Comparison between two supraglottic airway devices (The Laryngeal Mask Airway- Supreme™ (LMA-S™) versus The i-gel™) and two modes of mechanical ventilation (volume controlled ventilation versus pressure controlled ventilation-volume guaranteed) during laparoscopic gynaecological procedures

**Thesis**

Submitted for fulfillment of the MD Degree IN ANESTHESIA AND intensive care

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Introduction

For decades, endotracheal intubation or bag-and-mask ventilation were the mainstays of airway management. However, in 1983 the first supraglottic airway device (SAD), the laryngeal mask airway (LMA™) (Intavent Orthofix, Maidenhead, UK) changed this view. LMA™ combines features of the facemask with those of the endotracheal tube (ET), offering the ease of placement, hands-free maintenance and a relatively secure airway (Brain, 1983).

Several studies have reported the successful, safe use of the Laryngeal Mask Airway (LMA)-Classic devices in patients who are undergoing laparoscopic surgery (Galvin et al., 2007).

The change in the degree of gastric distension with positive pressure during peritoneal insufflation was similar with using either a LMA or an endotracheal tube, and that the ventilator parameters (pulse oxygen saturation, end tidal CO₂ tension and airway pressure) were acceptable using either a LMA or an endotracheal tube (Maltby et al., 2000).

The incidence of regurgitation during laparoscopic cases with a LMA was extremely low (Bapat et al., 1997).

The Laryngeal Mask Airway-Supreme™ (LMA-S™) is a disposable airway device with curved shaft to ease insertion, a gastric access tube to separate the respiratory and gastric tract to minimize the risk of aspiration and high oropharyngeal leak pressure (0LP) (Ferson et al., 2007, van Zundert et al., 2008).
Introduction

It is constructed of medical grade silicone, and has an inflatable cuff, a reinforced tip, and an elliptical, anatomically shaped, semi-rigid airway tube (Teoh et al., 2010).

The i-gel™ (Intersurgical, W0kingham, UK) has been introduced as a novel supraglottic airway (SAD) device since 2007. Its tip is composed of a soft, gel-like, transparent non-inflatable cuff made of thermoplastic elastomer. It has a widened, flattened stem with a rigid bite-block and an esophageal vent through which a gastric tube can be passed. It was intended to preclude the need for cuff inflation and buccal stabilization to reduce axial rotation and malposition. Many reports found that i-gel™ provides a good seal and effective ventilation during pressure-controlled ventilation (K.Hayashi et al., 2013, Richezet et al., 2008, Gatward et al., 2008, Bamgbade et al., 2008), protects against aspiration (Gibbis0n et al., 2008, Liew et al., 2008) and can be used as a conduit for tracheal intubation and rescue airway management (Uppal et al., 2009-I, Campbell et al., 2009, Joshi et al., 2008).

Conventional mechanical ventilations, volume-controlled (VC) or pressure-controlled, are still the principal modes of ventilation used in all age groups (Kucm0rek et al., 1996).

VC ventilation has the advantage of delivering a set tidal (Vt), whatever peak inspiratory pressure (PIP) is required to deliver it, whereas in pressure-controlled ventilation delivered tidal volume varies with the compliance and resistance of thorax and lungs but the set peak pressure is not exceeded (Ap0st0lac0se et al. , 1996).

In an attempt to make ventilation more patient friendly and gentler pressure-controlled ventilation-volume guaranteed (PCV-VG),
Introduction

ventilation was developed which has the distinct theoretical advantages of both VC and pressure-controlled ventilation (Apstolacose et al., 1996)

However, in pressure-controlled ventilation-volume guaranteed (PCV-VG), the Vt and the rate are predetermined and the ventilator delivers the Vt using also a decelerating flow but a constant pressure. The ventilator adjusts the inspiratory pressure needed to deliver the Vt breath-by-breath so that the lowest pressure is used. PCV-VG begins by first delivering a volume breath at the set Vt. The patient’s compliance is determined from this volume breath and the inspiratory pressure level is then established for the next breath. Hence, PCV-VG combines the benefits of decelerating flow of PCV with the safety of a volume guarantee at a lowest possible titrated inspiratory pressure (Keszler et al., 2006)
Aim Of the Work

The aim of this study is to compare how volume controlled ventilation (VCV) and pressure-controlled ventilation-volume guaranteed (PCV-VG) modes using two different supraglottic devices (The Laryngeal Mask Airway - Supreme™ (LMA-S™) versus The i-gel™) affect the lung mechanics, the respiratory parameters and the hemodynamic parameters during gynecological laparoscopic procedures.
Supraglottic airway devices

In 1981, Dr. Archie Brain (UK) developed an ingenious milestone for airway management; the classical laryngeal mask airway (cLMA). His idea was to reduce the size of the face mask so that it could be positioned over the laryngeal opening directly. He created a boat-shaped inflatable rubber cuff and attached it to a tracheal tube (Figure 8). The first prototype was inserted under deep halothane anaesthesia and a satisfactory airway was immediately obtained and inflating the lungs with gentle positive pressure was possible. Following prolonged research, the cLMA was released in 1988. Its use had spread rapidly and it gained a firm place in the anaesthetic practice (Jain RA, et al 2018).

Many modified types of the classical LMA were developed later, these include: flexible LMA in 1991, intubating LMA in 1997, disposable LMA in 1998, pro seal LMA in 2000, LMA CTrach in 2005 and most recently, the laryngeal mask airway supreme (Asai T, et al 2005).

A new airway device, similar to LMA family but without an inflatable cuff was introduced in 2006; the I-gel airway. The main feature of this device is perfect anatomical fit of its cuff to the pharyngeal and laryngeal framework (Levitan R, et al 2005).
Introduction

Many other supraglottic devices were also developed, they include: the oesophageal tracheal combitube in 1987, laryngeal tube airway in 1999, pharyngeal airway express in 2002, streamlined pharynx airway linear (SLIPA) in 2002 and the C0pra pharyngeal lumen airway in 2003 (Prabhat K, et al 2005).

Classification and description of supraglottic airway devices

Supraglottic airway devices are devices that ventilate patients above the level of the vocal cords and provide a perilaryngeal seal. They are designed to overcome the disadvantages of endotracheal intubation (HendersOn J, et al 2004).

Following the overwhelming success of the laryngeal mask airway (LMA), supraglottic devices are being developed with increasing frequency and this requires a classification system to arrange the wide

Figure 1: Early prototypes of the laryngeal mask airway.
Introduction

varieties Of this complex family Of devices. B0th Miller and Brimac0mbe suggested classificati0n systems f0r supraglottic airway devices (Donald M. et al 2004, Brimacombe J.et al 2004).

According t0 Miller, supraglottic airway devices can be classified int0 three main gr0ups with three different sealing mechanisms (Table I).

Table (I): Miller's classificati0n Of supraglottic devices.

<table>
<thead>
<tr>
<th>Classificati0n</th>
<th>Devices</th>
<th>Sealing Mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cuffed perilaryngeal sealsers</td>
<td>With0ut Directi0nal Sealing</td>
<td>Laryngeal mask airway (LMA).</td>
</tr>
<tr>
<td></td>
<td>With Directi0nal Sealing</td>
<td>Intubating LMA.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Soft seal LMA.</td>
</tr>
<tr>
<td></td>
<td>Cuffed Pharyngeal Sealers</td>
<td>Relies On simple OPs0sit10n Of the cuff that surr0unds the larynx.</td>
</tr>
<tr>
<td></td>
<td>With0ut Es0phageal Sealing Cuffs</td>
<td>Sealing site is at Or ar0und the entrance Of the larynx.</td>
</tr>
<tr>
<td></td>
<td>With Es0phageal Sealing Cuffs</td>
<td>C0bra pharyngeal lumen airway.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Laryngeal tube airway.</td>
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<tr>
<td></td>
<td></td>
<td>Laryngeal tube suction.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0es0phageal tracheal C0mbitube.</td>
</tr>
<tr>
<td>Cuffless Pre-shaped Sealers</td>
<td>Streamlined pharynx airway liner (SLIPA).</td>
<td>An anat0mically pre-shaped h0ll0w airway which seals the Outlet fr0m the pharynx at the base Of the t0ngue t0 the entrance t0 the es0phagus, as a result resilience Of the walls Of the shaped airway</td>
</tr>
</tbody>
</table>

According t0 Brimac0mbe, the extraglottic airway devices can be classified acc0rding t0 presence Or absence Of a cuff, r0ute Of inserti0n (nasal Or Oral) and the anat0mic l0cati0n Of the distal cuff (Table II).
Table (II): Brimacombe's classification of supraglottic airway devices.

<table>
<thead>
<tr>
<th>Uncuffed, Orally inserted laryngopharyngeal airways:</th>
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<tbody>
<tr>
<td>1) Williams airway intubator*.</td>
</tr>
<tr>
<td>2) Patil Oral airway*.</td>
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<tr>
<td>3) Ovassapian fiberoptic intubating airway*.</td>
</tr>
<tr>
<td>4) Combined oropharyngeal airway and dental pack.</td>
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<tr>
<td>5) Modified Connell airway.</td>
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</table>

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<tr>
<th>Cuffed, Orally inserted laryngopharyngeal airways:</th>
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</thead>
<tbody>
<tr>
<td>1) Mehta’s cuffed oropharyngeal airway.</td>
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<tr>
<td>2) Cuffed oropharyngeal airway.</td>
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<tr>
<th>Uncuffed, nasally inserted laryngopharyngeal airways:</th>
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<tbody>
<tr>
<td>1) Variable flange nasopharyngeal airway.</td>
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<td>2) Linder nasopharyngeal airway.</td>
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<tr>
<th>Cuffed, nasally inserted laryngopharyngeal airways:</th>
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<tr>
<td>1) Böheimer’s cuffed nasopharyngeal airway.</td>
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<tr>
<th>Cuffed, Orally inserted hypopharyngeal airway:</th>
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<tbody>
<tr>
<td>1) Classic LMA#.</td>
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<tr>
<td>2) Flexible LMA#.</td>
</tr>
<tr>
<td>3) Intubating LMA#.</td>
</tr>
<tr>
<td>4) Disposable LMA#.</td>
</tr>
<tr>
<td>5) Pr0Seal LMA#.</td>
</tr>
<tr>
<td>6) Glottic aperture seal airway#.</td>
</tr>
<tr>
<td>7) Streamlined pharynx airway liner#.</td>
</tr>
<tr>
<td>8) Soft seal laryngeal mask#.</td>
</tr>
<tr>
<td>9) Laryngeal tube airway.</td>
</tr>
<tr>
<td>10) Laryngeal tube suction.</td>
</tr>
<tr>
<td>11) Airway management device</td>
</tr>
<tr>
<td>12) Pharynx airway express</td>
</tr>
<tr>
<td>13) Cobra pharyngeal lumen airway.</td>
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<tr>
<th>Uncuffed, Orally inserted oesophageal airways:</th>
</tr>
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<tbody>
<tr>
<td>1) TracheO-oesophageal airway.</td>
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<tr>
<th>Cuffed, Orally inserted oesophageal airways:</th>
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</table>
**Introduction**

The laryngeal mask airway supreme (LMA-S)

- **Device description:**

  The LMA Supreme (LMA-S, Laryngeal Mask Company, UK) is a new supraglottic airway which is released in the market in February 2007 (LMA Supreme™ Instruction Manual, 2007).

  It is supplied as a single use device, sterilized and ready to use. All the components of the laryngeal mask airway Supreme are latex free. LMA-S is considered the most advanced form of LMA Classic because it combines the advantages of all the previous laryngeal mask airways; it brings together features of the LMA PrOSeal (high seal cuff, gastric access and bite block to facilitate ventilation, protect the airway and prevent airway obstruction, respectively), the LMA Fastrach (fixed curved tube to facilitate insertion) and the LMA Unique (single use to prevent disease transmission). (Ron M. et al 2009).

