

A portable inhalational induction device provides co-operative induction of anaesthesia in preanaesthetic area for children

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Background: We introduce a new, simple portable inhalational induction device (PD) that provides co-operative inhalational induction of anaesthesia using N₂O and subsequent sevoflurane in the preanaesthetic induction area in children.

Methods: Forty-five children (30 to 94 months old age, <35 kg) who were scheduled to undergo simple operations were assigned randomly to one of three regimens. Patients were encouraged by their parents to inhale N₂O followed by sevoflurane (PD N₂O-sevo group) or sevoflurane (PD sevo group) using a portable inhalational induction device in the preanaesthetic induction area until they were unable to respond to their names. They were then transferred to the operating room while maintaining inhalation of sevoflurane via the device. The control group underwent conventional inhalational induction in the operating room with the parents in attendance.

Results: Patients in the PD N₂O-sevo group had a higher co-operative inhalation frequency than the patients in the PD sevo or the control group. Anaesthesia induction in the PD N₂O-sevo and the PD sevo groups were faster than in the control group. Parent satisfaction score (0–100) was higher for the PD N₂O-sevo group than for the control group.

Conclusions: A new portable inhalational induction device allows faster induction in co-operation with parents present in the preanaesthetic induction area compared to conventional inhalational induction in the unfamiliar operating room with the parents in attendance. (Korean J Anesthesiol 2010; 58: 521-526)

Key Words: Inhalation induction, Nitrous oxide, Potable instrumentation, Sevoflurane.

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Introduction

Sevoflurane is commonly used for inhalational induction of anaesthesia in children without intravenous (i.v.) access [1,2]. However, inhalational induction of preschool children without i.v. access is often difficult because of fear and anxiety concerning unfamiliar environment of operating room, mask inhalation, immature reasoning and limited coping skills.

The oral premedication of benzodiazepine can be used to reduce preoperative anxiety for mask induction but it also could cause arousal distress or delayed recovery [3-5].

Other various measures such as use of preoperative medically trained clown for children, or interactive music therapy have been reported to allay preoperative anxiety but they did not relieve anxiety during mask induction of anaesthesia [6-8].

A few novel equipments to avoid 'mask fear' for the inhalation induction in children have been reported. Mahajan et al. [9] introduced a whistle fits into the open tail end of the reservoir bag that it blow only when patients breath from the bag. In Jagannathan's report [10], children were encouraged to breath through the mouth piece that is attached to breathing bag. These two devices, however, can be used only in connection with anaesthesia machine in the operating room.

We devised a new, simple and inexpensive portable inhalational induction equipment that can be used in the pre-anaesthetic induction area for the paediatric patients. The objective of this clinical study is to introduce the new device and approve the clinical feasibility by comparing variables with that of the conventional inhalational induction method.

We hypothesized that the portable inhalational induction device will provide more co-operative and faster induction with the help of parents in the preanaesthetic induction area than the conventional inhalational induction in operation room with attending parents dressed in 'mask and gown.'

The primary outcome is the frequency of co-operative inhalation via a mask. The secondary outcomes are anxiety score on mask introduction, mask acceptance score and parent satisfaction with the inhalational induction method of their children.

These variables were compared between three methods of inducing anaesthesia: a portable inhalational induction device with N₂O inhalation followed by sevoflurane inhalation or with sevoflurane inhalation in preanaesthetic induction area and a conventional inhalational induction in the operating room.

Materials and Methods

After the ethics committee of our institution approved this study, written informed consent was obtained from the parents of the subjects. Paediatric patients who were scheduled for

simple elective surgery and satisfied the inclusion criteria were enrolled. Inclusion criteria were age between 30 and 95 months old age, body weight less than 35 kg and ASA class 1 or 2. Children were excluded from the study if there was evidence of a reactive airway, an upper respiratory tract infection, the use of a medication known to affect cardio-respiratory function.

Forty-five patients were assigned using a computer generated random number table to one of three regimens by one of the investigators, who did not participate in the induction of anaesthesia. The treatments were: inhalational induction in the preanaesthetic induction area using the portable inhalational induction device with N₂O followed by sevoflurane (PD N₂O-sevo group, n = 15); or with sevoflurane (PD sevo group, n = 15); conventional inhalational induction in the operating room with an attending parent (control group, n = 15).

