ORIGINAL ARTICLE

A clinical study of low flow anaesthesia by conventional strategy vis a vis by computer simulation derived strategy

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ABSTRACT

Objectives: To achieve an optimal anaesthetic condition by using low flows in short duration procedures is not easy and it needs consideration of many factors to detail. Hence, a prospective, randomized study was conducted to develop an easily memorised dosing strategy by computer simulation study and it was compared with conventional strategy of low flow anaesthesia. The main target was to achieve an end-tidal concentration of isoflurane of 0.8 -1.2 vol% within 5 minutes of the start of low fresh gas flow and to maintain it for at least 30 minutes.

Methodology: We selected sixty patients and randomly divided them into two equal groups. Ethics committee approval and informed consent from the selected patients was obtained. In Group-I patients, conventional strategy was used, in which fresh gas flow (FGF) was set at 5.5 L/min (O2 1.5 L plus N2O 4 L) and isoflurane 1.5 Vol% was given for fifteen minutes followed by 2.5 L/min. (O2 1 L plus N2O 1.5 L) and isoflurane 2 Vol % for next five minutes. After twenty minutes flow was reduced to a final 0.8 L (<1 L) (O2 0.4 L plus N2O 0.4 L) and isoflurane 2.5 Vol% till the end of surgery. In Group-II, one of the three schemes designed by computer simulation studies fulfilling our objective of reaching the therapeutic window in less then five minutes was taken for clinical validation and comparison. Selected scheme had one fixed vaporizer setting, e.g. 2.5 vol% Isoflurane, with varying FGF rates of 4.5 L/min for first 3 minutes, 2.5 L/min for next 3 minutes, and 0.8 L/min thereafter. The ratio of N2O:O2 was 2:1, 3:2, and 1:1 consecutively.

Results: In Group-I patients time to achieve an end-tidal concentration of isoflurane of 0.8 -1.2 vol% (9.27 ± 2.46 minutes) was longer as compared to Group-II patients (4.24 ± 2.09 minutes) ($p<0.01$). Number of manipulations needed were more in Group-I (5.47 ± 1.57) than in Group-II patients (3 ± 0) ($p<0.01$). Dosing strategy obtained by computer simulation was found to be more economical, costing Indian Rupees 289.22 ± 36.37 as compared to conventional dosing strategy which costed Rs.327.54 ± 36.86 .($p<0.01$)

Conclusion: Three-step scheme derived by computer simulation study in which varying FGF rates with fixed vaporizer setting for isoflurane is an easily memorised, economical and effective dosing strategy for low flow anaesthesia.

Keywords: Anaesthesia; Isoflurane; Breathing Systems; Closed Circuit; Dosing Strategies;

Low Flow Anaesthesia; Computer simulation study

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INTRODUCTION

Low flow anaesthesia (defined as <one liter of FGF in a closed breathing system[1] is more economical, effective, safe, and environment friendly method of administering general anaesthesia, though it is associated with some minor disadvantages like possibility of CO_2 and other gas accumulation necessitating greater attention to detail[2]. Safe administration of low FGF is ensured by current practice of high standard anaesthesia and integrated monitoring equipment with continuous and comprehensive analysis of inspiratory and expiratory gases.[3] But low flow technique, despite its established advantages, has not received due place it deserves[4] and a major problem is the lack of a simple dosing strategy that aids in attaining and maintaining pre-defined concentrations of the inhaled anaesthetics[5,3].

FGF in low flow anaesthesia systems has to be precisely adjusted to the total gas uptake by the patient over a time period[5]. Closed system could be quantitative type (both the composition and volume of delivered fresh gases correspond to O_2, CO_2 and volatile anesthetic actually taken up by the patient) or non quantitative type (only the volume but not the composition of fresh gases corresponds to gas uptake by the patient)[5]. Cumbersome calculations, intricacies of low flows and their associated breathing systems are not very clear to many anesthesiologists making it unpopular for routine use[5,3]. An initial lengthy period of high FGF to flush out nitrogen and fill the breathing system with anesthetic vapors is common to all low flow techniques[6]. Frequent flow meter adjustments as well as changes in vaporizer dial settings make conventional dosing strategy cumbersome and time consuming. Total time required to attain low flows is longer with conventional technique[7] making it ineffective for short duration procedures; and attention to details, essential in this obviously beneficial cumbersome technique, leads to reluctance on the part of a busy anesthesiologist to use it routinely.[3]

