International Journal Dental and Medical Sciences Research
Volume 5, Issue 3, May - June 2023 pp 643-650 www.ijdmsrjournal.com ISSN: 2582-6018

Comparison of the clinical performance of I-gel, LMAProseal and LMA Supreme in children undergoing elective surgery- a randomized clinical trial CTRI/2018/04/013102

Dr. Amrita Mishra , Senior Resident, Department of Anaesthesia, Safdarjung Hospital

Dr. Vandana Talwar, Head of Department, Professor and consultant, Department of Anaesthesia, Safdarjung Hospital, New Delhi

Dr. Divya Gautam, Senior Resident, Department of Anaesthesia, Safdarjung Hospital

Dr. Pratibha Mudgal(Corresponding author), Assistant Professor , Department of Anaesthesia, Safdarjung Hospital, New Delhi

Date of Submission: 09-06-2023 Date of Acceptance: 20-06-2023

ABSTRACT:
Supraglottic airway device (SGA) is a generic description for devices that facilitate oxygenation and ventilation without entering into the vocal cords, thereby minimising postoperative complications. It blends the features of facemask and endotracheal tube, providing hands free maintenance of a relatively secured airway. Though various SGA devices have been widely compared in adults, paediatric sizes have been made available only in the last few years. Methods: we conducted a prospective, randomised clinical study on 120 ASA I & II pediatric patients in the age group of 3 to 10 years undergoing elective surgery, and divided into 3 groups (LMA Proseal, LMA Supreme and I-gel groups). Comparison of time of insertion, ease of insertion, airway leak pressures, and fibreoptic (FOB) assessment of device placement was done between these groups.Results: Time of insertion was recorded least with LMA Supreme group (p value=0.001). LMA Supreme and LMA Proseal were significantly easier to insert as compared to I-gel(p=0.004 and p=0.039 respectively). I-gel maintains a significantly higher airway leak pressure and has a better FOB view as compared to LMA Proseal(p value<0.001 and p value=0.001 respectively), which in turn is significantly better than LMA Supreme(p values=0.012 and p value<0.001 respectively).Conclusion:I–gel and LMA Proseal provide a significantly better airway seal as compared with LMA Supreme, thus making them the supraglottic devices of choice for paediatric laparoscopic surgery. The better fibreoptic view makes I-gel an ideal conduit for endotracheal intubation in difficult airway situations.
The least time of insertion and ease for insertion and ease of insertion makes LMA Supreme a valuable asset in emergent airway situations. Thus, the usage of supraglottic devices should be individualized depending upon the nature of surgery and airway management during anaesthesia.
Keywords – airway management, pediatric, supraglottic

MAIN POINTS
1. Time and ease of SGA insertion was found to be significantly less with LMA Supreme
2. LMA Supreme maybe a valuable asset as backup device in emergent airway situations, where it may function as an alternate to endotracheal intubation.
3. I-gel maintains a significantly high airway leak pressure when compared with LMA Proseal and LMA Supreme, thus making it the supraglottic device of choice in pediatric laparoscopic surgery.
4. The better fibreoptic view with I- gel makes it an ideal conduit for endotracheal intubation in difficult airway situations.

I. INTRODUCTION

Supraglottic airway device (SGA) is a generic description for devices that facilitate oxygenation and ventilation without entering through the vocal cords, thereby minimising postoperative complications. It blends the features

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Volume 5, Issue 3, May - June 2023 pp 643-650 www.ijdmsrjournal.com ISSN: 2582-6018

of facemask and endotracheal tube, providing hands free maintenance of a relatively secured airway. [1]

SGA offers several advantages over endotracheal intubation: ease and lesser time for insertion, avoidance of laryngoscopy and muscle relaxants, less hemodynamic and intraocular pressure changes and decreased stimulation of a reactive airway. SGAs are an established part in paediatric airway management both during routine or emergency surgeries as conduits in difficult airway management strategies and also for resuscitation.[1]

