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＊印のついている論文のみ別刷を添付

Ⅲ．研究成果の刊行物・別刷
(抜粋)

TIA

Transient Ischemic Attack

一過性脳虚血発作

急性期医療の実際

編集

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診断と治療社

III TIA 診療における医療連携

2 脳卒中に関する一般市民への啓発

中山クリニック 公益社団法人日本脳卒中協会　中山博文

Point

- 一過性脳虚血発作(TIA)後の脳梗塞を予防するには，TIA の症状と発作時の早期対応の必要性に関する市民啓発が不可欠である．
- TIA の脳卒中危険因子としての認知度は低い．
- 市民啓発の方法に関しては，新聞広告，テレビ放送，小冊子・チラシの各戸配布や講演会を高頻度で行うことによる啓発効果が示されており，これらを組み合わせた多角的介入がより効果的である．
- 公益社団法人日本脳卒中協会は，ブレイン・アタック　キャンペーン(脳卒中発症時の対応に関する市民啓発)のための啓発動画・音声を制作し，ポスター掲示，市民講座，ホームページ等による啓発を行っている．
- 積極的な TIA 市民啓発は，TIA 診療体制がある程度整備されてから行う必要がある．

はじめに

公益社団法人日本脳卒中協会は，平成 9 年の設立以来，脳卒中の予防をその主たる活動の一つとして，市民啓発，患者・家族への情報提供，医療従事者の教育に取り組んでいる(http://jsa-web.org)．最近，一過性脳虚血発作(transient ischemic attack：TIA)後，特に TIA 発作から間もない時期に脳梗塞発症リスクが高いこと，加えて，TIA 発作後早期の専門的治療によって脳梗塞の発症を 8 割予防することが可能であることが，海外の研究によって示された[1]．脳梗塞患者の約 2 割が発症前に TIA を経験しており[2]，わが国では年間約 20 万人が脳梗塞を発症していると推計されているので，単純計算で約 4 万人が TIA 後に脳梗塞を発症していることになる．発作後の早期治療介入によってその 8 割を予防できるとすると，約 3 万人の脳梗塞が予防可能ということになる．

これらの知見から，TIA 後の脳梗塞予防対策を見直す必要があると思われる．すなわち，TIA 発作後の迅速な対応が可能な診療体制の整備と，ハイリスク患者・一般市民への TIA の症状と発作後早期受診の必要性に関する啓発が求められる．本稿では，一般市民への脳卒中啓発

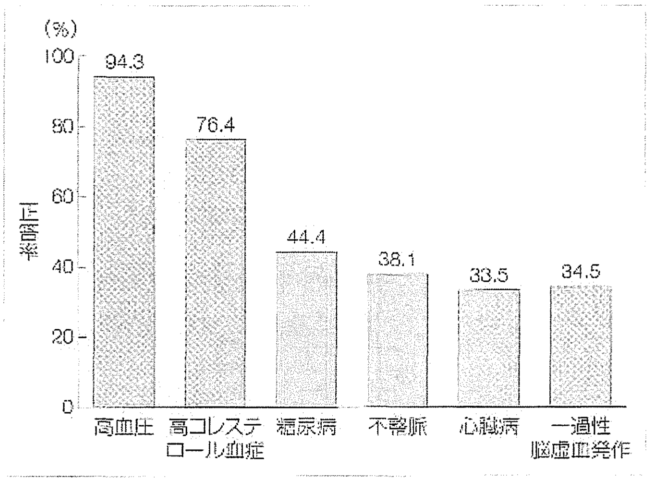

図1　一般市民の危険因子(疾患)の認識

に関するこれまでの取り組みを紹介し，今後の啓発について検討する．

1　TIA の認知度

日本脳卒中協会は，2006 年，秋田市，静岡市，呉市において，40 歳以上 75 歳未満の男女約 11,000 人を無作為抽出し，脳卒中の発症時の症状および対処法についての知識，情報源などに関する多項目選択式郵送アンケート調査(主任研究者：宮松直美)を実施した(回答率 49%)[3]．

危険因子については，9 割強の回答者が高血圧を，8 割弱が高コレステロール血症を選択したが，糖尿病や不整脈を選んだ回答者は 4 割，心臓病と TIA は 3 割と少なく，TIA の認知度が低いことが明らかになった(図 1)．

2　市民への啓発方法

TIA の認知度を上げるには，市民啓発が不可欠である．市民啓発には，テレビやラジオ，新聞などのマスメディアを用いた広告，チラシや小冊子の配布，学校教育，ポスター，教育講演，口コミなど，様々な方法がある．効果的に市民啓発を行うには，多くの人の耳目に触れ，教育効果が高く，費用を含めて実現可能な方法を用いなければならない．そのためには，一般市民の脳卒中に関する知識の状況と情報源を明らかにし，介入を行い，その効果を評価する必要がある．

ⓐ 一般市民の脳卒中に関する知識

前述の一般市民の知識調査[3]において，脳卒中の症状については，9 割弱の回答者が手足の運動麻痺や言語障害を選択したが，激しい頭痛，ふらつき，視野障害を選んだ回答者は各々 7 割，6 割，4 割弱と少なく，これらの症状の理解度が低いことが明らかになった(図 2)．また，5 割

