Effect of Out-of-Hospital Pediatric Endotracheal Intubation on Survival and Neurological Outcome
A Controlled Clinical Trial

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ALTHOUGH BAG-VALVE-MASK ventilation (BVM) and endotracheal intubation (ETI) are both widely used in the out-of-hospital setting in caring for critically ill or injured children, there has been no controlled study comparing the outcomes of pediatric or adult patients treated with these 2 procedures. In 1 out-of-hospital study, BVM did compare favorably to non-ETI advanced airway management techniques (pharyngeal tracheal lumen, laryngeal mask, and esophageal tracheal combination esophageal-tracheal tube) among adults and children, as measured by PO_2 and PCO_2 values on arrival in the emergency department (ED), frequency of vomiting, and patient outcome.[1]

There have been a number of descriptive studies of ETI in the out-of-hospital

Context Endotracheal intubation (ETI) is widely used for airway management of children in the out-of-hospital setting, despite a lack of controlled trials demonstrating a positive effect on survival or neurological outcome.

Objective To compare the survival and neurological outcomes of pediatric patients treated with bag-valve-mask ventilation (BVM) with those of patients treated with BVM followed by ETI.

Design Controlled clinical trial, in which patients were assigned to interventions by calendar day from March 15, 1994, through January 1, 1997.

Setting Two large, urban, rapid-transport emergency medical services (EMS) systems.

Participants A total of 830 consecutive patients aged 12 years or younger or estimated to weigh less than 40 kg who required airway management; 820 were available for follow-up.

Interventions Patients were assigned to receive either BVM (odd days; n = 410) or BVM followed by ETI (even days; n = 420).

Main Outcome Measures Survival to hospital discharge and neurological status at discharge from an acute care hospital compared by treatment group.

Results There was no significant difference in survival between the BVM group (123/404 [30%]) and the ETI group (110/416 [26%]) (odds ratio [OR], 0.82; 95% confidence interval [CI], 0.61-1.11) or in the rate of achieving a good neurological outcome (BVM, 92/404 [23%] vs ETI, 85/416 [20%]) (OR, 0.87; 95% CI, 0.62-1.22).

Conclusion These results indicate that the addition of out-of-hospital ETI to a paramedic scope of practice that already includes BVM did not improve survival or neurological outcome of pediatric patients treated in an urban EMS system.

JAMA. 2000;283:783-790   www.jama.com

setting. Reported success rates of pediatric ETI vary from 50% to 100%, depending on the patient's presenting illness or injury, the age of the patient, education level of the health care provider, and use of neuromuscular blocking agents to facilitate intubation.[2-10] Major complications of ETI, such as esophageal intubation, have been reported in as little as 1.8% and as many as 17% of pediatric patients in the out-of-hospital setting.[7,10] One study reported an overall complication rate of 22.6%, using succinylcholine to facilitate

intubation.[10] Despite the fact that retrospective studies comparing the survival of patients treated with BVM and ETI have generally found no difference, some investigators have suggested that ETI may

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Caring for the Critically Ill Patient Section Editor: Deborah J. Cook, MD, Consulting Editor, *JAMA*.
Advisory Board: David Bihari, MD; Christian Brun-Buisson, MD; Timothy Evans, MD; John Heffner, MD; Norman Paradis, MD.

be beneficial in certain patient subgroups, such as those with submersion injury and cardiopulmonary arrest.[4,6,11-13] Moreover, despite limited comparative data for BVM and ETI, and the high complication rates reported for pediatric ETI in the out-of-hospital setting, pediatric ETI is taught in 97% of paramedic training schools and widely used by out-of-hospital providers.[14]

This study compared the survival and neurological outcomes of pediatric patients assigned to receive BVM with those of patients assigned to receive ETI in the out-of-hospital setting.

METHODS
Setting
Los Angeles and Orange counties in California are 2 contiguous metropolitan urban areas of 4869 square miles (12 659 square kilometers) and population of greater than 12 million persons.[15-17] Approximately 25% of this population is younger than 13 years of age.

Both counties have 2-tiered 911 systems of basic and advanced life support units and provide online medical direction during out-of-hospital treatment of critically ill pediatric patients. In Los Angeles County alone, there was an average of 73 000 annual pediatric 911 calls during the study period. Critical pediatric patients were transported to 1 of 9 pediatric critical care centers or 1 of 13 trauma centers, unless the patient had airway obstruction or a similar problem that could not be managed in the out-of-hospital setting. In those cases, the patient was transported to the closest ED approved for pediatric patients.[18,19] In Orange County, all pediatric patients were transported to a designated paramedic receiving center and, after stabilization, often transported to a pediatric tertiary care facility.

