated external defibrillator; CPR, cardiopulmonary resuscitation; GOS, Glasgow Outcome Scale; IHCA, in-hospital cardiac arrest; OHCA, out-of-hospital cardiac arrest; ROSC, return of spontaneous circulation

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Ethics Commission of the Canton of Bern (KEK Nr.: 108/15). The need for informed consent was waived by the Ethics Committee.

Consent for publication

Not applicable.

Availability of data and materials

The datasets analysed during the current study are available from the corresponding author on reasonable request, with Ethics Committee approval.

Competing interests

RG is the ERC Board Director of Education and Training, and ILCOR Education, Implementation and Team Task Force Chair. All of the other authors declare that they have no conflicts of interests.

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Authors' contributions

AF participated in the statistical analysis and interpretation of the data, and was a major contributor to the final manuscript. DK participated in the primary data acquisition. LT participated in development of the concept of the study. JK participated in the follow-up data acquisition. RG participated in development of the concept of the study, interpretation of the data, and writing of the manuscript. JBE participated in the statistical analysis, follow-up data acquisition and interpretation of data, and was a major contributor to the manuscript. All of the authors have read and approved the final version of the manuscript.

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Figures

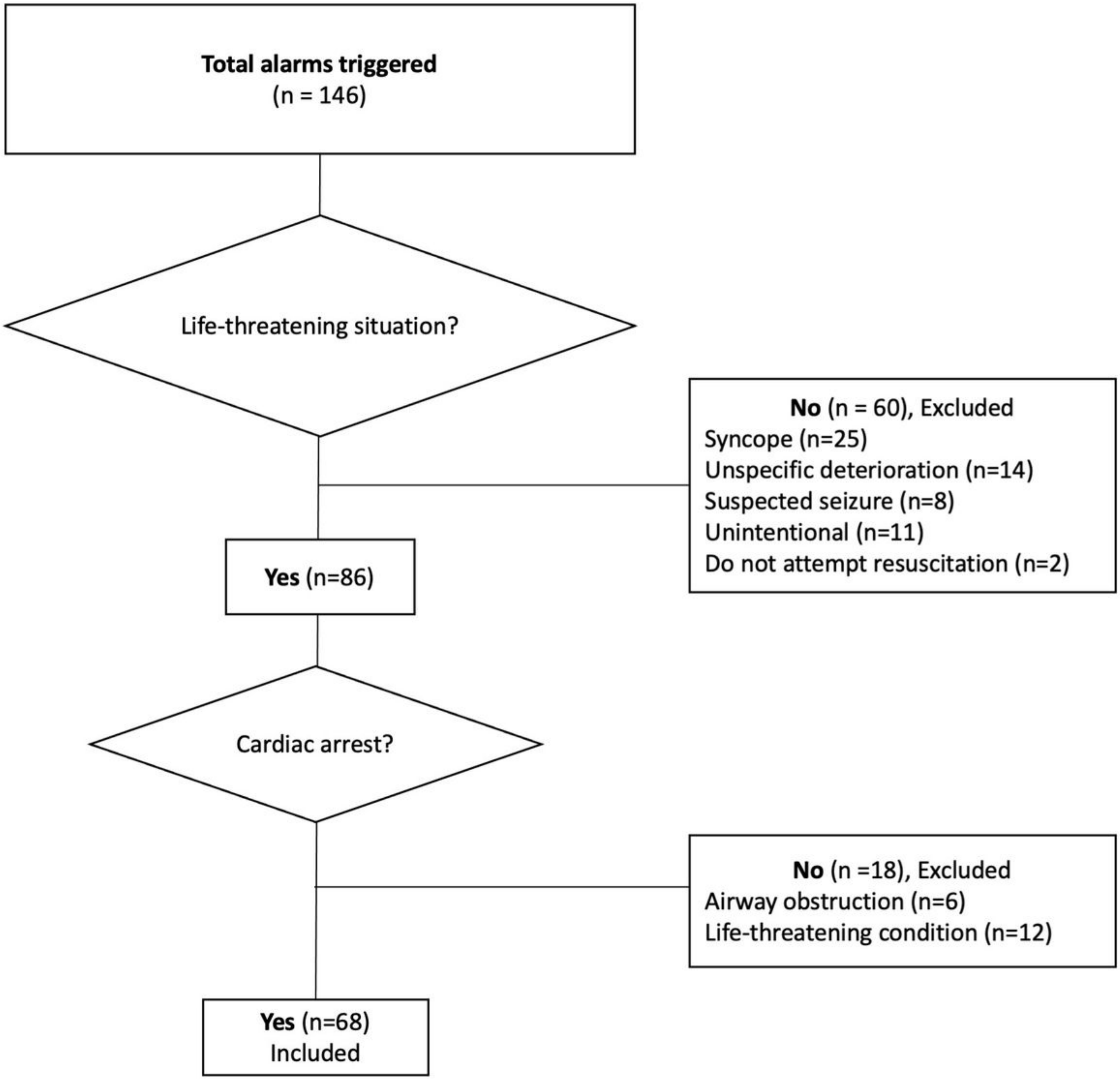

Figure 1

Study flowchart.

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