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A Comparative Study Of The Use Of Two Indirect Intubating Devices - Intubating Laryngeal Mask Airway And Video Laryngoscope (Cmac) With Respect To Ease Of Intubation And Post Intubation Hemodynamic Changes.

Dr R.Archana, Dr. Pankaj Punetha, DNB (Anaes), Dr. Kolli S. Chalam MD, PDCC

Anesthesiology (Primary DNB), Sri Sathya Sai Institute of Higher Medical Sciences. EPIP Area, Bengaluru - 560066, Karnataka

Department of Anesthesiology, Sri Sathya Sai Institute of Higher Medical Sciences, Bengaluru – 560066, Karnataka

Professor and Head, Department of Anesthesiology, Sri Sathya Sai Institute of Higher Medical Sciences, Bengaluru – 560066, Karnataka

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I. INTRODUCTION

Laryngoscopy is the visualization of the larynx for purpose of examination of the glottis or endotracheal intubation. Laryngoscopy can be performed either directly – the glottis is visualized by using a laryngoscope or indirectly – the glottis is viewed indirectly using optical devices. Indirect laryngoscopy involves the visualisation of larynx without the alignment of all the three axes (oral, pharyngeal and laryngeal). These devices can be used in neutral position (without extending cervical spine and flexing the neck) and thus have an important role in airway management.[1]

Indirect intubating devices have developed to overcome the shortcomings of direct laryngoscopy in difficult and routine scenarios. The indirect intubating devices which are in current use are flexible fibre optic laryngooscopes, video laryngoscopes, intubating laryngeal mask airway and fibre optic stylets[2]

An ideal indirect device should have the following features: it should facilitate rapid tracheal intubation, allow intubation in the neutral position, cause no tissue damage, require less expertise and have a high rate of success in all situations [3].

Direct laryngoscopy has been used in emergency and operation theatre for routine intubations, but may have a failure rate of 1.5 to 8.5% of the population. This is despite experienced operators, adequate positioning and normal mouth-opening. Its use is limited in patients with an anterioriorly placed larynx, obese patients, maxillofacial trauma and those with pathology of the oropharynx. An indirect laryngoscope proves to be beneficial in these scenarios when direct laryngoscopy is difficult[3].

Fibreoptic laryngoscopy devices are used through the endotracheal tube to guide the passage of endotracheal tube under vision However, in certain circumstances the fibreoptic scope may fail to allow intubation due to displacement of endotracheal tube, fogging of the scope by secretions or blood. These limitations and the requirement of expertise, make fiberoptic less suitable for certain difficult airways and emergency situations. Its role in awake intubation and as a second line device in difficult direct laryngoscopy is documented[3].

In order to surpass the shortcomings of fiberoptics, the next generation indirect device, the video laryngoscope has been developed. This device collects electronically processed images from a camera attached at its tip. The images of the airway are observed on a monitor attached. The Videolaryngoscopy is has gained popularity because of its ease of use, need of less expertise for obtaining a clear view for intubation and minimum manipulation as compared to fiberoptics and direct laryngoscopy. These factors contribute to their better performance in routine and emergency scenarios[4-5]. It has also evolved as a teaching device for doctors and paramedics.

Another type of indirect laryngoscopic devices is the intubating laryngeal mask airway. It is a modified version of the classic laryngeal mask airway. It is designed as a ventilatory device and when combined with a modified tracheal tube acts as a conduit for blind tracheal intubation. There is

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evidence that the intubating laryngeal mask airway is an effective means of maintaining ventilation and oxygenation in the pre hospital, operating theatre, and emergency department environments. Studies show the successful first time intubations and minimal time of intubation are more for intubating laryngeal mask airway than fibre optic devices[6-8]

The aim of this study is to compare the two indirect laryngoscopic devices - video laryngoscope and intubating laryngeal mask airways in terms of ease of intubation and hemodynamic responses. This study will be the first of its kind in evaluating the pros and cons of two devices in terms of their effectiveness.

In order to achieve optimal results it is necessary to compare these two devices in routine patients without limiting it to a particular cohort of patients. The outcome of this study will yield objective evidence for grading the use of these devices in routine scenarios and gives us quantitative and qualitative data for the future.

II. OBJECTIVES

2.1 Primary objectives.

The primary objective of this study is to compare the use of intubating laryngeal mask airway and Video laryngoscopy with respect to the ease of intubation and hemodynamic changes seen during intubation of ASA I and ASA II patients.

