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Sedation for Intragastric Balloon Positioning and Removal: What Respiratory Management?

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Introduction

Obesity has become an epidemic health problem worldwide[1]. Defined as a body mass index (BMI) greater than or equal to 30 kg/m^2, obesity is divided into class I (BMI of 30 – 34.9 kg/m^2), class II or severe obesity (BMI of 35 – 39.9 kg/m^2), and class III or morbid obesity (BMI greater than 40 kg/m^2). Some surgical literature further breaks down class III obesity into super obese which represents those with BMI greater than or equal to 45 or 50 kg/m^2[2].

In 2016, the World Health Organization (WHO) reported that 39% of adults aged 18 years and over were overweight (BMI > 25 kg/m^2), and 13% were obese (BMI > 30 kg/m^2)[3].

Obesity is a complex metabolic illness that increases the prevalence of various disease, including diabetes mellitus, hypertension, coronary heart disease, sleep apnea, stroke, gastro esophageal reflux disease, gall bladder disease, certain types of malignancy and many others[4]. Moreover, it is also a major avoidable health detriment. Current therapeutic approaches to obesity are lifestyle changes, pharmacologic treatment, and bariatric surgery. Weight-loss surgery provides the most sustained and effective therapeutic choice for obesity. Accessible methods include the adjustable gastric band, Roux-en-Y gastric bypass, or sleeve gastrectomy[5].

Regardless of its proven effectiveness, only 1% of obese patients eligible for the surgical procedure choose to undergo it[6]. The major issues with surgery are difficult accessibility, high costs, patient non-preference, and significant morbidity and mortality. Although its associated mortality has decreased considerably, the complication rate in the early and late stages of the bariatric procedure persist at 17% (95%CI: 11% - 23%)[5].

Therefore endoscopic bariatric treatment for obesity was recently introduced as minimally invasive and effective method. It includes intragastric balloons, gastroplasty techniques, aspiration therapy, and gastrointestinal bypass sleeves. Among them, the intragastric balloon (IB) has been the most frequently used in practice and the most studied for obesity treatment[7]. This device is placed in the stomach using esophagogastroduodenoscopy (EGD) a safe procedure that require sedation for reduce patient discomfort by inducing analgesia and amnesia and improves patient tolerance. The anesthesiology involvement in the care of patient who undergo IB placement by gastroscopy is recommended by many scientific societies worldwide[8] because of the morbid concomitant state of obesity that affects this patient.

Different anesthesiological techniques are currently used for intragastric balloon positioning and removal.

Intragastric balloon treatment for obesity

The IB may offer a minimally invasive and valuable method for managing obesity and related conditions. It is used to achieve weight loss in obese people, generally those with a body mass index (BMI) >35 kg/m^2, or 30 kg/m^2 with certain comorbidities. IB treatment may play a different role in bariatric treatment based on the grade of obesity[7].

Early intervention and preemptive therapy for weight reduction can be performed in obese patients at risk for disease development, at high risk for all-cause mortality, and with a high cardiovascular risk profile[9]. The objective of preemptive treatment is to achieve modest weight reduction, and, therefore, the overall risk/benefit ratio could validate the standards for procedures with this indication.

The goal of IB treatment is to achieve weight reduction in severely obese people, generally those with a BMI > 35 kg/m^2 with or without comorbidities, and who could not achieve long-term weight loss with a weight-control regimen. In addition, IB therapy could be performed in patients with a BMI ≥ 40 kg/m^2, as a preparation for bariatric treatment or in patients with increased surgical risks. Obese patients who reject bariatric surgical procedures or who do not have an approach for surgery can also opt for it. IB therapy used as a primary therapy could induce weight reduction and improve obesity-related comorbidities with a level of safety and efficiency comparable to that of bariatric surgery[10].

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Exclusion criteria include any situation that could increase the risks related to IBinsertion, such as a large hiatal hernia (> 5 cm), active ulcer in the stomach or duodenum, previous surgical resection of the stomach, inflammatory bowel disease, gastrointestinal neoplasm, oropharyngeal abnormalities, active gastrointestinal bleeding, coagulative disorder, variceal disease, alcoholic disease or drug abuse, psychiatric disease, pregnancy, use of anti-coagulants or anti-inflammatory drugs, and cardiovascular, pulmonary or cerebrovascular diseases[11].

Anesthesiological assessment and respiratory safety in obese patients

In obese patient undergoing endoscopy for IB positioning, sedation is an integral component of the procedure. Although the procedure can also be performed with awake patient, sedation provides a relief in patients' discomfort and anxiety, and allows proceduralists to focus on the endoscopic work[12].

