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Main prophylactic measures in bariatric endoscopy. Spanish EXPERT Recommendations Guideline

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ABSTRACT

Bariatric endoscopy (BE) encompasses a number of techniques —some consolidated, some under development— aiming to contribute to the management of obese patients and their associated metabolic diseases as a complement to dietary and lifestyle changes. To date different intragastric balloon models, suture systems, aspiration methods, substance injections and both gastric and duodenal malabsorptive devices have been developed, as well as endoscopic procedures for the revision of bariatric surgery. Their ongoing evolution conditions a gradual increase in the quantity and quality of scientific evidence about their effectiveness and safety. Despite this, scientific evidence remains inadequate to establish strong grades of recommendation allowing a unified perspective on prophylaxis in BE. This dearth of data conditions leads, in daily practice, to frequently extrapolate the measures that are used in bariatric surgery (BS) and/or in general therapeutic endoscopy. In this respect, this special article is intended to reach a consensus on the most common prophylactic measures we should apply in BE. The methodological design of this document was developed while attempting to comply with the following 5 phases: Phase 1: delimitation and scope of objectives, according to the GRADE Clinical Guidelines. Phase 2: setup of the Clinical Guide-developing Group: national experts, members of the Grupo Español de Endoscopia Bariátrica (GETTEMO, SEED), SEPD, and SECO, selecting 2 authors for each section. Phase 3: clinical question form (PICO): patients, intervention, comparison, outcomes. Phase 4: literature assessment and synthesis. Search for evidence and elaboration of recommendations. Based on the Oxford Centre for Evidence-Based Medicine classification, most evidence in this article will correspond to level 5 (expert opinions without explicit critical appraisal) and grade of recommendation C (favorable yet inconclusive recommendation) or D (inconclusive or inconsistent studies). Phase 5: External review by experts. We hope that these basic preventive measures will be of interest for daily practice, and may help prevent medical and/or legal conflicts for the benefit of patients, physicians, and BE in general.

Keywords: Bariatric endoscopy. Obesity. Prophylaxis. Law. Informed consent.

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INTRODUCTION

Bariatric endoscopy (BE) encompasses a number of techniques —some consolidated, some under development— aiming to contribute to the management of obese patients and their associated metabolic diseases as a complement to dietary and lifestyle changes.

To date different intragastric balloon (IB) models, suture systems, aspiration methods, substance injections and both gastric and duodenal malabsorptive devices have been developed, as well as endoscopic procedures for the revision of bariatric surgery. Their ongoing evolution conditions a gradual increase in the quantity and quality of scientific evidence about their effectiveness and safety.

Despite this, scientific evidence remains inadequate to establish strong grades of recommendation allowing a unified perspective on prophylaxis in BE. This dearth of data conditions leads, in daily practice, to frequently extrapolate the measures that are used in bariatric surgery (BS) and/or in general therapeutic endoscopy.

In this respect, this special article is intended to reach a consensus on the most common prophylactic measures we should apply in BE. The methodological design of this document was developed while attempting to comply with the following 5 phases:

- *Phase 1. Delimitation and scope of objectives,* according to the GRADE Clinical Guidelines.
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recommendation C (favorable yet inconclusive recommendation) or D (inconclusive or inconsistent studies).

— *Phase 5. External review by experts.*

We hope that these basic preventive measures will be of interest for daily practice, and may help prevent medical and/or legal conflicts for the benefit of patients, physicians, and BE in general.

PROPHYLAXIS OF THROMBOEMBOLISM IN BARIATRIC ENDOSCOPY

Venous thromboembolic disease (VTED) is a severe complication with medical, economical, and legal implications, that represents the leading medical cause of death in patients undergoing bariatric surgery (BS) (1). Actual data remain unknown in BE, where neither scientific evidence nor specific recommendations are available. However, while in BE procedures are less invasive and lengthy, the target population may often overlap.