2.2 Specific objectives

The specific objectives of the study are given below

-Number of attempts taken to intubate by an experienced laryngoscopist

-The time taken for intubation with the use of both the devices

-Requirement of additional manuveur if any

.Fall in Spo2 during the technique

-Variations in the blood pressures and heart rate immediately after intubation. (Recorded 1st 2nd, 3rd and 5th minute)

III. REVIEW OF LITERATURE

The vast majority of tracheal intubations involve the use of a viewing instrument of one type or another. Since its introduction by Kirstein in 1895, the conventional laryngoscope has been the most popular device used for this purpose. Further alternative devices like fibre optic scopes like Bullard laryngoscope and Upshard's laryngoscope have been developed to overcome the difficulties faced during difficult intubations**.** These devices further faced some pitfalls like fogging of lens during the procedure and trauma to the soft tissue. In order to overcome these limitations Dr. Jon Berall, a New York City internist and emergency medicine physician, designed the video laryngoscope in 1998. With digitalisation more advanced form of video laryngoscopes are now available.[9]

The laryngeal mask airway (LMA) is a supraglottic airway device developed by British Anaesthesiologist Dr. Archi Brain. It has been in use since 1988. Initially designed for use in the operating room as a method of elective ventilation, it is a good alternative to bag-valve-mask ventilation, freeing the hands of the provider with the benefit of less gastric distension. Used primarily in the operating room setting, the laryngeal mask airway has more recently come into use in the emergency setting as an important accessory device for management of the difficult airway. The laryngeal mask airway has further evolved as intubating laryngeal mask airway designed to serve as a conduit for intubation. The blind tracheal intubation with the intubating laryngeal airway in unanticipated difficult airway/emergency situations frequently fails despite of corrective manoeuvres and multiple attempts at intubation.

There are many studies performed to evaluate the success rate of the above mentioned devices .some of them that would give us a gross idea about the application of these devices are mentioned below:

Sakles et al performed a retrospective observational study using prospectively collected data including all patients intubated in a tertiary care university emergency department over a 24-month period, in which either direct laryngoscopy or video laryngoscopy (glidescope) was the initial device used. The authors found video laryngoscopy to have higher first-attempt success rate than direct laryngoscopy (75% versus 68%, p=0.03), and higher overall success rates in airways with two or more difficult airway predictors (70% versus 56%, p listed as 0.00). Failed direct laryngoscopy intubations were reportedly due mainly to inability to visualize the airway, while failed video laryngoscopy intubations were generally due to inability to direct the endotracheal tube into the visualized airway. Interestingly, direct laryngoscopy had a higher overall success rate in intubations requiring more than one attempt with the initial device (57% versus 38%, p=0.003)[10].

In an another meta analysis study with a total of 1061 participants comparing optical laryngoscope and direct laryngoscopy, the optical laryngoscope reduced the time significantly (airtraque) [mean difference -15s; CI-25 to -4 , P<0.00001]used by both experienced anaesthetists and novices and it increased the first attempt success rate only in novices (RR -1.25 CI1.05-1.49, P=0.07) to conclude it can be said from that optical laryngoscope facilitates a more rapid and accurate intubation by novices [11]

Literature shows comparison of Intubating laryngeal mask airway with other fibre optic devices and direct laryngoscopy, the results of these studies show intubating laryngeal mask airway as superior devices in un anticipated difficult airways as compared to direct laryngoscopy, however, considering intubating laryngeal mask airways with fibre optic devices, the fiberoptic devices are shown to have better scope in routine as well as in difficult airways.

A pressor response is encountered during laryngoscopy (direct / video assisted/ fibre optic) or while inserting any supraglottic device, this is due to stimulation of oro pharyngo larynx. This sympathetic reflex, though transient, can cause deleterious effects on pre-disposed and certain non-predisposed patients. Though the pressor response of direct laryngoscopy and intubating laryngeal mask airway have been studied, very few studies have been performed in studying the hemodynamic response, ease of intubation and complications comparing an intubating laryngeal mask airway and video laryngoscopy[12]

The difficult airway society recognises that blind intubation through the intubating laryngeal mask airway has a high success rate. However, the role of video laryngoscopes in difficult intubation scenarios and the cost effectiveness of their use in routine airway management are still under study.[13]

IV. ILMA CLINICAL TRIALS:

Use of intubating laryngeal mask airway as a rescue device and complications related to it such as the oro pharyngeal morbidity (lingual nerve /blood vessel compression caused by mal positioning of the shaft , pharyngeal trauma ,sore throat caused by increased cuff pressure) these could be well tackled by the experience of the operator , for this purpose this device should be used for routine scenarios ,so as to familiarise the anaesthesiologist in the insertion methods and preventable complications.[4]