Adult ETI has been within the paramedic scope of practice in both counties for more than 10 years and BVM for almost 30 years. Prior to the beginning of this study, pediatric ETI was not in the paramedic scope of practice in either county except as a pilot project in Long Beach, Calif.[20]

Training of Paramedics
For this study, 2584 licensed paramedics from 56 paramedic provider agencies received training in pediatric airway management and the research protocol during two 3-hour educational sessions. All training was performed by 2 primary educators (P.D.P. and S.M.G.) with the assistance of 2 additional trained educators using a standardized curriculum.[21] An additional 500 paramedic students in primary paramedic training received the pediatric airway management education using the same materials. Skills taught included sizing and placing oro- and nasopharyngeal airways, use of a length-based resuscitation tape (to determine patient weight, drug dosage, and equipment sizing), BVM, ETI, foreign body removal with pediatric Magill forceps, use of a carbon dioxide detector as an adjunct to clinical assessment of endotracheal tube placement, and endotracheal drug delivery.

Training included lecture, skill demonstration, and skills teaching using pediatric-sized mannequins. Mannequin training was chosen because previous work in adult patients showed it to be comparable to cadaver training, and 68% of paramedic primary training programs have discontinued animal model training, cadaver training, and operating room training of pediatric intubation because of logistical problems in obtaining these models or in organizing the training.[14] For instruction of BVM, a new technique called "squeeze, release, release" was used.[15,21,22] The paramedic was instructed to repeat the phrase "squeeze, release, release" to achieve a ventilation rate of no more than 20/min in a child older than 1 year, and a rate of no more than 30/min for an infant 1 year old or younger while maintaining an adequate expiratory phase. Paramedics were instructed to adequately ventilate but not to attempt hyperventilation.

Paramedics were only allowed to enroll patients into the study after they had successfully completed the airway management training and had successfully completed skills testing for BVM and ETI. Paramedics were trained to mastery of all skills. Strict criteria were used uniformly in skills testing of paramedics in BVM and ETI. Study investigators provided continuing education opportunities in pediatric airway management for paramedics throughout the study.

Subjects
Consecutive patients aged 12 years or younger or estimated to weigh 40 kg or less were entered into the study from March 15, 1994, to January 1, 1997, if they required airway management based on 1 or more of the following criteria: cardiopulmonary arrest (patient apneic without a palpable pulse); respiratory arrest (patient apneic only, with pulse present); respiratory failure (with respiratory rates >60/min or <12/min) with a nonpurposeful response or no response to pain; complete or severe partial airway obstruction; traumatic cardiopulmonary arrest; traumatic respiratory arrest; closed or open head trauma with a nonpurposeful response or no response to pain; and paramedic assessment that assisted ventilation was necessary.

Intervention
Patients were assigned by calendar day to receive BVM (odd days) or BVM followed by ETI (even days). The use of pediatric Magill forceps to remove a foreign body from the airway when basic life support maneuvers failed could be performed on either day.

Data Collection
A standardized form was completed in the ED by the paramedic and emergency physician and mailed to study investigators. The emergency physician completed sections of the study form pertaining to the pulse oximetry on ED arrival, appropriateness of mask size for BVM, endotracheal tube size and correct placement for ETI, and complications for both BVM and ETI.

Paramedics were instructed to page a 24-hour on-call investigator immediately after transfer of patient care to the ED staff. The on-call investigator discussed the case with the paramedic in a structured interview and recorded in-

formation on a standardized data collection form about the indication for airway management, complications, survival to admission (lived or died), previous neurological deficits, other out-of-hospital interventions, and the name of receiving hospital. In cases in which the patient presented in cardiopulmonary arrest, additional information was obtained, including presenting rhythm, occurrence of citizen-initiated cardiopulmonary resuscitation, downtime prior to arrest, out-of-hospital interventions (defibrillation and medications), and whether there was return of spontaneous circulation.

Study investigators (S.M.G. and P.D.P.) retrospectively reviewed inpatient medical records, transfer hospital records, coroner's reports, and emergency medical services (EMS) report forms to obtain demographic information, process of care data (eg, elapsed times), and outcome data for all patients.

Outcomes

The primary study outcome, survival to discharge from an acute care hospital, and the secondary outcome, neurological status at hospital discharge from the acute care hospital, were evaluated retrospectively. Each patient was assigned a neurological outcome category or score (normal or no change from baseline, mild disability, moderate disability, severe disability, coma or vegetative state, or death) based on a modified Pediatric Cerebral Performance Category Scale.[23] The interrater reliability of the neurological outcome score was assessed by having 2 study investigators (S.M.G. and P.D.P.) independently score a subsample of 31 cases. The interrater reliability was measured using a weighted κ statistic and associated confidence interval (CI). Patients who were stabilized at 1 acute care facility and then transported to other acute care facilities were evaluated for survival and neurological outcome at discharge from the final acute care facility at which they were treated.

