The Effect of Prolonged Face Mask Ventilation on Gastric Insufflation: A Prospective Observational Study

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ABSTRACT **Background:** Pulmonary aspiration is a potentially lethal perioperative complication that can be precipitated by gastric insufflation. Face mask ventilation (FMV), a ubiquitous anesthetic procedure, can cause gastric insufflation. FMV with an inspiratory pressure of 15 cm H_2O provides the best balance between adequate pulmonary ventilation and a low probability of gastric insufflation. There is no data about the effects of FMV > 120 seconds.

Objectives: To investigate the effect of prolonged FMV on gastric insufflation.

Methods: We conducted a prospective observational study at a tertiary medical center with female patients who underwent oocyte retrieval surgery under general anesthesia FMV. Pre- and postoperative gastric ultrasound examinations measured the gastric antral cross-sectional area to detect gastric insufflation. Pressure-controlled FMV with an inspiratory pressure of 15 cm H_2O was continued from the anesthesia induction until the end of the surgery.

Results: The study comprised 49 patients. Baseline preoperative gastric ultrasound demonstrated optimal and good image quality. All supine measurements were feasible. The median duration of FMV was 13 minutes (interquartile range 9–18). In the postoperative period, gastric insufflation was detected in only 2 of 49 patients (4.1%). There was no association between the duration of FMV and delta gastric antral cross-sectional area (-0.01; 95% confidence interval -0.04 to 0.01, $P = 0.31$).

Conclusions: Pressure-controlled FMV with an inspiratory pressure of 15 cm H_2O carries a low incidence of gastric insufflations, not only as a bridge to a definitive airway but as an alternative ventilation method for relatively short procedures in selective populations.

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KEY WORDS: face mask ventilation (FMV), gastric insufflation, gastric ultrasound, point-of-care ultrasound (POCUS), pulmonary aspiration

Pulmonary aspiration is a relatively infrequent but severe perioperative event that is a cause of anesthesia-related morbidity and mortality [1]. Many studies evaluate risk factors for pulmonary aspiration, with emergency procedures considered the most critical risk factor due to a full stomach [2]. As a result, various interventions, such as preoperative fasting guidelines, were introduced to minimize the risk of aspiration [3]. However, aspiration may occur even in fasted patients [4].

Pulmonary aspiration may occur due to gastric insufflation during ventilation in the setting of an unprotected airway, such as face mask ventilation (FMV) [5]. Over the years, much research has been conducted to identify the threshold of the positive ventilatory pressure beyond which the lower esophageal sphincter opens and gastric insufflation occurs. In the late 1980s and 1990s, several studies were conducted based on epigastric auscultation by a microphone or a stethoscope. Results showed that gastric insufflation occurred when the inspiratory pressure during FMV exceeded 20 cm H_2O [6-8]. In the last decade, as gastric ultrasound gained popularity and was incorporated in the recent subspecialty guidelines [9-11] as a tool for qualifying and quantifying gastric contents [12], the issue has become a research focus [13]. Some authors have compared the occurrence of gastric insufflation secondary to FMV with various ventilation volumes [14] while others compared it with various ventilation pressures.[15]. Research has shown that the FMV with an inspiratory pressure of 15 cm H_2O provides the best balance between adequate pulmonary ventilation and a low probability of gastric insufflation [15]. However, the duration of FMV in these studies was limited to the period of anesthesia induction.

This study is part of a larger parent prospective observational study that examined the impact of anxiety, ovarian stimulation, and FMV on gastric antrum size in women

undergoing oocyte pickup for in-vitro fertilization under general anesthesia. In this study we investigated the effect of a more prolonged period of FMV with a fixed positive pressure of 15 cm H_2O on gastric insufflation.

PATIENTS AND METHODS

ETHICS

The study was registered in the U.S. National Institutes of Health ClinicalTrials.gov (NCT04833530, registration date 06 April 2021). Ethics approval was provided by the institutional review board of Rabin Medical Center (Trial number, RMC 21-0010; chairperson, Prof. Ran Tur-Kaspa; registration date 21 March 2021). All included patients signed informed written consent. All methods were conducted following the relevant guidelines and regulations of Rabin Medical Center (Beilinson Campus) guidelines.

