Experience of endoscopic intra-gastric balloons removal during COVID-19 pandemic in 98 patients.

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Abstract

Introduction: During COVID-19 pandemic, all elective surgical interventions were suspended, including bariatric and metabolic (B&M) surgeries and endoscopic procedures. Delayed extraction of intragastric balloons associated with a higher complication rate [1]. Experts agreed that endoscopic bariatric procedures are semi-elective/urgent procedures and can be performed following specific protocol during this pandemic [2].

Objective: To share our experience of endoscopic removal of air-filled intragastric balloons during COVID-19 pandemic following a suggested algorithm.

Methods: Retrospective data review for patients who underwent endoscopic removal of intra-gastric balloons during COVID-19 pandemic in a tertiary hospital (29 February 2020 —15 June 2020).

Results: Ninety-eight patients with age ranged between 14 — 71 years, mean of 33.1 ± 10.9 years. Body mass index (BMI) was 32.8 ± 4.7 kg/m\(^2\). Thirty-four were females (34.7%). Three patients (3.1%) had type II diabetes (T2D), one (1%) had hypertension (HTN), one (1%) was asthmatic and one (1%) had coronary artery disease (CAD). Procedures were performed at 15.6 ± 7 minutes. No complications occurred. No patient developed COVID-19 symptoms within 14 days after removal. Thirteen patients (13.2%) had Reverse-Transcription Polymerase Chain Reaction (RT-PCR) swab tests for contact with COVID-19 positive patients and their results were negative. All the involved medical staff had negative RT-PCR tests results by the end of June 2020.

Conclusion: Following our suggested algorithm, endoscopic intra-gastric balloon removal during COVID-19 pandemic was safe with a favorable outcome.

Introduction

The novel coronavirus outbreak (2019-nCoV) was declared a Public Health Emergency of International Concern (PHEIC) on 30th January 2020, and a pandemic on 11th March 2020 [3]. After that, the pandemic has struck the globe inconsistently. Qatar reported the first case of Coronavirus (CoV-2) infection on 29th February 2020 [4]. Since then, the numbers of patients have been increasing progressively.

International guidelines have been issued, and most elective surgeries were postponed [1]. Additionally, IFSO guidelines recommended postponing the elective Bariatric and Metabolic (B&M) surgeries [5]. Accordingly, all elective bariatric procedures stopped in our center, and the practice became limited to urgent interventions for bariatric complications.

Gastrointestinal endoscopy is an aerosol-generating procedure with a higher risk of SARS-CoV-2 transmission to both patients and medical staff [6]. Nevertheless, bariatric surgery experts agreed that some endoscopic bariatric procedures are semi-elective/urgent procedures and can be performed
following specific protocol during this pandemic [2]. Intragastric balloons had been designed to remain in the stomach for six months. The delayed balloon extraction is associated with a higher complication rate [5]. This study shares our experience of endoscopic removal of air-filled intragastric balloons at their recommended time during COVID-19 pandemic between February to June 2020.

**Objective**

To share the outcomes of endoscopic intra-gastric balloon removal during COVID-19 pandemic following a certain algorithm based on IFSO recommendations. Patients’ demographics, operative time, complication rate, rate of COVID-19 infection in patients and the involved medical staff.

**Method**

A retrospective review of prospectively collected data for all patients who underwent endoscopic removal of intra-gastric balloons during COVID-19 pandemic in a tertiary hospital (29 February 2020 — 15 June 2020). Procedures were done following a certain algorithm, based on IFSO recommendations for elective surgeries during COVID-19 [2]. (see fig.1)

All patients had air-filled balloons for a minimum of six months and were due to removal. Only patients with negative COVID-19 RT-PCR swab tests had the procedure. All procedures were done under general anesthesia (GA), and patients had intubation.

**Study endpoints:**

*Patients’ demographics and operative time:* patients’ age, gender, BMI and presence of obesity-related comorbidities; T2D, HTN, asthma and CAD and the operative time have been reviewed.

*Complications rate:* rate of perforation, bleeding, and pancreatitis.

*Rate of COVID-19 infection in patients after endoscopy:* All patients were followed up for two weeks after the balloon removal. RT-PCR testing was not repeated routinely after endoscopy unless the patient had symptoms or contact with an infected individual.

*Rate of COVID-19 infection among procedure providers:* (two surgeons, two anesthetists and three nurses). All the involved staff in removals of intragastric balloon had COVID-19 RT-PCR testing for variable reasons; screening of theatre staff or due to contact with other COVID-19 patients. Results were reviewed by the end of June 2020. Intra-operative findings and weight loss results after intra-gastric ballooning were out of the scope of this study.