  The LMA Supreme has three main components; the airway tube, the drain tube and the inflatable cuff with its inflation line (Figure 2).
A) The airway tube:

At the proximal end of the LMA Supreme, the airway tube and the drain tube end on a manifold which is a rigid molded proximal component that forms separate airway and drain tube ports (Figure 3). Two rigid tubes project from this manifold; the larger one represents the proximal end of the airway tube while the smaller one represents the proximal end of the drain tube.
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The proximal end of the airway tube has a standard 15 mm diameter and it is designed to be connected to the airway circuit while the distal end opens at the laryngeal mask bowl. The airway tube has the following features:

- It is more rigid than the airway tube of the LMA Pr0seal but not as rigid as the metallic airway tube of the LMA Facet. Also, it has two lateral patented grooves. These two features prevent kinking which could lead to airway obstruction.
- It has an anatomically pre-shaped curvature with elliptical cross-section. This configuration permits easy and reliable insertion without the need for digital or introducer tool guidance and provides stability of the device after insertion.
- It has a built-in bite-block to reduce the potential for tube damage and obstruction by patient biting.
- A specially designed rigid tab fixed above the bite-block area that permits fixation using adhesive tape. Also, in the event of the device...
being displaced from the optimal position, the tab is easily manipulated to ‘re-place’ the device to the optimal position. The tab is then used to re-fix the device in this position. The distance of the tab from the upper lip should be more than 0.5 cm and less than 2 cm. If the tab is flush against the upper lip, it indicates that a larger size of LMA-Supreme should be used and if the tab is more than 1.5 cm from the upper lip then a smaller sized device should be used instead.

B) The drain tube (Figure 4):

The drain tube starts as the narrow tube at the manifold. This narrow tube is a continuation of the drain tube and allows equalization of the pressure at the upper oesophageal sphincter and atmosphere. Then, the drain tube is contained within the airway tube, runs distally along the posterior surface of the cuff end as a distal open tip that is designed to communicate and form a sealed junction with the upper oesophageal sphincter, when inserted with recommended insertion technique (LMA Supreme™ Instruction Manual., 2007).

The drain tube has the following functions:

It provides a useful conduit for venting gastrointestinal gases and liquids and may be used for the blind insertion of a standard well lubricated gastric tube to the stomach, offering easy access to liquid stomach contents (the configuration of this tube includes a dual cuff and internal webbing to prevent occlusion of the drain tube) (Sean H et al 2009).
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- The drain tube has an additional and important function; it may be used as a monitor of correct positioning of the LMA Supreme following insertion and then for continuous monitoring of mask displacement during its use. Incorrect positioning of the LMA Supreme results in a poor airway seal and an audible and immediately detectable leak through the drain tube. Thus leakage of gases through the drain tube during positive pressure ventilation immediately alerts the user to the displacement of the device from its optimal position (LMA Supreme™ Instruction Manual, 2007).

Figure 4: The airway tube and the drain tube.

C) Inflatable cuff and cuff inflation line (Figure 5):
The mask of the laryngeal mask airway supreme has an inflatable cuff. A cuff inflation line is attached to the mask and terminates in a pilot balloon and one-way check valve for mask inflation and deflation.

**Figure 5:** Inflation line and pilot balloon.

When the laryngeal mask airway supreme is fully inserted using the recommended insertion technique, the inflatable cuff should form the contour of the hypopharynx with the airway lumen facing the laryngeal opening, the distal tip of the cuff (which represents the distal end of the drain tube) at the upper oesophageal sphincter, its sides faces at the pyriform fossae and the upper border rests against the base of the tongue. Also, the design of the cuff bowl includes patented ‘epiglottic fins’ and the two lateral airway channels separated by a drain tube, this design prevents the occlusion of the airway by the epiglottis (Figure 6). Aperture bars are therefore not required. The new design of the inflatable cuff offers higher seal pressures around the laryngeal opening than the cuff of the LMA Classic during positive pressure ventilation (PPV) (Cook T, et al 2009).
**Introduction**

**The i-gel supraglottic device:**

The i-gel airway is a novel and innovative supraglottic airway management device, made of a medical grade thermoplastic elastomer, which is soft, gel-like and transparent. The i-gel is designed to create a non-inflatable anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures whilst avoiding compression trauma. This device has been developed after extensive literature searches related to supraglottic, extraglottic, periglottic and intraglottic airway devices dating back as far as the eighteenth century. Fresh cadaveric neck dissectons, direct and indirect pharyngeal-laryngeal endoscopies, X-rays, CT and MRI imaging data were all utilized in order to ensure the i-gel’s...
shape, softness and contours accurately mirrors those of the pharyngeal, laryngeal and perilaryngeal framework (Intersurgical Ltd. The user guide. i-gel® single use supraglottic airway. Wokingham: Intersurgical Ltd; 2012).

The i-gel is a truly anatomical device achieving a mirrored impression of these structures without causing multidirectional forces of compression or displacement trauma to the tissues and structures in the vicinity. The i-gel has evolved as a device that accurately positions itself over the laryngeal framework providing a reliable perilaryngeal seal and therefore no cuff inflation is necessary. The i-gel is formed of many parts; each of them has a specific function and differentiates it from other airway devices (Figure 7) (Levitan RM, et al 2005).

Figure (7): I-gel and its key components.

The novel soft non-inflatable cuff fits snugly onto the perilaryngeal framework (Figure 8) Intersurgical Ltd. The user guide. i-gel® single use supraglottic airway. Wokingham: Intersurgical Ltd; 2012.

mirroring the shape of the epiglottis, aryepiglottic folds, piriform fossae, peri-thyroid, peri-cricoid, posterior cartilages and spaces. Each receives an impression fit, thus supporting the seal by enveloping the laryngeal inlet. The tip lies in the proximal opening of the oesophageus, isolating the oesophageal opening from the laryngeal inlet. The cuff creates a deep tunneling effect whilst in-situ, thus making it more difficult for a downfolded epiglottis to block the distal airway channel. Sliding beneath the pharyngeal epiglottic folds it becomes narrower and
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deeper, creating an outward movement to fit snugly into the potential space of the perilaryngeal pouch. The outer cuff shape ensures that the blood flow to the laryngeal and peri-laryngeal framework is maintained and helps to reduce the possibility of neurovascular compression trauma to the nerves. The i-gel does not use aperture bars like some supraglottic airways (*Richez B et al 2008*).

The gastric channel runs through the device from its proximal opening at the right hand side of the flat connector wing to the distal tip of the non-inflatable cuff. Since the distal tip of the device fits snugly and anatomically correctly into the upper oesophageal opening, the distal opening of the gastric channel allows for suctioning, passing of a nasogastric tube and can facilitate venting (*Richez B et al 2008*).

An artificial epiglottis and a protective ridge help prevent the epiglottis from folding or obstructing the distal opening of the airway. The epiglottic ridge at the proximal end of the bowl rests at the base of the tongue, thus keeping the device moving upwards out of position and the tip moving out of the upper oesophagus (*Richez B et al 2008*).

The buccal cavity stabilizer has a built-in natural propensity to adapt its shape to the oropharyngeal curvature of the patient. It is anatomically widened and concaved to eliminate the potential for rotation, thereby reducing the risk of malposition. It also provides vertical strength to aid insertion (*Bamgbade OA, et al 2008*).

The innovative connector serves a number of functions; (*Bamgbade OA, et al 2008*).
- To provide a standard 15mm connection to the patient connection.

- A port of entry for the gastric channel (except size 1). The port is independent of the main 15mm connection and is located on the right hand side of the connection wing.

- An integral bite block – this function is provided by the distal (below the wing) part of the connection, which runs through the center of the proximal part of the buccal cavity stabilizer.

- To reduce the possibility of the airway channel occluding - the junction of the distal tip to the body of the connection is V-shaped, which significantly reduces the risk of kinking.

- As a guide to correct positioning - the integral part of the bite-block is marked with a horizontally placed black line, which signifies the optimum position of the teeth while the device is in situ.

- Easy visibility of key product information – this includes size and recommended weight. The information is located on the integrated bite block.

- The internal diameter of the connection is the same as the internal diameter of the airway channel to facilitate fiber-optically guided endotracheal intubation in cases of difficult or failed intubations.

**Figure (8):** The i-gel fits the perilymphageal structures.

1. Tongue  
2. Base of tongue  
3. Epiglottis  
4. Aryepiglottic folds
5. Piriform Fossa
6. Posterolateral cartilages
7. Thyroid Cartilage
8. Cricoid cartilage
9. Upper Oesophageal Opening

The i-gel is used to secure and maintain a patent airway in routine and emergency anaesthesia for operations of fasted patients during spontaneous or intermittent positive pressure ventilation (IPPV) (Wharton NM, et al 2008).

Steps for insertion:

Maintaining the sterility of the device during preparation and prior to insertion is important. Packaging is in the shape of a twin tray and tyvek pack. The inner tray acts as a stand/ mounting for the device and helps to maintain sterility until inserted (Gabbott DA, et al 2007).

The appropriate size i-gel (figure 9) is selected by assessing the patient’s anatomy. If the seal is not adequate, particularly during intermittent positive pressure ventilation (IPPV), a larger size may be required (Sharma S, et al 2007)

Table 4: Sharma S, et al 2007

<table>
<thead>
<tr>
<th>I-gel size</th>
<th>Patient weight guidance (kg)</th>
<th>Patient size</th>
<th>Maximum size of naso-gastric</th>
<th>Maximum size of cuffed</th>
</tr>
</thead>
</table>

Figure (9): Variable sizes of the i-gel. (60) Sharma S, et al 2007

Table (3): The i-gel sizes, patient weight, the largest NGT and maximum size of cuffed endotracheal tube that can be passed. (60)
Each part of the i-gel should be inspected before use to ensure it is intact, patent and ready to use. Then the following steps should be followed: (Gatward JJ, et al 2008)

**Wearing gloves.**

- Opening the i-gel package; on a flat surface, taking out the cage pack containing the device.
- In the final minute of pre-oxygenation, the cage pack should be opened and the device is transferred into the lid of the cage. A small bolus of a water-based lubricant is placed, such as K-Y Jell, onto the smooth inner surface of the device.
- The i-gel is grasped along the integral bite block and the front, back and sides of the cuff are lubricated with a thin layer of lubricant.
- The i-gel is placed back into the cage pack in preparation for insertion with the following precautions:
  - The device should not be placed onto the chest or pillow of the patient, always use the tray provided.
  - Unsterile gauze should not be used in lubricating the device.
  - The lubricant should be applied just before insertion.
  - Dentures or removable plates should be removed from the mouth before attempting insertion of the device.
  - The device and nasogastric tube should be inserted gently.
• The i-gel is a single use device.
  – The lubricated i-gel grasped firmly along the integral bite block. The device should be positioned so that the i-gel cuff outlet is facing towards the chin of the patient.
  – The patient should be in the sniffing position with head extended and neck flexed.
  – The chin should be gently pressed down before proceeding to insert the i-gel (Figure 10) *(Gatward JJ, et al 2008)*.

**Figure (10):** Insertion, positioning and fixation of the i-gel. *(Gatward JJ, et al 2008)*

  – The leading soft tip is introduced into the mouth of the patient in a direction towards the hard palate.
  – The device should be glided downwards and backwards along the hard palate with a continuous but gentle push until a definitive resistance is felt. Excessive force on the device during insertion should be avoided. It is not necessary to insert fingers or thumbs into the patient’s mouth during the process of inserting the device. If there is early resistance during insertion a ‘jaw thrust’ or ‘Insertion
with Deep R0tati0n’ is rec0mmended (figure 11) (S0ar J. et al 2007).

