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ORIGINAL CONTRIBUTIONS

Efficacy of Endoscopic Treatment of Post-Sleeve Gastrectomy Fistulas According to the Radiological Type

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Abstract

Background and Aims The originality of this retrospective study relies on the evaluation of the effectiveness of the endoscopic internal drainage (EID) according to the type of fistula.

Methods The type of fistula was classified initially according to a CT scan with oral opacification: fistula without a communicating abscess (type I), fistula with a communicating abscess (type II), and fistula with an abscessed sub- and sus-diaphragmatic communicating collection (type III). Treatment algorithm consisted of the insertion of a nasojejunal feeding tube (NJFT) for type I fistulas and the placement of a NJFT with EID with or without surgical drainage for types II and III.

Results Forty-nine patients were included. The clinical success rate with fistula healing was 100% in group I, 96% in group II, and 12% for group III ($p = 0.001$). Mean time for diagnosis of the fistula was significantly higher in type III ($p = 0.04$). The mean estimated size of the defect was higher in type II, 11.2 mm and III, 10 mm versus type I, 2.8 mm ($p = 0.001$). The average number of scheduled endoscopic sessions were 2, 2.7, and 5.2 for types I, II, and III, respectively ($p = 0.001$). The number of unscheduled reinterventions was also significantly higher in type III ($p = 0.03$). The NJFT was left in place for a significantly longer duration in type III (136 days) compared to types I (3, 13) and II (49) $p = 0.001$.

Conclusion This study shows that proper characterization of the type of fistula before the endoscopic treatment of post-sleeve fistulas improves the efficacy of the endoscopic treatment.

Keywords Sleeve gastrectomy · Fistulas · Endoscopy

Introduction

Bariatric surgery plays an important role in the treatment of morbid obesity. The number of laparoscopic sleeve gastrectomy (LSG) performed worldwide has grown exponentially over the last decade [1].

The main complication of LSG is the development of fistulas as a result of a staple line leak, which occur in 0 to 8% of the cases [2] and leads to significant morbidity [3]. The clinical presentation of the leak after LSG is variable, ranging from asymptomatic patients to sepsis with generalized abdominal tenderness and/or multiple organ failure. A radiological classification of fistula using CT scan has been proposed by Al Hajj et al. [4] to describe different types of fistula: type I fistula, a tiny leak; type II fistula, an extensive leak or abscess; or type III fistula, a complex leak with internal sub-diaphragmatic fistula or external gastro-cutaneous fistula.

Currently, there are no standardized guidelines for the treatment of LSG fistulas, which most often involves a combination of surgical, endoscopic, and medical treatment. The most widely used endoscopic technique to treat post-bariatric fistulas or leaks is temporary stenting with partially or fully covered self-expandable metallic stents (SEMS). This approach is associated with closure rates ranging from 62 to 87% [5, 6]. Recently, the use of double pigtail stents (DPS) placed through the fistula in order to guide the reepithelialization, associated with an exclusive enteral nutrition (EN), showed promising results [7–9]. As a first-line treatment, the efficacy

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rate was reported to be of 78% in a series of 61 patients, with 5 patients still under treatment [7].

In all available studies reporting the efficacy of endoscopic management, none have taken into account the different types of existing fistulas. Prior evaluation of the characteristics of the fistula by CT scan or by endoscopy using opacification could be important to choose the adequate endoscopic treatment.

Patients and Methods

From April 2015 to December 2017, a total of 49 patients with a median age of 41 ± 11 years (18–56) were diagnosed with post-LSG fistula in a tertiary center specialized in the management of bariatric adverse events (Hôpital Avicenne, Bobigny, France) (Table 1). Data were prospectively collected in all consecutive patients and were retrospectively analyzed.

Patients selected for this study were those who developed fistula following LSG confirmed by CT scan with opacification, and without prior endoscopic treatment. Those for whom the fistula was not identified, already healed, or consecutive to gastric Roux-en-Y bypass were excluded. This retrospective study was approved by the local ethics committee of the Assistance Publique des Hôpitaux de Paris.