Multiple risk factors for VTED are known in BS (Table 1.1), and various cost-effective prophylactic strategies are available (2,3):

1. Hygienic measures: early ambulation. The first and most effective measure of all.
2. Physical measures:
    a. Static → Gradually compressive elastic stockings (ES) (up to the knee or thigh root), with optimal ankle pressure at 18-20 mmHg decreasing proximally.
    b. Dynamic → Intermittent pneumatic compression (IPC) sleeves, with compressive pump.
3. Pharmacological measures → Drugs that modify the coagulation cascade, primarily by inhibiting factor Xa:
    a. Unfractionated heparins
    b. Low molecular weight heparins (LMWH)

Thromboembolic prophylaxis in bariatric endoscopy (TEPBE)

We still have no guidelines or specific recommendations available for VTED. Its actual incidence remains unknown and the condition is likely underdiagnosed: many cases remain unreported and others are overlooked because of being subclinical (4).

Bearing in mind the risk factors for VTED in BS (Table 1.1), we may establish recommendations for TEPBE. We know that patients with morbid obesity already are at moderate-high risk for VTED *per se,* and that some variables may increase said risk. However, in general, BMI is lower in the BE setting, procedures usually have limited durations (< 1 hour), most procedures are performed on an outpatient basis or during shorter hospital stays (< 24 hours), and there are few restrictions to early mobilization.

Based on the above, establishing a comparative parallelism with VTED prophylaxis as performed for major outpatient surgery (5), and extrapolating Caprini's score as accepted for BS to BE (6-10) (Table 1.2), we may see that patients undergoing BE are at low to moderate risk. Therefore, systematic use of hygienic measures (early ambulation) would be recommended for all patients, in association with physical measures (elastic stockings) for most. Pharmacological measures (low-dose LMWH) would be limited to patients with morbid obesity (Table 1.3) or on an individual basis according to the above moderate or high risk factors (Table 1.1).

ANTIBIOTIC PROPHYLAXIS IN BARIATRIC ENDOSCOPY (ABPBE)

The need for antibiotic prophylaxis (ABP) in bariatric procedures has always been a controversial subject. Overall, it has been indicated after considering the technique's bacteriemia risk and the patient's underlying conditions.

In this section we shall only discuss the need for antibiotic therapy to prevent surgical site infection (SSI). ABP for endocarditis in at-risk patients is already widely documented in various guidelines and recommendations.

To date no studies have assessed the risk for SSI in BE. Therefore, we must extrapolate the scientific evidence available for ABP in:

- *Gastroduodenal surgery:*

- Randomized, controlled studies have shown its efficacy, mainly with cephalosporins or penicillins (11-13).

- *Bariatric surgery:*
  - A recent systematic review recommends using cefazolin for the prophylaxis of SSI (14).
- *Gastroduodenal endoscopy*:
  - Both the ESGE and ASGE have developed clinical guidelines (15,16). In the last revision by ASGE evidence supporting the use of ABP (to prevent SSI) is only available for:
    - ERCP with incomplete biliary drainage.
    - Drainage or puncture of mediastinal and/or pancreatic cysts through echoendoscopy.
    - Placement of a PEG tube (13-16). It seems reasonable that this recommendation should be extrapolated to aspiration techniques such as Aspire-Assist.

Recommendations for antibiotic prophylaxis in bariatric endoscopy (ABPBE)

Infection risk is higher in the following situations (17):

- Permeation of mucosal integrity. This would be the case of endoscopic suturing, aspiration systems, prosthetic tissue anchors, or mucosal ablation. In other techniques, such as intragastric balloons or substance injections, mucosal damage would be minimal.
- Achlorhydria:
  - Gastric pH enhancers (H2 blockers and proton pump inhibitors - PPIs)
  - Chronic atrophic gastritis.
- Reduced gastric motility.
- Morbid obesity *per se.*
- Lengthy procedures.
- Patients with ASA ≥ 3.

— Delayed administration of antimicrobials.

