**ORIGINAL RESEARCH**

# Comparison of Ketamine -Propofol with Etomidate - Propofol Intravenous Induction for Supreme LMA insertion in Laparoscopic sterilization surgeries: A randomised control trial

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**ABSTRACT**
Endotracheal intubation is the definitive technique to secure the airway. It is the reliable method of securing the airway and is considered the standard of care for protecting the airway from aspiration.Endotracheal intubation requires expertise and is invasive requiring muscle relaxation. LMA Supremeplacement is quick and simple withnil or minimal use of neuromuscular inhibition and less postoperative morbidity.Appropriate mouth opening and little to no airway reflexes, such as choking, coughing, or laryngospasm, are required for a smooth and effective insertion. Although induction drugs like propofol and etomidate are known to dull laryngeal reflexes, patient movement, coughing, and gagging frequently make the situation uncomfortable along with erratic hemodynamic changes.In the current study, we compared ketamine-propofol mixture (ketofol) with etomidate - propofol (etofol) to assess the Supreme LMA insertion circumstances and hemodynamic changes in laproscopic tubectomies.The present study was a prospective, randomized, double blinded study carried out in a tertiary care hospital in Karnataka. Women undergoing elective laparoscopic tubectomies during the study period (Jan 2018 to Dec 2018) were considered for the present study. The study subjects were allocated to two different groups using software generated random numbers. Assessment of lma insertion among study subjects revealed that majority of patients in both the study groups had mouth opening after induction (84% in etofol group and 88% in ketofol group) (table 2). There was statistically no significant difference in the lma supreme insertion conditions among both the study groups.

**Key words:**Laryngeal Mask Airway (SLMA) Insertion, Ketamine–Propofol (Ketofol), Etomidate-Propofol (Etofol)



## INTRODUCTION

Short gynaecological surgeries such as Tubal ligation is commonly done laparoscopically (minimally invasive) these days. General anaesthesia with controlled ventilation remains the gold standard technique for laparoscopic surgeries.

Problems during the laparoscopic procedures are-Carbon dioxide insufflation (intra/extra peritoneal), Raised abdominal pressures and potential danger of regurgitation and aspiration. The anaesthesiologist must ensure patent airway and adequate ventilation during the laparoscopy.

Endotracheal intubation is the definitive technique to secure the airway. In difficult airway scenarios where endotracheal intubation is arduous, securing the airway becomes problematic. They have been proved to be a reliable method of securing the airway and is considered the standard of care for protecting the airway from aspiration. They have an implicit risk of patient trauma, from vocal cord injury to pharyngeal soft tissue injury and also produce hemodynamic responses to rigid laryngoscopy.

There is a need for an alternative to endotracheal intubation in securing the airway efficiently and a requirement of lesser degree of technical expertise for insertion.[2]

Supraglottic airway devices are frequently used in the airway management, filling a nook between the face

mask ventilation and tracheal tube in terms of both anatomical position and degree of invasiveness. These devices sit outside the trachea but provide a hands-free means of achieving a gas-tight airway. Laryngeal mask airway has gained wide acceptance for routine airway management, difficult airway and in emergency situations.

Shift from the use of endotracheal intubation to supra glottic device insertion for airway management is due to several reasons including ease of placement, lower drug requirement, reduced hemodynamic response, smoother emergence and lower incidence of sore throat.[2]

Dr. Archie Brain designed a new airway device, LMA-Supreme in 2007, with the modifications to separate the respiratory and gastro intestinal tract. It represents the most advanced laryngeal airway yet developed by Archie Brain, the inventor of original LMA airway, the LMA Classic[2,3]

The LMA-Supreme forms two seals: an effective first seal with the oropharynx (oropharyngeal seal)-high Oropharyngeal leak pressure (OLP), for safe controlled ventilation and an innovative second seal with the upper oesophageal sphincter (the oesophageal seal).[6] The optimised distal tip with gastric access functionally separates the digestive and respiratory tracts thus effectively protecting against regurgitation and gastric distension.[7]

The optimal conditions required for insertion of Supreme LMA-adequate jaw relaxation, abolishes reflexes such as Coughing/Bucking (airway reflexes). These conditions are obtained by providing a good depth of anaesthesia.[8]

The most frequently used intravenous anaesthetic agent for its placement is Propofol at a recommended induction dose of (1-2.5 mg/kg) which provides a good depth of anaesthesia and ideal conditions for insertion.

