ORIGINAL RESEARCH PAPER

Anesthesiology

PROSEAL™ LMA -A CLINICAL EVALUATION AND COMPARISON OF THREE TECHNIQUES OF INSERTION USING INTRODUCER, INDEX FINGER AND THUMB.

KEY WORDS: Proseal LMA ,Insertion technique,Success rate.

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ABSTRACT

Introduction: PLMA provides a more effective seal at larynx and allows insertion upto 16 Fr size nasogastric tube. It has higher orophayrngeal pressure and oesophageal leak pressure than classic LMA. It can be inserted by various techniques with the the introducer technique being the most commonly used . In our study we compared the insertion of PLMA via thumb guided , index finger guided and introducer method .

Material and Methods: The study was conducted at our hospital on 90 patients of ASA grade I and grade II, of either sex between age of 18-55 years scheduled for laparoscopic cholecystectomy. In the present study we compared three techniques of insertion of PLMA- using introducer, index finger, and thumb in terms of number of attempts required for successful placement, ease of insertion, time needed for insertion and feasibility of NG tube insertion.

Results: The first attempt success rate was 90% (27/30), 80% (24/30) and 66.67%(20/30) in introducer, index finger and thumb group respectively. The time taken in insertion was 22.10±5.01seconds in introducer group, 31.66 ± 8.22 second with index finger and 48.6 ± 9.96 seconds in thumb guided technique (p value <0.02).

Conclusion : The thumb guided insertion of PLMA was found to be inferior as compared to introducer and index finger guided technique in terms of first attempt success rate and time taken to insert.PLMA though provides good airway management for laparoscopic cholecystectomy and the morbidity is trival ,hence acceptable for clinical use.

INTRODUCTION

Endotracheal intubation forms a gold standard for securing airway but in even trained hands, it results in stress response to laryngoscopic manipulation.

Dr. Brain developed a supraglottic device LMA (laryngeal mask airway) which forms a seal around larynx and permits both spontaneous and positive pressure ventilation. Although LMA excels as a useful device for ventilation in routine and difficult airway, its use has been contraindicated in those with history of GE reflux, symptomatic hiatus hernia, peptic ulceration,. To overcome the short comings and minimize the risk of aspiration, Dr. Archie Brain developed a new LMA incorporating a drainage tube PLMADT, and named it proseal LMA(PLMA)[1]

Various studies have proven better efficacy of Proseal LMA over Classic LMA [2-4]

ProsealLMA provides a more effective seal at larynx and allows insertion upto 16 Fr size nasogastric tube. It has higher orophayrngeal seal pressure and oesophageal leak pressure than classic LMA.

Proseal LMA can be inserted by using index finger or introducer (clip-on, clip off) device provided by the manufacturer to facilitate insertion. Most of the studies follow the same index finger or introducer technique and newer studies incorporate guided techniques using Gum elastic bougie or suction catheter, or fiberoscope for correct placement[5-8]. The other technique clinically recommended by manufacturers using thumb for insertion of Proseal has been clinically evaluated in our study.

We compared three techniques of insertion of PLMA - using introducer, index finger, and thumb in terms of number of attempts required for successful placement, ease of insertion, time needed for insertion and feasibility of NG tube insertion.

MATERIALS AND METHOD

Anaesthetic Procedure

On arrival in the operation room patients were laid supine with head in sniffing position on a 7 cm size of pillow. IV access taken and monitors were attached,baseline parameters were recorded (HR, SPO2, NIBP). Appropriate size of proseal along with KY jelly, introducer & Nasogastric tube were kept on anesthesia machine. The proseal size selection was mode on basis of weight and inflation of cuff was done as recommended by manufacture.

-Mask Size 3	Wt. 30 – 50 kg.	Cuff Inflation 20 ml.
-Mask Size 4	Wt. 50 – 70 kg.	Cuff Infation 30 ml.

NG tube of 16 F was inserted in all cases.

Patients was premedicated with – glycopyrrolate 0.04 mg./kg. midazolam 0.2 mg/kg. tramadol 2mg/kg. ondensertron -0.1 mg /kg. intravenously. Patients were oxygenated 100% O2 and induction of anesthesia was done with thiopentone 5mg/kg. i.v. slowly. Ventilation with mask was assessed and then succinylcholine 1.5mg/kg. was administered. After the onset of muscle relaxation and IPPV, mouth was opened with non dominant hand and prepared Proseal of appropriate size was introduced carefully with right hand in single swift movement. The introduction of PLMA using one of three techniques, selected randomly.

