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JOUNI KUROLA

Evaluation of Pharyngeal Devices for Prehospital Airway Management

Doctoral dissertation

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Department of Anesthesiology and Intensive Care
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ABSTRACT

Prehospital advanced life support (ALS) procedures and treatment is widely used, although the impact of this concept on patient outcome is not scientifically proven. ALS care is provided by either a physician- or paramedic-manned ground or helicopter emergency service (HEMS) units in urban area. Definitive airway management is included in ALS care, and is considered of major importance. The need and indications for prehospital airway management includes trauma, cardiac arrest, severe respiratory distress and decreased level of consciousness due to medical or trauma related emergencies. Endotracheal intubation (ETI) has been a "golden standard" of definitive airway management method, but low success rates and risk of harmful effects have been reported. The question whether pharyngeal airways are suitable for prehospital airway management has been debated. Intubating laryngeal mask (ILMA) and laryngeal tube (LT) are widely used in anaesthesiology and preliminary reports support their use also in prehospital care. Present study was conducted to evaluate whether these devices can provide an alternative to endotracheal intubation in prehospital care.

The impact of prehospital ALS care provided by Eastern Finland HEMS during one year was evaluated by a panel (Study I). Health benefit was observed to be small from all missions of ALS unit, but airway management was the single most important aspect of ALS. Sixty firefighter-EMT (Emergency Medical Technician) students were educated to use laryngeal tube during their curriculum of airway management. In a scenario of witnessed cardiac arrest the use and performance of LT was compared to bag-valve-mask (BVM) ventilation in a manikin (Study II). Thirty of those same firefighter-EMTs were asked to insert LT or perform BVM to anesthetised patients six months later (Study III). All firefighter-EMT students inserted LT successfully (Study II-III) within reasonable time. After short verbal and picture-based training, cohort of participants to emergency congress was voluntarily asked to perform an airway management test using LT (Study V). ILMA, LT and CobraPLA were compared in anesthetised patients used by paramedic students. From volunteers 97 % (Study V) and from paramedic students 78% (Study IV) inserted LT successfully. Success of insertion, insertion times and spirometry values (Study II-III, V) were collected to evaluate the performance of LT. End-tidal carbon dioxide ($etCO_2$) and peripheral oxygen saturation (SpO_2) was used to detect the effectiveness of ventilation and oxygenation (Study IV). ILMA was inserted with a 97 % of success rate with normal ventilation and oxygenation parameters. (Study IV). Ventilation and oxygenation was sufficient with LT (Study III, IV) and ventilation parameters were superior to that of BVM (Study II)

In conclusion, definite prehospital airway management is an important part of prehospital care. LT or ILMA can be used an alternative to ETI especially by basic care providers. Whether these can replace ETI in prehospital care must be tested in real emergency cases.

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Medical Subject Headings: comparative study; emergency medical services; emergency medical technicians; emergency treatment; Finland; first aid; intubation, intratracheal/methods; laryngeal masks; respiration, artificial/methods

To Hannaleena, Minna-Riina and Santeri

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Kuopio, March 2006

Jouni Kurola

LIST OF ABBREVIATIONS

AED	Automated external defibrillator
ALS	Advanced life support
AMI	Acute myocardial infarction
ARDS	Acute respiratory distress syndrome
BLS	Basic life support
BMI	Body mass index
BVM	Bag-valve-mask
CobraPLA	Cobra perilaryngeal airway
COPA	Cuffed oropharyngeal airway
CPR	Cardiopulmonary resuscitation
cLMA	Classic laryngeal mask airway
FiO_2	Fraction of inspired oxygen
ECG	Electrocardiogram
EMS	Emergency medical service
EMT	Emergency medical technician
ERC	European Resuscitation Council
ETC	Esophago-tracheal Combitube
$EtCO_2$	end-tidal carbon dioxide
ETI	Endotracheal intubation
HEMS	Helicopter emergency medical service
HR	Heart rate
ICP	Intracranial pressure
ILMA	Intubating laryngeal mask
ISS	Injury severity score
LT	Laryngeal tube
LMA	Laryngeal mask airway
LTD	Laryngeal tube-disposable
LTS	Laryngeal tube-suction
MICU	Mobile intensive care unit
NIBP	Non-invasive blood pressure

PTLA	Pharyngotracheal lumen airway
PLMA	ProSeal laryngeal mask airway
RCT	Randomized controlled trial
RSI	Rapid sequence induction
SpO_2	Peripheral oxygen saturation

LIST OF ORIGINAL ARTICLES

This thesis is based on the following articles, which are referred to by their Roman numerals in the text:

I Kurola J, Wangel M, Uusaro A, Ruokonen E. Paramedic helicopter emergency services in rural Finland - do benefits justify the cost? Acta Anaesthesiol Scand 2002; 46:779-84

II Kurola J, Harve H, Kettunen T, Laakso JP, Gorski J, Paakkonen H, Silfvast T. Airway management in cardiac arrest--comparison of the laryngeal tube, tracheal intubation and bag-valve mask ventilation in emergency medical training. Resuscitation 2004; 61: 149-53

III Kurola J, Turunen M, Laakso JP, Gorski J, Paakkonen H, Silfvast T. Comparison of the laryngeal tube and bag-valve mask ventilation by emergency medical technicians— a feasibility study in anesthetized patients. Anesthesia & Analgesia 2005; 101: 1477-81

IV Kurola J, Pere P, Niemi-Murola L, Silfvast T, Kairaluoma P, Rautoma P, Castrén M. Comparison of airway management with the Intubating Laryngeal Mask®, Laryngeal Tube® and Cobra® by paramedical students in anaesthetized patients. Acta Anaesthesiol Scand 2006; 50: 40-44

V Kurola J, Kettunen T, Laakso JP, Gorski J, Paakkonen H, Silfvast T. Insertion of the laryngeal tube without preceding hands on training – feasibility of written instructions only in a manikin model. (Submitted).

1. INTRODUCTION

The concept of early advanced prehospital care to critically ill or injured patients is based on supporting and maintaining respiratory and circulatory functions before reaching definitive care. There is little evidence supporting this concept in critically ill medical patients (Isenberg and Bissell 2005). In cardiac arrest, early cardiopulmonary resuscitation (CPR) and prompt defibrillation are key elements, and use of advanced care is not supported by current data but recommended by guidelines (Stiell et al. 2004). Prehospital care of critically injured patients should provide necessary resuscitation to increase probability of overall survival and not delay the time to reach definitive care. The balance which procedures and treatments are of vital importance is debated (Liberman et al. 2000, Nicholl et al. 1998)

Airway management has been considered vitally important in emergency care. Indications for definitive airway management include trauma, cardiac arrest, respiratory distress and decreased level of consciousness from both traumatic and medical reasons. During prehospital phase, airway management is often preformed by non-physician care provider either in basic or advanced level of care. This poses a challenge for training, skill maintenance and devices used by prehospital care providers. The basic method in prehospital care is bag-valve-mask ventilation (BVM), but in advanced level, the "golden standard" of definitive airway management has been endotracheal intubation (ETI). ETI has a long learning curve (de Oliveira Filho 2002), skill maintenance is difficult, frequency per care provider of this procedure in prehospital setting is rare (Wang et al. 2005a) and success rates of below 50% have been reported (Bradley et al. 1998, Sayre et al. 1998) especially in basic level of care.

The benefit of advanced life support (ALS) procedures has been previously evaluated in prehospital care and health benefits have been found to be relatively small. Among these procedures and treatments, airway management seems to be the most important single factor (Lossius et al. 2002, Nicholl et al. 1998).

New pharyngeal airway devices have been mainly developed for day-surgery anaesthesia purposes. Laryngeal mask airway (LMA), esophageal-tracheal-Combitube (ETC) and cuffed oropharyngeal airway (COPA) have been studied and used in airway management during anaesthesia. Based on experiences from anaesthesiology, the question has raised whether these pharyngeal devices could be useful for prehospital airway management. Shorter learning curve and blind insertion without laryngoscope could offer benefit over ETI in prehospital care by inexperienced prehospital care providers.

This study was conducted to evaluate the usefulness of laryngeal tube (LT), intubating laryngeal mask (ILMA) and Cobra perilaryngeal airway (CobraPLA) in airway management among prehospital care provider students. In order to assess potential benefits of prehospital airway management in Easter Finland rural area, all missions of one ALS unit during one year were evaluated.

2. REVIEW OF THE LITERATURE

2.1 Prehospital emergency care

2.1.1 Development of prehospital care

During the late 1700s, Napoleon Bonaparte appointed Baron Dominique-Jean Larrey to develop a medical patient care system for the French Army. In 1797, Baron Larrey developed a method to send trained medical personnel into the field to provide medical care to the wounded soldiers and to provide medical care "en route" to the field hospital. In the United States, the first ambulance service was created in 1865 at Cincinnati General Hospital. During World War I (WWI) and especially during World War II (WWII), the military medical corps proved their worth in field assessment and early management of injured personnel. Although the military system of emergency care became well developed, the development of a civilian system lagged far behind until the experiences from wars in Korea and Vietnam raised the question if civilian trauma victims could benefit from early advanced care started on-scene. Until the concept that nonphysicians could be trained to provide emergency care arose, the majority of the prehospital care was merely transportation provided by the local mortuary (McSwain 2005).

Modern Emergency Medical Systems (EMS) and prehospital care can be considered to be founded after the 1966 publication of Accidental Death and Disability: The Neglected Disease of Modern Society (Howard 2000) and the early reports and experiences of J.F Pantridge in Ireland extending cardiac care in the field with mobile cardiac care unit (MICU) (Pantridge and Geddes 1967). This also encouraged pioneers such as Eugene

Nagel from Miami and Leonard Cobb from Seattle to start early programs with specially trained firemen to extend the treatment of cardiac arrest on scene (Baum et al. 1974, Nagel et al. 1968).

Also the first reported prehospital trauma training was done in USA when Dr. Farrington and Dr. Sam Banks developed a trauma training school for the Chicago Fire Department in 1957. It served as the prototype to the first EMT-Ambulance (EMT-A) training program (McSwain 2005). In 1970, US National Highway Traffic Safety Administration (US Department of Transportation) assigned Nancy Caroline to write a national curriculum for the education of prehospital emergency personnel and thus started the paramedic profession (Caroline 1977)

Experiences from Dr Pantridge influenced the development of prehospital emergency care in Europe. In Russia prehospital care was based on physicians and focused on acute cardiac patients (MOISEEV 1962). In the early sixties, Germany and France also started to place doctors to their ambulances. The history of paramedic profession is shorter in Europe than in US. In 1989 the designation "Rettungsassistent" was introduced and regulated by German state. They were first serving as an assistant to emergency physicians, but in 1995 it became legal for them to administer emergency care by themselves.

The first records in Finnish history of prehospital care date back to 1877, when the Finnish subsection of Russian Red Cross established a unit for wounded and sick soldiers sent to the Russo-Turkish War. In 1886, the first Finnish guidelines for First Aid were published in "First Aid in accident and fistfight", written C.F Wahlberg (Wahlberg CF 1886). During the Finnish Civil War in 1918 and WWII prehospital care was developed by the military. During WWII, the Finnish Red Cross had a major role in civil care. It became obvious that the transportation system was lacking and should be developed in different parts of the country. After the war, the first steps of developing nationwide prehospital transportation of sick and injured took place in 1953. These services were further developed, often in conjunction with fire brigades at least in larger towns. In 1956, the Ministry of Health set the standard for minimum equipment. In 1960s first steps of actual prehospital care were taken. The uniform way to alert help was developed, although no nationwide emergency number existed. First Aid possibilities were established to the ambulances. In 1965 in the annual meeting of Finnish Medical Association Dr. Eero Wilppula held a lecture where he pointed out that ambulances should be equipped with basic airway devices like Guedel airway and BVM. In late 1960s, emergency care was rapidly developing inside hospitals and first pioneers like Dr. Markku Murtomaa took the first steps to extend some of that treatment to the streets.

2.1.2 Development of prehospital care in Finland

Modern prehospital care in Finland started in the beginning of 1970s when a group of enthusiastic doctors and other health care providers established a group called "Intensive rescue team". It was operating in the Railway Station in Helsinki, as it was noted that majority of trauma patients came from there. The same founders established the first physician manned Mobile Intensive Care Unit (MICU) with Finnish Heart Association. This unit was based on the experiences of Dr. Pantridge in Belfast and was equipped to treat especially cardiac emergencies. The experiences of this unit lead the way to establish first educations to the prehospital care providers during 1970s. As in Helsinki the MICU became the physician manned unit, which was developing the Helsinki EMS, rest of the country had some pilot programmes for similar unit but they did not convince the local authorities and were stopped. In 1985, Ministry of Social Affairs and Health stated a policy to develop further prehospital care. This policy did not have legislative issues and it was not until 1994 that principles of prehospital care had its own legislative instructions. Legislation appointed this arduous task to the Health Care Districts, which were responsible for coordinating the local EMS. The next step of development was to further improve the possibilities of physicians to participate in prehospital care not only as an administrative part but also as a care provider. First helicopter EMS (HEMS) was founded in the to Uusimaa area in 1992 to provide ALS care in large area. Nowadays, four full time prehospital HEMS manned by specialists serve as a prehospital operational leaders and care providers, managed by State and local Health Care Districts (Järvinen 1998).

2.1.3 The Emergency Medical Service System

An emergency medical service is an organized system designed to provide care and transport to sick or injured patients to health care (Pozner et al. 2004). Same time as the actual emergency medicine developed, an organized system to provide prehospital emergency care was developed. Early on, the care providers in the United States were non-physicians such as paramedics. In Europe, many countries based their care by adding physicians to ambulances, which later developed into a specialty field of its own in many European countries.

In United States Federal Government passed the EMS Act in 1973. The Act identified 15 essential elements to be included in the development of an EMS system (Table 1).

EMS Factors	Patient Factors	System Factors
Personnel	Public teaching/education	Standard record keeping
Training	Mutual aid	Critical-Care units
Communication	Consumer participation	System review /evaluation
Transport	Access to care	Disaster planning
Emergency Facilities	Patient transfer	Public Safety agency

Table 1. Emergency medical service (EMS) components of development

A model of EMS systems varies not only between countries but also within countries. EMS systems can be categorized in many different ways, but for clarity, the system is described based on the chronological order of this service. EMS includes services needed for rapid response to acute emergencies. To be able to do this EMS has to operate as a system. The first link in this system is the dispatcher, who is responsible for the use of different EMS units. If units are capable to provide only one level of care it is called single-tiered system. Normally, an EMS system consists from basic and advanced levels of care. Also first responders and physicians can provide one level of care. These EMS systems with different levels care are called multi-tiered systems. When using units with different levels, varying from first responders to physicians, a key role of EMS systems function is in the dispatch center (Stout et al. 2000).

2.1.3.1 Emergency medical dispatch

The need for one common emergency telephone number was first issued in 1937 when Britain took 999 as national emergency telephone number for Police, fire brigades and medical emergencies. In 1960, United States a nationwide emergency number was introduced, which later became known as 911. The official emergency number inside European Union is 112, but many member countries have not been able to fulfil that requirement so far (European Union 1991).

The role of the dispatcher is to answer to the emergency call, gather information about the nature of the emergency and location. On the other hand, dispatcher communicates with the EMS units on the field, follow the mission and give instructions to locate the scene. In many centres this is computer assisted.

Many EMS systems have enhanced the role of the dispatcher. A dispatcher's responsibility is to collect enough medical information to prioritize which kind of medical help is needed and dispatched. Normally this is done by protocols and instructions from the leading medical authorities of EMS. These protocols can be local, national or even commercial (Clawson 1983). Protocols vary but there is evidence that some of these may improve sensitivity to detect cardiac arrest cases (Heward et al. 2004)).

During emergency call, dispatchers may give instructions to the laypersons on scene. This has been studied especially regarding cardiac arrest, where it may improve outcome (Kuisma et al. 2005, Roppolo et al. 2005).

2.1.3.2 Emergency medical service system and units

Daily system of EMS depends how large is the service area where units are supposed to cover. In many countries this may be based on communities or municipalities. In some areas where EMS is organized by fire brigades the service area is based on the same background as fire rescue service. It also may be within cities or cover a larger area based on health care district areas.

EMS units can be divided into different levels based on the care, which they are trained to provide. In many EMS, the first tiers are first responders who can provide first aid measures and in some cases some basic life support (BLS) techniques like use of automated external defibrillators (AED). Normally courses like first aid are mandatory for first responders. The purpose of the units is to minimize the time from the dispatch to the first basic treatment attempts. The vehicle of first responders is not necessarily able to transport patient into care facilities.

