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TECHNICAL INNOVATION

Micro-orifice Metabolic/Bariatric Surgery Under IV Sedation/Local Anesthesia

Porcine Feasibility Study

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Abstract
Background As the volume and scope of metabolic/bariatric surgery increases, there is a definite trend toward the development and utilization of simpler and safer procedures. The laparoscopic approach has certain disadvantages that can be avoided by a technique for abdominal access via a micro-orifice incision under intravenous (IV) sedation/local anesthesia, without general anesthesia, insufflation, and intubation.
Methods In a porcine model, we used the implantation of the TANTALUS™ System as a prototype for the micro-orifice, IV sedation/local anesthesia approach. The study was conducted in five ex vivo stomachs, four cadavers, and six in vivo animals, the last four of which underwent surgery under IV sedation/local anesthesia.
Results Accurate implantation of electrodes was achieved in all ex vivo, cadaver, and in vivo preparations with no mucosal penetration, confirmed by examination of the open porcine stomachs. Operative time in this learning setting was 1 h 43 min in the last three operated animals. Feasibility was established for using the single incision to tunnel and construct subcutaneous pockets for the pulse generator and the charge coil. No major operative or postoperative complications occurred.
Conclusions Using the TANTALUS™ System as a metabolic/bariatric surgery prototype model, this study successfully tested the feasibility of micro-orifice surgery, under IV sedation/local anesthesia. This study will be followed by human trials that may offer an alternative approach for the performance of metabolic/bariatric surgery.

Keywords Micro-orifice · IV sedation/local anesthesia · Metabolic/bariatric surgery

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Introduction

An evolution of technical approaches and instrumentation has paralleled the geometric increase of metabolic/bariatric surgery. As for all surgery, the first operative access was open surgery—a single incision of various lengths and varying location. All metabolic/bariatric operations were initiated by open technique. The first principle for the introduction of the laparoscopic approach was to replicate the results, and, above all, the safety, of the open approach. With time, laparoscopic technique became dominant and, in the proper hands, as safe and effective as open surgery.

There is a single limiting factor for all the laparoscopic operative approaches—the need for abdominal cavity insufflation to achieve visualization and, to achieve this, the need for general anesthesia and airway intubation. Can visualization be achieved without insufflation? Can metabolic/bariatric surgery be performed via micro-orifice (open) access under intravenous (IV) sedation/local anesthesia without general anesthesia, abdominal insufflation, and endotracheal intubation? We believe that it can. We have demonstrated the feasibility of this approach in a porcine animal model with the implantation of the TANTALUS™ System.

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The TANTALUS™ System, developed by MetaCure, Ltd (Bermuda) currently consists of three sets of gastric wall leads, each consisting of two bipolar electrodes, a subcutaneous implantable pulse generator (IPG) and a separate charge coil, an external charger, and an external programmer [1]. The fundic lead electro-mechanically senses the onset of eating, as do the antral leads; they subsequently initiate electrical stimulation of the stomach by the antral leads. The stimulation is delivered during the normal gastric contraction absolute refractory period and enhances the smooth muscle contractions without increasing the frequency of the contractions. In turn, through the stimulation of distal gastric stretch receptors, an increased afferent vagal input to the central nervous system is elicited [1, 2]. When the mechanism is activated at the beginning of a meal, early physiologic satiety is induced, limiting the amount of food intake.

Following laboratory and preclinical assessment [2–5], the TANTALUS™ System was successfully implanted laparoscopically [6–8], and its mechanism of action was subjected to analysis [9]. In the human, the system induced moderate weight loss and a significant reduction in the percent of hemoglobin A1c [8]. Currently, there are three randomized clinical trials of the TANTALUS™ System in progress, which will eventually involve over 100 patients, to test weight and type 2 diabetes control efficacy, as well as to measure the induced fluctuations in gut hormone levels, insulin sensitivity, and beta cell function.

Methods

Animals

Ex Vivo

Five excised porcine stomachs from Yorkshire pigs were used.

Cadavers

Four Yorkshire pigs, approximately 24 kg each, were used.

In Vivo

Six pigs, 31, 71, 72, 74, 74, and 75 kg each, were used.

Experimental Protocol

Ex Vivo

The three members of the surgical team practiced electrode implantation on the five excised porcine stomachs; subsequently, lead position and mucosal penetration were ascertained.

Cadavers

The three members of the surgical team practiced electrode implantation on the four 24-kg cadaver pigs; subsequently lead position and mucosal penetration were ascertained on necropsy.