Different stages of sedation have been described as reported by Gross et all: minimal, moderate, deep and general anesthesia. Generally, most diagnostic and uncomplicated therapeutic endoscopy can successfully performed under moderate sedation with patient responding purposefully to verbal commands or tactile stimulation. However, for longer and more complex procedures, as IB positioning, deeper levels of sedation until general anesthesia may be required[13].

In the literature there is no consensus regarding the most appropriate anesthetic technique for positioning and removal intragastric balloon that can be performed with conscious sedation plus local anesthesia, deep sedation or general anesthesia. Anyhow pre-operative evaluation, intra-operative care and post-operative management of patients must take into account the morbidity state of these patients due to obesity.

Traditionally, a higher BMI has been thought to be associated with an increased respiratory risk during procedural sedation/anesthesia. This may be due to obstructive sleep apnea (OSA), pulmonary hypertension, and restrictive lung disease, which are more common in patient with obesity. Additionally, airway management in obese patients results to be more difficult for rapid oxygen desaturation, challenges with mask ventilation and intubation, and increased susceptibility to the respiratory depressant effects of sedatives[14]. For all these reasons the obese patient before IB positioning must undergo a careful preoperative evaluation. Particular attention should be focused on screening patients for sleep-disordered breathing and those with difficult airway management.

Respiratory assessment

Several respiratory changes are present in obese patients. Obesity reduces both pulmonary and total chest compliances[15]. Decreased pulmonary compliance reduces functional residual capacity, which cannot overpass the closing capacity. As a consequence, obese patients are prone to increased intrapulmonary shunt V/Q mismatching. Thus, the obese patient may be hypoxic, with increased alveolar-arterial oxygen partial pressure, increasing the risk for postoperative atelectasis[16].

Sleep-disordered breathing

Obesity is often associated to sleep-disordered breathing. It's ranging from obstructive sleep apnea (OSA) through obesity hypoventilation syndrome (OHS)[17]. OSA is defined as a minimum of 10 s of total respiratory cessation that occurs more than 30 times a night. This results from the increased adipose tissue in the pharyngeal walls, increasing pharyngeal wall compliance, with the tendency to collapse during negative pressure on inspiration[18]. Severe OSA occurs in 10-20% of patients with BMI >35 Kg/m^2, but it is often undiagnosed[14]. Other studies suggest that between 40% and 90% of obese patients have OSA[20]. Overall, a diagnosis of OSA is associated with a greater than doubling of the incidence of postoperative desaturation, respiratory failure, postoperative cardiac events and ICU admission[21]. The presence of multiple and prolonged oxygen desaturations increases the sensitivity to opioid-induced respiratory depression[22]. However, if identified pre-operatively and treated appropriately with continuous positive airway pressure (CPAP), the risk of complications is much reduced[23].

Increasing severity of OSA is associated with older age, cardiovascular disease depending on heart strain, and development of left ventricular dysfunction. It is also associated with a difficult airway management[24]. The combination of chronic hypoxemia and hypercapnia in patients with OSA increasing the susceptibility to anesthetics and opioids effects which may precipitate acute hypoventilation and respiratory arrest in the early postoperative period[25]. Formal OSA's diagnosis is with polysonnography and nocturnal CPAP is the usual treatment in patients with significant degree of OSA. It's essential to screen for sleep disordered breathing and for this purpose several screening tools are available as the STOP-BANG questionnaire. This is the best validated in obese patients, is easy to calculate and has shown good correlation with the severity of postoperative apneas[26]. A STOP-BANG score of5 or greater indicates the possibility of significant sleep disordered breathing, but even in the presence of a low STOP-BANG score, a history of marked exertional dyspnea, morning headaches and ECG evidence of right atrial hypertrophy may indicate the presence of sleep disordered breathing[27]. Patients with undiagnosed OSA or with poor compliance to CPAP therapy are at high risk of peri-operative respiratory or cardiac complications. To avoid these is important the use of nocturnal CPAP also in the hospital setting[28].

Airway management

Airway management in obese patients may be problematic. Obesity is associated with a 30% greater chance of difficult/failed intubation. In effect obese patients present more often small oral cavity, small mouth opening, large neck circumference, impaired head and neck movements, possible short sternomental or thyromental distance, that are all predictors for difficult laringoscopy also in non-obese patients. Even better several studies report a weak relationship between BMI alone and difficult intubation[29].

In the airway management in obese patients, particular attention must be placed on possible difficult mask ventilation (DMV), whose risk assessment is mandatory in the preanesthetic valuation[30]. Age >55 years, BMI >26 kg/m^2, lack of teeth, presence of beard, history of snoring are considered independent risk factors for DMV, and the presence of two of these criteria indicate at best a DMV[31]. A large study of 14,369 patients confirms these DMV risk factors, except the lack of teeth, including Mallampati class III or IV. Furthermore this study provide limited mandibular protrusion as another independent DMV predictor[32].

