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Laparoscopic vagal nerve blocking device explantation: case series and report of operative technique

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Abstract

Background Vagal nerve blockade with the vBloc device (ReShape Lifesciences, St. Paul, MN) has been shown to provide durable 2-year weight loss in patients with moderate obesity. These devices may require removal. We present a series of patients and report our technique for laparoscopic removal of this device.

Methods From December 2009 to December 2016, the medical records of patients who underwent laparoscopic explantation of a vagal blocking device at our institution were retrospectively reviewed. All patients initially underwent device placement as part of a multi-center, randomized, controlled trial. The device leads were removed with the application of firm traction in order to safely dissect them away from the stomach and esophagus as the body tended to form a fibrotic capsule surrounding the leads. Operative details, length of stay, 30-day post-operative complications, demographics and reasons for device removal were reported.

Results Thirty patients were identified. Median age was 54 (37–65) years. Average operative time was 227.63 (± 100.21) min. Median time from implantation to removal was 41 (11–96) months. Removal reasons included device malfunction (7 patients, 23.3%), pain at the neuroregulator site (5 patients, 16.7%), retrosternal or epigastric pain (11 patients, 36.7%), weight regain or dissatisfaction with weight loss (15 patients, 50%), and severe nausea (2 patients, 6.7%). Two patients (6.7%) had Clavien–Dindo grade II complications following explantation. Thirteen patients (43.3%) had dense adhesions noted at the time of operation. Seroma formation at the neuroregulator site was the most common complication (7 patients, 23.3%).

Conclusion The vagal nerve blocking device can be safely removed laparoscopically with a low 30-day complication rate. Surgeons should be familiar with the details of the device appearance, the typical lead location, and should anticipate dense adhesions surrounding the leads. In addition, experience operating in the region of the gastroesophageal junction is imperative.

Keywords Vagal blocking device · Bariatric surgery · vBloc

Obesity is a growing healthcare epidemic. Many different treatment approaches, both surgical and medical, have been extensively studied to assist patients with durable weight loss [1, 2]. The vagal blocking device has shown promise as a surgical method for weight loss without altering anatomy. In theory, blocking vagal impulses increase the feeling of satiety, diminishing overeating [2–4]. The EMPOWER trial was the first randomized controlled trial of a vagal nerve blocking device, establishing the safety of device placement, although with disappointing weight loss results [5]. However, the ReCharge trial, a randomized controlled trial comparing the device to a sham device, did show weight loss for the vBloc device (ReShape Lifesciences, St. Paul, MN), with weight loss present at 2 years for moderately obese patients with an obesity-related comorbidity [6]. Given the results of this study, the FDA approved the device in 2015 for use in patients with BMI 40 to 45, or with BMI 35 to 39.9 with an obesity-related health condition.

A certain portion of patients will subsequently require device removal as some patients in the ReCharge study had their device explanted while on trial [6]. The purpose of

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this study is to report the clinical outcomes of vagal blocking device removal in a series of patients and describe our method for laparoscopic removal of the device.

Methods

After institutional review board approval, data were collected from consecutive patients that underwent vagal blocking device removal at a single tertiary care institution in a retrospective manner. Patients had previously signed informed consent to participate in the ReCharge or EMPOWER studies. The need for additional consent was waived for the current study. Reason for removal, BMI at time of implantation, BMI at time of explantation, and other concurrent planned operations were recorded. Operative time, estimated blood loss (EBL), length of stay, and surgical complications within 30 days of operation were also documented.

Description of the vagal blocking device

The vBloc device consists of several components. The implantable neuroregulator is 5.5 × 5.5 cm in size and is implanted in the subcutaneous tissues of the left upper quadrant of the abdomen. There are two leads that attach to the neuroregulator device and are attached to the anterior and posterior vagal trunks at the hiatus. These vagal trunk leads are first sutured to the anterior wall of the stomach by suture wings to ensure proper lead location without torsion or tension (Fig. 3). At their distal extent are cuffs which are placed around the anterior and posterior vagal nerves and secured to the wall of the esophagus via small hole in a small tab at the very tip of the cuff. The proximal end of the leads are then brought through the fascia to connect to the neuroregulator [7]. The device and its elements are shown in Fig. 1.