But Propofol often leads to cardio respiratory instability and cerebral depression especially in high risk and geriatric patients at induction levels. Thus, combination of Propofol with another induction agent will help in reducing the dosage of propofol and its side effects.

Ketamine is an induction agent-preserving respiratory drive. It's sympathomimetic action results in increased blood pressure and heart rate. Ketamine and propofol mixture in a poly propylene syringe are chemically stable, physically compatible and can be stored at room temperature.[10,11]

Etomidate, is an induction agent with minimal cardio vascular side effects. Making it especially useful for cardiac-compromised patients.[12,13]

With this background this study was conceptualized to compare the effects of Ketamine-Propofol (Ketofol) and Etomidate-Propofol (Etofol) mixture on ease of supreme laryngeal mask airway (SLMA) insertion and hemodynamics in post-partum females undergoing elective laparoscopic tubectomies.

## METHODOLOGY

The present study was a prospective, randomized, double blinded study carried out in a tertiary care hospital in Karnataka. Women undergoing elective laparoscopic tubectomies during the study period (Jan 2018 to Dec 2018) were considered for the present study. The study subjects were allocated to two different groups using software generated random numbers. One group (ketofol group) was given IV Ketamine (1mg/kg) with IV Propofol (1mg/kg) in the same 20 ml syringe with additional normal saline to make the volume 20 ml in total and the other group etofol group) was administered IV Etomidate (0.2mg/kg) with IV Propofol (1mg/kg) in similar manner.

Patients with ASA grade I/II and modified Mallampatti class I/II were included in the study. Patients with mouth opening of less than 2.5 cm, BMI of more than 30 kg/m2, reduced ulmonary compliance, oral/perioral pathology or any major co-morbidity were excluded from the study. All the inclusion and exclusion criteria were looked into during pre-anaesthetic evaluation. The details of the study were explained to the patients in their vernacular language and an informed written consent was obtained from all patients before enrolling them to the study. A total of 100 post -partum women were enrolled in the study with 50 women in each group. Ethical approval for the study has been obtained from institutional ethical committee.

## STATISTICAL ANALYSIS

The data was collected and entered in the MS Excel master sheet. Data was tabulated and analyzed after completion of data collection using SPSS (Statistical Package for the Social Sciences) version 22. Categorical data have been presented as percentage (%) and quantitative data as mean (standard deviation). Further analysis of qualitative variables was done using Pearson's chi-square test and Fisher exact tests while quantitative variables were analyzed by student T-test.

## RESULTS

The present study was carried out among women undergoing elective laparoscopic tubectomies between Jan 2018 to Dec 2018 and a total of 50 patients each were randomly allotted to two groups (etofol and ketofol group). The baseline characteristics of both the groups were analysed to know the comparability of the group. The mean (±SD) age of patients in etofol group was 28.48 ± 3.69 years and the same for ketofol group was 28.46 ± 4.22 years. The mean weight of study participants in both groups were also similar (etofol group 59.36 ± 5.97 kg and ketofol group 58.32 ± 4.46 kg) (table 1). Upon comparing the ASA grade of the patients it was observed that approximately three-fourth patients in both groups (74% in etofol group and 76% in ketofol group) belonged to ASA grade I and the remaining

were in grade II (26% in etofol group and 24% in ketofol group). Assessment of mouth opening among study subjects revealed that majority of patients in both the study groups had full mouth opening (84% in etofol group and 88% in ketofol group) (table 2). There was statistically no significant difference for all the above baseline parameters among both the study groups (table 1 & 2).