An ETI attempt was defined as placement of a laryngoscope in the pa-

tient's mouth with the intent of intubation, regardless of whether an endotracheal tube was passed into the oropharynx or trachea. Successful intubation was defined as placement of an endotracheal tube into a child's trachea or main stem bronchus as determined by the emergency physician or by the study investigator after review of all available data pertaining to the intubation attempt and subsequent treatment in the ED.

Study investigators used a strict algorithm for defining complications specific to ETI (eg, main stem intubation, recognized dislodgment, unrecognized dislodgment, esophageal intubation) that was used uniformly in all cases of possible successful intubation.

Definition of Subgroups

Members of the study's steering committee defined 10 clinically important subgroups prior to the collection of study data: sudden infant death syndrome, submersion injury, head injury, multiple trauma, foreign body aspiration, seizure, child maltreatment, cardiopulmonary arrest, respiratory arrest, and reactive airway disease. We considered subgroups defined both by the etiology of the illness or injury that was apparent to out-of-hospital providers and by the etiology of the illness or injury based on retrospective review of the final medical record. Patient subgroup assignments were based on all the information available, including the out-of-hospital EMS form, the inpatient medical record, and the coroner's report; the subgroups were not mutually exclusive. Two nurse educators assigned patients to the appropriate subgroups. If there was any disagreement between the nurse educators about the appropriate subgroup assignments, the principal investigator reviewed the patient file and the final assignment was based on a majority of investigators agreeing on the assignment. There were no significant disagreements in the assignment of subgroups.

Institutional Review Board Approvals

This study was approved by institutional review boards (IRBs) or medical staff office representatives, who serve as the IRBs at their institutions, at all of the 115 paramedic receiving facilities in the study region. The study was approved with waiver of consent for the patients enrolled.
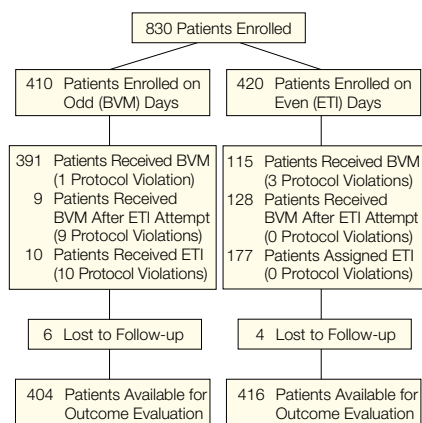
Monitoring of Enrollment

After all the paramedic provider agencies were educated, the accrual rate of patients enrolled was monitored. As a secondary check, base hospital nurses and EMS agency staff checked data to ensure that all eligible patients were enrolled.

Statistical Analysis

Data were entered into a database (Paradox 3.5, Borland, Scotts Valley, Calif) and analyzed using the SAS statistical software package (SAS 6.12, SAS Institute, Cary, NC). Proportions were compared using the χ^2 or Fisher exact tests, and odds ratios (ORs) with 95% CIs were calculated using the logit function. Odds ratios for 2×2 tables with a single 0 cell were calculated by adding 0.5 to each cell value. Descriptive statistics for continuous variables are expressed as medians with interquartile ranges (IQRs). Continuous variables were compared using the Wilcoxon rank sum test. $P<.05$ was considered statistically significant. Except for the planned interim data analyses described below, no correction was made for multiple comparisons.

We initially believed the vast majority of patients enrolled would be infants in cardiopulmonary arrest. Based on this assumption, the study was designed to have a power of 80% to detect an increase in survival to hospital discharge from 5% to 10%, using a 2-tailed α of .05. We used the group sequential design of O'Brien and Fleming with 3 interim analyses.[24-26] The required sample size was 800 patients, with interim analyses occurring after each 200 patients. The power of this

Figure. Patient Flow Diagram

BVM indicates bag-valve-mask ventilation; ETI, endotracheal intubation.

Table 1. Patient Demographics by Pediatric Airway Management Group*

	No. (%) of Patients		P Value
	BVM	ETI	
Age, y, median (interquartile range)	1.2 (0-3.5)	1 (0.25-3.3)	.77
Sex, male	247/403 (61)	236/415 (57)	.20
Ethnicity†			
Hispanic	172 (45)	174 (44)	
White	106 (28)	102 (26)	
Black	69 (18)	75 (19)	.89
Asian	25 (6)	26 (7)	
Other	10 (3)	15 (4)	
ED disposition‡			
Died	219 (54)	231 (56)	
Intensive care unit	83 (20)	77 (18)	
Transfer	67 (17)	78 (19)	
Operating room	14 (3)	16 (4)	.81
Ward or nursery	11 (3)	8 (2)	
Home or against medical advice	9 (2)	6 (1)	
Patients declared dead without resuscitation in the ED§	123/367 (34)	110/369 (30)	.28
Final diagnosis‖			
SIDS	59 (14)	82 (19)	.049
Submersion injury	56 (14)	43 (10)	.13
Head injury	27 (7)	36 (9)	.28
Multiple trauma	37 (9)	51 (12)	.15
Foreign body aspiration	13 (3)	13 (3)	.95
Status epilepticus	38 (9)	33 (8)	.47
Child maltreatment	24 (6)	22 (5)	.70
Cardiopulmonary arrest	293 (71)	303 (72)	.83
Respiratory arrest	55 (13)	55 (13)	.89
Reactive airway disease	12 (3)	11 (3)	.80

