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Intragastric balloon positioning and removal: sedation or general anesthesia?

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Abstract
Background Different anesthesiological techniques are currently used for intragastric balloon positioning and removal. The aim of this study is to compare different anesthesiological approaches for balloon positioning and removal in a large multicentric patient population.
Methods Retrospective multicenter study was conducted. From May 2000 to April 2008, 3,824 patients underwent BIB® placement [1,022 male/2,802 female; mean age 39.5 ± 14.7 years, range 12–71 years; mean body mass index (BMI) 44.8 ± 9.7 kg/m^2, range 28.0–79.1 kg/m^2; excess weight (EW) 59.1 ± 29.8 kg, range 16–210 kg; %EW 89.3 ± 31.7, range 21.4–262]. Patients were allocated to three groups according to anesthesiological technique used: conscious sedation (group A), deep sedation (group B), and general anesthesia (group C). Intragastric balloon was placed after diagnostic endoscopy and removed after 6 months. Both positioning and removal were done under different protocols. Conscious sedation was obtained with topical lidocaine spray, adding diazepam (0.05–0.1 mg/kg iv) or midazolam (0.03–0.05 mg/kg iv). Deep sedation was obtained with propofol alone or adding other drugs such as midazolam, meperidine/fentanyl or meperidine/fentanyl + midazolam. General anesthesia was obtained with midazolam premedication (0.01–0.02 mg/kg iv) followed by induction with propofol (1–1.5 mg/kg iv) + Norcuron (80 mcg/kg iv) + fentanyl (0.5–1 mcg/kg iv), and maintenance with propofol (50–150 μg/kg/min) or sevorane. Oxygen saturation, hemodynamic stability, major anesthesiological complications and related mortality, patient satisfaction, time to return to autonomous walking, duration of procedure, and hospital stay were considered.
Results Sedation-related mortality was absent. A significant number of patients with bronchoinhalation during balloon removal was observed with general anesthesia ($P < 0.001$).
Conclusions BIB positioning and removal should be performed under conscious sedation for patient safety and comfort, and technical success.

Keywords BIB · Intragastric balloon · General anesthesia · Deep sedation · Conscious sedation · Morbid obese

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The BioEnterics Intragastric Balloon (BIB®) is currently placed as a temporary treatment before bariatric or other surgical procedures [1–3]. Different anesthesiological techniques are currently used for intragastric balloon positioning and removal. While local anesthesia with conscious sedation seems to give patients discomfort, general anesthesia can be dangerous due to high bronchoaspiration risk (especially during BIB removal, when the patient can have food remnants in the stomach because of the BIB) and due to life-threatening obesity-related complications [4–6]. The aim of this study is to compare different anesthesiological approaches for BIB positioning and removal in a large multicentric patient population.

Patients and methods

Patients were recruited from the database of the Italian Collaborative Study Group for LAP-BAND and BIB (GILB), in which 18 centers are actively involved in intragastric balloon positioning. The BioEnterics® Intragastric Balloon (Allergan,

Irvine, CA, USA) was used in all patients who were selected according to National Institutes of Health (NIH) criteria and guidelines for bariatric surgery [7]. All centers followed the same exclusion criteria: all conditions precluding safe endoscopy, including esophagitis, large hiatal hernia (>5 cm), chronic therapy with steroids or nonsteroidal drugs, active peptic ulcer or its previous complications, previous gastric surgery, lesions considered at risk for bleeding or anticoagulant therapy, pregnancy, and physical inability to maintain regular follow-up. Patients were independently evaluated by internists, dieticians, and psychologists for preoperative selection. *Helicobacter pylori* test was performed in all patients. BIB was placed after diagnostic endoscopy and removed after 6 months in all centers. Inflation was performed under direct vision by using saline (500–700 ml) and methylene blue (10 ml) solutions. After 6 months the BIB was removed by endoscopy after complete deflation using a dedicated instrument. Both positioning and removal were done under conscious or deep sedation or general anesthesia.

Sedation and anesthesia

Conscious sedation was obtained with topical lidocaine spray adding diazepam (0.05–0.1 mg/kg iv) or midazolam (0.03–0.05 mg/kg iv). Deep sedation was obtained with propofol alone or adding other drugs such as midazolam, meperidine/fentanyl or meperidine/fentanyl + midazolam. General anesthesia was obtained with midazolam premedication (0.01–0.02 mg/kg iv), followed by induction with propofol (1–1.5 mg/kg iv) + Norcuron (80 mcg/kg iv) + fentanyl (0.5–1 mcg/kg iv), and maintenance with propofol (50–150 μg/kg/min iv) or sevorane.