**Statistics:**

Data were described using mean ± standard deviation or percentages and number as applicable. No sample size calculation was done, the study is a data review, and the total number of patients was 98. A
P-value of <0.05 was considered statistically significant. No data was missing.

**Results**

Ninety-eight patients underwent endoscopic removal of intra-gastric balloons. Patients’ age ranged between 14 — 71 years, with a mean of 33.1 ± 10.9 years. BMI 32.8 ± 4.7 kg/m². Thirty-four were females (34.7%). Procedures were performed at 15.6 ± 7 minutes. Three patients had T2D (3.1%), one had HTN (1%), one was asthmatic (1%), and one had CAD (1%). No complications occurred. Patients have been watched for COVID-19 symptoms within 14 days after removal; none developed symptoms while thirteen patients (13.2%) had RT-PCR swab tests for contact with COVID-19 positive patients and their results were negative. All the involved medical staff in intragastric balloon removals had RT-PCR tests and results were negative by the end of June 2020.

**Discussion**

To the best of the authors’ knowledge, this study is the first to report and share the experience of endoscopic intra-gastric balloon removal during the era of COVID-19 pandemic. Due to the current worldwide situation, elective B&M surgeries stopped, and the practice became limited to sporadic emergency cases. American college of surgeons issued COVID-19 elective cases triage guidelines and divided the B&M surgeries into elective, emergency and semi-elective/urgent cases [1]. Endoscopic bariatric procedures were not included in this triage [1]. Experts from bariatric surgery community published a review to restart elective surgeries during the pandemic, and endoscopic intra-gastric balloon removal was described as semi-elective/urgent procedure that can be done under certain precautions at the current situation [2].

COVID-19 pandemic has struck the world aggressively, and Qatar was no exception. The first case of CoV-2 infection was reported in Qatar, on 29th February 2020 [4]. Since then, the numbers of patients have been increasing progressively. In compliance with the issued international guidelines, and as a part of the national response to the pandemic, all elective surgical interventions were suspended, including bariatric endoscopic procedures.

Delayed intragastric balloon removal is one of the time-sensitive procedures that carry an increased risk of complications, e.g. migration. Two of our patients with over-due intragastric balloons, encountered migration and both presented with small bowel obstruction. One required laparoscopic surgical exploration to remove the balloon. The other patient successfully passed the balloon with conservative management. Accordingly, avoidance of further complications mandated to structure a practical algorithm to proceed with the removal of the intragastric balloons during the current COVID-19 pandemic.

Gastrointestinal endoscopy carries a higher risk of COVID-19 transmission to both patients and providers, given the role of the gastrointestinal tract in viral transmission and aerosol generation during endoscopy. Our proposed algorithm aimed at protecting the patients and the involved healthcare workers. All patients
had GA and intubation. Although intubation itself is an AGP, GA was preferred. It minimizes coughing, irritation and aerosolization that accompany sedation during endoscopy.

Our reported data has shown that the proposed algorithm is effective in mitigating the risk of infection to both patients and healthcare workers. No post-procedure COVID-19 disease, complications nor mortality occurred.

Several case series of COVID-19 hospitalized patients showed that pre-existing hypertension and diabetes were highly prevalent. Our report included three patients with T2D, one with HTN and one was asthmatic. One had CAD with no reported COVID-19 infection, morbidity, nor mortality.

To comply with social distancing and minimizing the risk of infection teleconsultations, and follow-up were adopted. Skillful surgeons/endoscopists played an essential role in reducing operative time (15.6 ± 7 minutes). Patients claimed adherence to self-isolation after discharge. However, thirteen patients (13.2%) had RT-PCR swab tests for contact with COVID-19 positive patients, and their results were negative.

Limitations of this study: The paper shares the outcomes of intragastric balloons removal during a specific era. This report may help in planning the future practice in case further surges of COVID-19 occurred. However, there are limitations; the retrospective design and the RT-PCR testing was not done routinely for patients post endoscopic removal. Hence, some patients might have asymptomatic COVID-19 infection.

**Conclusion**

The result of this study proves that endoscopic intragastric balloons removal during COVID-19 era can be performed safely for both patients and health care providers with a favourable outcome.

Authors have nothing to disclose.

**Declarations**

**Ethics:**
The current study was conducted after the research protocol was approved by the institutional review board of the Medical Research Centre at Hamad Medical Corporation. The requirement for consent was waived. IRB approval number is 05-165

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Figures
Figure 1

Algorithm for endoscopic removal of intragastric balloons during COVID-19 pandemic.

*All pre- and post-procedure consultations and follow up were via tele-medicine, Reverse-Transcription Polymerase Chain Reaction (RT-PCR), Corona virus (CoV-2)