Normally second tiers are trained BLS care provides operated by ground units. Based on experiences in the United States, in many countries these providers are called emergency medical technicians (EMT); they also can be divided into basic and intermediate EMTs depending on training. In the US EMT-Basic training is 110 h and in many countries, this program has been adopted with slight modifications. Most ambulances throughout the western world are staffed by EMT-Bs or equally trained providers. The level of care varies depending on the EMS and local health care authorities. Normally they are capable of providing some airway management techniques and in some countries, even endotracheal intubation (ETI) is allowed to lifeless patients together with the use of AED. They may also be able to administer intravenous fluids and use the patients own medication according to predefined protocol (aspirin, nitro-glycerine, inhaled bronchodilatators) and adrenaline during cardiac arrest (Pozner et al. 2004).

The first advanced care providers are universally called paramedics, who are often third tiers. In United States, EMT-Paramedic course is approximately 1000 h consisting various advanced life support techniques. Also this model has been adopted by many countries but also specialised, and registered nurses may provide care in advanced level in some countries (Langhelle et al. 2004).Normally these units are ambulances, but in large areas without other advanced care providers, they may use a helicopter. In advanced level, treatment is normally guided by protocols. These protocols define treatment, procedures, the process of care and target hospital to care providers. Advanced procedures include various airway techniques including ETI and cricothyrotomy. Emergency i.v. medications can be used according to protocol and needle thoracostomy can be performed in case of tension pneumothorax. In cardiac cases, the use of manual defibrillator is commonly allowed and they can also perform cardioversion and transcutaneous pacing.

The role of physician considered as a fourth tier varies between US and Europe. In the US, the backbone of prehospital care is in the paramedics system. In the early phases of EMS development, physicians were mainly sent on scene to provide medical oversight. Still, in those places with good results from paramedics based prehospital care, physicians have important role of medical direction (Benitez and Pepe 2002). Today, in North America most regional or municipal EMS programs appoint or contract with a physician or a group of physicians for indirect and direct medical control and guidance (Stone et al. 2000).

In Europe, emergency physicians have more role of actual care provider on emergency situations (Dick 2003). The role of physicians is prominent in Eastern European countries, France, Germany, Italy, Belgium and Turkey (Huemer et al. 1994). The concept of physician manned HEMS is widely used in Austria, Germany, France and Norway (Huemer et al. 1994). Variations in EMS care providers between United States, Europe and Finland is presented in table 2.

	United States	Europe	Finland
Dispatch number	911	112	112
First responders	Fire Departments	Fire Department, Voluntary citizens	Fire Department
Basic care providers	EMT	EMT, Nurses	EMT, Practical Nurses
Advanced care providers	EMT-Paramedics	EMT-Paramedics Physicians	EMT-Paramedics Physicians

Table 2. Emergency Medical Service system care providers in United States, Europe and Finland. (EMT=Emergency Medical Technician)

2.1.3.3 Emergency medical service in Finland

In Finland, municipalities are responsible by law for organizing prehospital emergency care within their jurisdiction (Ministry of Social Affairs and Health 1972). They can arrange the service from health care centres, buy it from municipal services (eg. fire brigades), or buy it from private companies. Funding of this service comes from municipalities through taxation and partly from The Social Insurance Institution of Finland. Municipalities form Health Care Districts who are responsible for the coordination, planning and standing orders of EMS. Health Care Districts are mainly responsible for specialized medical care in Finland, and therefore especially advanced level of prehospital care is under its supervision (Ministry of Social Affairs and Health 1989).

There is fifteen joint Emergency Response Centres in Finland responsible to answer and evaluate emergency calls and dispatch appropriate units related to police, fire, health or social emergencies. All these are reached under one common number (112) and centres are managed by State. Emergency response centre operators have their own educational program in Emergency Services College (Ministry of the Interior 2000)

First tiers are called First Responders. In rural area these are voluntary laypersons organized by the local fire brigade. To have completed a basic education course for First Responders is mandatory. Skills are related to First Aid with some basic skills added. Airway management is based on BVM and oropharyngeal airway. The use of more advanced methods is not accepted are. Normally First Responders have no possibilities to transport patients.

The law for prehospital care divides care into basic and advanced level. Although the legislation does not precisely describe the different procedures and treatments, which can be provided in different levels, it defines the structure of prehospital care units (Ministry of Social Affairs and Health 1994).

The structure of EMS depends whether it is urban or rural. In urban areas, multi-tiered system is established often with basic care providers as a first tiers and advanced care as the second tier. In Helsinki City area, also third tier is possible by way of a physician unit. In rural areas, a first tier operative is normally basic care provider and advanced care is possible via physician manned HEMS unit.

In basic level of care methods for airway management are BVM, oropharyngeal airway. ETI is possible for cardiac arrest cases. In advanced level paramedics can use ETI as a first line airway management to cardiac arrest victim but also to other patients with medical or trauma related airway emergencies.

HEMS in Finland is provided by Foundations funded indirectly by State via Finland's Slot Machine Association to cover expenses for flying and also Health Care Districts to cover medical costs starting from 2006. In 2005 there are six HEMS base in operation. Two of them are purely medical HEMS manned with emergency physician and another two engage also in Search and Rescue (SAR) missions with similar emergency physician as a care provider. Last two serve both EMS and SAR missions with part time physicians and paramedics. The use of HEMS is coordinated via Health Care Districts.

2.2 Rationale and impact of prehospital advanced care

The concept that prehospital care should include capability to provide ALS care is adopted in EMS systems throughout the World. Critically ill medical patients nowadays receive ALS care, which previously was only possible inside the hospital (Pantridge and Geddes 1967). Although never validated in a randomized controlled study (RCT), this concept called "stay and play" in contrast to "scoop and run" was implemented also to trauma patients after Korean and Vietnam War (Gold 1987).

In 1990, 98.5 % of large US cities had ALS capabilities, and 82% of those had ALS responders to all emergencies (Keller and Forinash 1990). In Finland there is no valid data regarding capability to provide ALS care by EMS, but it can be estimated that all major towns have ALS units and rural areas can be partly be covered by physician manned HEMS units.

In medical patients, ALS care consists from various medical therapies and procedures in order to support and maintain respiratory and circulatory function. Advanced airway management with ETI is included. ALS care providers are commonly trained to treat circulatory failure with external pacing and cardioversion, but the need of these procedures is unknown. Intravenous drugs include both supportive pharmacologic agents like dopamine and definitive treatments such as thrombolytics. Use of ALS care in cardiac arrest is not supported by recent data. This was studied in a multicentre controlled trial with a design of before (rapid defibrillation) and after (ALS care included). Increase of survival to admission to hospital was noted (10, 9% vs. 14, 6 %) but no difference in survival to hospital discharge (5 % vs. 5, 1 %) (Stiell et al. 2004). The impact of ALS care in other medical conditions has not been properly studied. In a recent meta-analysis no benefit was detected from ALS care compared to BLS in patients with acute myocardial infarct (AMI) or decreased level of consciousness (Isenberg and Bissell 2005). This meta-analysis consisted only one large multi-centre study (Stiell et al. 2004) and other studies were small. Also new therapies like thrombolytics were not included. Prehospital thrombolysis has been evaluated in a separate meta-analysis consisting at six randomized trials: decrease in all-cause hospital mortality was noted favouring prehospital thrombolysis (OR 0, 83; CI 0, 70- 0, 98). In this meta-analysis, time from onset of chest pain to receive thrombolysis in prehospital group was 104 minutes, and in rural areas, it is only achieved by prehospitally given thrombolysis (Morrison et al. 2000). This meta-analysis shows especially well that organizing EMS response times and geographical coverage in advanced level is important.

In trauma patients two major interventions are included in ALS care. Treatment of hypovolemic shock with crystalloid or colloid solutions has been widely accepted treatment. However, the report from Houston with prospective comparison of hypotensive penetrating trauma patients receiving either immediate or delayed fluid resuscitation showed that more patients in delayed group survived to hospital discharge (70 % vs. 62%). After this study, a meta-analysis consisting of four RCTs and Cochrane systematic review was published and found no evidence to support prehospital fluid resuscitation

(Dretzke et al. 2004). However, these studies cannot conclusively be extrapolated to blunt and especially to head trauma. Regarding blunt trauma fluid resuscitation is still suggested and the policy of "moderate hypotensive fluid resuscitation" is commonly used in prehospital advanced trauma care (Roberts et al. 2005).

Airway management is prioritized in trauma victims. Although overall beneficial effects of ALS care including definitive airway management cannot be demonstrated in large and pooled studies like meta-analysis (Liberman et al. 2000), these studies may be affected by different EMS design and case mix. Ineffectively or unsuccessfully managed airways can adversely affect to results and extrapolating these results is not always justified.

2.3 Emergency Airway management

2.3.1 Indications for emergency airway management

Poor airway control regardless of the underlying mechanism or disease can thread breathing leading to insufficient oxygenation and ventilation resulting hypoxemia and respiratory acidosis. Poor airway control also increases the risk of aspiration of gastric contents which can further worsen oxygenation leading to pneumonia and acute respiratory distress syndrome (ARDS).

Emergency airway management is needed related in both pre-hospital and in-hospital emergencies. Emergency departments (ED) are responsible for vast majority of emergency airway managements. In an urban ED with 60 000 patient visits per year, 300 patients arrived with prehospital ETI and 610 were intubated in ED. Of all patients needing ED airway management trauma accounted 47,7% and medical emergencies 52,3 %. This gives a rate of 10 per 1000 emergency visits needing emergency airway management (Sakles et al. 1998).

In a prospective study from Singapore, the need for airway intervention was 2, 3 per 1000 ED visits over 4 year period. From these visits 76, 2 % were medical emergencies and 23,8 % trauma related. The most common causes requiring immediate airway control were cardiac arrest (37,7%), congestive heart failure (20,8 %) and head trauma (8,3%). Indications for airway management with ETI were apnoea, hypoxia and airway protection (Wong et al. 2004).

2.3.1.1 Maintenance of oxygenation

For aerobic metabolism, a human individual needs a constant supply of oxygen. Oxygen stored in the blood is enough for only a few minutes. Organs especially susceptible to hypoxemia are the brain and the heart. Worsening oxygenation leads to lowered consciousness, heart rhythm disturbances and myocardial failure. Without treatment, death is inevitable. Maintaining an open airway plays a key role to ensuring normal gas exchange. Hypoxemia (<90 % arterial oxygen saturation) due to poor airway control has been demonstrated to be a problem especially in head trauma (Price et al. 2003). This can adversely affect to outcome of neurotrauma patients (Chesnut et al. 1993, Stocchetti et al. 1996). Medical disorder is a common finding among patients needing rapid airway management. These accounted 52,3 % of all ED patients needing definitive airway management. From these, the most common causes were drug overdose (9,5 %), decreased level of consciousness (7,4 %), seizure (5,6%), cardiac arrest (4,8%), congestive heart failure (4,8%) and chronic obstructive pulmonary disease (4,6%)(Sakles et al. 1998).

Trauma can jeopardize oxygenation by several mechanisms. Head trauma alone or associated with other trauma in torso can cause lowering consciousness and poor airway control. Chest trauma can cause tensionpneumothorax, pneumothorax, pulmonary contusion, rib fractures or open chest wounds, which all are common causes for worsening oxygenation needing airway control and mechanical ventilation. Blunt or penetrating facial or neck trauma associated with bleeding, can also directly jeopardize airways.

2.3.1.2 Preventing hypercarbia

Tissue metabolism constantly produces carbon dioxide which is removed from the body through lungs. Inability to sufficiently remove CO_2 leads rapid rise of arterial CO_2 concentration which is normally maintained within 4,5 kPa to 5,5 kPa. Bloods buffer systems cannot cope with rapid changes and exceeding these CO_2 values result in fall of blood pH. This leads to acidosis which disturbs enzymatic cell function, especially in the nervous system. Thus, the major effect of acidosis is depression of the central nervous system, which leads eventually decreasing level of consciousness and poor airway control. High CO_2 levels in blood also dilates arterial vessels in brain leading in increase of cerebral blood flow. In case of head trauma or other acute cerebrovascular disease with elevated intracranial pressure (ICP) this mechanism can cause secondary injury which can further raise ICP resulting risk of brain ischemia or herniation. This produces a challenge in emergency situations to ensure sufficient ventilation, either spontaneous or assisted to prevent rise in CO_2. Decreased level of consciousness always jeopardizes airway and requires rapid airway management (Bullock et al. 1996, Zink 2001).

2.3.1.3 Prevention of aspiration

Aspiration of acidotic gastric contents is associated with poor airway control. This can lead to both direct lung injury and impaired oxygenation; with complications including secondary pneumonia and ARDS (Bernard et al. 1994).

Preventive measures for aspiration of gastric contents is needed and related to the fact of a full stomach during emergency airway management regardless of the underlying disease. The risk of aspiration is especially relevant with drug overdoses, which are common problem in emergency medicine requiring airway management (Sakles et al. 1998).

2.3.2 Indications for prehospital airway management

Although indications for prehospital airway management are identical with general indications for emergency airway management, prehospital setting sets various challenges to when airway management is indicated, how it is managed and who performs procedures.

Prehospital environment differs from the hospital environment. Scene and patient may be difficult to reach, in cold environment procedures are difficult to perform and lack of light may bring additional difficulties. Prehospital care providers are usually non-physicians with limited experience to for advanced airway management. This is true especially in rural setting where number with need for emergency airway management is small per care provider. In addition, assistant personnel may similarly lack experience and back-up is not always available. In different levels of training various methods of airway management can be used, but in difficult airway situations, even trained paramedics may not have necessary skills and tools needed for adequate, safe and reliable airway management. The decision, when and how to manage the airway in prehospital setting, is mainly based on standing orders. As an indication for airway management standing orders normally refers to cardiac arrest, trauma, respiratory distress and altered consciousness due to medical causes and gives further instructions how to proceed in these situations.

The frequency of need for prehospital airway management was evaluated from prehospital patient care reports from Commonwealth of Pennsylvania during one year. From 1 544791 patient care reports 11 484 ETIs were reported showing that ETI was a rather uncommon procedure in 0,7% from all missions (Wang et al. 2005a).

In prospective large (n=742) multicentre study in prehospital airway management the most common indications for airway management by intubation were cardiac arrest (61,7 %), respiratory distress (13,9 %), trauma (7,4 %), suspected stroke/intracranial bleeding (3,8 %), altered mental status (3,6 %) and suspected drug overdose (3,0 %)(Wang et al. 2003).

2.3.2.1 Cardiac arrest

In cardiac arrest, compressions should be started promptly with ventilation to ensure tissue oxygenation. Depending on training and level of prehospital care provider, different basic or advanced airway adjuncts can be used to manage and ensure effective ventilation with high oxygen concentration. A victim of cardiac arrest has no signs of life and no pharyngeal reflexes, which make the use of advanced airway methods easier than in patients with reflexes. Multiple attempts to place of airway devices may interrupt compressions and ventilations and further worsen the outcome (Valenzuela et al. 2005). Prevention of aspiration of gastric contents during resuscitation is also considered indication for advanced airway management (Stone et al. 1998). On the other hand, it has been shown that multiple and failed attempts to place advanced airway device may actually cause aspiration (Mort 2004).

2.3.2.2 Trauma

In trauma cases the most common reason for prehospital airway management is head trauma and decreased level of consciousness, which jeopardize sufficient oxygenation and ventilation and increases risk of aspiration. In cases with Glasgow coma score 8 or less, prehospital advanced airway management has been recommended (Bullock et al. 1996). In large (n= 10314) retrospective analysis, advanced prehospital airway management improved outcome of moderate and severe traumatic brain injury (Davis et al. 2005). In another retrospective analysis, this effect was not detected and on contrast, prehospital advanced airway management was associated with adverse outcome (Wang et al. 2004b). Both these studies are influenced by retrospective nature and different result may be explained by other factors in the treatment of head trauma.

In blunt or penetrating facial or neck trauma, patient's rapid and advanced airway management may be needed for anatomical reasons, or due to secretions blocking airway. There is need to protect airway from massive swelling in burn and chemical injuries. Also chest trauma with compromised breathing may be an indication to prehospital advanced airway management.