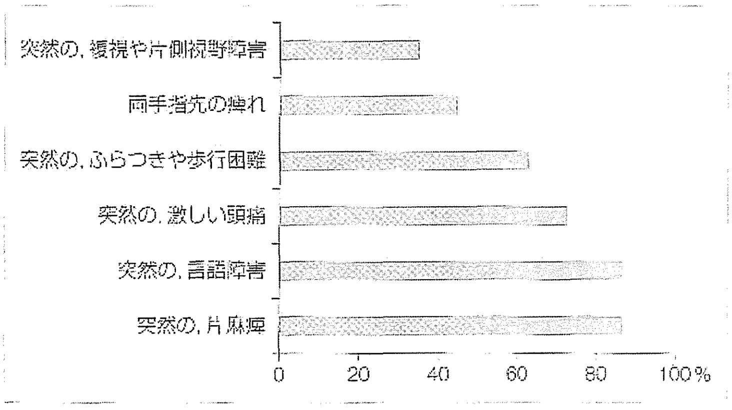

図2 一般市民の症状の認識

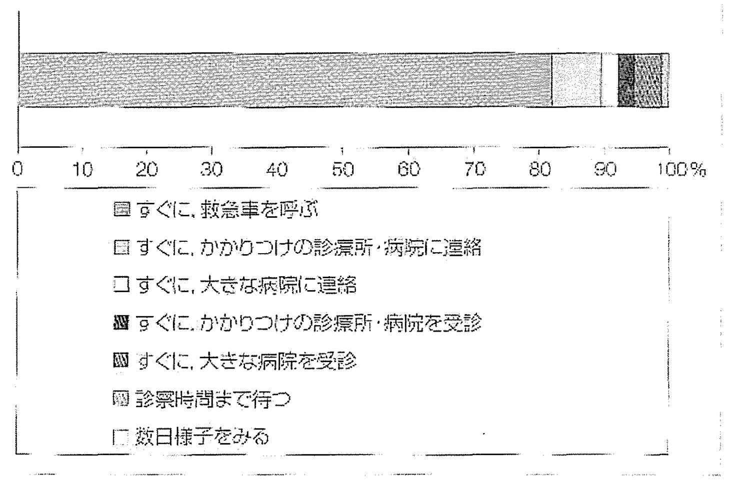

図3 一般市民の発症時の対応

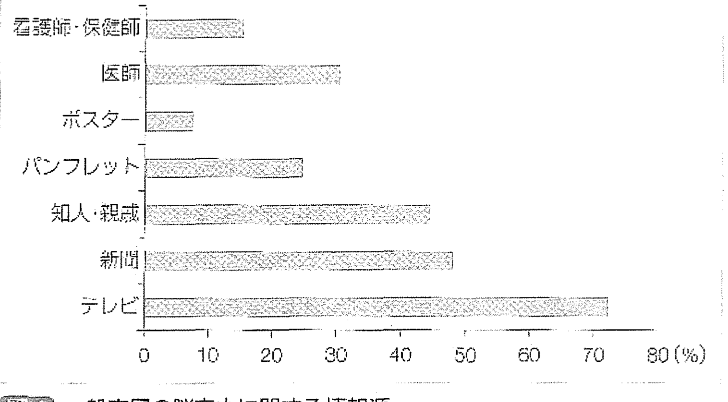

図4 一般市民の脳卒中に関する情報源

弱の回答者が「両手指の痺れ」を脳卒中の症状と理解しており，「突然」「片側で」という特徴が十分に理解されていないことが示唆された．

脳卒中発症時の対応については，8割の回答者は救急車を呼ぶと回答し，1割はすぐに医療機関に連絡すると回答している（図3）．したがって，発症時の救急受診の必要性はかなり認識されていると考えられる．

一般市民の脳卒中に関する情報源は，7割の回答者がテレビを，5割が新聞を選択したのに対し，医師や看護師・保健師を選んだのは，各々3割，2割弱であった（図4）．この結果から，テレビや新聞を介したキャンペーンが，より多くの市民の耳目に触れると思われる．

ⓑ チラシ・小冊子，新聞等による啓発効果

チラシ・小冊子，講演会，新聞の啓発効果について，日本脳卒中協会と厚生労働科学研究費補助金による循環器疾患等生活習慣病対策総合研究事業　超急性期脳梗塞患者の救急搬送および急性期病院受け入れ体制に関する実態調査研究班（主任研究者：木村和美，以下「厚労科研研究班」）が行った地域介入比較対照研究の結果を紹介する．

研究対象地域は，日本脳卒中協会が2006年に知識調査（一次調査）を実施した秋田市（強力介入地域），呉市（軽度介入地域），静岡市（対照地域）である．約2年間にわたり，強力介入地域ではチラシ11回・小冊子2回の各戸配布と13回の講演会を行い，軽度介入地域ではチラシと小冊子各1回の各戸配布と5回の講演会を行った．この間，別途，公共広告機構の支援キャンペーンとして新聞広告キャンペーンも行われていた．新聞広告の掲載は新聞社の自主性に任されているため，掲載頻度をコントロールすることはできず，強度介入地域では21回，軽度介入地域では4回，対照地域では15回新聞掲載された．

分析には，一次調査で脳卒中の主要5症状を完答できなかった人が，介入後新たに完答できるようになることに対する影響因子を，多変量ロジスティック回帰分析で明らかにした．

2008年度に，二次調査への同意が得られている5,509人に知識調査を行い，3,860人（70%）から回答を得ることができた．一次調査での5症状完答者およびデータ欠損等を除く2,789名中，介入後の新たな5症状完答者は561人（20%）であった．

二次調査参加者を介入強度（居住地）および公共広告機構の新聞広告を見た/見ないにより6群に分類し，「対照地区・新聞広告なし」群を参照とした脳卒中症状5項目の完答オッズ比を検討したところ，軽度介入/新聞広告なし，強度介入/新聞広告なし，対照/新聞広告あり，軽度介入/新聞広告あり，強力介入/新聞広告あり，の順に症状完答オッズ比が上昇した（図5）．

この結果から，チラシや小冊子の各戸配布・講演会による強力介入はマスメディアによる情報提供と同程度の効果があること，低頻度の配布物・講演会のみでは十分な知識の向上は得られないが新聞広告などとの複合により知識は向上すること，さらにその効果は介入強度が増すとより顕著であることが明らかになった[4]．

ⓒ テレビによる啓発効果

テレビによる啓発活動の効果については，日本脳卒中協会と厚労科研研究班，NHK岡山放送局，川崎医科大学脳卒中医学教室が地域介入比較対照研究を行った[5]．

2009年4月から1年間，岡山県（介入地域）において，「脳卒中防止キャンペーン」を実施し，NHK岡山放送局は，キャンペーン期間を通して，ほぼ毎日1日2回以上の1分間スポットと週1回の約15分の特集番組を放送した．

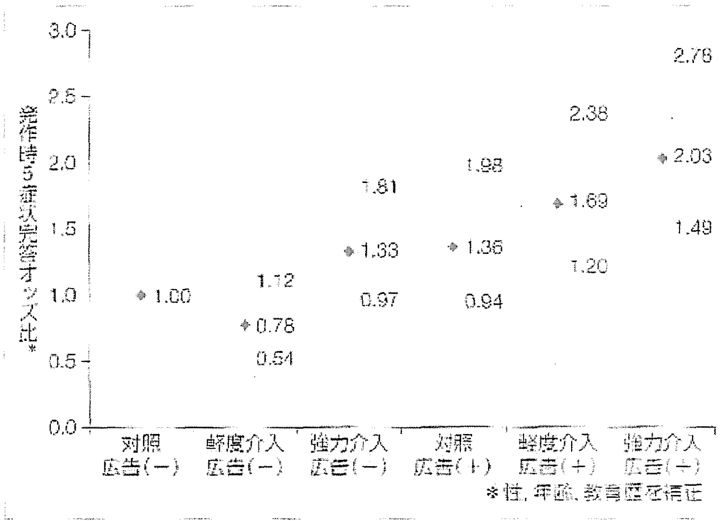

図5 発症時5症状完答オッズ比（介入強度・公共広告機構新聞広告への曝露の有無別）

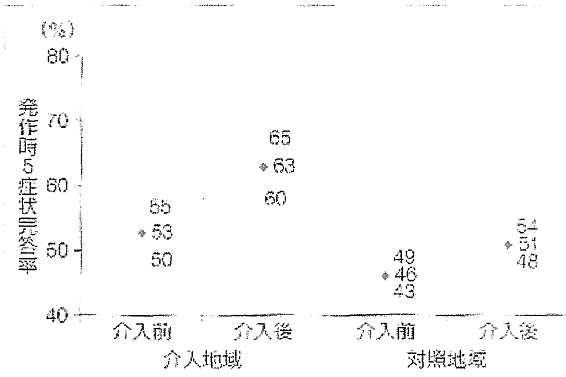

図6 テレビキャンペーンによる介入前後の脳卒中の5症状完答率

介入前後に，介入地域（岡山県岡山市）と対照地域（広島県呉市）において，電話帳から無作為に抽出された40～74歳の市民1,960人（各地域980人）に対し，脳卒中の発作時症状についての電話調査を実施し，脳卒中の発作時症状は，正答5症状とダミー5症状からなる10症状から正しいと思うものをすべて選択するよう求めた．

介入前の調査では，介入地域では53%，対照地域では46%の市民が発作時5症状を完答した（図6）．テレビ放送による1年間の啓発活動の後，介入地域では発作時5症状を完答できた市民が有意に増加したが（63%），対照地域では介入後に有意な差は認められなかった（51%）．

