

INITIAL AIRWAY MANAGEMENT IN PATIENTS WITH OUT-OF-HOSPITAL CARDIAC ARREST: TRACHEAL INTUBATION VS. BAG-MASK VENTILATION.

A European, multicenter, randomized controlled trial

CAAM TIAL

Frédéric Adnet

Samu 93 – Urgences – Inserm U942

Avicenne University Hospital

93000 Bobigny, France

Trial funded by French Ministry of Health (PHRC 2013)

Declaration of interest

- I have nothing to declare

Rationale

- **Benefit of endotracheal intubation (ETI) during CPR is unclear.**
- **Observational studies suggest Bag-Mask ventilation (BMV) is associated with better survival than ETI**
- **Quasi-randomized trial in children suggested no significant difference in survival or neurologic outcome with ETI vs. BMV**

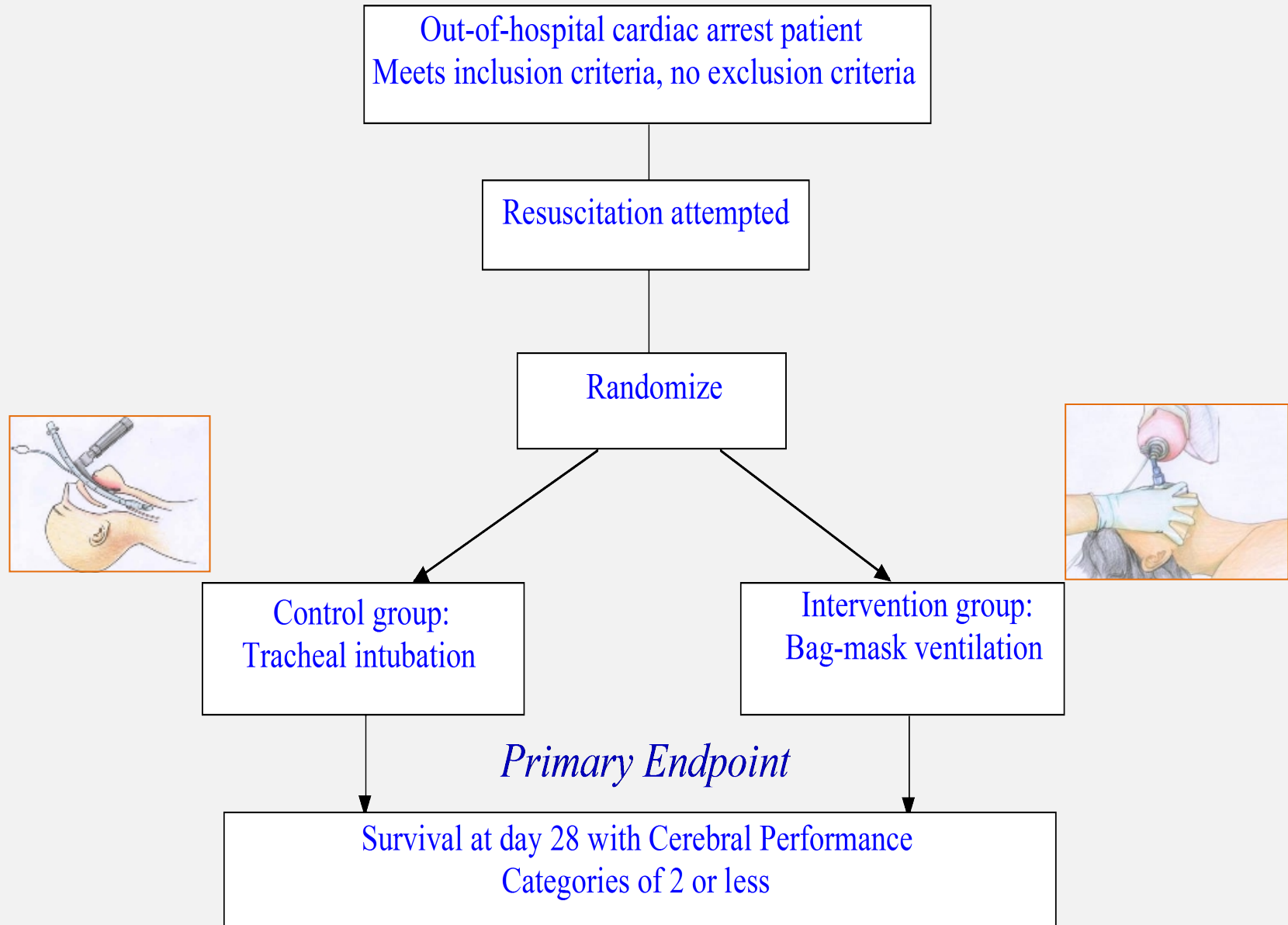
Hypothesis

- **Bag-Mask Ventilation (BMV) is less complex technique than ETI, appears to be safe and may avoid adverse effects of tracheal intubation (ETI) during CPR**
- **We conducted a non-inferiority, multicenter, randomized controlled trial of BMV versus ETI.**