**Table 1: Comparison of baseline parameters of study groups**

| Parameter | Etofol group | Ketofol group | Total | p value |
|---|---|---|---|---|
| **Age (in years)** | | | | |
| Mean | 28.48 | 28.46 | 28.47 | 0.980 |
| Standard deviation | 3.69 | 4.22 | 3.95 | |
| **Body weight (in kg)** | | | | |
| Mean | 59.36 | 58.32 | 58.84 | 0.326 |
| Standard deviation | 5.97 | 4.46 | 5.27 | |

**Table 2: Comparison of ASA grade and mouth opening among study groups**

| Parameter | Etofol group | | Ketofol group | | Total | | p value |
|---|---|---|---|---|---|---|---|
| | No. | % | No. | % | No. | % | |
| **ASA grade** | | | | | | | |
| Grade I | 37 | 74% | 38 | 76% | 75 | 75% | 0.817 |
| Grade II | 13 | 26% | 12 | 24% | 25 | 25% | |
| Total | 50 | 100% | 50 | 100% | 100 | 100% | |
| **Mouth opening** | | | | | | | |
| Full | 42 | 84% | 44 | 88% | 86 | 86% | 0.564 |
| Partial | 08 | 16% | 06 | 12% | 14 | 14% | |
| Total | 50 | 100% | 50 | 100% | 100 | 100% | |

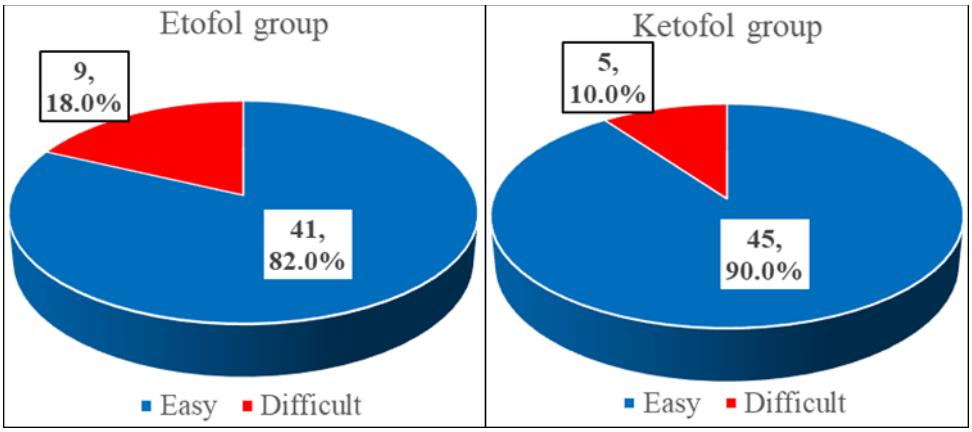



**Figure 1: Ease of LMA supreme insertion among study groups (p value-0.249)**

Ease of LMA supreme insertion is assessed as easy, difficult, and impossible. In etofol group SLMA was easily inserted in 41 patients (82%) and with difficulty in nine patients (18.0%) whereas the same for ketofol group was 45 patients (90%) and five patients (10%) respectively. None of the patients in both study groups were in impossible category. Though the number of patients in whom the SLMA was easily inserted was relatively higher in ketofol group but there was statistically no significant difference.

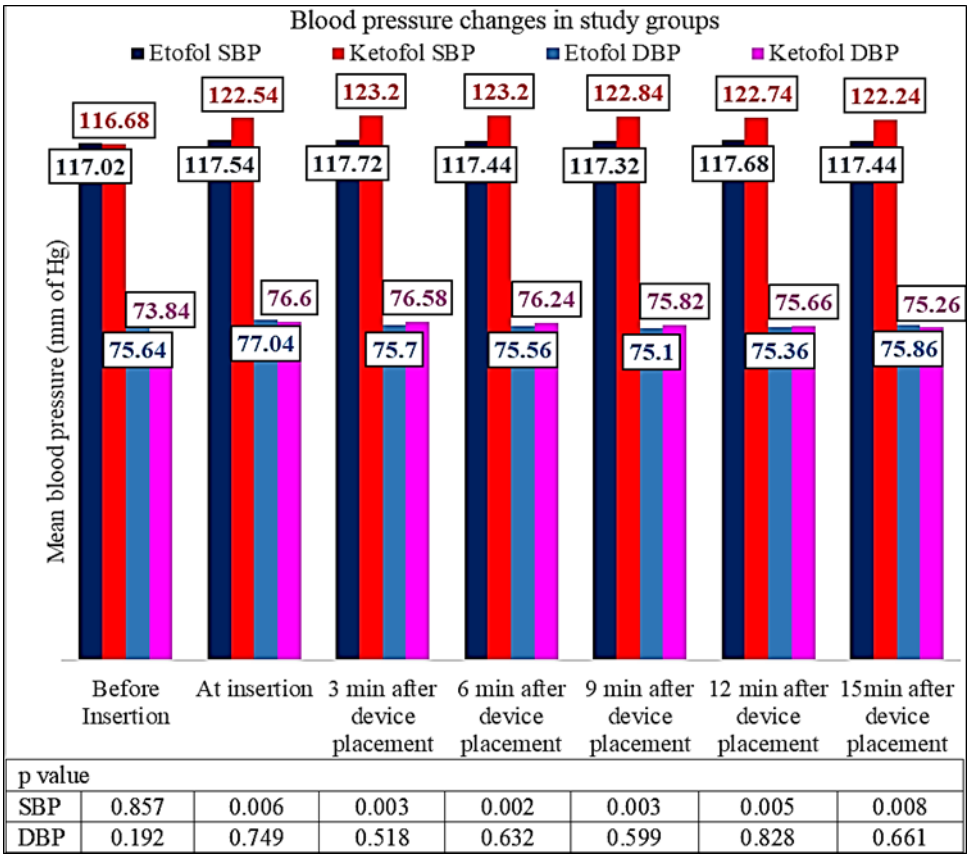
**Table 3: Distribution of study subjects based on associated signs and symptoms during SLMA insertion**