Fistula Classification and Treatment Algorithm

Diagnosis of leak/fistula was confirmed using an abdominal CT scan with oral contrast or by endoscopy using opacification. The three types of fistula were type I fistula, a tiny leak < 2 cm; type II fistula, extensive leak > 2 cm or abscess; and type III fistula, a complex leak with internal sub-diaphragmatic fistula or external gastro-cutaneous fistula. Radiological classification of the three anatomical types of post-LSG fistula was used to optimize decision of the endoscopic treatment (Fig. 1).

In all patients, a unified protocol was used for the management of leaks. Sepsis was controlled with an appropriate antibiotic therapy. Our endoscopic treatment algorithm (Fig. 2) consisted of the insertion of a nasojejunal feeding tube (NJFT) for type I fistulas and the placement of NJFT with endoscopic internal drainage (EID) with or without surgical drainage depending on the septic status and the size of the collection for types II and III (Table 1). Acute septic patients were directly operated for abdominal lavage and laparoscopic drainage. With the NJFT, all patients were only on enteral nutrition.

Study Endpoints

The primary endpoint of the study was the clinical success rate. Secondary endpoints were interval time for the diagnosis of the fistula, size of the orifice fistula defect, duration of

Table 1 Characteristics of study population and results of the endoscopic treatment

Type	I (16)	II (25)	III (8)	*p* value
Study population				
Male/female ratio	5/11	6/19	2/6	Ns
Mean age ± sd (range)	42.1 ± 12 (18–56)	41.6 ± 12 (18–60)	40.4 ± 10 (25–56)	Ns
BMI before surgery sd (range)	46.1 (35–63)	46.1 (35–63)	46.8 (35–70)	Ns
Interval time for diagnosis (days) (range)	5 (2–32)	5.8 (2–67)	20.7 (5–122)	$p = 0.04$*
Acute (days 0–7) *n*, (%)	12 (75%)	15 (60%)	2 (25%)	
Early (days 7–42) *n*, (%)	4 (25%)	9 (36%)	5 (63%)	
Late (> 42 days) *n*, (%)	0 (0)	1 (4%)	1 (12%)	
Endoscopic treatment				
Success rate (%)	16 (100)	24 (96)	1 (12)	$p = 0.001$*
Size defects (mm)	2.8 (1–4)	11.2 (5–20)	10 (5–15)	$p = 0.001$**
Mean endoscopic session	2 (1–3)	2.7 (2–5)	5.2 (2–10)	$p = 0.03$*
Mean duration of treatment for healing (days)	21.3 (15–35)	52.2 (35–75)	70#	$p = 0.01$*
Surgical drainage (%)	7 (44)	14 (56)	8 (100)	$p = 0.03$*
Time with nasojejunal feeding tube (days)	13 (5–21)	49 (35–70)	136 (50–450)	$p = 0.01$*
Complication (%)	0 (0)	4 (16)	5 (63)	$p = 0.02$*
Sepsis		3	5	
Bleeding		1		

