# ED50 of sevoflurane for I-Gel removal in anesthetized children in cataract surgeries using subtenon block

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## ABSTRACT

**Objective:** The aim of this study was to determine the minimum concentration of sevoflurane required for I-Gel removal in 50% children undergoing elective cataract surgery. **Design:** A prospective observational study. **Setting:** A single tertiary care surgical center. **Materials and Methods:** Our study enrolled 20 American Society of Anesthesiologists I and II children aged 2-10 years, undergoing elective cataract surgery. Anesthesia was induced with sevoflurane and oxygen/nitrous oxide mixture and a size 2 I-Gel was inserted. A subtenon block was administered in all children before surgical incision. Sevoflurane was used for maintenance of anesthesia. Predetermined end-tidal concentration of sevoflurane was maintained for 10 min at the end of surgery before I-Gel removal was attempted. End-tidal concentrations were increased/decreased using the Dixon up-down method (with 0.2% as a step size) in the next patient depending on the previous patient's response. Patient responses to I-Gel removal were classified as "movement" or "no movement". **Results:** Minimum concentration of sevoflurane required for successful removal of a I-Gel in 50% (ED50) and 95% (ED95) of children was 0.44% (95% confidence interval [CI], 0.34-0.52%) and 0.77% (95% CI, 0.63-1.2%), respectively. **Conclusion:** A very low end-tidal concentration of sevoflurane (ED50 of 0.44% ED95 of 0.77%) is required for I-Gel removal in children in cataract surgery with the supplementation of subtenon block.

**Key words:** *Cataract surgeries, I-Gel removal, pediatric, sevoflurane, subtenon block*

## INTRODUCTION

I-Gel is one of the newer second generation noninflatable supraglottic airway devices, which is made up of a transparent, soft, gel-like elastomer[1] which results in higher seal pressures with negligible tissue compression when compared with other inflatable supraglottic airway devices.[1,2]

Several studies have compared the performance of pediatric version of I-Gel™ (Intersurgical Ltd., Wokingham, and Berkshire, UK) with classic laryngeal mask airway (CLMA) and found comparable results with respect to ease of insertion, hemodynamic variables, and postoperative complications.[3-6]

However, the minimum alveolar concentration (MAC) of sevoflurane required for CLMA removal for 50% of unpremeditated children (ED50) is reported to be in the range of around 2.0%.(1.84-1.90%).[7,8] We hypothesize that ED50 of sevoflurane to be in the same range with that of CLMA. The MAC of sevoflurane for 50% (ED50) and 95% (ED95%) successful removal of I-Gel in children has not been studied to date and therefore, we planned this study to determine the sevoflurane ED50 and ED95 for I-Gel removal in children undergoing cataract surgeries with the supplementation of subtenon block.

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## MATERIALS AND METHODS

This was a single center, prospective, observational study to determine the dose-response curve, as well as ED50 and ED95 of sevoflurane for removal of I-Gel in pediatric subjects. Study was done in accordance to the Consolidated

Standards of Reporting Trials guidelines (CONSORT 2010 Checklist) and following the principles of the Declaration of Helsinki and was registered with the Clinical Trial Registry of India (CTRI) with an assigned number of CTRI/2014/03/004507.

The study proceeded after obtaining approval of Institute Ethics Committee of Post Graduate Institute of Medical Education and Research, Chandigarh, India (NK/1252/Department/4131). Written informed parental consent was obtained before enrolment of each child. Paediatric subjects of either sex aged 1.5-8 years, weighing 10-20 kg having American Society of Anesthesiologists physical status I/II of undergoing elective cataract surgery were recruited in the study. Children with recent upper respiratory tract infection, increased risk for aspiration, airway anomalies, and cardiorespiratory or cerebrovascular disease were excluded from the study.

Premedication was not administered to any child. Induction and maintenance of anesthesia were achieved with sevoflurane and oxygen with preservation of spontaneous breathing. After establishing intravenous access, size 2 I-Gel was inserted for maintenance of airway after achieving sufficient depth of anesthesia. Anesthesia was maintained with 2-3% sevoflurane in oxygen and nitrous oxide. A subtenon block with 0.08-0.10 ml/kg of 0.5% bupivacaine was administered in all children 8-10 min before surgical incision. 0.5 μg/kg of an intravenous fentanyl bolus was administered, whenever the heart rate or mean arterial pressure increased >20%. Heart rate, noninvasive blood pressure, electrocardiogram, $SpO_2$, end-tidal sevoflurane ($ET_{SEVO}$), MAC, and ET $CO_2$ were monitored intraoperatively.