Study outline

Patients were allocated to three groups according to anesthesiological technique used: conscious sedation (group A), deep sedation (group B), and general anesthesia (group C). Oxygen saturation, hemodynamic stability, major anesthesiological complications and related mortality, patient satisfaction, time to return to autonomous walking, duration of procedure, and hospital stay were considered. A sedation score (1 = awake/alert; 2 = sometimes drowsy/easily roused; 3 = often drowsy/easily roused; 4 = often drowsy/difficult to rouse; 5 = asleep/stirs to touch) was used to evaluate patient recovery time. A comfort score (1 = low comfort, to 4 = high comfort) was used to evaluate patient satisfaction.

Data are reported as mean ± standard deviation except as otherwise indicated. Statistical analysis was done by means of Student *t*-test or Fisher exact test or χ^2 test. $P < 0.05$ was considered significant.

Results

From May 2000 to April 2008, 3,824 patients underwent BIB placement (1,022 male/2,802 female; mean age 39.5 ± 14.7 years, range 12–71 years; mean BMI 44.8 ± 9.7 kg/m^2, range 28.0–79.1 kg/m^2; EW 59.1 ± 29.8 kg, range 16–210 kg; %EW 89.3 ± 31.7, range 21.4–262). Patients were allocated according to their anesthesiological treatment (Table 1). General anesthesia or sedation-related mortality was absent (Table 2). A significant number of patients with bronchoinhalation during balloon removal

Table 1 Demographics of BIB-treated patients according to anesthesiological procedure; data expressed as mean ± standard deviation (range)

	Group A (conscious sedation)	Group B (deep sedation)	Group C (general anesthesia)	Total
Patients	2,787	621	416	3,824
Age (years)	38.4 ± 16.7 (18–71)	37.1 ± 17.9 (20–69)	41.2 ± 14.7 (21–62)	39.5 ± 14.7 (18–71)
Sex (M/F)	715/2,072	209/412	98/318	1,022/2,802
BMI (kg/m^2)	43.2 ± 8.7 (30.0–55.7)	45.9 ± 10.9 (31.1–56.9)	49.2 ± 12.7 (32.8–79.1)	44.8 ± 9.7 (28.0–79.1)
EW	57.3 ± 28.1 (16–151)	61.1 ± 30.8 (22–175)	89.1 ± 32.8 (26–210)	59.1 ± 29.8 (16–210)
%EW	83.3 ± 27.7 (21.4–182)	93.3 ± 34.7 (29.4–212)	99.8 ± 37.8 (43.4–262)	89.3 ± 31.7 (21.4–262)

Table 2 Complications according to patient group allocation

	Group A (conscious sedation)	Group B (deep sedation)	Group C (general anesthesia)
Mortality	No	No	No
Major complications[a]	No	No	20/416 (4.8%)
Oxygen desaturation ($SaO_2 < 90\%$)	128/2,787 (4.6%)	72/621 (11.6%)	No
Short mask ventilation	No	4/621 (0.6%)	No
Hemodynamic instability	No	No	No

[a] Bronchoinhalation during BIB removal $SaO_2 \sim 20\%$

was observed in group C ($P < 0.001$). No significant differences in oxygen desaturation and short mask ventilation were observed between groups A and B. Time to return from sedation to baseline mental functions (Tables 3, 4) was significantly longer in group C patients ($P < 0.001$).

Table 3 Recovery time according to different groups

	Group A	Group B	Group C
Time to return to sedation score 3 (min)	0	2 ± 1	10 ± 6
Time to return to sedation score 1 (min)	0	3 ± 1	15 ± 4
Discharge time from procedure unit (min)	4 ± 1	7 ± 2	20 ± 5
Time to autonomous walking (min)	15 ± 15	30 ± 5	240 ± 30

Table 4 Patient satisfaction and related functions

	Group A	Group B	Group C
Comfort score	1	3	3
Time to return to baseline mental functions (min)	0	10	60
Event memory (%)	20	5	5

Discussion

The BioEnterics® Intragastric Balloon (BIB®) is a well-established device for temporary treatment in morbidly obese patients [8, 9]. Moreover, it has been recommended as a weight-reduction adjuvant therapy before bariatric surgery and before all kinds of planned surgery in the morbidly obese to reduce life-threatening comorbidities and lessen surgical risk [10–17]. For these reasons general anesthesia for BIB placement and removal is partial nonsense. Usually, the intragastric balloon is used to reduce anesthesiological and surgical risks of bariatric surgical procedures in patients with life-threatening complications or very high BMI.