Figure (11): Jaw thrust (left), Inserti0n with deep r0tati0n (right). (62) S0ar J. et al 2007

– At this p0int the tip Of the airway sh0uld be l0cated int0 the upper Oes0phageal Opening and the cuff sh0uld be l0cated against the laryngeal framew0rk. The incis0rs sh0uld be resting on the integral bite-bl0ck. In general, the i-gel is self-retaining. H0wever, i-gel may be taped Or tied d0wn by the anaesthetic assistant if required. (61) Gatward J.J, et al 2008

So0metimes a feel Of ‘give-way’ is felt bef0re the end p0int resistance is met. This is due t0 the passage Of the b0wl Of the i-gel thr0ugh the faucial pillars (pharyng0-epigl0ttic f0lds). Once resistance is met and the teeth are l0cated on the integral bite bl0ck, repeated pushing Of i-gel d0wn sh0uld be av0ided. N0 m0re than three attempts in One patient sh0uld be attempted (S0ar J. et al 2007).

Once c0ns0ci0usness is regained and pr0tective reflexes such as c0ughing and swall0wing have returned; gentle sucti0n ar0und the airway device in the pharynx and hyp0pharynx sh0uld be d0ne. Once the patient is awake Or easily ar0usable with verbal c0mmands, the i-gel can safely be rem0ved by asking the patient t0 Open his/her m0uth wide, and replaced with an Oxygen mask. In patients with the p0ssibility Of a heightened gag r0flex (i.e. sm0kers, asthmatics Or patients with COPD), i-gel sh0uld be rem0ved in deeper planes Of anaesthesia and, after rem0val, the airway maintained with a guedel airway and Oxygen mask until
Introduction

Protective reflexes have returned and the patient becomes arousable (S0ar J. et al 2007).

Two modes of ventilation

Conventional mechanical ventilations, volume-controlled (VC) or pressure-controlled, are still the principal modes of ventilation used in all age groups (Kucm0rek et al., 1996).
VC ventilation has the advantage of delivering a set tidal (Vt), whatever peak inspiratory pressure (PIP) is required to deliver it, whereas in pressure-controlled ventilation delivered tidal volume varies with the compliance and resistance of the thorax and lungs but the set peak pressure is not exceeded (Ap0st0lac0se et al., 1996).

In an attempt to make ventilation more patient friendly and gentler, pressure-controlled ventilation-volume guaranteed (PCV-VG) was developed which has the distinct theoretical advantages of both VC and pressure-controlled ventilation (Ap0st0lac0se et al., 1996).

However, in pressure-controlled ventilation-volume guaranteed (PCV-VG), the Vt and the rate are predetermined and the ventilator delivers the Vt using an accelerating flow but a constant pressure. The ventilator adjusts the inspiratory pressure needed to deliver the Vt breath-by-breath so that the lowest pressure is used. PCV-VG begins by first delivering a volume breath at the set Vt. The patient’s compliance is determined from this volume breath and the inspiratory pressure level is then established for the next breath. Hence, PCV-VG combines the benefits of decelerating flow of PCV with the safety of a volume guarantee at a lowest possible titrated inspiratory pressure (Keszler et al., 2006).
Patients and methods

• **Ethics Committee:**
  - The study protocol will be approved by the institutional ethical committee of Benha university hospitals.
  - Informed patient written consent will be obtained before enrollment in the study.

• **Type of Study:**
  Prospective, single blind randomized clinical study.

• **Methods of randomization:**
  Patients will be randomized into two groups. An online randomization program will be used to generate random number lists. Patient randomization numbers will be concealed in opaque envelopes which will be opened by the study investigator.

• **Methods of blindness:**
  Members of the study group involved in obtaining functional data will be blinded to randomization for the period of data acquisition and analysis.

• **Inclusion Criteria:**
  - Age from 18 to 60 years.
  - ASA physical status: I, II and III
  - Type of Operations: Patients undergoing gynecological laparoscopic procedures.
Introduction

- **Gr0ups all0cati0n:**
  Patients will be rand0mly all0cated int0 tw0 main gr0ups each 0f which will be subdivided int0 tw0 subgr0ups:

**Gr0up 1 : LMA-Supreme™** gr0up (LMA) that will be subdivided int0 tw0 subgr0ups:
- subgr0up a: LMA-Supreme™ with v0lume c0ntr0lled ventilati0n (LMA-VC)
- subgr0up b: LMA-Supreme™ with pressure c0ntr0lled ventilati0n v0lume guarntee

- (LMA-PCVG)

**Gr0up 2 : i-gel™** gr0up (IG) that will be subdivided int0 tw0 subgr0ups:
- subgr0up a i-gel™ with v0lume c0ntr0lled ventilati0n (IG-VC)
- subgr0up b: i-gel™ with pressure c0ntr0lled ventilati0n v0lume guarntee (IG-PCVG)

- **Exclusi0n Criteria:**
  - Major Obstructive Or restrictive pulm0nary disease (defined as less than 70% 0f the predicted values)
  - Suspected difficult intubati0n (based 0n a hist0ry 0f difficult airway, inter-incis0r distance < 20 mm, cervical spine path0l0gy, m0dified Mallampati class 4, Or thyr0mental distance < 65 mm).
Introduction

- Inability to maintain stable mechanical ventilation settings for 30 min (inability to maintain an appropriate end-tidal CO2 and SpO2 less than 94%).
- The patient with history of preoperative sore throat, regurgitation or aspiration, gastric reflux, hiatus hernia, history of allergy to any of study drugs.
- Patients with BMI <18.5 or >30 kg/m².
- A planned operative time > 4 h.

- Preoperative visit:

The day before surgery all patients will be interviewed to explain the procedure. Also routine investigations in the form of twelve leads electrocardiography (ECG), complete blood count (CBC), coagulation profile (bleeding time, prothrombin time, international normalized ratio and partial thromboplastine time), liver functions, kidney functions as well as arterial blood gases (ABG) will be fulfilled.

- Patient preparation:

Thirty minutes before the procedure, IV access (A 20G i.v. cannula) will be established and IV midazolam 0.01-0.02 mg/kg will be given.

- Anesthetic techniques:

- General anaesthesia:

  **Before the induction of general anaesthesia:**

  Monitoring of the patients in the form of 5-Lead ECG, Arterial Blood Pressure (Non invasive blood pressure), arterial line placement and Pulse Oximeter will be conducted.
**Introduction**

- **Choice Of the supraglottic device:**

  The size of the airway will be chosen in accordance to manufacturers’ recommendations. For the **LMA-Supreme™**, a size 3 will be used if < 50 kg, a size 4 if 50–70 kg and a size 5 if 70–100 kg for the **i-gel™**, a size 3 will be used if 30–60 kg, a size 4 for 50–90 kg and a size 5 for > 90 kg.

- **Induction Of general anaesthesia:**

  Preoxygenation with 02 .100% will be administered via face mask before induction of anesthesia for at least five deep breaths. General anaesthesia will be induced with propofol 1–3 mg/kg followed by succinylcholine 0.6 mg/kg. After three minutes of intermittent positive pressure ventilation (IPPV) using face mask; the device will be inserted by senior anaesthetists experienced in using the SAD, according to the manufacturer’s recommendations.

  Before insertion, a water-soluble lubricant will be applied to the rear of the cuff. With the patient’s head in the sniffing position, the device will be grasped along the integral bite block and introduced continuous into the mouth towards the hard palate until resistance is felt. The cuff of the **LMA-Supreme™** will be inflated with air to attain a cuff pressure of 60 cmH2O. Correct insertion will be assessed by proper chest expansion, chest auscultation, the presence of end-tidal CO2 (ETCO2) waveform with a plateau on the capnogram, absence of audible leak, and lack of gastric insufflation. The presence of gastric insufflation will be detected by epigastric auscultation.

  A plan will be made to revert to **LMA-Classic™** after three failures, and if this failed to endotracheal tube insertion. Particular
Attention will be paid to the ease of insertion, seal/leak pressure and evidence of trauma from insertion.

After obtaining a proper position with the i-gel™, leak pressure will be measured. The fresh gas flow will be set at 3 L/min and pressure adjustment valve will be set at 40 cmH2O. Leak pressure will be recorded when airway pressure reached a plateau.

A lubricated gastric tube (UltraMed-EGYPT, size 14 FG for the LMA Supreme™, and 12 FG for the i-gel™). These gastric tubes will be prelubricated with a water-soluble lubricant then inserted down the drainage tube.

Ease of LMA Supreme™, i-gel™ and gastric tube insertion will be graded subjectively on a scale from 1 to 4 (1 = very easy, 2 = easy, 3 = difficult and 4 = very difficult).

Mechanical ventilation will be done with an Avance (GE, CS2, USA). Once a SAD insertion will be achieved, the oropharyngeal cuff leak pressures will be obtained by closing the expiratory valve of the anesthesia circuit with a fixed gas flow rate of 3 L/min and noting the airway pressure at which equilibrium will be reached.

In the volume controlled subgroups, baseline ventilation of the lung will be done with volume-controlled ventilation and a tidal volume of 8 ml/kg ideal body weight (IBW). The initial respiratory rate of 12 breaths per minute will be adjusted during laparoscopy to maintain an end-tidal carbon dioxide pressure of 30-35 mmHg. Five minutes after SAD insertion and mechanical ventilation, the first blood samples will be taken for blood gas analysis; the blood samples will be taken from the radial artery and then peritoneal insufflation will be initiated.
Introduction

In the pressure controlled volume guarantee setups, baseline ventilation of the lung will be done with pressure-controlled ventilation, and this will be initiated with a peak airway pressure that provided a tidal volume of 8 ml/kg IBW with an upper limit of 35 cmH2O. Five minutes after SAD insertion and mechanical ventilation, a first blood will be taken for blood gas analysis and peritoneal insufflation will be initiated.

In all groups, a carbon dioxide pneumoperitoneum will be induced with a maximal intrabdominal pressure of 15 mmHg, and the maximal allowed head-down Trendelenberg position will be 15°. Then, the second blood gas analysis will be done 15 minutes after peritoneal insufflation. In all the patients, the FiO2 will be maintained at 50%. The end-tidal CO2, the peak airway pressure, the leak pressure, the compliance, the airway resistance and the arterial oxygen saturation will be continuously monitored during the procedure and they recorded at T1: 5 minutes after insertion of the laryngeal airway, T2: 5 minutes after CO2 insufflation, and T3: 15 minutes after CO2 insufflation. The peak airway pressure, the leak pressure, the compliance and the airway resistance will be measured by spirometry via an Avance (GE, CS2, USA). The inspiratory/expiratory ratio (I/E) will be 1:2. Crystalloid solution (8-10 ml/kg) will be used as maintenance fluid intraoperatively.

- After Induction Of general anaesthesia:

0.15 mg/kg of rocuronium is given as a maintenance dose every 30 minutes till the end of the procedure. Anaesthesia will be maintained with isoflurane 1 Mac. End tidal CO2 will be monitored after endotracheal intubation with side steam capnography.
Introduction

Heart rate and mean arterial blood pressure (MAP) will be maintained within ± 20% of the preoperative baseline by giving IV bolus doses of fentanyl approximately 1 mcg/kg if the MAP or heart rate increased more than 20% from the baseline. Hypotension will be treated with intravenous ringer’s solution 15 ml/kg and ephedrine 5 mg as needed to keep MAP more than 60 mm Hg. Bradycardia (HR < 60/min.) will be treated with atropine 0.01-0.02 mg/kg.

- Recovery:

At the end of surgery, the effects of neuromuscular blocking drug will be reversed with neostigmine (0.04 mg/kg) and atropine (0.02 mg/kg). The airway device will be removed upon return of spontaneous breathing and eye opening of the patient. The airway device will be then inspected for the presence of visible blood.

Forty-five minutes later, patients will be assessed by a blinded independent observer for postoperative sore throat, dysphonia or dysphagia.

- Measurements:

All measurements are done at three different intervals T1: 5 minutes after insertion of the laryngeal airway, T2: 5 minutes after CO2 insufflation, T3: 15 minutes after CO2 insufflation.

