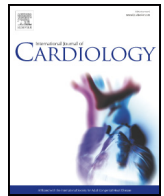




Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Acute hospital administration of amiodarone and/or lidocaine in shockable patients presenting with out-of-hospital cardiac arrest: A nationwide cohort study

Chien-Hua Huang^a, Ping-Hsun Yu^b, Min-Shan Tsai^a, Po-Ya Chuang^c, Tzung-Dau Wang^d, Chih-Yen Chiang^e, Wei-Tien Chang^a, Matthew Huei-Ming Ma^a, Chao-Hsiun Tang^c, Wen-Jone Chen^{a,f,*}

^a Department of Emergency Medicine, College of Medicine, National Taiwan University, Taipei, Taiwan

^b Department of Emergency Medicine, Taipei Hospital, Ministry of Health and Welfare, Taipei, Taiwan

^c School of Health Care Administration, Taipei Medical University, Taipei, Taiwan

^d Department of Internal Medicine (Cardiology), College of Medicine, National Taiwan University, Taipei, Taiwan

^e Division of Cardiology, Department of Internal Medicine, Cardinal Tien Hospital Yonghe Branch, New Taipei City, Taiwan

^f Department of Internal Medicine, Lotung Poh-Ai Hospital, Yilan County, Taiwan

ARTICLE INFO

Article history:

Received 8 August 2016

Received in revised form 10 October 2016

Accepted 6 November 2016

Available online xxxx

Keywords:

Amiodarone

Lidocaine

Out-of-hospital cardiac arrest

Shockable rhythm

1-Year survival

ABSTRACT

Background: Terminating ventricular fibrillation (VF) or pulseless ventricular tachyarrhythmia (VT) is critical for successful resuscitation of patients with shockable cardiac arrest. In the event of shock-refractory VF, applicable guidelines suggest use of anti-arrhythmic agents. However, subsequent long-term outcomes remain unclear. A nationwide cohort study was therefore launched, examining 1-year survival rates in patients given amiodarone and/or lidocaine for cardiac arrest.

Methods: Medical records accruing between years 2004 and 2011 were retrieved from the Taiwan National Health Insurance Research Database (NHIRD) for review. This repository houses all insurance claims data for nearly the entire populace (>99%). Candidates for study included all non-traumatized adults receiving DC shock and cardiopulmonary resuscitation immediately or within 6 h of emergency room arrival. Analysis was based on data from emergency rooms and hospitalization.

Results: One-year survival rates by treatment group were 8.27% (534/6459) for amiodarone, 7.15% (77/1077) for lidocaine, 11.10% (165/1487) for combined amiodarone/lidocaine use, and 3.26% (602/18,440) for use of neither amiodarone nor lidocaine (all, $p < 0.0001$). Relative to those given neither medication, odds ratios for 1-year survival via multiple regression analysis were 1.84 (95% CI: 1.58–2.13; $p < 0.0001$) for amiodarone, 1.88 (95% CI: 1.40–2.53; $p < 0.0001$) for lidocaine, and 2.18 (95% CI: 1.71–2.77; $p < 0.0001$) for dual agent use.

Conclusions: In patients with shockable cardiac arrest, 1-year survival rates were improved with association of using amiodarone and/or lidocaine, as opposed to non-treatment. However, outcomes of patients given one or both medications did not differ significantly in intergroup comparisons.

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1. Introduction

Out-of-hospital cardiac arrest is a major challenge worldwide, associated with high mortality. Patients with shockable rhythms are better able to recover and survive, although the likelihood of survival to discharge is still poor (~20%) [1,2]. It is critical that any precipitating ventricular tachyarrhythmia (VT), namely ventricular fibrillation (VF) or pulseless VT, is terminated during resuscitation. However, it is not uncommon for VF to recur, becoming resistant to electrical shock [3,4]. Use of anti-arrhythmic agents may encourage conversion of VF to a perfusing rhythm and help prevent recurrences of VF [5,6]. Their

administration after DC resuscitative shocks has been shown to increase return of spontaneous circulation (ROSC) and survival to admission in instances of out-of-hospital cardiac arrest [7].