*Statistical difference between groups I and II versus III

**Statistical difference between groups II and III versus I

Only 1 patient

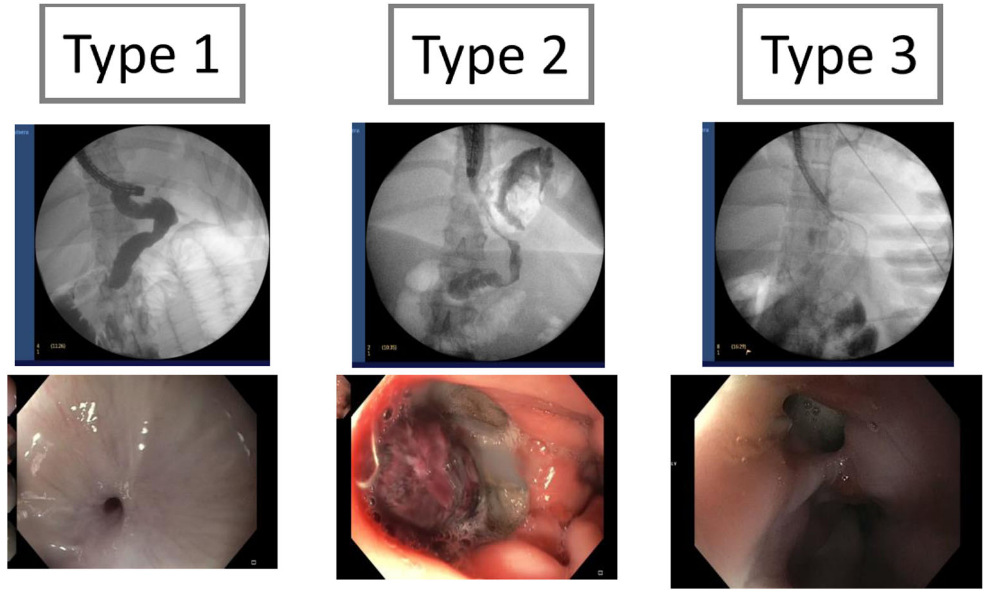


Fig. 1 Radiological and endoscopical features of the three types of fistula

feeding with a NJFT, duration of treatment for healing, need for surgical drainage, number of reinterventions, and complications rate.

Clinical success was defined as complete closure of the fistula confirmed either by the absence of contrast leak on a subsequent contrast study and/or clinical improvement following double pigtail removal. Interval time for diagnosis was defined as time between the surgical sleeve gastrectomy and the diagnosis of the fistula. Duration of treatment for healing was defined as time from the first endoscopic examination until the absence of free contrast media extravasation. Reinterventions were divided between scheduled reinterventions (for tube upsizing/exchange) and unscheduled reinterventions (for adverse event management or relapse).