*BVM indicates bag-valve-mask ventilation; ETI, endotracheal intubation; ED, emergency department; and SIDS, sudden infant death syndrome.
†Data were available for 382 patients in the BVM group and 392 in the ETI group.
‡Data were available for 403 patients in the BVM group and 416 patients in the ETI group.
§Information was not available for 84 patients.
‖Data were available for 410 patients in the BVM group and 420 in the ETI group.

study design was verified using Monte Carlo simulation.

Because interim analyses of the data occur relatively infrequently using the classical group-sequential monitoring plan, and because of initial concern that patients in 1 treatment group might experience much better or worse outcomes than the other, 2 additional parallel monitoring plans were used. First, a Bayesian decision theoretical group-sequential monitoring plan, incorporating analyses of the data after every 32 patients, was applied to data on survival to hospital admission from the ED. This data-monitoring plan is an extension of that published by Lewis and Berry[27] using a quadratic decision-loss function and a 2-tailed loss function.

The boundaries of the Bayesian plan were chosen to yield a classical 2-tailed α of .05. The second monitoring plan was a case-by-case safety analysis by an independent safety reviewer.

All data were analyzed according to the intention-to-treat principle. If, because of an error in applying the odd-even assignment, a treating paramedic approached a patient fully intending to apply the opposite treatment to that dictated by the calendar-day assignment (protocol violation), then that patient remained in the treatment group assigned by enrollment date. However, because paramedics in reality would not have endotracheal tubes if their scope of practice included BVM alone, secondary analyses were performed on the main outcomes, grouping patients by the treatment intended by the paramedic and by actual treatment received.

Additional information regarding the implementation of the Pediatric Airway Management Project will be published elsewhere.[15]

RESULTS

A total of 830 patients were entered into the study. Of these, 420 patients (51%) were assigned to receive ETI and 410 patients (49%) were assigned to receive BVM. There were 23 (3%) protocol violations. Patients subject to protocol violations were left in their assigned group by a strict intention-to-treat principle. Ten patients were excluded because of incomplete records, leaving a total of 820 patients available for analysis of outcomes (**FIGURE**).

Patients in the BVM group were not statistically different, considering the multiple comparisons made, from those in the ETI group regarding age, ethnicity, sex, percentage of patients declared dead in the ED without resuscitation, and in apparent etiology of illness or injury (**TABLE 1**).

Results on Survival and Neurological Outcome

Information was available on 820 patients for the analysis of survival and neurological outcome. Survival in the

BVM group (123/404 [30%]) was not significantly different from that in the ETI group (110/416 [26%]) (OR, 0.82; 95% CI, 0.61-1.11). The interrater reliability for the neurological outcome scale was excellent (weighted κ = 0.978; 95% CI, 0.934-1.000). Neurological outcomes are shown in **TABLE 2**. There was no significant difference in the number of patients with a good neurological outcome (defined as normal, mild deficit, or no change from baseline function) in the BVM group (92/404 [23%]) and the ETI group (85/416 [20%]) (OR, 0.87; 95% CI, 0.62-1.22).

Secondary analysis of the main outcomes (survival and neurological status) show that, by paramedic intent, survival in the BVM group was 119 (31%) of 387 and in the ETI group was 114 (26%) of 433 (OR, 0.81; 95% CI, 0.6-1.09). The rate of good neurological outcome in the BVM group was 91 (24%) of 387 and in the ETI group was 86 (20%) of 433 (OR, 0.81; 95% CI, 0.58-1.12).

By treatment received where data were available, survival in the BVM group was 208 (33%) of 635 and in the ETI group was 25 (14%) of 185 (OR, 0.32; 95% CI, 0.20-0.50). The rate of good neurological outcome in the BVM group was 162 (26%) of 635 and in the ETI group was 15 (8%) of 185 (OR, 0.26; 95% CI, 0.15-0.45). A total of 10 patients are missing survival and neurological outcome information; by treatment received, these were 8 patients in the BVM group and 2 patients in the ETI group. The results of survival and neurological outcome by paramedic intent is no different than the primary analysis, but the results of survival and neurological outcome by treatment received shows a statistically significant survival and neurological outcome benefit of BVM. This result shows why it is vital to analyze data by the intention-to-treat principle; in this case, an erroneous conclusion could be reached if the data were analyzed by treatment received, because the success of intubation is not independent of prognosis, and those patients most likely to be suc-cessfully intubated (cardiopulmonary arrest) are most likely to die of their disease process.

