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# Reflux events detected by multichannel bioimpedance smart feeding tube during high flow nasal cannula oxygen therapy and enteral feeding: First case report

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## ABSTRACT

The use of high flow nasal cannula (HFNC) oxygen therapy is common in patients with respiratory distress to prevent intubation or ensure successful extubation. However, these critical patients also need medical nutritional support and practitioners are often reluctant to prescribe oral or enteral feeding, leading to a decrease in energy and protein intake. Vomiting and aspiration are the major concerns. A new technology detecting the presence and duration of gastro-esophageal reflux and preventing aspiration in real-time has been developed and our case shows how HFNC oxygen therapy exposes patients to significantly more reflux events as compared to mechanical ventilation. This is the first description of this technique observed in critical care.

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## 1. Introduction

High flow nasal cannula (HFNC) oxygen therapy has become one of the most commonly used tools to improve oxygenation in hypoxemic respiratory failure to avoid intubation as well as to ensure success of extubation [1–3]. However, this technique is associated with poor oral or enteral intake as described in children [4] and in adults [5]. Practitioners frequently fear that patients will vomit or aspirate. The ESCIM [6] and ESPEN [7] guidelines recommend to start oral or enteral feeding early in such “patients”, additionally the new ESPEN-WHO COVID-19 recommendations [8] recommend to “give early enteral nutrition (within 24–48 hours of admission)” but HFNC and non-invasive ventilation (NIV) may be a barrier to the implementation to these guidelines. Since HFNC is a relatively new technique, not much is known regarding the gastrointestinal tolerance to the insufflation of 40 to 60 L/min to the nasopharynx.

Several techniques have been developed to analyze the presence of reflux such as pepsin detection [9] or other diagnostic tools such as functional scintigraphy and esophageal pH [10]. However, these techniques are all experimental. Our case describes the use of a new smART+ naso-oro-gastric feeding tube equipped with multichannel bioimpedance sensors that can detect both minor/

massive reflux events, prevent aspiration with the ability to stop feeding and inflate an esophageal balloon when a reflux event occurs, reroute the potential aspiration to an outer bag in real-time. The smART+ feeding tube is part of the smART+ Platform that also includes the ability to instruct the user on correct positioning of the tube (initially and in continues use). When out-of-position is detected, the platform is stopping feeding, and dual feeding machine, compensation algorithms and mechanism for compensating the losses of feeding or fluids due to reflux events or feeding pause to prevent malnutrition are included. In addition, continuous metabolic monitoring and algorithm to choose best formula in on-going use according to the ICU nutrition ESPEN guidelines are integrated. The smART+ platform also includes a continuous and real-time urine flow monitoring for alerting on low urine flow according to KDIGO (Fig. 1). The smART+ feeding tube is a part of the smART+ Platform, (ART MEDICAL, Netanya, Israel. [www.artmedical.com](http://www.artmedical.com)). The detection of reflux events are performed using algorithms combining multichannel intraluminal bioimpedance sensors. Minor reflux is defined as gastric content above the lower esophageal sphincter (LES) but not more than 12 cm above and massive reflux is defined as gastric content 12 cm above the LES. The smART+ GRV drainage bag is intended to be used for collection of residual gastric content that are expelled during the duration of reflux events, which means that the technology allows gastric decompression per individual reflux event and is not waiting for a potential risk in accumulated volume after ~4–6 h.