STUDY DESIGN

This article is based on a subset of data from a larger parent prospective observational study that examined the impact of anxiety, ovarian stimulation, and FMV on gastric antrum size in women undergoing oocyte pickup for in-vitro fertilization under general anesthesia. The study was segmented into two separate manuscripts. In the first manuscript, we explored the effect of preoperative anxiety and ovarian stimulation on gastric antrum size [16]. The current article represents the second segment of the study.

SETTINGS

We consecutively recruited women between 07 April and 09 August 2021. The study was conducted at Rabin Medical Center (Beilinson Campus), Petah Tikva, Israel.

PARTICIPANTS

In-vitro fertilization is the standard practice in assisted reproductive technology, and general anesthesia is often required during oocyte retrieval, which forms one of the fundamental steps during the process [17]. Recruitment of many follicles is feasible and even needed to increase success rates. Follicular aspiration from these stimulated, highly vascularized ovaries requires satisfactory surgical conditions, provided by minimizing breathing efforts and avoiding abdominal movements that may disrupt the process. Therefore, as the standard of care in our institution, these procedures are usually performed under general anesthesia with FMV.

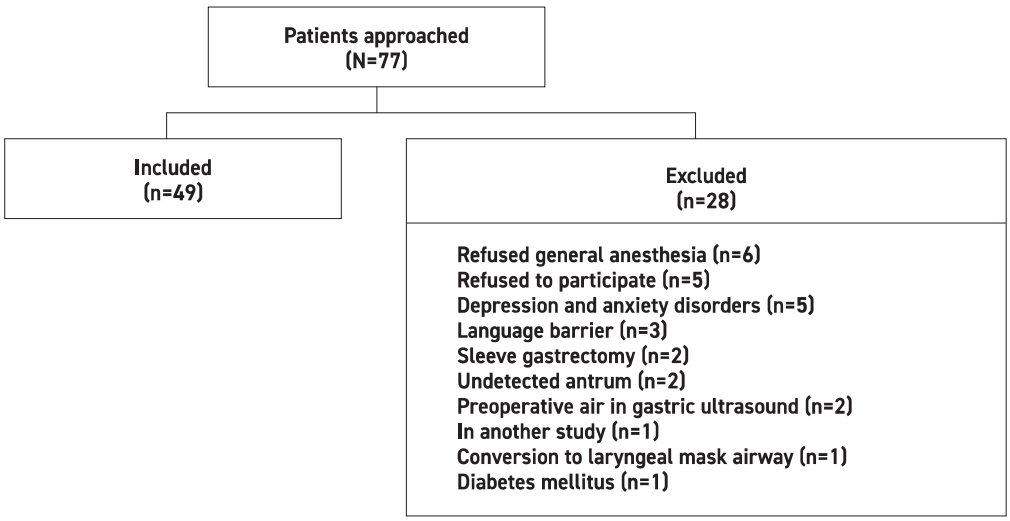
INCLUSION CRITERIA

Women undergoing oocyte retrieval for in-vitro fertilization under general anesthesia and FMV were included. They were 18 years of age or older and met American Society of Anesthesiologists Physical Status Classification ≤ 2.

EXCLUSION CRITERIA

Patients were excluded if they refused to participate, were diagnosed with diabetes mellitus or depressive and anxiety disorders, were prescribed regular antidepressant medications, had a history of bariatric surgeries, or showed air artifacts in the preoperative gastric ultrasonography [Figure 1].

Figure 1. Enrollment flow diagram



STUDY PROTOCOL AND OUTCOMES

Preoperative gastric ultrasonography was performed in the supine position using a point-of-care ultrasound machine (SonoSite EDGE, Inc., Bothell, WA, USA) fitted with a curvilinear array transducer (low-frequency 5-2 MHz) to measure the baseline cross-sectional area (CSA) of the gastric antrum. As per standard protocol [18], the transducer was placed in the epigastric region in a parasagittal plane just right of the midline. The gastric antrum is anteriorly bordered by the liver and posteriorly by the pancreas, with the inferior vena cava lying posterior to the pancreas. Once a clear image was obtained, it was frozen during gastric antral contractions to evaluate the relaxed width of the gastric antrum. The antral CSA was measured by tracing the entire circumference along the serosal layer using the trace caliper tool.