In contrast to cardiac arrest, pharyngeal reflexes still exist in patients with medical or trauma related airway emergency which makes airway management more challenging. The need of anaesthetics, analgesics and even muscle relaxants is in many cases obvious. When considering ETI as an advanced airway management, rapid sequence induction (RSI) is considered as "golden standard". Term RSI refers to use of anaesthetics, analgesics and muscle relaxants. Term sedation refers to procedure without muscle relaxant. In a Danish observational study (n= 220) of severe trauma patients (Injury Severity Score>15), 84 % of prehospitally intubated trauma patients were given drugs (sedation or RSI) before intubation attempt (Christensen et al. 2003). In another retrospective analysis from US regarding 2700 prehospitally intubated patients, 17% had trauma and 12 patients (<1%) had burn injury. In trauma patients, 70 % were given muscle relaxant to facilitate intubation (Bulger et al. 2002). It also seems that if prehospital trauma intubation can be performed without any drugs, mortality is high. In a study from UK from 492 patients which could be intubated without any drugs, only one survived to hospital discharge (data missing in 6 patients) indicating that these patients are either unsalvageable or cannot be saved by airway management only (Lockey et al. 2001).

2.3.2.3 Respiratory distress

Acute respiratory failure is a common medical emergency. Common underlying disorders are congestive heart failure, acute exacerbation of chronic pulmonary disease, acute asthma and respiratory failure related to sepsis. In many cases, respiratory failure has lasted for several days, but the call for help is postponed until the respiratory distress is severe. This may lead to rapid worsening of oxygenation and breathing exhaustion. To be able to efficiently ventilate and oxygenate patient, an artificial airway is needed. Again, the question whether this is possible without the use of medication is raised. These patients are often haemodynamically unstable and the use of medications needed for airway management, may also cause haemodynamic collapse and seriously affect oxygenation and ventilation in cases when airway procedure is prolonged or failed.

In retrospective analysis of prehospital intubations (n=2700), 82% was due to medical emergency. From those respiratory compromise/distress accounted for 11 % (n=293) (Bulger et al. 2002). In another trial of prehospitally intubated patients (n= 742), respiratory distress accounted for 13,9% from all patients and from 208 non-cardiac arrest patients 58 (28 %) received either RSI or sedation (Wang et al. 2004b).

2.3.2.4 Decreased level of consciousness

Several medical conditions cause decreased level of consciousness. Cardiac emergencies like arrhythmias, neurological disorders like intracranial haemorrhages, stroke and prolonged seizures, metabolic disorders, infection and drug overdose are common causes for EMS system activation. Although not all of these patients need prehospital airway manoeuvres, all those patients with progressively lowering consciousness are in risk of hypoxia, hypoventilation and aspiration. In the case of neurological disorder, the risk of elevated ICP possesses a challenge to rapid identification and airway management. The problems related to head trauma are similar in cases with intracranial haemorrhage.

Data from USA shows that neurological events accounted 15 % from indications for on-scene ETI (Bulger et al. 2002) and in a prospective study, these events accounted for 3,8 % and altered mental status 3,6 %(Wang et al. 2004b). The need for prehospital airway management in drug overdose and prolonged seizures seems to be reasonably rare (3 % and 0,8% respectively) (Wang et al. 2004b).

2.4. Devices used for prehospital emergency airway management

The need for prehospital airway management seems to be evident. Based on different levels of training, care providers can use different devices. Historically, ETI has been the method of choice for definitive airway management in advanced level, but experiences from anaesthesiology have raised the question whether the role of ETI can be re-evaluated and whether pharyngeal airways could be more widely used in prehospital care.

2.4.1 Bag-valve mask ventilation

In ancient history before discoveries of physiology, Galen described the anatomy of the respiratory system in AD 177. The next reference of artificial ventilation concerns mouth-to mouth ventilation by Bagellardus in 1472 when he issued this concept to midwives. Anatomist Andreas Vesalius, who lived in 16th century, discovered the relationship between ventilation and heart function. John Fothegill recognized and reported in 1745 the importance of rescue breathing to otherwise apparently dead (Baker 1971).

After discoveries of carbon dioxide by Black in 1754 and oxygen by Priestley, Lavosier and Scheele in 1775, mouth-to mouth respiration was replaced by positive pressure ventilation, introduced by John Hunter in 1776. It was firstly performed by bellows and later with pistons (Baker 1971). These formed a base for development of modern bag-valve-mask ventilation devices.

The basic method to assist ventilation in EMS setting is bag-mask devices. The structures of these consist of self-inflating bag, which is in normal commercially manufactured models approximately 1600 ml for adult use. It ends to non-rebreathing valve to which face mask or airway device is connected. The connector is standard size. In the base of bag is inlet system for oxygen flow. This should allow a maximum of 30 l/min inflow. Also in the base of bag is oxygen reservoir to allow delivery of high oxygen concentrations. Some commercially available bag-valve sets consist of a pressure relief valve, usually to relief over 40 cmH_2O pressures. Face masks come with different models and shapes. Usually infant and child models are round shaped for good face sealing and for older children and adults more anatomically shaped modes are preferred. In a prospective manikin trial (n=30) with non-physician care providers comparing different face masks in BVM it was noticed that acceptable face sealing was not achieved with all masks and in these cases tidal volumes were insufficient (Stewart et al. 1985).

Picture 1. Ventilation bag with a reservoir attached. Below face mask from size 1 to 5

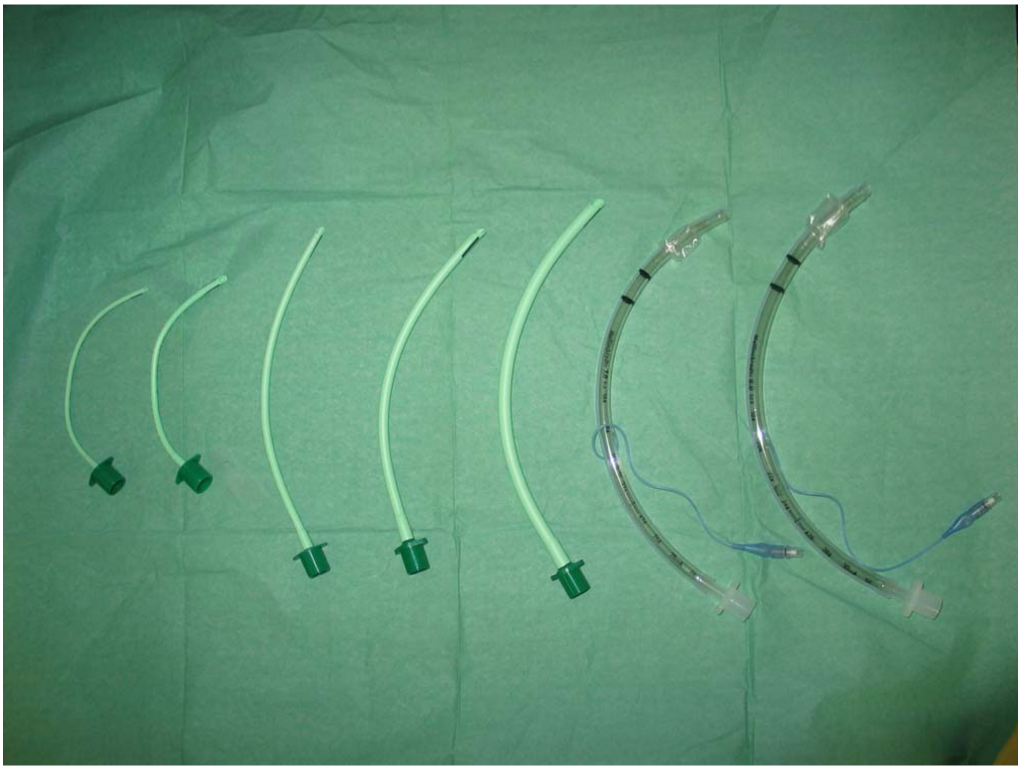
The use of BVM ventilation can be done by one or two rescuers. Previous study reported that inexperienced care providers cannot simultaneously effectively seal face mask, maintain open airway and use bag to provide sufficient tidal volumes (Seidelin et al. 1986). The two rescuer technique improves the efficacy of ventilation in anesthetized patients when one rescuer holds and seals the mask and the other compresses bag (Wheatley et al. 1997). Stomach inflation during BVM is a complex problem. It may lead to regurgitation and aspiration (Lawes and Baskett 1987). During BVM, gastric inflation seems to be related to high tidal volumes and peak airway pressures. The distribution of gas during BVM is dependant on lower oesophageal sphincter pressure (Bowman et al.

1995), respiratory system compliance (Davis et al. 1995) and the technique of BVM. Current guidelines recommends to use smaller tidal volumes of 5-7 ml/kg or approximately 500 ml in adults delivered over 1 to 1,5 seconds with an fraction of inspired oxygen(FiO_2) ≥0.4 during BVM (Wenzel et al. 2001, Handley et al 2005). This guideline refers to cardiac arrest situation, but can be extrapolated to other emergencies needing BVM.

The effectiveness of BVM ventilation skills of prehospital care providers has been questioned. In a manikin study regarding EMTs ability to provide sufficient BVM less than half could provide sufficient BVM in terms of tidal volume and rate/minute (Elling and Politis 1983). In another manikin study with similar approach, 67 % of EMTs performed approvable ventilation skills (Cummins et al. 1986). In both studies, difficulties were noticed with mask sealing and two-rescue technique was suggested. These findings are in concordance with a more recent study, comparing first responder's abilities to ventilate anesthetized patients, either with BVM or small portable ventilator via face mask. In this study, BVM caused more gastric insufflation (Noordergraaf et al. 2004).

2.4.2 Endotracheal intubation

The realization that tracheotomy could be used to relieve obstruction of the upper airway was described in ancient times. Alexander the Great was reputed to have performed a tracheotomy using his sword upon a choking soldier. Interest in intubation rather than incising the airway grew with anecdotal reports in late 1700 and early 1800 century. Sir William MacEwen published in 1880 in British Medical Journal a report of 3 patients who were intubated for management of different conditions. This technique was soon adopted to anaesthesia and called as "inhalational endotracheal anaesthesia". This technique needed a device for glottic visualization and Chevalier Jackson described a device called laryngoscope for that purpose in 1913. Sir William MacIntosh invented a curved blade to laryngoscope (Croft 2002). In 1930 Dr Magill introduced forceps to ease the endotracheal tube placement (Sternbach 1984) and in 1946 Mendelson described a case of massive aspiration during childbirth (Maltby 1990). After that Morton and Wylie described rapid sequence intubation and Dr Sellick described a method of cricoid pressure to prevent from aspiration in 1961. The original endotracheal tube was a rubber tube with one opening at the end without cuffs. In the late sixties a tube with multiple openings and a rubber cuff was introduced, later manufactured commercially from silicone and other synthetic materials (Stoller JK 1999).



Picture 2. Endotracheal tubes from size 2 to 8

The modern technique for emergency endotracheal intubation is a direct visualization of glottic area and vocal cords with a laryngoscope equipped either with curved or straight blades. Passage of endotracheal tube should be preferably seen between vocal cords, cuff inflated and proper tube placement confirmed by symmetrical lung auscultation and end tidal CO_2 monitoring. This method has variants depending on nature of airway needed, anatomical reasons or inability to visualize vocal cords. Endotracheal intubation has become "golden standard" of emergency airway management for various reasons. It allows effective and controlled positive pressure ventilation, use of positive end-expiratory pressure, ensures a delivery of high oxygen concentrations and protects the airway from gastric contents or blood and mucus from upper airways. It also allows suction of secretions from airways (Pepe et al. 1985).

Safe and effective placement of an endotracheal tube requires considerable skills and experience. Unless initial training is sufficient and ongoing practice and experience are adequate, patient may be viable to several potentially harmful or even lethal complications. Trauma to the oropharynx, ventilation withheld for unacceptably long periods, delayed or interrupted chest compressions in cardiac arrest patients, oesophageal or bronchial intubation, bronchial trauma, failure to secure the tube and failure to recognize misplacement of the tube are all reported complications, when intubation is performed by inadequately trained and inexperienced care provider (Bradley et al. 1998, Dunford et al. 2003, Mort 2004, Spaite and Criss 2003, Valenzuela et al. 2005).

Firstly endotracheal intubation was restricted to hands of physicians involved to either inhospital or prehospital emergency care. One of the first pioneers to teach a non-physician prehospital personnel these skills was Dr Nagel from Miami, Florida (Nagel

1975). Skill teaching spread to wide use in both rural and urban EMS. This skill was considered as effective tool also in prehospital care (Pepe et al. 1985).

Early reports showed approvable success rates when intubation was performed in prehospital care by paramedics. In a prospective study from US from 178 patients including both medical and trauma indications for airway management 96,6% was intubated prehospitally with success by trained paramedics (Jacobs et al. 1983). This finding has been recently confirmed by another study from US where a paramedic performed nasal or orotracheal intubation to mixed patients of airway emergencies with a 84 % of success rate (Colwell et al. 2005).

In patients with a compromised airway and need for emergency intubation, pharyngeal reflexes may be present. Intubation without abolishing the reflexes may be difficult or impossible. Laryngoscopic attempts stimulate the airway and cause noxious stimuli (Takahashi et al. 2002). This causes physiological changes resulting in hypertension and tachycardia called "pressor response". This response can induce myocardial and cerebrovascular injury (Gajapathy et al. 1983). On the other hand, critically ill patients often experience hypoxia, hypercarbia and acidosis, which cause extreme sympathetic activity that is associated with labile blood pressure, increase in myocardial oxygen consumption and tachycardia (Horak and Weiss 2000). The concept of RSI is considered as a standard tool for experienced anaesthesia, emergency and critical care physicians. This technique has advantages but requires considerable amount of training and is debated whether non-physicians can adopt these skills (Reynolds and Heffner 2005).

Trained paramedics have used RSI to facilitate intubation in prehospital setting. In a prospective study of head injured patients with GCS 3-8 (n=114), paramedics used succinylcholine and midazolam to facilitate intubation with a intubation success rate of

84,2 % and Combitube™ for salvage device for 14,9% (Ochs et al. 2002). In another trial of paramedic RSI (n=54) over half (57%) of these patients were detected to have desaturation periods during RSI and 19% even marked bradycardia (Dunford et al. 2003). Because of these findings and the debate whether paramedic performed RSI can actually improve patient outcome in selected or mixed patient groups, this technique for paramedics in prehospital setting has been questioned (Spaite and Criss 2003).

2.3.3 Oropharyngeal airway

The oropharynx can be the primary site of airway obstruction. Such an obstruction is usually caused by relaxation of the tongue and the musculature of the mandible, allowing posterior movement of the tongue and the epiglottis to obstruct the airway. This is especially common during emergencies causing unconsciousness and during anaesthesia.

In 1908 Sir Frederic William Hewitt reported on a rubber oropharyngeal airway. This pilot model was relatively short and straight with metal mouthpiece, but was a forerunner for later models. The model, which is still in use, was introduced by Dr. Arthur Guedel in 1933 (Guedel AE 1933). This model was made in rubber, consisted a phalange to keep it in front of the patient's teeth and a metal reinforcement in proximal to prevent obstruction if the patient bit down. It also was curved in the distal portion shaped to prevent tongue depressing to the posterior part of pharynx. Dr. Guedel introduced this airway device for the use in case of laryngeal spasm, which was a serious problem in those days during anaesthesia. Later this airway called "Guedel airway" became a standard oropharyngeal airway during either spontaneous breathing or assisted ventilation via face mask in anaesthesia and emergency care (Baskett 2004, Guedel 1933).

Picture 3. Oropharyngeal airways from size 000 to size 6

Oropharyngeal airway has proven efficacy over the mask-ventilation without Guedel type airway. In a Japanese study tidal volumes were significantly better with an oropharyngeal airway placed than without (Koga et al. 2001).

Oropharyngeal airway is available with different sizes from infant to adults. Although its placement seems to be easy after training, incorrect direct insertion can displace the tongue into the hypopharynx and result in airway obstruction (Marsh et al. 1991). In semi-conscious patients it can provoke retching, vomiting or laryngospasm by activation of the gag-reflex. During ventilation or insertion aspiration of gastric contents can occur in emergency situations and also anecdotally, aspiration of the oropharyngeal device itself or its part has been reported (Lee et al. 2001, Nandalan and Hiremath 2004).

In the hands of inexperienced and infrequent users, oropharyngeal airway still cannot perform very well compared to more recent pharyngeal airways. In ten volunteers, with no previous experience of resuscitation, LMA produced superior insertion and ventilation values over Guedel airway and mask ventilation (Alexander et al. 1993).