In a prospective randomised cross over study conducted_by M S Avidan et al, comparing direct laryngoscopy and intubating laryngeal mask airway (ILMA), the participants succeeded 98 % intubation success via intubating laryngeal mask airway (89/91), while the intubation success rate of direct laryngoscopy was 84%(49/58).Mean insertion time of ILMAs was 19.6 seconds, with 78% of insertions achieved in 26s. It also concluded saying that ILMAs are suitable for emergency intubating devices but it cannot be used in non -trained professional in airway management[14]

Randomised controlled trial by Langeron O et al showed that in patients with difficult intubation physical status (Mallampati class III or IV, thyromental distance < 65 mm, inter incisor distance < 35 mm) .The rate of successful tracheal intubation with intubating laryngeal mask airway was 94% and comparable with fibreoptic intubation device (92%). The number of attempts and the time to succeed was not significantly different between groups and the adverse events occurred significantly more frequently in fibreoptic intubation group (due to desautration and bleeding) than in ILMA group (18 vs. 0%, P < 0.05).[15]

In a study conducted by Elif Bengi Sener et al showed that the intubation time was shorter in the conventional laryngoscopy group than in the intubating laryngeal mask airway group (16.33±10.8 vs. 43.04±19.8 s, respectively) (p<0.001). The systolic and diastolic blood pressures in the intubating laryngeal mask airway group were higher than those in the conventional laryngoscopy group at 1 and 2 min following intubation (p<0.05). The rate pressure product values (heart rate x systolic blood pressure) at 1 and 2 min following intubation in the intubating laryngeal mask airway group (15970.90±3750 and 13936.76±2729, respectively) were higher than those in the conventional laryngoscopy group (13237.61±3413 and 11937.52±3160, respectively)[16]

However another study report done by Kihara S et al concludes both the intubating laryngeal mask airway (Fastrach)and the optical stylet (Trachlight lightwand) attenuate the hemodynamic stress response to tracheal intubation compared with the Macintosh laryngoscope in hypertensive, but not in normotensive, anesthetized paralyzed patients.[17]

V. VIDEO LARYNGOSCOPY

During emergencies or resuscitation, prompt and successful management of difficult airways can improve outcomes and decrease

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mortality and morbidity. The advantages offered by this new device allow pre-hospital staff or inexperienced doctors to secure a definitive airway with less difficulty. This is perhaps a leap from the conventional Macintosh laryngoscope. A unique advantage of video laryngoscopy is to allow 'tele-intubation' in situations when specialist staffs are not available

Clinical trials of video laryngoscope are limited and their use in difficult airways / difficult visualisation is still under way. Some of the Meta analysis and randomised control trial of video laryngoscope are described below:

A study conducted by Frank Herbstre et al concluded that after a course, the students trained with the video laryngoscope had an intubation success rate on a manikin 19% higher (95% CI 1.1%–35.3%; P -0.001) and intubated 11 seconds faster (95% CI 4–18s) when compared with those trained using a conventional laryngoscope. The incidence of "difficult (manikin) laryngoscopy" was less frequent in the group trained with the video laryngoscope (8% vs. 34%; P _ 0.005)[18]

A study conducted by Aziz MF et al adds to the growing body of evidence that video laryngoscopy(C-MAC) has a role in routine and difficult airway management. The use of video laryngoscopy resulted in more successful intubations on first attempt (138/149; 93%) as compared with direct laryngoscopy (124/147; 84%), P = 0.026. Cormack-Lehane laryngeal view was graded I or II in 139/149 of C-MAC attempts versus 119/147 in direct laryngoscopy attempts (P < 0.01). Laryngoscopy time averaged 46 s (95% CI, 40-51) for the C-MAC group and was shorter in the direct laryngoscopy group, 33 s (95% CI, 29-36), P < 0.001. The use of a gum-elastic bougie and/or external laryngeal manipulation were required less often in the C-MAC intubations (24%, 33/138) compared with direct laryngoscopy (37%, 46/124, P = 0.020). The incidence of complications was not significantly different between the C-MAC (20%, 27/138) versus direct laryngoscopy (13%, 16/124, P = 0.146)[19].