男女別に検討すると，介入地域の女性のみ介入後に発作時5症状の完答者割合が有意に増加しており，介入期間中のテレビによる啓発活動への接触機会は，女性が男性に比して多く，本研究で示された男女差はキャンペーンへの曝露の男女差により説明し得ると考えられた．

本研究により，テレビ放送による脳卒中啓発活動は，一般市民，特に女性において，脳卒中発作時症状の認識に効果的であることが示された．

ⓓ 中学校における啓発効果

中学生への授業や資材配布による啓発効果については，「循環器病研究開発費　新しい脳卒中医療の開拓と均てん化のためのシステム構築に関する研究班」（主任研究者　峰松一夫）が，中学生とその保護者を対象とする比較対照研究を行っている[6]．介入群においては，中学生に脳卒中教室（45 分）を行い，パンフレット，マグネットシート，クリアファイル等の啓発資材を配布し，クラスにポスターを掲示し，保護者には啓発資料を配布している．対照群に対しては，調査終了まで啓発活動は行われていない．

介入前，介入直後，介入 3 カ月後に行われた多項目選択式アンケート調査によって，介入群の中学生，保護者の介入後の脳卒中の危険因子，症状，対処方法に関する知識の向上が示されている．

3 ブレイン・アタック　キャンペーン

脳卒中発症時の迅速な受診を促すことを目的とする，脳卒中の症状と発症時の迅速な受診の必要性に関する市民啓発活動を「ブレイン・アタック　キャンペーン」と呼び，日本脳卒中協会では，全国キャンペーンとローカルキャンペーンを行っている．

全国キャンペーンとしては，平成 18 年 7 月～平成 20 年 6 月まで，公共広告機構（現　AC ジャパン）支援キャンペーンとして，新聞広告を用いたキャンペーンを実施した．平成 20 年 7 月からは，テレビ，ラジオ，新聞，雑誌の 4 メディアによるキャンペーンに格上げされ，平成 24 年 6 月末まで実施された．

AC ジャパンの支援キャンペーンが平成 24 年 6 月で終了になったため，日本脳卒中協会オリジナルの啓発動画・音声（発症時対応篇）を制作し，啓発動画をホームページ（http://www.jsa-web.org/）で供覧している．

また，毎年 5 月 25～31 日に開催される脳卒中週間には，脳卒中の症状と発症時の対応方法を記載したポスターを，日本脳卒中協会会員が所属する全国の医療機関，全国理容生活衛生同業組合連合会加盟理髪店，株式会社ローソン近畿支社のコンビニなどで掲示していただいている．

ローカルキャンペーンとしては，全国に 48 カ所ある日本脳卒中協会支部が，市民講座を毎年約 80 回開催している．加えて，平成 22 年と 23 年には，AC ジャパンの広告に基づくブレイン・アタック　キャンペーンポスターを東京都内の駅約 2,000 カ所に掲示していただいた．

4 今後の啓発活動

ⓐ 現実的かつ効果的市民啓発方法

新聞広告やテレビ放送による啓発は効果的であるが，広告料金を支払って実施するとなると，経費がかかりすぎる．行政に働きかけて，行政が持っているテレビ・ラジオ枠を使わせていただくのが現実的である．加えて，市民講座や健康イベントなどを開催する際に，マスコミに声

をかけて取材してもらうと，参加できなかった多くの市民にも情報提供できる．

今後の実現可能な啓発モデルとして，行政の広報，学校教育，医療福祉機関における啓発等を組み合わせた都道府県をあげた多角的啓発を，栃木県において，行政，医師会等関係団体，研究班*等のご協力のもとに，平成24年10月から開始した（栃木県脳卒中啓発プロジェクト）．実施前後の知識調査によって啓発効果を検証し，このモデルの啓発効果が実証されれば，他の都道府県においても展開していく計画である．

*厚生労働科学研究費補助金 循環器疾患・糖尿病等生活習慣病対策総合研究事業「慢性期ハイリスク者・脳卒中および心疾患患者に適切な早期受診を促すための地域啓発研究」および，循環器病研究開発費「新しい脳卒中医療の開拓と均てん化のためのシステム構築に関する研究」

ⓑ TIA市民啓発

TIAの市民啓発については，現場の混乱を避けるために，TIA診療体制がある程度整備されるまで待つ必要がある．目下，「一過性脳虚血発作（TIA）の診断基準の再検討，ならびにわが国の医療環境に則した適切な診断・治療システムの確立に関する研究」班（研究代表者 峰松一夫）がTIAの定義，診断基準と初期対応に関する新しいガイドラインを検討中であり，それらについてのコンセンサスが形成された後，各地域のTIA診療体制が整備されるであろう．大規模なTIA市民啓発を開始するタイミングについては，それまでの間，慎重に検討する必要があると思われる．

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Association of Prehospital Advanced Airway Management With Neurologic Outcome and Survival in Patients With Out-of-Hospital Cardiac Arrest

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Importance It is unclear whether advanced airway management such as endotracheal intubation or use of supraglottic airway devices in the prehospital setting improves outcomes following out-of-hospital cardiac arrest (OHCA) compared with conventional bag-valve-mask ventilation.

Objective To test the hypothesis that prehospital advanced airway management is associated with favorable outcome after adult OHCA.

Design, Setting, and Participants Prospective, nationwide, population-based study (All-Japan Utstein Registry) involving 649 654 consecutive adult patients in Japan who had an OHCA and in whom resuscitation was attempted by emergency responders with subsequent transport to medical institutions from January 2005 through December 2010.

Main Outcome Measures Favorable neurological outcome 1 month after an OHCA, defined as cerebral performance category 1 or 2.

Results Of the eligible 649 359 patients with OHCA, 367 837 (57%) underwent bag-valve-mask ventilation and 281 522 (43%) advanced airway management, including 41 972 (6%) with endotracheal intubation and 239 550 (37%) with use of supraglottic airways. In the full cohort, the advanced airway group incurred a lower rate of favorable neurological outcome compared with the bag-valve-mask group (1.1% vs 2.9%; odds ratio [OR], 0.38; 95% CI, 0.36-0.39). In multivariable logistic regression, advanced airway management had an OR for favorable neurological outcome of 0.38 (95% CI, 0.37-0.40) after adjusting for age, sex, etiology of arrest, first documented rhythm, witnessed status, type of bystander cardiopulmonary resuscitation, use of public access automated external defibrillator, epinephrine administration, and time intervals. Similarly, the odds of neurologically favorable survival were significantly lower both for endotracheal intubation (adjusted OR, 0.41; 95% CI, 0.37-0.45) and for supraglottic airways (adjusted OR, 0.38; 95% CI, 0.36-0.40). In a propensity score–matched cohort (357 228 patients), the adjusted odds of neurologically favorable survival were significantly lower both for endotracheal intubation (adjusted OR, 0.45; 95% CI, 0.37-0.55) and for use of supraglottic airways (adjusted OR, 0.36; 95% CI, 0.33-0.39). Both endotracheal intubation and use of supraglottic airways were similarly associated with decreased odds of neurologically favorable survival.

Conclusion and Relevance Among adult patients with OHCA, any type of advanced airway management was independently associated with decreased odds of neurologically favorable survival compared with conventional bag-valve-mask ventilation.