TABLE 3 lists the survival and neurological outcome of patients in the BVM and ETI groups by their illness or injury subgroup. When the final diagnosis for each patient was determined by chart review, 3 of the 10 subgroups (respiratory arrest, child maltreatment, and foreign body aspiration) showed a significant worsening in survival or neurological outcome with ETI relative to BVM.

Process of Care Results

Of 410 BVM group patients, 391 (95%) received BVM alone, 9 (2%) received BVM after an intubation attempt, and 10 (2%) were intubated. Of 420 ETI group patients, 115 (27%) received BVM only, 128 (30%) received BVM after unsuccessful ETI attempts, and 177 (42%) were intubated. Of the 420 patients treated on ETI days, paramedics attempted intubation in 305 (73%) and, of these 305 patients, 174 (57%) were successfully intubated and 3 were esophageally intubated.

Paramedics reported "good" chest rise in 332 (83%) of 398 patients in the

Table 2. Intended Airway Management Method and Neurological Outcome*

	No. (%) of Patients	
	BVM (n = 404)	ETI (n = 416)
Normal or no change from baseline	39 (10)	33 (8)
No change from baseline status	33 (8)	25 (6)
Mild disability	20 (5)	27 (6)
Moderate disability	6 (1)	7 (2)
Severe disability	10 (2)	6 (1)
Coma/vegetative	15 (4)	12 (3)
Death	281 (70)	306 (74)

*BVM indicates bag-valve-mask ventilation; ETI, endotracheal intubation. There were no significant differences in outcomes between the 2 groups.

Table 3. Outcomes by Patient Subgroup*

	No. (%) of Patients		
	BVM	ETI	OR (95% CI)
Survival by Final Diagnosis			
SIDS	0/58 (0)	0/80 (0)	Undefined
Submersion injury	18/55 (33)	20/43 (47)	1.79 (0.78-4.07)
Head injury	8/25 (32)	9/36 (25)	0.71 (0.23-2.19)
Multiple trauma	7/37 (19)	12/51 (24)	1.32 (0.46-3.77)
Foreign body aspiration	9/13 (69)	5/13 (38)	0.28 (0.06-1.41)
Seizure	35/37 (95)	26/32 (81)	0.25 (0.05-1.33)
Child maltreatment	10/24 (42)	3/22 (5)	0.07 (0.01-0.58)†
Cardiopulmonary arrest	24/290 (8)	24/301 (8)	0.96 (0.53-1.73)
Respiratory arrest	46/54 (85)	33/54 (61)	0.27 (0.11-0.69)†
Reactive airway disease	6/12 (50)	3/10 (30)	0.43 (0.07-2.50)
Overall	123/404 (30)	110/416 (26)	0.82 (0.61-1.11)
Good Neurological Outcome by Final Diagnosis‡			
SIDS	0/58 (0)	0/80 (0)	Undefined
Submersion injury	12/55 (22)	15/43 (35)	1.92 (0.78-4.70)
Head injury	2/25 (8)	4/36 (11)	1.44 (0.24-8.52)
Multiple trauma	2/37 (5)	6/51 (12)	2.33 (0.44-12.27)
Foreign body aspiration	9/13 (69)	3/13 (23)	0.13 (0.02-0.76)†
Seizure	34/37 (92)	26/32 (81)	0.38 (0.09-1.68)
Child maltreatment	2/24 (8)	0/22 (0)	0.20 (0.01-4.40)
Cardiopulmonary arrest	10/290 (3)	15/301 (5)	1.47 (0.65-3.32)
Respiratory arrest	35/54 (65)	27/54 (50)	0.54 (0.25-1.18)
Reactive airway disease	6/12 (50)	3/10 (30)	0.43 (0.07-2.50)
Overall	92/404 (23)	85/416 (20)	0.87 (0.62-1.22)

*BVM indicates bag-valve-mask ventilation; ETI, endotracheal intubation; OR, odds ratio; CI, confidence interval; and SIDS, sudden infant death syndrome. Subgroup designations are not mutually exclusive.
†This category was significant for patients with ETI compared with the BVM group.
‡Good neurological outcome was defined as no disability, no change from baseline, or mild disability.

Table 4. Median Out-of-Hospital Care Times by Pediatric Airway Management Group*

| | Minutes, Median (Interquartile Range) | | |
Period	BVM	ETI	P Value
Dispatch to arrive on scene	5 (4-6)	5 (4-7)	.45
Scene time	9 (5-13)	11 (7-16)	<.001
Transport time	6 (4-8)	6 (4-9)	.21
Total time	20 (16-26)	23 (18-29)	<.001

*BVM indicates bag-valve-mask ventilation; ETI, endotracheal intubation.

