International Journal of Medical Research Professionals
P-ISSN: 2454-6356; E-ISSN: 2454-6364
DOI: 10.21276/ijmrp

Original Research Article.

Ease of Insertion and Hemodynamic Changes During AMBU AURA Gain And I-Gel Insertion in Patients Undergoing General Anaesthesia: A Prospective Randomized Comparative Study

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ABSTRACT

Background: Both Ambu Aura Gain and i-gel are promising supraglottic airway devices used during general anaesthesia but have different designs and characteristics. However limited literature evaluates which device has more merits. This prospective, randomized study compares the ease of insertion and hemodynamic changes of Ambu Aura Gain and i-gel in patients undergoing general anaesthesia.

Methods: Two hundred patients aged between 18 and 60 years of both sexes, belonging to American Society of Anaesthesiology grades I and II scheduled for elective surgeries under general anaesthesia at Government Medical College and Rajindra Hospital, Patiala were recruited for the study between April 2019 and November 2020. The patients were divided into Group I (Ambu Aura Gain) and Group II(i-gel). Ease of insertion, hemodynamic parameters and complications were compared.

Results: Ease of insertion was evaluated with insertion procedure, duration and attempts between the groups. i-gel showed better ease of insertion in comparison to Ambu Aura Gain. Post insertion heart rate and diastolic blood pressure was significantly lower transiently in i-gel group. However, there was no statistically significant difference in systolic blood pressure and mean arterial pressure. The peripheral capillary oxygen saturation (Spo_2) was higher in i-gel group and there were no adverse events in both the groups.

Conclusion: Both Ambu Aura Gain and I-Gel are promising supraglottic airway devices but i-gel showed favourable responses regarding ease of insertion and hemodynamic parameters as compared to Ambu Aura Gain.

Keywords: Ambu Aura Gain, i-gel, SAD's (supraglottic airway devices).

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Article History:

Received: 25-02-2022, **Revised:** 02-07-2022, **Accepted:** 30-07-2022

Access this article online	
Website: www.ijmrp.com	Quick Response code
DOI: 10.21276/ijmrp.2022.8.4.004	

INTRODUCTION

Airway management includes a set of maneuvers and medical procedures performed to maintain patency of airway and adequate ventilation.[1] The Laryngeal Mask Airway (LMA) offers a much less invasive way of maintaining the airway as it is placed above the glottis and does not require instrumentation i.e laryngoscopy which is a major cause of the pressor responses.[2]

Of lately supraglottic airway devices (SADs) are gaining popularity as preferred devices for elective and emergency airway management. The Fourth National Audit Project and the All-India Difficult Airway Association (AIDAA) have encouraged the use of second-generation SAD equipped with the passage of a gastric tube in difficult airway scenarios.[3,4] The Insertion of supraglottic airway devices provides smooth induction of anesthesia without hemodynamic instability and their insertion is easier and faster than intubation, especially for those unfamiliar with endotracheal intubation.[5,6]

Ambu® Aura Gain™ (AG) supraglottic airway has a preformed curve which allows easy insertion & rapid placement, also has a built-in gastric port for easy gastric tube placement[7].It is a versatile device used in short surgical, minor therapeutic or diagnostic procedures which accommodates a bigger endotracheal tube (ETT) , has integrated bite absorption area which prevents airway occlusion, has navigation marks for guiding flexible scope, Magnetic Resonance Imaging (MRI) safe, has high seal pressures and made of Phthalate-free material.

i-gel is another single use supraglottic airway device anatomically designed, made of a soft thermoplastic elastomer[8], stable and easier to insert when compared with other supraglottic airway devices.[9,10] It is without an inflatable cuff, achieving a mirrored impression of pharyngeal, laryngeal and perilaryngeal structures providing reliable seal. It consists of elliptical buccal cavity stabilizer which incorporates a circular airway lumen and a lumen

for gastric tube insertion and has a built-in bite block. It is now being widely used in routine elective surgery, resuscitation, and prehospital emergency airway management. Both Ambu Aura Gain and i-gel have their own share of limitations also besides the numerous benefits.

Majority of studies have investigated the performances of ProSeal™ LMA and endotracheal tube in laparoscopic cholecystectomy. There is limited literature available on the comparison of Ambu Aura Gain and i-gel. The primary objectives of our study were to compare ease of insertion, number and duration of insertion attempts, hemodynamic changes during device insertion and maintenance of general anaesthesia and secondarily to note any adverse events during or after the insertion of devices.