Obesity is associated with decreased posterior airway space behind the base of the tongue, impaired airway patency during sleep and is a risk factor for OSA. Collapse of the pharynx with obstruction of upper airways occurs during anesthesia similarly to OSA[33]. In DMV patients the risk of difficult tracheal intubation (DTI) is also significantly increased[32,34]. In the international literature there are some controversies to demonstrate that obesity *per se* is associated with an increased risk of DTI[35,36]. The lack of consensus have some explanation: first the lack of universal definition of DTI, therefore difficult laryngoscopy, defined as a Cormack grade III or IV, is often used as a surrogate outcome of DTI[37]. Furthermore, the relationship between BMI and DTI risk may be not linear and there is no consensus about the cut-off values stratifying the risk related to BMI. In a large cohort study the authors concluded that BMI >35 kg/m^2 is a weak but statistically significant predictor of DTI and may be more appropriate than weight in multivariate models for DTI prediction[29]. DTI risk assessment should be performed in a careful manner and with some specificities in obese patients. Mallampati classification, thyromental distance, mouth opening measured by interincisive distance are recommended in DTI screening[38]. In obese patient high BMI and a neck circumference ≥ 43 cm should be specifically searched in preoperative airway assessment, indicating an increased DTI risk when they occur[39,40]. For the airway management in obese patients the preoxygenation is essential and strongly recommended from any guidelines. Optimization of preoxygenation allow to tolerate a longer period of apnea without oxygen desaturation and consequently increased the desaturation safety period[41,42]. The equipment for emergency airway management, including laryngeal mask and a fiberoptic bronchoscope, should be immediately available.

Anesthesiological management during intragastric balloon positioning and removal

All obese patients undergoing intragastric balloon positioning needa preliminary multidisciplinary evaluation: metabolic-endocrinological, psychological, surgical and anesthesiological. Preliminary tests will be performed: hepatic and renal function, lipid profile and coagulation, an ECG and the chest X-ray[43] and an expert team of anesthesiologists in obesity should be involved[44].

The patients at high risk of peri-operative complications are those with central obesity and metabolic syndrome, rather than those with isolated extreme obesity[45].

Monitor should be: electrocardiography and heart rate, pulse oximetry, nasal capnography and non-invasive blood pressure during the whole procedure.

To performer IB positioning and removal the patient is placed in the left lateral position before sedation/anesthesia consisting in easily reversible drugs with fast onset and offset[46].

Propofol is the most commonly used induction agent for obese subjects because for is highly lipophilic it distributes rapidly from the plasma to peripheral tissues. Redistribution from the effect site into the plasma, and subsequently into peripheral tissues, accounts for its short duration of action after a single bolus dose. Cardiac output is a significant determinant of its peak plasma concentration. Soits favorable pharmacokinetic profile take into account its popularity in using for sedation during endoscopic procedures: a rapid onset of action (30 - 40 seconds), the ability to achieve adequate sedation, and a short duration of effect (4 - 8 minutes) leading to rapid recovery. Propofol dosage for induction and maintenance of sedation/anesthesia is based on lean body weight. However some form of depth of anesthesia monitoring is strongly recommended since more rapid redistribution of induction agents into the larger fat mass means that patients wake up more quickly than non-obese patients after a single bolus dose.

Changes in distribution volume in the obese are drug-specific, although lipophilic drugs will have a larger volume of distribution than hydrophilic one. Drug dosage can be calculated on total body weight, BMI, lean body mass (ideal body mass +20%) or ideal body weight. Expert recommendation is that lean or adjusted body weight are used as the scalars for calculating anesthetic drug dose in obese patients rather than total body weight[47].

Its safety and effectiveness during sedation in endoscopy has been demonstrated when compared to traditional agents such as benzodiazepines and opioids[48]. Wang et al revealed that it provided excellent sedation for patients undergoing gastrointestinal endoscopy procedures because it also shortened recovery and discharge periods, improved greater patient cooperation when compared to traditional sedation, and it is not associated with increased cardiopulmonary complications[49]. Various techniques can be used in propofol administration: intermittent bolus or continuous infusion method, but also patient-controlled sedation andtarget-controlled infusion (TCI). With this method, the desired concentration of drugs in plasma or at the effect site, can be achieved by an automatic administration system based on a pharmacokinetic computer calculation[50]. So, it results in a more precise control of drug concentration, avoiding peaks and troughs of propofol level. Hsu et al[51] used this administration system during colonoscopy and/or upper GI endoscopy and noted that propofol at low Ce (1.5e2.5 mg/mL) is effective and has fewer cardiovascular events. Propofol TCI sedation results excellent and reduces cardiovascular and respiratory depression compared to propofol intermittent bolus in midazolam/alfentanil regimen[52].