Table 5. Complications of Pediatric Airway Management for All Patients*

| | No. (%) of Patients | | |
	BVM (n = 364)	ETI (n = 363)	P Value
None	194 (53)	187 (51)	.60
Gastric distention	114 (31)	27 (7)	.20
Vomiting	50 (14)	52 (14)	.82
Aspiration	51 (14)	53 (15)	.84
Oral/airway trauma	4 (1)	8 (2)	.24

*BVM indicates bag-valve-mask ventilation; ETI, endotracheal intubation. This information was missing for 103 patients and a given patient may have had more than 1 complication.

BVM group (12 patients were missing data) and in 315 (82%) of 382 patients in the ETI group (38 patients were missing data) (P = .62).

There were 94 patients who were assigned to receive BVM and 89 patients assigned to receive ETI who had a pulse strong enough to be reliably read by the pulse oximeter on arrival in the ED. Median pulse oximetry values in these patients were not significantly different between these groups (BVM, 98% [IQR, 93%-100%]; ETI, 97% [IQR, 92%-100%]; P = .29). These values did not significantly change even when patients receiving BVM were compared with the 27 patients who had a pulse on arrival in the ED and were successfully intubated in the field (ETI, 95%; [IQR, 89%-100%]; P = .43).

The attempt and success rate of intubation by age of patient is outlined below. Age groups were divided into younger than 3 years, 3 to 8 years, and older than 8 years. Of 830 children, 608 (73%) were younger than 3 years, 155 (19%) were aged 3 to 8 years, and 67 (8%) were older than 8 years. Of the 420 patients in the ETI group, attempt rates

for ETI were not statistically different between age groups (<3 years, 225/310 [73%]; 3-8 years, 56/78 [72%]; and >8 years, 24/32 [75%]). Apparent success rates (in the ETI group) were also not statistically different between age groups, although it appears that the trend is for increased success with increasing age of the patient (<3 years, 127/225 [56%]; 3-8 years, 34/56 [61%]; and >8 years 16/24 [67%]).

TABLE 4 lists out-of-hospital care times by intended method. Scene times and total times were significantly longer for patients in the ETI group.

Complication rates for BVM and ETI are shown in TABLE 5. There was no significant difference in the rate of complications common to both airway methods. Of 186 patients in both groups in whom intubation was believed successful and complications could be determined, 3 patients (2%) were esophageally intubated, 12 (6%) suffered unrecognized dislodgment of the endotracheal tube en route to the ED, 15 (8%) experienced recognized dislodgment of the endotracheal tube, 33 (18%) received main stem intubation, and 44 (24%) were intubated with a tube of the incorrect size. All but 1 of the patients receiving esophageal intubation or with unrecognized dislodgment of the endotracheal tube died. A total of 26% of intubated patients were placed in spinal immobilization; however, spinal immobilization did not affect the rate of dislodgment: 14 (16%) of 88 were not immobilized, and 5 (18%) of 28 were immobilized (P = .98). Carbon dioxide detectors were used in 144 (77%) of 187 patients intubated but were not uniformly maintained during transport of the patient.

The median hospital length of stay was not different between the 2 groups (0 days [IQR, 0-2 days] for both groups; P = .75), nor was the median number of days in the intensive care unit (BVM, 0 days [IQR, 0-1 days]; and ETI, 0 days [IQR, 0-2 days]; P = .89).

COMMENT

Children requiring airway management are frequently encountered in the out-of-hospital setting.[28,29] The perceived need for rapid airway management for children and the successful incorporation of ETI in the scope of practice for adults have led many EMS providers to believe that out-of-hospital ETI should be the standard of care for children as well. So strong is this belief that pediatric ETI was recently added as an optional skill to the national standard curriculum for basic EMS technicians,[30] who have much more limited training than the paramedics participating in the study reported here.

Our results demonstrate that pediatric ETI does not improve patient outcome in a rapid-transport urban EMS system. When performed using the "squeeze, release, release" technique, BVM results in the same outcome as ETI without the potential fatal complications of ETI.

Unlike previous work, our data were analyzed according to the intention-to-treat principle. This allows an unbiased estimate of the effect of incorporating ETI into the paramedic scope of practice, even though ETI is not successfully used in 100% of the patients in whom it is indicated.