MATERIALS AND METHODS

The study was conducted on 200 patients at Government Medical College and Rajindra Hospital, Patiala after taking approval from institution Ethics Committee.

The patients with ASA grade 1 and 2, willing to participate in the study, between 18 and 60 years of age, of both sexes, with mallampati grade 1 and 2 and elective surgeries lasting less than two hours were included. Patients with ASA grade 3 and above, anticipated difficult intubation, with full stomach, severe hepatic or renal disease, regurgitation, with suspected or detected nervous system, respiratory, renal, neuromuscular or psychiatric disorders, cardiovascular abnormalities, baseline heart rate <60 beats per minute, morbid obesity, prone position, refusal for consent and head and neck surgeries were excluded from the study.

Pre-anaesthetic checkup was done a day prior to surgery. Detailed clinical history, general physical examination, systemic examination, Airway assessment and relevant haemodynamic parameters like pulse rate, systolic blood pressure, diastolic blood pressures, respiratory rate were recorded. Relevant investigations like Complete blood count (CBC), Bleeding time (BT)/ Clotting time (CT), Prothrombin time index (PTI), Fasting blood sugar (FBS), Renal function test (RFT), Liver function test (LFT), S. Electrolytes, Electrocardiogram (ECG) and Chest X-ray were checked, and patient were kept fasting for eight hours. A written informed consent was obtained from all patients. All patients received tab Ranitidine 150mg and tab Alprax 0.25mg one night before surgery as premedication. All the patients were randomly divided into two groups of 100 each. Randomization was done by simple envelope method. Group I: Patients in whom Ambu Aura Gain was used and Group II: Patients in whom i-gel was used. Ambu Aura Gain/ i-gel insertion was performed by an anaesthesiologist who was experienced and trained in various types of Ambu Aura Gain/i-gel or other airway insertional devices.

After confirming nil oral status, intravenous access was established with an 18G Cannula on arrival in the anaesthetic room. Pulse oximeter, noninvasive BP apparatus, End tidal carbon dioxide ($EtCO_2$) monitor and ECG leads were connected to the patient in the operation theatre. After stabilization period of 5 min, the baseline values of heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), SpO_2 and $EtCO_2$ were recorded. The patients were preoxygenated with 100% oxygen via a face mask for 5 min and induced with i.v. glycopyrrolate (0.004 mg/kg), butrum (30 mcg/kg), propofol (2mg/kg). On confirming loss of the eye lash reflex, succinylcholine (1.5mg/kg, i.v) was given. After one min, in Group I, Ambu Aura Gain of an appropriate size lubricated with 2% xylocaine gel and in Group II, i-gel lubricated with 2% xylocaine gel was inserted and secured using the standard technique. They were fixed in midline. Air was injected following the manufacturer recommendation in Ambu Aura Gain supraglottic device. Proper placement of both devices was confirmed by bilateral equal chest movements or air entry, absence of gastric insufflations on gentle Intermittent positive pressure ventilation (IPPV) and square wave capnography. Ventilation was adjusted in such a way that the $EtCO_2$ level maintained below 45 mmHg and SpO_2 above 95%. Haemodynamic Parameters-HR, SBP, DBP, MAP, SpO_2 and $EtCO_2$ were recorded just before induction, immediately after insertion and at 1, 3-, 5-, 10- and 15-min. Ease of insertion was compared by four grades.[11]

Grade 1: Excellent (no resistance to insertion).

Grade 2: Good (slight resistance to insertion).

Grade 3: Poor (moderate resistance to insertion).

Grade 4: Impossible.

If Ambu Aura Gain and i-gel insertion was unsuccessful after two attempts, the patients intubated with conventional methods and were excluded from the study.

Statistical Analysis was conducted using IBMM SPSS Statistics (version 20). Data was expressed as mean ±standard deviation or proportions as appropriate. Data sets were checked for distribution pattern. Independent t-test was used to compare the two groups. Chi-square test applied as appropriate. A p value of <0.05 is considered as statistically significant.

RESULTS

The study was conducted on two hundred patients and all of them completed the study successfully. The group I (Ambu Aura Gain) and group II (i-gel) had hundred patients each. The mean age in group I was 43.28±10.34 years and in group II was 41.81±12.57 years. There were 42% males and 58% females in group I, 39% males and 61%females in group II. The mean weight in group I was 66.54±7.97 Kg and in group II was 66.29±8.82 Kg. There was no difference between the groups in terms of age, weight and gender distribution. (Table 1)

There was no significant difference with respect to baseline heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure in both the groups before induction of anaesthesia.