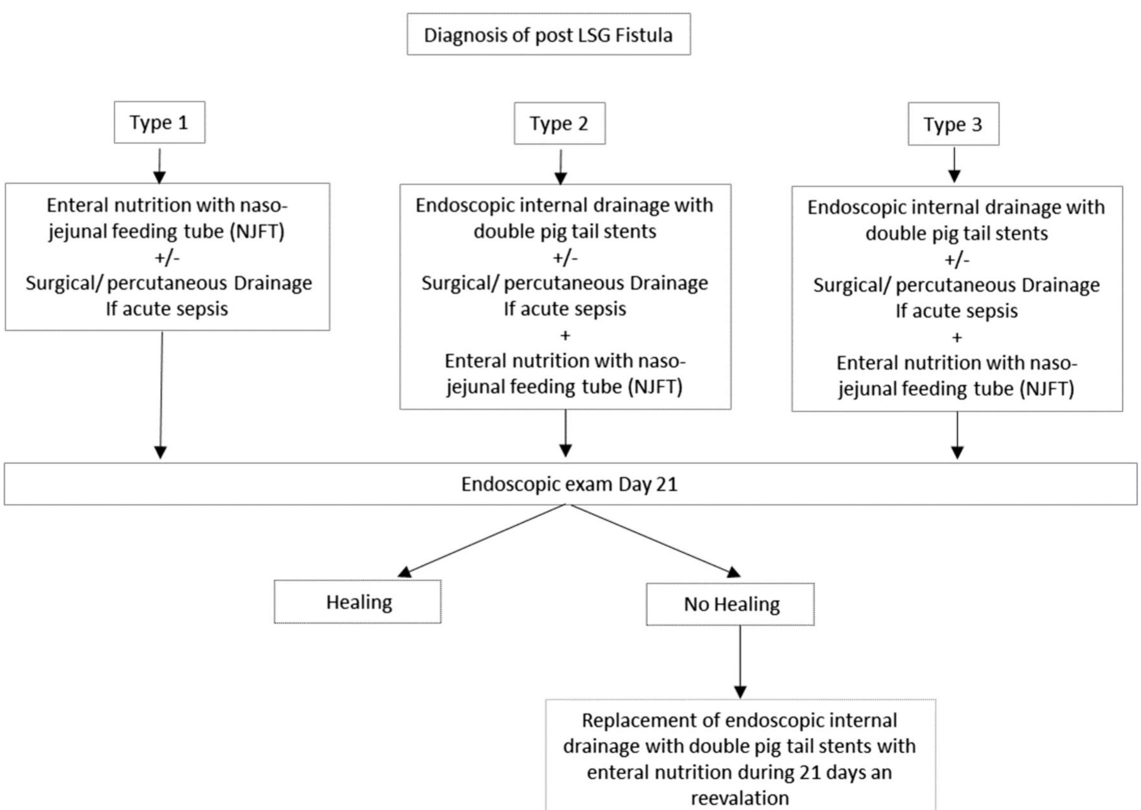


Fig. 2 Treatment algorithm. NJFT, nasojejunal feeding tube. DPS, double pigtail stent

Patient demographics, surgical and endoscopic procedure details, characteristics of the fistula, clinical success, duration of feeding with a NJFT and other treatments for healing, adverse events, and number of reinterventions during follow-up were also recorded.

Endoscopic Technique

Gastroscopy was performed under general anesthesia while using carbon dioxide (CO_2) insufflation and contrast opacification to evaluate the leak for fistula classification. For all the types of fistula, a NJFT was inserted and its lower tip was left in the third part of the duodenum. For types II and III fistulas, we inserted a DPS (Advanix®, Boston Scientific®, MA, USA) from the perigastric collection cavity to the stomach. A 7 or 10 Fr stent was used according to leak shape and size and to collection extent. The stents were delivered across the orifice placing one end inside the cavity to be drained and the other end in the digestive lumen in order to avoid migration. The stents were changed every 3 weeks until complete fistula healing.

Postoperative Care

Follow-up visits with a complete laboratory workup were scheduled at 2 weeks after the procedure, then at 1, 3, 6, 9, and 12 months, and then yearly.

Statistical Analysis

The mean and standard deviation of the parameters studied during the observation period were calculated for the three treatment groups and compared using the analysis of variance tests. Intragroup comparison was performed with the paired t test. $P < .05$ was taken as significant. All analyzed data were performed using SPSS.

Results

Baseline

Forty-nine patients were included (13 males/36 females), with a mean age of 41 ± 11 years (18–56) and an average initial body mass index (BMI) of 46 ± 11 kg/m^2 (38–70). According to Al Hajj et al. [4] classification, 16 patients had a type I fistula (33%), 25 a type II (51%), and 8 a type III (16%).

Mean interval time diagnosis of the fistula was 5 days (2–32) for type I, 5.8 (2–67) for type II, and 20.7 (5–122) for type III, with a statistical difference between groups I and II versus III ($p = 0.04$) (Fig. 4). An acute leak (within 7 days) was present in 75% of case in type I, 60% in type II, and 25% in type III, an early leak (within 16 weeks) in 25, 36, and 63%, and a late leak (after 16 weeks) in 0, 4, and 12%, respectively (Table 1). Mean follow-up for the 49 patients treated was 57 days (13–450). There were no statistical differences for age and BMI in the three groups.

Outcomes

Primary Endpoint

The clinical success rate of the procedure with complete fistula healing was 100% (16/16) in the type I, 96% (24/25) in the type II, and 12% (1/8) in the type III with a statistical difference between types I and II versus III ($p = 0.001$) (Fig. 3). The failure in type II fistula has been due to a stent migration into the spleen and patient underwent splenectomy with total gastrectomy after massive upper gastrointestinal bleeding. Seven patients with type III developed a chronic fistula with failure of repetitive endoscopic procedures and were finally treated by total gastrectomy with a Roux-en-Y esophago-jejunostomy.