Respiratory changes in obese patients must be considered when a deep sedation or general anesthesia is chosen with a particular attention on screening patients for sleep-disordered breathing and difficult airway management. These patients often have undiagnosed OSA with an increased risk of post-procedural oxygen desaturation, respiratory failure and cardiac events. Upper airway collapsibility and impair arousal response, caused by sedation and opioids, should exacerbate OSA symptoms[53]. So faster desaturation and need for ventilator support are common in obese patients. Indeed a prospective study conducted by Wani et al. showed two times the risk of sedation related complications and need for airway maneuver for obese undergoing advanced endoscopic procedures[54]. Also during endoscopic retrograde cholangiopancreatography (ERCP), Berzin et al. prospectively assessed that higher BMI was strongly associated with adverse respiratory events[55]. Capnographic monitoring of respiratory activity results critical in reducing the incidence of oxygen desaturation through early identification of hypoventilation[56,57]. Anesthesiologists seldom applied non-invasive ventilation like bi-level positive airway pressure (BiPAP) in fear of aspiration and abdominal distention despite it was widely used to augment ventilation and CO_2 washout in the setting of respiratory failure. On the other hand, oxygen supplementation through nasal cannula is widely used before and during the procedure. An oxygen supply system with high humidified flows nasal cannula (HFNC) can be used to optimize the oxygenation levels both during the preliminary phase and during the whole procedure. HFNC use in procedural sedation results interesting for its ability to provide steady FiO_2 with high air flow rates and minimal interference with endoscopic devices inserted through the oral route. HFNC seems create positive end expiratory pressure (PEEP), by impeding expiratory flow, between 5 – 7.5 cm H_2O[58,59]. Indeed Lucangelo et al. proved that patients who received HFNC had higher ratio of arterial partial pressures of oxygen (PaO_2)/FiO_2 than those who received Venturi mask during bronchoscopy with conscious sedation[60]. Sago et al. utilized HFNC in dental procedures and it results that patients who received it had better PaO_2 compared to those who received oxygen at 5L/min through nasal cannula[61].

If hypopnea/apnea (defined as < 6 breaths per minute) occur during airway obstruction, chin lift, jaw thrust or insertion of a nasopharyngeal cannula will be necessary .This type of cannula represents a good device in case of collapse of upper airway as often occurs in these patients because it provides unobstructed spontaneous ventilation, end-tidal CO_2 monitoring, continuous positive airway pressure, and the possibility of assisted ventilation[62].

If hypoxemia (defined as a pulse oximetry of < 90% for any duration) persists despite these maneuvers, bag mask ventilation or endotracheal intubation should be considered. So the equipment for difficult intubation should be available and any difficult should be managed in accordance with guidelines.

In our experience of intragastric balloon positioning, which includes about 100 obese patients/year, ,we place the nasopharyngeal cannula before the procedure as soon as the patient sleep in presence of obesity grade II or more, in patients with positive STOP-BANG score and in case of anticipated difficulty in airway management.

High bronchoaspiration risk, especially during intragastric balloon removal, is due to presence of food residues in the stomach because of the balloon. Therefore aggressive mask ventilation should be avoided and ramped position should be used wherever possible[63,64].

Adequate time and resources must be devoted to wake up of obese OSA patients in a monitored area. In the case of complications, the possibility of hospitalization in PACU must be provided.

Conclusion

There are an increased number of obese patients who are undergoing intragastric balloon positioning. Actuallysedation/anesthesia is becoming an integral component of this procedure to reduce the patient's anxiety and discomfort and allow the operator to complete the procedure. To chooseappropriately the anesthesiological strategy, multiple factors need to be taken into an account. The obese patients have an increased risk of sedation-related complications for high prevalence of obstructive sleep apnea often undiagnosed. In addition, patients with morbid obesity can have restrictive lung disease, pulmonary hypertension and development of significant alveolar-to-arterial oxygen gradients. Obese patients are also at greater risk of developing cardiovascular complications. Data on the association of obesity and sedation related outcomes in obese patients undergoing sedation/anesthesia for intragastric balloon positioning and removal are limited. In addition, the optimal sedation regimen for achieving deep sedation in these high risk patients is unclear. Most society guidelines on sedation in this patient population are based on expert opinion so more population based studies are needed in order to plan carefully sedation for these high morbidity patients.

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