One anaesthetist administered inhalational induction to all patients and did not participate in assessing the variables. The procedure was explained and demonstrated for the patients and their parents in the preanaesthetic induction area on the day of the operation. A trained research nurse blinded to the purpose of this study recorded the variables during anaesthesia.

The preanaesthetic induction area was continuous with the reception area and complied with standards for an anaesthetizing location, including the availability of suction, oxygen delivery, positive pressure ventilation and monitoring (anaesthesia machine) and resuscitative drugs and equipment. Gas samples were obtained from the breathing zone of the anaesthetist during ten simulated inductions using a portable inhalational induction device before the study was commenced. During each induction simulation, three gas samples were obtained at 90 s intervals.

The portable inhalational induction device consists of a face mask, a T-shaped connector containing two one-way valves, adaptors, a corrugated tube, a Y-connector, two on-off valves and two 5 l reservoir bags (Fig. 1). The two one-way valves of the connector were obtained from a baby resuscitator (Ambu Baby Resuscitator, Ambu International A/S, Denmark) and maintained uni-directional flow from the reservoir bags to the patient, thus preventing re-breathing of exhaled gas. Gas flow from the reservoir bags to the corrugated tube was opened using the on-off valve (Jaqno siphon,® Jaqno Co., Gwangmeung, Korea) located between the reservoir bag and the Y-connector.

The anaesthesia machine (Ohmeda, Madison, WI) was primed with 8 vol% sevoflurane in an oxygen mixture at a flow rate of 4 L/min for 5 min. This gas mixture was used to fill one reservoir bag for the PD N₂O-sevo group and two reservoir bags for the PD sevo group. For the PD N₂O-sevo group, the second of the two reservoir bags was filled with 50% N₂O in oxygen using another anaesthesia machine that had been primed with N₂O (2 L/min) and O₂ (2 L/min) for 5 min. Concentrations of N₂O

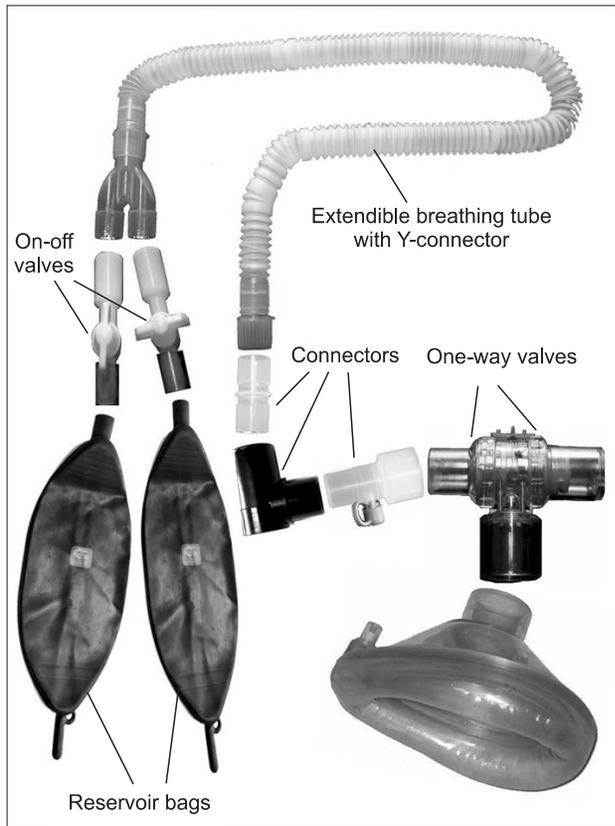


Fig. 1. Composition of the portable inhalational induction device. The portable inhalational induction device comprises a face-mask, a T-shaped connector containing two uni-directional valves, three connectors, one extendible corrugated breathing tube, one Y-connector, two on-off valves, and two 5 L reservoir bags.

and sevoflurane during filling and discharging of the reservoirs were measured 15 times for each group before the study using continuous gas analysis equipment (Datex-Ohmeda S/5; Datex-Ohmeda Inc., Louisville, CO).