Various SGAs are currently available in paediatric sizes. LMAProseal is a reusable device made of silicon with an additional drain tube parallel to the airway tube for venting of gastric contents. The sizes currently available in children are 1, 1.5, 2 and 2.5.[2,3,]. LMA Supreme was launched in March 2007, is made of PVC and blends features of LMA Proseal and LMA Fast trach. The drain tube enters through the centre of the device. It is available in sizes 1.5, 2 and 2.5 in children. [4, 5]I-gel has been in use in paediatrics since 2010. It has a non-inflatable laryngeal mask of thermoplastic elastomer that helps to improve the airway seal at body temperature. It is available in sizes 1.5, 2 and 2.5.[4,6,] Presently a number of paediatric sizes of SGA devices are available. These include the LMA classic, Flexible LMA, Cobra perilaryngeal airway, Air Q and LMA-Unique.

Though various SGA devices have been widely compared in adults, pediatric sizes have been made available only in the last few years. A meta-analysis in 2017 described different supraglottic airway devices in pediatric patients and emphasized the need for further research in this area[7].

In this prospective, randomised clinical study we compared the performance characteristics of three second generation SGA devices- LMAProseal, LMA Supreme and I-gel in children undergoing surgery requiring LMA insertion. Our primary objective was to compare the airway leak pressures and secondary objective was to compare insertion characteristics and fibreoptic assessment of device placement between LMAProseal, LMA Supreme and I-gel in paediatric patients undergoing elective surgery. As per the available literature, performance characteristics of three SGA devices have never been compared together in the paediatric age group.

II. MATERIALS AND METHODS

This prospective randomised clinical study was conducted in the Department of Anaesthesia and Intensive Care at XXX Hospital, written informed consent from the parents and ethical committee clearance was obtained for all patients. It included 120 paediatric patients divided into three groups of 40 each (Group P – LMAProseal, Group S – LMA Supreme and Group I – I-gel), based on a computer generated list. Children in the age group of 3-10 years, ASA Grade I and II, with normal airway and scheduled for elective surgery undergoing infra-umblical surgeries were included in the study. Those with active respiratory tract illness on the day of surgery or with potential risk for gastro-oesophageal regurgitation were not included in the study.

All patients were given syrup pedichloryl 50 mg/kg, two hours prior to surgery. The standard induction technique consisted of inhalational induction with sevoflurane 8% and 50% N_2O and O_2, followed by obtaining an intravenous (IV) access and fentanyl administration at 2ug/kg, and propofol 1mg/kg, if required. After checking ventilation of lungs, muscle relaxation with vecuronium 0.1 mg/kg was provided, and a well lubricated SGA using water based gel was inserted after ventilating for 3 minutes with O_2, N_2O and sevoflurane. Size of the SGA was decided as per the patient's ideal body weight and manufacturer's recommendations. The cuff was inflated to reach an intra-cuff pressure of 60 cm of H_2O, and ease and time of insertion were noted. The time of insertion was measured from facemask removal till bilateral chest movement was observed. Ease of insertion was graded on a subjective scale of 1-4(none/mild/moderate resistance/inability to place the device).[3]Number of attempts, airway manipulations(neck extension or flexion/ chin lift/ jaw thrust/gentle manipulation of device)and complications during insertion were noted.

Effective airway was judged by bilateral chest movement, bilateral equal air entry heard on auscultation, square waveform in capnograph tracing with value, and without gastric insufflation. In the event of failure of device insertion - airway obstruction (SpO_2< 92%, obstructive noises or abnormal thoraco-abdominal movements) or

International Journal Dental and Medical Sciences Research
Volume 5, Issue 3, May - June 2023 pp 643-650 www.ijdmsrjournal.com ISSN: 2582-6018

inadequate ventilation (not able to generate adequate tidal volume or a significant leak); the SGA was removed and re-insertion attempted. Number and type of manipulations, reinsertion attempts and complications, if any, were noted. After three attempts of device placement it was considered a failure and endotracheal intubation was done thereafter.