On the other hand, such agents also have pro-arrhythmic effects, with a potential to induce or exacerbate rhythm disturbances [8–11], and may promote hypotension and depressed cardiac function during resuscitation [7]. Administration of amiodarone for DC-resistant VF during resuscitation is known to improve ROSC and survival to admission. A recent randomized, double-blind trial shows the neither amiodarone nor lidocaine resulted in a significantly higher rate of survival or favorable neurologic outcome than the rate with placebo among patients with out-of-hospital cardiac arrest due to initial shock-refractory VF or pulseless VT [12]. However, the case number could be inadequate due to the survival rates in the placebo group and the amiodarone group

* Corresponding author at: No. 7, Zhongshan S. Rd., Taipei City 100, Taiwan.
E-mail address: wjchen1955@ntu.edu.tw (W.-J. Chen).

differed less than anticipated when the trial was designed. There was no data is currently available on outcome as long as one year [13]. Lidocaine has proved successful in rescuing failed VT conversion via amiodarone [14,15]. It is thus feasible that a combination of drugs may more effectively interrupt the various mechanisms of VT [16]. A significant percentage of patients in clinical practice are receiving both amiodarone and lidocaine during resuscitation although the outcomes have yet to be clarified [17,18].

In 2015 resuscitation guidelines, use of anti-arrhythmic agents is suggested for initial shock-refractory VF-related cardiac arrest [19,20]. American Heart Association guideline lists amiodarone as treatment of choice for Class IIb indication [19]. Nevertheless, survey data from the resuscitation outcomes consortium reveals substantial variation in preparation and use of anti-arrhythmic agents during resuscitation (lidocaine, 96%; amiodarone, 55%; both, 54%) [17].

Using a nationwide insurance database, we reviewed the use of anti-arrhythmic agents in patients sent to emergency departments for out-of-hospital cardiac arrest. In addition to examining survival to discharge, 1-year survival rates were determined and compared for various treatment subsets.

2. Methods and materials

2.1. Data source

Medical records/reports accruing between years 2004 and 2011 were retrieved from the Taiwan National Health Insurance Research Database (NHIRD) for review. This repository releases anonymous secondary data for research purposes and houses all claims data from the National Health Insurance (NHI) program in Taiwan. Launched in 1995, the NHI provides coverage for >99% of the entire Taiwanese population of 23.74 million [21]. The database details all patient demographics and orders for medical care. Taiwan's NHI Bureau is responsible for comprehensive review of medical records and examination reports [22]. Disease diagnoses are coded according to the International Classification of Disease, Ninth Revision, Clinical Modification (ICD-9-CM). The study protocol was approved by the National Taiwan University Hospital Research Ethics Committee.

2.2. Study design

This retrospective, observational, and nationwide population-based cohort study of patients with non-traumatic out-of-hospital cardiac arrest was designed to investigate the impact of amiodarone and lidocaine usage on survival outcomes. Subjects were selected entirely from the NHIRD, all undergoing DC shock and cardiopulmonary resuscitation during short emergency room stay between January, 2004 and December, 2011. Grounds for exclusion were stipulated as follows: 1) age <18 years, 2) trauma-related event, 3) emergency room stay >6 h, or 4) non-level one triage. Patients were categorized and triaged into level-one if vital signs were extremely unstable and needed immediate resuscitation when presented to emergency department. Admission to intensive care unit is important for bundled post-cardiac arrest care. Staying in emergency department, which could be related to the unavailable of intensive care due to no vacancy, could confound the quality of post-cardiac arrest care. We excluded the patients with >6 h emergency department stay to decrease the possible confounding effects on outcomes of inadequate post-cardiac arrest care in the study. Any known recipients of lidocaine or amiodarone (oral or intravenous) within 1 year previously were also excluded to minimize therapeutic interference. Patients were followed from cardiac arrest index date to 1-year survival status or death. Analysis was based on data from emergency rooms and hospitalization and not from ambulance or from resuscitation on the scene in the study.

2.3. Use of anti-arrhythmic agents

Data on usage and doses of intravenous amiodarone and lidocaine given during resuscitation were obtained for each patient. Epinephrine or vasopressin use was also examined. Patients were grouped according to treatments received as both (amiodarone and lidocaine), amiodarone (amiodarone only), lidocaine (lidocaine only), and neither. Cardiac resuscitation protocols were basically following the resuscitation guidelines [20]. The dosage of amiodarone or lidocaine follow the resuscitation guidelines. The initial dosage of amiodarone was 300 mg intravenously, another 150 mg could be given if shockable rhythm was not converted and defibrillated. The initial dosage of lidocaine was 1.0 to 1.5 mg per kilogram intravenously, another 0.5 to 0.75 mg per kilogram could be given if shockable rhythm was not converted and defibrillated. The initial dosages were the same in most of the patients and hospitals. The use of maintenance therapy depended on the physicians' judgment in considering the clinical situations. The EMS system is a two-tiered system comprising firefighter-based emergency medical technicians (EMTs) with basic life support (BLS) skills as well as early defibrillation capability using automated external defibrillator (AED) and advanced life support (ALS) capability [23]. The ALS protocol includes tracheal intubation and intravenous epinephrine [24]. Amiodarone and lidocaine were administered in emergency room settings, enabling NHIRD tracking.