2.4.4 Cuffed oropharyngeal airway

The cuffed oropharyngeal airway (COPA) was first described by Greenberg and Toung as a potential airway for spontaneous ventilation anaesthesia (Greenberg RS and Toung T 1992). It is a modified Guedel airway with an inflatable distal cuff and a standard (15 mm) proximal connector for attachment to ventilation system. Cuff is designed so that when inflated it should displace patient’s tongue, form a airtight seal with the pharynx and elevate the epiglottis from the posterior pharyngeal wall, providing a clear airway. Cuff is inflated via its own line with a possibility to measure cuff pressure. COPA is available in four sizes from 8 to 11 referring to the distance between flange and distal end (Brimacombe and Berry 1998).

Picture 4. Cuffed oropharyngeal airway

It seems to provide simple method to ventilate patients “hands free” in the hands of experienced anaesthesiologist (Brimacombe and Berry 1998, Fanelli et al. 2000). However, a need for some degree of head positioning was observed to provide optimum ventilation and sealing (Brimacombe and Berry 1998, Greenberg et al. 1998).

The insertion and ventilation has been studied when used by non-anaesthesia staff to anesthetised patients. In two separate studies with similar design COPA was found superior to basic BVM in terms of insertion and ventilation (Clayton et al. 2001) and the other suggested that COPA secured adequate ventilation in terms of measured tidal volume (Rees and Gabbott 1999).

In a manikin model of cardiopulmonary resuscitation (CPR) with both experienced and inexperienced users, COPA was slower to insert compared to Laryngeal Mask Airway (LMA) and more manipulation was required for adequate ventilation (Garcia-Guasch et al. 2001).

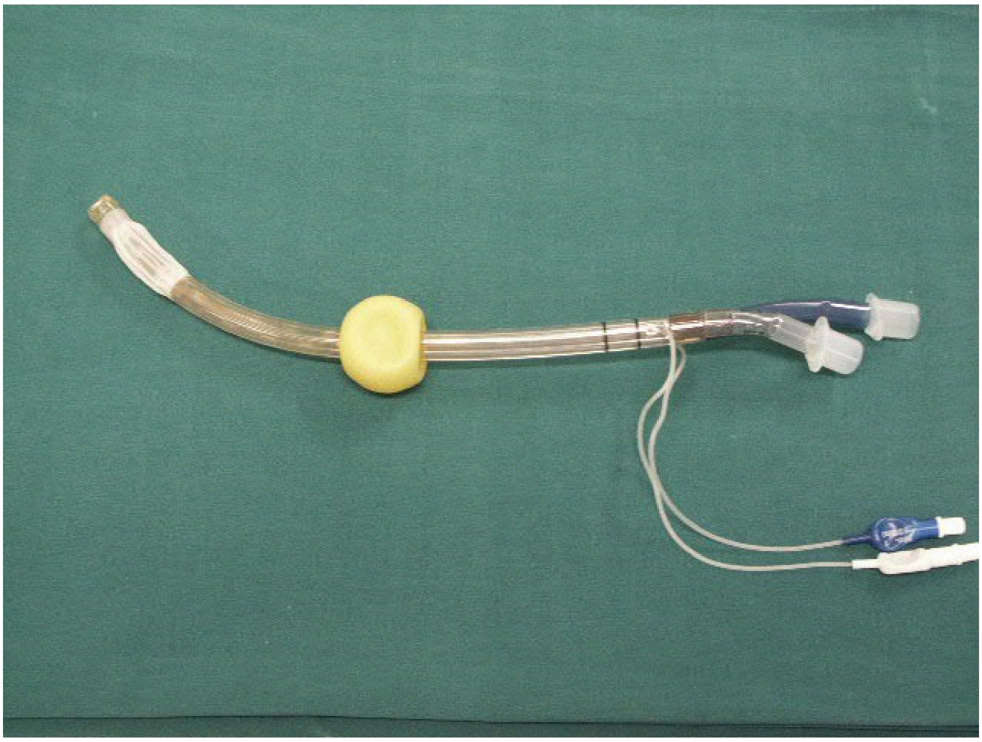
Although COPA does not protect from aspiration of gastric contents, insertion of COPA is possible when cricoid pressure is applied; this may hypothetically be an advantage when trying to prevent aspiration (Dravid et al. 2000). In addition, the insertion of COPA is associated with smaller cardiovascular changes during insertion than LMA (Casati et al. 1999).

COPA has not gained success in prehospital emergency care. Protection of airway is comparable to that with oropharyngeal airway and in emergency airway management this seems to have affected to the use of COPA.

2.4.5 Combitube^{TM}

The oesophageal-tracheal Combitube^{TM} (ETC) was developed at late 1980`s for non-medical inexperienced users as an alternative for ETI for needs of simple airway in case of CPR. It has been widely accepted among anaesthesiologists to be used in cases of difficult airway and also among prehospital personnel dealing especially with cardiac arrest cases (Agro et al. 2002).

ETC is a double lumen airway allowing ventilation in either the oesophageal or tracheal position, with one lumen resembling an endotracheal airway with a distal open end and a second lumen resembling an oesophageal obturator type airway with distally blocked end and perforations for air passage at pharyngeal level. The lumens are separated by a partition wall. At the proximal end of the fused tube, two small tubes connect to the pharyngeal and the tracheoesophageal lumens. ETC has two cuffs. After inflation, proximal cuff presses against the base of the tongue in a ventrocaudal direction and closes the soft palate in a dorsocranial direction. The distal cuff is located at the distal end of the fused double–lumen tube and serves to seal either the oesophagus or trachea after insertion. Two printed marks at the proximal end of the tube indicate proper depth of insertion.



Picture 5. Esophago-tracheal-Combitube

ETC was originally designed to be inserted blindly and patients head in neutral position but it can be inserted with assistance of a laryngoscope. ETC is inserted blindly along the surface of the tongue with a gentle downward curved dorsocaudal movement until the printed marks lie between teeth. After insertion proximal cuff is inflated with 85 to 100 ml of air depending of the size of ETC and distal cuff is inflated with 10 ml of air. With blind insertion, ETC is placed in the oesophagus in more than 95 % of cases (Frass et al. 1987). Therefore. the first attempt to ventilation is via to the pharyngeal lumen. Confirmation of the placement is done by chest movement, lung auscultation or monitoring $etCO_2$. If ventilation is negative through pharyngeal lumen, ventilation is attempted via tracheal lumen and confirmed as previously described. If ventilation is difficult with both lumens, ETC is probably inserted too deep and should be withdrawn 2-3 cm after cuff deflation (Agro et al. 2002).

Although ETC was invented primarily to be used in CRP especially for inexperienced care providers, it is studied also in management of airway during elective surgery. In a study of 200 patients anesthetized for elective surgery six insertion failures were reported and 97% patients were ventilated successfully. In 27% of patients a notable upper airway trauma was recognized (Gaitini et al. 2001). Comparable ventilation and oxygenation with similar airway pressures was found with ETI in a study comparing ETI, ETC and BVM in anesthetized patients when airway management was performed by anaesthesiologist (Frass et al. 1989).

After preliminary data, ETC has been studied widely also when used by inexperienced prehospital care providers. Several studies have focused on cardiac arrest. When successfully placed, ventilation and oxygenation via ETC is found comparable to those with ETI in a study with in-hospital cardiac arrest patients (Frass et al. 1988). A study from British Columbia, compared pharyngotracheal lumen airway (PTLA), LMA, Guedel airway and ETC in 470 cardiac arrest patients when inserted by EMTs. ETC was superior in terms of adequacy of airway patency and ventilation (Rumball and MacDonald 1997). In another retrospective study from Japan, comparing ETC, oesophageal gastric tube airway (EGTA) and LMA in cardiac arrest patients (n= 12 020), ETC had an 82,4 % insertion success rate compared to 82,7 % of EGTA and 72,5 % in LMA (Tanigawa and Shigematsu 1998). Similar success rates (79 %), has been found in a prospective study when EMT-Ds attempted to place ETC to 195 unconscious patients (Ochs et al. 2000). European Resuscitation Council (ERC) has included ETC as an alternative airway in advanced cardiovascular life support (Nolan et al. 2005).

ETC has also been studied as a salvage airway in case of failed prehospital intubation attempt. In a prospective series of 12 patients with failed RSI performed by flight nurses, ETC was placed successfully to 10 patients (Blostein et al. 1998). In another prospective study in 420 patients involving San Diego paramedics, ETC was used as an salvage after failed RSI. RSI was successful in 84,5 % (n= 355) patients. ETC was successful in 58 (95,1 %) of the 61 attempts (Davis et al. 2003).

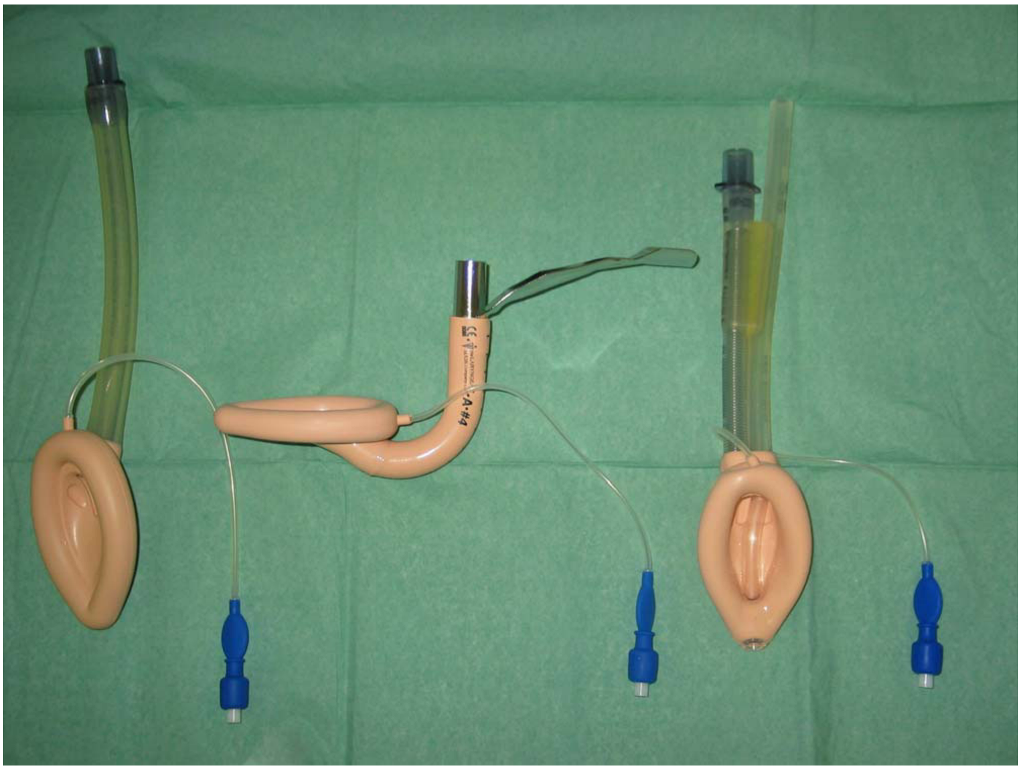
Hypothetically ETC protects against aspiration of gastric contents like ETI. Distal cuff ends to the upper part of oesophagus and seals it. When compared to LMA in anesthetized patients, the incidence of gastroesophageal reflux was low and similar to LMA (Hagberg et al. 2004).

Improper use of ETC may be fatal. The two lumen tube offers a possibility to misidentify the right lumen for ventilation. In one retrospective data of EMS system showed that in 2 % of "successful" placements, actually the wrong lumen was chosen for ventilation (Lefrancois and Dufour 2002). For this reason the use of ETC is recommended only with a conjunct use of either etCO_2 monitoring or with oesophageal detector device (Nolan et al. 2005). Another possible complication is oesophageal trauma. In a report of 1139 cardiac arrest patients with a use of ETC, eight patients showed with subcutaneous emphysema, four died in emergency department and two revealed a large oesophageal rupture in autopsy (Vezina et al. 1998). After this report, several case reports of esophageal trauma related to use of ETC has been published (Krafft et al. 1998b, McGlinch et al. 2004, Richards 1998, Stoppacher et al. 2004). It seems that this trauma is related to hyperinflation of the distal cuff and this effect may have an additive effect with esophageal pressure changes during CPR (Krafft et al. 1998a). In Finland, this device has never been a vast success in anaesthesiology and emergency care.

2.4.6 Laryngeal Mask Airway

The Laryngeal Mask Airway was invented and designed by Dr Archie Brain working in Royal London Hospital in 1981. Dr. Brain delivered anaesthesia for dental operations using Goldman dental mask. In searching alternative and better ways to deliver and maintain airway during anaesthesia he developed first models of LMA from rubber tube. Inflatable cuff was added and different sizes manufactured. The final model was with three different sizes modified in 1988 using latex and silicon. Inside hospitals in UK, it gained vast success during 1989 and the approval of FDA in US by 1991 lead to widespread use also in United States (Brain 1991).

LMA is a pharyngeal airway device composed of a tube with a cuffed mask-like projection at the distal end. Insertion of LMA is done in relatively neutral position of head, introducing LMA into pharynx along the hard and soft palate. If the cuff is slightly inflated during insertion it makes insertion easier by making cuff firm. LMA is advanced further to pharynx until resistance is felt as the distal part of the tube is located in hypopharynx. The cuff is inflated and it seals the larynx, leaving the distal opening of the tube just above the glottis, providing a clear and secure airway.



Picture 6. Laryngeal mask airway. From left Classic laryngeal mask (cLMA), Intubating laryngeal mask (ILMA) and ProSeal laryngeal mask (PLMA)

After initial success Dr Brain further improved and invented three major models from the original LMA, Classic laryngeal mask (cLMA), ProSeal laryngeal mask (PLMA) and Intubating laryngeal mask (ILMA). These models have different features.

2.4.6.1 Classic laryngeal mask

The original LMA is now called as the classic LMA (cLMA), which was easy to use also by inexperienced staff; its insertion was rapid when done by an anaesthesiologist, it improved haemodynamic stability during induction of anaesthesia, reduced anaesthetic requirements for airway tolerance, lowered frequency of coughing during emergency, improved oxygen saturation during emergency and lowered incidence of sore throats in adults (Brimacombe 1995, Brimacombe 1996, Verghese and Brimacombe 1996). In anaesthesia further studies involved the use in ambulatory surgery units where it has gained popularity with general anaesthesia delivered without muscle relaxant (Keller et al. 1998, Wat et al. 1998). cLMA was found to perform well in terms of safety and efficacy in paediatric and infant anaesthesia (Lopez-Gil et al. 1996a). Among anaesthesia residents, the learning curve of cLMA was found to be steep (Lopez-Gil et al. 1996b). In a meta-analysis, risk of aspiration during anaesthesia is low and comparable to that for outpatient anaesthesia with face mask (Brimacombe and Berry 1995). At the first two decades of its use, cLMA has been used in anaesthesia of approximately 100 million patients worldwide. In UK, at least 30 % of anesthetised patients are managed using laryngeal mask (Verghese and Brimacombe 1996).

Among inexperienced users, such as nurses, respiratory therapists and EMS care providers successful insertion rates during cardiac arrest has been found to range from 64 % to 100% (Kokkinis 1994, Leach et al. 1993, Samarkandi et al. 1994, Tanigawa and Shigematsu 1998). It seems that training to use of a cLMA is simpler than the ETI because laryngoscopy and visualization is unnecessary (Davies et al. 1990, Pennant and Walker 1992, Reinhart and Simmons 1994). It seems also that it provides more secure and reliable ventilation than a face mask alone in cardiac arrest situations, performed by inexperienced care providers (Alexander et al. 1993, Martin et al. 1993). Although cLMA does not offer 100% protection over aspiration of gastric contents it seems that during CPR the incidence of regurgitation can be reduced using cLMA (Stone et al. 1998). Use of cLMA has been suggested in cardiac arrest cases by ERC in their resuscitation guidelines from 2000 and is widely used as back-up device in prehospital care (Nolan et al. 2005).

2.4.6.2 ProSeal laryngeal mask

To further improve the features of LMA a new device was engineered by Dr. Brain and introduced as ProSeal Laryngeal Mask (PLMA) in 2000. PLMA consists of standard feature of cLMA, with an additional tube (drainage tube), which in proximal part is 18 F attached to the lateral part of ventilation tube. In the distal end it opens to the tip of the cuff. When correctly positioned PLMA, tip with the opening is wedged against upper oesophageal sphincter. If placed too proximally, drainage tube connects with the airway, which is noticed by gas leaks during ventilation from the drainage tube. This tube allows also the passage of nasogastric tube to the oesophagus, which allows suction of gastric contents that could theoretically prevent aspiration. The second new feature is a posterior cuff inflated via same valve-pilot balloon system as the main cuff. This may result better sealing allowing higher airway pressures during positive pressure ventilation (Brain et al. 2000). In the preliminary reports of PLMA indicated that PLMA was as easy to insert as cLMA, detection of correct position by drainage tube could be performed, sealing pressure was twice as high compared to cLMA and nasogastric tube passage was easy (Brain et al. 2000).