Antibiotic selection should be based on the pathogens most commonly associated with the area to be endoscopically examined. Extrapolating to BE the clinical practice guidelines developed by different international societies (11) for gastrointestinal surgery and therapeutic endoscopy we may conclude the following:

- Most common micro-organisms in SSI-derived cultures include coliforms (*E. coli*, *Proteus* species, *Klebsiella* species), staphylococci, streptococci, enterococci, and occasionally *Bacteroides* species (18).
- The antibiotic recommended as first-choice is a first- or second-generation cephalosporin (11,12).

As regards optimal *dosing time,* we consider that:

- The antibiotic should be administered one hour before (except vancomycin and ciprofloxacin, which require being administered two hours before) (11,19).
- Other studies show effectiveness over a wider therapeutic window (20) or no statistically significant differences in dosing time (21).

We must adjust antibiotic *dose* as follows:

- Adjust to patient weight (11,19). While it was traditionally recommended that higher doses be used for patients with morbid obesity, recent studies suggest that higher cefazolin doses do not manage to reduce SSI rates as compared to standard doses (22).
- In prolonged procedures a repeat dose should be used to maintain adequate blood levels, based on the antibiotic's half-life, or with every 1,500 cc of blood loss (11,19).

Final ABPBE recommendations are listed in table 2.

UPPER GASTROINTESTINAL BLEEDING PROPHYLAXIS AND *H. PYLORI* ASSESSMENT IN BARIATRIC ENDOSCOPY (BE)

During the first year after BS, ulcer and bleeding at the anastomosis represent one of the commonest complications (0.6-3.6 %) (23). Of uncertain etiopathogenesis, this has been directly associated with gastric acid, non-steroidal anti-inflammatory drugs (NSAIDs) and steroids, gastric reservoir size, active smoking, diabetes, *H. pylori*, and non-resorbable sutures. Therefore, the ASMBS recommends (24) that NSAIDs be discontinued, and gastro-protective agents (PPIs or, alternatively, H2-blockers or sucralfate) be prophylactically used during the first year after BS, accompanied by *H. pylori* eradication (grade C).

3.1 Gastro-damaging drugs in bariatric endoscopy

Usually, NSAIDs must be discontinued or replaced with a COX-2 inhibitor, or a PPI must be added at standard doses when discontinuation is not an option. Administering a COX-2 inhibitor alone or a combination of NSAID and PPI seem equally effective options except in maximum-risk situations such as a prior history of upper gastrointestinal bleeding, where adding a PPI to the COX-2 inhibitor would be required (25).

We consider that devices with balloons and anchors (Endobarrier®) should not be recommended for patients requiring sustained anticoagulation or antiaggregation, because of their high risk for bleeding during the endoluminal stay. In these cases other endoscopic options should be studied.

As regards primary suturing and repair, as well as aspiration therapy, we advise applying current ASGE recommendations to BE (26), as discussed in table 3.1.

Infection with *H. pylori* in bariatric endoscopy

The ASMBS does not recommend routinely screening for *H. pylori* before BS (grade D), except in case of digestive symptoms after BS (grade C) or in patients at high risk. The SECO recommends oral endoscopy and *H. pylori* assessment for gastric exclusion techniques given the difficulty of reaching the excluded gastric remnant; this is not so

clear for gastric sleeve cases.

Regarding BE no randomized studies are available on the need to investigate *H. pylori* (Table 3.2). However, we consider that BS references should be taken into account, as well as the current recommendations for *H. pylori* assessment and eradication in the general population. Assessing the presence of *H. pylori* in patients undergoing BE with a history of gastroduodenal ulcer seems reasonable (grade A) (27).

For restrictive BE (intragastric balloon, suture systems), the *H. pylori* assessment protocol could be similar to that implemented in cases of surgical gastric sleeve. Since no gastric exclusion is present and bleeding rate is minimal, routine systematic screening cannot be recommended. Because of its similarities with PEG, systematic *H. pylori* screening is also not warranted when aspiration systems are used.

Bulbar anchors seem to bring about a higher percentage of ulcers in malabsorptive techniques. Therefore, further studies pending, *H. pylori* detection and eradication would have to be carried out on an individual basis.