- Lung Mechanics:

  - Peak airway pressure (cmH2O)
  - Leak pressure (cmH2O)
  - Compliance (ml/cmH2O)
  - Expiratory tidal volume (ml)
Introduction

- **Haemodynamic parameters:**
  - heart rate and mean arterial blood pressure (MAP) will be recorded.

- **Respiratory parameters:**
  - PH
  - PaO2
  - PaCO2
  - EtCO2

(PaCO2, partial arterial carbon dioxide tension; PaO2, partial arterial oxygen, EtCO2 end tidal CO2).

- **Complications:**
  - **Complications during insertion:** trauma, partial obstruction, cough.
  - **Complications at recovery:** trauma, partial obstruction, cough, laryngeal spasm,

- **Data Management and Statistical Analysis:**
  - Analysis of data will be done by using SPSS version 16.
  - Quantitative data will be presented as mean ± Standard deviation.
  - Qualitative data will be presented as numbers and percentages.
  - Quantitative data will be analysed by using ANOVA test.
  - Qualitative data will be analysed by using Chi-square test.
  - P – Value < 0.05 will be considered statistically significant.
  - P – Value < 0.01 will be considered statistically highly significant.
  - Sample size calculation:
To estimate the sample size, a pilot study will be conducted to determine the effect size. Providing an $\alpha$ error $= 0.05$, and a power of 80%.
Results

This study was conducted to compare the efficacy of the non-inflatable cuff of The i-gel™ with the inflatable cuff of the LMA-Supreme™ in providing an adequate seal during gynaecological laparoscopic procedures in the Trendelenburg position in patients with apparent normal airways receiving two modes of controlled mechanical ventilation in the form of: volume controlled ventilation (VCV) and pressure-controlled ventilation-volume guaranteed (PCV-VG), and their effect on the lung mechanics, the respiratory parameters and the hemodynamic parameters.

80 patients aged from 18 to 60 years, ASA physical status: I, II and III undergoing gynaecological laparoscopic procedures, Patients will be randomly allocated into two main groups each of which will be subdivided into two subgroups:

**Group 1**: LMA-Supreme™ group (LMA) that will be subdivided into two subgroups:

- **Subgroup a**: LMA-Supreme™ with volume controlled ventilation (LMA-VC)
- **Subgroup b**: LMA-Supreme™ with pressure controlled ventilation-volume guaranteed (LMA-PCVG)

**Group 2**: i-gel™ group (IG) that will be subdivided into two subgroups:

- **Subgroup a**: i-gel™ with volume controlled ventilation (IG-VC)
Introduction

- **subgroup b: i-gel™** with pressure controlled ventilation volume guaranteed (IG-PCVG)

An online randomization program will be used to generate random numbers. Patient randomization numbers will be concealed in opaque envelopes which will be opened by the study investigator.

**Demographic characteristics and duration of surgery:**

Demographic characteristics showed no difference in age, BMI, ASA physical status, or duration of surgery between groups (table 1).

As regard age; the mean age in group LMA-VC was 29.65±5.24 years, in group LMA-PCVG was 31.1±5.26 years, in group IG-VC was 33.6±7.14 years, and in group IG-PCVG was 28.9±5.19 years. Statistical analysis using ANOVA test was used and showed no statistical difference between the groups (p-value=0.063).

As regard BMI; the mean BMI in group LMA-VC was 72.9±8.26 Kg/m², in group LMA-PCVG was 70.6±6.55 Kg/m², in group IG-VC was 70.9±7.02 Kg/m², and in group IG-PCVG was 74.1±5.94 Kg/m². Statistical analysis using ANOVA test was used and showed no statistical difference between the groups (p-value=0.41).

As regard ASA physical state; in group LMA-VC there was 15 patients ASA I, 3 patients ASA II, and 2 patients ASA III, in group LMA-PCVG there was 14 patients ASA I, 4 patients ASA II, and 2 patients ASA III, in group IG-VC there was 16 patients ASA I, 1 patient ASA II, and 3 patients ASA III, in group IG-PCVG there was 17 patients ASA I, 2 patients ASA II, and 1 patient ASA III. Statistical analysis using chi-square test was used and showed no statistical difference between the groups (p-value=0.85).

As regard duration of surgery; the mean duration of surgery in group
LMA-VC was 45.7±7.99 minutes, in group LMA-PCVG was 46.5±10.27 minutes, in group IG-VC was 44±10.33 minutes, and in group IG-PCVG was 48.5±7.08 minutes. Statistical analysis using ANOVA test was used and showed no statistical difference between the groups (p-value=0.47).
Introduction

Comparing the studied groups regarding demographic data and time of surgery

<table>
<thead>
<tr>
<th>Variable</th>
<th>LMA-VC group (n=20)</th>
<th>LMA-PCVG group (n=20)</th>
<th>IG-VC group (n=20)</th>
<th>IG-PCVG group (n=20)</th>
<th>ANOVA</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (ys)</td>
<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>29.6 ±5.24 20-38</td>
<td>31.1 ±5.26 22-39</td>
<td>33.6 ±7.14 20-44</td>
<td>28.9 ±5.19 20-37</td>
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<td>Weight (kg)</td>
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<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
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<tr>
<td></td>
<td>72.9 ±8.26 61-88</td>
<td>70.6 ±6.55 60-82</td>
<td>70.9 ±7.02 60-84</td>
<td>74.1 ±5.94 60-83</td>
<td>1.14</td>
<td>0.33 (NS)</td>
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<tr>
<td>BMI (kg/m²)</td>
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<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
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</tr>
<tr>
<td></td>
<td>27.2 ±2.01 24-32</td>
<td>27.1 ±2.09 23-30</td>
<td>26.2 ±1.99 22-29</td>
<td>27.0 ±1.69 23.5-29.5</td>
<td>0.98</td>
<td>0.41 (NS)</td>
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<tr>
<td>Time of surgery (mi)</td>
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<td>Mean ±SD Range</td>
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<td>Mean ±SD Range</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>45.7 ±7.99 30-60</td>
<td>46.5 ±10.27 30-60</td>
<td>44.0 ±10.33 30-60</td>
<td>48.5 ±7.08 35-60</td>
<td>0.85</td>
<td>0.47 (NS)</td>
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<td>3</td>
<td>2</td>
<td>2</td>
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</table>

ASA: X²=3.3  P=0.76
Bar chart showing the mean value of age among the studied groups.
Bar chart showing the distribution of weight and BMI among the studied groups.

Bar chart showing the distribution of time of surgery among the studied groups.
Introduction
**Introduction**

**Peak airway pressure:**

The PAP levels in group LMA-VC, group LMA-PCVG, group IG-VC, and in group IG-PCVG showed no change during the study period at T1, T2, T3. The statistical analysis between groups was non-significant at T1, T2, T3 (P > 0.05).

Comparing the studied groups regarding PAP:

<table>
<thead>
<tr>
<th>Variable</th>
<th>LMA-VC group (n=20)</th>
<th>LMA-PCVG group (n=20)</th>
<th>IG-VC group (n=20)</th>
<th>IG-PCVG group (n=20)</th>
<th>ANOVA</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PAP T1</td>
<td>16.7 1.68 14-20</td>
<td>16.2 1.36 14-18</td>
<td>16.5 1.79 14-19</td>
<td>16.2 1.23 14-18</td>
<td>0.51</td>
<td>0.67 (NS)</td>
</tr>
<tr>
<td>PAP T2</td>
<td>17.1 1.41 15-20</td>
<td>16.5 .99 15-18</td>
<td>16.8 1.46 14-19</td>
<td>16.6 .82 16-18</td>
<td>0.89</td>
<td>0.45 (NS)</td>
</tr>
<tr>
<td>PAP T3</td>
<td>16.6 1.18 14-19</td>
<td>16.4 0.94 15-18</td>
<td>16.8 1.19 15-19</td>
<td>16.5 0.68 16-18</td>
<td>0.59</td>
<td>0.62 (NS)</td>
</tr>
</tbody>
</table>
Introduction

Bar chart showing the distribution of PAP among the studied groups.

Comparing the studied groups regarding LP

The LP levels in group LMA-VC, group LMA-PCVG, group IG-VC, and in group IG-PCVG was highly significant (p<0.001) during the study period at T1, T2. The LP levels in group LMA-VC, group LMA-PCVG, group IG-VC, and in group IG-PCVG was non-significant (P > 0.05) during the study period at T3.

Post-hoc analysis of LP values at T1:
The LP levels in group LMA-PCVG was significantly higher than group LMA-VC. The LP levels in group IG-PCVG was significantly higher than group IG-VC. The LP levels in group LMA-VC was nearly the same as in group IG-VC.

The LP levels in group IG-PCVG was nearly the same as in group LMA-PCVG.

Post-hoc analysis of LP values at T2:

The LP levels in group LMA-PCVG was significantly higher than group LMA-VC. The LP levels in group IG-PCVG was significantly higher than group IG-VC. The LP levels in group LMA-VC was nearly the same as in group IG-VC. The LP levels in group IG-PCVG was nearly the same as in group LMA-PCVG.

<table>
<thead>
<tr>
<th>Variable</th>
<th>LMA-VC group (n=20)</th>
<th>LMA-PCVG group (n=20)</th>
<th>IG-VC group (n=20)</th>
<th>IG-PCVG group (n=20)</th>
<th>ANOVA</th>
<th>P</th>
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<tr>
<td></td>
<td>Mean ±SD</td>
<td>Range</td>
<td>Mean ±SD</td>
<td>Range</td>
<td>Mean ±SD</td>
<td>Range</td>
</tr>
<tr>
<td>LP T1</td>
<td>25.0 1.74</td>
<td>22-28</td>
<td>27.0† 1.12</td>
<td>25-29</td>
<td>25.0 1.55</td>
<td>22-27</td>
</tr>
<tr>
<td>LP T2</td>
<td>26.0 1.21</td>
<td>24-28</td>
<td>27.0† 1.02</td>
<td>25-29</td>
<td>26.0 1.07</td>
<td>24-28</td>
</tr>
<tr>
<td>LP T3</td>
<td>27.0 0.64</td>
<td>26-28</td>
<td>27.0 0.91</td>
<td>25-29</td>
<td>27.0 0.91</td>
<td>25-28</td>
</tr>
</tbody>
</table>

Significant ANOVA was followed by post-hoc multiple comparisons using Bonferroni test to detect the significant pairs:

*→ significant in comparison with LMA-VC
†→ significant in comparison with IG-VC
Introduction

Bar chart showing the distribution of LP among the studied groups.

Comparing the studied groups regarding compliance:

The compliance levels in group LMA-VC, group LMA-PCVG, group IG-VC, and in group IG-PCVG was highly significant (p<0.001) during the study period at T1, T2, T3.

Post-hoc analysis of C values at T1:

The C levels in group LMA-PCVG was significantly higher than group LMA-VC. The C levels in group IG-PCVG was significantly higher than group IG-VC. The C levels in group LMA-VC was nearly the same as in group IG-VC. The C levels in group IG-PCVG was nearly the same as in group LMA-PCVG.

Post-hoc analysis of C values at T2:

The C levels in group LMA-PCVG was significantly higher than group LMA-VC. The C levels in group IG-PCVG was significantly higher than group IG-VC. The C levels in group LMA-VC was nearly the
same as in group IG-VC. The C levels in group IG-PCVG was nearly the same as in group LMA-PCVG.
Introduction

Post-hoc analysis of C values at T3:

The C levels in group LMA-PCVG was significantly higher than group LMA-VC. The C levels in group IG-PCVG was significantly higher than group IG-VC. The C levels in group LMA-VC was nearly the same as in group IG-VC. The C levels in group IG-PCVG was nearly the same as in group LMA-PCVG.