In group I the ease of insertion was grade 1,2,3 &4 in 79%,19%,2%,0% and in group II were 94%,6%,0% 0% patients respectively. Chi-square test was applied to check for the association between the two groups. There was statistically significant difference between the two groups. (P=0.032). The i-gel was significantly easier to insert than Ambu Aura Gain. (Figure 1)

The mean heart rate in immediate post insertion,1,3,5,10 &15 minutes in group I and II are shown as in Fig.2.There was statistically significant difference between the groups in immediate post insertion period. (P=0.038). There was no statistically significant difference between the mean systolic BP between group I and group II at immediate post insertion,1,3,5,10 &15 minutes(P>0.05) (Figure 3). The mean diastolic BP in group I and group II in immediate post insertion and I minute was 84.84±7.06,86.68±6±.96 and 82.33±6.48,84.47±6.46. There was

statistically significant difference between the two groups (P=0.010 & 0.021). However, there was no significant difference between the groups at 3,5,10 &15 minutes (Figure 4). There was no statistically significant difference between group I &II in mean arterial pressure in immediate post insertion, I, 3, 5, 10 & 15 minutes (P>0.05) (Figure 5). The mean SpO_2 values in immediate post insertion, 3, 5, 10 &15 minutes in group I and group II were 97.25±3.27, 99.42±2.03 (P=0.001); 96.10±2.01, 95.32±2.12 (P=0.008); 96.58±2.70, 94.76±1.76 (P=0.001); 95.21±1.96, 93.57±5.73 (P=0.007) and 95.84±3.26, 92.96±5.78 (P=0.001). There was statistically significant difference. However, there was no significant difference between the groups at I min (p=0.475). Table:2 There was no statistically significant difference between the groups in EtCo2 values in immediate post insertion period, 1, 3, 5, 10 &15 minutes. (P>0.05). There were no adverse events in both the groups.

Table 1: Distribution of patients according to Age, Weight and Gender

Parameters	Group I	Group II	P-value		Significance
(1) Age (yrs)	43.28±10.34	41.81±12.57	0.076		(NS)
(2) Weight (Kg)	66.54±7.97	66.29±8.82	0.877		(NS)
(3) Gender (Male/Female)	42%/ 58%	39%/61%	Chi-Square value	0.141	(NS)

Table 2: Comparison of Spo_2 at different time interval in Group I and Group II

Time Interval	Group	N	SpO_2		p-value	Sig.
			Mean	Std. Deviation		
Immediate Post Insertion	I	100	97.25	3.27		
	II	100	99.42	2.03	0.001	S
1 min	I	100	95.90	1.81		
	II	100	96.09	1.93	0.475	NS
3 min	I	100	95.32	2.12		
	II	100	96.10	2.01	0.008	S
5 min	I	100	94.76	1.76		
	II	100	96.58	2.70	0.001	S
10 min	I	100	93.57	5.73		
	II	100	95.21	1.96	0.007	S
15 min	I	100	92.96	5.78		
	II	100	95.84	3.26	0.001	S