First study of PLMA described the use in 300 anesthetized patients. Insertion was successful in 98 % of patients and graded easy in 91 %. Mean airway seal pressure was 29 cmH_2O and 59 patients had a sealing pressure over 40 cmH_2O. Gastric tube placement was successful in 99 % of patients and no gastric insufflation was detected (Evans et al. 2002).

When comparing cLMA and PLMA in a randomized crossover study (n=180), PLMA was found to provide 12 cmH_2O higher sealing pressures in anesthetized patients than cLMA. Contrast to the previous study, PLMA had a success rate of 81 % compared to 90 % with cLMA. In three attempts a success of 99% was achieved in PLMA group. Nasogastric tube passage was successful in 92 % of patients (Cook et al. 2002). This same finding was observed in a larger (n= 384) multi-centre study comparing cLMA and PLMA (Brimacombe et al. 2002b). Comparing PLMA and laryngeal tube (LT) in anesthetized patients (n= 70) PLMA was found to be easier to insert, with a 77 % first attempt success compared to 51% in LT. Hands free ventilation (no corrective manipulations needed) was achieved in 91 % of patients in PLMA group compared with 62 % in LT group (Figueredo et al. 2003). Basically the same findings were observed in another study comparing PLMA and LT in anesthetized patients. Sealing pressures were equal, but PLMA was quicker to insert and provider more efficient ventilation (Cook et al. 2003b).

There is only one study in PLMA among inexperienced users. Comparing the use of cLMA and PLMA in anesthetized patients with post-anaesthesia care nurses after manikin training only, first attempt success rate was similar with 83 % in PLMA group and 85 % in cLMA group. In addition, insertion times and overall success rates were similar (Coulson et al. 2003).

2.4.6.3 Intubating laryngeal mask (ILMA)

Intubating Laryngeal Mask (ILMA) was developed based on experiences of difficult airway and managing those situations with a modified cLMA. Modification included an option to perform intubation blindly via cLMA (Heath and Allagain 1991). Early discoveries lead to development of a new version of LMA to further improve the possibility of blind tracheal intubation in cases of difficult airway. ILMA was bioengineered by Dr. Brain using magnetic resonance scans of the adult upper airway in the beginning of 1990s (Brain et al. 1997).

ILMA is a curved LMA with a normal LMA cuff including different cuff sizes from 3 to 5. The proximal part of ILMA is a round tube made from metal and has a steel handle. The ILMA has a wider diameter compared to cLMA (1, 3 mm vs. 0, 9 mm) and is shorter than cLMA (14, 5 cm vs. 20 cm). ILMA has its own spiral reinforced, silicone tracheal tube. Tracheal tube up to size 9 can be used to intubate via ILMA (Kapila et al. 1997).

ILMA is inserted using the same principle as cLMA. The patient's head can maintain a neutral position and ILMA is guided via hard and soft palate until resistance of the hypopharynx can be reached. To be able to keep cLMA in midline during insertion process, manoeuvres with the other hand in the pharynx are often needed. With ILMA one can use the handle to insert and guide the device firmly in midline to the hypopharynx and additional manoeuvres are not needed (Brain et al. 1997). The intubation is done after verification of a correct ILMA position and successful ventilation. After that, a cuffed tracheal tube is passed via lumen in ILMA. In the cuff of ILMA is tracheal tube guiding ramp, which permits the tube to move against the anterior wall of pharynx and pushes the tube a bit downward towards the tracheal opening.

First studies assessing the use of ILMA found it easy to insert during anaesthesia (n=100, 100 % success at first attempt) and tracheal intubation was possible blindly in 93 patients and in 72 at first attempt. Of remaining 28 patients requiring two or more attempts, two major difficulties were observed, including tube passage obstruction (n= 25) or oesophageal intubation (n= 3) (Kapila et al. 1997).

In another multi-centre study from UK, 500 ASA 1 and 2 patients were anesthetised using ILMA. In all cases, ILMA was successfully inserted in a mean time of 14 seconds. Ventilation was satisfactory in 95 %, difficult in 4 % and unsatisfactory in 1% of cases. Blind intubation was possible in 96,2 % cases with three or fewer attempts. With 19 patients blind intubation was not possible, but in 17 patients from these, ILMA was used for the first time by attending anaesthesiologist. In conclusion, ILMA was found to be fast and easy to insert and blind intubation was possible in majority of cases (Baskett et al. 1998).

After initial success, ILMA combined with blind intubation was used in cases of known or suspected difficult airway management during anaesthesia. One of the first reports came from Japan describing the use of ILMA in 30 patients with known or suspected difficult airway. Intubation was performed to 28 patients successfully via ILMA (Fukutome et al. 1998). Case reports of successful use of ILMA after failed fiberoptic intubation were also published (Watson et al. 1999). This led to prospective randomized study comparing fiberoptic intubation and blind intubation through ILMA in cases of difficult airway during anaesthesia. One hundred patients (Mallampati class 3-4) were enrolled to this study. Successful tracheal intubation with ILMA was possible in 94 % of cases compared to 92 % in fiberoptic group (Langeron et al. 2001).

In emergency, airway management related to trauma is often done in demanding prehospital environment with limited experience. ILMA without blind intubation, ETC and ETI was compared when used by manikin trained Navy Seal Special operations corpsmen during simulated trauma scenarios under fire. In this manikin study all techniques were adopted by corpsmen and in simulated cases ILMA (mean 22,3s) was inserted more rapidly that ETI and ETC (mean 36,5 s and 40 s respectively) (Calkins and Robinson

1999). In two other manikin studies showed that previously inexperienced critical care nurses and house officers could insert and ventilate manikin with great success (100% insertion and ventilation success rate) when using ILMA without blind intubation technique in simulated emergency cases (Dorges et al. 2000b, Dorges et al. 2001).

The question whether medical and non-medical inexperienced care providers can use ILMA for blind intubation was studied in a manikin model. Without any given instructions, 59% of all participants successfully intubated via ILMA. Medical care providers had an initial 83% success rate. When given a standardized 60 second instructions 97 % of all participants successfully intubated manikin via ILMA (Levitan et al. 2000).

There are two studies comparing the use of cLMA and ILMA in inexperienced medical care providers in anesthetised patients after minimal or no training. In first of them physicians without prior anaesthetic experience successfully (98,7 %) inserted both devices, but ILMA provided more adequate ventilation without leak and was preferred in subjective evaluation by study participants (Choyce et al. 2001). In the other study novice medical staff inserted both cLMA and ILMA with similar results of success rate (82, 1 % vs. 81, 5 %), insertion time (62, 6 s vs. 60 s) and expired tidal volumes (781 ml vs. 767 ml) (Burgoyne and Cyna 2001). It seems that ILMA has same advantages as cLMA with simpler insertion technique.

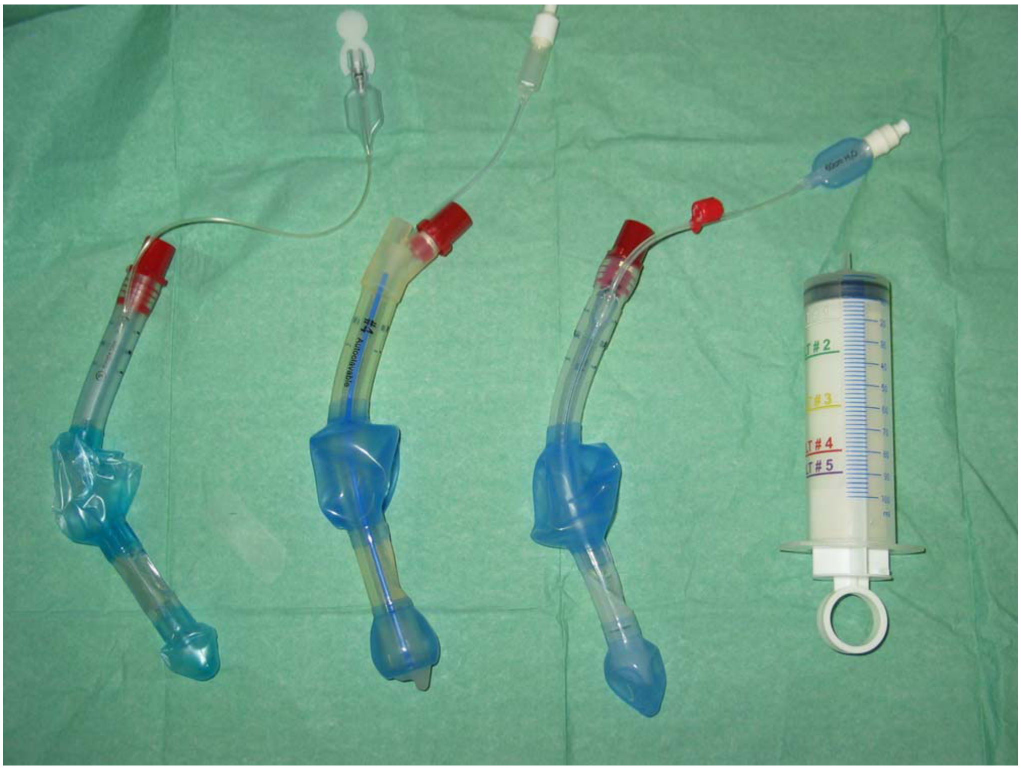
ILMA was also studied in anesthetised patients in a model of trauma in a group of ambulance care provides, doctors with intubation experience and doctors without intubation experience. They were given a short lecture and anesthetised patients (n=80) were under cricoid pressure and in-line stabilization of cervical spine during insertion of ILMA. All participants successfully inserted and ventilated via ILMA. Intubation and

successful ventilation via ILMA was not possible varying from 2 % to 20 % in different groups. Successful intubation was in place varying from 30 s to 36 s (Reeves et al. 2004).
It seems that cardiovascular responses are not different during insertion of ILMA with or without blind intubation compared to those with intubation via direct laryngoscopy (Choyce et al. 2002).
When ILMA is used without the feature of blind intubation the risk of aspiration exists, especially with cases of emergency airway management. According to the literature, the risk of aspiration with the ILMA during anaesthesia is rare and about 2 per 10,000 elective cases (Brimacombe and Berry 1995).
Cuff design in both cLMA and ILMA may cause leak during positive pressure ventilation. This is especially true if the position is suboptimal, normally related to too proximally placed cLMA or ILMA. This result air leak, and may cause the care provider to increase cuff pressure causing superficial nerve damage. Correct positioning of LMA when the tip is wedged against the upper oesophageal sphincter may actually prevent aspiration, but this is only the case with correct positioning (Keller et al. 2000).

2.4.7 Laryngeal Tube

Laryngeal Tube (LT) was developed and introduced in European market late 1999 (Agro et al. 1999). Originally, the aim was to develop a single lumen airway based on the knowledge and experiences of ETC. It was originally designed for the purpose of general anaesthesia, but also for used in emergency airway management in different situations.
Original LT is a multiple use, single lumen, silicon tube with two cuffs. The distal cuff lies in the end of the tube and is somewhat cone shaped. The second cuff is larger and

shaped to fit into the patient's oropharynx. Both cuffs are low-pressure cuffs and inflated via same pilot balloon- valve system. Between cuffs, there are two ventilation outlets and the distal opening is large enough to allow suction of airways and also passage of bronchofiberoscope. In the proximal part of LT is a standard 15 mm connector for ventilation device. Original LT comes with a size range from 0 to 5, designed to fit from newborns to large adults. The size is also indicated with a different connector colour. The package includes also includes a inflation syringe colour coded for optimal cuff volume in each LT size. In the proximal part of LT is also a mark, which at correct depth comes between the patient's teeth.



Picture 7. From left: LTD (Single use laryngeal tube), LTS (Laryngeal tube with suction channel) , LT (Multi-use classic laryngeal tube) and inflation syringe

LT is inserted with patients head in neutral position. The tube is inserted via hard palate with somewhat curved motion downwards to the marked recommended depth, until a distinct resistance is felt. After that, cuffs are inflated with incoming syringe to recommended volume. The purpose of distal cuff is to fit and seal the upper oesophageal opening and the second cuff to seal the anterior base of tongue and posterior the oropharynx. Ventilation via distal openings should be free, with a detection of lung sounds, chest rise movement and end tidal CO_2 outflow.

Later developments modified original LT with two distinctive models. Laryngeal Tube-S (LTS) has the same features as LT, but consists also of a side lumen which opens in the distal part to the tip of LTS allowing suction of gastric contents. LTS comes with sizes 3 to 4. Latest model is a disposable LT (LTD), developed on the basis of LT consisting same features, but with slightly different materials to make it single use and cheap.

In the first studies of LT it was used during routine anaesthesia. Insertion was successful to all anesthetised patients (n=30) with a fast and easy insertion (median of 21 s) similar to these with cLMA. Sufficient oxygenation and ventilation with no gastric distension was noted. Mean airway leak pressures ranged from 24 to 40 cmH_2O at cuff pressures of 60 to 90 mmHg (Dorges et al. 2000a). These findings were duplicated in another study from Japan with a similar leak pressure (Asai et al. 2000).

When comparing LT and cLMA in randomized crossover study with patients under general anaesthesia (n=22) similar insertion features were found, but LT proved to provide better leak pressure than cLMA (26 vs. 19 cmH_2O). In cLMA group gastric insufflation was noted in three patients compared to none in LT group (Asai et al. 2002b). In another study (n=50) with similar comparison of LT and cLMA these findings were duplicated also with a finding of better leak pressure related to use of LT (Ocker et al. 2002). In third study with again the same design (n=72) insertion, oxygenation, ventilation were similar in LT and cLMA but leak pressure was higher in LT group. In this study, the complications related to the use of airway devices ranging from complications during induction of anaesthesia (bleeding etc.) to 24 h post operation (sore throat etc.). There were no differences in these complications between LT and cLMA (Cook et al. 2003a). In another early study of LT compared to cLMA findings totally opposite to these, previously introduced, studies were found. These patients (n= 34) were under general anaesthesia but spontaneously breathing. Of seventeen patients in LT group only seven were managed successfully with LT because of difficult or impossible insertion. These airways were successfully managed by cLMA. In cLMA group all patients were managed successfully with cLMA. This finding has been debated later and one explanation may be the use of prototype LT which had some changes for later studies. Another explanation to this different result may be the sedative anaesthesia during study (Miller et al. 2001). Theoretically, PLMA may offer better sealing than cLMA and LT. To test this hypothesis PLMA was compared against LT. Again, similar insertion features were found, but now the leak pressure was higher in PLMA group in recommended cuff volumes (29 vs. 21 cmH_2O) and similar in maximum cuff volumes (Brimacombe et al. 2002a).

Although originally designed for anaesthesia purposes, the performance of LT was also studied in a model of cardiac arrest. In the first study, it was compared to ventilation through face mask and ETI in a manikin model. The findings indicated that the ventilation performance was superior to BVM in terms of tidal volumes and reduced risk of gastric insufflation. LT performed equally compared to ETI (Genzwuerker et al. 2001). In another manikin study, LT was compared to ILMA. In this study, first successful ventilation was faster with LT than ILMA (mean 19 vs. 38 s). Ventilation volumes were not different and gastric inflation was not detected (Dorges et al. 2001). These findings were supported in a case report of successful use of LT after failed ETI during cardiac arrest in prehospital care provided by physician unit (Genzwuerker et al. 2002a).

The efficacy and performance of the LT by inexperienced personnel was tested in a randomized cross-over study comparing LT and cLMA in a manikin. The performance was tested among 28 firefighter students. Insertion was found to be easy in both groups. Tidal volumes were higher and the incidence of gastric insufflation was lower in the LT group (Asai et al. 2002a).

A group of nurses were trained to use LT with a short theory and manikin training. After that within a 21-month period, thirty attempts to place LT during cardiac arrest were performed in prehospital phase. The insertion was successful in 83,3 % of patients, with 70 % successful in the first attempt. Ventilation was possible trough LT in 80 %. During resuscitation, LT was stable in 93, 3 % of patients and dislodged in three patients (Kette et al. 2005).

One concern of the use of LT is that the large oropharyngeal cuff may cause ischemic damage to the oropharynx. In a study with cadavers, findings indicated that if cuff volume exceeds 80-100 ml the mucosal pressure increases and potentially exceeds mucosal perfusion (Brimacombe et al. 2002c). Previously manufacturer recommended the intracuff volume to be adjusted by patient's weight and after preliminary experiences revised these recommendations to be based on patient's height. A study comparing the relation of intracuff volume to patient's height or weight, both parameters correlated to correct intracuff volume but in one third of patients based on cuff pressure it would become overinflated (Asai and Shingu 2005). Recently the manufacturer's recommendations include the use of cuff inflator with a pressure gauge and instructions not to exceed intracuff pressure of 60 mmHg.