The present study of developing a simple, easy to remember technique of low FGF to achieve and maintain necessary depth of anaesthesia in the shortest possible time for surgical procedures of short duration is based on extensive research by Lerou JG et al[3,8-10]. Clinical validation of computer simulated studies by comparing it with conventional technique was thought to be essential to prove its usefulness and benefits. Computer simulation studies were carried out initially using formulae and a physiological model developed by Lerou JG et al[8]. Three different schemes as described in Table 1 were developed by computer simulation studies and Scheme III which was found to be more appealing and suitable for our requirements was clinically validated as in Group-II patients and this was compared with low flow anaesthesia by conventional technique in Group-I patients.

METHODOLOGY

Purpose of the study: To develop an easily memorised, economical and effective dosing strategy for low flow anaesthesia by computer simulation studies and to validate the same clinically by comparison with conventional low flow technique.

Study Type: Interventional

Study design: A prospective, treatment, parallel assignment, single blind (subject), randomized, controlled, study.

Location: Pravara Hospital, which is a Teaching Hospital attached to Rural Medical College, affiliated to Pravara Institute of Medical Sciences, Loni (India).

Duration of study: Six months.

Approval from institutional ethics committee of Pravara Institute of Medical Sciences was obtained.

Sixty patients of either sex, ASA I and II, aged 20 to 40 years, undergoing elective surgery of 45-60 minutes duration with negligible blood loss and who were willing to give written consent to participate in the study were enrolled. Patients unwilling to get enrolled in this study, patients having any systemic diseases, and those undergoing surgery of long duration with expected large hemodynamic shifts were excluded. They were randomly distributed to two groups after informed written consent;

Group-I: Low flow anaesthesia technique based on Conventional Dosing Strategy. (n=30)

Group-II: Low flow anaesthesia technique by utilizing Dosing Strategy developed by computer simulation studies (Scheme III out of three schemes developed). (n=30)

Method of Randomization: Block randomization

Randomization was carried out based on blocking. Blocks of size 4 with treatment allocation of 1:1 for Group-I and Group-II were created. A block of 4 patients was assigned to either of the groups.

blocks created.

Primary outcome Measures: Time required for end tidal concentration of isoflurane to reach the therapeutic window from zero minute.

Secondary Outcome Measures: Following parameters were registered;

1. Number of manipulations—flow meter settings and dial adjustments of the vaporizer required to reach and to remain in the therapeutic window.

The technique of anaesthesia was similar in both groups until switch over to low FGF utilizing closed circuit. Fabius anaesthesia machine with integrated closed circuit and ventilator, with multimodular monitor- Cardiocap 5 (Datex Ohmeda) was used in all cases. Basic monitoring of all parameters like pulse rate, blood pressure, oxygen saturation, ECG and end tidal carbon dioxide was done at every ten minutes intervals. Intravenous inj. fentanyl 2 μg/kg was given for analgesia. Induction of general anaesthesia was achieved by administration of 5 mg/kg of thiopentone sodium intravenously, followed by inj. vecuronium 0.12 mg/kg. Initial mask ventilation was followed by ventilation through cuffed endotracheal tube with FGF of 8 L/min (N_2O:O_2 ratio 1:1) for 3 minutes by Magill breathing system followed by closed circuit system with soda lime canister and this switchover time, was taken

as zero minute for the present study. Additional doses of thiopentone and fentanyl were given whenever patient showed signs of light anaesthesia. Intravenous fluids were administered as per calculations to maintain normovolemic status. At the end of surgery neuromuscular block was reversed with inj. neostigmine 0.04 mg/kg and inj. glycopyrrolate 0.008 mg/kg. Postoperative recovery was found to be good and no instance of recall was observed in patients of both groups.