The 73% ETI attempt rate reported here is similar to the 66% rate reported by Aijian et al,[4] and the 68% rate reported by Losek et al.[6] Our 57% success rate for intubation is lower than the rates reported by several other investigators.[2,4,5,9] There are several possible causes of this difference. First, the young age distribution of our patients (median age, 1.2 years; 73% of patients were younger than 3 years of age) may have contributed to a lower overall ETI success rate. Aijian et al[4] reported a 50% rate of successful ETI in children younger than 1 year of age, and Losek et al[6] reported a 54% rate of successful ETI in children 18 months of age or younger. Second, the current study design minimized the effect of documentation bias on ETI success rates. Previous studies have relied solely on the written EMS report to determine the number of intubation attempts and, therefore, success rates of ETI were likely overestimated because the number of attempts was likely underestimated.

The determination of complication rates for BVM and ETI was an important aspect of this study. Although a specific algorithm that incorporated data from the paramedic EMS form, the study form, and the hospital chart was used by investigators to assign complications of ETI, it is likely that the true rates of esophageal intubation and unrecognized dislodgment were underestimated. In cases in which the paramedic stated to the investigator that the "tube became dislodged" on transfer of the patient to the ED staff, an assignment of "recognized dislodgment" was made by investigators; however, it is possible that in some of these cases the patient was primarily esophageally intubated or that the tube became dislodged early and was only recognized at the time of transfer of the patient to ED staff.

The high dislodgment rate found in this study may be attributed to the short tracheal length of children and the constant movement that occurs in the out-of-hospital setting. Study investigators tried to lessen the unrecognized dislodgment rate by giving specific instructions for securing the endotracheal tube, the use of spine board immobilization, and the use of carbon dioxide detectors, but this complication still occurred at an unacceptable rate.

Finally, this study showed that there was a significant difference (favoring BVM) in survival of patients in 2 subgroups (respiratory arrest and child maltreatment) and in neurological outcome in 1 subgroup (foreign body aspiration). It is possible that in subgroups in which the inherent survival rate is high, the use of ETI adversely affects outcome because of the introduction of increased periods of hypoxia with intubation attempts and additional risk of fatal complications. It is also possible that these results reflect a type I error, resulting from the number of subgroups analyzed. Despite the number of subgroups analyzed, no subgroup experienced a statistically significant improvement in outcome with ETI.

The EMS medical director must decide which pediatric airway management method to use in the out-of-hospital setting as, even in cardiopulmonary arrest, intubation may be delayed until the patient arrives in the more controlled environment of the ED. Our data suggest that BVM is as effective as ETI in an urban EMS system and demonstrate increased scene time and overall time when ETI is used. Although several authors have suggested a benefit of ETI for selected subgroups,[5,11-13] analysis of subgroups in our study failed to show favorable outcomes for ETI vs BVM and, in fact, showed a detrimental effect in survival in 2 subgroups and in neurological outcome in 1 subgroup. It may be more prudent for EMS leaders to focus on effective BVM and rapid transport and to delay pediatric ETI until arrival in the ED. This delay may prevent the potentially fatal complications of ETI observed in this study and yield the same or better outcome results.

If ETI is to be delayed until arrival in the ED, it is important that EMS personnel are skilled in the technique of BVM. In this study, BVM received emphasis equal to ETI in the educational program. As with ETI, the techniques and methods of BVM were carefully reviewed, and a rigorous BVM education program was implemented. Thus, to ensure success in the out-of-hospital airway management of children, the importance of basic airway maneuvers cannot be overemphasized.

This study was conducted in urban-suburban, rapid-transport EMS systems, and our conclusions may not be valid for rural environments or for EMS systems with prolonged transport times. In addition, all patients entered into the study were intubated without the use of sedatives or paralytic agents.

A potential limitation of the study was the use of mannequins to train paramedics. Mannequin-based training of paramedics has been previously validated for adult intubation and may provide a more practical approach to training a large number of students.[31]

Another limitation is the difference in the number of protocol violations in the 2 groups (20 vs 3). This may have occurred because protocol violations on BVM days (when paramedics instead performed ETI) were more likely to have been noted by study investigators than were those on ETI days (paramedics never intended to provide ETI and provided BVM only), as BVM was a potentially acceptable treatment on ETI days. In addition, some of the paramedics may have had a preconceived notion that ETI was the best method and were more likely to commit a protocol violation on BVM days in favor of ETI. Given that the data were analyzed by intention to treat, it is unlikely this 2.3% protocol violation rate had any effect on study results.

Another limitation is the possibility that subjective assessment of inclusion criteria, combined with paramedic knowledge of the treatment assignment for a study day, might have influenced patient enrollment. While this is possible, there are no data to suggest that this occurred to any significant extent. Over 3 months, we conducted a comprehensive survey of prehospital coordinators and reviewed EMS records from the Los Angeles and Orange counties' EMS agencies to independently identify all patients who might have qualified for the study. During that time, only 1 possible missed subject was detected (based on a retrospective review of EMS records it was not possible to conclusively determine whether the patient qualified for the study).