The anxiety state of the patients was evaluated when they arrived at the preanaesthetic induction area and when they were introduced to the mask used to induce anaesthesia according to the modified Yale Preoperative Anxiety Scale [11].

Sedation scores (0, awake/alert; 1, sleep/responds appropriately; 2, somnolent/arouses to light stimuli; 3, deep sleep/arouses to deeper physical stimuli; and 4, unarousable to stimuli) [12] were determined when the patient arrived at the preanaesthetic induction area, when the patient was separated from the parents and when i.v. access was established.

Premedication was not administered. Children were reassured by the parents and the anaesthetist when they were fitted with the leads of portable electrocardiogram, non-invasive blood pressure and oxygen saturation monitors before commencement of inhalational induction.

On the day of surgery, the parents were asked to encourage

their children to inhale the gas via a scented face mask and were informed that, if the patient did not comply, the mask would be forcibly applied by the anaesthetist and that this would induce mild sedation within two or three breaths.

Patients of PD N₂O-sevo group (n = 15) were encouraged by their parents and an anaesthetist to inhale the 50% N₂O 10 times and then to inhale the sevoflurane.

Patients of PD sevo group (n = 15) were encouraged by their parents and an anaesthetist to inhale the sevoflurane via a face-mask in the preanaesthetic induction room. When the patients did not respond to the name, they were transferred to the operating room, during which inhalation of sevoflurane was maintained via the portable inhalational induction device and patients were monitored continuously for the PD N₂O-sevo and PD sevo groups.

For the control group (n = 15), anaesthesia was induced in the operating room using a face mask connected to breathing circuit of anaesthesia machine with a parent in attendance.

Once anaesthesia was induced, an i.v. cannula was inserted and atropine (0.02 mg/kg) was injected. Vecuronium bromide (0.1 mg/kg) was administered to facilitate endotracheal intubation. General anaesthesia was maintained with 2–3 vol% sevoflurane and 50% N₂O in O₂ at a flow ratio of 1 : 1. Fentanyl (1 µg/kg) was used as an adjuvant analgesic during surgery if needed.

The duration of the anaesthesia induction was defined as the interval between commencement of encouragement to breathe the gas and the time at which the patient ceased to respond to his or her name assessed every 5 second.

Mask cooperation level during induction of anaesthesia was assessed (1 = easy, 2 = slightly resistant, 3 = markedly resistant) [13].

The number of co-operative inhalations and the total number of inhalations (co-operative plus inhalations commanded by parent) until the patient ceased to respond to his or her name were recorded.

Complications during anaesthesia were grouped into five main categories: coughing, laryngospasm, breath-holding, involuntary or purposeful movement of a limb and excessive salivation [14]. Bradycardia (heart rate < 100 beats/min), hypoxia (SpO₂ < 95%) and respiratory depression (respiration rate < 8 breaths/min) during anaesthesia were also recorded. The interval between discontinuation of sevoflurane inhalation and extubation was recorded.

Emergence delirium scores (1, no symptoms of emergence delirium; 2, mild symptoms such as occasional movement or crying and no need for restraint; 3, marked symptoms of emergence delirium such as thrashing or a need for restraint or constant crying) [15] were recorded in the post-anaesthetic recovery room. Children were discharged from the recovery

room at the discretion of the anaesthetist, based on discharge criteria [16], and the recovery time was noted.

Parents were asked to score their degree of satisfaction with the anaesthesia induction method and their child's recovery using a 100 mm linear visual analogue scale (0 = very dissatisfied, 100 = very satisfied).

The sample size required for this study was estimated from a pilot study involving 10 patients per group. For a two-tailed α error of 5% and a β error of 10%, at least 13 patients per group were estimated to be required to detect a 2.6 times higher incidence of co-operative gas inhalation for the PD N₂O-sevo group (median, range was 17.5, 0–22) compared with the control group (6, 0–14).