The second concern of LT is that the blind ending that seals the oesophageal opening may provoke oesophageal rupture in case of extensive vomiting. Further development leads to engineering a LTS with an added suction channel, similar that to PLMA. Early findings indicated that the insertion, ventilation, oxygenation and sealing were similar that to LT in anesthetised patients (Dorges et al. 2003). LTS has also been compared to PLMA undergoing general anaesthesia. Both devices performed in very similar features in this study, and compared to previously reported performances (Gaitini et al. 2004).

Recent reports indicate that insertion of LT during manual in-line stabilization mimicking the case of cervical spine injury is more difficult that allowing neck movement. In the first study with anesthetized patients (n=21) the insertion of LT were found either difficult (n=2) or impossible (n=19) during manual in-line stabilization (Asai et al. 2004). In another study comparing ILMA and LT in similar study design (n=51) insertion was found to be more difficult in terms of first attempt success in LT (n=16/51) than with ILMA (n=42/51) (Komatsu et al. 2005).

2.4.8 Cobra Perilaryngeal Airway

CobraPLA was invented by Dr Alfery and it was introduced in 2003. It is a supraglottic airway device with same features as cLMA and COPA. It consists of a breathing tube with a wide distal end and cuff attached just proximal to the wide part which also has ventilation outlets with grilles. In the proximal part is a standard 15 mm connector for ventilation device. The cuff is inflated via pilot balloon-valve system attached to the breathing tube.

CobraPLA is inserted along the surface of tongue downwards with a patients head in sniffing position. When resistance is felt, the distal end lies in the hypopharynx and the cuff just proximal to it. Manufacturer recommends a slight withdrawal from this position. When properly inserted the wide end holds both soft tissues and the epiglottis away from the distal portion of CobraPLA. It is made of transparent polyvinyl chloride and is single use. Manufacturer has eight sizes, which are based on patient’s weight. Different sizes have different recommended cuff volumes.

Picture 8. Cobra perilaryngeal airway

CobraPLA was first studied in a group (n=28) of anesthetised ASA 1-2 patients. Insertion and ventilation data were collected. In 57, 1% of patient's insertion was successful at first attempt and ventilation was possible. Remaining twelve patients needed further device and airway manipulations before successful ventilation was achieved. Oxygenation and ventilation parameters were stable throughout study period in all patients after successful insertion. No airway complications were detected in recovery room and 24 h post anaesthesia (Agro et al. 2003). In second study with the same design four anaesthesia residents inserted CobraPLA to anesthetized patients (n=110) after manikin training. Insertion was considered as easy in 77, 3% of patients and difficult in 22, 7 %. Ventilation was possible to all patients, but airway leak was detected in half of patients and CobraPLA replaced to large size. Authors recommended choosing one size bigger than recommended by manufacturer (Agro et al. 2004).

After these preliminary studies, CobraPLA was compared to cLMA. Five anaesthesiologist inserted CobraPLA and cLMA in randomized order to ASA 1-2 anesthetized (n=81) patients. Airways were successfully managed by CobraPLA in 39/40 patients and 41/41 patients in cLMA group. Insertion time and number of attempts were similar. CobraPLA offered better sealing airway pressure than cLMA (mean 23 vs. 18 cmH_2O). Evaluation of complications revealed a same amount of oropharyngeal irritation in both groups (Akca et al. 2004).

Because CobraPLA is shorter than most supraglottic airway devices its tip does not reach to seal oesophageal opening to the pharynx. Hypothetically, devices that cover the oesophageal opening prevent aspiration of gastric contents. CobraPLA is not recommended to cases with imminent risk factors for gastro-oesophageal reflux or regurgitation. First report of pulmonary aspiration was published in 2004. A 33 –year old woman with no risk factors was anesthetised for gynaecological procedure. After 15 min of uneventful anaesthesia, airway pressures raised and aspiration observed. Later patient fully recovered (Farrow and Cook 2004). In a recent report, this problem was reappraised. In a study aimed to evaluate the CobraPLA in 100 anesthetised patients and compare the clinical performance with cLMA two pulmonary aspirations occurred after enrolling 29 patients. Both patients recovered, but study was halted by the Local Research Ethics Committee. Again, the concerns were raised whether the design of CobraPLA actually makes gastric insufflations more likely and resulted in aspiration. Authors warranted for more safety data until CobraPLA should be further marketed (Cook and Lowe 2005). CobraPLA has not been studied when used by inexperienced users.

2.5 Training and practices for prehospital emergency airway management

Emergency airway management in prehospital setting has been considered as an utmost importance. Basic airway management method is BVM, but in advanced level of care the golden standard has been ETI, but as previously introduced, this method has been seriously questioned by low success rates and alternative techniques has been widely introduced and accepted. There is no doubt that ETI is effective when managed by experienced care providers with necessary adjuncts. ETI still is the standard of care and recommended by new ERC guidelines for critically ill out–of-hospital patients cared for by advanced-level rescuers such as paramedics (Nolan et al. 2005).

Key to successful ETI is sufficient training and skill maintenance. The learning curve for ETI has been best demonstrated in the training of anaesthesia residents. In a study from Brazil common practical procedures of 11 first-year anaesthesia residents were observed and collected during one year period. As a result to reach a 95 % successful intubation rate with one or two attempts an mean number of 127 intubations had to be performed (de Oliveira Filho 2002). The National (US) Standard Paramedic Curriculum recommends that paramedic students perform at least five live ETIs during their studies. To evaluate the effects of cumulative ETIs to success rate of ETI, data from sixty paramedic training centre was achieved and reported success/failures over two-year period. Paramedic students (n=802) performed a median of seven ETIs during study period. A total number of 7635 ETIs were performed and with a success rate of 87, 4 %. Most of the ETIs were performed in operating rooms (82, 7%), minority in emergency department, prehospital setting or intensive care unit. In logistic regression analysis, the cumulative number of ETIs was associated with increased odds ratio to successful ETI. This was most significant with those ETIs performed in prehospital setting or in ICU (Wang et al. 2005b).

Another challenge with ETI is skill maintenance. In the US there is no national consensus related to paramedic profession and skill retention. In individual states, requirements for ongoing rehearsal for practical procedures have been stated. This problem has been clearly shown by Wang et al in a study collecting the frequency of ETI during one year among paramedics in Pennsylvania (12.3 million inhabitants). In 1 544 791 patient care reports 11 484 ETIs were reported by 5 245 rescuers. The median ETI frequency was one/rescuer (range 0-23). Over 67% from rescuers performed two or fewer ETIs/year and over 39 % performed none/year. This study was done in mixed urban/rural setting and can be extrapolated to very many EMS systems throughout the world (Wang et al. 2005a).

ETI remains also the conventional teaching method for airway management in most medical schools throughout the World. The skills are normally related to the curricula of anaesthesia and intensive care. Various courses of emergency medicine and advanced trauma and cardiovascular care also consists sections of airway management often with ETI introduced as the golden standard. Still, most of physicians are not involved in emergency care, anaesthesia or intensive care medicine after graduating thus resulting poor skill retention and too few ETI frequencies to maintain necessary skills. Training of airway management and ETI usually consists from didactic lessons and manikin training. Also, compulsory live training in operating room is added in curriculum in some institutions varying between countries. This concept has been challenged by alternative airway devices. In a prospective cohort study, ninety-three medical students were taught to use ETI, ETC and cLMA. Skills were tested in a manikin at 0 and 6 months. ETI showed to be the worst in insertion rate, insertion time and these worsened significantly during 6 month follow-up. During follow-up, the skills of cLMA insertion were least deteriorated (Tiah et al. 2005).

In Finland, basic level care providers in prehospital setting are firefighter-EMTs trained in either the Emergency Services College in Kuopio or Rescue School in Helsinki. Practical Nurses, which also have modules for prehospital emergency care, can provide basic prehospital care. In both of these curricula, ETI is considered as a standard airway management in cardiac arrest cases and BVM with oropharyngeal airway in other cases needing prehospital airway management. Live ETI possibilities are normally not possible to all students in these educational programs due to lack of opportunities inside hospitals. Some hospitals also have policies that nurse-students cannot perform invasive procedures to hospital patients. The curricula related to airway management of Practical Nurses consist of lessons, manikin simulations and practical live rehearsals. The actual volume of airway education varies related to institutions, because 80 institutions around Finland can gives a module of Study Programme to Prehospital Care to Practical Nurse students. The

Ministry of Education has given basic goals to the institutions for this module. Regarding airway management the prehospital ETI for cardiac arrest patients is considered as nationwide standard.

The curricula of firefighter-EMT education for prehospital care is best described and standardized mainly because only two institutions gives that education. Total prehospital module is 19 weeks and during that time the course of airway management consists from 9 hours of didactic lessons and 16 hours of manikin training. Live ETI is not possible for all students. The use on LT was added to the curriculum from the beginning of 2004 so both ETI and LT are included.

In advanced level the curricula of paramedic training consists of advanced airway management course with ETI as a standard method and some pharyngeal method as a backup device. Courses vary from institution to another, consisting from didactic lessons, manikin trainings, live ETIs in operating rooms and also in prehospital setting during rehearsals in EMS unit.

Previously has been reported that in prehospital care the success rates of ETI are poor especially in rural areas, procedure is rare and skill maintenance is difficult. The need for devices, which are efficient, easier to adopt than ETI, risk of possibly harmful effects are small and skill maintenance can be arranged with reasonable rehearsals is evident. Experiences from pharyngeal devices are based on anaesthesiology and some studies related to emergency care. Further studies are needed to evaluate the usefulness of these devices in prehospital emergency care.

3. AIM OF THE STUDY

The study was performed to determine the usefulness of alternative airway devices among Finnish prehospital basic and advanced care providers related to their curriculum

The specific aims of this thesis were

1. To evaluate the role and the impact of advanced airway management in Finnish rural area (Study I)
2. To evaluate if LT could be an emergency airway device for basic prehospital care providers in Finland (Study II-V)
3. To compare three supraglottic airway devices among students trained for advanced prehospital care (Study IV)

4. PATIENTS AND METHODS

4.1 Study subjects and patients

Sixty firefighter-EMT students from Emergency Services College, Kuopio in their first semester of their education were asked to participate in a voluntary test evaluating the use of different methods for airway management. The students were then randomly divided to form 30 teams of two rescuers to perform the study protocol in a manikin (Study II). After six months thirty firefighter-EMT students from same class were asked again to participate in a test comparing the use of the LT and BVM in anesthetized patients (Study III). In study IV thirty-two paramedic students who had completed their BLS courses in airway management (Arcada Polytechnic Department of Care, Helsinki) were asked to voluntarily participate to the study. Upon registration and during the National Emergency Conference in June 2003 in Kuopio, the delegates (190 altogether) were informed that they had a chance to test their ventilation skills using a novel device and that results are going to be collected and reported. No details of the study protocol were revealed at this point. Sixty-seven care providers voluntarily participated to test as a work background related to either prehospital or in-hospital environment (Study V).

All eligible ASA 1-2 day-surgery outpatients scheduled for a gynaecological procedure requiring general anaesthesia during study period in Kuopio University Hospital day-surgery (Study III) or in Helsinki University Hospital Department of Obstetrics and Gynaecology (Study IV) unit were asked to participate in the study. Thirty patients were enrolled to the study III and ninety-six patients to study IV after consent was obtained during normal preoperative evaluation by the attending anaesthesiologist. Institutional review boards of the Kuopio University Hospital (Study I, III) and Helsinki University Hospital (Study IV) approved the design of the studies. Emergency Service College approved the design for studies II and V. Description of different studies is collected in table 3.

	Study I	Study II	Study III	Study IV	Study V
Study aim	To evaluate health benefits of ALS unit	To compare the performance of LT, ETI and BVM used by firefighter-EMTs	To compare the performance of LT and BVM used by firefighter-EMTs	To compare the performance of ILMA, LT and CobraPLA used by paramedic students	To evaluate the use of LT after short verbal and picture related instructions
Design	Retrospective analysis	Prospective and randomized study	Prospective and randomized study	Prospective and randomized study	Prospective study
Setting	Panel evaluation of HEMS missions during one year	Simulated cardiac arrest scenario with manikin	Anesthetized patients	Anesthetized patients	Simulated apneic patient scenario in manikin

Table 3. Brief description of individual studies comprising the present thesis. ALS= advanced life support, LT=laryngeal tube, ETI=endotracheal intubation, BVM= bag-valve-mask ventilation, EMT= emergency medical technician, ILMA= intubating laryngeal mask, CobraPLA= Cobra perilaryngeal airway, HEMS= helicopter emergency medical service

4.2 Data collection

Prehospital patient care record sheets (n= 588), which show where the Eastern Finland HEMS was dispatched between 1.1.1999 and 31.12.1999 were reviewed retrospectively for procedures and treatment. Two hundred and six patients received ALS care by HEMS and patients were transported to definitive care. Hospital records were reviewed to obtain the accuracy of prehospital treatment and hospital mortality from these 206 patients. Specific time points for HEMS missions were obtained from databases of the three dispatch centres in the catchment area. Time intervals from call to on-scene, from on-scene to hospital and on-scene treatment time were calculated. The potential benefit of HEMS was estimated and divided into four categories (life saving benefit, beneficial effect, no evidence for better outcome and no beneficial effect or patient died) by a panel based on procedures, given treatment and transportation time saving by HEMS (Study I).

The scenario of a simulated witnessed cardiac arrest (Study II) and apneic patient (Study V) was used. To test and compare airway devices AMBU® Mega Code Trainer (Ambu Corp., Copenhagen, Denmark) manikin was used. To obtain data on ventilation a connector for side-stream spirometry (Datex-Ohmeda CS 3, Datex Corp, Helsinki, Finland) was inserted in the lower part of the trachea of the manikin to obtain data on ventilation. The setup was tested and validated before studies by connecting the spirometry adapter to a Datex CS 3 monitor and ventilated the manikin with BVM as well as after ETI and connecting the manikin to a Servo 900C ventilator (Siemens AG, Munich, Germany). Time data was obtained by observed not otherwise participating to scenario (Study II,V) Measurements of gastric insufflation were not made (Study II, V).

Anesthetized patients were monitored with 3-lead electrocardiogram (ECG) for heart rate (HR), peripheral oxygen saturation (SpO_2), non-invasive blood pressure (NIBP) and $etCO_2$ (Study III, IV) and Entropy was added to study IV. Ventilation volumes and airway pressures were measured with a side-stream spirometry device (Datex-Ohmeda CS 3, Datex Corp., Helsinki, Finland) placed between the LT or the mask and the bag reservoir (Study III). Standardized anaesthesia was induced with fentanyl and propofol and maintained with sevoflurane (Study III) or propofol (Study IV). The depth of anaesthesia was judged by attending anaesthesiologist based on clinical parameters (Study III) or entropy values (Study IV). Before start of study protocol, an airway device was randomly selected using sealed envelopes, which contained the order to follow (Study III, IV). After permission from attending anaesthesiologist, firefighter-EMT students were asked to perform BVM or insert LT during one minute of study period, during which ventilation parameters were measured and success of insertion, insertion times, $etCO_2$ and SpO_2 values were collected (Study III, IV). In study IV paramedic students used three devices (LT, ILMA and CobraPLA) in random order to different anesthetised patients. Haemodynamic data was obtained before and after induction and after insertion of airway device (Study IV).

Independent of the student's success with each device, he/she was asked to grade his subjective opinion about the clinical usefulness of the device on a Likert scale from 1 (completely dissatisfied) to 5 (completely satisfied with the properties of the device) and to rank them in the order from the best to the worst (Study IV) (Likert 1978).

At the beginning of the test, the LT, the syringe for cuff inflation and a bag-valve ventilator (Laerdal Inc. Stavanger, Norway) were ready on a table. Each participant was tested separately, and told that he or she was expected to insert the LT in a scenario with a witnessed collapse and no respiratory efforts left. No prior patient assessment or ventilations were to be performed. The participants were asked to insert the LT, inflate the cuffs, verify correct positioning by auscultation, fix the tube and start BVM ventilation aiming at normoventilation. If insertion was unsuccessful or difficult, an instructor could give further advice on how to proceed (Study V).