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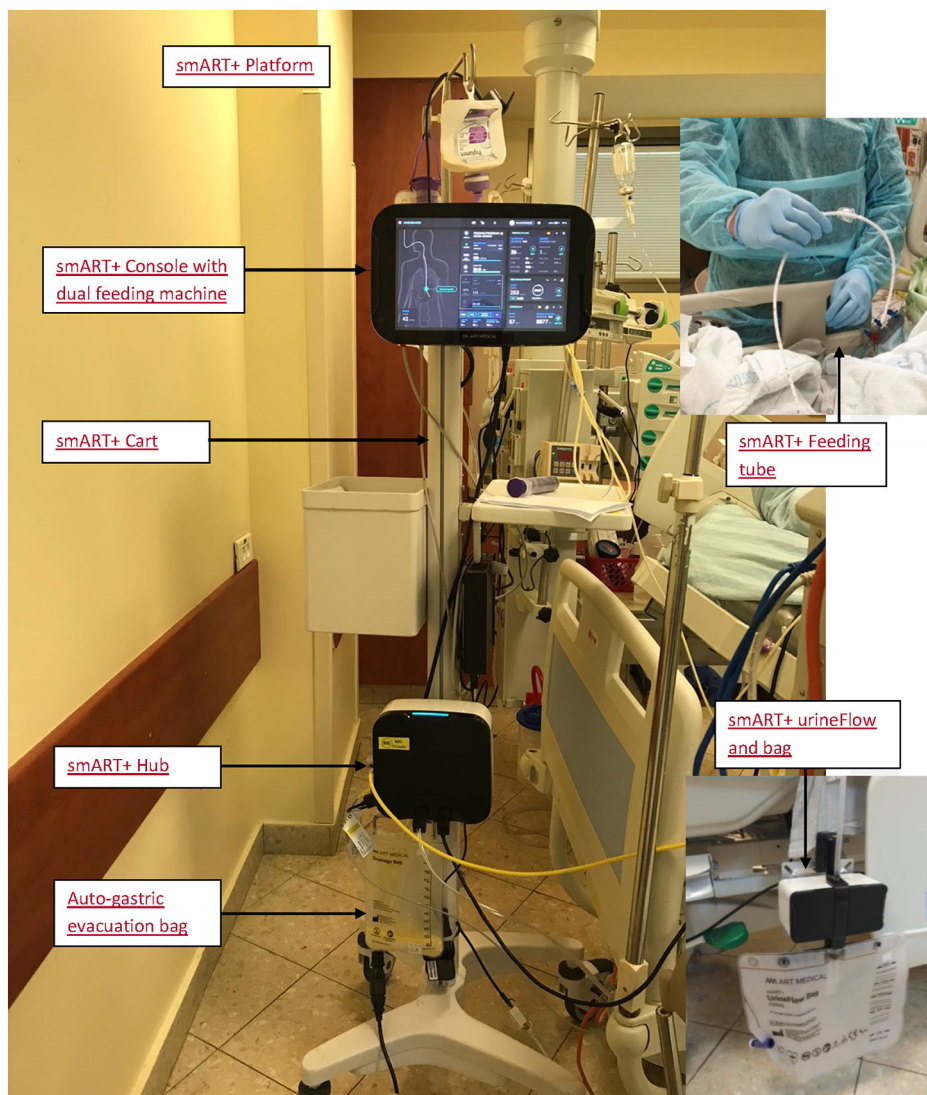


Fig. 1. smART platform description.

## 2. Case report

We describe the case of a 69 years old female with pelvic metastatic ovarian cancer that was admitted for acute respiratory failure and acute kidney injury (AKI). The differential diagnosis of AKI was obstructive uropathy versus secondary to tumor lysis syndrome (TLS). Admission APACHE II and SOFA were 34 and 11 respectively. She was intubated and a chest tube was inserted for large left pleural effusion. The patient received rasburicase for TLS, Piperacillin/Tazobactam empirically and noradrenaline for septic shock that developed following several hours after admission. Urinary tract ultrasound and abdominal CT scan didn't show hydro-nephrosis. Retrograde pyelography was not performed due to the deterioration of the patient. Continuous renal replacement therapy was started. The smART+ feeding tube was inserted according to the initial positioning instructions displayed on the platform screen, and confirmed by Xray (for study purposes). Any displacement of the tube during on-going use was detected by the system, accompanied with an alarm and paused the built-in feeding pump.