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OUT-OF-HOSPITAL CARDIAC arrest (OHCA) is a major public health problem, occurring in 375 000 to 390 000 individuals in the United States each year.[1] The rate of survival after OHCA has increased with advances in care via initiatives such as the American Heart Association's 5-step Chain of Survival.[2] However, the rate is still low, with recent estimates reporting 8% to 10%.[3-5] Better survival has been associated with the improvement in early access to emergency medical care, early cardiopulmonary resuscitation (CPR), rapid defibrillation, and integrated post–cardiac arrest care.[6] Early advanced life support is often considered of benefit in that it provides intravenous drug therapy and advanced airway management.[6]

Although advanced airway management, such as endotracheal intubation or insertion of supraglottic airways, has long been the criterion standard for airway management of patients with OHCA,[7] recent studies have challenged the survival benefit of advanced airway management compared with conventional bag-valve-mask ventilation in this clinical

For editorial comment see p 285.

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setting.[8-14] However, large-scale studies evaluating the association between advanced airway management and patient-centered outcomes such as neurological status do not exist. Thus, whether prehospital advanced airway management by emergency medical service (EMS) personnel increases or decreases the rate of favorable neurological outcome among adults with OHCA remains to be determined.[15,16]

The purpose of the current study was to examine whether CPR with any type of out-of-hospital advanced airway management by EMS personnel, compared with CPR with conventional bag-valve-mask ventilation, would be associated with favorable neurological outcome in adult OHCA. In addition, we postulated that both advanced airway techniques (endotracheal intubation or use of supraglottic airways) would be similarly associated with favorable neurological outcome after OHCA.

METHODS

Study Design and Participants

The All-Japan Utstein Registry of the Fire and Disaster Management Agency (FDMA) is a prospective, nationwide, population-based registry system of OHCA in adults and children, with Utstein-style data collection.[17] This study enrolled all adults aged 18 years or older who had had OHCA and for whom resuscitation was attempted by EMS personnel with subsequent transport to medical institutions from January 1, 2005, to December 31, 2010. Patients were excluded from the analysis if out-of-hospital airway management or age was not documented. Cardiac arrest was defined as the end of cardiac mechanical activity determined by the absence of signs of circulation.[17-19] The ethics committees of Kinki University Faculty of Medicine and Massachusetts General Hospital approved the study with a waiver of informed consent.

Study Setting

The population of Japan was roughly 128 million in 2010, with approximately 107 million people aged 18 years or older.[20] The EMS system in Japan has been described previously.[21] Briefly, in Japan, municipal governments provided EMS through 802 fire stations with dispatch centers. All EMS personnel performed CPR according to the Japanese CPR guidelines, which are based on the American Heart Association and the International Liaison Committee on Resuscitation.[2,22,23] In most cases, an ambulance crew consisted of 3 EMS personnel, including at least 1 emergency lifesaving technician who had completed extensive training. These technicians were authorized to insert an intravenous line, to use semiautomated external defibrillators, and to lead CPR. In 1991, emergency lifesaving technicians were also permitted to use supraglottic airway devices (laryngeal mask airway, laryngeal tube, and esophageal-tracheal twin-lumen airway device) for patients with OHCA under medical control direction.[21] Beginning in 2004, endotracheal intubation could be performed by specially trained emergency lifesaving technicians who had completed an additional 62 hours of training sessions and performed 30 supervised successful intubations in operating rooms.[24]

Under medical control direction in the placement of an advanced airway device, the choice of either endotracheal intubation or supraglottic airway was at the discretion of each specially trained emergency lifesaving technician. Advanced airway management was performed, with efforts limited to a total of 2 attempts, after checking initial rhythm and using defibrillation when appropriate, along with chest compression and bag-valve-mask ventilation. Advanced airway device placement with successful ventilation was confirmed by an esophageal detection device and/or an end-tidal carbon dioxide monitor (quantitative or colorimetric).[24] The performance of CPR including prehospital advanced airway management was reviewed by local medical control committees.

Data Collection and Quality Control

Data were collected prospectively with an Utstein-style data form that included sex, age, etiology of arrest, bystander witness status, first documented cardiac rhythm, presence and type of CPR by bystander, administration of epinephrine by EMS personnel, and technique of airway management. A series of EMS times of call receipt, vehicle arrival at the scene, contact with patients, initiation of CPR, and hospital arrival were recorded based on the clock used by each EMS system. Outcome measures included return of spontaneous circulation before hospital arrival, 1-month survival, and neurological status 1 month after the event. To collect 1-month follow up data, the EMS personnel in charge of each patient with OHCA queried the medical control director at the hospital. Patient neurological status was determined by the treating physician; the EMS received a written response. If the patient was not at the hospital, the EMS personnel conducted a follow-up search.

Data forms were completed by the EMS personnel caring for the patients, and the data were integrated into the Utstein registry system on the FDMA database server. Forms were logically checked by the computer system and were confirmed by the FDMA. If the data form was incomplete, the FDMA returned it to the respective fire station and the data were reconfirmed.

Study End Points

The primary end point was favorable neurological outcome 1 month after cardiac arrest, defined a priori as Glasgow-Pittsburgh cerebral performance category 1 (good performance) or 2 (moderate disability).[17] The other categories—3 (severe cerebral disability), 4 (vegetative state), and 5 (death)—were regarded as unfavorable neurological outcomes.[17] Secondary outcome measures were return of spontaneous circulation before hospital arrival and 1-month survival.

Statistical Analysis

We compared outcomes between any advanced airway management and bag-valve-mask ventilation for all adult OHCA. Then, we compared outcomes between either advanced airway technique (endotracheal intubation or supraglottic airways) and bag-valve-mask ventilation. With the full cohort, 3 unconditional logistic regression models (unadjusted, adjusted for selected variables, and adjusted for all covariates) were fit using each of the 3 end points as a dependent variable. A set of potential confounders was chosen a priori based on biological plausibility and a priori knowledge. These selected variables included age, sex, cause of cardiac arrest, first documented rhythm, witnessed status, type of bystander CPR, use of a public access automated external defibrillator, epinephrine administration, and time intervals from receipt of call to CPR by EMS and from receipt of call to hospital arrival. All covariates included the selected variables above and year, lifesaving technician presence, physician presence in ambulance, defibrillation by EMS personnel, insertion of intravenous line, and prefecture.

Our data derive from 367 837 patients who underwent bag-valve-mask ventilation and 281 522 who underwent advanced airway management. On the assumption of an incidence of 3.0% favorable neurological outcomes in the bag-valve-mask group, the study has 90% power to detect a difference as small as 0.16% between the groups for the primary outcome with a 2-sided significance level of $P<.05$.