Regarding endoscopic gastric bypass repair, although *H. pylori* should have been assessed before surgery, we deem it advisable to screen for it, most particularly if no screening was made before bypass surgery.

The *H. pylori* eradication regimen used should not differ from standard practice for the general population.

Upper gastrointestinal bleeding in bariatric endoscopy

In reported studies endoscopic transmural suture systems seem safe procedures with only isolated bleeding cases. When it occurs, bleeding seems to be self-limited because of suture pressure on tissue (8,28-31). Significant bleeding has also not been reported in the initial reports of series using the aspiration system (32).

With the endoluminal duodeno-jejunal bypass (Endobarrier) isolated bleeding cases were reported in initial series (29,33), despite treatment with PPIs, associated with tears at the stent anchorage site.

The rate of gastrointestinal ulcers by IB varies according to each study and balloon type. Taking the Orbera® balloon as a reference, it has a peptic ulcer rate of 0.02-2.6 % (34). The other balloons commercially available also seem safe except for the Spatz2®

(4) and Dual® (35) models, although their newer generation are apparently also safe. Therefore, the rate of upper gastrointestinal bleeding in BE seems to be extremely low. This might be conditioned by the usual preventive use of PPIs, acknowledged by most BE units. Hence, it seems reasonable to maintain this recommendation (Table 3.1) while looking forward to further randomized studies.

Both PPI dose and duration must be individualized. Tentatively, a standard dose should be recommended bearing in mind that we are dealing with obese patients and these procedures represent a direct aggression on the gastric mucosa. Thus, when using suture, aspiration, or repair systems a period of 2-4 weeks might be considered, and for anchored stents and IB the same period the device will stay inside the gastroduodenal cavity.

PREVENTION OF LEGAL CONFLICT IN BARIATRIC ENDOSCOPY

We must demand of BE its compliance with quality criteria. Extrapolating the surgical criteria for ideal BS (36,37), as adapted to BE (38), this must be effective and safe, have scarce side effects, be reproducible and reversible, require few revisions, and provide adequate quality of life. When these requirements fail to be met, particularly regarding effectiveness and safety, legal conflicts may arise (39). To this day, the incidence and resolution of these conflicts remain to be accurately reported, and the mechanisms to avert and/or prevent them remain to be specifically documented. Furthermore, in the future, lawsuit risk may increase as newer devices emerge and the techniques become more widespread, which will require that informed consent (IC) forms be adapted and updated according to applicable laws and jurisprudence (39,40).

Prior study and assessment. Subsequent control and follow-up

The first step in the prevention of legal conflicts lies in defining and establishing patient inclusion criteria for endoscopic bariatric therapy: ensuring a correct indication (multidisciplinary medical assessment and diagnostic tests), establishing recommendations to report expected outcomes, and ruling out contraindications are key stepping stones. We must give patients all the relevant information in writing in a protocolized manner. This must be clearly recorded in the case history, and properly

signed in the IC form specific for each endoscopic technique (39).

After the procedure, all patients should receive a real-time, fully typed out discharge report including recommendations, guidelines, specific hygienic, dietary and medication advice, and a schedule of further care and follow-up visits. These should be offered according to the medical protocol in each center, with prior patient agreement, and in accordance with the specific consensus approved. Each center must keep track of adverse effects, including their severity and the characteristics of their resolution. An association or intrinsic relationship with an hospital and a 24-hour emergency room where an endoscopist and surgeon experienced in solving potential complications are available is of vital importance (41-44).

Human and structural resources

BE units must rely on a staff and material endowment model able to provide adequate resources for the care of obese patients and their families. This includes office size, common hospital areas, furniture, endoscopic materials, ancillary products and instruments.

Of endoscopists, nurses and other staff involved in procedures and patient follow-up adequate certification, training and experience should be demanded. Scientific developments, research, and technical updates should be supported (42). To achieve this it is advisable to be a member of BE scientific society or task force for certified training and both medical and legal counseling when needed.