4.4 Statistical methods

Results were analysed using the Windows SPSS software (SPSS® Inc. Chicago, USA) version 10.0 (Studies I-IV) and version 12 (Study V). A non-parametrical t-test was used to test difference between groups (I-III). The Kruskall-Wallis test was used to detect differences within the group and Mann–Whitney test with Bonferroni correction to detect differences between the groups. To detect group variation in repeated measures of respiratory, circulatory and ENT values within groups we used Friedman's test (Study IV). A logistic regression model was fitted to assess explanatory background variables on the successful insertion of the LT in less than 30 s, the ability to maintain normoventilation (defined as 7 l/min), and the need for further instructions to insert LT (Study V). Descriptive statistics of variables are given as the mean with standard deviation (SD) (Study III, IV) and the median with interquartile range (IQR) (Study I, II, IV).

5. RESULTS

5.1 Impact of prehospital advanced life support and airway management

From the total amount of dispatched paramedic HEMS missions (Study I), 208/588 (35 %) needed ALS care. ALS care was considered as life saving or beneficial in 45 patients and from these, in forty patients (89%) it was due to ALS procedures. Overall, 40/208 patients received ETI or cLMA as a backup device. There were three patients, who were considered as having received a life saving benefit from ALS care and two of those received ETI. Forty-two patients were estimated to have had beneficial health effects from ALS care and 16 (38%) of those received ETI.

5.2 Performance of bag-valve mask ventilation

In a simulated cardiac arrest model (Study II), first measurable ventilation occurred from the beginning of the test, when BVM was used in a median of 81,0 sec (IQR 56,3 – 102,3 sec). Students were advised to use a ventilation-compression ratio of 2:15 when BVM was used. This produced an expired minute ventilation of median 2,6 l/min (IQR 1,3 – 4,6 l/min).

When BVM was used in anesthetized patients, (Study III) the measured expired minute volume was a mean of 6,7 l ± 2,4. The corresponding expired tidal volume was 495 ml ± 151. Peak airway pressure was 19,2 mmHg ± 8,6 and minute ventilation airway leak 3,2 l ± 1,7. During ventilation $etCO_2$ was a mean of 4,2 kPa ± 1,0. Normoxia was maintained throughout the study period. Expired minute ventilation with BVM was significantly lower than in LT with a median of 7,1 l/min ($p < 0,0001$; Study II). LT produced similar expired minute ventilation in Study V (6,5 l/min). Also ETI produced significantly better expired tidal volumes compared to BVM with a median of 6,3 l/min in manikin ($p < 0, 0001$; Study II). No difference between expired tidal volumes was noticed, when BVM or LT was used to anesthetized patients (Study III)

5.3 Performance of laryngeal tube

5.3.1 Insertion of laryngeal tube

In a simulated cardiac arrest scenario comparing LT, ETI and BVM (Study II), LT was successfully inserted at first attempt by all care providers (n=20). Measured from the beginning of the test (scene arrival), insertion of LT and initiation of ventilation occurred at a median of 64,0 sec (IQR 50 - 85 sec).

In another manikin study simulating apneic patient (Study V), a total of 65 of the 67 participants (97 %) successfully inserted the LT. Thirty-seven (57 %) of them succeeded on the first attempt without the need for any other instructions than those provided before the beginning of the test. The median time needed for insertion measured from the opening of the mouth to the first measurable ventilation in the whole group was 31,5 s (IQR 25,0 – 47,3). In the group with no need for instructions median time was 28,0 s (IQR 23,0 – 34,0), and for those who needed instructions it was 48,0 s (IQR 28,0 – 68,0).

All Fire-EMT students (n=15) inserted LT successfully to anesthetized patients (Study III). A mean number of 1,4 ± 0,7 attempts were needed to place the LT correctly. Eleven students (73%) successfully placed the LT on the first attempt. They needed 48,2 s ± 14,7 from opening the patient's mouth until the first measurable ventilation was recorded.

For the whole group the mean time needed for insertion from opening the mouth until initiation of ventilation was 80,0 s ± 58,0.

When comparing LT, ILMA and CobraPLA to anesthetized patients (Study IV), 14/32 (44%) successfully inserted LT on first attempt. With additional two attempts a total of 25/32 (78%) students successfully inserted LT. There were seven patients (21%) to whom students could not insert LT. During insertion of LT, eight cuff ruptures occurred and the device had to be replaced. These were counted as unsuccessful insertions. The time needed for successful insertion at the first attempt was 24,9 ± 7,4s.

LT was inserted faster than ETI to manikin (p< 0, 0001; Study II). Comparing the success of insertion on first attempt of LT to ILMA and CobraPLA, no differences were detected in success rate or insertion times (Table 4).

	Study II (median with IQR)	Study III (mean ±SD)	Study IV (mean ±SD)	Study V (median with IQR)
ETI	95 (79-110)	NS	NS	NS
LT	64 (50-85)	48,2 ±14,7	22,9 ±7,5	31.5 (25.0 – 47.3)
ILMA	NS	NS	24,9 ±7,4	NS
CobraPLA	NS	NS	26,4 ±6,0	NS

Table 4. Successful insertion times on first attempt (seconds). NS=not studied, IQR=interquartile range, ETI=endotracheal intubation, LT= laryngeal tube, ILMA=intubating laryngeal mask, CobraPLA= Cobra perilaryngeal airway

5.3.2 Ventilation and oxygenation with laryngeal tube

In the manikin study (Study II) with a scenario of a cardiac arrest, students were advised to ventilate the "patient" with a ventilation-compression ratio of 2:15 when using BVM and LT. Expired minute ventilation (l/min) from the beginning of the first ventilation was a median of 7,1 l/min (IQR 5,8 – 7,8 l/min) in the LT group.

Participants were advised to aim for normoventilation after insertion of LT in simulated cases of apneic patient (Study V). This produced a minute volume ventilation for the whole group a median of 6,5 l (IQR 5,2 – 8,3) and peak airway pressure 13,6 mmHg (IQR 10,7 – 16,5).

In logistic regression analysis, no relationship between background variables (education, emergency work experience, use of BVM and frequency of ETI) and the three main variables related to successful use of LT (successful insertion in less than 30 seconds, ability to maintain normoventilation (7 l/min) and need for further instructions during insertion) were detected.

When LT was inserted to anesthetized patients by firefighter-EMTs (Study III), the expired minute volume was 6,2 l ± 2,2. Corresponding tidal volume was 464 ml ± 135. Peak airway pressure was 23,5 mmHg ± 9,7 and airway leak 2,4 l/min ± 1,4. During ventilation $etCO_2$ was 4,8 kPa ± 0,5. Normoxia was maintained during whole study period.

Comparing ventilation parameters to ETI (Study II) or ILMA and CobraPLA (Study IV), no statistically significant differences were detected in expired minute volume (Study II), SpO_2 and $etCO_2$ (Study IV).

5.4 Performance of intubating laryngeal mask airway

In the study comparing ILMA, LT and CobraPLA (Study IV) we found that 24/32 (75%) of the students successfully inserted the ILMA at the first attempt. With an additional two attempts a success rate of 31/32 (97%) was achieved. One attempt was considered as a total failure. The time needed for successful insertion at the first attempt was a mean 22,9 ± 7,5 s. Normoxia was maintained during the study period.

In this study, students were asked to subjectively evaluate different devices. The students graded the ILMA as the best with regard to overall usefulness and when asked to nominate the best device. Regarding the rate of total insertion failures ILMA performed significantly better with one failure compared to seven in LT and CobraPLA (Study IV). In table 5 insertion success rates and failures of different devices are presented.

	Study II		Study III		Study IV		Study V	
	First attempt success	Failures	First attempt success	Failures	First attempt success	Failures	First attempt success	Failures
ETI	100%	None	NS	NS	NS	NS	NS	NS
LT	100%	None	73%	None	44%	21%	57%	0,3%
ILMA	NS	NS	NS	NS	75%	0,3%	NS	NS
CobraPLA	NS	NS	NS	NS	22%	21%	NS	NS

Table 5. Success rates and total failures of different airway devices. NS=not studied, ETI=endotracheal intubation, LT= laryngeal tube, ILMA=intubating laryngeal mask, CobraPLA= Cobra perilaryngeal airway

5.5 Performance of Cobra perilaryngeal airway

In anesthetised patients (Study IV), CobraPLA was successfully inserted in 7/32 (22%) patients. With two additional attempts success rate was raised to 25/32 (78%) leaving seven (21 %) failures to insert the device with three attempts. The time needed for successful insertion at the first attempt was a mean of 26,4 ± 6,0 s. Problems related to gastric insufflation were noted in twenty patients and also a tendency to choose too large a device when following the weight criteria given by the manufacturer. When CobraPLA was successfully inserted, normoxia was maintained during study period.

CobraPLA performed significantly worse in first attempt success rate than ILMA. Insertion times were comparable to those with LT and ILMA but gastric insufflation was not noted in other devices than with CobraPLA.

5.6 Performance of endotracheal intubation

In simulated cardiac arrest scenario (Study II), all students (n=20) performed ETI at the first attempt. Initiation of ventilation, measured from the beginning of the test, occurred at a median of 95,0 sec (IQR 79 - 110 sec). Expired minute ventilation from the beginning of the first ventilation was a median of 6,3 l/min (IQR 5,7 – 9,0 l/min).

6. DISCUSSION

6.1 Impact of prehospital airway management

In the present study, we found that paramedic manned HEMS with advanced care capability carried out 208 missions where ALS was needed (Study I). From those patients 45 (22%) were estimated to have had either life saving or remarkable benefit and in forty patients (89 %) it was considered to be related to ALS procedures. From those forty patients, sixteen received ETI, so overall benefit related to advanced airway care was 36 % of those patients who benefited from advanced care. This finding is in concordance with Norwegian findings related to benefit of physician manned HEMS unit. In this study, from overall 1106 patients 74 were estimated to have benefited from this service. From these 74 patients 88% were benefited by ALS care and procedures given by attending physician (Lossius et al. 2002).

The overall benefit of prehospital advanced life support is under debate. The term advanced refers to more extensively trained prehospital care providers e.g. paramedics, prehospital nurses and physicians, and the capability to provide various kind of emergency treatments on-scene. Treatments that are normally referred as advanced include advanced airway management, including ETI and surgical airway, fluid therapy, intravenous medication to various emergencies and advanced procedures like cardioversion, pacing and needle or tube thoracostomy. All of these require more training and skill, and some of those are time-consuming. There is an ongoing debate on whether these skills are unnecessary and difficult to maintain and whether definite care is delayed because of them, thereby diminishing chance of survival. (Dretzke et al. 2004, Isenberg and Bissell 2005, Liberman et al. 2000, Morrison et al. 2000, Roberts et al. 2005). In

Finland, response times and distances to nearest hospital providing definitive care may be long and results from studies regarding patients from more urban areas cannot always be extrapolated into rural environments.

The OPALS study from Canada, evaluating the outcome of patients in cardiac arrest (n=5638), did not support the use of ALS care for cardiac arrest patients. From 4247 patients 3605 patients were successfully intubated (Stiell et al. 2004). Recent studies support the fact that early recognition, early CPR and timed defibrillation are key elements for successful resuscitation from cardiac arrest (Handley et al. 2005, Larsen et al. 1993, Wik et al. 2003). The rationale that the need for prehospital advanced airway management is mainly maintained because of cardiac arrest cases is not supported, but after successful resuscitation a clear airway is needed, especially related to rural areas with long transportation times to definite care. Therefore, not all results of previous studies can be generalized.

The report regarding the benefit of paramedic skills in trauma comes from the UK, where the Health Technology Assessment group of the NHS conducted a study to evaluate this topic. The study was conducted as a non-randomized cohort study between advanced vs. basic care on-scene. A total of 114 / 2045 trauma deaths were noted within 6 months of the incidents. From these deaths, 86 /1440 (6,0%) were related to advanced care provider on-scene and 28/605 (4,6 %) to basic care. After adjusting the case mix, the odds of death in patients with advanced care to the odds of death with basic care was 2,02 (CI 1,05-3,89). The increased risk was noted in "bleeding injuries" and not in head injuries and other trauma. A panel evaluation was added to assess avoidable deaths. These cases included cases that were not in the previously described part of the study. From 120 cases with advanced care, the on-scene panel assessed that seventeen deaths (14, 2 %)

were possibly avoidable and eight (6, 7%) probably avoidable. From 59 patients, when basic care was on-scene, four were considered as possibly avoidable and none probably avoidable (Nicholl et al. 1998). This study did not evaluate the benefit of different advanced procedures, but interestingly the panel experts were asked what could have been done differently in patients with either possibly or probably avoidable deaths. The need for a more definitive airway management was considered as a factor in 9/21 (43%) of both advanced and basic care groups with possibly avoidable deaths. The same factor was noticed in half of patients with probably avoidable deaths. Although in this study the impact of prehospital advanced trauma care was found to be minimal, it supports the fact that from these advanced procedures airway control is a major factor of providing health benefit.

Regarding the patient's outcome after prehospital airway management, the studies mainly have ETI as an airway management device. The single reported RCT study comes from California, where a prospective and randomized (odd and even days) trial compared survival and neurological outcome either BVM or ETI treated prehospital airway in children under 12 years. Intubation was successful in 57 % of 305 patients. There was no difference in survival to hospital discharge (BVM 30% vs. ETI 26%) or good neurological outcome (BVM 23% vs. ETI 20%) (Gausche et al. 2000). There are no similar outcome studies regarding adults and whether these results can be extrapolated to adult population remains uncertain. On the other hand, if prehospital airway management is producing a health benefit, it must have a good success rate. In this study, success rate of as low as 57% of ETI may represent multiple and prolonged ETI attempts with a possibility of adverse effects on outcome.

The studies supporting the use of ETI as a device to manage prehospital airway are retrospective. The most cited study comes from San Diego consisting mixed trauma patients. A total of 1092 cases were analysed, from which 51,7 % (n=565) received ETI and hospital mortality in this group was 26,0%. Those remaining were managed with BVM and mortality was higher (36,2 %) (Winchell and Hoyt 1997). This retrospective analysis did not report the success rate of ETI. Again, failed ETI may have adversely affected the outcome of BVM group. In more recent, retrospective analysis of 10 314 moderate to severe head injury patients, patients received treatment either from aero medical crew consisting paramedic or physician or both, or from ground BLS unit with no advanced airway methods until arrival on ED. In the group of more severely injured patients (Head Abbreviated Injury Score over 3 and preintubation score of 3 to 8), those patients who received ETI by aero medical crew (n=531) had lower mortality than those with ED intubation (n= 428) with an adjusted odds ratio of 1, 42 (CI 1,13- 1,78) (Davis et al. 2005). This is a large study, but has problems due to its retrospective nature.

Airway management with ETI seems to have disadvantages that may have adversely influenced the patient's outcome. The question whether airway management with other devices may cause better result is still undetermined.

6.2 Airway management with bag-valve mask ventilation

In this study, the firefighter-EMT students' performance in a simulated cardiac arrest scenario with two rescuers showed that the first ventilation using BVM measured from arrival to the scene started late and produced a low minute volume. This result was affected not only by the difficulty to perform single rescuer BVM, but also shows the reality of time consuming task to prepare equipments of BVM, connecting oxygen, choosing right mask etc. The difficulties in a real emergency raises not only these issues, but also the mask fitting problems, secretions in patients' pharynx and possible aspiration of gastric contents. These findings are in concordance with other studies showing that in a simulated manikin scenario BVM ventilation seems to be difficult and time-consuming (Cummins et al. 1986, Elling and Politis 1983, Seidelin et al. 1986, Wheatley et al. 1997).

In anesthetised patients, these same firefighter-EMT students performed surprisingly well in this study. Normoventilation and normoxia were maintained throughout a minute long study period. Minute ventilation was adequate (mean of 6, 7 l/min) if it is based on mean weight on this group (mean of 72 kg). The leak via face mask (mean of 3, 2 l/min) showed that there were problems related to mask sealing. The overall good results compared to previous manikin study may be explained by different scenario (equipments ready, peaceful environment etc) and also because of good opportunities to visually monitor the efficacy of BVM by chest movement. On the other hand, there is no doubt that students were under pressure resulting from unfamiliar environment, external observers and a live patient.

The results from this study are somewhat different from a previously reported study from the Netherlands, with first-responders as care providers. Comparing first-responders ability to use either BVM or portable oxygen-driven manually triggered ventilators, it was shown that 50 % of anesthetized patients (n=105) could not be adequately ventilated with BVM. Also notable gastric distension occurred, which was not observed in present study (Noordergraaf et al. 2004). These differences can only be explained by different training.