After the end of surgery, nitrous oxide was switched off, and the target $ET_{SEVO}$ was maintained for 8-10 min before I-Gel removal was attempted. The sevoflurane end-tidal concentration of was kept at 2% in first child. $ET_{SEVO}$ was increased or decreased by 0.2% in the next child depending on the previous child's response according to Dixon's method.[9] After each I-Gel removal, child was observed for 1 min for any "Movement" or "No Movement." It was designated as "movement" or unsuccessful removal of I-Gel in case of purposeful movement of extremities, difficult mouth opening, clenching of teeth, coughing, breath holding, laryngospasm, and desaturation during or within 1 min of SAD insertion. An independent observer assessed these responses. Any adverse events were recorded.

### Statistical analysis

Data were represented as mean and standard deviation or number with percentages. Chi-square test and *t*-test were applied for categorical variables and continuous variables, respectively. Sevoflurane ED50 was calculated using Dixon up and down method.

Further analyzing with a probit regression, dose-response curve was obtained with ED50 and ED95 with 95% confidence interval (CI). Sample size was calculated on the basis of fact that a minimum of six crossover pairs were required for the statistical analysis.[9] Data analysis was done using SPSS version 17.0. (Contractor/manufacturer is SPSS Inc., 233 South Wacker Drive, 11th Floor, Chicago, IL 60606-6412)

## RESULTS

Totally, 22 children were assessed for study eligibility of which parents of 2 children refused to participate, therefore the total of 20 children met the inclusion criteria and were included in the study [Figure 1].

Demographic data in the form of patient and anesthesia characteristics such as age, gender, weight, duration of anesthesia, and duration of surgery are shown in Table 1. ED50 and ED95 of sevoflurane for I-Gel removal using probit regression analysis were 0.44% (95% CI, 0.34-0.52%) and 0.77% (95% CI, 0.63-1.2%), respectively [Figure 2 and Table 2].

**Table 1: Patients and anesthesia characteristics**

| Variables | Sevoflurane (*n* = 20) |
|---|---|
| Age, years | 4.9 (2.1) |
| Body weight, kg | 16.5 (4.6) |
| Gender: Males/females | 13/7 |
| Duration of surgery, min | 17.3 (3.2) |
| Duration of anesthesia, min | 32.6 (3.3) |

Values are expressed as mean (SD) or proportion. Compared using Chi-square or Student's *t*-test. SD: Standard deviation