Table 1. Patient Characteristics and Duration of Surgery

	Control (n = 15)	PD sevo (n = 15)	PD N ₂ O-sevo (n = 15)
Age (months)	66 (30–91)	59 (30–85)	63 (36–94)
Gender (M/F)	8/7	8/7	9/6
Weight (kg)	21 (4.3)	19 (3.8)	21 (4.4)
Duration of surgery (min)	36.6 (20–116.6)	38.3 (13.8–108.3)	36.6 (18.3–116.6)

Values are expressed as the median (range), numbers or mean (SD). Control: conventional inhalational induction, PD sevo: inhalational induction with sevoflurane from a portable inhalational induction device, PD N₂O-sevo: inhalational induction with N₂O followed by sevoflurane from a portable inhalational induction device. P > 0.05.

Table 2. Time Associated with Induction of Anaesthesia and Recovery (min)

	Control (n = 15)	PD sevo (n = 15)	PD N ₂ O-sevo (n = 15)
Induction	5.8 (4–10)	4.5 (3.5–6.3)*	4.3 (3.3–5.3)*
Interval between discontinuation of sevoflurane and extubation	12.3 (8.3–14.8)	10.5 (5–16.5)	8 (5–15)
Recovery	48 (42–73)	42 (25–68)*	47 (33–60)

Values are expressed as the median (range). Control: conventional inhalational induction, PD sevo: inhalational induction with sevoflurane from a portable inhalation induction device, PD N₂O-sevo: inhalational induction with N₂O followed by sevoflurane from a portable inhalational induction device. *P < 0.05 vs. the control group.

Table 3. Frequency of Gas Inhalation during the Induction of Anaesthesia

	Control (n = 15)	PD sevo (n = 15)	PD N ₂ O-sevo (n = 15)
Frequency of co-operative gas inhalation	8 (0–15)	9 (1–15)	18 (0–22)*,†
Total frequency of gas inhalation (co-operative plus forcible)	10 (8–15)	10 (7–15)	19 (14–22)*,†
Numbers of patients with mask co-operation score of 1, 2 or 3	6, 6, 3	8, 4, 3	14, 0, 1*
Sedation score (0–4), before induction	0 (0–0)	0 (0–0)	0 (0–0)
, during separation	3 (2–3)	3 (2–3)	3 (2–3)
, during i.v. access	4 (3–4)	4 (3–4)	4 (3–4)
Anxiety scale (5–22), before induction	13 (6–21)	10 (5–20)	14 (5–22)
, on mask application	17 (10–25)	11 (6–21)*	15 (6–22)
Numbers of patients with emergence delirium score of 1, 2 or 3	0/6/9	0/7/8	0/8/7

Values are expressed as the median (range) or numbers. Control: conventional inhalational induction, PD sevo: inhalational induction with sevoflurane from a portable inhalational induction device, PD N₂O-sevo: inhalational induction with N₂O followed by sevoflurane from a portable inhalational induction device. *P < 0.05 compared with the control group. †P < 0.05 vs. the PD sevo group.

Continuous data such as age, weight, time, inhalation frequencies and gas concentration were analysed using an one-way ANOVA followed by a least significant difference (LSD) for multiple comparisons. Gender distributions were analyzed by the Chi-squared test. Scores were analysed using the Kruskal-Wallis test followed by Bonferroni method for multiple comparisons. Statistical significance was defined as P < 0.05.

Results

Patient characteristics and duration of the operation were similar for all three groups (Table 1). Inhalational induction was faster for the PD N₂O-sevo and PD sevo groups than for the control group (P < 0.001, Table 2). Recovery time was shorter for the PD sevo group than for the control group (P = 0.028, Table 2).

The frequency of co-operative inhalation and total number of gas inhalation during induction were higher in the PD N₂O-sevo group than in the PD sevo and control groups (P < 0.001, Table 3).

The transition to sevoflurane after inhalation of N₂O was easily accomplished by all except one of the patients in the PD N₂O-sevo group. He initially refused to inhale N₂O but did not exhibit discomfort when he inhaled sevoflurane after being forced by his parents to take 10 breaths of N₂O. One patient in the control group rejected co-operative inhalation.

Mask cooperation was better in the PD N₂O-sevo group than in the control group (P = 0.016, Table 3).