Extrapolating these results to emergency airway management is not straightforward. The concern of emergency BVM is mainly related to aspiration of gastric contents. There is little evidence of the incidence of aspiration during cardiac arrest, but an autopsy study (n=232) of unsuccessful resuscitations after cardiac arrest revealed that almost third (29%) of the patients had actually signs of pulmonary aspiration and almost half (46 %) had full stomach (Lawes and Baskett 1987). Another study comparing the incidence of regurgitation (presence of gastric material in tracheal tree requiring suctioning), while using BVM and cLMA during in-hospital cardiac arrest (n=797), observed that regurgitation occurred in 12, 4 % of BVM managed patients (n=466) (Stone et al. 1998).

It seems that in an unprotected airway, stomach distension caused by BVM may result in aspiration, if BVM is prolonged and other measures are not taken to secure and protect the airway.

6.3 Laryngeal tube in airway management

6.3.1 Simulated manikin scenarios

When study participants were trained only with pictures and written information (Study V) first attempt success rate of 57 % was achieved. When additional two attempts were allowed, the success rate rose to 97 %. Firefighter-EMT students were trained within their curriculum of airway management to use LT (Study II) and a first attempt success rate of 100% was achieved. The time required for successful insertion from the scene arrival to first ventilation had a median of 64 seconds (Study II) and from the opening of the mouth to the first ventilation had a median of 31 seconds (Study V).

These findings are in agreement with other simulation studies with manikin when LT was used by inexperienced care providers. LT was inserted with 100% success rate by non-anaesthesia house officers in a median of 19 seconds, supposedly from the beginning of opening of the mouth to first ventilation (Dorges et al. 2001). A similar finding was observed with Fire Academy students inserting LT, with 100% first attempt success rate. Successful ventilation was noted in previous studies and in agreement of the present study (Asai et al. 2002a, Dorges et al. 2001).

In simulated scenarios, airway devices can be tested in a situations mimicking realistic ones with confusing factors present, such as prioritizing tasks when limited staff is available, defibrillation in cardiac arrest and preparing equipments ready. These all are present in a real prehospital situation. In addition, the element of pressure from the scenario is normally present as in real emergency. On the other hand, a manikin has no secretions in the airway, it does not vomit and it does not have pharyngeal reflexes. These are factors that manikin studies do not very well reflect, making the care provider's ability to use devices in real patients or during emergency airway management difficult to extrapolate to real life. In the case of LT, there is also the question that LT may "fit" well to the airway of some manikins. From studies evaluating LT, two (Study II, V) used Ambu Megacode Trainer® and in the other two different manikins (Asai et al. 2002a, Dorges et al. 2001).

Based on these and previous studies, it seems that inexperienced users can insert a LT with a good success rate in simulated scenarios with a manikin and this produces acceptable ventilation parameters.

6.3.2 Anesthetised patients

All firefighter-EMT students (Study III) and over two-thirds of paramedic-students (Study IV) successfully inserted LT to elective ASA 1-2 patients within reasonable time. Previously superior insertion rates and times have been reported when experienced anaesthesiologists have used LT, but comparing these success rates to those with prehospital care providers does not necessarily resemble the real performance of a device when used by prehospital care providers (Asai et al. 2000, Cook et al. 2003a). There are no previous studies of the performance of LT to anesthetized patients when used by inexperienced care providers such as EMTs.

Previously, two preliminary studies have reported the use of LT by prehospital care providers during cardiac arrest. In a small series of five patients to whom LT was inserted by paramedics, successful insertion and ventilation was achieved to all but one (Asai et al. 2003). In another study from Italy reported a 70 % first attempt success rate when performed by nurses in out-of-hospital cardiac arrest related to non-traumatic origin. Overall evaluation showed that both insertion and ventilation was successful in 86, 7 % of patients (Kette et al. 2005).

In the present study, inexperienced users could successfully insert LT to anesthetised patients. The variation of first attempt success rate may at least partly be explained by the fact that in study III a used multiple-use LT was used whereas in study IV a disposable single-use LT was used. There was a unacceptably high number (8) of cuff ruptures related to use of disposable laryngeal tube (LTD) which affected the result of successful insertion of LTD. This may be a cuff material problem and is described in a case report (Niemi-Murola et al. 2005).

In terms of minute ventilation and tidal volume, LT performed well enough, maintaining etCO_2 within normal range and normoxia in the present study. One advantage of LT has been presented to be the good sealing pressure related to large pharyngeal cuff. This pressure has been reported to vary from 24 to 26 cmH_2O. In the present study a mean tidal volume of 464 ml produced a mean peak airway pressure of 23, 5 mmHg± 9,7 (32 cmH_2O;). This resulted a mean minute volume leak of 2, 4 l which is in concordance of previously reported sealing pressures and air leakage (Asai et al. 2000, Asai et al. 2002b). Good sealing ensures sufficient ventilation and oxygenation during emergencies related especially to cardiac arrest. During chest compressions the airway pressures may raise and sealing become a restrictive variant for successful ventilation.

The question whether large pharyngeal cuff of LT can cause pressure related ischemic changes to the base of tongue has been debated. Based on manufacturers' recommendations the cuff inflation volume should be based on either height (fixed volume to different sizes of LT) or measuring inflation pressure and not exceeding 60 cmH_2O (Asai and Shingu 2005). In prehospital care this hardly is a problem. When prehospital ALS or hospital care is available the LT may be changed to ETI by more experienced care providers. The time frame to this is normally within reasonable limit minimizing the risk of permanent damage.

The sympathetic activation response ("pressor response") to the insertion of LT was found to be minimal in the present study (Study IV). No changes in blood pressure or heart rate were detected. This same conclusion has been previously reported (Genzwuerker et al. 2002b).

The learning curve of LT seems to be steeper than ETI. In the present study, the same students who were participating study II performed LT insertion and ventilation in study III. Before manikin based study I, firefighter-EMT students were trained to use LT within their normal airway curriculum. Only manikin training and lessons were used. The first attempt success rate of 100% was achieved. After a six-month period, these same students received only minimal retraining before study III in anesthetized patients. A first attempt success rate of 73 % and overall success rate of 100% was achieved. It seems that learning to use of LT is easy and skill maintenance is fairly good at least if this is compared to previously reported poor skill maintenance of ETI (Tiah et al. 2005).

6.4 Intubating laryngeal mask airway in anesthetised patients

The concept of LMA has been widely studied and approved in the use of anaesthesia and emergency airway management. Considering the role of LMA in airway management during inhospital or prehospital emergency the classical model of LMA is suggested by ERC (Nolan et al. 2005). After introducing the cLMA two major modifications were developed, namely intubating laryngeal mask airway (ILMA) and ProSeal laryngeal mask airway (PLMA). In the present study, ILMA was chosen for the following reasons.

Firstly, based on clinical judgement the cLMA is designed for anaesthesia purposes. Especially during prehospital emergency patients head is prone to movements, which may cause dislodgement of cLMA. This hypothesis is supported by the study from London comparing cLMA and ILMA in the hands of inexperienced users. Air leak was observed with cLMA with lower airway pressures than with ILMA possibly suggesting the suboptimal positioning of cLMA (Choyce et al. 2001). The ventilation tube of cLMA is made of silicone material and in the case of biting, it can be partially or totally obstructed. The insertion of cLMA may need guidance with the index finger and this may add some difficulty to the insertion, but especially if patients' reflexes exist. The use of index finger is recommended in insertion guidelines regarding both cLMA and PLMA by the manufacturer (Laryngeal Mask Company Limited 2005). Basically, PLMA has the same features as cLMA but also an additional tube for suctioning and nasogastric tube passage. Same problems as described in the use of cLMA during prehospital airway management can be encountered with PLMA. Secondly, ILMA can be easily inserted without need for additional manipulation in the mouth, and it has metal ventilation tube preventing biting. ILMA is designed to be inserted in neutral position enabling the insertion also in case of trauma and suspected cervical spine injury. ILMA was originally developed for the purposes of difficult airway during anaesthesia. The possibility of endotracheal tube (ETT) passage blindly via ILMA can be considered as an advantage during emergency airway management as well. If after correct positioning of ILMA ventilation is successful, ETT passage should be easy, but not possible in every case as previously showed in anesthetised patients; failure of blind intubation varied from 7 % (prehospital care providers) to 20 % (novices with short training) (Reeves et al. 2004). This suggests that the possibility of blind intubation via ILMA in the prehospital phase may not bring substantial benefit over ventilation without ETT, because failed attempts may cause further damage or swelling to the glottic area and jeopardize otherwise successful ventilation.

In the present study, 75 % of the paramedic students inserted ILMA successfully to anesthetized patients at first attempt and with an additional two attempts, success rate was 97 %. Ventilation after successful insertion was possible to all patients with no notable gastric distension (Study IV). These results are similar to previous findings when used by inexperienced care providers to anesthetized patients. Success rates varies from 100 % (Choyce et al. 2001, Reeves et al. 2004) to 81,5 %(Burgoyne and Cyna 2001). These differences can be explained with differences of overall experience in airway management and variations in training to use ILMA. In three previous studies of ILMA, times for successful insertion and ventilation varied from 62 s to 23 s as compared to 23 s in the present study (Burgoyne and Cyna 2001, Choyce et al. 2001, Reeves et al. 2004). The short times for successful ventilation may resemble the ease of insertion with no need for additional manoeuvres after introducing ILMA into the pharynx.

When paramedic students evaluated the subjective impression of the overall usefulness of devices, ILMA was graded as most useful. These findings are similar when subjectively comparing the usefulness of cLMA to ILMA. All 24 participants were confident to use ILMA in an emergency situation and 15 of them would choose it preferably compared to cLMA (Choyce et al. 2001).

The minimal sympathetic response from the insertion of ILMA has been considered as one possible advantageous feature. The insertion of cLMA has been found to be more haemodynamically stable in terms of blood pressure and heart rate raise (Brimacombe 1995). In present study (Study IV), we found that insertion of ILMA caused minimal or no changes to blood pressure and heart rate. On the other hand, previous studies regarding the pressure response to ILMA, have found no differences compared to ETI when the feature of blind intubation with ILMA has been used (Choyce et al. 2002). In a prehospital setting, it is possible that care providers are not able to premedicate patients prior to airway manoeuvres or medication is limited. In cases with some degree of pharyngeal reflexes left, a sympathetic response could be harmful especially to patients with underlying cardiovascular disease or elevated intracranial pressure.

6.5 Cobra perilaryngeal airway in anesthetised patients

In previous studies the successful insertion rate of CobraPLA has varied from 57, 1 % to 100% (Agro et al. 2003, Agro et al. 2004, Akca et al. 2004). The insertion has been found difficult in 22, 7 % of patients although successful ventilation was achieved (Agro et al. 2004). In the present study, we found the performance of CobraPLA unsuitable for airway management in the hands of paramedic students. The first attempt success rate was 22 % and after two additional attempts, it raised to 78 %. The mean time for successful insertion was 26 seconds (Study IV). The insertion time is comparable to previous studies but poor success rate can indicate that learning curve is longer and correct positioning needs further manipulation, which is difficult to teach to prehospital care providers. The major concern related to use of CobraPLA, was the fact that gastric insufflation was noted in 20 patients in the present study. This finding is in concordance with two reports describing pulmonary aspiration related to use of CobraPLA (Cook and Lowe 2005, Farrow and Cook 2004). Both of the reports describe cases of aspiration to be related in anaesthesia with normal fastening, in emergency cases the fact of full stomach may further enhance the possibility of aspirating gastric contents.

6.6 Protection of aspiration with pharyngeal airways

Aspiration of gastric contents has been major concern regarding the use of different pharyngeal airways during emergency airway management. The incidence of aspiration regarding different types of airway emergencies is poorly known. In cardiac arrest cases, the reports vary. In a study comparing cLMA and BVM, the overall incidence of regurgitation before airway management was attempted was 46, 7 % (Stone et al. 1998). During CPR, the ventilation performed with BVM followed by ETI resulted that 12,4 % of patients aspirated. If cLMA was used alone or followed with ETI the incidence of regurgitation dropped to 3, 5 % (Stone et al. 1998). Compressions given during cardiac arrest is likely to cause pressure changes also in the abdominal area and together with the relaxation of lower and upper oesophageal sphincters and the likelihood of aspiration is increased. In other emergencies where compressions are not required, aspiration may be a result of airway manoeuvres causing pharyngeal reflex stimulation and vomiting. This has well been demonstrated by previous retrospective study evaluating in-hospital intubations in critically ill patients. ETI was performed to 3035 patients and 60 cardiac arrests occurred during intubation procedure. Twenty-seven patients (45 %) aspirated during intubation procedure resulting concomitant hypoxemia and cardiac arrest. From 72 % of these patients, oesophageal intubation was recognized (Mort 2004). Although these patients were in hospital patients and intubations were performed by anaesthesia residents, it is not overestimated to extrapolate these findings to out-of-hospital patients. The second iatrogenic cause for aspiration is gastric distension due to stomach ventilation. In the present study, use of CobraPLA resulted in stomach distension in twenty patients (Study IV), whereas BVM and the LT did not (Study III). This is in contrast to a previous study reporting gastric distension in 29% of BVM ventilated, anesthetized patients when performed by inexperienced users (Noordergraaf et al. 2004).

ILMA and cLMA have similar tips, which are positioned to the upper oesophagus when correctly in place. The incidence of LMA associated aspiration was evaluated in a meta-analysis consisting both elective and emergency anaesthesia publications. The rate of aspiration was 2 per 10000 cases, which is comparable to the aspiration rate of ETI (Brimacombe and Berry 1995). PLMA has an opening in the tip of the device allowing nasogastric tube passage and suction. This feature is can be advantageous in cases of aspiration, but has not yet previously been studied.

LT has a large distal cuff, which may seal the upper oesophageal opening more tightly than cLMA or ILMA. There is one previous study evaluating also the gastric insufflation between LT and cLMA. During anaesthesia none of the patients had gastric insufflation when LT was used (n=21). In three cases when cLMA (n=22) was used gastric insufflation was noted. These findings are preliminary and whether this has relevance or is yet undetermined (Asai et al. 2002b).

6.7 Future implications

Common practice of prehospital ETI by paramedical care providers should be further evaluated also in Finland. Whether the success rates, complications and patient's outcome are in concordance with previous findings is yet unknown. Prehospital environment has many differences geographically compared to more dense urban areas in central Europe or United States so recommendations should be evaluated also locally, before adopting them in practice (Wang et al. 2004a)

Laryngeal tube and intubation laryngeal mask as pharyngeal airways seem to have attractive features for prehospital emergency use. Short learning curve for success of insertion and ventilation was noted in present study supported by previous findings (Asai et al. 2002a, Asai et al. 2003, Burgoyne and Cyna 2001, Choyce et al. 2001, Kette et al. 2005). Whether these devices can be recommended as first-line airway management devices for basic life support, must be further evaluated in prehospital emergency patients.

6.8 Study limitations

The main limitation of present study is that no real emergency patients were used to evaluate the performance of different pharyngeal airway devices. The controlled environment of airway management during anaesthesia limits the reliability of extrapolation of these results directly to pre-hospital care. Airway management to manikin differs that from human patients and performance of different devices does not necessarily resemble the situation in patients with real airway emergency. To facilitate airway management different medications may be needed in real situation. This study did not focus on that matter as basic care providers normally do not use medications for airway management. The challenge whether pharyngeal devices perform equally in real emergency patients remains as future implication that should be studied.

Another limitation was the retrospective design to evaluate the need and benefit of ALS care in HEMS unit. Selection of patients to evaluation, evaluation process and retrospective data collection may have affected to result. These results also may not be applicable to other, more urban areas with different case mix. Also these results do not necessarily apply to HEMS with physician involved.

7. SUMMARY AND CONCLUSIONS

Based on the present study the following conclusion can be drawn:

1. Airway management is important part of prehospital care to critically ill or traumatized patients treated in Eastern Finland rural areas. Although health benefits from ALS care seems to be small, the benefit from airway management is comparable to previous studies.
2. Present study finds LT to be a useful device. It can be used also by basic care providers. Short learning curve, success of insertion and ventilation in inexperienced hands, good skill maintenance and minimal harmful effects especially compared to ETI makes it attractive alternative to ETI. Whether it can replace totally ETI in basic level of care must be confirmed in studies with real emergency patients.
3. Present study supports the use of ILMA without blind intubation feature as an alternative supraglottic airway device in prehospital airway management. This is supported by the good insertion and ventilation success rate and also the positive subjective evaluation from paramedic students. The CobraPLA seems less suitable to be used in prehospital care. The poor insertion success rate and possibly harmful effects of gastric insufflation are factors to be considered and further evaluated.

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