Group – I n=30-PLMA insertion using the introducer supplied by manufacturer in the kit.

Group – II n=30 -PLMA insertion with index figure in a manner recommended for standard laryngeal mask airway insertion.

Group – III n=30-PLMA insertion with thumb instead of index finger.

Pre-insertion preparation consisted of complete deflation of cuff of the mask, placing the introducer tip into strap at the junction of cuff and two tubes folded around introducer, proximal end of airway tube was made in matching slot, applying KY jelly on the post surface in group -1. In the other two techniques i.e. group -II with the index finger and group – III with the thumb ,PLMA was pre-prepared in similar way except the introducer is not placed in PLMA.

Techniques of insertion

In Group I (n=30), PLMA insertion by introducer:-

After induction of anesthesia and on achievement of muscle

relaxation, the head was extended and neck was flexed, mouth was opened using non dominant hand and prepared proseal was inserted by flattening the mask tip against the hard palate, the introducer blade was kept close to the chin and PLMA was rotated inward in one smooth circular movement following the curve of the introducer. The PLMA was advanced into hypopharynx until a definite resistance was felt. The PLMA tube was held with the non-dominant hand to stabilize the tube, and the introducer was removed. The placement was such that the tip of PLMA was firmly pressed against upper esophageal sphincter. The cuff was inflated to obtain the seal.

In group – II (n=30) PLMA insertion by index finger:-
After the head of the patient being extended and neck flexed, The PLMA was held like a pen in the dominant hand and mouth was opened with non dominant hand. The index finger was placed at the junction of cuff and two tube such that the finger tip is pushed into the introducer strap. The cuff tip was inserted, pressed again at the hard palate and flattened against it. Using the index finger as guide the PLMA was pressed backward toward the other hand. It was advanced into the hypopharynx till a definitive resistance is felt. Holding the airway tube with other hand the index finger was removed. The cuff was inflated.

In group -III (n=30) insertion by means of thumb:-
The prepared PLMA was held with the thumb in the strap. The insertion was carried out in the similar manner as that of index finger. However the thumb was used to extend the head just prior to complete insertion. The fingers was extended over the head so that the thumb was pressed further inwards. Holding the upper end of airway tube, the thumb was removed.

The cuff was inflated (according to proseal size as recommended by manufacturer in all the three techniques). The mask was fixed and connected with the anesthesia machine. Ventilation was started manually with 100% oxygen through bain circuit ,nasogastric tube of 16F was inserted through the drain tube. The patients were than maintained on O_2 : N_2 50% :50%, halothane 0.5%. The muscle relaxation was acquired by vecuronium bromide.

Proper placement of the proseal was judged clinically by :- absence of oropharyngeal air leak (detected by listening over the mouth), absence of gastric air leak (detected by listening with a stethoscope over the epigastrium), absence of drain tube drain tube air leak (detected by placing lubricant over the proximal end of the drain tube). A well – lubricated gastric tube of appropriate size was then inserted through the drain ,if there was no air leak up the drain tube. Correct gastric tube placement was assessed by suction of fluid or detection of injection air by epigastric stethoscopy.

More then three attempts were considered as failure.
A record was maintained for ease of insertion as easy, difficult or failure for each attempt in the performa. The time taken for insertion of proseal was the time from picking up the proseal from anesthesia machine, opening the mouth completing and inserting the proseal and inflating the cuff was recorded.

The adequacy of ventilation was accessed as good – clean airway without complication ,fair- clean airway with complication i.e. airway requiring intraoperative manipulation or failed. Then after assessment of proper ventilation, a lubricated 14F NG tube was passed down the drainage tube nothing the ease of insertion. If any difficulty was encountered, the reason for it was noted . the time taken for NG tube insertion was recorded as 10 -20 sec, 20-40 sec, 40-60 sec. The total duration of PLMA placement was recorded as 25-32 sec, 32-38 sec, 38-44 sec. All the observation were recorded in a specially prepared performa.

Through out the procedure anesthesia was maintained using standard technique of O_2 :N_2O (50-50) halothane 0.3-0.5% and vecuronium bromide 0.08 mg per kg on controlled ventilation as loading dose then maintainance dose of 0.02mg per kg.

At the end of surgical procedure the neuromuscular blockage was reversed by injection neostigmine and injection glycoprolate. On complete reversal of the reflexes, adequate muscle power and respiration PLMA was removed. Patient was oxygenated by mask and bain circuit on 100% oxygen for 3-5 miniutes.