Informed consent (IC)

A major part of the potential for conflict between doctor and patient should be clearly elucidated in the contract-agreement referred to as "informed consent" (39,45,46). This document may be defined as "*the express act of will, freely manifested, specific and determined, duly and accurately informed, documented and validated, whereby a (physically and legally) competent patient accepts the diagnostic and/or therapeutic procedures to be performed on him/her by a physician, with whom he/she previously decided to start a patient-doctor relationship, in the terms established by law, and which in no manner or circumstance entails relinquishment of patient rights, or*

exonerates per se from individual, subjective legal liability or institutional, objective liability in general" (47). The mandatory nature of IC represents an inescapable regulatory requirement. Non-acceptance of, or refusal to signing, the IC formally contraindicated any BE technique, as well as any other related procedures.

Informed consent contents

All endoscopic procedures should be included in the *care-providing or curative medicine* category. BE also is a part of this curative medicine: in addition to the disease obesity represents in and of itself, it also treats other associated physical and psychological comorbidities. However, in BE patient information requires a more extensive, detailed approach. Therefore, in order to preserve as much as possible an endoscopist's legal safety, from a purely legal perspective, IC forms could be designed and legally framed with a *cosmetic, voluntary* medicine approach (45,46,48,49).

IC relies on two basic tenets: autonomy of will, and patient freedom. To be valid, it must include the following constituent properties (46):

1. Adequate information.
2. Understandable information.
3. No coercion on patient decision making.
4. Complete patient autonomy in decision making.

The information a patient must receive is a well established right in Spanish law (Law 41/2002, of November 14) (40,46). It must be objective and extremely complete, specific for each technique and individualized according to each patient's characteristics. It also must include the nature of the bariatric endoscopic technique, its indication and benefits, and a prognosis concerning its likely outcomes. Also the odds of a failed procedure must be contemplated, together with contraindications, potential risks, mishaps, undesirable effects, and sequelae, whether transient or permanent, common or exceptional. The severity of potential complications or adverse outcomes must be specified, as well as the possibility of requiring major surgery, and the likelihood of mortality, in case of an untoward course. It also may reflect the patient's refusal to be made aware of other uncommon complications not

included in the IC form. Mention must be made of alternative procedures and of the prognosis should the procedure fail to be performed. Inclusion of the medical recommendation and of patient commitment to comply with the medical-dietary follow-up schedule, and to adhere to any necessary lifestyle changes after the procedure is also advisable

Formal informed consent characteristics

The information provided must be explained and delivered by the attending physician or other specialist in the Health Area in clear, simple terms (46,50) (Table 4).

Who should inform and sign?

The law establishes that "*It is the patient's attending physician who should ensure the former's right to information.*" Also, however, "*The professionals who tend to him/her during the care process, or perform on him/her any technique or procedure, will be responsible for providing him/her with information and obtaining his/her consent"* (art. 4.3 and 3 of Law 41/2002) (40,45). Furthermore, the IC form must be signed by the patient or the patient's legal representative.

Time from IC signing to endoscopy

The law does not establish a minimum time lapse from IC signing by the patient to endoscopic procedure performance (Law 41/2002, of November 14) (40) except in the Valencian Community (art. 43.9 of Law 10/2014, of December 29), which specifies " *sufficiently in advance and, in all cases, at least 24 hours."*

IC administration is an act that "*must be carried out with sufficient time and dedication … in a comprehensible manner adjusted to his/her needs, to allow him/her to come to grips with or assess the potential consequences that might result from the intervention upon his/her specific condition, and in his/her view, choose, reject or delay a specific therapy according to its risks, and even visit a different specialist or center (...). To recap, it is an act of information where also the patient plays an active role to accordingly consent or refuse the proposed intervention"* (Supreme Court sentence 1065/2007, Civil Chamber, Section 1, of October 4) (SCS of November 15, 2006 [RJ

2006, 8059]) (45).