| Parameter | Etofol group | | Ketofol group | | Total | | p value |
|---|---|---|---|---|---|---|---|
| | No. | % | No. | % | No. | % | |
| **Laryngospasm** | | | | | | | |
| None | 42 | 84% | 46 | 92% | 88 | 88% | 0.218 |
| Partial | 08 | 16% | 04 | 8% | 12 | 12% | |
| Total | 50 | 100% | 50 | 100% | 100 | 100% | |
| **Coughing and Gagging** | | | | | | | |
| Mild | 06 | 12% | 03 | 6% | 09 | 9% | 0.739 |
| Moderate | 01 | 2% | 01 | 2% | 02 | 2% | |
| None | 43 | 86% | 46 | 92% | 89 | 89% | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Total | 50 | 100% | 50 | 100% | 100 | 100% | |

**HEMODYNAMIC CHANGES**

The anesthetic agents have a definitive impact on the hemodynamics of an individual. In the present study we monitored the systolic blood pressure, diastolic blood pressure and heart rate of the study subjects from before the start of procedure, during insertion and subsequently every 3 minutes till 15 minutes post placement of SLMA device.




| p value | | | | | | | |
|---|---|---|---|---|---|---|---|
| SBP | 0.857 | 0.006 | 0.003 | 0.002 | 0.003 | 0.005 | 0.008 |
| DBP | 0.192 | 0.749 | 0.518 | 0.632 | 0.599 | 0.828 | 0.661 |

**Figure 2: Comparison of changes in blood pressure among study groups**

The baseline mean systolic blood pressure of study subjects in both the groups were comparable (117.02 mm of Hg in etofol group and 116.68 mm of Hg in ketofol group) with statistically no significant difference between the groups (p value-0.857). Subsequently, from the time of insertion till 15 minutes post insertion the mean systolic BP of etofol group was similar, but subjects in ketofol group had relatively higher blood pressure. There was statistically significant difference in mean systolic blood pressure between etofol group and ketofol group. However, there was no significant difference between the two study groups with respect to mean diastolic blood pressure (figure 2).

**Table 4: Comparison of heart rate among study groups**

| Heart Rate at different time point | Mean (SD) | | p value |
|---|---|---|---|
| | Etofol group | Ketofol group | |
| Before insertion | 87.20 (7.91) | 88.32 (7.02) | 0.456 |
| At insertion | 87.36 (7.02) | 91.36 (6.81) | 0.005 |
| 3 minutes after airway device placement | 87.32 (7.36) | 91.78 (7.68) | 0.004 |
| 6 minutes after airway device placement | 87.14 (7.01) | 91.72 (6.92) | 0.001 |
| 9 minutes after airway device placement | 86.68 (7.33) | 91.80 (7.04) | 0.001 |
| 12 minutes after airway device placement | 86.58 (7.10) | 91.54 (6.71) | 0.001 |
| 15 minutes after airway device placement | 86.70 (7.08) | 91.52 (7.00) | 0.001 |

The baseline heartrate (before insertion) of study subjects in both the groups were comparable with etofol group having a mean heartrate of 87.20 beats/minute and ketofol group having a mean heartrate of 88.32 beats/minute. However, the mean heartrate of ketofol group at the time of insertion of SLMA device was significantly higher (p value-0.005) than the etofol group. Similar were the results

at 3 minutes following placement of device and also the consequent readings till 15 minutes after placement of the device.