SGA insertion was followed by gastric tube insertion, and its placement was confirmed by injecting air and epigastric auscultation. Ease, time of insertion and number of attempts required for gastric tube insertion were noted. [3,5]The time of insertion was determined from the start of insertion of the gastric tube till placement confirmation was noted. Ease of placement was graded on a scale of 1 to 3 as easy, difficult or inability to pass the gastric tube.

After an effective airway was established, Airway leak pressure was measured. After closing the expiratory valve with a fresh gas flow of 3L/min , plateau is reached without allowing the pressure to reach above 40cm of H_2O , and then it was released completely. The value at which airway pressure reached a plateau was noted as the airway leak pressure. During leak pressure testing epigastric auscultation was performed to note for any presence or absence of gastric insufflation.

Anatomical placement of the SGA device was determined using a flexible fibreopticscope(FOB) of size 3.7 mm. It was introduced till 1 cm away from the airway opening proximally and the view was graded from 1 to 5(grade 1- only larynx was seen, grade 2- larynx alongwith posterior surface of epiglottis was seen, grade 3- larynx and tip of anterior surface of epiglottis seen, less than 50% visual obstruction of epiglottis to larynx, grade 4- downfolding of epiglottis with its anterior surface was seen, more than 50% visual obstruction of epiglottis to larynx, grade 5- epiglottis downfolded and larynx not visible .[4,8]

Maintainance of anaesthesia was done with isoflurane in N_2O and O_2 with supplementation of vecuronium and fentanyl when required. Hemodynamic parameters, quality of the airway (clear, partial intermittent obstruction, complete intermittent obstruction ,complete obstruction) and inhaled and exhaled tidal volumes were noted, in addition to routine monitoring intraoperatively. Number and method of airway manipulations, failure of device – defined as inadequate ventilation (inability to generate 7-10 ml/Kg tidal volumes or an audible leak through the drain tube despite device advancement), end tidal CO_2> 44 mm Hg, airway manipulations that could not be correct obstruction, or need for replacement of device with a tracheal tube, and any other adverse effects were noted.

Isoflurane was switched off 5 minutes prior, and neuromuscular blockade was reversed with IV neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg at the end of surgery. SGA device was removed after oropharyngeal suctioning when the patient became awake and was responding to commands. Complications like airway activation (coughing, bronchospasm and laryngospasm),oxygen saturation (SpO_2) less than 92%, blood staining of device and any lip or dental trauma were noted. Patients were monitored till 24 hours postoperatively for any complications or side effects.

III. STATISTICAL ANALYSIS

The presentation of the Categorical variables was done in the form of number and percentage (%). On the other hand, the quantitative data with non-normal distribution as median with 25th and 75th percentiles.The data normality was checked by using Kolmogorov-Smirnov test. The cases in which the data was not normal, we used non parametric tests. The following statistical tests were applied for the results:

1. The comparison of the variables which were quantitative and not normally distributed in nature were analysed using Kruskal Wallis test. If p-value was <0.05 then post hoc analysis by Dunn's multiple pairwise comparison test was carried out.
2. The comparison of the variables which were qualitative in nature were analysed using Chi-Square test. If any cell had an expected value of less than 5 then Fisher's exact test was used.

The data entry was done in theMicrosoft EXCEL spreadsheet and the final analysis was done with the use ofStatistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, ver 25.0.

For statistical significance, p value of less than 0.05 was considered statistically significant.

IV. RESULTS

Demographic characteristics of patients and surgery duration were found comparable between the groups. Size 2 SGA was the most commonly inserted in all the groups. (Table 1)

Time taken for SGA insertion was found to be significantly less in Group S as compared to Group P (p value=0.001) and I (p value<0.001)(Table 2).

There was no significant difference between groups in the number of attempts, airway manipulation and complications during SGA insertion or in gastric tube insertion characteristics (Table 2).

Airway leak pressure was significantly higher in Group I vs Group P(p value<0.001), Group P vs Group S(p value=0.012) and in Group I vs Group S(p value<0.001) (Table 3 and figure 1).