Another retrospective study by Aziz MF et al demonstrating the role of video laryngoscope (glidoscope) in airway management showed that Overall success for Glidescope intubation was 97 %(1,944 of 2,004). As a primary technique, success was 98%(1,712 of 1,755), whereas success in patients with predictors of difficult direct laryngoscopy was 96% (1,377 of 1,428).Success for Glidescope intubation after failed direct laryngoscopy was 94% (224 of 239). Complications were noticed in1% (21 of 2,004) of patients and mostly involved minor soft tissue injuries, but major complications, such as dental, pharyngeal, tracheal, or laryngeal injury, occurred in 0.3% (6 of2,004) of patients. The strongest predictor of Glidescope failure was altered neck anatomy with presence of a surgical Scar, radiation changes, or mass.[20]

A meta analysis was done by David W Healy et al regarding the efficacy of modern video laryngoscopes (glidescope, pentax AWS, storez C MAC) in oral endotracheal intubation. The study concluded that the evidence of efsficacy for video laryngoscopy in the difficult airway is limited. What evidence exists is both randomized prospective and observational in nature, requiring a scheme that evaluates both forms and allows recommendations to be made[21].

A meta analysis by Su YC et al. on the comparison of video laryngoscopes with direct laryngoscopy for tracheal intubation showed that during tracheal intubation, video laryngoscopes can achieve a better view of the glottis and have a similar success rate [rate ratio 1.0; 95% confidence interval (CI) 0.99-1.01]. Overall, the time to tracheal intubation was not different between the video laryngoscopes and direct laryngoscopy (standardised mean difference 0.19; 95% CI -0.37-0.75). However, in a subgroup analysis, video laryngoscopes shortened the time taken for difficult intubation (standardised mean difference, -0.75; 95% CI -1.24 to -0.25).so it was concluded that Video laryngoscopes are a good alternative to direct laryngoscopy during tracheal intubation. The advantage seems to be more prominent when difficult intubation is encountered.[22]

There are limited reports available for the use of video laryngoscopy and intubating laryngeal mask airway in regular operation theatre set up. The advantages and disadvantages of one device over the other have yet to be established. This will help to evolve a better, more affordable and feasible device for optimal intubations. This study will give us an idea on the use of the two devices in regular setup and will establish certain standards on their indications and contraindications which will eventually add on to the existing literature of videolaryngocopy and intubating laryngeal mask airway.

VI. MATERIALS AND METHODS

6.1. Study area

The study will be conducted in the Department of Anesthesiology at Sri Sathya Sai Institute of Higher Medical Sciences, EPIP Area, Whitefield, Bengaluru.

6.2. Study population

Patients undergoing elective surgery under general anesthesia with endotracheal intubation

6.3. Study design

Prospective observational clinical study

6.4.Method of collection of data

6.4.1 Sampling Size and Technique –

100 consecutive patients undergoing elective surgical procedures under general anesthesia with endotracheal intubation will be subjects of the study.

6.4.2 Selection of patients

Criteria for Inclusion

All patients above the age of 18 years of ASA grade I and II scheduled for elective surgery under general anaesthesia with endotracheal intubation

Criteria for Exclusion

- Patients undergoing emergency surgery
- Patients with facial trauma
- Those indicated for rapid sequence induction
- Patients scheduled for fiber optic tracheal intubation (unstable cervical spine, previous impossible intubation, tumors' of the oro pharyngeal region, burn contractures of neck)
- Patients with airway control other than endotracheal tube
- Patients with gross oral cavity obstructive lesion / gross dental mal occlusion
- Patient with syndromic morphology
- Patient with BMI 35kg/m^2 and pregnant patients

6.5. Data collection technique

Patients will be assessed preoperatively for the physical status. After induction and adequate muscle relaxation, video laryngoscopy and intubating laryngeal mask airway will be used in randomized selected patients using slot technique. The time taken for intubation, number of attempts and hemodynamic response like heart rate Systolic blood pressure, diastolic blood pressure, mean arterial pressure, and post intubation will be studied.

6.6. Method of Study

- After obtaining permission from the ethical committee and written informed consent of the patients, they will be subjected to a physical assessment of the airway. In the operation theatre patient's blood pressure, heart rate, ECG will be recorded. Patient will also be connected to pulse oximeter to measure SpO2 before induction.
- Premedication using Inj. Glycopyrrolate 0.01mgkg^{-1} will be administered intramuscularly 45 minutes prior to induction of anesthesia.
- Inj Lidocaine 1.5-2mg /kg^{-1} will be given to attenuate the pressor response.
- Anesthesia will be induced with Inj. Thiopentone 5mgkg^{-1}, Inj. Fentanyl 2μgkg^{-1}. Inj. Rocuronium 0.6mgkg^{-1} is the muscle relaxant used for intubation.
- Patients will be maintained on bag and mask ventilation with O_2:N_2O, 50:50 and with Isoflurane, after adequate depth of induction patients will be intubated using intubating laryngeal mask airway or Video laryngoscope alloted by computerized randomization technique.
- Intubation time , number of attempts to intubate ,additional maneuvers required for intubation are recorded along with hemodynamic responses post intubation like systolic blood pressure , diastolic blood pressure , heart rate, mean arterial pressure will be recorded at 1st , 2nd 3rd and 5th minute
- SpO2 changes during intubation and immediately after intubation are recorded