## DISCUSSION

For patients having gynecologic laparoscopy, second-generation supraglottic airway devices with high seal airway pressures and a stomach drainage tube are appropriate. Without utilizing a muscle relaxant, a S LMA is inserted under anaesthesia that is deep enough to block upper airway reflexes and prevent undesired reactions such gagging, coughing, bronchospasm, and occasionally laryngospasm. According to investigations by Abdi et al[18] and W.H.L Teoah et al[52], may easily introduce S LMA during laparoscopic procedures.

Propofol, a novel intravenous induction agent, is appropriate for insertion S LMA in today's care ambulatory anaesthesia practice, but it also induces hemodynamic depression, supporting the use of combinations of induction agents and lowering their total dosages.

In contrast to studies by Mehmet Ali Erdogan et al[15] and Ranju singh, Madhur Arora, and Homay Vajifdar[46], which showed better mouth opening in Ketofol group as compared to propofol group, in our study, mouth opening was graded as full in 84% of the Etofol group and 88% in the Ketofol group, showing no difference.Our data showedjaw relaxation was good among most subjects in both the groups, 82% of Etofol group and 88% in Ketofol group. In Kulkarni KR, Dalal NR[43] Study Ketofol group.

## SWALLOWING

In our study, neither the Etofol group (43%) nor the Ketofol group (45%) showed any swallowing response to SLMA insertion.

In the study by Ranju Singh, Madhur Arora, and Homay Vajifdar[46], swallowing response occurred in 6 out of 50 (12%) patients receiving fentanyl and propofol as opposed to 17 out of 50 (34%) patients receiving ketamine and propofol. This difference was statistically significant.

The swallowing response in the Ketofol group in Bacha Aberra, Adugna Aregawi, Girmay Teklay, and Hagos Tasew[42] investigation was nonexistent in 55/60 and 54/60 in the Propofol group.

In the Nirmala.B.C[51] research, the swallowing response was mild in 14/50 patients receiving propofol and 15/50 patients receiving thiopentone sodium with fentanyl, which was not statistically significant. The reaction was moderate in 5/50 patients receiving thiopentone sodium with fentanyl and 0/50 patients receiving propofol.

In our investigation, neither group's head nor body moved in reaction to the insertion of the SLMA: Etofol 82% and group Ketofol 92%. 18% of those in the ETOFOL group and 8% of those in the KETOFOL group responded in part. When the reaction was compared between the two groups, it was statistically insignificant.

In the S Uzun, A Gözaçan, Canbay, and S Ozgen[49] study, head and body movements were substantially more frequent in the Etomidate - Remifentanil group than in the Propofol - Remifentanil group (14/25 developed motions as opposed to 2/25).

In the study by Ranju Singh, Madhur Arora, and Homay Vajifdar[46], 32/50 patients in group and 38/50 patients in group K showed limb and head movements. This variation was substantial.

Less head and body movement was observed in the propofol group compared to the thiopentone group in the study by Patrick Scanlon et al[45].

In the Salman OH[44] research, the Fentanyl + Propofol group demonstrated greater head and body movements than the Nalbuphine + Propofol group.

## EASE OF INSERTION

In our study, LMA Supreme was easy to insert in 41 of the ETOFOL group and 45 of the KETOFOLgroup. In contrast, 5 of the KETOFOL group and 9 of the ETOFOL group reported difficulty inserting.

In Bacha Aberra, Adugna Aregawi, Girmay Teklay and Hagos Tasew42study 59/60 had simple addition of LMA in Ketofol bunch and 58/60 in Propofol bunch

In Shirishkumar Gulabrao Chavan50 study, Simplicity of LMA addition, mean was 2.93 in Propofol bunch and was 2.90 in Sevoflurane bunch

In S Uzun, A Gözaçan, Ö Canbay and S Ozgen49studyLMA addition was troublesome in 19/25 in Etomidate + Remifentanil bunch and was 9/25 in Propofol + Remifentanil bunch. indicating a significant distinction.