Informed consent safekeeping

Each healthcare center must archive the medical records of its patients, and keep them for an adequate period, according to each particular case, of at least five years starting on the discharge date for each care-providing process (art. 14.2 and 17 of Law 41/2002, of November 14) (40,45). However, each Autonomous Community is competent to regulate on this subject. For example, in Catalonia the article 12 of Law 21/2000 establishes that ICs must be kept, together with other records detailed in said Law, for at least 15 years starting on the discharge date for each care-providing process, and 5 years for the remaining records in the medical history file. Therefore, in general we deem it advisable to keep the aforementioned records in their totality for 15 years. Should a legal authority request a given IC form, the attendant physician may see it and review it as he/she wishes before its submission outside of the hospital.

Image or video recording

There is a legal obligation to obtain image release rights for a number of scenarios other than strictly care provision ones, such as teaching, scientific, informational or advertising activities (Organic Law 1/1985, of May 5), and to this end obtaining a different, specific, express IC is advisable. Excluded from this release agreement are those photographs or videoclips that were recorded for case file completion in the setting of as-usual clinical work.

This document, in addition to being individualized, must specify aspects such as the purpose of image or voice recordings, type of authorization, geographic setting, and time limits. Similarly, it must be stated whether an economic retribution was agreed upon for remuneration. Furthermore, the data concerning the person responsible for the file, and his/her registration in the Agencia Española de Protección de Datos (AEPD), must be well identified in the document, as well as the goal for its collection, its recipients, and the possibility to exercise the rights of access, rectification, cancellation and opposition (45,46).

CONCLUSIONS

Regarding the prophylactic measures that may be applied before bariatric endoscopy (BE), according to the above discussion in the sections of the present article, we consider that the following conclusions should be highlighted:

1. Thromboprophylaxis measures must be individualized according to each patient's risk factors. Hygienic measures (early ambulation) should always be recommended, and in many cases supplemented by physical aids (elastic stockings). Intermittent pneumatic compression sleeves and LMWH should be reserved for patients with risk factors or morbid obesity (especially if BMI > 50 kg/m²) scheduled to receive suture systems, malabsorptive stents or surgical revision.

2. Antibiotic prophylaxis for surgical/endoscopic site infection seems adequate in case of suture systems, tissue anchors, and aspiration systems. It seems to be unnecessary for intragastric balloons. In general, a single prior dose of antibiotic should suffice.

3. It seems reasonable to recommend preventive PPIs. In general, standard doses should be used for suture, aspiration, and repair systems for 2-4 weeks, and for as long an anchored malabsorptive stent or a balloon will stay in the body.

4. IBs and malabsorptive stents must be advised against for patients requiring anti-platelet agents and, above all, sustained anticoagulation. For the rest of procedures suppression and replacement regimens should be followed according to cardiovascular risk and established therapeutic endoscopy guidelines.

5. No evidence is available to support a systematic recommendation of *H. pylori* screening except before revision endoscopy for an excluded stomach, and in cases where patient history so requires. The same standards used for therapeutic gastroscopy or gastric restrictive bariatric surgery would apply here. The eradication regimen should no differ from the updated protocol in force.

6. To avert legal conflict a previous, adequate medical assessment should be performed of the patient, as well as a correct post-procedural monitoring of the outcome according to the hospital's protocol and scientific guidelines recommendations. A specific, correctly filled out IC form for each endoscopic technique should always be present. This will be handed out to patients with sufficient

time in advance to facilitate concern solving, and should be safekept for at least 15 years.

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REVISTA ESPAÑOLA DE
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Table 1.1. Primary risk factors for VTED in bariatric surgery

High BMI	Advanced age
Immobility	Male gender
Obesity-hypoventilation syndrome	Shortness of breath at rest
Pulmonary hypertension	Surgical time longer than 3 hours

Prior thrombotic events	Heart failure
Prothrombotic states	Surgery other than adjustable gastric banding
Venous stasis	Hospital stay longer than 3 days
Hormonal therapy	Laparotomic surgery
Reintervention in the immediate postoperative period	

VTED: venous thrombo-embolic disease.