We performed an ultrasonography image quality score ranging from 1 to 3, in which 1 = poor, 2 = average, and 3 = good image quality.

After the initial ultrasound, general anesthesia was induced intravenously with propofol 2 mg/kg^{-1} (Fresenius Kabi, Germany) and fentanyl 75 μg (Rafa Laboratories, Israel). Once eyelash reflex loss had occurred to ensure proper mouth opening, a Guedel oropharyngeal airway (Besmed Health Business Corp., Taiwan) and a well-fitting disposable transparent face mask (#5 Inflatable Air Cushion Mask, Besmed Health Business Corp. Taiwan) were placed sequentially. FMV was conducted using a two-handed jaw-thrust technique followed by a head-tilt. Pressure-control ventilation was delivered by a Fabius® GS premium ventilator (Dräger Medical, Lübeck, Germany) with an inspiratory pressure of 15 cm H_2O, I:E ratio of 1:2, respiratory rate of 15 breaths min^{-1} and FiO_2 of 0.5 with air. No positive end expiratory pressure was added. Pressure-controlled FMV was conducted from the beginning until the end of the procedure. Anesthesia was maintained with small boluses of propofol (20–30 mg) as needed. Immediately following the surgery, FMV was stopped, and a postoperative gastric ultrasonography examination was performed.

The primary outcome was the incidence of gastric insufflation, which was defined as any acoustic posterior shadowing in the postoperative gastric ultrasound. Acoustic posterior shadowing is an artifact produced by air that blurs the posterior gastric wall and deeper structures. It has previously been described as *frosted glass appearance*. This situation makes the gastric antral CSA measurement unfeasible.

Secondary outcomes included gastric antral CSA difference between pre- and postoperative and image quality scores.

DATA COLLECTION

Patient characteristics were collected, including demographics (i.e., age, height, weight, and body mass index [BMI]), medical history (i.e., co-morbidities, concomitant medications, smoking status as well as history of postoperative nausea and vomiting, or motion sickness), perioperative data (i.e., duration of the procedure, nausea, and vomiting), and gastric ultrasonography parameters (i.e., pre- and postoperative: image quality score, gastric antral CSA, and gastric insufflation).

STUDY SIZE

This research represents a secondary analysis of the parent research; therefore, no sample size calculation was performed.

STATISTICAL METHODS

All continuous variables were assessed for normality of distribution using histograms and Q-Q plots. Due to the non-normal distribution of the variables, continuous variables are presented as median (1st to 3rd quartiles). Before the performance of linear regression models, statistical assumptions (i.e., linearity and independence of covariates) were assessed. The dependent variable was delta gastric antral CSA (the difference between pre- and postoperative antral CSA), while the duration of FMV, age, and BMI (in adjusted models) were independent variables. Non-linear associations between the duration of FMV and delta gastric antral CSA were assessed using three restricted cubic splines. *P-value* < 0.05 was considered statistically significant, and 95% confidence intervals (95%CI) were reported. Statistical analysis was performed using R Statistical Software, version R 4.1.2 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Our analysis included 49 patients. The enrollment flow diagram is presented in Figure 1. Patient characteristics and postoperative data are listed in Table 1.

The image quality was good in all included patients. In addition, optimal ultrasonographic conditions allowed the visualization of anatomical landmarks with clear identification of the gastric antrum, and the cross-sectional area measurements were achievable without difficulty.

The difference in the antral CSA between preoperative and postoperative was negligible [Table 2]. FMV median (1st to 3rd quartiles) duration was 13 minutes (9–18), ranging from 2 to 32 minutes.

Table 1. Patient characteristics and perioperative data

Variable	N=49	
Demographics		
Age in years (interquartile range)	36	(33–39)
BMI (kg/m²) (interquartile range)	23.7	(21.2–27.5)
Medical history		
Co-morbidities		
Healthy	32	(65.3%)
Hypothyroidism	5	(10.2%)
Other diseases*	5	(10.2%)
Asthma	3	(6.1%)
Gastrointestinal**	2	(4.1%)
Hematologic***	3	(6.1%)
Cardiovascular§	1	(2.0%)
Medications		
No medications	38	(77.5%)
Levothyroxine	6	(12.2%)
Other medications§§	3	(6.1%)
Bronchodilators	3	(6.1%)
Beta-blockers	1	(2.0%)
Motion sickness	13	(26.5%)
PONV	9	(18.4%)
Smoking	5	(10.2%)
Postoperative data		
Nausea in PACU	5	(10.2%)
Vomiting in PACU	0	(0%)
Duration of FMV	13	[9-18]