<table>
<thead>
<tr>
<th>Variable</th>
<th>LMA-VC group (n=20)</th>
<th>LMA-PCVG group (n=20)</th>
<th>IG-VC group (n=20)</th>
<th>IG-PCVG group (n=20)</th>
<th>ANOVA</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C T1</td>
<td>35.0 ±2.0 32-38</td>
<td>40.0*± 1.91 36-43</td>
<td>35.0 ±1.16 33-37</td>
<td>40.0*± 2.05 35-44</td>
<td>50.2</td>
<td>&lt;0.001 (HS)</td>
</tr>
<tr>
<td>C T2</td>
<td>20.0 ±2.00 17-23</td>
<td>24.0*± 1.83 21-27</td>
<td>20.0 ±2.12 17-24</td>
<td>24.0*± 1.29 22-26</td>
<td>31.4</td>
<td>&lt;0.001 (HS)</td>
</tr>
<tr>
<td>C T3</td>
<td>19.0 ±1.65 17-22</td>
<td>22.0*± 1.37 19-24</td>
<td>19.0 ±1.77 17-22</td>
<td>22.0*± 1.80 19-25</td>
<td>21.7</td>
<td>&lt;0.001 (HS)</td>
</tr>
</tbody>
</table>

Significant ANOVA was followed by post-hoc multiple comparisons using Bonferroni test to detect the significant pairs

*→ significant in comparison with LMA-VC
†→ significant in comparison with IG-VC
Comparison of the studied groups regarding Vte:

The Vte levels in group LMA-VC, group LMA-PCVG, group IG-VC, and in group IG-PCVG was highly significant \((p<0.001)\) during the study period at T1, T2, T3.

Post-hoc analysis of Vte values at T1:

The Vte levels in group LMA-PCVG was significantly higher than group LMA-VC. The Vte levels in group IG-PCVG was significantly higher than group IG-VC. The Vte levels in group LMA-VC was nearly the same as in group IG-VC. The Vte levels in group IG-PCVG was nearly the same as in group LMA-PCVG.
P0st-h0c analysis of Vte values at T2:
The Vte levels in gr0up LMA-PCVG was significantly higher than gr0up LMA-VC. The Vte levels in gr0up IG-PCVG was significantly higher than gr0up IG-VC. The Vte levels in gr0up LMA-VC was nearly the same as in gr0up IG –VC. The Vte levels in gr0up IG-PCVG was nearly the same as in gr0up LMA-PCVG.

P0st-h0c analysis of Vte values at T3:
The Vte levels in gr0up LMA-PCVG was significantly higher than gr0up LMA-VC. The Vte levels in gr0up IG-PCVG was significantly higher than gr0up IG-VC. The Vte levels in gr0up LMA-VC was nearly the same as in gr0up IG –VC. The Vte levels in gr0up IG-PCVG was nearly the same as in gr0up LMA-PCVG.

<table>
<thead>
<tr>
<th>Variable</th>
<th>LMA-VC gr0up (n=20)</th>
<th>LMA-PCVG gr0up (n=20)</th>
<th>IG-VC gr0up (n=20)</th>
<th>IG-PCVG gr0up (n=20)</th>
<th>AN0VA</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vte T1</td>
<td>Mean 549.2 ± 8.47 535-565</td>
<td>Mean 524.2†† ± 8.47 515-540</td>
<td>Mean 553.7 ± 12.55 530-570</td>
<td>Mean 534.2†† ± 8.49 530-570</td>
<td>66.7</td>
<td>&lt;0.001 (HS)</td>
</tr>
<tr>
<td>Vte T2</td>
<td>Mean 524.5 ± 6.86 515-540</td>
<td>Mean 543.0†† ± 8.49 530-560</td>
<td>Mean 517.5 ± 11.41 500-535</td>
<td>Mean 529.2†† ± 8.47 520-550</td>
<td>32.2</td>
<td>&lt;0.001 (HS)</td>
</tr>
<tr>
<td>Vte T3</td>
<td>Mean 545.2 ± 11.05 520-565</td>
<td>Mean 534.5†† ± 9.44 520-550</td>
<td>Mean 543.0 ± 8.49 530-560</td>
<td>Mean 529.2†† ± 8.49 520-550</td>
<td>12.5</td>
<td>&lt;0.001 (HS)</td>
</tr>
</tbody>
</table>

Significant AN0VA was f00l0wed by p0st h0c multiple c0mparisons using B0nfer0niti0 test t0 detect the significant pairs
*→ significant c0mparisons with LMA-VC
†→ significant c0mparisons with IG-VC
Bar chart showing the distribution among the studied groups.
Comparing the studied groups regarding heart rate:

The HR levels in group LMA-VC, group LMA-PCVG, group IG-VC, and in group IG-PCVG showed no change during the study period at T1, T2, T3. The statistical analysis between groups was non-significant at T1, T2, T3 (P > 0.05).

<table>
<thead>
<tr>
<th>Variable</th>
<th>LMA-VC group (n=20)</th>
<th>LMA-PCVG group (n=20)</th>
<th>IG-VC group (n=20)</th>
<th>IG-PCVG group (n=20)</th>
<th>ANOVA</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HR T1</td>
<td>76.5 ±2.54 72-80</td>
<td>77.2 ±3.12 72-84</td>
<td>77.9 ±4.77 71-88</td>
<td>78.3 ±5.33 71-88</td>
<td>0.77</td>
<td>0.51 (NS)</td>
</tr>
<tr>
<td>HR T2</td>
<td>73.5 ±2.16 70-78</td>
<td>74.5 ±2.85 70-80</td>
<td>73.1 ±2.85 70-78</td>
<td>73.3 ±1.95 70-78</td>
<td>1.16</td>
<td>0.33 (NS)</td>
</tr>
<tr>
<td>HR T3</td>
<td>75.4 ±2.06 72-79</td>
<td>75.3 ±2.07 72-79</td>
<td>73.9 ±2.45 70-78</td>
<td>74.8 ±1.85 72-78</td>
<td>1.94</td>
<td>0.13 (NS)</td>
</tr>
</tbody>
</table>

Bar chart showing the distribution of HR among the studied groups.
Comparing the studied groups regarding mean arterial pressure:
The MAP levels in group LMA-VC, group LMA-PCVG, group IG-VC, and in group IG-PCVG showed no change during the study period at T1, T2, T3. The statistical analysis between groups was non-significant at T1, T2, T3 (P > 0.05).

<table>
<thead>
<tr>
<th>Variable</th>
<th>LMA-VC group (n=20)</th>
<th>LMA-PCVG group (n=20)</th>
<th>IG-VC group (n=20)</th>
<th>IG-PCVG group (n=20)</th>
<th>ANOVA</th>
</tr>
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<tr>
<td></td>
<td>Mean ±SD  Range</td>
<td>Mean ±SD  Range</td>
<td>Mean ±SD  Range</td>
<td>Mean ±SD  Range</td>
<td></td>
</tr>
<tr>
<td>AP T1</td>
<td>98.4 ±5.06 90-107</td>
<td>99.6 ±3.77 94-107</td>
<td>98.2 ±4.89 89-107</td>
<td>97.7 ±4.64 90-105</td>
<td>0.57</td>
</tr>
<tr>
<td>AP T2</td>
<td>105.0 ±3.79 97-110</td>
<td>105.1 ±3.45 98-110</td>
<td>105.6 ±4.42 97-113</td>
<td>106.9 ±3.40 99-112</td>
<td>1.04</td>
</tr>
<tr>
<td>AP T3</td>
<td>98.4 ±4.42 90-109</td>
<td>98.9 ±4.86 90-107</td>
<td>98.6 ±5.31 89-109</td>
<td>99.9 ±4.88 93-108</td>
<td>0.36</td>
</tr>
</tbody>
</table>

Bar chart showing the distribution of MAP among the studied groups.

Comparing the studied groups regarding PH:
The PH levels in group LMA-VC, group LMA-PCVG, group IG-VC, and in group IG-PCVG showed no change during the study period at T1, T2, T3. The statistical analysis between groups was non-significant at T1, T2, T3 (P > 0.05).
Bar chart showing the distribution of PH among the studied groups. Comparing the studied groups regarding PaO₂:
The PaO₂ levels in group LMA-VC, group LMA-PCVG, group IG-VC, and in group IG-PCVG showed no change during the study period at T1, T2, T3. The statistical analysis between groups was non-significant at T1, T2, T3 (P > 0.05).
### Table

<table>
<thead>
<tr>
<th>Variable</th>
<th>LMA-VC group (n=20)</th>
<th>LMA-PCVG group (n=20)</th>
<th>IG-VC group (n=20)</th>
<th>IG-PCVG group (n=20)</th>
<th>ANOVA</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>PaO2 T1</td>
<td>Mean: 268.7 ± 11.79</td>
<td>Mean: 269.7 ± 15.51</td>
<td>Mean: 267.0 ± 11.96</td>
<td>Mean: 272.7 ± 12.71</td>
<td>0.68</td>
<td>0.56(NS)</td>
</tr>
<tr>
<td>PaO2 T2</td>
<td>Mean: 230.7 ± 9.21</td>
<td>Mean: 230.0 ± 10.88</td>
<td>Mean: 229.5 ± 10.50</td>
<td>Mean: 229.0 ± 11.19</td>
<td>0.102</td>
<td>0.96(NS)</td>
</tr>
<tr>
<td>PaO2 T3</td>
<td>Mean: 214.5 ± 8.09</td>
<td>Mean: 213.0 ± 7.67</td>
<td>Mean: 214.7 ± 8.18</td>
<td>Mean: 212.7 ± 7.85</td>
<td>0.33</td>
<td>0.80(NS)</td>
</tr>
</tbody>
</table>

**Bar chart showing the distribution of PaO2 among the studied groups.**
Comparing the studied groups regarding PaCO₂:

The PaCO₂ levels in group LMA-VC, group LMA-PCVG, group IG-VC, and in group IG-PCVG was highly significant (p<0.001) during the study period at T1. The PaCO₂ levels in group LMA-VC, group LMA-PCVG, group IG-VC, and in group IG-PCVG was significant (p<0.05) during the study period at T2, T3.

Post-hoc analysis of PaCO₂ values at T1:

The PaCO₂ levels in group LMA-PCVG was significantly lower than group LMA-VC and group IG-VC. The PaCO₂ levels in group IG-PCVG was significantly lower than group IG-VC and group LMA-VC. The PaCO₂ levels in group LMA-VC was nearly the same as in group IG-VC. The PaCO₂ levels in group IG-PCVG was nearly the same as in group LMA-PCVG.

Post-hoc analysis of PaCO₂ values at T2:

The PaCO₂ levels in group IG-PCVG was significantly lower than group IG-VC and group LMA-VC.

Post-hoc analysis of PaCO₂ values at T3:

The PaCO₂ levels in group IG-PCVG was significantly lower than group LMA-VC.
### Table

<table>
<thead>
<tr>
<th>Variable</th>
<th>LMA-VC group (n=20)</th>
<th>LMA-PCVG group (n=20)</th>
<th>IG-VC group (n=20)</th>
<th>IG-PCVG group (n=20)</th>
<th>ANOVA</th>
<th>P</th>
</tr>
</thead>
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<td>±SD</td>
<td>Range</td>
<td>Mean</td>
<td>±SD</td>
<td>Range</td>
<td></td>
</tr>
<tr>
<td>PaCO₂ T1</td>
<td>28.6 ± 1.89</td>
<td>26-32</td>
<td>26.4 ± 1.14</td>
<td>24-28</td>
<td>28.8</td>
<td>1.67</td>
</tr>
<tr>
<td>PaCO₂ T2</td>
<td>30.1 ± 2.41</td>
<td>27-33</td>
<td>28.6 ± 1.66</td>
<td>27-33</td>
<td>30.1</td>
<td>2.10</td>
</tr>
<tr>
<td>PaCO₂ T3</td>
<td>31.7 ± 1.61</td>
<td>28-33</td>
<td>30.3 ± 2.00</td>
<td>27-33</td>
<td>31.4</td>
<td>1.72</td>
</tr>
</tbody>
</table>

*Significant ANOVA was followed by post hoc multiple comparisons using Bonferroni test to detect the significant pairs

*→ significant in comparison with LMA-VC

†→ significant in comparison with IG-VC

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**Bar chart showing the distribution of PaCO₂ values.**

- **PaCO₂ T1:** Range 26-32, Mean 28.6 ± 1.89, 26.4 ± 1.14
- **PaCO₂ T2:** Range 27-33, Mean 30.1 ± 2.41, 28.6 ± 1.66
- **PaCO₂ T3:** Range 28-33, Mean 31.7 ± 1.61, 30.3 ± 2.00

---

*Mean ±SD Range*
Comparing the studied groups regarding EtCO₂:

The EtCO₂ levels in group LMA-VC, group LMA-PCVG, group IG-VC, and in group IG-PCVG was significant (p<0.05) during the study period at T1. The EtCO₂ levels in group LMA-VC, group LMA-PCVG, group IG-VC, and in group IG-PCVG was non significant (P > 0.05) during the study period at T2, T3.