GROUP-I: Conventional Study Group:

Anaesthesia for this group was based on the guidelines given by Baun.[7] In this group, at zero minute, FGF was set at 5.5 L / min (O_2 1.5 L plus N_2O 4 L) and isoflurane 1.5 vol% and given for fifteen minutes, followed by 2.5 L/min. (O_2 1 L plus N_2O 1.5 L) and isoflurane 2 vol% given for next five minutes. After twenty minutes, flow was reduced to a final 0.8 L (~1 Liter) (O_2 0.4 L plus N_2O 0.4 L) and isoflurane 2.5 vol % till the end of surgery as described in Table 1. FGF and vaporizer settings were intermittently altered to ensure that end tidal values remained in the desired therapeutic window.

Computer study:

Different dosing strategies were obtained by computer simulation studies initially based on our clinical experience and knowledge. One of our coauthor, a computer engineer and expert performed the simulations and selected the dosing strategies to satisfy our requirements. For simulation, a forty years old male, 1.65 meters tall, weighing 55 kg was considered. The end tidal concentration of O_2, N_2O, CO_2 and

isoflurane to be maintained in the therapeutic window were as predicted. Therapeutic window was identified as;

1. The end-expiration isoflurane concentration of 0.8–1.2 vol % to be achieved in 5 min;

2. Remain stable for at least 30 min with total FGF < 1 L/min and with 'minimal-flow' limited to total FGF=0.8 L/min in present study.

3. The ratio of N_2O to O_2 maintained between 66 to 50 %: 33 to 45 % respectively.

For simulation studies, formulae and physiological model developed by Lerou JG et al [8] were used. Three schemes were designed by computer simulations with different dosing strategies. All three schemes developed by computer simulation study and conventional study scheme are described in detail in Table I. The main difference in the three schemes is related to the nature of manipulations needed in FGF rates and vaporizer settings. (FGF rate and composition was kept constant but vaporizer settings altered in Scheme I, FGF rate and composition as well as vaporizer settings were altered in Scheme II and in Scheme III changes were made in FGF rate and composition but vaporizer settings were kept constant.) Scheme III was selected for clinical validation due to reasons mentioned in discussion part of this paper.

GROUP-II: Scheme III was used to administer low flow anaesthesia in thirty patients of this group. In this scheme, vaporizer setting for isoflurane was kept constant at 2.5 vol% and flow rates for oxygen and nitrous oxide were altered in three steps as shown in detail in Table 1.

Inspiratory and expiratory O_2 and N_2O, as well as inspiratory and end-expiratory isoflurane concentrations were recorded and tabulated in each case of both groups. The scheme was continued till the end of surgery or up to 60 minutes whichever was earlier. The amount of isoflurane, O_2 and N_2O consumed in each case of both groups was calculated and averaged for all cases to calculate the cost per case. All monitored data were saved and recovered from the trend analysis. The integrated infrared multigas monitor sampled gas from a point between the Y-piece and the tracheal tube to assess inspired and end-expiratory CO_2, isoflurane, as well as N_2O concentrations averaged over the whole respiratory cycle. Isoflurane was delivered to all patients by the same vaporizer (Dragor vapor).

Statistical analysis:

The statistical analysis was performed by Stata 10 software. Data are presented as mean ± standard deviation. Two sample *t*-test was used to determine in-group differences for continuous variables and the $\chi 2$ test was used to compare male and female distribution among two groups. A p value < 0.05 was considered statistically significant.

The sample size was not calculated before the start of the study. Post-hoc power analysis was carried out for "Time to enter into therapeutic window from Zero minute (Minutes)" and "Number of manipulations required to remain in therapeutic window". Estimated power for two-sample comparison of means was 1.00

RESULTS

Table 1 describes different schemes out of which conventional dosing strategy was used in Group-I patients and Scheme III was used in Group-II patients.