Secondary Endpoint

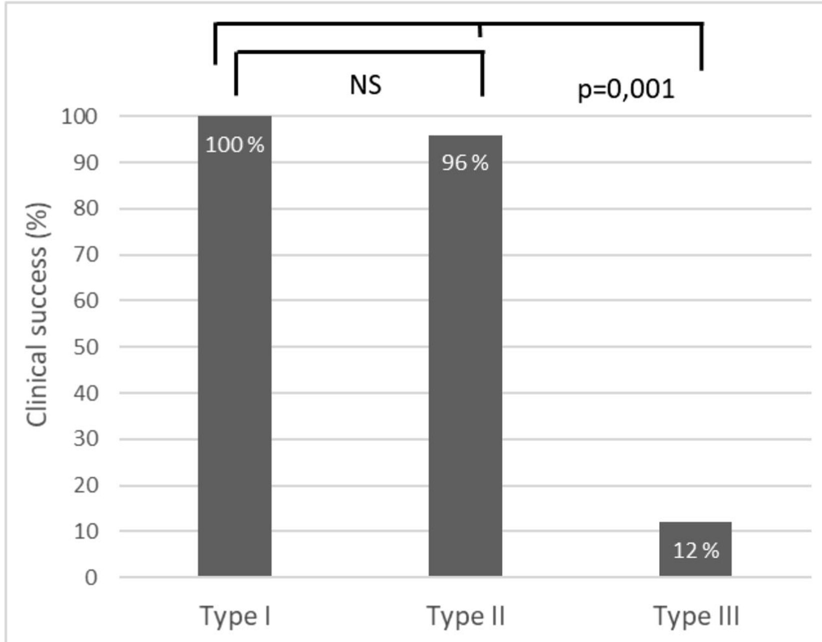
On endoscopy, all the patients had an obvious defect in the upper part of the last staple line at the level of cardia or below. The mean estimated size of the defect was higher in types II and III, 2.8 mm [1–4] for type I, 11.2 mm (5–20) for type II, and 10 mm (5–15) for type III ($p = 0.001$) (Fig. 5).

The average number of scheduled endoscopic sessions required was 2 (1–3), 2.7 (2–5), and 5.2 (2–10) for types I, II, and III, respectively, with a significant statistical difference between groups I and II versus III ($p = 0.001$). The number of unscheduled reinterventions (for adverse event management) was 0 for type I, 3 (12%) for type II, and 5 (63%) for type III with a significant statistical difference between types I and II versus III ($p = 0.03$).

The NJFT was left in place for an average of 13.3 (5–21), 49 (35–70), and 136 days (50–450) for types I, II, and III, respectively, with a significant statistical difference between types I and II versus III ($p = 0.001$) (Fig. 6). Duration of treatment for healing was 21 (15–35), 52.2 (30–75), and 70 days (only 1/8 patients) for groups I, II, and III, respectively, with a statistical difference between types I and II versus III ($p = 0.001$) (Fig. 7).

The endoscopic treatment was associated to surgical drainage in 44% of cases (7/16) in type I, 58% (15/25) in type II, and 100% (7/7) in type III with a significant statistical difference between types I and II versus III ($p = 0.003$).