2.4. Baseline patient characteristics and variables

Age, gender, and urbanization level in Taiwan were examined for each patient. According to the Taiwan National Health Research Institute, four tiers of urbanization were defined, ranging from most urbanized areas at level 1 to least urbanized at level 4, based on a composite score obtained by calculating the population density (people/km²), the proportion of people in the population with a college or above educational level (%), the proportion of people over the age of 65 (%), the proportion of the population engaged as agricultural workers (%), as well as the number of physicians per 100,000 people [25]. Whether or not coronary angiography was done upon admission was also assessed, as were comorbidities and cardiovascular risk factors and prior malignancy (see Table 1 in Ref [26]). Severity of illness was scored using the Charlson Comorbidity Index (CCI) [27]. Hospitals were classified as medical centers if the specific requirements for medical staff and ability for specific treatment were qualified in regular hospital accreditation (see Table 2 in Ref [26]). There were 651 hospitals in Taiwan including 19 tertiary centers and 97 secondary centers. There were 289 hospitals having both cardiac catheterization laboratory and intensive care unit services.

2.5. Outcomes

The primary clinical endpoint was 1-year survival. All patients were followed for 1 year after the day of event or until loss to follow-up or death. Survival to intensive care unit (ICU) admission and survival to discharge were additionally analyzed.

2.6. Statistical analysis

To compare baseline characteristics of the four groups, chi-square test was applied for categorical variables and ANOVA for parametric continuous variables. Multiple logistic regression analysis was utilized to estimate independent effects of anti-arrhythmic agents on survival outcomes. Baseline characteristics (age, gender, and urbanization levels); comorbidities and risk factors (diabetes mellitus, hypertension, coronary artery disease, heart failure, atrial fibrillation, chronic kidney disease, chronic pulmonary obstructive disease, asthma, and prior malignancy); CCI scores; and Boolean (true/false) coronary angiographic status were included in the backward stepwise multiple logistic regression model and then verified by forward stepwise method. A dummy variable was defined for treatments used (both, amiodarone only, lidocaine only, and none), with none serving as reference.

In the multiple logistic regression models, a bootstrap approach was used. Correspondence among bootstrap hazard ratios (HRs) was tested in 1000 replications. Differing criteria in sensitivity analysis were used to validate regression model findings. Participants were further studied by advanced age, gender, severity of illness, presence of heart failure, and coronary angiographic status to assess potential confounding effects on measured outcomes.

All computations relied on standard software (SAS v9.4; SAS Institute, Cary, NC), setting statistical significance at $p < 0.05$.

3. Results

3.1. Characteristics of study population

There were 172,016 instances of patient resuscitation during the study period. After excluding patients on the basis of age (<18 years), trauma-related episodes, non-level one triage, emergency room stay >6 h, lack of shockable rhythm during resuscitation, and prior use of amiodarone or lidocaine (within 1 year of episode), the remaining 27,463 patients subjected to DC shock and cardiopulmonary resuscitation (Fig. 1) were analyzed. Patient totals by treatment group were 6459 (23.51%) for amiodarone, 1077 (3.92%) for lidocaine, 1487 (5.41%) for both amiodarone and lidocaine, and 18,440 (67.14%) for neither (Table 1). By comparison, mean age and CCI scores were lower and male gender was proportionately greater in the group given both amiodarone and lidocaine during resuscitation. The percentage of patients undergoing coronary angiography was also higher in this group.

3.2. Differing outcomes among groups

The 1-year survival rate was higher in the group receiving both agents (11.10%), as opposed to amiodarone only (8.27%), lidocaine only (7.15%), or neither (3.26%, $p < 0.0001$). The dual treatment group also surpassed the other groups in terms of survival to ICU admission (34.10%) and survival to discharge (12.25%) (Table 2).

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