During the next three days the patient started to stabilize and noradrenalin dose decreased from 0.12  $\mu\text{g}/\text{kg}/\text{min}$  to 0.03  $\mu\text{g}/\text{kg}/\text{min}$ . At day 4, she underwent extubation after successful spontaneous breathing trial. HFNC oxygen therapy was prescribed immediately from 11:40 am

to prevent reintubation. Previous to 11:40 am, sensors detected only 60 episodes of short time refluxes for a total duration of 10 min. After extubation and during HFNC therapy, that continued for around 357 min, the sensors detected a tremendous increase in long and continuous reflux events: more than 20 per hour minor reflux events with a total duration of 236 min and an average of 40 min per hour, as well as massive reflux events with a total duration of 49 min and an average of 8 min per hour as shown in Fig. 2. During a total of 357 min the patient experience 285 min (80% of the time) of reflux events and a total of 33 ml of gastric content was evacuated by the system in real time in order to prevent tracheal aspiration, see Fig. 2. In parallel on each reflux event the system shuts-off feeding in the duration of the reflux and compensate the losses in off-reflux time. She required reintubation at around 6:20 pm and the reflux events decreased accordingly (See Fig. 2). Fig. 3 shows the gastric residual volume observed during the reflux events.

The patient developed secondary infection from unknown origin. Tigacyclin was started due to carbapenem resistant enterobacteriaceae presence in a rectal swab. The patient's condition deteriorated and required increasing doses of noradrenaline and FiO<sub>2</sub>. After consultation with the family, withhold therapy was decided upon in this patient suffering from uncontrolled metastatic cancer disease with irreversible septic shock. The patient died seven days after admission.

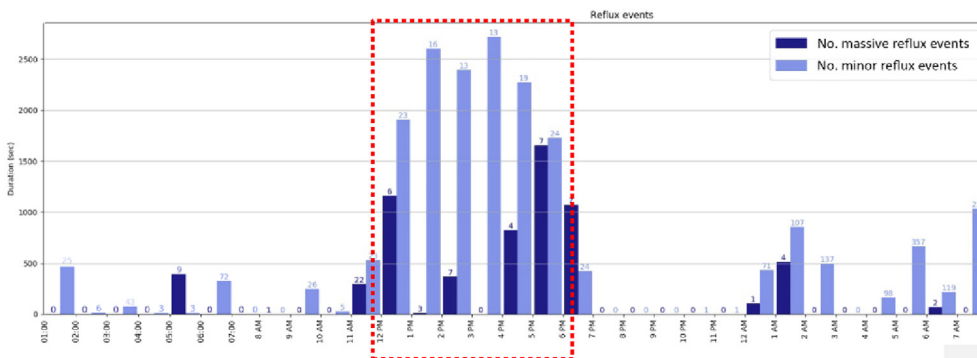


Fig. 2. Number of minor and massive reflux during high flow nasal cannula oxygenation therapy. The numbers above the bars state the number of reflux events, and on the left side, you can see the total duration (in seconds) of those events in the specific hour.

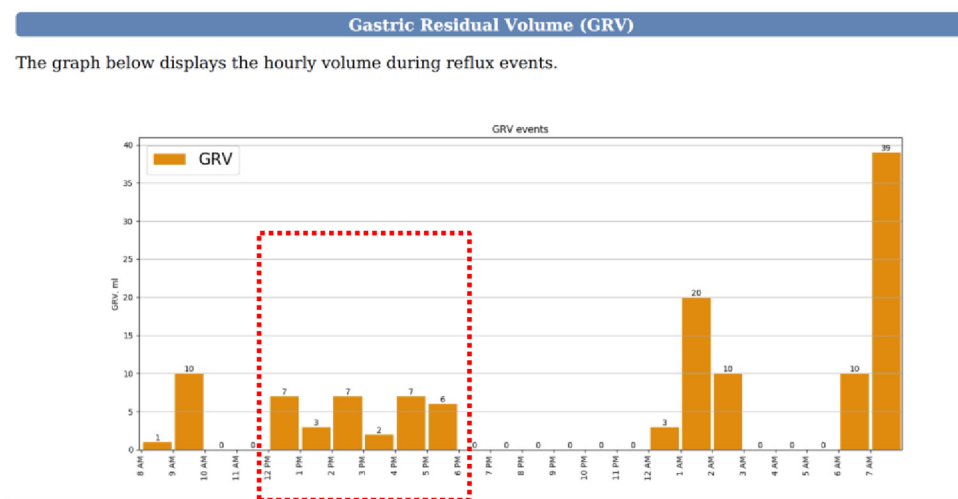


Fig. 3. Gastric residual volume during reflux events.

