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Functional Analysis of LIMB-OTM Adult Anaesthesia Circle Circuit at different Fresh Gas Flows during Spine Surgery

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ABSTRACT

Purpose: *The present prospective clinical study was aimed at analysing the functional characteristics as well as the safety of the recently introduced Limb O anaesthesia breathing circuit during controlled mechanical ventilation at different fresh gas flows during spine surgery.*

Method: *The study was conducted on 50 adult healthy patients, who underwent spine surgery under general anaesthesia for more than three hours. The study was conducted with a decremental reduction of FGF in stages from the conventional 4 L/min. to 2 L/min; 1.5 L/min. and 1. L/min. The vital parameters studied during the study period included five lead ECG, HR, ABP, SpO2, ABG; Serum Electrolytes, Oropharyngeal temperature and urine output. The ventilation monitoring included: Tidal volume, Minute volume; Respiratory rate; Dynamic as well as static compliance of Peak Airway pressure and Mean airway pressure; PEEP value; FIO2; MAC of volatile anaesthetics. In addition, inspired as well as the expired EtCO2 values were monitored with a special consideration.*

Results: *The study demonstrated that biluminal single tube anaesthesia circuit performed well with no statistically significant differences in the studied parameters as long as the FGF was above 1.5 L/min. Rebreathing was observed with a low flow of 1.0 L/min. FGF and thus the study was restricted to 15 patients in this group.*

Conclusion: *The present study concludes that the minimum FGF of 1,5 L/min. is required to conduct a safe routine anaesthesia practice. while using 2.7 mts. long biluminal single tube Limb-O circuit.*

Keywords
Limb-OTM adult Anaesthesia Circuit, Controlled ventilation.

Introduction
Kaul TK, et al. [1] observed that, an ideal anaesthesia breathing circuit should be simple, safe, and inexpensive; sturdy, compact, lightweight; with ability to deliver warm and humidified inspired gases; effectively eliminate CO**2** even at low fresh gas flow; able to protect patients from barotrauma; should offer low resistance with a uniform internal di ameter; and have minimal dead space. Likewise, the brochures available describing the recently introduced biluminal single tube Limb O anaesthesia Circuit by Vital Signs as well as Olive Vent LiM-BO 2.7 mts. Q tube meets all the requirements of an ideal anaesthesia breathing circuit. In addition, this innovative bilumen single tube is supposed to have a lower compressible volume loss; low Ins. / Exp. resistance and the patients efforts; effectively transfers heat from the expiratory to inspiratory side of the circuit, thus aiding the patient to remain normo-thermic with a reduced infection rate. In addition, the 2.7 mts. Long Limb-O' breathing system is latex free; uses less plastic, light weight and can be inter-changed easily as an anaesthesia; transport as well as ICU ventilator circuit without wasting time. However, the available literature is silent on the minimum fresh gas flow {FGF}that is required for its safe use.

Aim of the Study
The aim of the present clinical study on the newly available 2.7 mts. long tube biluminal breathing circuit was to evaluate its

performance at different fresh gas flows; so as to arrive at a safe minimal fresh gas flow that is required while conducting routine anaesthesia practice using circle system.

Method

Study design

The present observational prospective cohort study included a convenience cohort population of patients who were scheduled to undergo elective prolonged neurological surgery both in supine as well as in prone position. This observational retrospective review was conducted at a tertiary care teaching hospital, between January to june2020. The study followed the Declaration of Helsinki and the Ethics Committee approved the project protocol. Written informed consent was obtained from the patients to participate in the observational study.

Sample

Participants included 50 subjects belonging to both the sex; ASA I and II; weighing between 65 to 75 Kg.; and aged around 50 years.