In international literature, reports specifically regarding the problem of anesthesiological management of intragastric balloon placement and positioning are lacking. Several authors refer to their center's approach (Table 5), but the description is sometimes not detailed or includes only a simple citation.

The only real advantage of general anesthesia for intragastric balloon positioning compared with conscious or deep sedation can be assumed to be better airway control after endotracheal intubation. Technical disadvantages are difficult intubation in obese patients with higher inhalation risk during laryngoscopy and other maneuvers linked to balloon introduction or extraction. Other disadvantages of general anesthesia are longer hospital stay and higher cost

Table 5 Sedation procedures reported in international literature

Author	Year	Patients, *n*	Initial mean BMI, kg/m^2	Procedure
Loffredo [15]	2001	77	46.6	Conscious sedation
Totté [23]	2001	126	37.7	General anesthesia
Doldi [22]	2002	322		General anesthesia
Busetto [10]	2004	43	58.4	Deep sedation
Sallet [9]	2004	483		General anesthesia (4%)
				Sedation (96%)
Roman [24]	2004	176	31	General anesthesia
Al-Momen [21]	2005	44	45	Conscious sedation
Herve [20]	2005	100	34.03	General anesthesia
Alfalah [12]	2006	10	64	General anesthesia
Angrisani [11]	2006	175	54.4	Conscious sedation
Fernandez [6]	2006	10	>60	Conscious sedation
Melissas [16]	2006	204	42.3	Conscious, unconscious sedation, and general anesthesia
Mui [18]	2006	15	39.4	Conscious sedation (diazepam)
de Goederen [17]	2007		>40	Conscious sedation
Ganesh [19]	2007	20	31.5	General anesthesia ($n = 7$)
				Conscious sedation ($n = 20$)
Coskun [4]	2007	165	41.8	Deep sedation

of used resources. Moreover, the contraction of the back of the throat, evoked by touching the soft palate (gag reflex), is not influenced by conscious or deep sedation. This aspect is mandatory during BIB removal because of the possibility of food remaining in the stomach. In fact, although liquid diet is prescribed to patients for the 3–4 days before removal, it is not improbable to find semisolid food in the stomach due to slow gastric emptying linked to the intragastric balloon action mechanism. In the present multicenter experience, life-threatening bronchoinhalation during BIB removal ($SaO_2 \sim 20\%$) occurred in 20/416 (4.8%) and was treated by bronchoaspiration.

Recently, Fernandez recommended that BIB positioning and removal should be performed with conscious sedation (midazolam 0.05 mg/kg iv + ramifentanil 0.05–0.15 μg/kg/min according to ideal weight) under monitoring of an anesthesiologist [6]. This approach was considered to increase the cooperation of the patient because of the discomfort of the procedure and the possibility of complications. Coskun and Aksakal in their experience with deep sedation with propofol (0.5–0.75 mg/kg iv) with 102 intragastric balloon positionings and 63 removals observed only 2 (1.2%) cases of prominently marked hypoventilation periods with $SpO_2 < 90\%$ [4]. In these patients, the procedure was discontinued immediately and their respiration was supported by manual mask ventilation with 100% oxygen via anesthesia machine. A higher rate of this occurrence was observed in the present experience (72/621; 11.6%), but in only 4/72 (5.5%) was manual mask ventilation successfully performed.

On the basis of the reported results in the present large multicenter experience we conclude that we can support the conscious/deep sedation techniques for intragastric balloon placement and removal because of their safety, comfort, and technical success.

Disclosures Teresa Messina, Alfredo Genco, Roberto Favaro, Roberta Maselli, Fiore Torchia, Francesco Guidi, Roberto Razza, Nadia Aloi, Marco Piattelli, and Michele Lorenzo have no conflicts of interest or financial ties to disclose.

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