Table 1.2. Caprini score as adapted to some series representative of BE

Author	**Procedure**	**BMI (kg/m²)**	**Age (years)**	**Comorbidities**	**Caprini**
Genco 2013 (7)	Intragastric balloon	28.6 ± 0.4	38.7 ± 3.6	1 % respiratory disease	1 → 0.7 %
López-Nava 2014 (8)	POSE	38.0 ± 4.8	43.8 ± 11.0	Not described	2 → 0.7 %
López-Nava 2016 (9)	Gastroplasty (ESG-Apollo)	38.5 ± 4.6	44.5 ± 8.2	Not described	2 → 0.7 %
Vilarrasa 2017 (10)	Endobarrier	33.4 ± 1.9	54.1 ± 9.5	100 % DM2	2 → 0.7 %

Table 1.3. Thromboprophylaxis recommendations in bariatric endoscopy

Proc.	BMI kg/m²	Prophylaxis indication	Estimated Caprini score	Thromboprophylaxis measures				Level of Evidence / Grade of Recommendation
				EA	CM	IPCD	LMWH	
IB	< 30	NR	0	Yes	No	No	No	D / 5
	30-40	No evidence	0-1	Yes	Yes / No	No	No	D / 5
	40-50	Suggested	0-2	Yes	Yes / No	No	No	D / 5
	> 50	Suggested	0-2	Yes	Yes / No	No	No	D / 5
Suture systems	< 30	Suggested	0-1	Yes	Yes	Yes / No	No	D / 5
	30-40	R	0-1	Yes	Yes	Yes / No	No	D / 5
	40-50	R	1-2	Yes	Yes	Yes	Yes / No	D / 5
	> 50	R	1-2	Yes	Yes	Yes	Yes	D / 5
Malabsorptive stents	< 30	Suggested	0-1	Yes	Yes	Yes / No	No	D / 5
	30-40	R	0-1	Yes	Yes	Yes / No	No	D / 5
	40-50	R	1-2	Yes	Yes	Yes	Yes / No	D / 5

	> 50	R	1-2	Yes	Yes	Yes	Yes	D / 5
Aspiration systems	< 30	NR	0	Yes	No	No	No	D / 5
	30-40	No evidence	0-1	Yes	Yes / No	No	No	D / 5
	40-50	Suggested	0-2	Yes	Yes / No	No	No	D / 5
	> 50	Suggested	0-2	Yes	Yes / No	No	No	D / 5
Repair / post-surgical revision	< 30	Suggested	0-1	Yes	Yes	Yes / No	No	D / 5
	30-40	R	0-1	Yes	Yes	Yes / No	No	D / 5
	40-50	R	1-2	Yes	Yes	Yes	Yes / No	D / 5
	> 50	R	1-2	Yes	Yes	Yes	Yes	D / 5

Proc.: procedure; IB: intragastric balloon; R: recommended; NR: not recommended; EA: early ambulation; CM: compressive measures; IPCD: intermittent pneumatic compression devices; LMWH: low molecular weight heparin.

Table 2. Antibiotic prophylaxis recommendations in bariatric endoscopy

Technique	First choice	Alternative
Aspiration (Aspire Assist®)	Cefazolin 2 g IV 1 h before*	Clindamycin or vancomycin + aminoglycoside[a] or aztreonam[b] or fluoroquinolone[c,d]
Endoscopic suturing (POSE®, ESG-Apollo®, TORe-Apollo®, ROSE®)		
Tissue anchors (Endobarrier®)		
Duodenal mucosal ablation (Fractyl®)		
Intragastric balloons	Not required	
Substance injections		

[a] Gentamycin or tobramycin.
[b] Because of growing resistance in *E coli* to fluoroquinolones and ampicillin-sulbactam, the local susceptibility profile should be reviewed before use.
[c] Ciprofloxacin or levofloxacin.
[d] Fluoroquinolones are not deemed first-choice drugs in the pediatric population (incidence of adverse events).
*Further studies are needed to recommend covering biliary germs that might prevent cholangitis/liver abscesses.