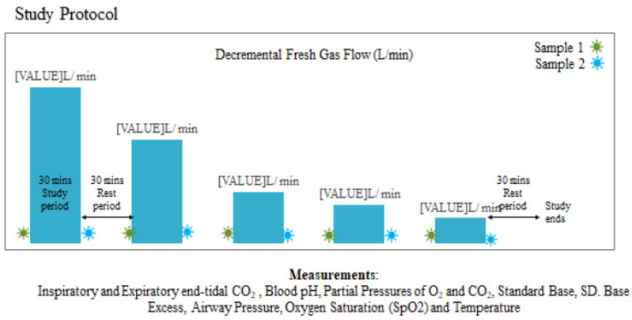
Study measurement

The prospective clinical study was conducted at an advanced the Neuro-Operation Theatre of 0ur, that is equipped with a high end Avance C52 Datex Ohmeda Anaesthesia Workstation. The workstation is equipped with a ventilation monitor as well as a five-channel colour vital monitor. To start with : a]. Anaesthesia workstation was set to deliver 4 L/Min. of fresh gas flow (FGF) comprising 50 : 50% of Oxygen and Nitrous Oxide respectively along with Sevoflurane or Isoflurane at a desired MAC value.. The canister was charged with Fresh Soda lime to its brim. b]. Vital Monitoring with trending and data retrieving facility included two channel five lead ECG; including ST segment analysis: Invasive arterial blood pressure; ABG; Serum Electrolytes, SpO**2**; Body Temperature from the Oropharynx; in addition hourly urine output was measured using urometer bag. c]. The ventilation monitoring included: set as well as the delivered values or the expired values along with the alarm setting of: Tidal volume, Minute volume; Respiratory rate; Airway pressure; PEEP value; FIO2; MAC value of volatile anaesthetics; d]. special importance was given to Inspired as well as the expired EtCO2 values at different FGF.

Sampling Protocol

Graph 1 explains the sampling protocol that was followed during the study period under general anaesthesia using the new circuit. Definition of "Sample" indicates that the study parameters were measured and documented at a distinct fixed time frame of 30 minutes called "phase" before making the next decremental change inth 2L/min.FGF; phase 3 with 1.5 L/min. FGF and the phase 4 with 1l/min. FGF; along with a rest period of 30 minutes for recalibration. Whereas sample one and sample two represents beginning of the newly reset FGF and at the end of 30 minutes of breathing period respectively. Graph 1

Table 1 Details that the study that was conducted on 50 subjects who underwent protracted neurosurgical procedures under general anaesthesia with IPPV using the newly introduced long biluminal circuit. All the study subjects were of aged within fifty years and there was no statistically observed difference in their age or weight of the study subjects belonging to both the sex. Regarding the duration of the surgery, either supine or prone position during surgery were identical in the study group.



Demographic observations

Table 1: Demographic variables:

	Male (n-24)	Female (n-26)
Age in Years	48.6±12.9	47,8±11.8
Weight in KG.	65.2±6-7	67.2±5.5
Duration in hours	6,3±07	6.3±07
Prone position	10	10
Supine position	15	15

Statistical Analysis

Need for a ML based approach to model the case outcomes: Statistical Method:

- While the overall study was planned to expose 50 individuals to all the FGF decrements including the low gas flow (< 1L/ min), owing to the occurrence of rebreathing (*event of interest; inspired Et-CO2 ≥ 0.5 mmHg*) the study observations was truncated after the first 15 subjects and the remaining patients were exposed only up-to 1.5L/min and not below that.
- Given the difficulty in managing rebreathing and subsequent risks of surgical outcomes post operatively- it was decided to truncate the observations as mentioned earlier to only 15 subjects *[exposed group]* and rest of the 35 subjects *[non-exposed group]* went through the entire protocol and all other measurements were made except at a fresh gas flow of 1L/ min.
- In order to overcome the lack of observations at < 1.0L/ min FGF rates, a 2-step analytical approach was undertaken to establish the optimal FGF flow for the current circuit of interest.
- A Machine Learning based nearest neighbours algorithm was applied to match relevant cases for obtaining the expected inspired Et-CO2 for the non-exposed group accurately, followed by testing for occurrence of rebreathing at various FGF levels.

Nearest Neighbour (NN) algorithm to accurately establish the values in the non-exposed group: *NN based hot deck imputation methodology*

- A machine learning based approach using the Nearest

Neighbour algorithm was used to create a hot deck case matching pair based on the existing data set to predict missing values of interest in the non-exposed patients. The expected data was ranked based on Euclidean distance and the rank classifier was flagged to improve the accuracy of the case matching pairs. The values were assigned from the most relevant matching Pairs.

- Key Highlights: NN assumes the data to be in a numeric space. In other words, metrics/features/variables should be quantitative in nature to create a hot deck case matching based on distance like Euclidian distance. In the current analysis the algorithm was tweaked to accommodate the mix of both quantitative and qualitative variables. The values were range transformed before training the model algorithm.
- The following variables were included for matching - Inspiratory and Expiratory end-tidal CO2, Blood pH, Partial Pressures of O2 and CO2, Standard Base, SD. Base Excess, Airway Pressure, Oxygen Saturation (SpO2) and Temperature.
- R software was used to run the all the analysis.

Statistical analysis to test whether there is increase in both inspired and expired CO2 with an FGF of 1.0 L/ min. *A single tailed paired T-test to check whether there is increase in both inspired and expired CO2 with 1.0 L/min FGF when compared to higher FGF:*

- After an exploratory data analyses and establishing the normality of the data. Relationships between the independent and dependent variables of interest were measured.
- There was no significant correlation between co-variates.
- Post the model data creation, the single tailed paired samples t-test was used to assess the occurrence of rebreathing *(increase in inspired Et-CO2 > 0 mm Hg)* at various FGF levels.