Design

- **Primary Outcome: survival to 28 days with good neurological outcome.**
- **Secondary outcomes included ROSC, survival at hospital admission, adverse effects.**
- **1000 patients per arm is required to have 80% power to demonstrate non-inferiority with margin fixed at 1%.**

Study Setting: 20 pre-hospital emergency medical services centers (SAMU): 15 in France and 5 in Belgium

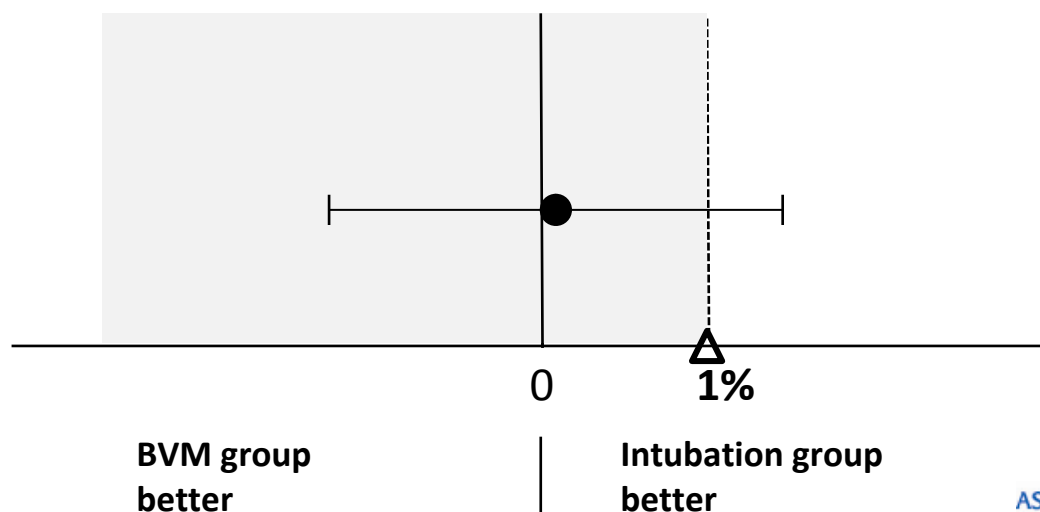


Baseline Characteristics (ITT population = 2040)

Characteristics	BMV group (N=1018)	ETI group (N=1022)
Age – yr, mean \pm SD	65.7 \pm 15.5	63.8 \pm 15.6
Female gender – no. (%)	332 (32.6)	332 (32.5)
Arrest occurring at home – no. (%)	776 (76.2)	811 (79.4)
Bystander witnessed – no. (%)	719 (70.6)	708 (69.3)
Shockable first rhythm – no. (%)	168 (16.5)	155 (15.2)
Number of shocks – median (interquartile range)	3 (1, 7)	3 (1, 6)

Primary outcome (ITT analysis)

Primary outcome	BMV (N=1018)	ETI (N=1022)	Difference	[95% CI]
Survival with good neurological status at day 28	N= 42 (4.2%)	N= 43 (4.3%)	0.11	[-1.64; 1.87]



Outcomes (ITT analysis)

Outcomes	BMV group (N=1018)	ETI group (N=1022)	P value
Return of spontaneous circulation – no. (%)	348 (34.2)	397 (38.9)	0.03
Survival at hospital admission– no. (%)	294 (28.9)	333 (32.6)	0.07
Survival at day 28 – no. (%)	55 (5.4)	54 (5.3)	0.90

Safety analysis

Item	BMV group (N=1028)	ETI group (N=1001)	p
BMV or ETI failure – no. (%)	64 (6.3)	26 (2.5)	<0.0001
BMV or ETI difficulty – no. (%)	186 (18.1)	134 (13.4)	0.004
Regurgitation of gastric content	152 (14.9)	79 (7.7)	<0.0001

Conclusion

- **Our trial was inconclusive regarding the demonstration of non-inferiority of BMV compared with TI for airway management during CPR in OHCA patients**
- **However, this randomized study did not confirm superiority of BMV reported in observational studies**
- **On the other hand, BMV is associated with increased complications and difficulty.**