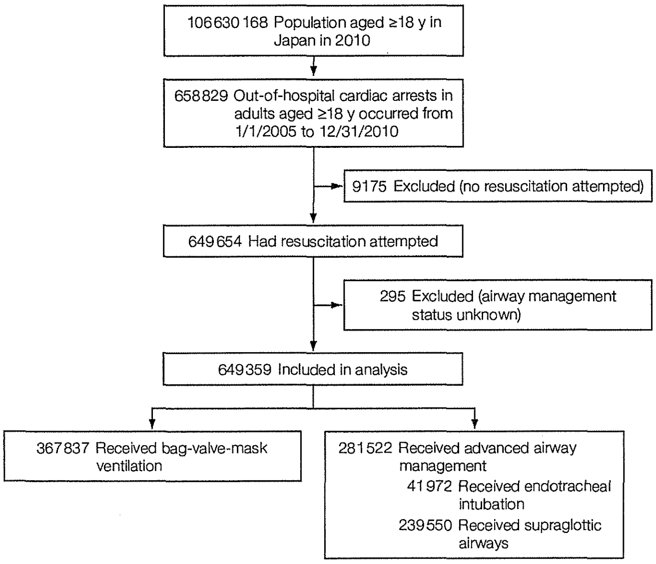
Prehospital advanced airway management was not randomly assigned in the study population; therefore, we used a propensity score approach to condition on potential selection bias and confounding. With a multivariable logistic regression model that did not take end points into account, we computed the propensity score, which represented the probability that a patient with cardiac arrest would undergo prehospital advanced airway management. Specifically, a full nonparsimonious model was fit with advanced airway management as the dependent variable, which included the variables in TABLE 1 in addition to dummy variables for the 47 prefectures in Japan as the independent variables. To maximize the efficacy of propensity score matching, missing values for categori-

Table 1. Out-of-Hospital Cardiac Arrest Population Baseline Characteristics According to Airway Management[a]

Characteristics	No. (%) Advanced Airway Management (n = 281 522)	No. (%) Bag-Valve-Mask Ventilation (n = 367 837)
Patients per year		
2005	44 503 (15.8)	55 988 (15.2)
2006	47 568 (16.9)	55 940 (15.2)
2007	46 398 (16.5)	57 404 (15.6)
2008	46 479 (16.5)	63 617 (17.3)
2009	47 244 (16.8)	64 924 (17.7)
2010	49 325 (17.5)	69 951 (19.0)
Age, mean (SD), y	73.2 (15.5)	72.7 (16.9)
Male sex	167 094 (59.4)	213 071 (57.9)
Etiology of cardiac arrest		
Cardiac	165 310 (58.7)	194 423 (52.9)
Noncardiac	116 212 (41.3)	173 414 (47.1)
External causes[b]	46 315 (16.5)	70 693 (19.2)
Respiratory disease	15 557 (5.5)	22 382 (6.1)
Cerebrovascular disease	13 960 (5.0)	17 522 (4.8)
Malignant tumor	7095 (2.5)	14 824 (4.0)
Other	33 285 (11.8)	47 993 (13.0)
Initial cardiac rhythm		
Ventricular fibrillation or tachycardia	21 867 (7.8)	26 366 (7.2)
Pulseless electrical activity/asystole	259 655 (92.2)	341 471 (92.8)
Bystander witness status[c]		
No witness	159 014 (58.1)	208 689 (58.1)
Layperson	100 647 (36.8)	111 992 (31.2)
Health care practitioner	14 227 (5.2)	38 666 (10.8)
CPR by bystander		
No bystander CPR	160 622 (58.0)	234 811 (64.7)
Compression-only CPR	76 562 (27.7)	85 971 (23.7)
Conventional CPR	39 567 (14.3)	42 396 (11.7)
Use of public-access AED by bystander	1299 (0.5)	1998 (0.6)
CPR by emergency responder		
Emergency lifesaving technician present in ambulance	279 954 (99.5)	333 151 (90.6)
Physician present in ambulance	6754 (2.4)	10 269 (2.8)
Defibrillation by emergency responder	33 016 (11.8)	36 937 (10.1)
Epinephrine administered	29 515 (10.6)	10 709 (2.9)
Insertion of intravenous line	102 586 (36.5)	38 132 (10.4)
Time from call to CPR by emergency responder, median (IQR), min	8 (7-11)	9 (7-12)
Time from call to hospital arrival, median (IQR), min	32 (26-39)	28 (23-36)
Time from CPR by emergency responder to ROSC, median (IQR), min[d]	14 (8-20)	6 (3-12)

Abbreviations: AED, automated external defibrillator; CPR, cardiopulmonary resuscitation; IQR, interquartile range; ROSC, return of spontaneous circulation.
[a]Data are expressed as No. (%) of population unless otherwise indicated. All baseline characteristic comparisons between the 2 groups were statistically significant at $P<.001$.
[b]Defined as cardiac arrest due to trauma, hanging, drowning, intoxication, or asphyxia.
[c]Percentages do not sum to 100 because of missing data.
[d]Calculated for cases with ROSC.

Figure 1. Study Participant Selection



cal variables included in the propensity score model (bystander witness status, bystander CPR, use of a public access automated external defibrillator, use of epinephrine, defibrillation by EMS, and insertion of intravenous line) were dummy coded using the missing indicator method (eTable 1; available at http://www.jama.com). Using the match algorithm by Parsons,[25] based on propensity score, a subgroup of patients with cardiac arrest requiring advanced airway management were matched with unique control patients who underwent bag-valve-mask ventilation. Then, 3 conditional logistic regression models (unadjusted, adjusted for selected variables, and adjusted for all covariates) were fit with each of the 3 end points as a dependent variable.

All statistical analyses were performed with SAS statistical software, version 9.3 (SAS Institute Inc). All statistical tests were 2-tailed. The chosen type 1 error rate was $P<.05$, except when testing the subgroup of patients with endotracheal intubation or supraglottic airways for which a Bonferroni adjustment for multiplicity was used ($P<.025$).

RESULTS

A total of 658 829 adult patients with OHCA were documented. Among 649 654 resuscitation attempts, 295 arrests with unknown airway management status were excluded (FIGURE 1). Of the remaining 649 359 patients, 367 837 (56.7%; 95% CI, 56.5%-56.8%) underwent bag-valve-mask and 281 522 (43.4%; 95% CI, 43.2%-43.5%) underwent advanced airway management, including 41 972 (6.5%; 95% CI, 6.4%-6.5%) with endotracheal intubation and 239 550 (36.9%; 95% CI, 36.8%-37.0%) with supraglottic airways.

Table 1 shows the demographic characteristics for adult OHCA by type of airway management. The mean age of all patients was 73 years; the majority were male. TABLE 2 summarizes survival outcomes by airway management among all patients. Overall, rates of return of spontaneous circulation, 1-month survival, and neurologically favorable survival were 6.5% (95% CI, 6.5%-6.6%), 4.7% (95% CI, 4.7%-4.8%), and 2.2% (95% CI, 2.1%-2.2%), respectively. The rates of neurologically favorable survival were 1.0% (95% CI, 0.9%-1.1%) in the endotracheal intubation group, 1.1% (95% CI, 1.1%-1.2%) in the supraglottic airway group, and 2.9% (95% CI, 2.9%-3.0%) in the bag-valve-mask ventilation group. The unadjusted model using the full cohort demonstrated significant negative associations between any advanced airway management and the 3 end-point measures ($P<.001$ for all) (Table 2). Similarly, in the adjusted model using the selected variables and all variables, both advanced airway techniques (endotracheal intubation and supraglottic airways) were independent negative predictor of all 3 outcomes ($P<.001$for all; Table 2).

To assess the robustness of the results, we performed a series of sensitivity analyses (TABLE 3). First, in an analysis of patients lost to follow-up, when assuming that all missing patients in the bag-valve-mask group (n=444) had an unfavorable neurological outcome and all missing patients in the advanced airway group (n=366) had a favorable outcome, advanced airway management was still a significant negative predictor of favorable neurological outcome after adjusting for selected variables (adjusted odds ratio [OR], 0.43; 95% CI, 0.42-0.45). When adjusting for achievement of return of spontaneous circulation in addition to the selected variables, the adjusted association of endotracheal intubation and supraglottic airways with poor neurological outcome persisted (OR, 0.51 [95% CI, 0.45-0.56] and OR, 0.52 [95% CI, 0.49-0.54], respectively) (Table 3). Similarly, the adjusted association persisted with stratification by achievement of return of spontaneous circulation, etiology of cardiac arrest, first documented rhythm, and type of witness status (Table 3).