Computer study: Results of computer simulation studies have been depicted in Figure I. It shows predicted end tidal concentration of isoflurane reaching the therapeutic window in the desired time frame in the three different schemes tested. In all the schemes, isoflurane reached the end tidal concentration of 0.8% within first three minutes and remained between 0.8 to 1.2% steadily for more than 60 minutes. Inspired O_2 concentration remained in a range between 30 to 45 vol% and averaged N_2O concentrations

Table 1: Sequences of Fresh Gas Flow and vaporizer settings of is of lurane dosing Schemes (I to III) tested by computer simulation and Conventional dosing strategy

Stage	Time (min)	N_2O (L/min)	O_2 (L/min)	Isoflurane (Vol %)
Computer controlled studies schemes				
Scheme I				
1	0	0.5	0.5	5
2	5	0.5	0.5	3.5
3	10	0.5	0.5	2.5
4	15	0.5	0.5	2
Scheme II				
1	0	1.5	1.5	4
2	5	0.75	0.75	3
3	10	0.5	0.5	2.5
4	15	0.4	0.4	2.5
Scheme III				
1	0	3	1.5	2.5
2	3	1.5	1	2.5
3	6	0.4	0.4	2.5
Conventional dosing strategy				
1	0	4	1.5	1.5
2	15	1.5	1	2
3	20	0.4	0.4	2.5

Table 2: Age and gender wise distribution of patients

Characteristics		Group-I (n = 30) (Mean±SD)	Group-II (n = 30) (Mean±SD)
Age (in years)		34.33 ± 8.18	35.33 ± 8.36
Gender	Male [No. of Patients(%)]	14(47)	13(43)*
	Female No. of Patients(%)]	16(53)	17(57)*

*p-value > 0.05.

Table 3: Time to reach and number of manipulations required to remain in the therapeutic window

	Time to reach the therapeutic window from Zero minute (Minutes) Mean±SD (Range)	Number of manipulations required to remain in window Mean±SD (Range)
Group-I	9.27±2.46 (6–14)*	5.47±1.57** (4-8)*
Group-II	4.24±2.09 (3-8)*	3±0** (3-3)*

Table 4: Comparison of consumption of gases (mean ± SD)

	Isoflurane ml	Oxygen Lit	Nitrous Oxide Lit
Group-I	16.84±1.94	41.74±3.93	58.83±4.87
Group-II	14.87±1.87*	36.77±2.62*	47.67±3.64*

Table 5: Comparison of cost

Cost (Indian Rupees) Mean±SD			
	Isoflurane	Oxygen	Nitrous Oxide
Group-I	327.54±36.86	1.67±0.15	17.65±1.46
Group-II	289.22±36.37*	1.47±0.10*	14.3±1.09*

Figure 1: Predicted end tidal concentration of isoflurane with 3 schemes derived from computer study