Post-hoc analysis of EtCO₂ values at T1:

The PaCO₂ levels in group LMA-PCVG was significantly higher than group IG-VC. The PaCO₂ levels in group IG-PCVG was significantly higher than group IG-VC. The PaCO₂ levels in group IG-PCVG was nearly the same as in group LMA-PCVG.

<table>
<thead>
<tr>
<th>Variable</th>
<th>LMA-VC group (n=20)</th>
<th>LMA-PCVG group (n=20)</th>
<th>IG-VC group (n=20)</th>
<th>IG-PCVG group (n=20)</th>
<th>ANOVA</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
<td>Mean ±SD Range</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EtCO₂ T1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3.34</td>
<td>0.024 (S)</td>
</tr>
<tr>
<td></td>
<td>29.1 ±2.15 26-33</td>
<td>30.1† ±2.02 27-33</td>
<td>28.5 ±1.73 26-32</td>
<td>30.2† ±1.79 27-33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EtCO₂ T2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2.1</td>
<td>0.12 (NS)</td>
</tr>
<tr>
<td></td>
<td>29.8 ±1.84 27-33</td>
<td>30.9 ±2.04 27-33</td>
<td>29.9 ±1.99 27-33</td>
<td>31.0 ±1.94 28-33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EtCO₂ T3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2.62</td>
<td>0.057 (NS)</td>
</tr>
<tr>
<td></td>
<td>30.2 ±2.02 27-33</td>
<td>31.0 ±1.79 28-33</td>
<td>30.1 ±1.81 28-33</td>
<td>31.5 ±1.50 28-33</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Significant ANOVA was followed by post-hoc multiple comparisons using Bonferroni test to detect the significant pairs.

† → significant in comparison with IG-VC
Bar chart showing the distribution of EtCO₂ among the studied groups.

**Complications:**

**Complications during insertion:**

In group LMA 5.0% of patients (2 patients) suffered from trauma during insertion of the LMA, in group IG NO patients suffered from trauma during insertion of the IG.

In group LMA 5.0% of patients (2 patients) suffered from Partial Obstruction during insertion of the LMA, in group IG 5.0% of patients (2 patients) suffered from Partial Obstruction during insertion of the IG.

In group LMA 7.5% of patients (3 patients) suffered from Cough during insertion of the LMA, in group IG 5% of patients (2 patients) suffered from Cough during insertion of the IG.

**Complications at recovery:**

In group LMA 7.5% of patients (3 patients) suffered from trauma at recovery, in group IG 5% of patients (2 patients) suffered from trauma at recovery.
In group LMA 7.5% of patients (3 patients) suffered from Partial Obstruction at recovery, in group IG 5.0% of patients (2 patients) suffered from Partial Obstruction at recovery.

In group LMA 5% of patients (2 patients) suffered from Cough at recovery, in group IG 5.0% of patients (2 patients) suffered from Cough at recovery.

In group LMA 5% of patients (2 patients) suffered from Laryngeal spasm at recovery, in group IG 5.0% of patients (2 patients) suffered from Laryngeal spasm at recovery.

<table>
<thead>
<tr>
<th>Complications during insertion</th>
<th>Gr0up LMA</th>
<th>Gr0up IG</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gr0up LMA-PCVG</td>
<td>Gr0up LMA-VC</td>
</tr>
<tr>
<td>Trauma</td>
<td>2(5%)</td>
<td></td>
</tr>
<tr>
<td>Partial Obstruction</td>
<td>2(5%)</td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td>3(7.5%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Complications at recovery</th>
<th>Gr0up LMA</th>
<th>Gr0up IG</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gr0up LMA-PCVG</td>
<td>Gr0up LMA-VC</td>
</tr>
<tr>
<td>Trauma (sore throat)</td>
<td>3(7.5%)</td>
<td></td>
</tr>
<tr>
<td>Partial Obstruction</td>
<td>3(7.5%)</td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td>2(5%)</td>
<td></td>
</tr>
<tr>
<td>Laryngeal spasm</td>
<td>2(5%)</td>
<td></td>
</tr>
</tbody>
</table>

**Statistical analysis (added t0 the end 0f patients and meth0ds)**

The collected data were tabulated and analyzed using SPSS software (Sps Inc, Chicago, ILL Company) data were expressed as mean ± standard deviation and range. Data were tested for normality using Shapiro-Wilk test, assuming normality at P>0.05, they were
Introduction

proved to be normally distributed so ANOVA test was used to detect the difference between the studied groups. Significant ANOVA was followed by post hoc multiple comparisons using Bonferroni test to detect the significant pairs. The accepted level of significance in this work was stated at 0.05 (P <0.05 was considered significant).

- \( P \text{ value} >0.05 \) is non significant (NS)
- \( P<0.05 \) is significant (S)
- \( P\leq0.001 \) is highly significant (HS)
Discussion

This study was conducted to compare the efficacy of the non-inflatable cuff of the i-gel™ with the inflatable cuff of the LMA-Supreme™ in providing an adequate seal during gynaecological laparoscopic procedures in the Trendelenburg position in paralysed patients with apparent normal airways receiving two modes of controlled mechanical ventilation in the form of: volume controlled ventilation (LMA-VC) and pressure-controlled ventilation-volume guaranteed (LMA-PCVG), and their effect on the lung mechanics, the respiratory parameters and the hemodynamic parameters.

80 patients aged from 18 to 60 years, ASA physical status: I, II and III undergoing gynaecological laparoscopic procedures, Patients will be randomly allocated into two main groups each of which will be subdivided into two subgroups:

**Group 1 : LMA-Supreme™ group (LMA)** that will be subdivided into two subgroups:

- subgroup a: LMA-Supreme™ with volume controlled ventilation (LMA-VC)
- subgroup b: LMA-Supreme™ with pressure controlled ventilation-volume guaranteed (LMA-PCVG)

**Group 2 : i-gel™ group (IG)** that will be subdivided into two subgroups:

- subgroup a: i-gel™ with volume controlled ventilation (IG-VC)
- subgroup b: i-gel™ with pressure controlled ventilation-volume guaranteed (IG-PCVG)
An online randomization program will be used to generate random number lists. Patient randomization numbers will be concealed in opaque envelopes which will be opened by the study investigator.

The results of the present study demonstrated that both the LMA Supreme and i-gel achieved comparable oropharyngeal leak pressures and proved to be effective ventilatory devices for gynaecological laparoscopic procedures.

Demographic characteristics showed no difference in age, BMI, ASA physical status, or duration of surgery between groups.

As regards the hemodynamic changes in the present study, there were no statistically significant differences between the two studied groups as regards heart rate, mean arterial blood pressure.

When each group was analyzed individually regarding the cardiovascular findings, there were more or less similar findings. In both groups.

As regards the heart rate, in the present study, both groups showed a decrease in heart rate at T2, i.e., 5 minutes after peritoneal insufflation than T1, i.e., 5 min after insertion of SAD and T3, i.e., 15 minutes after peritoneal insufflation, this could be explained by vagal response to peritoneal insufflation.

As regards the mean arterial blood pressure, in the present study, both groups showed an increase in the mean arterial blood pressure at T2, i.e., 5 minutes after peritoneal insufflation than T1, i.e., 5 min after insertion of SAD and T3, i.e., 15 minutes after peritoneal insufflation, this could be attributed to the stress response to peritoneal insufflation.
Jindal et al, 2009 in their study compared the I-gel against SLIPA and LMA airways found that the I-gel was the least of the three airway devices to produce hemodynamic changes.

Also, Vandana et al. 2011 recommended the I-gel airway as a better alternative device for the preseal laryngeal mask airway (PLMA) with controlled ventilation and for securing airway in difficult airway management since it produces lesser hemodynamic changes and it was easier to insert than PLMA.

Also, Ayman et al. 2009 in their comparative study between the LMA-S and the endotracheal tube reported that the hemodynamic responses to insertion and removal of the LMA-S were much less than that for the endotracheal tube.
Respiratory mechanics

The leak pressure or the airway sealing pressure is the threshold inspiratory pressure at which air leak occurs. It was measured just after device insertion by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/minute and recording the airway pressure (maximum allowed 40 cmH₂O) at which leak occurred. Gas leakage was determined at the mouth by the audible leak or by detection of an audible noise using a stethoscope placed just lateral to the thyroid cartilage (Bergmann I et al. 2014).

The leak pressure was done in the present study to evaluate the efficacy of the seal created by the airway devices. The value of the leak pressure is important as it indicates the feasibility of positive pressure ventilation and the degree of airway protection from the supra-cuff soring.

In the present study, the leak pressures of both airway devices were almost close with statistically no significant difference between them.

In accordance with the present study, Theiler et al. 2009 reported very close results. They found no statistically significant difference between the two airway devices as regards the sealing pressure. The mean leak pressure was 26 ± 8 cmH₂O for the LMA-S and 27 ± 9 cmH₂O for the I-gel airway with P value of 0.441.

On the other hand, Chew et al. 2010 reported that the leak pressure of the LMA-S was significantly higher than that of the I-gel airway (25.6 versus 20.7 cmH₂O, P= 0.011).
Als0, m0re 0r less similar values 0f the mean leak pressures were rep0rted by 0ther studies. Verghese et al. 2009 f0und in their c0mparison 0f the LMA-S against the pr0seal laryngeal mask airway (PLMA) that the airway sealing pressure f0r the LMA-S was 28.47 cmH$_2$O while that 0f the PLMA was 28.58 cmH$_2$O. There was n0 significant statistical difference between the tw0 devices as regards the leak pressure.

On the c0ntrary, Lee et al., 2009 rep0rted that the leak pressure 0f the LMA-S was significantly l0wer than that 0f the PLMA (27.9±4.7 versus 31.7±6.3 cmH$_2$O, P=0.007).

The later study was in agreement with an0ther study carried Out by Eschertzhuber et al., 2009 , they f0und that the airway sealing 0f the PLMA is significantly higher than that 0f the LMA-S (33 versus 28 cmH$_2$O).

Tan et al. 2010 in their evaluati0n 0f the LMA-S perf0rmance in 100 patients with n0rmal airway rep0rted that the mean gl0ttis seal pressure was 25±6.5 cmH$_2$O.

Als0, R0n M 2009 rep0rted in his study 0f the LMA-S that the mean leak pressure was 28 cmH$_2$O.

Timmermann et al. 2009 evaluated size (4) LMA-S in a pr0spective clinical and fiber0ptic study On 100 w0men and the results were cl0se t0 that 0f the previ0us studies with mean leak pressure 0f 28.1± 3.8 cmH$_2$O.