Finally, an additional limitation was that study investigators were not blinded to assigned group at the time of chart review. Data were collected independently, however, by 2 investigators who were unaware of any results of the study until all data were gathered.

CONCLUSIONS

The addition of pediatric ETI to the paramedic scope of practice, compared with BVM alone, does not improve survival or neurological outcome. For ETI in this setting, scene time was prolonged and fatal complications were frequent. These results call into question the current practice of

paramedics intubating children in an urban, out-of-hospital setting, as well as the rationale of allowing less-experienced personnel, such as basic emergency medical technicians to intubate children. Emergency medical services systems should focus on training its providers to perform effective BVM, coupled with expeditious transport, and defer pediatric ETI until the patient arrives in the ED.

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In Reply: To make evidenced-based recommendations related to breast cancer screening of elderly women, the efficacy (or lack thereof) of screening mammography needs to be better defined. Additional time preference and utility data are also needed, and guidelines for a threshold for average life expectancy gained and cost per year of life saved are required. In the meantime, elderly women and their physicians must decide whether to continue or discontinue screening mammography at age 70 years. In an effort to build a clinically relevant and useful model to facilitate this decision, we focused on the 2 most important factors that would influence decisions about screening in the elderly: (1) level of breast cancer risk determined by age and BMD measurement, and (2) time preference or discount rate.

Even without precisely defining an individual woman's physiologic age, breast cancer risk, discount rate and utilities, a clinician can make a reasonable recommendation based on our model. Elderly women with normal or high BMD and a strong preference for preventive care may choose to undergo mammography while women with existing comorbid conditions and low BMD whose chance of dying of breast cancer is very low may choose not to undergo mammography since the chance of benefiting from screening is very small. Given the small average gains in life expectancy (2.1 days) from screening elderly women with normal to high BMD, even those at relatively high risk and without comorbid conditions, the chance that average life expectancy would be increased to more than 30 days (a gain from a preventive intervention considered to be large[1]) is small.

Although the number of cases is small, Dr Rozenberg and colleagues report some interesting data that support the association between breast cancer and high BMD. Other studies have found that high estrogen levels are associated with breast cancer,[2] suggesting a central role for estrogen in both diseases.

Technically, Drs Seidenwurm and Breslau are correct that time costs are part of the total cost of an intervention. However, it is often assumed that quality adjusted life years incorporate these time costs. Therefore, it would be redundant to include them as a separate cost.[3]

It is important to recognize that older women differ significantly in their risk for breast cancer and their preferences for a small gain in life expectancy and the potential harms of screening mammography. The emphasis should be to identify groups of elderly women willing to undergo mammography (with its attendant harms—time, money, discomfort, additional tests and surgeries) and who are also most likely to benefit from screening. Conversely, it is important to identify elderly women who are unlikely to benefit from screening so they will not be subjected to the potential harms of mammography.[4] Our goal is to help physicians identify those elderly women who may benefit the most from screening mammography and to help elderly women make an informed decision about continuing screening mammography.

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CORRECTIONS

Incorrect Numbers: In the Original Contribution entitled "Effect of Out-of-Hospital Pediatric Endotracheal Intubation on Survival and Neurological Outcome: A Controlled Clinical Trial" published in the February 9, 2000, issue of THE JOURNAL (2000;283:783-790), there were incorrect numbers in 2 tables. On page 787, in Table 3, the numbers "3/22 (5)" for "Child maltreatment" under "Survival by Final Diagnosis" for "ETI" should have read "1/22 (5)." The related odds ratio and 95% confidence interval values remain correct. On page 788, in Table 5, the numbers "27 (7)" for "Gastric distention" under "ETI" should have read "98 (27)." The related *P* value in that table remains correct.

Incorrect Academic Degree and Missing Citations: In the Original Contribution entitled "Impact of Disseminating Quality Improvement Programs for Depression in Managed Primary Care: A Randomized Controlled Trial" published in the January 12, 2000, issue of THE JOURNAL (2000;283:212-220), an incorrect academic degree was cited and 2 citations were omitted in the text and reference list. In the byline on page 212, the academic degrees for Lisa V. Rubenstein should be MD, MSPH. Also, the following 2 references should have been cited in the article:

32. Muñoz RF, Miranda J. *Group Therapy for Cognitive-Behavioral Treatment of Depression, San Francisco General Hospital Depression Clinic, 1986.* Santa Monica, Calif: RAND; 2000. Document MR-1198/4.
33. Muñoz RF, Aguilar-Gaxiola SA, Guzmán J. *Manual de Terapia de Grupo para el Tratamiento Cognitivo-conductual de Depresión, Hospital General de San Francisco, Clínica de Depresión, 1986.* Santa Monica, Calif: RAND; 2000. Document MR-1198/5.

These references should be cited with reference 31 on page 215, middle column, at the end of the first sentence in the first full paragraph.