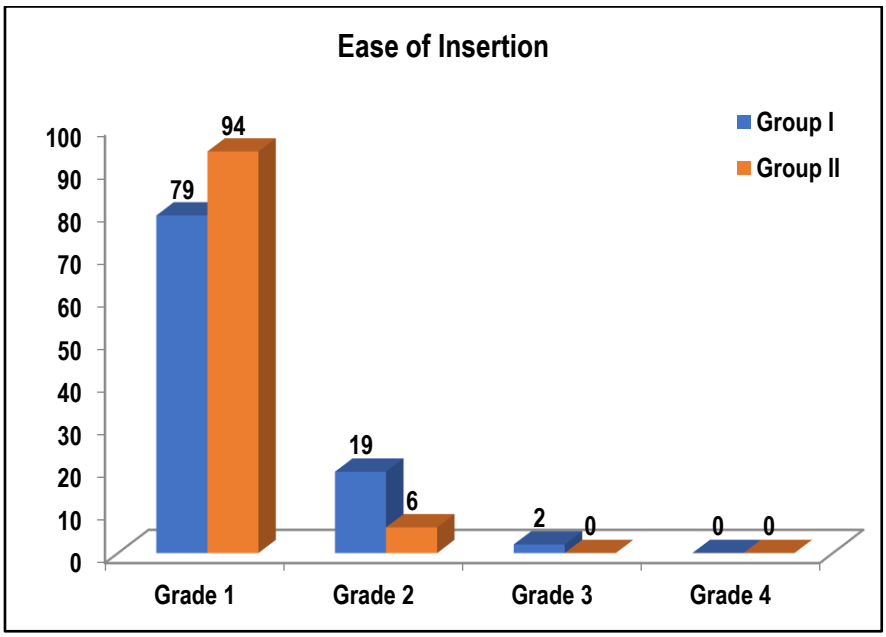

Fig 1: Ease of Insertion

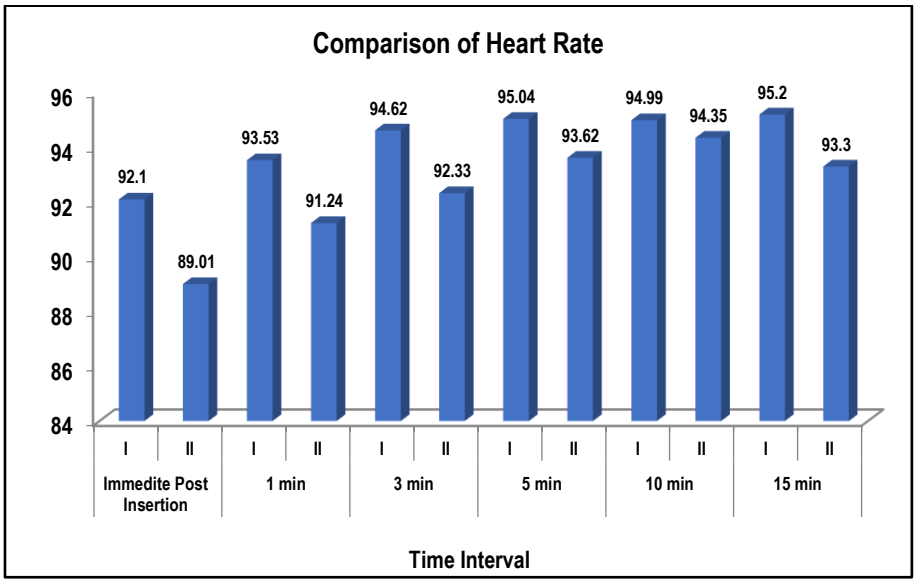

Fig 2: Comparison of Heart Rate

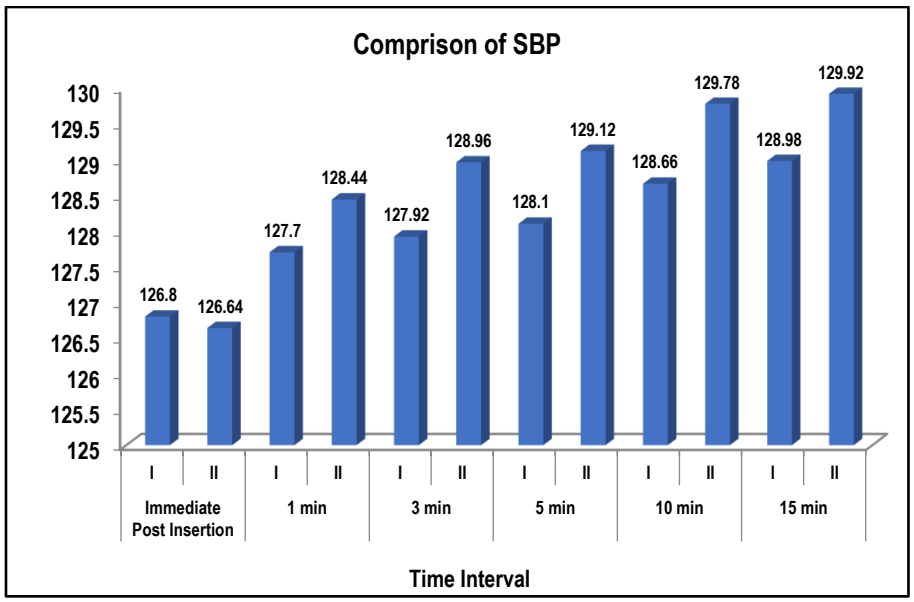

Fig 3: Comparison of SBP

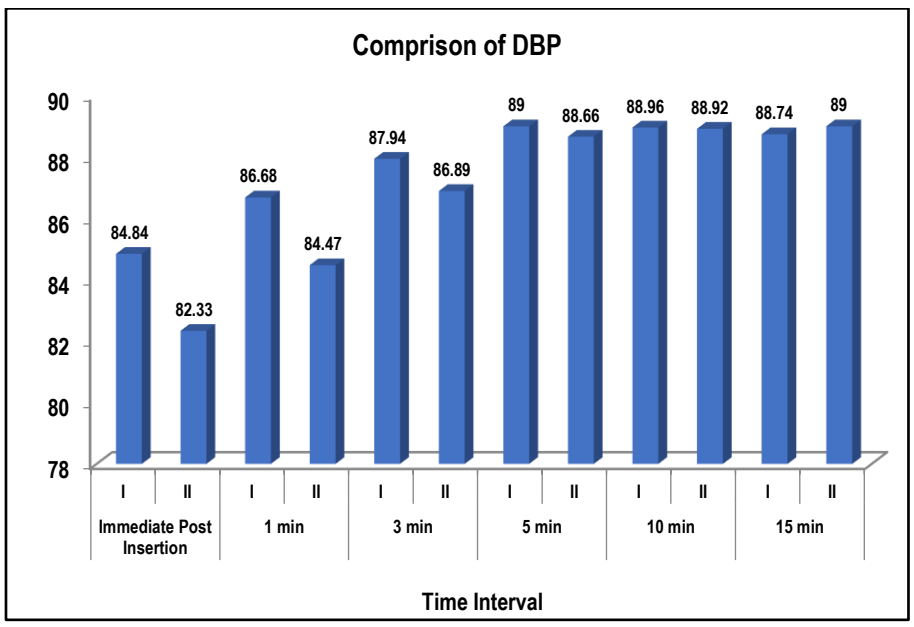

Fig 4: Comparison of DBP

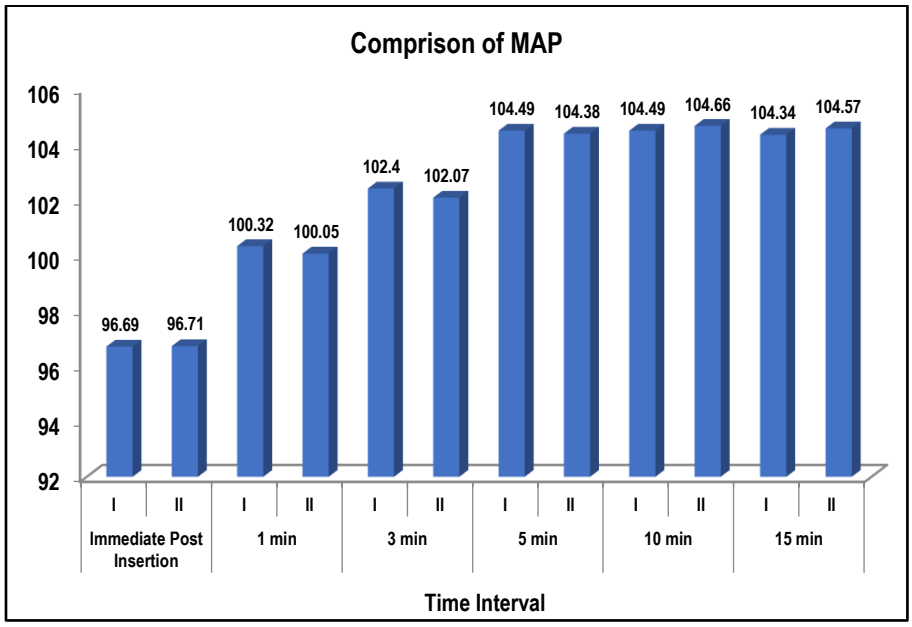

Fig 5: Comparison of MAP

DISCUSSION

In our study we compared the use of Ambu Aura Gain and i-gel supraglottic airway devices during surgical procedures under general anaesthesia. The demographic profile of the patients i.e Age, weight and gender distribution are similar and there was no statistically significant difference between the groups (Table: 1). The important finding of this study was that both Ambu Aura Gain and i-gel are successful airway devices as far as first attempt success rates are concerned but ease of insertion was significantly more with i-gel. (p=0.032). There was more grade I patients in i-gel group as compared to Ambu Aura Gain group which included grade I, II & III patients (Figure: 1). In literature there are limited data comparing Ambu Aura Gain and i-gel. Our study findings are in corroboration with that of Sabuncu U et al who studied the time taken and attempts of SAD's and concluded that i-gel^{R} was easily inserted as compared to ETT & Aura Gain (P=0.041).[12] Milhara T et al also found that five patients in i-gel group and two patients in Ambu Aura Gain group required second insertion attempt, four patients in i-gel group and one patient in Ambu Aura Gain group required airway manipulation once both Ambu Aura Gain and i-gel had high insertion success rates and suitable for clinical use(p=0.031).[13] In another study, Madeshia A et al recognized that 90% of children had no resistance during insertion of Ambu Aura gain and 93% during insertion in i-gel^{TM}. However moderate resistance was felt in 10% of children in Aura Gain group and 6.67% children in i-gel ^{TM} group respectively and there was statistically significant difference(p=0.02).[14]