BMI = body mass index, FMV = face mask ventilation, PACU = post-anesthesia care unit, PONV = postoperative nausea and vomiting
*Systemic lupus erythematosus, epilepsy, neurofibromatosis, spontaneous chronic urticaria, and fibromyalgia
**Irritable bowel syndrome and ulcerative colitis
***Thalassemia, antiphospholipid syndrome, and thrombophilia
§Hypertension and arrhythmias
§§Omalizumab, mesalazine, hydroxychloroquine, metformin, and buprenorphine

Of the 49 patients with no baseline air in the preoperative gastric ultrasound, only two (4.1%) presented signs of gastric insufflation in the postoperative period [Figure 2]. In these two patients, the duration of FMV was 7 and 19 minutes, respectively, and no different conditions or events occurred during the procedure compared to those with no signs of gastric insufflation.

We found no association between the duration of FMV and delta gastric antral CSA (unadjusted β coefficient -0.00; 95%CI -0.03, 0.02; $P = 0.78$); this also held after adjusting for the known confounding factors age, BMI, and presence of co-morbidities (adjusted β coefficient -0.01; 95%CI -0.04, 0.01; $P = 0.31$).

We did not find a statistically significant non-linear relationship between the duration of FMV and delta gastric antral CSA as assessed by modeling with three restricted cubic splines, $P = 0.80$.

DISCUSSION

In this study, we found that prolonged pressure-controlled FMV with an inspiratory pressure of 15 cm H_2O caused only a small incidence of gastric insufflation.

In 2014, Bouvet and colleagues [15] investigated gastric insufflation at various inspiratory pressures (10, 15, 20, and 25 cm H_2O). They found statistically significant increases in the incidences of gastric insufflation with inspiratory pressure, from 19% (group 10 cm H_2O) to 59% (group 25 cm H_2O). They concluded that FMV with an inspiratory pressure of 15 cm H_2O provided the best balance between adequate pulmonary ventilation and a low gastric insufflation probability (35%). However, only 17 participants were enrolled in the 15 cm H_2O group, and the duration of FMV was limited to 120 seconds.

Four years later, Lee et al. [19] compared the incidence of gastric insufflation between pressure-controlled FMV and manual FMV. They found that the incidence of gastric insufflation was significantly higher in the manual FMV group (48%) compared with the pressure-controlled FMV group (12%). However, there were certain limitations to that study. First, neuromuscular blocking agents were used. Second, the study was conducted on pediatric patients. Last, the duration was limited to the period of anesthesia induction.

Our study included 49 female patients for oocyte retrieval surgery under general anesthesia using pressure-controlled FMV with an inspiratory pressure of 15 cm H_2O. Pressure-controlled FMV was continued from the induction of general anesthesia until the end of the surgery with a median duration of 13 minutes (ranging 2–32 minutes). Interestingly, gastric insufflation was only detected in two patients (4.1%). These two patients did not have an exceptionally prolonged duration of FMV, and there were no distinct characteristics compared to those without signs of gastric insufflation. In the remaining 47 patients, the gastric antrum was entirely well-defined, and gastric

Table 2. Perioperative gastric ultrasound data

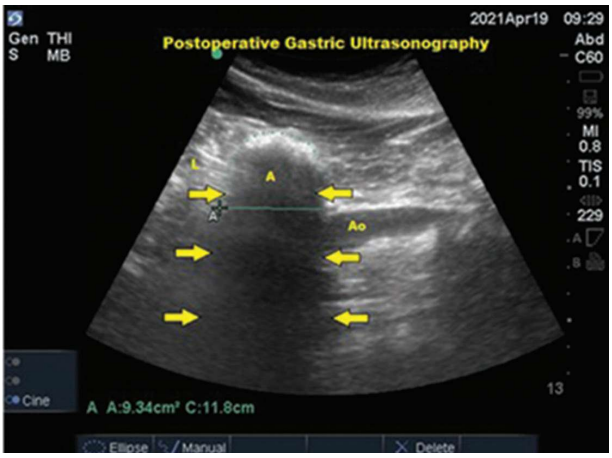
Variable	Gastric ultrasonography					
	Preoperative		Postoperative		Delta	
Image quality score	3	3–3	3	3–3	0	0–0
Gastric antral CSA (cm^2)	3.8	3.2–4.4	4.0	3.2–4.8	0.2	0.0–0.5