Table 4. Concentrations of N₂O and Sevoflurane in the Reservoir Bags during Filling and Discharge

	Control (n = 15)	PD sevo (n = 15)	PD N ₂ O-sevo (n = 15)
Filling (sevoflurane, vol%)		8.2 (0.0)	8.1 (0.0)
Discharge (sevoflurane, vol%)	8.0 (0.0)	7.9 (0.1)	7.8 (0.1)
Filling (N ₂ O, %)			50.9 (0.9)
Discharge (N ₂ O, %)			49.6 (0.9)

Values are expressed as the mean (SD). Control: conventional inhalational induction, PD sevo: inhalational induction with sevoflurane from a portable inhalational induction device, PD N₂O-sevo: inhalational induction with N₂O followed by sevoflurane from a portable inhalational induction device.

The anxiety scores upon the introduction of the anaesthesia mask were lower for the PD sevo group ($P = 0.015$) than for the control group.

No additional drugs (fentanyl or inotropics) were administered in any of the three groups.

One patient in the PD N₂O-sevo group developed bradycardia (90 beats/min) just after transfer from the gurney to the operating table.

Complications such as cough, laryngospasm, breath-holding, involuntary or purposeful movement of a limb, excessive salivation, hypoxia ($SpO_2 < 95\%$), or respiratory depression (respiration rate < 8 breaths/min) during anaesthesia were not observed. There were no episodes of nausea, vomiting, airway irritability or shivering during the recovery period. Parent satisfaction score (0–100) was higher for the PD N₂O-sevo group (median, range; 95, 80–100) than for the control group (80, 50–100) ($P = 0.008$).

The mean concentration of sevoflurane during filling and discharge did not differ between groups (Table 4).

Discussion

This clinical study is not primarily a study of the equipment itself but of place of induction (in the preanaesthetic area vs. operating room), parents' possibilities to support (in the preanaesthetic area vs. operating room with mask and gown), sequential N₂O and sevoflurane inhalation vs. sevoflurane.

In our study results, the frequency of co-operative gas inhalation was higher for the PD N₂O-sevo group than for the PD sevo or the control groups. The co-operative gas inhalation via a mask is a form of an active participation of children and it was more likely in conditions when the children were willing to accept mask application with lower anxiety and when the N₂O was inhaled first.

The control group patients exhibited an increasing degree of anxiety while they were moving into the operating room and showed higher anxiety for the mask introduction than the

patients in the PD sevo group. The portability of the inhalational induction device is clinically important as it allows induction in the preanaesthetic induction area in more co-operation with parents present compared to the conventional inhalational induction that is performed in the unfamiliar operating room with passive parents dressed in hat and gown, eventually face mask.

The mask cooperation was better in the PD N₂O-sevo group than in the control group. The transition to sevoflurane after inhalation of N₂O was easily accomplished by all except one patient in the PD N₂O-sevo group. Mild sedation by the N₂O may have reduced the incidence of rejection to sevoflurane and contributed to the greater satisfaction of parents of the PD N₂O-sevo group patients relative to that of the parents of control group patients.

The concept of using N₂O inhalation to induce light sedation [17] has several advantages, including rapid onset of sedation, the ability to titrate the flow ratio according to its effect, analgesia and rapid recovery from sedation [17]. However, successful application of N₂O depends on the patient's willingness to accept placement of the mask. Encouragement of patients to accept mask by parents in the preanaesthetic induction area may help to inhale N₂O more co-operatively than in the operating room.

The absence of airway complications and hypoxia during anaesthesia shows that the portable inhalational induction device is clinically acceptable. Assembly of the device requires only 1.5–2 min after a short period of becoming acquainted with the assembly procedure.

The mean level of sevoflurane in the preanaesthetic induction area was below the 0.5 parts per million (ppm) limit at all times (0.2 ± 0.07 ppm), as was the N₂O level (11.4 ± 2.0 ppm; threshold limit = 25 ppm) [18].

The anaesthetist who performed the induction knew which method was to be used but did not participate in measuring variables. A disadvantage of the portable inhalational induction device is that the reservoir bag has to be pre-filled with gas.

In conclusion, the portable inhalational induction device allows faster induction in co-operation with parents present in the preanaesthetic induction area compared to conventional inhalational induction method with parents present in unfamiliar operating room.

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