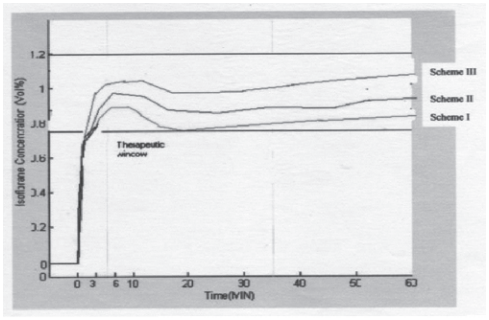


Figure IIa: Comparison of end tidal concentration of isoflurane

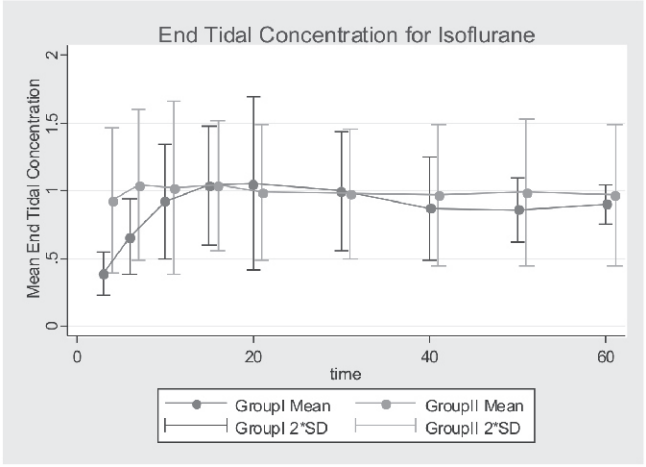


Figure IIb: Comparison of end tidal concentration of oxygen

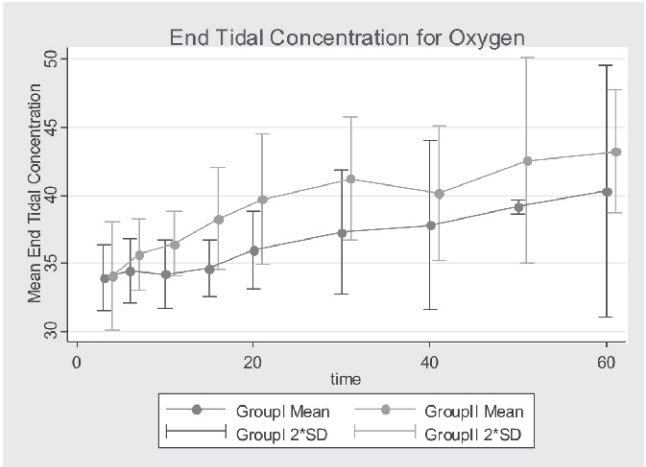
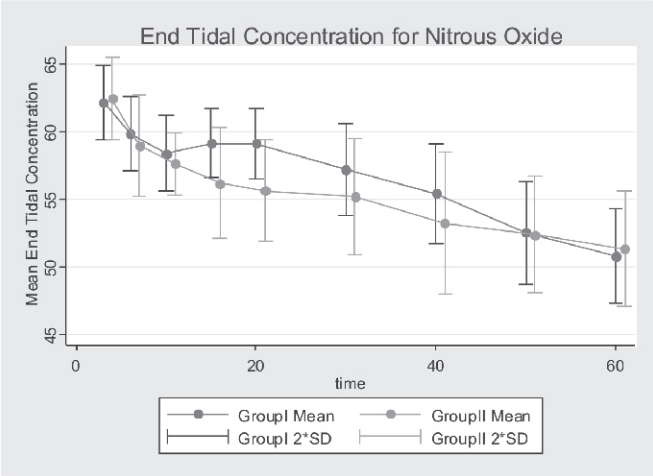


Table 6 : Trends of end tidal concentrations of anesthetic agents with time

Time (min)	Isoflurane		Oxygen		Nitrous Oxide	
	Group-I	Group-II	Group-I	Group-II	Group-I	Group-II
	Mean ± SD £	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD £
3	0.39 ± 0.08	0.93 ± 0.27*	33.93 ± 1.21	34.07 ± 2.01*	62.21 ± 1.37	62.48 ± 1.54*
6	0.66 ± 0.14	1.04 ± 0.28*	34.43 ± 1.17	35.62 ± 1.29*	59.87 ± 1.38	58.99 ± 1.87*
10	0.92 ± 0.21	1.02 ± 0.32*	34.17 ± 1.26	36.41 ± 1.18*	58.37 ± 1.4	57.65 ± 1.15*
15	1.04 ± 0.22	1.04 ± 0.24*	34.6 ± 1.05	38.25 ± 1.87*	59.17 ± 1.29	56.18 ± 2.05*
20	1.05 ± 0.32	0.99 ± 0.25*	35.97 ± 1.42	39.7 ± 2.4*	59.13 ± 1.28	55.65 ± 1.87*
30	1.0 ± 0.22	0.98 ± 0.24*	37.27 ± 2.28	41.22 ± 2.25*	57.2 ± 1.7	55.22 ± 2.14*
40	0.87 ± 0.19	0.97 ± 0.26*	37.8 ± 3.10	40.14 ± 2.45*	55.46 ± 1.85	53.25 ± 2.65*
50	0.86 ± 0.12	0.99 ± 0.27*	39.17 ± 4.14	42.54 ± 3.78*	52.53 ± 1.89	52.38 ± 2.15*
60	0.90 ± 0.07	0.97 ± 0.26*	40.3 ± 4.64	43.22 ± 2.26*	50.81 ± 1.77	51.33 ± 2.12*

* p > 0.05

Figure IIc: Comparison of end tidal concentration of nitrous oxide



remained in a range between 55 to 65 vol% in low flow or minimal flow conditions.

Table 2 shows age and gender wise distribution of patients among two groups. There is no significant difference in both the groups, which are comparable regarding mean age and male/female percentage. (p>0.05).