Continuous variables are presented as median [1st to 3rd quartiles]
CSA = cross-sectional area

Figure 2. Sagittal sonogram showing gastric insufflation. The duration of FMV was 21 minutes. Note the presence of air in the gastric antrum due to FMV. The yellow arrows mark the acoustic posterior shadowing artifact.
A = gastric antrum, Ao = aorta, FMV = face mask ventilation, L = liver, SMA = superior mesenteric artery

[A] Preoperative gastric ultrasonograpy

[B] Postoperative gastric ultrasonograpy



antral CSA measurement was feasible. Overall, our study conditions with a more prolonged FMV did not correlate or significantly increase the delta gastric antral CSA (the difference between pre- and postoperative antral CSA). In addition, none of the patients vomited in the post-anesthesia care unit, but five (10.2%) experienced nausea. The lack of vomiting may be related to the antiemetic effect of propofol or helped by the fact that they followed and complied with the standard fasting guidelines.

In our study, the FMV was set to an inspiratory pressure level of 15 cm H_2O. We found a much lower incidence of gastric insufflation (4.1%) than Bouvet et al. (35%) [15]. Nevertheless, this 4.1% incidence was based on a small sample size, in which the calculated 95% confidence intervals could be estimated between 0% and 9.6%.

Also, the difference with Bouvet et al. may be attributed to how FMV is delivered, thus reinforcing the previous findings by Lee et al. [19]. Pressure-controlled FMV allows the ventilator to deliver standardized respiratory mechanics, which include peak inspiratory pressure, ramp inspiratory flow, and inspiratory times that may translate into different forces applied on the lower esophageal sphincter. In contrast, manual FMV carries large variability in respiratory parameters and mechanics due to human factors. Rapid bag squeezing might quickly increase the inspiratory flow rate and pressure that may open the lower esophageal sphincter and lead to gastric insufflation. Moreover, pressure-controlled FMV enables two-hand mask ventilation, potentially allowing better face mask sealing compared with one-hand ventilation by manual FMV.

STRENGTHS AND LIMITATIONS

To enhance the study's internal validity and quality control, the investigators completed a training program, including dedicated teaching and a portfolio of live scans. Moreover, one of the investigators (CA) with experience in gastric ultrasonography assessed, reviewed, and verified all measurements before statistical analysis.

Our study has certain limitations. First, although this was the initial study to assess the effects of prolonged FMV on gastric insufflation, the sample size was still considered small; a larger cohort may yield more robust findings. Second, the dynamic nature of the stomach is an inherent limitation of any research utilizing gastric ultrasonography. Despite following a strict ultrasonography scanning protocol, the peristaltic contractions may have added an element of variability between successive measurements that cannot be completely defined. Third, the ultrasonography examiners were unblinded to the duration of FMV. Fourth, the selected study population was homogenous, with no known risk factors for perioperative aspiration. Since all the patients were admitted for elective cases while fasting for at least 6 hours, a more heterogeneous group with higher risk factors for perioperative aspiration may yield different results. Last, all measurements were conducted only supine for study purposes. Although gastric ultrasound in right lateral decubitus is a more reliable method and deemed the validated standard to assess the risk of pulmonary aspiration, we estimate that our fasted patients presented with a low risk of aspiration or empty stomach. The baseline measurements of antral CSA in the supine position were consistent and comparable to those in previous FMV studies [15,20].

CONCLUSIONS

Pressure-controlled FMV with an inspiratory pressure of 15 cm H_2O carries a low incidence of gastric insufflation, not only as a bridge for a definitive airway during induction of general anesthesia, but also as an alternative ventilation method for relatively short procedures in non-obese, non-paralyzed fasted patients. Furthermore, larger, high-quality studies that evaluate more diverse groups are warranted to define these findings better.

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