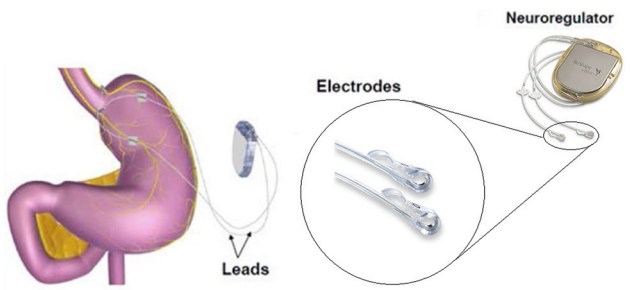

Fig. 1 vBloc system. Leads are affixed to the stomach with suture wings. The electrodes in the cuffs are secured around the vagal trunks. The neuroregulator is placed in a subcutaneous pocket above the fascia in the left upper abdomen. Reproduced with permission [13]

Description of device explantation procedure

The patient is positioned supine with both arms out and feet together with a footboard in place. The operating surgeon stands on the patient's right side and the assistant stands on the patient's left side. Ports are placed as demonstrated in Fig. 2, and the patient is placed in steep reverse Trendelenberg.

While in most cases, the anterior and posterior leads are easily identified traveling towards the hiatus (Fig. 3), there are often adhesions from the left lobe of the liver to the anterior surface of the stomach which can incorporate and obscure the leads. Significant adhesions are also often encountered at the esophageal hiatus, and should be carefully taken down with a combination of sharp and electrocautery dissection. At the index operation, each lead would have been affixed to the anterior wall of the stomach or sometimes to the lesser curve to prevent torsion and tension of the lead by a suture wing with two sutures in each

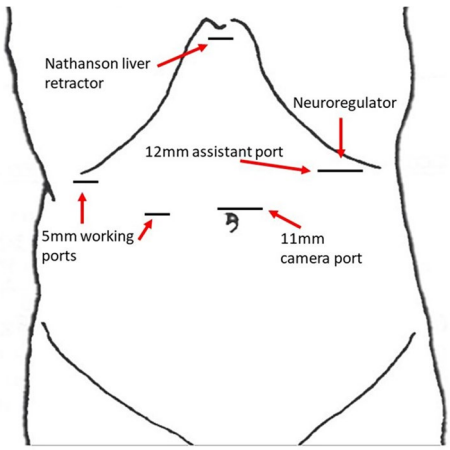

Fig. 2 Typical port placement for laparoscopic vagal blocking device removal

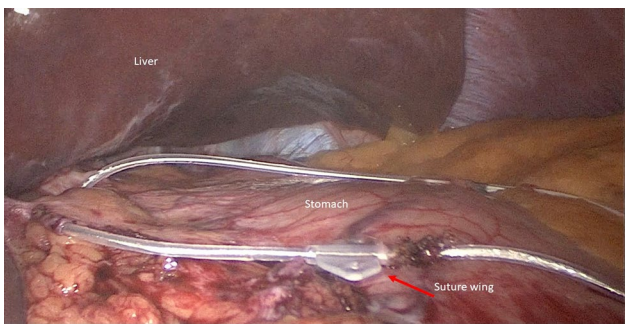

Fig. 3 Device leads coursing towards the hiatus. The suture wings are secured to the stomach with two stitches. The cuffs are covered by adhesions at the hiatus

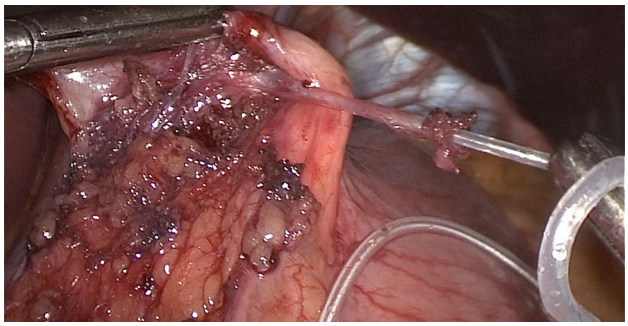

Fig. 4 Dense adhesions surrounding the cuff

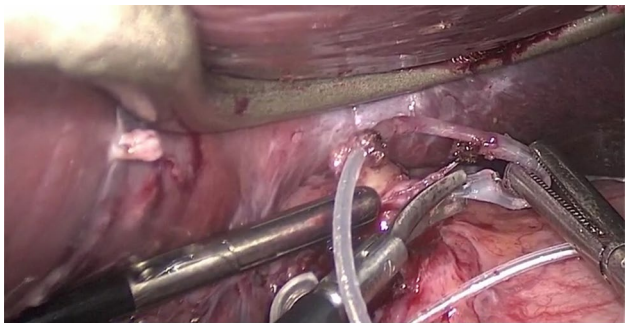

Fig. 5 The tab through which the stitch which was placed securing the cuff in place around the anterior vagal trunk is cut