Patients were observed and examined postoperatively immediately after the procedure, in the recovery room, and 8 hours later for sore throat, altered taste in mouth, difficulty in phonation, dysphonia, pain in throat, croup, trauma etc.

The data were tabulated and analyzed using **Analyze _It** statistical software. The quantities data were analyzed Analysis of variance (ANOVA) and students test. Quantitative data were analyzed using Chi- squre test and Fisher's test.

OBSERVATIONS & RESULTS

Demographic Profile, Airway Assessment Data Table 1

	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	P value
Age (Years)	32.87±8.028	38.433±10.63	38.06±11.52	0.0655
Sex (M:F)(n)	7:23	8:22	10:20	0.67
Weight (kg)	46.87±8.03	49.2±6.69	48.93±8.2	0.439
Height (cm)	152.96±5.30	153.7±6.18	154.37±5.77	NS
ASA (I:II) (n)	28:2	29:1	28:2	0.80

Values are given as Mean ± SD where appropriate

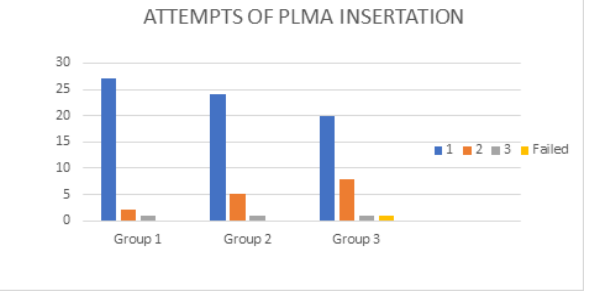

Figure-1

Comparison of PLMA Insertion techniques Table - 2

	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	P value
Attempts taken for PLMA insertion (1:2:3:4) (n)	27:2:1	24:5:1	20:8:1 Failed	
No. of cases req. alternate technique (n)	0	0	1	
Successful PLMA placement in 1st attempts	27	24	20	<0.02
Successful PLMA placement in 2 attempts	29	29	28	NS
Successful PLMA placement in 3 attempts	28	25	19	NS
Ventilation (Good/Fair)	2	5	10	<0.05
Total insertion time (sec.)	22.16±5.01	31.66±8.22	48.8±9.96	<0.02
Trauma (n)	3	5	7	NS
Sore Throat	2	5	8 (1 Failed)	

Values are given as Mean ± SD where appropriate

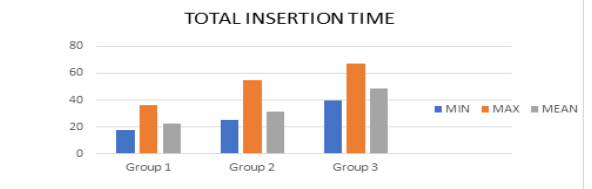

Figure- 2

Successful NG insertion in first Attempt
Table – 3

	N	Successful NG insertion	Failed	P value
Group 1	30	30 (100%)	0	<0.05
Group 2	30	27 (90%)	3 (10%)	
Group 3	30	25 (83.33%)	5 (13.88%)	

Successful NG tube insertion in first attempt is 100%, 90%, 83.33% in group 1, 2, and 3 respectively.

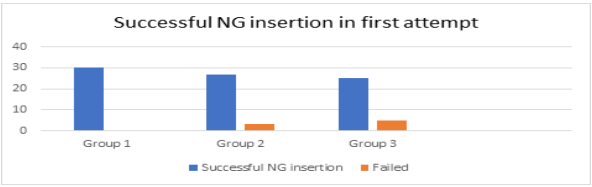

Figure -3

Results

1. We could successfully insert and use Proseal LMA for airway management in 96.66% (89/90) patients undergoing laparoscopic cholecystectomy.
2. Our first attempt success rate was 90% (27/30), 80% (24/30) and 66.67%(20/30) in introducer, index finger and thumb group respectively. The overall first attempt success rate using introducer or index finger being 85%, is comparable with the literature. However no data exist for comparison for insertion using thumb.
3. The time taken in insertion with introducer was (22.16± 5.01 seconds),(31.66 ± 8.22 second) with index finger. Thumb insertion took significantly longer time (48.6 ± 9.96 seconds).
4. Ventilation was satisfactory in all patients
5. On successful insertion of mask, a NG tube can be easily passed through the drain tube in majority of patients for gastric decompression.
6. Use of Proseal LMA for anesthesia for laparoscopic cholecystectomy does not result in significant gastric distension interfering with surgery.
7. Proseal LMA insertion is not associated with significant trauma to soft tissues or laryngopharyngeal morbidity.