The groups were comparable as far as preinduction parameters of HR, SBP, DBP, MAP, SpO_2, $EtCO_2$ are concerned as there was no statistically significant difference amongst them(p>0.05).

Another primary outcome seen was the effect on haemodynamic responses during the procedure which were measured in immediate post insertion period and at 1, 3, 5, 10 & 15 minutes. There was significantly higher heart rate in Ambu Aura Gain group in immediate post insertion period (Figure:2) as compared to study by Madesia A et al where there was significant increase in heart rate after insertion of airway devices in both the groups but difference was not statistically different(p=0.58).[14] This could be due to induction by thiopentone in their study as compared to propofol in our study. There was significant difference in DBP in immediate post insertion and at I min between the groups (Figure:4) which is contrary to results found in Sabuncu U et al[12] and Madeshia A et al[14] in which no significant increase in DBP was found. The transient rise in heart rate and DBP could be due to irritation caused in supraglottic area during insertion as it could be due to increased sympathetic reflex and sympathoadrenal activity[15] as Ambu Aura Gain cuff needs to be inflated while i- gel has non inflatable cuff that adjust with the hypopharynx itself. The intensity of response is also related to the intensity of stimuli applied to the base of tongue.[16] These could be well tolerated in patients without comorbidity but can cause concern in patients with coexisting cardio or cerebrovascular diseases.[17] There were no significant changes in SBP and MAP in our study (p>0.05) which is contrary to that of Sabunchi et al as significant difference in mean SBP was detected (p=0.017) which could be due to muscle relaxant rocuronium[12] used in their study as compared to vecuronium in our study which stabilizes the haemodynamic parameters.