VII. DATA ANALYSIS PLAN

Statistical methods like Chi square test, Fisher test, Student t-test, Anova or any other relevant statistical method will be utilized to compare and validate the study.

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STUDY PROFORMA

SRI SATHYA SAI INSTITUTE OF HIGHER MEDICAL SCIENCES
DEPARTMENT OF ANAESTHESIOLOGY

Case No: Date:
Name: IP Number:
Age: Gender:
Height: Weight: BMI:

Address:

Diagnosis:
Procedure:

Pre-Anesthetic Evaluation

History:

History of Obstructive Sleep Apnea: Yes / No

History of previous Anesthetic exposure: GA / Regional
If GA, any history of difficult intubation

History of co-morbidities, duration and treatment details
Diabetes Mellitus:
Hypertension:
Rheumatoid Arthritis:
Ankylosing Spondylitis:
Others:

Drug History:
History of drug allergies: Yes / No

General Physical Examination

Pulse Rate: Blood Pressure:

Respiratory Rate: Temperature:

Systemic Examination

Cardiovascular System:

Respiratory System:

Central Nervous System:

Per Abdomen:

ASA Grade :

Airway assessment

Physical evaluation

I. External Appearance:

II. Neck Movements: Normal / Restricted

III. Assessment of Tempero-Mandibular Joint (TMJ) function

1. Mouth opening / Interincisor gap: < 3 cm > 3 cm

2. Protrusion of the mandible Class:

Class A	The lower incisors can be protruded anterior to the upper incisors
Class B	The lower incisors can be brought edge to edge with the upper incisors
Class C	The lower incisors cannot be brought edge to edge

IV. Oral Cavity

Dentition :

Modified Mallampatti Classification Class :

Class 0	Tip of the epiglottis visible
Class I	Faucial pillars, uvula, soft and hard palate visible
Class II	Uvula, soft and hard palate visible
Class III	Soft palate and base of uvula visible
Class IV	Only hard palate visible

V. Assessment of Mandibular Space

1. Thyromental distance (Patil's test)

>6.5 cm 6-6.5 cm <6 cm

2.Sternomental distance

> 12.5 cm < 12.5 cm

Anaesthetic Management

Premedication: Inj. Glycopyrrolate 0.01mgkg^{-1}, IM, 45 minutes before surgery

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Inj. lignocaine 1.5-2mg/kg$^{-1,}$IV,3 minutes prior to induction

Induction of Anaesthesia:

Inj. Fentanyl	Inj. Thiopentone	Inj. Rocuronium
2µgkg^{-1} IV	5mgkg^{-1} IV	0.6mgkg^{-1} IV

Bag and mask ventilation: Easy 2 Hands Assistant required

After adequate induction of the selected patients and the patients are intubated using Intubating laryngeal mask airways or video laryngoscopy based on computerised randomisation technique. And the parameters are evaluated.

Parameters for assessment

Type of Intubating Device Used**:** Video Laryngoscopy[A] or Intubating Laryngeal Mask Airway[B] (A/B)

1	Time taken to intubate				
2	Number of attempts at intubation:				
3	Lowest recorded SpO2: during or immediately after intubation attempts				
4	Need of additional manoeuvres (if required):				
5	Hemodynamic responses post intubation				
	Parameters	@1minute	@2minutes	@3minutes	@5minutes
	SBP				
	DBP				
	MAP				
	HR				

SBP-SYSTOLIC BLOOD PRESSURE
DBP-DIASTOLIC BLOOD PRESSURE
MAP-MEAN ARTERIAL PRESUURE
HR HEART RATE

APPROVAL OF ETHICAL COMMITTEE AND ITS COMPOSITION:
APPROVAL OF SCIENTIFIC COMMITTEE & ITS COMPOSITION:
(Signature of the Candidate)
(Signature of the Guide)
(Signature of the Head of Department)
(Signature of the Head of Institution)