Demographic characteristics were similar between the propensity-matched groups (TABLE 4). FIGURE 2 and eTable 2 summarize survival outcomes by airway management among propensity-matched patients. The unadjusted model showed significant negative associations between advanced airway management, regardless of its technique, and the 3 end-point measures ($P < .001$ for all). In the multivariable models using selected and all variables, significant negative associations were detected between any type of advanced airway management and the 3 outcome measures (Figure 2). In particular, the adjusted OR for neurologically favorable survival was 0.45 (95% CI, 0.37-0.55; $P < .001$) for endotracheal intubation and 0.36 (95% CI, 0.33-0.39; $P < .001$) for supraglottic airways compared with bag-valve-mask ventilation after controlling for the selected variables.

COMMENT

In this nationwide population-based cohort study of patients with OHCA, we found that CPR with advanced airway management was a significant predictor of poor neurological outcome compared with conventional bag-valve-mask ventilation. Unlike an earlier study that was underpowered to identify this clinically important association,[11] our study was sufficiently large to clearly demonstrate the negative association between advanced airway management and neurologically favorable survival after cardiac arrest. Furthermore, both endotracheal intubation and supraglottic airways were similarly associated with a decreased chance of favorable neurological outcome. The observed associations were large and persisted across different analytic assumptions.

Our clinical data are consistent with findings from several studies in trauma and pediatric patients.[7,8] These studies have suggested that prehospital endotracheal intubation may lead to a decreased rate of favorable neurological outcome, and only a few studies have demonstrated benefit from endotracheal intubation.[7] Additionally, several studies of OHCA have demonstrated the association between endotracheal intubation and decreased survival to hospital discharge.[9,10,13] An important unanswered question regards the mechanism connecting endotracheal intubation with poor outcomes. It has been well documented that prehospital intubation is a complex psychomotor task and that EMS personnel have difficulty gaining and maintaining competency in this skill.[7] Endotracheal intubation by unskilled practitioners can produce ad-

Table 2. Unconditional Logistic Regression Analyses for Outcomes Comparing Prehospital Advanced Airway Management vs Bag-Valve-Mask Ventilation

			Advanced Airway Management					
			Overall		Endotracheal Intubation		Supraglottic Airway	
Model	Total No. of Patients	Bag-Valve-Mask Ventilation, No. (%)	No. (%)	OR (95% CI) vs Bag-Valve-Mask[a]	No. (%)	OR (95% CI) vs Bag-Valve-Mask[a]	No. (%)	OR (95% CI) vs Bag-Valve-Mask[a]
Total	649359	367837 (56.7)	281522 (43.4)		41972 (6.5)		239550 (36.9)	
Return of spontaneous circulation								
Unadjusted	649326	25904 (7.0)	16299 (5.8)	0.81 (0.79-0.83)	3514 (8.4)	1.21 (1.16-1.25)	12785 (5.3)	0.74 (0.73-0.76)
Adjusted for selected variables[b]				0.67 (0.66-0.69)		0.86 (0.82-0.89)		0.64 (0.62-0.65)
Adjusted for all variables[c]				0.57 (0.56-0.58)		0.73 (0.70-0.77)		0.54 (0.52-0.55)
One-month survival								
Unadjusted	649350	19643 (5.3)	10933 (3.9)	0.72 (0.70-0.73)	1757 (4.2)	0.77 (0.74-0.81)	9176 (3.8)	0.71 (0.69-0.72)
Adjusted for selected variables[b]				0.73 (0.71-0.75)		0.83 (0.79-0.88)		0.72 (0.70-0.74)
Adjusted for all variables[c]				0.62 (0.60-0.64)		0.69 (0.65-0.73)		0.61 (0.59-0.63)
Neurologically favorable survival								
Unadjusted	648549	10759 (2.9)	3156 (1.1)	0.38 (0.36-0.39)	432 (1.0)	0.35 (0.31-0.38)	2724 (1.1)	0.38 (0.37-0.40)
Adjusted for selected variables[b]				0.38 (0.37-0.40)		0.41 (0.37-0.45)		0.38 (0.36-0.40)
Adjusted for all variables[c]				0.32 (0.30-0.33)		0.32 (0.29-0.36)		0.32 (0.30-0.33)

Abbreviation: OR, odds ratio.
[a] $P < .001$ for all.
[b] Selected variables are a predefined set of potential confounders including age, sex, cause of cardiac arrest, first documented rhythm, bystander witness, type of cardiopulmonary resuscitation (CPR) initiated by bystander, use of a public access automated external defibrillator by bystander, epinephrine administration, time from receipt of call to CPR by emergency medical service, and time from receipt of call to hospital arrival.
[c] Adjustment for all variables included in Table 1 and dummy variables for the 47 prefectures in Japan.

verse events, such as unrecognized esophageal intubation, tube dislodgement, iatrogenic hypoxemia, and bradycardia.[26] Furthermore, prehospital intubation may influence patient outcome by affecting the execution of simultaneous basic life support procedures, resulting in ineffective chest compressions with significant interruptions.[7]

Most studies of prehospital airway management using supraglottic airways have focused on process measures, such as success rates and speed of placement. Most of these found higher success rates and faster placement for the supraglottic airways.[27-29] From a physiological perspective, one might expect this to translate into better outcomes because of fewer interruptions of chest compressions. However, we observed that not only endotracheal intubation but also supraglottic airways were independently associated with a lower rate of neurologically favorable survival. Our finding is consistent with a recent study that failed to demonstrate a survival advantage with supraglottic airways in patients with OHCA.[12] Assuming the validity of our study, a more secure airway, regardless of its technique, would be detrimental. Previous studies have shown that inadvertent hyperventilation after advanced airway management can cause increased intrathoracic pressure, leading to decreased coronary and cerebral perfusion pressure among intubated patients with OHCA.[30,31] The literature has also reported that hyperoxia among patients following resuscitation from cardiac arrest was associated with increased mortality.[32,33] These unanticipated physiologic effects may offset the potential benefits of proper advanced airway management.