In Group P, majority of patients (60%) were found to have grade 2 FOB view, in Group S majority of patients (60%) were found to have grade 3 FOB view and in group I majority of patients (72.5%) were found to have grade 1 view. Group I was found to have a significantly better FOB view as compared to Group P (p value=0.001) and Group S (p value=0.001), and Group P had a significantly better FOB view than Group S (p <0.001),(Group I>Group P>Group S), (p value<0.001). (Table 4)

There was a significant difference in ease of device insertion between the groups (p=0.004). Ease of insertion was graded as 1 in 92.5%, 97.5% and 70% of patients in Groups P, S and I respectively. Group P (p=0.039) and Group S (p=0.004) were found to be significantly easier to insert as compared to Group I.(Table 5)

All the groups were comparable to each other as regards the haemodynamic parameters, quality of airway and inhaled and exhaled tidal volumes. Postoperative complications were noted in 7.5% of cases in all the groups, with no significant differences between them.

V. DISCUSSION

Supraglottic airways are placed above the larynx to secure the patient's airway. They can also be used to facilitate endotracheal intubation, and have become an important part of in paediatric airway management, especially in difficult airway situations and neonatal resuscitation.[9]In this prospective randomised study, we compared the performance characteristics of three second generation SGAs, I-gel, LMA Supreme and LMAProseal in children undergoing elective surgeries.

In our study, we found that I-gel maintains a significantly higher airway leak pressure and has a better fibreoptic (FOB) view as compared to LMA Supreme and LMAProseal in children. However, the LMAProseal and LMA Supreme are significantly easier to insert as compared to the I-gel.Time taken for insertion of LMA Supreme was significantly less as compared to LMAProseal and I gel.

I-gel was found to have a significantly higher airway leak pressure, 23.70±1.57 cm of H_2O as compared to the LMAProseal (20.02±2.20 cm of H_2O)and LMASupreme (18.62±2.01cm of H_2O) and LMAProseal was found to have a significantly higher airway leak pressure as compared to LMA Supreme . Thus we found that I-gel maintains a significantly higher airway leak pressure followed by LMAProseal, followed by LMASupreme.

Various other studies have compared I-gel with LMAProseal and have found a higher airway leak pressure with I-gel. Jagannathan et al compared I–gel with LMASupreme in ASA Grade I-III children in the age group of 3 months-11 years. Median airway leak pressure was significantly higher for the I-gel (20 cm of H_2O vs 17 cm of H_2O).[4] Das et al compared size 2 I-gel with the LMAProseal and LMA Classic of the same size in 90 ASA Grade I and II children undergoing lower abdominal surgeries. The airway leak pressure of I-gel (27.1±2.6 cm of H_2O) was significantly higher than that of the LMAProseal (22.73±1.2 cm of H_2O) and the LMA Classic (23.63±2.3 cm of H_2O).[10] Mitra et al also compared I-gel with LMA Prosealin 60 ASA I and II paediatric patients, and found that I-gel maintains a significantly higher airway leak pressure (27.12±1.69 vs 22.75±1.46 cm of H_2O). [11]

ZehraIpeket al did comparison between size 2 LMA Proseal and size 2 LMA Supreme in children with spontaneous breathing. The oropharyngeal leak pressures were found to be higher with LMA Proseal (24.6+/- 5.5 vs 21.3+/- 4.2 respectively).[12]

The results of our study are consistent with most of the other studies mentioned above. I-gel has a non-inflatable laryngeal mask made of a gel like thermoplastic elastomer designed to improve the airway seal as the device warms to body temperature. The soft, non-inflatable cuff is designed to provide an anatomical impression that fits over the laryngeal inlet, thus providing an effective seal to support high airway pressures.LMA Proseal was found to have higher airway leak pressures as compared to LMA Supreme. Although the paediatric- sized Proseal doesn't have a dorsal cuff, but the cuff being made up of silicone , has greater ability to mould into shape easily as compared with polyvinyl chloride cuffs this gives it better airway sealing characteristics. Thus making I-gel and LMA Proseal more useful in laproscopic surgery.[13,14]

We assessed the anatomical position of the SGA in relation to the glottic opening by passing a paediatric fibreoptic bronchoscope through the airway tube. I-gel was found to have a significantly better FOB view as compared to LMAProseal and LMASupreme; and LMAProseal was found to have a significantly better FOB view as compared to LMASupreme. Thus FOB view was found to be significantly better with I-gel in which majority of patients (72.5%) had a Grade I view, as compared to LMAProseal in which majority (60%) had a Grade 2 view, and LMA-S in which majority (60%) had a Grade 3 view.