	UGIB prophylaxis	Level of Evidence / Grade of Recommendation	Recommended treatment (measure, drug, dose, duration, route, alternative)	Anticoagulants	Antiaggregants
IB	R	D/5	Recommended: - PPI, standard dose,[1] PO, for the duration of the IB. Alternative: - Famotidine 40 mg PO	Advice against balloons and malabsorptive stents with anchors. For the rest of procedures: *Low cardiovascular risk[2]:* Discontinue warfarin 3-5 days before, and reinstate at 24 h. Newer anticoagulants[5]: discontinue 2-3 days before,[3] and reinstate at 48-72 h. *High cardiovascular risk[4]:* Discontinue warfarin 3-5 days before + bridging therapy, and reinstate at 24 h. Newer anticoagulants[5]: discontinue 2-3 days before[3], and reinstate at 48-72 h.	Advice against balloons and malabsorptive stents with anchors. For the rest of procedures : *Low[2] and high[4] cardiovascular risk:* Discontinue thienopyridines[6] 5 days before. In case of double antiaggregation, discontinue thienopyridines[6] 5 days before and maintain ASA 100 mg. Reinstate double antiaggregation after assessing hemostasis
Suture system	R	D/5	Recommended: - PPI, standard dose, PO, 2-4 weeks Alternative: - Famotidine 40 mg PO, 2-4 weeks		
Malabsorptive stent	R	D/5	Recommended: - PPI, standard dose, PO, for the duration of the stent. Alternative: - Famotidine 40 mg PO		
Aspiration	R	D/5	Recommended: - PPI, standard dose, PO, 2-4 weeks Alternative: - Famotidine 40 mg PO, 2-4 weeks		
Bariatric surgery repair (ROSE, TORe)	R	D/5	Recommended: - PPI, standard dose, PO, 2-4 weeks Alternative: - Famotidine 40 mg PO, 2-4 weeks		

Table 3.1 UGIB prophylaxis in bariatric endoscopy

R: recommended; IB: intragastric balloon.

[1]In case of florid symptomatology a double-dose PPI may be instated for a few weeks, and then maintained at standard dose until discontinuation.

[2]Biological aortic prosthesis without risk factors for stroke, $CHADS_2 \leq 2$ or venous thromboembolism > 12 months with no other risk factors.

[3]For a normal glomerular filtration rate. To adequately adjust discontinuation time we must be aware of the patient's glomerular filtration rate.

[4]Mitral prosthesis, metallic aortic prosthesis, ischemic stroke within the last 6 months, rheumatic valvular heart disease, $CHADS_2 \geq 5$, severe thrombophilia or venous thromboembolism within the last 3 months.

[5]Newer anticoagulants: dabigatran, rivaroxaban, apixaban, edoxaban.
[6]Thienopyridines: clopidogrel, prasugrel, ticagrelor.

Table 3.2. *H. pylori* assessment and eradication in bariatric endoscopy

	Indication for systematic *H. pylori* assessment[2]	**Level of Evidence / Grade of Recommendation**
IB	NR[1]	D/5
Suture systems	NR[1]	D/5
Malabsorptive stents	NR[1]	D/5
Aspiration	NR[1]	D/5
Endoscopic revision of BS	R	D/5

R: recommended; NR: not recommended; BS: bariatric surgery.

[1]No consistent scientific evidence is available to recommend the systematic assessment of *H. pylori.*

[2]Follow the general indications for *H. pylori* assessment and treatment as used for the general population.

Table 4. Some general recommendations for the IC form for bariatric endoscopy

IC forms	**IC structure**
Boil down to one or two pages Short, concise though complete statements Use simple, lay words, and avoid technical or medical terms Easy to read, with spaces and a big font Discuss the specific technique and the condition to be treated Use the first person singular in the text General view and detail illustrations	Goal of the technique Sedation or anesthesia Alternatives and/or consequences of not undergoing the procedure What the technique consists of One or two illustrations Relevant safe consequences Complications or undesirable events Patient history Other specific risks of the patient and technique Modification of the planned technique Compliance with recommendations and controls

IC: informed consent.