NN algorithm output: *Imputation for a non-exposed subject to 1L/ min FGF was done based on an exposed subject to 1L/min FGF with a least similarity score as illustrated below*

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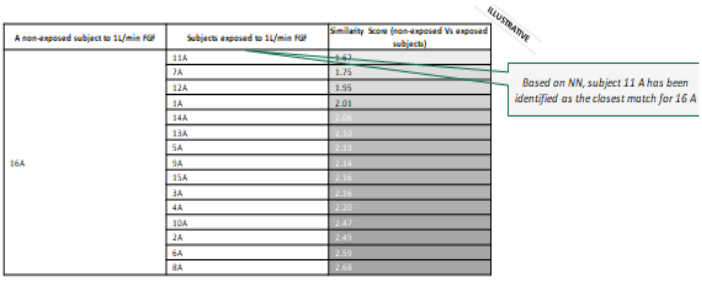
NN algorithm output: *Imputation for a non-exposed subject to 1L/ min FGF was done based on an exposed subject to 1L/min FGF with a least similarity score (as illustrated below}.*

- Similarity scoring was modeled on the basis of Euclidean distance of the nearest neighbor, relevancy was established based on the following attributes:
- Inspiratory and Expiratory end-tidal CO2, Blood pH, Partial Pressures of O2 and CO2, Standard Base, SD. Base Excess, Airway Pressure, Oxygen Saturation (SpO2) and Temperature associated with 6 L/min FGF to 1.5 L/min FGF



Graph 2 Test for rebreathing between 1.5L/ Min and 1L/ min FGF at the start of test period:

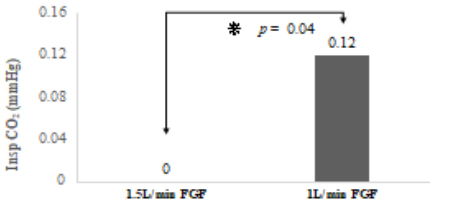
Graph 2: Delineates the main concern about rebreathing that may occur when the FGF is reduced from 1.5 L/min. to 1 L/min. The comparative observation on sample 1taken with FGF of 1,5 vs. 1 L/min.; shows that there was a significant rebreathing at 1 L/min FGF as indicated by an increase in EtCO2 values as well as the inspired CO2 values.

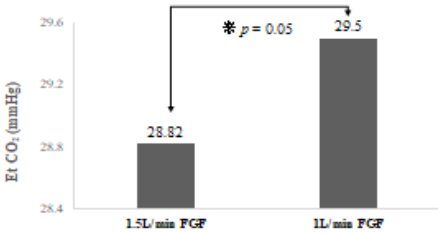
Graph 3 Test for rebreathing between 1,5 L/min and 1 L/min. FGF: Sample 2.

Graph 3: Delineates the main concern about rebreathing that may occur at the end of 30 minutes with FGF 1.5 L/min. vs. 1 L/min. The comparative observation on sample 2 taken at the end of 30 minutes with FGF of 1,5 vs. 1 L/min.; shows that there was a significant rebreathing at 1 L/min FGF as indicated by an increase in EtCO2 values as well as the inspired CO2 values.

Test for rebreathing between 1.5L/ Min and 1L/ min FGF at the start of test period
Sample 1

p-Value ≤0.05 and negative mean associated with both values denote that there is increase in CO_2 with 1.0 L/min fresh gas flow (FGF) when compared to 1.5 L/min FGF





N	Mean	SD Dev	SD Err	Minimum	Maximum
50	-0.1200	0.4798	0.0679	-90.0000	0.0000

Mean	95% CL Mean		SD Dev	95% CL SD Dev	
-0.1200	-infty	-0.0062	0.4798	0.4008	0.597

N	t value	Pr < t
49	-1.77	0.04

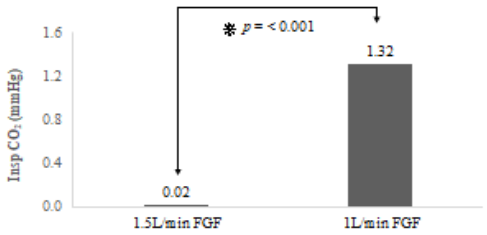
N	Mean	SD Dev	SD Err	Minimum	Maximum
50	-0.6800	2.9028	0.4105	-90.0000	6.0000