High-quality prospective clinical trials of prehospital airway management would be instrumental in revealing causality between airway manage-

Table 3. Sensitivity and Stratified Analyses of Multivariable Associations With Neurologically Favorable Survival and Airway Management in the Total Patient Population[a]

Model	Total No. of Patients	Bag-Valve-Mask Ventilation, No. (%)	Advanced Airway Management: Overall, No. (%)	Overall, OR (95% CI) vs Bag-Valve-Mask[b]	Endotracheal Intubation, No. (%)	Endotracheal Intubation, OR (95% CI) vs Bag-Valve-Mask[b]	Supraglottic Airway, No. (%)	Supraglottic Airway, OR (95% CI) vs Bag-Valve-Mask[b]
Sensitivity analysis								
Including loss to follow-up	649359	10759 (2.9)	3522 (1.3)	0.43 (0.42-0.45)	457 (1.1)	0.44 (0.39-0.48)	3065 (1.3)	0.43 (0.41-0.45)
Adjusted for ROSC[c]	648517	10759 (2.9)	3156 (1.1)	0.51 (0.45-0.56)	432 (1.0)	0.51 (0.45-0.56)	2724 (1.1)	0.52 (0.49-0.54)
Stratification by achievement of ROSC prior to hospital arrival								
ROSC[d]	42203	8660 (33.5)	2184 (13.4)	0.61 (0.57-0.65)	297 (8.5)	0.65 (0.57-0.75)	1887 (14.5)	0.60 (0.56-0.64)
No ROSC	607123	2098 (0.6)	969 (0.4)	0.65 (0.60-0.71)	134 (0.4)	0.71 (0.59-0.85)	835 (0.4)	0.65 (0.59-0.70)
Stratification by etiology								
Cardiac origin	359733	8199 (4.2)	2410 (1.5)	0.36 (0.34-0.38)	293 (1.3)	0.36 (0.32-0.41)	2117 (1.5)	0.36 (0.34-0.38)
Noncardiac origin	289626	2560 (1.5)	746 (0.6)	0.46 (0.42-0.50)	139 (0.7)	0.51 (0.43-0.61)	607 (0.6)	0.45 (0.41-0.49)
Stratification by initial rhythm								
Ventricular fibrillation or ventricular tachycardia	48233	5296 (20.1)	1697 (7.8)	0.36 (0.34-0.39)	189 (6.6)	0.34 (0.29-0.40)	1508 (8.0)	0.37 (0.34-0.39)
Pulseless electrical activity/asystole	601126	5463 (1.6)	1459 (0.6)	0.40 (0.38-0.43)	243 (0.6)	0.47 (0.42-0.54)	1216 (0.6)	0.39 (0.37-0.42)
Stratification by witness status								
Not witnessed	367363	1635 (0.8)	665 (0.4)	0.49 (0.44-0.53)	80 (0.4)	0.47 (0.37-0.59)	585 (0.4)	0.49 (0.44-0.54)
Witnessed by layperson	212639	5690 (5.1)	2068 (2.0)	0.39 (0.37-0.41)	303 (1.8)	0.43 (0.38-0.49)	1765 (2.1)	0.38 (0.36-0.43)
Witnessed by EMS	52893	3383 (8.8)	383 (2.7)	0.29 (0.26-0.32)	43 (2.3)	0.27 (0.20-0.37)	340 (2.8)	0.29 (0.26-0.33)

Abbreviations: EMS, emergency medical service; OR, odds ratio; ROSC, return of spontaneous circulation.
[a] Unconditional logistic regression models adjusted for selected variables including age, sex, cause of cardiac arrest, first documented rhythm, bystander witness, type of cardiopulmonary resuscitation (CPR) initiated by bystander, use of a public access automated external defibrillator by bystander, epinephrine administration, time from receipt of call to CPR by EMS, and time from receipt of call to hospital arrival.
[b] $P < .001$ for all.
[c] Adjusted for achievement of ROSC in addition to the above selected variables.
[d] Adjusted for time from cardiopulmonary resuscitation by EMS to ROSC in addition to the above selected variables.

ment and outcomes. However, such trials are logistically and methodologically difficult in this clinical setting.[26,34] Additionally, as trials are often designed to address specific questions in select groups, the characteristics of trial populations may differ significantly from those of the general population. As an alternative, our prospective nationwide cohort data reflect the effectiveness of prehospital airway management in the natural setting of a "real" population and current clinical practice, therefore enhancing the potential generalizability of the findings. In addition, multiple studies arrived at similar conclusions despite differing populations, disease groups, and designs.[7-10,12,13] There are plausible mechanisms to support this conclusion. Thus, our data lend significant support to the concept that prehospital intubation and its alternatives are less effective, or even harmful, than was previously believed.

Should clinicians avoid advanced airway management during CPR based on the best available observational evidence? Although one option would be to remove advanced airway management from the skill set of all out-of-hospital rescuers, that approach would disregard situations in which advanced airway management would be expected to be efficacious, especially for long-distance transfers and respiratory failure not yet with cardiac arrest.[35] Future research will need to identify whether there are subsets of patients for whom prehospital advanced airway management is beneficial. In addition, as observational studies cannot establish causal relationships in the way that randomized trials can, a rigorously conducted and adequately powered clinical trial evaluating this criterion standard in patients with OHCA now seems timely and necessary. While awaiting results of such a trial, we believe that decision makers for communities and national organizations should rethink the approach to prehospital airway management and need to invest more resources in optimizing the first 3 links in the chain of survival for the promotion of better outcomes among patients with OHCA.

This study has several limitations. First, as with any observational study, the negative association between any type of out-of-hospital advanced airway management and favorable neurological outcome does not necessarily prove causality and might be confounded by unmeasured factors. Despite a rigorous adjustment for confounding factors with a propensity score–matched analysis, there are other variables that may have contributed for which our study was unable to control or that were not collected a priori. Examples of potential confounding variables include rural or urban distinction, location of cardiac arrest, time interval from cardiac arrest onset to CPR among unwitnessed cardiac arrests, individual rescuer training levels, hospital-level variables, and postresuscitation care such as induced hypothermia therapy. Additionally, one might surmise that patients

Table 4. Baseline Characteristics of Propensity-Matched Patients With Out-of-Hospital Cardiac Arrest According to Airway Management

Characteristics	No. (%)[a] Advanced Airway Management (n = 178 614)	Bag-Valve-Mask Ventilation (n = 178 614)
Patients per year		
2005	27 058 (15.1)	27 795 (15.6)
2006	28 002 (15.7)	28 367 (15.9)
2007	28 448 (15.9)	28 494 (16.0)
2008	30 771 (17.2)	30 284 (17.0)
2009	31 294 (17.5)	30 784 (17.2)
2010	33 041 (18.5)	32 892 (18.4)
Age, mean (SD), y	72.9 (15.8)	72.9 (16.8)
Male sex	104 427 (58.5)	104 575 (58.5)
Etiology of cardiac arrest		
Cardiac	99 383 (55.6)	99 586 (55.8)
Noncardiac	79 231 (44.4)	79 028 (44.2)
Initial cardiac rhythm		
Ventricular fibrillation or tachycardia	13 519 (7.6)	13 557 (7.6)
Pulseless electrical activity/asystole	165 095 (92.4)	165 057 (92.4)
Bystander witness status[b]		
No witness	102 437 (57.4)	102 435 (57.3)
Layperson	60 143 (33.7)	60 581 (33.9)
Health care practitioner	11 704 (6.6)	11 149 (6.2)
CPR by bystander[b]		
No bystander CPR	106 591 (59.7)	105 753 (59.2)
Compression-only CPR	46 814 (26.2)	47 290 (26.5)
Conventional CPR	22 850 (12.8)	23 224 (13.0)
Use of public access AED by bystander	921 (0.5)	924 (0.5)
CPR by emergency responder		
Emergency lifesaving technician present in ambulance	177 076 (99.1)	178 316 (99.3)
Physician present in ambulance	4772 (2.7)	4581 (2.6)
Defibrillation by emergency responder	19 509 (10.9)	19 584 (11.0)
Epinephrine administered	10 159 (5.7)	9744 (5.5)
Insertion of intravenous line	37 602 (21.1)	36 051 (20.2)
Time from call to CPR by emergency responder, median (IQR), min	8 (7-11)	8 (7-11)
Time from call to hospital arrival, median (IQR), min	31 (25-38)	29 (23-37)

Abbreviations: AED, automated external defibrillator; CPR, cardiopulmonary resuscitation; IQR, interquartile range.
[a] Data are expressed as No. (%) of population unless otherwise indicated.
[b] Percentages do not sum to 100 because of missing data.