In an observational study by Beringer et al to investigate the efficacy and usability of the I-gel in children, FOB inspection revealed a clear view of the cords in 87% of cases.[6] I-gel has a built-in bite block and an epiglottic rest to prevent epiglottic downfolding, thus revealing a clear view of the vocal cords, ie Grade I view is seen in majority of the patients. On the other hand epiglottic downfolding occurs with LMAProseal and LMASupreme, thus reducing clarity of the FOB view.

Fukuhara et al compared the fibreoptic views of I-gel and LMAProseal in 134 children and found that I-gel was significantly better than LMAProseal, especially in bigger children.[15] Hosten et al compared LMAProseal with LMASupreme in 60 paediatric patients in the age group of 9 months-5 years. They reported that fibreoptic views were significantly better with LMAProseal than with LMASupreme. Thus findings in the above mentioned studies are consistent with our study.[16]In contrast, N. Jagannathan et al compared LMAProseal and LMASupreme in children between 6 months-6 years of age and found no difference in the fibreoptic assessment of the device between the groups.[6] The better fibreoptic view correlates with adequate ventilation and ease of using the supraglottic device as a conduit for endotracheal intubation.[17]

In our study, insertion time was found to be significantly less with LMASupreme (14.25±3.11 secs) as compared to LMA Proseal(17.50±4.24 secs) and I-gel (18.38±4.29 secs). No significant difference was found in the time for LMA insertion between LMAProseal and I-gel. Our results were consistent with other studies. Kus et al compared LMASupreme and I-gel in difficult paediatric airway, and found insertion time for LMASupreme to be significantly less than I-gel, ie 11.2±1.8 vs 13.5±2.4 seconds.[18] LMASupreme with its more rigid and curved design, does not require digital guidance or assistance with other equipment and thus requires lesser time for insertion and can prove beneficial in emergency situations.[19]On the other hand,I-gel is bulky with has a wide conical semi-rigid non-inflatable mask, which may prolong time for device insertion.[20]

In a meta-analysis comparing all the three devices, LMASupreme was found to be easier to insert as compared to I-gel.LMA Supreme provided similar oropharyngeal leak pressure and first insertion success rate as compared to LMA ProSeal and I gel, but had significantly faster insertion rates. [7]

Ease of insertion of SGA was graded on a subjective four point scale. In our study, LMA

Proseal and LMASupreme were found to be easier to insert as compared to I-gel. No resistance during insertion of LMA Proseal, LMA Supreme and I-gelwas found in 92.5%, 97.5% and 70% of patients respectively. First attempt insertion rate was 97.5% with LMASupreme, 95% with LMA Proseal and 92.5% with I-gel, with no significant differences between the groups. Kus et al found the first attempt successful insertion rates to be comparable between LMASupreme and I-gel. We did not find any differences between groups in number of attempts and airway manipulation for insertion of SGA, quality of airway and gastric tube insertion characteristics, hemodynamic parameters and postoperative complications. This is consistent with findings of other studies, conducted by Das and Mitra et al[10,11]

The results of our study may not be applicable in spontaneously breathing patients, as it was conducted in paralysed patients. The airway leak pressure is affected by neuromuscular blockade in patients with laryngeal mask airway insertion.[21]This is one of the limitations of our study.