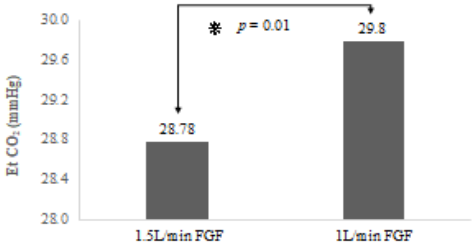
Mean	95% CL Mean		SD Dev	95% CL SD Dev	
-0.6800	-infty	0.0085	2.9028	2.4248	3.6172

dF	t value	Pr < t
49	1.66	0.05

Test for rebreathing between 1.5L/ Min and 1L/ min FGF at the start of test period
Sample 2

p-Value ≤0.05 and negative mean associated with both values denote that there is increase in CO_2 with 1.0 L/min fresh gas flow (FGF) when compared to 1.5 L/min FGF





N	Mean	SD Dev	SD Err	Minimum	Maximum
50	-0.1300	0.4629	0.0655	-2.0000	-1.0000

Mean	95% CL Mean		SD Dev	95% CL SD Dev	
-0.1300	-infty	-0.1902	0.04629	0.3867	0.5768

dF	t value	Pr < t
49	-19.86	<0.001

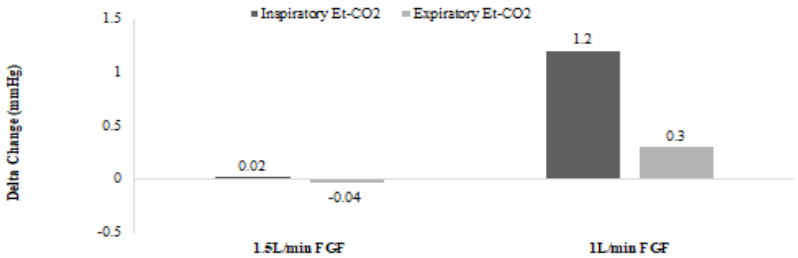
N	Mean	SD Dev	SD Err	Minimum	Maximum
50	-1.0200	2.8463	0.4025	-10.0000	5.0000

Mean	95% CL Mean		SD Dev	95% CL SD Dev	
-1.0200	-infty	-0.3451	2.8463	2.3776	3.5469

dF	t value	Pr < t
49	-2.53	0.01

REBREATHING
Significant occurrence of rebreathing noted between the start and end period for FGF of 1L/ min

Delta change between the start and end period of FGF sequence shows a significant rebreathing (insp. Et-CO_2 > 0mmHg)



Graph 4 Observed CO2 values from sample 1 to sample 2:

Graph 4: Summarises the observed changes from Sample 1 to the Sample 2 drawn after 30 minutes into the study. The observed inference dictates that there was a statistically significant increase in rebreathing that warranted to restrict the study at 1 L/min FGF in 15 patients. Towards the statistical inference, the data from the 15 patients was exponentiated to the full complement of 50 patients. All the measured parameters under the study were within their basal values. except for an early sign of rebreathing at low FGF of 1 L/min., R software was used to run the all the analysis

Excessive Humidification

During the study, unusually large amount of vapor condensation was noticed in the circuit after using the circuit for over three hours. Even some amount of water used to start accumulating at the dependent area causing some bubbling during movement of gases. This problem was solved by introducing HMV filter at the patient end as well as at the inspiratory limb near the circle absorber.

The present study is in conformity with the previous investigation conducted by Sanjay Kalani, et al. [2] titled "Comparison of Limb-OTM Circuit with Conventional Dual Limb Circuit in Controlled Ventilation". They conducted a comparative analysis of the functional characteristics of Lmb-O anesthesia breathing circuit vs. conventional dual limb circuit in controlled mechanical ventilation on 60 orthopedic surgery patients. They found that the group of patients under Limb-O circuit maintained low compliance and retained high temperature of gases in comparison to conventional group, During the present study the measured nasopharyngeal temperature remained constant over the course of the study lasting more than 6 hours. Chitra RT, et al. [3] reported two incidences of wrong connection of the breathing circuit. The patient end of Limb-O breathing circuit was attached to reservoir bag end and actual bag end of breathing system was connected to face mask. The wrong connection was identified only by the blue lining of the circuit. They recommend that the person who initiates the machine check should finish it and put the anaesthesia machine in the final pre-use position. Instead of the second reservoir bag, the 'test lung' can be used to simulate the lung while checking the ventilator.

Conclusion

The present prospective clinical study found that minimum FGF of 1,5 L/min. is required for a safe routine anaesthesia practice. while using 2.7 mts. long biluminal single tube Limb-O circuit. One may have to incorporate more than one HMV filter at either end of the circuit when it is intended to be used for a long period of time lasting more than three hours.

Acknowledgement

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