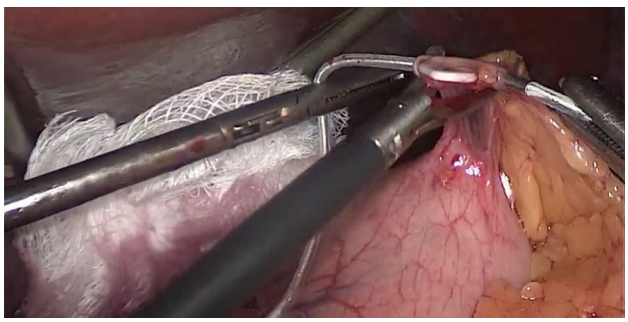

Fig. 6 Removal of the suture wings. Adhesions and the stitch securing the wing to the stomach are divided sharply

wing. During device removal, these sutures should be cut and the suture wings freed from the tissues (Fig. 6). Once a lead has been freed from the stomach and liver, following it to its most distal extent, the cuff will become apparent at its contact point with the corresponding branch of the vagus nerve. The density of adhesions often increases as one nears the gastroesophageal junction (Fig. 4). Great care must be taken to avoid injury to the stomach and esophagus during this portion of the procedure. Cautery may be used on the anterior surface of the lead, although any adhesiolysis done near the esophagus should be performed with sharp dissection. Once the cuff has been released from the tissues, the stitch securing the tip of the cuff can be cut with scissors (Fig. 5). The leads are then divided just below the abdominal wall fascia and are removed through the 12 mm assistant port. If there is any concern for possible injury to the stomach or esophagus, an endoscopic assessment is performed at this time, and, if detected, any injuries should be repaired. At this point, a planned concurrent bariatric procedure may be performed assuming lead explantation was uneventful.

Following lead extraction, the neuroregulator is removed. This is done by extending the 12-mm assistant port incision at the prior implantation site scar. The remaining proximal portion of the intraabdominal leads are easily pulled through the fascia and removed while still attached to the neuroregulator. The device pocket incision is then closed in multiple layers.

Table 1 Patient characteristics (n = 30)

Female gender	30 (100%)
Median age (years)	54 (37–65)
BMI at initial implantation[a]	42.8 ± 2.9
BMI at explantation[a]	43.0 ± 5.0
Median time from implantation to explantation (months)	41.0 (11.3–95.9)

[a]Mean with standard deviation reported and median with range reported

Results

Thirty patients underwent laparoscopic device removal at our institution during the study period. All were female with a median age of 54 (37–65) years. The median time from initial implantation to explantation was 41 months (11.3–95.9 months). Patient characteristics are reported in Table 1.

The most common reason for device explantation was unsatisfactory weight loss (15 patients, 50%). The next most common reason was retrosternal or epigastric pain with device use (11 patients, 36.7%). Seven patients (23.3%) had a device malfunction including inability to charge the device, and lead breakage. The remaining patient-reported reasons for explantation are recorded in Table 2.

Operative details and surgical complications are noted in Table 3. The median operative time for all device explantations was 210 min (101–498 min). Median operative time for patients undergoing concurrent procedures was 302 min (182–498), while those who did not have a concurrent procedure had a median operative time of 195 min (182–399). Median estimated blood loss (EBL) was 25 mL (5–200 mL) for those without a concurrent procedure and 25 mL (5–75 mL) for those that did have a concurrent procedure. Median length of stay was 1 day

Table 2 Reported reasons for device removals

Weight loss satisfaction	1 (3.3%)
Device malfunction	7 (23.3%)
Neuroregulator device discomfort	5 (16.7%)
Retrosternal or epigastric pain	11 (36.7%)
Unsatisfactory sustained weight loss	15 (50.0%)
Nausea	2 (6.7%)

Patients were able to provide more than one reason for removal

Table 3 Operative characteristics and complications (n = 30)

Operative time (min)[a]	195 (101–399)
Estimated blood loss (mL)[a]	25 (0–200)
Length of stay (days)[a]	1 (0–4)
Esophagogastroduodenoscopy performed	9 (30%)
Concurrent bariatric procedure performed	7 (23.3%)
Dense adhesions noted	13 (43.3%)
Clavien–Dindo grade II complications	2 (6.7%)
Neuroregulator site seroma	7 (23.3%)

[a]Median with ranges reported

(0–4 days) after surgery. Eleven patients (36.7%) were discharged on post-operative day 0 with the majority of patients (53.3%) discharging on post-operative day 1. Dense adhesions were specifically noted in 13 patients (43.3%). In one patient, a planned concurrent sleeve gastrectomy was aborted due to dense adhesions. Nine patients (30%) had esophagogastroduodenoscopy at the time of surgery due to concern for injury, finding no injury or leaks. In one patient, the posterior lead was noted to have eroded into the proximal stomach requiring primary laparoscopic repair of the gastrotomy. This patient and two others (10%) underwent post-operative esophagram to evaluate for leak which were negative in all cases.