Table 3 shows the time and number of manipulations required to reach and remain in the therapeutic window. The number of manipulations required was greater (5.47±1.57 as against 3±0) (p<0.01) and the time necessary was longer to achieve an end-tidal concentration of isoflurane 0.8–1.2 vol% range in the conventional group as compared to the computer simulated group (9.27±2.46 as against 4.24±2.09 minutes) (p<0.01).

Table 4 compares Consumption and cost of anesthetic agents in both groups.

Dosing strategy obtained with the help of Computer simulation and used in Group-II patients was found to be more economical costing Indian Rupees289.22 ± 036.37 in comparison to conventional dosing strategy used in Group-I patients which costed Rs.327.540 ± 036.86. (p<0.01).

Table 5 compares the trends of end tidal concentrations of anesthetic agents with time in both groups. This is also presented in the graphical form in Figure IIa, IIb and IIc.

DISCUSSION

Although there are a number of strategies utilizing many mathematical and non mathematical calculations[6] described in literature to attain a satisfactory anaesthesia in low flow conditions, a consensus is yet to be reached on the best possible method[7]. Circle-systems are often used with inappropriate high flow rates and recommendations have been made repeatedly for the reduction of flow rates in order to reduce costs[11]. The emphasis in our study is to simplify matters for a busy anesthesiologist to help him adopt low flow technique, which has a tremendous potential in developing countries. The comparison between established conventional methods with strategies developed by computer simulation studies, if found to be beneficial, would be a big step in that direction. If any strategy has a practical value and it is desired to be adopted by the practitioners, it should be appealing, attractively simple, easily memorised yet effective. Since an average clinical anesthesiologist does not have access to a computer-controlled system, he has to resort to manual adjustments of the vaporizer settings and rotameters based on personal experience. Complex dosing strategy adds to the problems and gets low acceptability. A practical dosing scheme should offer a balance between feasibility, reliability, and the potential for being economical.[3] Ensuring a proper depth of anaesthesia to deliver ideal

surgical anesthesia on one hand and to ensure minimal variations in the physiological parameters of the patient on the other is the prime responsibility of the anesthesiologist. If these conditions are met, the anesthesiologist can focus his attention on patient care during a busy anesthetic period and rely on the effectiveness and reliability of the dosing strategy.

Safety of the patient is the prime concern at all times when studies of this nature are undertaken. Hence, before recommendation for clinical use in patients, we developed the schemes using computer simulation studies first. The computer expert, a co-worker in our study, planned his studies on the guidelines developed by Lerou JG et al[3,8], and to suit our requirements of the low flow being restricted to 0.8 L/min. We planned our study based on the fact that the uptake of anesthetic agents is not only dependent on FGF rate and vaporizer settings but also varies with ventilator parameters of the patient and the physical properties of the gaseous and volatile anesthetic agents.[8] It is well known that the composition of anesthetic gas mixture in high flow conditions varies directly with the FGF rate but in low flow conditions it varies with composition of exhaled gases.[11-13]. A study by Coetzee JF[11] has confirmed the well known phenomenon that during low flow rates there are discrepancies between vaporizer settings and inspired (or end-tidal) vapor partial pressures[12,13] and the discrepancy is more marked with soluble agents.

Reasons for selecting Scheme III for clinical validation:

Of the three schemes tested by the computer simulation studies, Scheme III proved to be the most suitable one from our point of view. In this scheme the end tidal concentration of isoflurane reached the therapeutic window in the desired time frame with minimal alterations in the settings of flow rate with fixed vaporizer setting. Although it might appear that Scheme III is less economical than Scheme II, because of relatively high gas flow rates, it definitely is helpful from the point of flushing the breathing circuit and the circle absorber. Lower gas flow rate initially not only alters the gas composition, affecting the patient needs, but also results in triggering of monitor alarms necessitating repeated changes in the flow settings. There are clinically important arguments against the use of schemes I and II, both using 5% and 4% settings on the isoflurane vaporizer. At such high settings, vaporizer output may deviate more than what is set on the vaporizer dial than at lower levels[14,15]. Thus, schemes I and II were thought to be less reliable than III. Furthermore, scheme III requires fewer adjustments than in scheme I and II and that too in a shorter time frame. Nevertheless, scheme I might be a good choice for those who wish to use a fresh gas flows patients to maintain desired end tidal values were 5.47±1.57(range 4–8) and the frequency of changes was more than in Group-II patients in whom only three changes were required in the initial stages ($p < 0.01$). Manipulations had to be made throughout the surgery in Group-I patients. The average time required to reach the therapeutic window was 9.27±2.46 in Group-I as against 4.24±2.09 in Group-II which is highly significant ($p < 0.01$). Majority of patients in Group-II satisfactorily entered the therapeutic window in the desired time frame and remained there for the entire duration of surgery, whereas Group-I patients took longer time to enter the window and the fluctuations were greater necessitating more alterations in settings of rotameters and the vaporizer dial. The average measured O_2 and N_2O were in close agreement with those predicted in the computer study. Oxygen concentration slowly increased from approximately 33 to 45 vol% whereas N_2O concentration slowly decreased from approximately 66 to 50 vol% in both the groups. The average measured O_2 and N_2O concentrations remained in predicted levels as in the computer study. In the present study the cost and consumption of anesthetic gases and agents in Group-II patients is more economical than in Group-I patients ($p < 0.01$). The major part of consumption was in the initial preinduction and high flow phase.

Low flow anaesthesia by close circuit has no doubt proved to be more economical than routine anaesthesia by semi-closed circuit[17]. Lerou JG et al[3] have shown that a three-step scheme using 3 vol% isoflurane in a 'full flow' of 3 L/min and a 'half flow' of 1.5 L/min, each for 3 min, with 'maintenance' of 0.5 L/min thereafter, is an easily memorised dosing strategy maintaining an end-expiratory concentration of approximately 1 vol% for 60 min. Our results suggest that similar three-step scheme using a fixed dial setting of isoflurane vaporizer in the entire period of study with three changes in the fresh flow rate of gases in the initial six minutes maintains the end tidal concentration of anesthetic agents in the predicted therapeutic window. Closed monitoring of end tidal vapor concentrations and hemodynamic variables is essential during rapid induction of anaesthesia with a potent agent. Implementation of results of this type of studies can be useful but it needs no reiteration that individual needs of patients have to be closely looked into at all times.[18]

CONCLUSION

Three-step scheme using fixed concentration of isoflurane (2.5%) in the initial high flow phase (3 L/min N_2O + 1.5 L/min O_2 for first three minutes) and then with intermediate (1.5 L/min N_2O + 1 L/min O_2 for the next three minutes) and low flow (0.4 L/min N_2O + 0.4 L/min

O_2 thereafter) is an easily memorised, economical and effective dosing strategy. This may simplify matters for a busy anesthesiologist to readily adopt and implement low flow techniques in routine anesthesia practice.

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★★★

An interesting case

All blue discolorations are not cyanosis

A female patient, ASA grade 1, diagnosed with primary infertility reported to Shaikh Zayed Hospital for operative laparoscopy. Routine general anaesthesia was administered to the patient and an endotracheal tube was passed. On monitoring, all of her physical parameters were within normal limits with pulse oxygen saturation at 98%. Patient was put in Trendelburg position for the surgical procedure. After a lapse of about 15min, both of her hands, lips and face suddenly turned blue. Pulse oximeter failed to read SpO2, inspite of a good plethesmograph. Her pulse was normal at 80/min, B.P 160/80mmHg and a normal ECG trace. The anesthesia resident, present at there, was horrified when I was called. Patient was rapidly evaluated and100% oxygen was given. Tube was checked for dislodgment and bilateral air entry was confirmed. Blood sample was sent for ABGs. On inspection and auscultation, ETT was in proper position and ABGs were normal. Surprisingly, the patient remained normal hemodynamically. The operating table was set in neutral position and insufflated CO2 was let out from the abdomen. On enquiry from the operating obstetrician, it was found that 20cc methylene blue had been injected in the cervix and the surgeon also reported of veins turning blue. The patient remained blue for next 12hrs in the postoperative period and saturation came to 94% after 1hr. We learned from this case that the anesthetists should be well aware of the surgical procedure as well as the drugs being used by the surgeons.

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