Fig. 3 Clinical success rate (%) according to each type of fistula



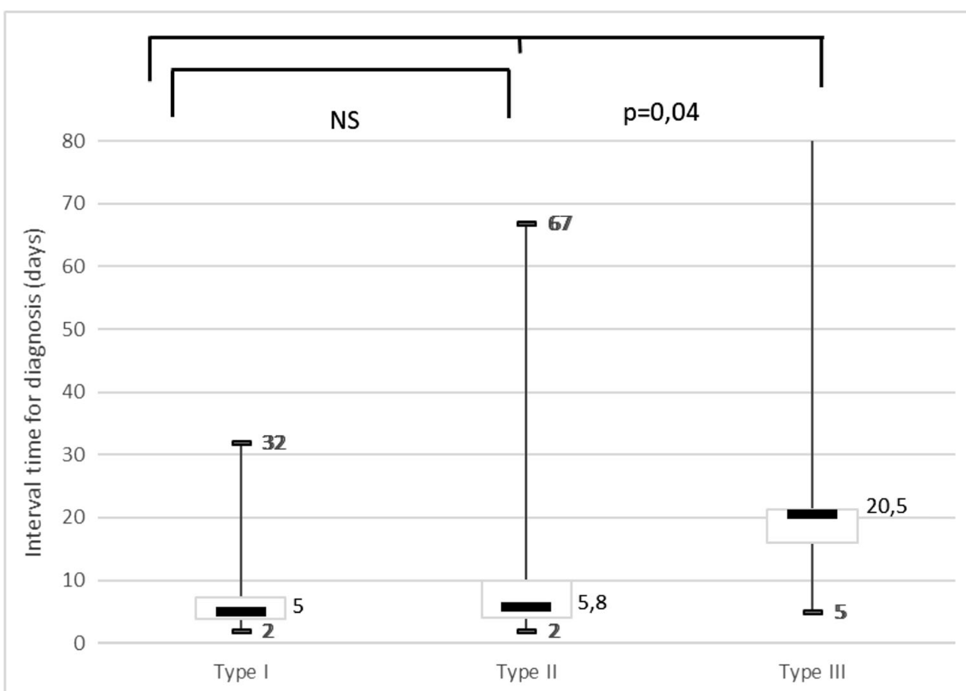
Adverse Events

No complication occurred in type I. In type II, there were four (16%) complications: 3 patients developed sepsis after DPS placement, requiring its early removal and placement of a new one for all 3 patients with a favorable outcome, and complementary radiological drainage for one of them; one patient developed bleeding when DPS was implanted due to its migration into the splenic vessels. In type III, 5 patients (68%) ($p = 0.002$ for types I and II versus III) presented with sepsis, of which, three needed complementary radiological or surgical drainage, and all had an early change in DPS.

Discussion

Post-sleeve fistulas are a serious complication of bariatric surgery associated with significant and prolonged morbidity,