In c0ntradicti0n t0 the present and previ0us studies, H0wes et al. 2010 rep0rted that the 0r0pharyngeal sealing pressure 0f the LMA-S was as a l0w as 22 cmH$_2$O.
As regards the leak pressure of the I-gel airway, *Ishwar et al. 2009* in their comparative study between the I-gel airway and the pr0seal LMA (PLMA) c0ncluded that the airway sealing pressure of the I-gel was significantly l0wer than that of the PLMA (25.27 versus 29.6 cmH_2O, P <0.05).

*Ashish et al. 2009* in their study of the I-gel f0und that the mean 0r0pharyngeal seal pressure was as l0w as 20 cmH_2O (16-40 cmH_2O).

In the present study, The LP levels in gr0up LMA-PCVG was significantly higher than gr0up LMA-VC .The LP levels in gr0up IG-PCVG was significantly higher than gr0up IG-VC. The LP levels in gr0up LMA-VC was nearly the same as in gr0up IG –VC. The LP levels in gr0up IG-PCVG was nearly the same as in gr0up LMA-PCVG at T1and T2 this c0uld be explained by the decelerating inspirat0ry f1ow ventilati0n during PCVG m0de 0f ventilati0n .

In the present study, The PAP levels in gr0up LMA-VC ,gr0up LMA-PCVG, gr0up IG-VC, and in gr0up IG-PCVG sh0w n0 change during the study peri0d at T1,T2,T3 . the statistical analysis between gr0ups was n0n significant at T1,T2,T3 (P > 0.05).

In an0ther study on 100 patients by *Gabb0t and Beringer 2007*, it was observed that peak airway pressures ab0ve 30 cmH_2O were p0ssible in the vast maj0rity 0f patients. The mean leak pressure on sustained pressure with a circle gas f1ow 0f 3L/min and the APL valve c10sed was 24 cmH_2O. They als0 o bserved that the seal pressure appeared t0 impr0ve 0ver time in a number 0f patients and p0sulated that this might be due t0 the therm0plastic pr0perties 0f the gel cuff which may f0rm a m0re efficient seal ar0und the larynx after warming t0 b0dy temperature.
In the present study, the C levels in group LMA-PCVG was significantly higher than group LMA-VC. The C levels in group IG-PCVG was significantly higher than group IG-VC. The C levels in group LMA-VC was nearly the same as in group IG-VC. The C levels in group IG-PCVG was nearly the same as in group LMA-PCVG at T1, T2 and T3.

In the present study, the Vte levels in group LMA-PCVG was significantly higher than group LMA-VC. The Vte levels in group IG-PCVG was significantly higher than group IG-VC. The Vte levels in group LMA-VC was nearly the same as in group IG-VC. The Vte levels in group IG-PCVG was nearly the same as in group LMA-PCVG at T1, T2 and T3.

In PCV, the ventilator produces an inspiratory flow aimed at achieving and maintaining the preset pressure in the proximal airway. This pressure progressively equilibrates with alveolar pressure, resulting in an exponentially decelerating inspiratory flow. The Vt becomes dependent on the preset pressure, the TI, and the respiratory system compliance and resistance.

However, PCV does not guarantee minute ventilation because any change in the respiratory system compliance or resistance will affect the Vt delivery. 

In addition, when using PCV, the flow-time curve is continuously monitored to adjust the optimal inspiratory and expiratory times. The minimum TI is the time required for inspiratory flow to reach zero, which ensures that inspiratory pressure reaches the alveolar level. Further lengthening of TI increases the mean airway pressure and can improve
the arterial oxygenation \textit{Marini JJ, et al 1992}.

Irrespective of the I/E ratio and the duration of the end inspiratory pause, attention should be paid to keep a sufficient expiratory time to allow end-expiratory flow to reach zero and avoid the development of intrinsic PEEP \textit{Bardoczky GJ, 1998}.

However, in pressure-controlled ventilation–volume guaranteed, the micropressor compares the Vt of the previous breath, using exhaled Vt to minimize the possible artifacts due to any leak of the endotracheal tube, and adjusts the working pressure up or down within preset limits to try to deliver the set Vt. However, the term ‘guarantee’ is somewhat misleading, because the Vt does fluctuate around the target value \textit{Abubakar KM et al 2001}.

\textit{Munoz et al, 1993}. Failed to demonstrate any important difference between PCV and controlled mechanical ventilation, with decelerating inspiratory flow waveform. They concluded that the differences in the airway pressures detected by the ventilator were spurious and were due to the place (inspiratory line) where these pressures were measured. The difference between the peak pressure measured in the endotracheal tube has statistical, but not clinical, value and was lower in controlled mechanical ventilation with the decelerating flow waveform.

In addition, \textit{Davis et al 1996} suggested that VCV with decelerating flow waveform and PCV can provide improved oxygenation compared with VCV with square flow waveform when Vt, I/E, and PEEP were held constant in patients with acute respiratory distress syndrome. They believed that this was because of an increase in mean airway pressure and
the salutary effects of the decelerating flow waveform (square pressure waveform) on intrapulmonary distribution of gases.

PCV-VG is considered one of the dual-control, breath-to-breath, pressure-limited, time cycled modes of ventilation. However, inspecting the waveforms leads clinicians to realize that dual control does not guarantee a set VT. "Branson RD et al., 2005"

"Jaber et al. 2005" showed that, during VSV (VSV is a pressure-limited mode that uses a target VT and minute ventilation for feedback control; thus, the level of pressure support is continuously adjusted to deliver the preset VT), a dual-control mode responsive to VT, a ventilator demand increase induced by the additional of dead space leads to a decrease in pressure support, whereas no change occurs during standard PSV. The response to an added respiratory load required greater effort during VSV than during PSV. These findings are in agreement with ours, as pressure control ventilator—volume guaranteed added nothing more than pressure control ventilator either in respiratory mechanics or oxygenation.

However, "Cheema et al. 2001" examined the feasibility and efficacy of volume guarantee in 40 premature newborn infants. In a cross-over trial, they compared synchronized intermittent positive pressure ventilation with and without VG in infants with acute respiratory distress syndrome, and synchronized intermittent mandatory ventilation with and without VG during the weaning phase. In both VG groups, infants were able to achieve equivalent gas exchange using statistically significant lower peak airway pressure, and fewer excessively large VTs during the volume guarantee periods were recorded. Because of their short duration..."
Of the study, no major conclusions could be drawn, other than that the ventilator performs as intended and no short-term adverse effects were evident.

In addition, Samantaray and Hemanth 2011 concluded that, during mechanical ventilation in postcardiac surgical patients without pre-existing lung disease, pressure-regulated volume control mode was found to be advantageous in the later stages of ventilation as it results in significantly lower mean airway pressure and improved oxygenation index compared with the PCV mode. They explained their results by the fact that, although both PCV and PRVC use a decelerating flow pattern, which has been shown beneficial in acute lung injury, PRVC combines the benefits of decelerating flow of PCV with the safety of a volume guarantee at the lowest possible titrated inspiratory pressure. The results of both studies are different from ours as our patients were healthy and paralyzed and we used fixed VT, whereas they made excessive VT. One of the beneficial effects of the guarantee mode. Consequently, their finding cannot be generalized.

Complications

When comparing complications caused by both devices, results were statistically insignificant

Complications during insertion:

In group LMA 5.0% of patients (2 patients) suffered from trauma during insertion of the LMA, in group IG N0 patients suffered from trauma during insertion of the IG
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In group LMA 5.0% of patients (2 patients) suffered from Partial Obstruction during insertion of the LMA, in group IG 5.0% of patients (2 patients) suffered from Partial Obstruction during insertion of the IG.

In group LMA 7.50% of patients (3 patients) suffered from Cough during insertion of the LMA, in group IG 5.0% of patients (2 patients) suffered from Cough during insertion of the IG.

Complications at Recovery:

In group LMA 7.5% of patients (3 patients) suffered from trauma at recovery, in group IG 5% of patients (2 patients) suffered from trauma at recovery.

In group LMA 7.5% of patients (3 patients) suffered from Partial Obstruction at recovery, in group IG 5.0% of patients (2 patients) suffered from Partial Obstruction at recovery.

In group LMA 5% of patients (2 patients) suffered from Cough at recovery, in group IG 5.0% of patients (2 patients) suffered from Cough at recovery.

In group LMA 5% of patients (2 patients) suffered from Laryngeal spasm at recovery, in group IG 5.0% of patients (2 patients) suffered from Laryngeal spasm at recovery.

None of the patients in both groups suffered from desaturation at any time throughout the procedure. This could be attributed to the process of pre-oxygenation done for all the patients before the start of induction with 100% Oxygen using a face mask for three minutes. Also, the patients were ventilated with 100% Oxygen by face mask between
insertion attempts (if any) to provide adequate oxygen reserve. All the patients were also free of cardiovascular or pulmonary disease.
Summary

In 1983 the first supraglottic airway device (SAD), the laryngeal mask airway (LMA™) (Intavent Orthofix, Maidenhead, UK) changed this view. LMA™ combines features of the facemask with those of the endotracheal tube (ET), offering the ease of placement, hands-free maintenance and a relatively secure airway (Brain, 1983).

Several studies have reported the successful, safe use of the Laryngeal Mask Airway (LMA)-Classic devices in patients who are undergoing laparoscopic surgery (Galvin et al., 2007).

The change in the degree of gastric distension with positive pressure during peritoneal insufflation was similar with using either a LMA or an endotracheal tube, and that the ventilator parameters (pulse oxygen saturation, end tidal CO2 tension and airway pressure) were acceptable using either a LMA or an endotracheal tube (Maltby et al., 2000).

The incidence of regurgitation during laparoscopic procedures with a LMA was extremely low (Bapat et al., 1997).

The Laryngeal Mask Airway-Supreme™ (LMA-S™) is a disposable airway device with curved shaft to ease insertion, a gastric access tube to separate the respiratory and gastric tract to minimize the risk of aspiration and high oropharyngeal leak pressure (OLP) (Ferson et al., 2007, van Zundert et al., 2008).

It is constructed of medical grade silicone, and has an inflatable cuff, a reinforced tip, and an elliptical, anatomically shaped, semi-rigid airway tube (TeOh et al., 2010).
The i-gel™ (Intersurgical, W0kingham, UK) has been introduced as a novel supraglottic airway (SAD) device since 2007. Its tip is composed of a soft, gel-like, transparent non-inflatable cuff made of thermoplastic elastomer. It has a widened, flattened stem with a rigid bite-block and an esophageal vent through which a gastric tube can be passed. It was intended to preclude the need for cuff inflation and buccal stabilization to reduce axial rotation and malposition. Many reports found that i-gel™ provides a good seal and effective ventilation during pressure-controlled ventilation (K.Hayashi et al., 2013)

Conventional mechanical ventilations, volume-controlled (VC) or pressure-controlled, are still the principal modes of ventilation used in all age groups (Kucmerek et al., 1996)

VC ventilation has the advantage of delivering a set tidal (Vt), whatever peak inspiratory pressure (PIP) is required to deliver it, whereas in pressure-controlled ventilation delivered tidal volume varies with the compliance and resistance of thorax and lungs but the set peak pressure is not exceeded (Apostolacose et al., 1996)

In an attempt to make ventilation more patient friendly and gentler pressure-controlled ventilation-volume guaranteed (PCV-VG), ventilation was developed which has the distinct theoretical advantages of both VC and pressure-controlled ventilation (Apostolacose et al., 1996)

However, in pressure-controlled ventilation-volume guaranteed (PCV-VG), the Vt and the rate are predetermined and the ventilator delivers the Vt using also a decelerating flow but a constant pressure. The
ventilator adjusts the inspiratory pressure needed to deliver the Vt breath-by-breath so that the lowest pressure is used. PCV-VG begins by first delivering a volume breath at the set Vt. The patient’s compliance is determined from this volume breath and the inspiratory pressure level is then established for the next breath. Hence, PCV-VG combines the benefits of decelerating flow of PCV with the safety of a volume guarantee at a lowest possible titrated inspiratory pressure (Keszler et al., 2006).