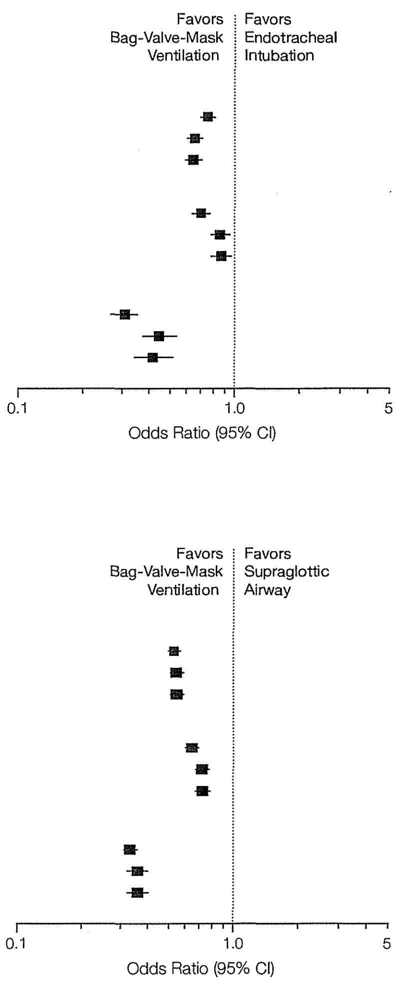
with return of spontaneous circulation prior to any airway management would have subsequently received bag-valve-mask ventilation rather than advanced airway management. These patients may have had neurologically favorable survival more frequently because of early return of spontaneous circulation rather than choice of airway management. However, the subgroup analysis limited to patients who achieved return of spontaneous circulation prior to hospital arrival demonstrated that advanced airway management, regardless of its type, still remained a significant negative predictor for the outcome even after adjusting for time interval from CPR to return of spontaneous circulation. Similarly, in the subgroup analysis of patients who did not achieve return of spontaneous circulation, the adjusted association of advanced airway management with poor neurological outcome persisted. Both suggest that this choice of airway management is the important variable.

Our study is also limited by the absence of information regarding the process of intubation. Indeed, up to 20% of out-of-hospital tracheal intubation efforts may fail.[36] However, we defined advanced airway management as suc-

Figure 2. Results of Conditional Logistic Regression Models Using One of the End Points as a Dependent Variable With Propensity-Matched Patients

A Endotracheal intubation vs bag-valve-mask ventilation

Model	Total No. of Patients	No. (%) Endotracheal Intubation	No. (%) Bag-Valve-Mask Ventilation	Odds Ratio (95% CI)[a]
Total		26013 (7.3)	178614 (50.0)	
Return of spontaneous circulation				
Unadjusted	357228	1734 (6.7)	14824 (8.3)	0.76 (0.71-0.81)
Adjusted for selected variables[b]				0.66 (0.61-0.72)
Adjusted for all variables[c]				0.64 (0.58-0.70)
1-month survival				
Unadjusted	357228	1069 (4.1)	10373 (5.8)	0.70 (0.65-0.76)
Adjusted for selected variables[b]				0.87 (0.79-0.97)
Adjusted for all variables[c]				0.88 (0.79-0.98)
Neurologically favorable survival				
Unadjusted	357228	257 (1.0)	5799 (3.2)	0.31 (0.27-0.35)
Adjusted for selected variables[b]				0.45 (0.37-0.55)
Adjusted for all variables[c]				0.42 (0.34-0.53)



B Supraglottic airway vs bag-valve-mask ventilation

Model	Total No. of Patients	No. (%) Supraglottic Airway	No. (%) Bag-Valve-Mask Ventilation	Odds Ratio (95% CI)[a]
Total		152601 (42.7)	178614 (50.0)	
Return of spontaneous circulation				
Unadjusted	357228	6933 (4.5)	14824 (8.3)	0.53 (0.51-0.54)
Adjusted for selected variables[b]				0.54 (0.52-0.56)
Adjusted for all variables[c]				0.54 (0.52-0.56)
1-month survival				
Unadjusted	357228	5718 (3.8)	10373 (5.8)	0.63 (0.61-0.65)
Adjusted for selected variables[b]				0.71 (0.68-0.74)
Adjusted for all variables[c]				0.72 (0.68-0.75)
Neurologically favorable survival				
Unadjusted	357228	1697 (1.1)	5799 (3.2)	0.33 (0.32-0.35)
Adjusted for selected variables[b]				0.36 (0.33-0.39)
Adjusted for all variables[c]				0.36 (0.33-0.40)

Full models for the primary outcome analysis are included in eTable 2.

[a] For all odds ratios, $P < .001$.

[b] Selected variables are a predefined set of potential confounders including age, sex, cause of cardiac arrest, first documented rhythm, bystander witness, type of cardiopulmonary resuscitation (CPR) initiated by a bystander, use of public access automated external defibrillator by bystander, epinephrine administration, time from receipt of call to CPR by emergency medical service, and time from receipt of call to hospital arrival.

[c] All variables included all covariates in Table 1 and variables for 47 prefectures in Japan.

cessful endotracheal intubation or supraglottic airway placement only. Thus, in our study, failed advanced airway management cases reverted to and were classified as bag-valve-mask ventilation cases. This would have biased our conclusions toward the null.

Another limitation is that our analysis of a nationwide population-based cohort describes that in Japan only. Similar studies with data from other countries may result in different findings. In particular, one might hypothesize that training of airway management for Japanese EMS personnel is relatively suboptimal, resulting in poor outcomes. However, the certification process for EMS personnel credentialed to perform endotracheal intubation in Japan is stricter than that in other countries. Indeed, the national paramedic curriculum in the United States requires students to perform 5 successful endotracheal intubations to graduate; 25 successful intubations are required in the United Kingdom and 30 are required in Japan.[37-39] Furthermore, existing literature suggests that intubation proficiency is attained by EMS personnel after 15 to 20 successful endotracheal intubations (predicted intubation success threshold of 90%).[40] This would serve not to reduce the potential generalizability of our inference to other settings.

Finally, as with all epidemiological studies, data integrity, validity, and ascertainment bias are potential limitations. The use of uniform data collection on the basis of Utstein-style guidelines for reporting cardiac arrest, large sample size, and a population-based design were intended to minimize these potential sources of biases.

This large, nationwide, population-based cohort study showed that CPR with prehospital advanced airway management, whether endotracheal intubation or supraglottic airways, was independently associated with a decreased likelihood of favorable neurological outcome compared with conventional bag-valve-mask ventilation among adults with OHCA. Our observations contradict the assumption that aggressive airway intervention is associated with improved outcomes and provide an opportunity to reconsider the approach to prehospital airway management in this population.

Author Contributions: Dr Hasegawa had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Hasegawa, Brown.
Acquisition of data: Hasegawa, Hiraide.
Analysis and interpretation of data: Hasegawa, Chang, Brown.
Drafting of the manuscript: Hasegawa.
Critical revision of the manuscript for important intellectual content: Hasegawa, Hiraide, Chang, Brown.
Statistical analysis: Hasegawa, Chang.
Obtaining funding: Hiraide.
Administrative, technical, or material support: Brown.
Study supervision: Hasegawa, Hiraide, Brown.
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