In the study conducted by Mehmet Ali Erdogan et al.15, Proseal LMA insertion was challenging in 3/40 of the Ketofol group and in 6/40 of the Propofol group. which is comparable to our study, which found that the Ketofol group had a lower incidence of difficult LMA insertion (5/50), but was not significantly different from the Etofol group.

## COUGHING / GAGGING

In our study, six people in the ETOFOL group and three in the KETOFOL group experienced mild coughing and gagging, while one person in each group experienced moderate coughing and gagging. However, when the two groups were compared, the p value is 0.739.

In the S Uzun, A Gözaçan, Canbay, and S Ozgen[49] study, the gagging and coughing response was significantly different: 8/25 people developed this condition in the Etomidate + Remifentanil group, whereas 2/25 people developed this condition in the Propofol + Remifentanil group.

In the Scanlon P, Carey M, Power M, and Kirby F[45] study, the Propofol group experienced 20% coughing and gagging, while the Thiopentone group experienced 59 percent. In the Salman OH[44] study, a

statistically significant difference was found between the two groups, with the Fentanyl + Propofol group experiencing more coughing and gagging than the Nalbuphine + Propofol group.

In Shirish kumar Gulabrao Chavan[50]study mean of Hacking/Choking was 3.00 in Propofol bunch and 2.97 in Sevoflurane bunch.

Coughing and gagging were observed in 4/50 patients in the Fentanyl + Propofol group compared to 14/50 patients in the Ketofol group in the Ranju Singh, Madhur Arora, and Homay Vajifdar[46] study (p = 0.027). which is comparable to the KETOFOL group (6/50) and the ETOFOL group (3/50) in our research, but there is no significant difference (p = 0.739).

**LARYNGOSPASM**

In our study, 4 in the KETOFOL group and 8 in the ETOFOL group experienced partial laryngospasm.

Total laryngospasm was not common in any of the two groups.

Between the two groups, there was no discernible difference in the prevalence of laryngospasm .

In the Scanlon P[45] research, laryngospasm occurred 9% more frequently in the Propofol group than in the Thiopentone group. (p < 0.05)

Laryngospasm was not observed in either group in investigations by Salman OH[44], Shirishkumar Gulabrao Chavan[50], and Ranju Singh[46] (P = 1.0).

**ATTEMPTS OF INSERTION**

In our study, SLMA insertion was successful on the first try in 84% of the Etofol group and 92% of the Ketofol group.

8 in the ETOFOL group required a second attempt to insert the SLMA, while only 3 in the KETOFOL group required a second attempt. In total, 89 successfully inserted the SLMA on their first attempt, while 11 subjects required a second attempt.

In the Kulkarni KR, Dalal NR[43]study, the number of LMA insertion attempts was statistically insignificant (P = 0.137) but was higher in the Ketofol group (2 attempts were required in 7/40 patients) than in the Butrophanol + propofol group (2 attempts were required in 2/40 patients).

LMA insertion on the second attempt was - 3/60 in the Ketofol group and 2/60 in the Propofol group in the Bacha Aberra[42] study (p = 0.648).

**HEMODYNAMIC PARAMETERS**

The hemodynamic parameters were continuously tracked. HR, SBP, and DBP were tracked at baseline, immediately following SLMA insertion, and at intervals of one minute, three minutes, six minutes, nine minutes, twelve minutes, and fifteen minutes.

Between the two groups, all of the hemodynamic variables were comparable.

**HEART RATE**

Heart rate was 87.20 +/- 7.91 beats per minute in the ETOFOL group and 88.32 +/- 7.02 beats per minute in the KETOFOL group at baseline, respectively, in our study. The readings between the two groups at subsequent intervals were statistically significant.

According Hamzeh Hosseinzadeh et al.[43]; however, in contrast to etofol group, the ketofol group experienced a significant increase followed by a decrease in HR one and six minutes after intubation, respectively.

In Ossama Hamdy Salman[44] Fentanyl+propofol bunch, HR went higher than gauge values 1 and 3 min after cLMA position, then, delicately dipped under benchmark values at 5 minute. The Nalbuphine+Propofol group's HR variations also followed a similar pattern.