Fig. 4 Interval time for diagnosis (days) according to each type of fistula



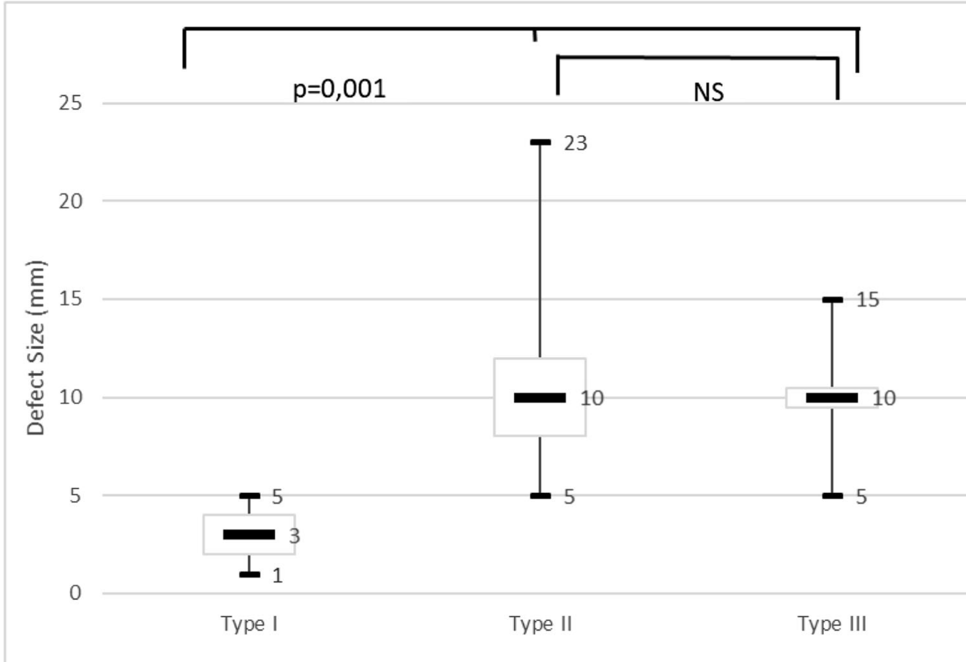


Fig. 5 Defect size (mm) of the fistula according to each type

remaining one of the most feared complications. Several types of fistulas exist ranging from a simple leak to a complex fistula. Several endoscopic techniques used for the management of this complication are described in the literature (stents, clips, glue) with clinical success rates ranging from 73 to 86% [7, 10, 11] and complication rate from 22 to 49% [5, 6]. However, none of these studies reported the success rate according to the characteristics of the fistulas.

The originality of our study is based on the use of a radiological or endoscopic classification to guide the appropriate treatment. The radiological classification used was developed in 2001 for fistulas of the upper digestive tract and then adapted to bariatric surgery [4, 12].

An alternative recent radiological classification based on the scan results separating four types of fistulas was proposed. We did not use this classification in our study because types II and III do not modify the endoscopic and surgical management [13].

Our study was performed only on patients who were naive to any endoscopic treatment using an algorithm established before the start of the study. The particularity