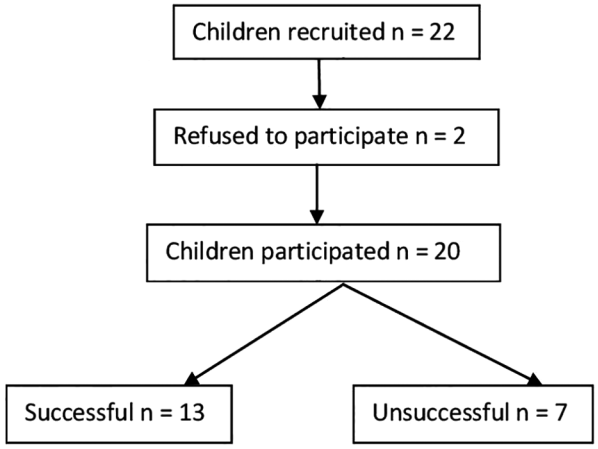


**Figure 1:** Subject cohort flow diagram

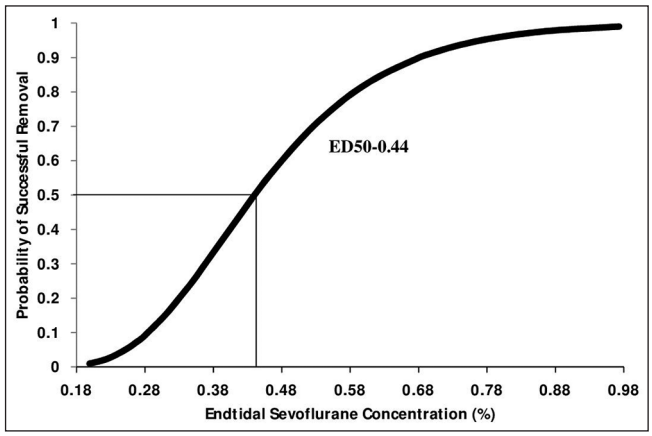


**Figure 2:** Successful — unsuccessful sequence, successful, unsuccessful

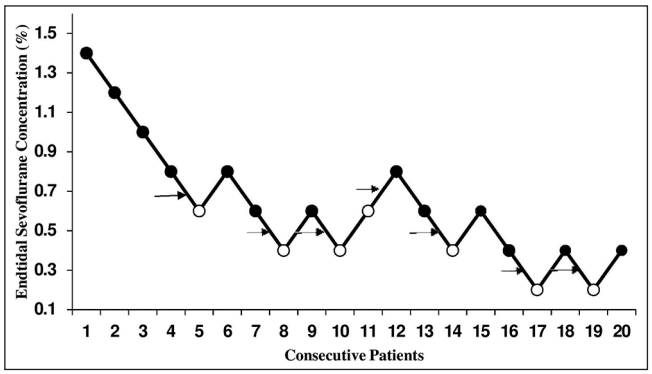


**Figure 3:** Dose-response curve for sevoflurane plotted from the probit analyses of individual end-tidal concentrations and the respective patient reactions to the removal of I-Gel. The concentrations at which there were 50% probabilities of successful I-Gel removal were 0.44%

The sequence of successful and unsuccessful removal of I-Gel is shown in Figure 3. I-Gel was successfully removed in 13 (65%) out of 20 children.

Movement occurred in 4 patients (at 0.25% each). No other complication such as coughing, clenching, laryngospasm, breath holding, or desaturation occurred in any of the children.

**Table 2: Estimated values of the coefficient of probit analysis**

| Variables | Sevoflurane ($n$ = 20) |
|---|---|
| Intercept | 2.407 |
| Slope | 13.4999 |
| $EC_{50}$ (95% CI) | 0.44 (0.34-0.52) |
| $EC_{95}$ (95% CI) | 0.77 (0.63-1.2) |

$(P/1\text{-}P) = B_0 + \beta B_{1X}$; $B_0$=Intercept; $B_1$ = Slope; X = $ET_{SEVO\ 90}$; $ET_{SEVO}$: End-tidal sevoflurane; CI: Confidence interval

## DISCUSSION

Our results showed ED50 and ED 95 of sevoflurane for I-Gel removal in children undergoing cataract surgery supplemented with subtenon block to be 0.44% and 0.77% and none of the children had any of the major airway related events.

This is the first study in literature to determine the minimum concentration of sevoflurane (ED50 and ED95) for I-Gel removal in children.

Studies have shown the ED50 of sevoflurane for removal of other supraglottic devices like CLMA to be around 2%.[7,8] Thus, we found ED50 of sevoflurane for I-Gel removal to be even less than one-fourth of the ED50 of sevoflurane required for CLMA removal and is better tolerated than other supraglottic devices such as LMA. It is because of this low EC that there are negligible airway-related events following removal of the device in our study. These results are probably because of the soft consistency of mask of the device without an inflatable cuff[1,2,10-12] facilitating smooth removal of the device with negligible tissue trauma and reducing the chances of airway complications due to airway stimulation by the device resulting in lesser chances of failure at removal with lesser hemodynamic changes[13] which may lead to improved recovery time and fewer postoperative complications.[2] In our study, there were no significant airway complications apart from movement which suggested smooth removal of I-Gel in these children.

Such a lower end-tidal sevoflurane concentration for I-Gel removal can also be beneficial in penetrating eye injuries or in glaucomatous patients in preventing any rise in intraocular pressure and also preventing suture dehiscence.[14,15]

One of the limitations of the study is the use of Dixon's method with probit regression analysis for calculation of ED95, but this method has been used in many studies by researchers. [7,8]

Due to non-availability of medical air we used nitrous oxide which could lead to inaccurate measurement but ensured that no end-tidal nitrous oxide was present at the time of removal of I-Gel and thus minimized the any chances of error.

Another limitation is the absence of the control group without subtenon block. We used subtenon block as we have omitted the use of opioids which could have a confounding systemic effect on the end-tidal concentration of sevoflurane.

## CONSORT 2010 checklist of information to include when reporting a randomized trial*

| Section/topic | Item number | Checklist item | Reported on page number |
|---|---|---|---|
| Title and abstract | | | |
| | 1a | Identification as a randomized trial in the title | 1 |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | 1, 2 |
| Introduction | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale | 3 |
| | 2b | Specific objectives or hypotheses | 3 |
| Methods | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | 4 |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | NA |
| Participants | 4a | Eligibility criteria for participants | 4 |
| | 4b | Settings and locations where the data were collected | 4 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 4, 5 |
| Outcomes | 6a | Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed | 5 |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | NA |
| Sample size | 7a | How sample size was determined | 5 |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | 5 |
| Randomization | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | 4, 5 |
| | 8b | Type of randomization; details of any restriction (such as blocking and block size) | 4 |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | 4 |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | 4 |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | NA |
| | 11b | If relevant, description of the similarity of interventions | |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | 5 |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | NA |
| Results | | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | 6, Figure 1 |
| | 13b | For each group, losses and exclusions after randomization, together with reasons | NA |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | 6 |
| | 14b | Why the trial ended or was stopped | 6 |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | Table 1 |
| Numbers analyzed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | 6 |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% CI) | 6 |
| | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | Figure 1 |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory | 6 |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | 6 |