### 3. Discussion

Our case shows the association between HFNC therapy and minor or massive reflux detected by the ART MEDICAL smART+ technology platform. Gastro-esophageal reflux is one of the main predisposing factors to aspiration [11,12] and currently there are no means to detect reflux and/or prevent the consequential aspiration in real-time. The current interventions available to prevent aspiration and ventilator associated events are keeping the patient in the semi-recumbent position (head of bed elevation 30–45 degrees) and mouth hygiene [13–15], as selective oral or digestive contamination [16]. These recommendations are for mechanically ventilated patients. However, patients who need to be fed orally or enterally while pending mechanical ventilation, an approach to safely feed patients while not endangering their ability to breathe has to be taken [16]. Only few studies have described the oral and enteral intake in non-mechanically ventilated patients. They have demonstrated that among patients receiving NIV for acute respiratory distress syndrome (ARDS), energy and protein intake was inadequate. Seventy eight percent of the patients met less than 80% of the nutritional requirements [17]. One hundred and seven out of 150 patients had a poor oral intake or enteral nutrition in another study of patients treated with NIV [18]. Airway complications (53% VS 32%,  $P < 0.04$ ) and median non-invasive ventilation duration (16 versus 8 days,  $p = 0.02$ ) were increased in patients with poor intake in comparison to those with higher intake. The ESCIM recommendations [6] propose to start enteral feeding in critically ill patients. However, nasogastric tubes (NGTs) result in air leakage that may compromise the effectiveness of NIV. Second, NIV

causes stomach dilation due to insufflation of air into the stomach [19] that may affect diaphragmatic function and compromise NIV ventilation. Terzi et al. [20] showed that nearly 60% of patients were starved during the first 2 days of NIV and only 2.6% received enteral nutrition. HFNC has been recommended in hypoxemic respiratory failure and is included in the Surviving Sepsis guidelines for SARS-CoV-2 infections [21] the WHO COVID-19 guidance, and by the Chinese health authorities in their Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia Ver.7 [22], despite risks of aerosolized particles dissemination. Oral or enteral nutrition is decreased as shown in a previous study from our team [23]. In 42 HFNC therapies applied to 40 patients, 21 patients receiving enteral nutrition reached only 365 (247–1193) Kcal/d and 18.5 (13.9–33.3) g/day protein. Oral nutrition (in 13 patients) as opposed to tube feeding, was associated with higher calorie (621 kcal/d) and protein (22 g/d) intake. This study showed the poor calorie and protein intake in patients receiving HFNC.

Our case report in which we detected such a large amount of reflux, further increases the fear of oral feeding even more. This large amount of reflux can be explained by the large amount of air inflated into the stomach leading to an increase in pressure higher than the patient's natural inhalation pressure. As a result, upon exhalation, the pressure drops in the lungs and in stomach, which forces gastric content into the esophagus and increased the risks of aspiration. Some experts suggest to prescribe (peripheral) parenteral nutrition to prevent the dangers of reflux and aspiration while administrating energy/protein requirements. smART+ technology is a system which includes a nasogastric tube equipped with multiple sensors to detect reflux as well as with the

ability to automatically stop feeding, evacuate the stomach and inflate an esophageal balloon (in massive reflux events) in order to prevent aspiration and compensate the losses of feeding due to reflux events. The detection of the reflux events is performed by using algorithms combining multichannel intraluminal bioimpedance sensors embedded on the smART+ feeding tube. The smART+ system has been validated and received both CE and Israeli AMAR approvals. However, our case description has some limitations. The definition of minor and massive reflux above or below 12 cm from the lower esophageal sphincter was guided by technical reasons, to prevent of too frequent triggers on the sensor. In addition, this case is unique but is the first to describe a correlation between HFNC and reflux events and has to be confirmed in the future.

#### 4. Conclusions

This is the first description of continuous reflux monitoring of a patient treated with HFNC and mechanical ventilation. We show a very high number of minor and massive reflux events suggesting that this oxygen therapy may put patients at increased risk of aspiration.

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