Seven patients (23%) had concurrent procedures during explantation of the vagal blocking device. Four of these patients had conversions to other bariatric surgical procedures: 3 patients underwent Roux-en-Y gastric bypass, and 1 had sleeve gastrectomy. There were no post-operative complications associated with these procedures. The decision to proceed with another bariatric procedure at the time of surgery was made by the attending surgeon. Only one patient was unable to undergo a planned concurrent sleeve gastrectomy, due to dense adhesions and concern for possible intraoperative vagal nerve injury. However, postoperatively, the patient did well, and was able to undergo the desired sleeve gastrectomy 2 weeks later. One additional patient underwent a Roux-en-y gastric bypass 3.6 years after the explantation procedure. No other patients had subsequent bariatric procedures at the time of this review.

There were 13 total complications (43.3%), with two classified as Clavien–Dindo grade II (6.7%). Minor complications included neuroregulator site seroma (7 patients, 23.3%), persistent post-operative nausea (1 patient, 3.3%), post-operative pain (1 patient, 3.3%), contact dermatitis due to surgical glue (1 patient, 3.3%), and reflux-like symptoms (1 patient, 3.3%). The two Clavien–Dindo grade II complications were a port site infection treated with antibiotics, and an intraabdominal abscess which was managed with antibiotics and percutaneous drainage.

Discussion

Bariatric surgery has been shown to improve weight loss, diabetes control, and overall survival in obese patients [8, 9]. Multiple surgical techniques have been developed to combat obesity, most of which modify the patient's anatomy permanently, as with a Roux-en-y gastric bypass or sleeve gastrectomy. However, some patients prefer options that do not alter anatomy [2]. The vBloc vagal blocking device remains an option in the bariatric surgery armamentarium without permanent alteration of anatomy.

Although the exact mechanism of action of vagal nerve blockade for weight loss is unknown, rodent studies blocking vagal impulses showed increased satiety without a decrease in hunger [3]. Increased gene expression of proteins like leptin, interleukin-1β and tumor necrosis factor, among others, have been seen in response to vagal nerve stimulation suggesting the mechanism of action is through increased satiety via vagal nerve signaling [3]. The EMPOWER trial device required the patient to wear an external charging belt daily, while the ReCharge trial device was fully implantable [5, 10]. Although the EMPOWER trial did not show greater weight loss in the patients with the active device compared to controls [5], the subsequent ReCharge trial did show significant weight loss in the experimental group, with 26% excess weight loss at 12 months [10], and 21% excess weight loss at 24 months [6].

Any implantable device has a certain incidence of the need for explantation. Half of the patients in this series listed weight regain as a reason for device explantation. The second most common reason for explantation was reflux-like symptoms. This was also a common adverse reaction reported in the ReCharge trial, with 47 events reported, although 60% of dyspepsia events eventually resolved [6, 10, 11]. The etiology behind the increased reflux-like symptoms remains unclear but is suspected to be secondary to the electrical current running through the two vagal trunks.

Other common reasons for explantation were device malfunction and neuroregulator site pain. Although the neuroregulator can be replaced or revised with a relatively straightforward extraperitoneal procedure, replacement of

the leads requires a general anesthetic and laparoscopic approach. If one or both of the leads need to be replaced, this may be done using our technique described above. The incidence of device malfunction and neuroregulator site pain were noted in the ReCharge trial [12], with 9 revisions in 8 participants within the first year of the study [12] and 4 additional revisions in 76 patients in the second year of the study. Only one patient required lead replacement due to device malfunction [6].

There were two Clavien–Dindo complications grade II or higher after explantation, both infectious in nature. Superficial surgical site infections are relatively uncommon in laparoscopic surgery, although were reported in the EMPOWER trial [5], and can often be treated with wound care. Our patient with an intraabdominal abscess was found to have a device lead cuff that had eroded into the stomach at the gastroesophageal junction. This gastrotomy was repaired primarily, but her recovery was complicated by an intraabdominal abscess which was managed with percutaneous drainage and intravenous antibiotics. An esophagram failed to reveal a leak to account for the abscess. Over 40% of our patients were found to have dense adhesions associated with the device noted at the time of surgery which may increase the risk of damage to surrounding structures during dissection. Because of this, explantation of the vBloc device is a technically challenging procedure; however, this study shows it can be performed safely with few complications. It is essential that surgeons comfortable operating at the esophageal hiatus are familiar with the details and location of the device to ensure its safe removal.

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Compliance with ethical standards

Disclosures Dr. Bruce Wolfe was a site investigator for the EMPOWER and ReCharge trials for ReShape Lifesciences. He received no financial remuneration for his role in the studies. Dr. Erin Gilbert was a co-investigator for the ReCharge trial for ReShape Lifesciences and received no financial remuneration for her role in the study. Drs. Worrest and Mattar have no conflicts of interest or financial ties to disclose.

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