**CONSORT (Continued)**

| Section/topic | Item number | Checklist item | Reported on page number |
|---|---|---|---|
| Discussion | | | |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and if relevant, multiplicity of analyses | 8 |
| Generalizability | 21 | Generalizability (external validity, applicability) of the trial findings | 7 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | 7, 8 |
| Other information | | | |
| Registration | 23 | Registration number and name of trial registry | Institute Ethics Committee of Post Graduate Institute of Medical Education and Research, Chandigarh, India. (NK/1252/ Department/4131) |
| Protocol | 24 | Where the full trial protocol can be accessed if available | |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | NA |

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 explanation and elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomized trials, noninferiority and equivalence trials, nonpharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: For those and for up to date references relevant to this checklist, see www.consort-statement.org. CONSORT: Consolidated standards of reporting trials; NA: Nonavailable; CI: Confidence interval

## CONCLUSION

It can be concluded that a very low end-tidal concentration of sevoflurane (ED50 of 0.44% ED95 of 0.77%) is required for I-Gel removal in children in cataract surgery with the supplementation of subtenon block.

## REFERENCES

1. Intersurgical I-gel User Guide. I-gel supraglottic airway, adult and paediatric sizes. Intersurgical Wokingham; 2010.
2. Richez B, Saltel L, Banchereau F, Torrielli R, Cros AM. A new single use supraglottic airway device with a noninflatable cuff and an esophageal vent: An observational study of the i-gel. Anesth Analg 2008;106:1137-9.
3. Lee JR, Kim MS, Kim JT, Byon HJ, Park YH, Kim HS, *et al.* A randomised trial comparing the i-gel (TM) with the LMA Classic (TM) in children. Anesthesia 2012;67:606-11.
4. Goyal R, Shukla RN, Kumar G. Comparison of size 2 i-gel supraglottic airway with LMA-ProSeal™ and LMA-Classic™ in spontaneously breathing children undergoing elective surgery. Paediatr Anaesth 2012;22:355-9.
5. Das B, Mitra S, Jamil SN, Varshney RK. Comparison of three supraglottic devices in anesthetised paralyzed children undergoing elective surgery. Saudi J Anaesth 2012;6:224-8.
6. Lee JH, Cho HS, Shin WJ, Yang HS. A comparison of supraglottic airway i-gel™ vs. classic laryngeal mask airway in small children. Korean J Anesthesiol 2014;66:127-30.
7. Lee JR, Lee YS, Kim CS, Kim SD, Kim HS. A comparison of the end-tidal sevoflurane concentration for removal of the laryngeal mask airway and laryngeal tube in anesthetized children. Anesth Analg 2008;106:1122-5.
8. Lee JR, Kim SD, Kim CS, Yoon TG, Kim HS. Minimum alveolar concentration of sevoflurane for laryngeal mask airway removal in anesthetized children. Anesth Analg 2007; 104:528-31.
9. Dixon WJ, Massey FJ. Introduction to Statistical Analysis. 4th ed. New York: McGraw-Hill 1983. p. 426-41.
10. Theiler LG, Kleine-Brueggeney M, Luepold B, Stucki F, Seiler S, Urwyler N, *et al.* Performance of the pediatric-sized i-gel compared with the Ambu AuraOnce laryngeal mask in anesthetized and ventilated children. Anesthesiology 2011; 115:102-10.
11. Nolan JP, Soar J, Zideman DA, Biarent D, Bossaert LL, Deakin C, *et al.* European resuscitation council guidelines for resuscitation 2010 section 1. Executive summary. Resuscitation 2010;81:1219-76.
12. Levitan RM, Kinkle WC. Initial anatomic investigations of the I-gel airway: A novel supraglottic airway without inflatable cuff. Anesthesia 2005;60:1022-6.
13. Jindal P, Rizvi A, Sharma JP. Is I-gel a new revolution among supraglottic airway devices?: A comparative evaluation. Middle East J Anaesthesiol 2009;20:53-8.
14. Ismail SA, Bisher NA, Kandil HW, Mowafi HA, Atawia HA. Intraocular pressure and haemodynamic responses to insertion of the i-gel, laryngeal mask airway or endotracheal tube. Eur J Anaesthesiol 2011;28:443-8.
15. Sahin A, Tüfek A, Cingü AK, Caça I, Tokgöz O, Balsak S. The effect of I-gel™ airway on intraocular pressure in pediatric patients who received sevoflurane or desflurane during strabismus surgery. Paediatr Anaesth 2012;22:772-5.

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