VI. CONCLUSION

In this randomised clinical study, we compared the performance characteristics of three second generation SGA devices – LMAProseal, LMA Supreme and I-gel in ASA Grade I and II children between the ages of 3-10 years undergoing elective surgeries. We conclude that I-gel maintains a significantly higher airway leak pressure and has a better fibreoptic view as compared to LMA Proseal and LMA Supreme, thus making it the supraglottic device of choice in paediatric laparoscopic surgery. The better fibreoptic view correlates with adequate ventilation, thus making I-gel an ideal conduit for endotracheal intubation in difficult airway situations.

The time of insertion was least with LMA Supreme and both LMA Supreme and LMA Proseal were significantly easier to insert as compared to I-gel.ThereforeLMA Supreme maybe a valuable asset as backup device in emergent airway situations,where it may function as an alternative to endotracheal intubation.Thus all the three devices have their own advantages and their usage should be individualized depending upon the nature of surgery and airway management during anaesthesia.

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International Journal Dental and Medical Sciences Research
Volume 5, Issue 3, May - June 2023 pp 643-650 www.ijdmsrjournal.com ISSN: 2582-6018

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Table 1:-Comparison of patient characteristics, size of SGA and duration of surgery between group P, S and I.

Patient characteristics, size of SGA and duration of surgery	Group P(n=40)	Group S(n=40)	Group I(n=40)	Total	P value
Gender					
Female	12 (30%)	14 (35%)	16 (40%)	42 (35%)	0.644†
Male	28 (70%)	26 (65%)	24 (60%)	78 (65%)	
Age(years)	6.5(5-8.25)	7(5-8.125)	7(4.375-8.125)	7(4.875-8.125)	0.841‡
Weight(kg)	19.5(15.75-26)	18(15-23.25)	18(14-27)	18.5(15-26)	0.595‡
Height(m)	120(108.75-126.5)	118.5(108.75-126.5)	118(106-126)	119(108-126)	0.629‡
Duration of surgery(minutes)	60(48.75-71.25)	60(56.25-75)	60(45-75)	60(45-75)	0.502‡
Size of SGA	2(2-2.5)	2(2-2.125)	2(2-2.5)	2(2-2.5)	0.454‡

† Chi square test, ‡Kruskal Wallis test

Table 2:-Comparison of insertion characteristics of SGA and gastric tube between group P, S and I.

Insertion characteristics of SGA and gastric tube	Group P(n=40)	Group S(n=40)	Group I(n=40)	Total	P value
Time taken for insertion(seconds)	15(15-20)	15(13.75-15)	15(15-20)	15(15-20)	<.001‡ P vs S:<.001 P vs I:0.341 S vs I:<.001
Number of attempts					
1	38 (95%)	39 (97.50%)	37 (92.50%)	114 (95%)	0.870*
2	2 (5%)	1 (2.50%)	3 (7.50%)	6 (5%)	
Airway manipulation	3 (7.50%)	1 (2.50%)	3 (7.50%)	7 (5.83%)	0.697*

International Journal Dental and Medical Sciences Research
Volume 5, Issue 3, May - June 2023 pp 643-650 www.ijdmsrjournal.com ISSN: 2582-6018

Complications	3 (7.50%)	3 (7.50%)	3 (7.50%)	9 (7.50%)	1*
Gastric tube insertion					
Ease of insertion					
1	39 (97.50%)	39 (97.50%)	38 (95%)	116 (96.67%)	1*
2	1 (2.50%)	1 (2.50%)	2 (5%)	4 (3.33%)	
Number of attempts					
1	38 (95%)	40 (100%)	37 (92.50%)	115 (95.83%)	
2	1 (2.50%)	0 (0%)	3 (7.50%)	4 (3.33%)	0.222*
3	1 (2.50%)	0 (0%)	0 (0%)	1 (0.83%)	
Time of insertion(seconds)	15(15-16.25)	15(15-15)	15(15-16.25)	15(15-15)	0.537‡

* **Fisher's exact test, ‡Kruskal Wallis test**

Table 3:-Comparison of airway leak pressure between group P, S and I.