Aparna Gundeshwar Kulkarni[14], found that Group Demedetomidine + Propofol had a higher incidence of bradycardia, especially at 1 and 3 minutes after LMA insertion, when the difference in heart rates was statistically significant (P = 0.001). During the remainder of the surgery, the HR of the two groups were almost identical.

Kulkarni KR, Dalal NR[43] study, After LMA insertion, the Ketofol group's PR was significantly higher, and it remained on higher side in the ketamine group throughout. Which is like our review, where Ketofol bunch showed critical ascent in pulse post LMA Preeminent addition.

**SYSTOLIC BP (SBP)**

The mean SBP change at gauge was 117.02(+/ - 9.89) mm of Hg for ETOFOL bunch and 116.68 (+/ - 8.92) mm of Hg for KETOFOL bunch. Ensuing readings between the two gatherings were viewed as clinically and genuinely huge

In Mehmet Ali Erdogan et al15 Systolic pressure was altogether higher in the ketofol bunch contrasted the propofol bunch at t2 (P\0.05) and t3 (P\0.05). There were measurably critical reductions in SBP when contrasted and baseline measurements for the two gatherings consistently

Aparna Gundeshwar Kulkarni14,. The MAP was practically comparative in both the gatherings all through medical procedure, the thing that matters was not genuinely critical (P > 0.05).

Kulkarni KR, Dalal NR43 , noted post induction, group Ketofol showed altogether lesser fall in SBP when contrasted with group Butorphanol + Propofol. After LMA insertion, group Ketofol had a statistically significant increase in SBP compared to group Butorphanol + Propofol. This is comparable to our study, in which the Ketofol group saw a significant rise in SBP following the insertion of LMA Supreme.

In Hamzeh Hosseinzadeh12 study, SBP was more steady in groups Etomidate and Propofol + Etomidate contrasted and group Propofol while the distinction between groups Etomidate and Propofol + Etomidate was not huge featuring the hemodynamic strength in these groups ,diminishing the required propofol portion and addition of etomidate as an adjuvant.

**DIASTOLIC BP (DBP)**

Prior to insertion, the ETOFOL group's mean DBP was 75.64 (+/- 6.03) mm of hg and the KETOFOL group's mean DBP was 73.84 (+/-7.58) mm of hg.

There is no genuine massive distinction between the standard as well as ensuing readings of mean DBP between the two gatherings (P>0.05).

When comparing DBP at various intervals, both groups are comparable to one another.

In the Kulkarni KR, Dalal NR43 study, a statistically insignificant comparison of DBP between the groups at baseline and during the post-induction period was found. However, data shows a statistically significant rise in DBP in group KP after LMA insertion at the first and third minutes.

In Hamzeh Hosseinzadeh12 study, DBP examination, between the three groups with benchmark as well as during post induction period was huge measurably.

**CONCLUSION**

In gynecological laparoscopic surgeries, the use of supraglottic airway devices (SADs) with a gastric emptying tube is increasing.

In laparoscopic gynecological surgeries, the LMA-Supreme, a single-use, latex-free laryngeal mask airway with gastric access, is just as effective as the ETT as an airway device.

A better oesophageal seal, which reduces the risk of gastric distension and aspiration, rapid placement, a lower hemodynamic response, airway trauma, and pharyngolaryngeal morbidity are potential benefits.

In laparoscopic tubectomy surgeries, IV Etomidate (0.2 mg/kg) and Ketamine (1 mg/kg) for Co induction with Propofol (1 mg/kg) provide comparable insertion conditions for LMA Supreme.

However, compared to Ketamine with Propofol induction, Etomidate with Propofol induction produced a stable hemodynamic profile, which may be useful in cases of cardiovascular comorbidities.

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37. Dr Stuart Maxwell Ketamine: Recent Evidence and Current Uses Dr Alistair Gales1†, Clinical Fellow, Royal Cornwall Hospitals NHS Trust, UK 2 Anaesthetic Trainee, Royal Cornwall Hospitals NHS Trust, UK Edited by: Dr William English, Consultant Critical Care Medicine and Anaesthesia, Royal Cornwall Hospitals NHS Trust, UK † Corresponding author email: Alistair.gales@nhs.net Published 12 June 2018
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