There was significant difference in SpO_2 parameters between the groups in immediate post insertion, at 3, 5, 10 & 15 min which might be because of lesser time taken for resuming adequate ventilation in i-gel as compared to Ambu Aura Gain. This is very much in concordance with study by Subunchi et al (p=0.05).[12] However, Madeshia et al[14] found no significant difference in SpO_2 recordings in the study groups.

There was no significant difference detected in $EtCO_2$ parameter which very much corroborates with finding in the studies done by Sabunchi U et al[12] and Madeshia A et al.[14]

During laparoscopic surgeries the risk of passive regurgitation from stomach increases due to gastric insufflation[18].All our insufflations were performed in supine position with abdominal insufflation pressure of 8-10 mmHg (<15 mmHg) and all procedures were completed in reverse trendelenberg position with tilt of <15 degrees. This could be the reason for no aspiration in our study which is very much in line with the study findings enumerated by Park et al in his research.[19] But in perioperative

period one patient in their study had laryngospasm post extubation and one patient in each group had soft tissue damage while there were no peri and post operative adverse events noted. There were no adverse events in both the groups in our study.

CONCLUSION

Both Ambu Aura Gain and i-gel are promising SAD's used during general anaesthesia for laparoscopic cholecystectomy and other procedures as far as application of ease of insertion, attempts, perioperative and postoperative complications are concerned. However, i-gel showed better ease of insertion and haemodynamic stability as compared to Ambu Aura Gain.

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Source of Support: Nil. **Conflict of Interest:** None Declared.

Cite this article as: Gurlivleen Kaur, Sukhwinder Kaur, Balwinder Kaur, Parmod Kumar, Tripat Kaur Bindra. Ease of Insertion and Hemodynamic Changes During AMBU AURA Gain And I-Gel Insertion in Patients Undergoing General Anaesthesia: A Prospective Randomized Comparative Study. Int J Med Res Prof. 2022 July; 8(4): 15-20. DOI:10.21276/ijmrp.2022.8.4.004