Airway leak pressure	Group P(n=40)	Group S(n=40)	Group I(n=40)	Total	P value
Median(25th-75th percentile)	19.5(18-21.25)	18.5(17-20.25)	24(22.75-25)	21(18-23)	<.001‡ P vs S:0.054 P vs I:<.001 S vs I:<.001

‡Kruskal Wallis test

Table 4:-Comparison of FOB grading between group P, S and I.

FOB grading	Group P(n=40)	Group S(n=40)	Group I(n=40)	Total	P value
Grade 1	12 (30%)	1 (2.50%)	29 (72.50%)	42 (35%)	<.001* P vs S:<.001* P vs I:<.001* S vs I:<.001*
Grade 2	24 (60%)	12 (30%)	11 (27.50%)	47 (39.17%)	
Grade 3	3 (7.50%)	24 (60%)	0 (0%)	27 (22.50%)	
Grade 4	1 (2.50%)	3 (7.50%)	0 (0%)	4 (3.33%)	
Total	40 (100%)	40 (100%)	40 (100%)	120 (100%)	

* **Fisher's exact test**

Table 5:-Comparison of ease of insertion between group P, S and I.

Ease of insertion	Group P(n=40)	Group S(n=40)	Group I(n=40)	Total	P value
1	38 (95%)	39 (97.50%)	28 (70%)	105 (87.50%)	<.001* P vs S:1* P vs I:0.007* S vs I:0.002*
2	2 (5%)	1 (2.50%)	10 (25%)	13 (10.83%)	
3	0 (0%)	0 (0%)	2 (5%)	2 (1.67%)	
Total	40 (100%)	40 (100%)	40 (100%)	120 (100%)	

* **Fisher's exact test**

LIST OF FIGURE LEGENDS
Figure 1–Comparison of Airway leak Pressure between the groups

International Journal Dental and Medical Sciences Research
Volume 5, Issue 3, May - June 2023 pp 643-650 www.ijdmsrjournal.com ISSN: 2582-6018

Group I>Group P>Group S (p<0.001), Group I vs Group P: p value<0.001
Group P vs Group S: p value=0.012, Group I vs Group S: p value<0.001

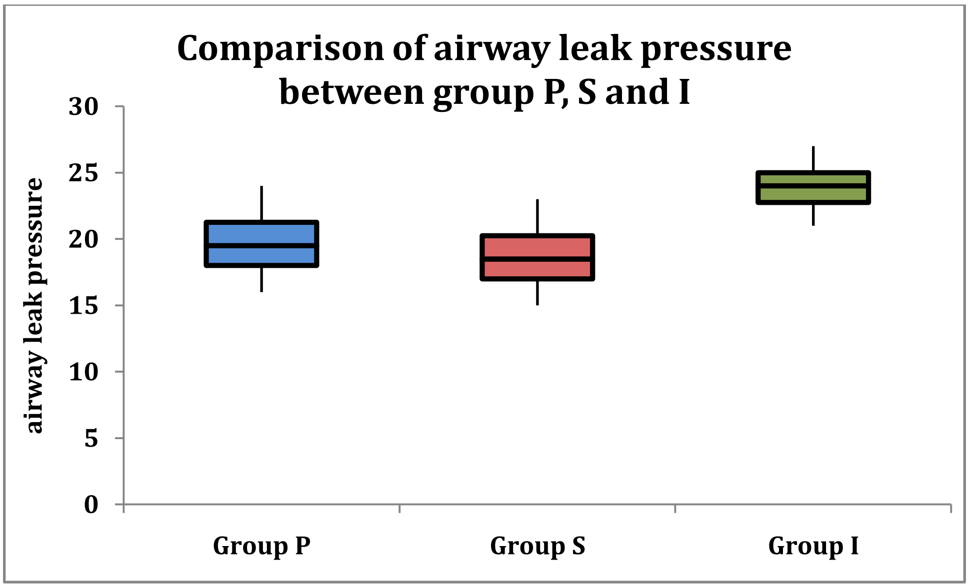

Figure 1:-Comparison of airway leak pressure between group P, S and I.(non-parametric variable, Box-whisker plot)