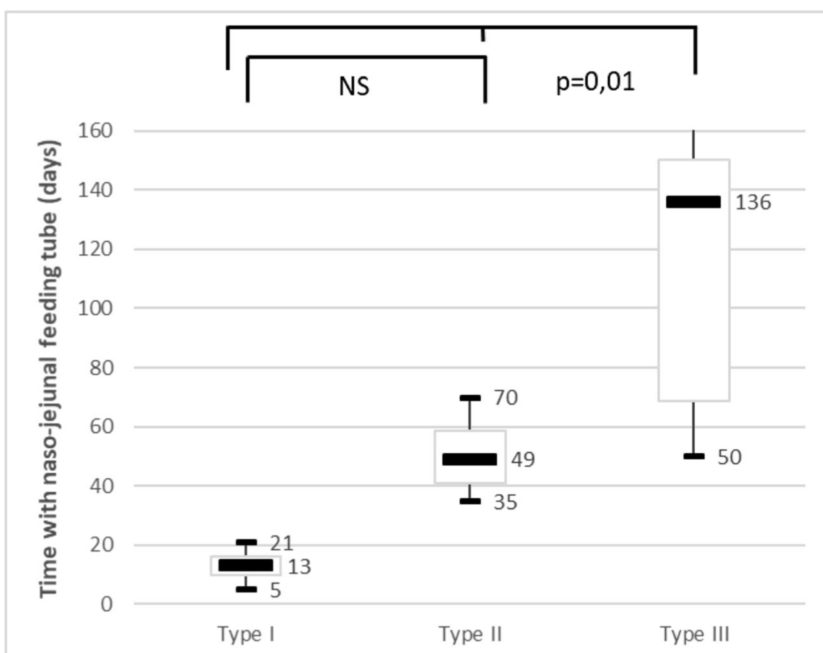


Fig. 6 Time with nasojejunal feeding tube according to each type of fistula

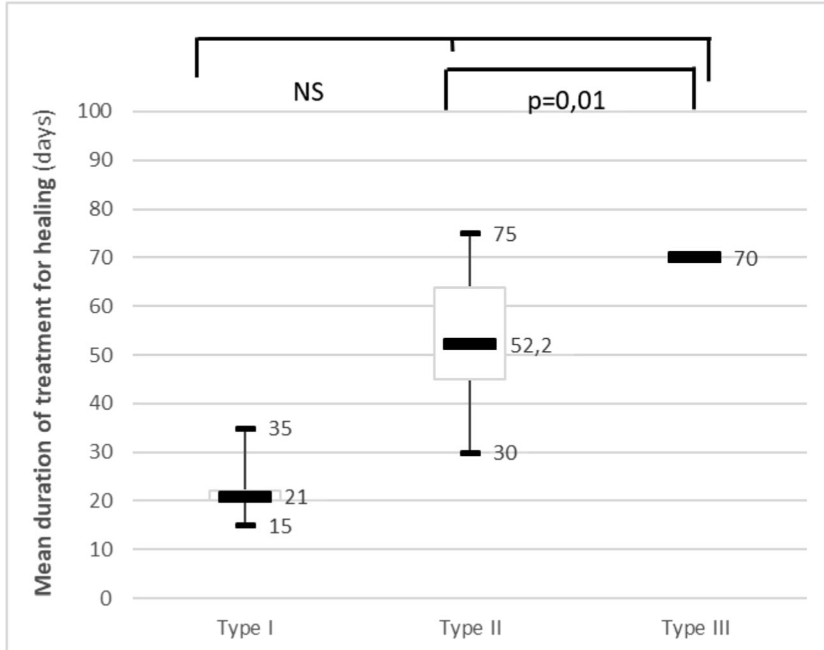


Fig. 7 Mean duration of treatment for healing according to each type of fistula

of this algorithm also involves the systematic use of exclusive enteral nutrition until cicatrization of the fistulous orifice. Exclusive enteral nutrition allows the patient to regain an adequate metabolism leading to the healing of the fistula.

The results of the study suggest that treatment of type I fistula relies solely on enteral nutrition for an average duration of 15 days. Type I fistulas are easy to treat because there is no underlying infected collection and the scarring is thereby completed naturally without the need for occluding it with clips or stents.

On the other hand, because of the presence of an underlying abscess in type II fistulas, internal drainage is essential to allow directed healing. Fistula healing is best obtained when combined with enteral nutrition.

For type III fistulas, endoscopic treatment can manage acute infectious complications, but it rarely allows complete healing and 88% of the patients in this group required gastrectomy after several failed endoscopic treatment attempts. Late diagnosis of fistula was significantly associated with a type III complex fistula. Type III fistulas require a longer duration of treatment and enteral nutrition and have a higher complication rate.

This study shows us that the association of DPS with enteral nutrition permitted the healing of 97% of all type I and type II simple fistulas.

In addition, this kind of procedure was associated with less complication rate than classical endoluminal metallic stent.

In view of these results, we suggest this approach to be considered a standard in the management of post-sleeve fistulas.

Several biases exist in our study. This is a monocentric study with a small population sample and a retrospective analysis of the data even if the collection of data was prospective. However, we considered all consecutive patients and being the only referral center of our geographical area limited the bias in patient selection.

This study shows that it is essential to characterize the type of fistula before the endoscopic treatment of post-sleeve fistulas to better guide the proper management. In addition, postoperative monitoring of patients is essential to detect a fistula as early as possible. A standardized method of fistula identification combined with an algorithm for treatment with DPS and EN was needed.

Authors' Contributions A. Sportes: Design of the protocol, performance of endoscopic treatment, inclusion of patients, collection of data, preparation of the manuscript

G. Aireini: Performance of endoscopic treatment, inclusion of patients, collection of data

R. Kamel: Preparation of the manuscript

C. Pratico: Performance of endoscopic treatment

JJ. Raynaud: Inclusion of patients, collection of data

JM. Sabate: Revision of the manuscript, statistical analysis

G. Donatelli: Performance of endoscopic treatment, revision of the manuscript

R. Benamouzig: Design of the protocol, revision of the manuscript

Compliance with Ethical Standards

This retrospective study was approved by the local ethics committee of the Assistance Publique des Hôpitaux de Paris.

Conflict of Interest The authors declare that they have no conflicts of interest.

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