**Patients and Methods**: After local ethical committee approval and patient informed written consent, this prospective, randomized, single-blind, clinical study was conducted on 80 patients between 18-60 years old, ASA I, II and III undergoing gynaecological laparoscopic procedures. These patients will be randomly allocated into two main groups each of which will be subdivided into two subgroups:

- **Group 1**: LMA-Supreme™ group (LMA) that will be subdivided into two subgroups:
  - subgroup a: LMA-Supreme™ with volume controlled ventilation (LMA-VC)
  - subgroup b: LMA-Supreme™ with pressure controlled ventilation volume guarantee (LMA-PCVG)

- **Group 2**: i-gel™ group (IG) that will be subdivided into two subgroups:
  - subgroup a: i-gel™ with volume controlled ventilation (IG-VC)
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- subgr0up b: i-gel™ with pressure contro0led ventilati0n v0lume guarntee (IG-PCVG).

Patient preparati0n:

Thirty minutes before the procedure, IV access (A 20G i.v. cannula) will be established and IV midaz0laml 0.01-0.02 mg/kg will be given.

Anesthetic techniques:

General anaesthesia:

Before the induction of general anaesthesia:

Monitoring of the patients in the form of 5-Lead ECG, Arterial Blood Pressure (No invasive blood pressure), arterial line placement and Pulse Oximeter will be conducted.

Choice of the supraglottic device:

- The size of the airway will be chosen in accordance to manufacturers’ recommendati0ns. For the LMA-Supreme™, a size 3 will be used if < 50 kg, a size 4 if 50–70 kg and a size 5 if 70–100 kg for the the i-gel™, a size 3 will be used if 30–60 kg, a size 4 for 50–90 kg and a size 5 for > 90 kg.

Induction of general anaesthesia:

PreOxygenati0n with 02 .100% will be administered via face mask before induction of anesthesia for at least five deep breaths. General
anaesthesia will be induced with propofol 1–3 mg/kg followed by rocuronium 0.6 mg/kg. After three minutes of intermittent positive pressure ventilation (IPPV) using face mask; the device will be inserted by senior anesthesiologists experienced in using the SAD, according to the manufacturer’s recommendations.

Before insertion, a water-soluble lubricant will be applied to the rear of the cuff. With the patient’s head in the sniffing position, the device will be grasped along the integral bite block and introduced continuously into the mouth towards the hard palate until resistance is felt. The cuff of the LMA-Supreme™ will be inflated with air to attain a cuff pressure of 60 cmH2O. Correct insertion will be assessed by proper chest expansion, chest auscultation, the presence of end-tidal CO2 (ETCO2) waveform with a plateau on the capnogram, absence of audible leak, and lack of gastric insufflation. The presence of gastric insufflation will be detected by epigastric auscultation.

A plan will be made to resort to LMA-Classic™ after three failures, and if this failed to endotracheal tube insertion. Particular attention will be paid to the ease of insertion, seal/leak pressure and evidence of trauma from insertion.

After obtaining a proper position with the i-gel™, leak pressure will be measured. The fresh gas flow will be set at 3 L/min and pressure adjustment valve will be set at 40 cmH2O. Leak pressure will be recorded when airway pressure reached a plateau.

A lubricated gastric tube (UltraMed-EGYPT, size 14 FG for the LMA Supreme™, and 12 FG for the i-gel™). These gastric tubes
will be prelubricated with a water-soluble lubricant then inserted down the drainage tube.

Ease of LMA Supreme™, i-gel™ and gastric tube insertion will be grade subjectively on a scale from 1 to 4 (1 = very easy, 2 = easy, 3 = difficult and 4 = very difficult).

Mechanical ventilation will be done with an Avance (GE, CS2, USA). Once a SAD insertion will be achieved, the oropharyngeal cuff leak pressures will be obtained by closing the expiratory valve of the anesthesia circuit with a fixed gas flow rate of 3 L/min and noting the airway pressure at which equilibrium will be reached.

In the volume controlled subgroups, baseline ventilation of the lung will be done with volume-controlled ventilation and a tidal volume of 8 ml/kg ideal body weight (IBW). The initial respiratory rate of 12 breaths per minute will be adjusted during laparoscopy to maintain an end-tidal carbon dioxide pressure of 30-35 mmHg. Five minutes after SAD insertion and mechanical ventilation, the first blood samples will be taken for blood gas analysis; the blood samples will be taken from the radial artery and then peritoneal insufflation will be initiated.

In the pressure controlled volume guarantee subgroups, baseline ventilation of the lung will be done with pressure-controlled ventilation, and this will be initiated with a peak airway pressure that provided a tidal volume of 8 ml/kg IBW with an upper limit of 35 cmH2O. Five minutes after SAD insertion and mechanical ventilation, a first blood will be taken for blood gas analysis and peritoneal insufflation will be initiated.
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In all groups, a carbon dioxide pneumoperitoneum will be induced with a maximal intra-abdominal pressure of 15 mmHg, and the maximal allowed head-down Trendelenberg position will be 15°. Then, the second blood gas analysis will be done 15 minutes after peritoneal insufflation. In all the patients, the FiO2 will be maintained at 50%. The end-tidal CO2, the peak airway pressure, the leak pressure, the compliance, the airway resistance and the arterial oxygen saturation will be continuously monitored during the procedure and they recorded at T1: 5 minutes after insertion of the laryngeal airway, T2: 5 minutes after CO2 insufflation and T3: 15 minutes after CO2 insufflation. The peak airway pressure, the leak pressure, the compliance and the airway resistance will be measured by spirometry via an Avance (GE, CS2, USA). The inspiratory/expiratory ratio (I/E) will be 1:2. Crystallloid solutions (8-10 ml/kg) will be used as maintenance fluid intraoperatively.

After Induction Of general anaesthesia:

- 0.15 mg/kg of rocuronium is given as a maintenance dose every 30 minutes till the end of the procedure. Anaesthesia will be maintained with isoflurane 1 Mac. End tidal CO2 will be monitored after endotracheal intubation with side steam capnography.

Heart rate and mean arterial blood pressure (MAP) will be maintained within ± 20% of the preoperative baseline by giving IV bolus doses of fentanyl approximately 1 mcg/kg if the MAP or heart rate increased more than 20% from the baseline. Hypotension will be treated with intravenous ringer’s solution 15 ml/kg and epinephrine 5 mg as needed to keep MAP more than 60 mm Hg. Bradycardia (HR < 60/min.) will be treated with atropine 0.01-0.02 mg/kg.
• **Recovery:**

- At the end of surgery, the effects of neuromuscular blocking drug will be reversed with neostigmine (0.04 mg.kg)1 and atropine (0.02 mg.kg). The airway device will be removed upon return of spontaneous breathing and eye opening of the patient. The airway device will be then inspected for the presence of visible blood.

- Forty-five minutes later, patients will be assessed by a blinded independent observer for postoperative sore throat, dysphagia or dysphonia.

• **Exclusion Criteria:**

- Major obstructive or restrictive pulmonary disease (defined as less than 70% of the predicted values)

- Suspected difficult intubation (based on a history of difficult airway, inter-incisor distance < 20 mm, cervical spine pathology, modified Mallampati class 4, or thyromental distance < 65 mm).

- Inability to maintain stable mechanical ventilation settings for 30 min (inability to maintain an appropriate end-tidal CO2 and SpO2 less than 94%).

- The patient with history of preoperative sore throat, regurgitation or aspiration, gastric reflux, hiatus hernia, history of allergy to any of study drugs.

- Patients with BMI <18.5 or >30 kg/m2.

- A planned operative time > 4 h.
• **Measurements:**

  - All measurements are done at three different intervals T1: 5 minutes after insertion of the laryngeal airway, T2: 5 minutes after CO2 insufflation, T3: 15 minutes after CO2 insufflation.

• **Lung Mechanics:**

  - Peak airway pressure (cmH20)
  - Leak pressure (cmH20)
  - Compliance (ml/cmH20)
  - Expiratory tidal volume (ml)

• **Haemodynamic parameters:**

  - heart rate and mean arterial blood pressure (MAP) will be recorded.

• **Respiratory parameters:**

  - PH
  - PaO2
  - PaCO2
  - EtCO2
(PaC0₂, partial arterial carbon dioxide tension; PaO₂, partial arterial oxygen, EtC0₂ end tidal C0₂).

- **Complications:**
  - **Complications during insertion:** trauma, partial obstruction, cough.
  - **Complications at recovery:** trauma, partial obstruction, cough, laryngeal spasm.

**Results:** Demographic characteristics showed no difference in age, BMI, ASA physical status, or duration of surgery between groups.

As regards the hemodynamic changes in the present study, there were no statistically significant differences between the two studied groups as regards heart rate, mean arterial blood pressure the leak pressures of both airway devices were almost close with statistically no significant difference between them.

The LP levels in group LMA-PCVG was significantly higher than group LMA-VC. The LP levels in group IG-PCVG was significantly higher than group IG-VC. The LP levels in group LMA-VC was nearly the same as in group IG-VC. The LP levels in group IG-PCVG was nearly the same as in group LMA-PCVG at T1 and T2 this could be explained by the decelerating inspiratory flow ventilator during PCVG mode of ventilation.

The C levels in group LMA-PCVG was significantly higher than group LMA-VC. The C levels in group IG-PCVG was significantly higher than group IG-VC. The C levels in group LMA-VC was nearly the same as in group IG-VC. The C levels in group IG-PCVG was nearly...
the same as in group LMA-PCVG at T1, T2 and T3.

The \( V_{te} \) levels in group LMA-PCVG was significantly higher than group LMA-VC. The \( V_{te} \) levels in group IG-PCVG was significantly higher than group IG-VC. The \( V_{te} \) levels in group LMA-VC was nearly the same as in group IG-VC. The \( V_{te} \) levels in group IG-PCVG was nearly the same as in group LMA-PCVG at T1, T2 and T3.

**Conclusion:**

- Both the laryngeal mask airway supreme and the I-gel airway are suitable airway devices that can be used as alternatives to the endotracheal tube during elective surgeries under general anaesthesia in patients who are not at risk of aspiration.

- Both devices are easy to insert and take almost the same time to establish effective and satisfactory airway for ventilation.

- Insertion of both devices produces similar changes in the hemodynamic.

- The airway sealing pressures of both devices are very close and within the acceptable range to apply positive pressure ventilation.
CONCLUSIONS

From this study the following can be concluded:

- Both the laryngeal mask airway supreme and the I-gel airway are suitable airway devices that can be used as alternatives to the endotracheal tube during elective surgeries under general anaesthesia in patients who are not at risk of aspiration.

- Both devices are easy to insert and take almost the same time to establish effective and satisfactory airway for ventilation.

- Insertion of both devices produces similar changes in the hemodynamic

- The airway sealing pressures of both devices are very close and within the acceptable range to apply positive pressure ventilation.
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- Incidences of mucosal injury and trauma caused by the airway device manifested as postoperative sore throat and bleeding on the device after its removal were minimal and almost the same between both groups.
**RECOMMENDATIONS**

From this study the following can be recommended:

- The use of both the LMA-S and the I-gel airway for the maintenance of the airway during positive pressure ventilation in fasted patients undergoing elective surgeries under general anesthesia.

- Further studies should be carried out to assess the insertion and the use of both devices in spontaneously breathing patients without muscle relaxants for short elective surgeries.

- Further studies should be undertaken to assess the use of both devices in cases of difficult intubation and also to correlate their ease of insertion to the Mallampati score.

- Further studies should be carried out to compare the hemodynamic changes of both devices to that of the endotracheal tube and to the other supraglottic devices.

- Further studies should be undertaken to assess the use of both devices in resuscitation, emergency situations and in patients with full stomach.

- Further studies should be undertaken to assess the use of the I-gel airway as an intubation device under fiberoptic guidance in known or unexpected difficult intubation.