DISSCUSSION

The study was conducted at our hospital on 90 patients of ASA grade I and grade II, of either sex between age of 18-55 years scheduled for laparoscopic cholecystectomy.

We aimed to evaluate the three techniques of insertion of Proseal LMA as recommended by the manufacturers using the introducer tool, index finger or thumb.

Brimacombe and Kellar used PLMA with and without introducer and found that the insertion is difficult without an introducer. All the initial studies on Proseal LMA have been done using either the introducer tool or index finger or both till Hawoth et al introduced use of gum elastic bougie for facilitating PLMA insertion which is essentially a guided technique.

Brimacombe and Kellar used and compared the GEB with introducer tool technique in cases of failed digital insertion and found bougie to be superior. Brimacombe et al compared digital, introducer and GEB and recorded higher first attempts sucesss with GEB guided insertion technique. [9-10]

There is not much mention on clinical use of thumb for PLMA insertion (as used in our study) in the literature through manufacturer have recommended it as one of the methods of Proseal insertion (LMA website)[11]

In a recent study three insertion techniques- digital, rotational or pharyngoscopic techniques of insertion of PLMA have been compared and pharyngoscopic technique of insertion was found to be more successful with lower incidence of complications.[12]

We did not use any guide like GEB to increase the success rate because our study was primarily aimed towards ascertaining the clinical effectiveness of three technique initially recommended by the manufacturer.

We used only clinical criteria of adequate ventilation as expansion of the chest with minimal leakage after cuff insufflations , nondistention of epigastrium ,and successful placement of NG tube as the test for successful placement. We did not do fibropitic evaluation of placement of PLMA insertion as reported by Brimacombe and Keller and later by other studies. [13-16]

We found that the first attempt success rate was 90%((27/30) in introducer group, 80%(24/30) in index finger group and 66.67% (20/30)in thumb guided group the difference being statistically significant. Though the first attempt success rate with the digital technique were similar to previous studies.

The success rate increased in second attempt and resulted in100% success in introducer and finger group while it was 96.665 with thumb group. Hence insertion of PLMA with thumb has proven to be a inferior technique as compared to index finger or introducer for 1st attempt success in our study. PLMA being made of soft silicon rubber is more liable to be improperly placed around the glottis with the thumb. The thumb being shorter it was difficult to guide the PLMA to the glottis properly and it resulted in folding of the cuff. It was easier to guide PLMA over the palate to the hypopharynx due to length of finger. The results were comparable to other studies. The success rate of introducer was similar to index finger in our study.

We defined time of insertion as time taken from picking up of PLMA for insertion till time at which the positive pressure ventilation was started.

In our study the mean time taken for insertion was 22.16+-5.01sec. in introducer group, 31.66+-8.22 sec in index finger group and 48.8+-9.96 sec in thumb group respectively. The difference being statistically significant did not result in any clinical problem or arterial desaturation as observed using pulse oximetry. We have recorded a first time success rate and overall insertion success rate similar to several studies available in literature and have relied only on clinical judgement of the malposition of the PLMA. If the ventilation has not being found to be satisfactory, we have resorted to reinsertion (Maximum three chance of insertion). We have not resorted to several maneuvers used by various investigators namely, reinsertion using a lateral approach with a cuff entering the side of hard plate because of the study designed used by us. However a lateral approach was necessary in few of our cases in thumb insertion group.

We have also not used other technique like reinsertion with a drainage tube stiffened by priming it into the distal end with a GEB or stylet or GEB guided reinsertion. We however resorted to digital correction by sweeping the finger beind the cuff whenever necessary.

Brimacombe at el (2002)[17] conducted a multicentric study comparing PLMA with CLMA and reported an insertion time of 22 ±18 (5-120) seconds and 38±56 (9-420) seconds respectively.

We were able to successfully introduce 14F orogastric tube in the first attempt in 100% of our patients (30/30) in introducer group. The first attempt success of NG- tube insertion through DT was 90% (27/30) and 83.33% (25/30) in index finger or thumb insertion technique respectively. The results are predictably better with introducer, ensuring least downfolding of the bowl tip, which may otherwise result in difficulties with NG tube placement.

Conclusion

PLMA provides goods conditions for airway management and anesthesia during laparoscopic cholecystectomy. The introducer tool insertion and index finger insertion technique are equally effective and successful.

Proseal insertion with the thumb as a sole guide is inferior to the introducer or index finger and hence not recommended as the technique for Proseal LMA insertion. Further, the morbidity following use of Proseal is trivial and acceptable for clinical use.

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