In Vivo

This study was evaluated and approved by the University of Minnesota Institutional Animal Care and Use Committee (IACUC).

Six healthy Yorkshire adult pigs were acclimated for a minimum of 3 days in research animal resources housing before the study. On the day of the study, the animals were kept NPO for an 8-h period, individually identified, and premedicated with Telazol (6 mg/kg) intramuscularly. This allowed for the placement of a peripheral intravenous line in an ear vein. The animals were moved to the animal operating room and monitored by continuous electrocardiography, pulse oximetry, end tidal CO_2 volume ($ETCO_2$) monitoring, and intermittent noninvasive blood pressure determinations.

The first two procedures were performed under general anesthesia. The first animal underwent implantation of the three leads, with no implantation of the IPG and the charge coil, and was sacrificed immediately after surgery. The second animal underwent implantation of the gastric leads, with implantation of the IPG and the charge coil, and was maintained for follow-up assessment. The final four animals underwent IV sedation/local anesthesia, had gastric leads, IPG, and charge coil implantation, and were maintained for follow-up (see Table 1).

Follow-up consisted of 17 to 18 days to observe the healing process, feeding, activity, and animal weight, as well as verification of the capacity of the devices to perform by charging and interrogation. The device therapy was not activated during follow-up, and therefore, no impact on the animals' normal weight gain was expected. Each long-term animal was placed in an abdominal compression wrapping to reduce seroma formation and promote fluid reabsorption from the IPG and charge coil subcutaneous pockets.

Operative Procedure

Access

Abdominal access was obtained by a 6.0- to 7.5-cm midline incision, approximately 6 cm below the xiphoid (Fig. 1).

Table 1 Assessment of in vivo implantations

	Animal ID					
	MWMP 01	MWMP 07	MWMP 08	MWMP 09	MWMP 10	MWMP 11
Anesthesia type	General	General	IV sedation/local	IV sedation/local	IV sedation/local	IV sedation/local
Operating time (h/min)	1:25	2:25	2:10	1:41	1:48	1:40
Observations	Single epigastric incision, multiple peri-incisional pocket sites exploration, acute, no wound closure	Single epigastric incision plus 2 lateral incisions for the IPG and charge coil	Single epigastric incision, L-shape pockets	Single epigastric incision, L-shape pockets	Single epigastric incision, L-shape pockets	Single epigastric incision, L-shape pockets
Operative complications	None	None	Temporary IV line kinking and animal movement	None	None	None
General accuracy of lead implantations	Yes	Yes	Yes	Yes	Yes	Yes
Lead migration	–	No	No	No	No	No
Animal weight (kg)						
At surgery	31	73	74	74	75	72
At end of study	31	90	91	91	88	84

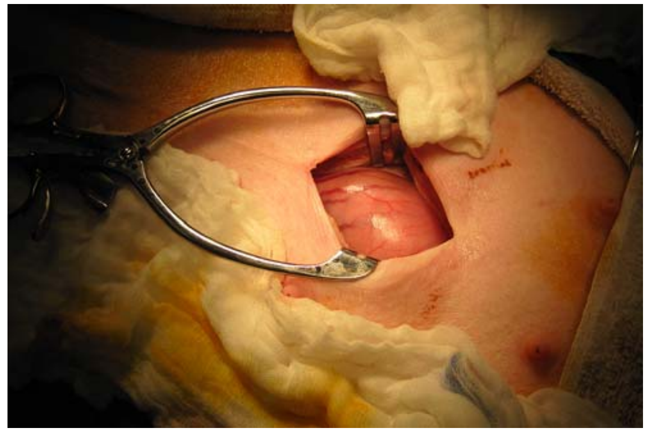

Fig. 1 Mini-laparotomy access site for surgery

Lead Implantation

Once entry into the abdominal cavity was obtained, the fundus of the stomach, the site for the implantation of the fundic electrodes, moved into the field by gentle downward retraction of the stomach using alternating non-crushing clamps. After implantation of the fundic electrodes, the anterior antral electrodes were implanted with the appropriate area isolated and brought into the operative field by again using non-crushing clamps to obtain the appropriate gastric wall exposure. To achieve the mirror-image implantation of the posterior antral electrodes, entrance was gained into the lesser sac by taking down the greater curvature omental attachments and rotating the stomach with non-crushing clamps from left to right to expose the posterior antrum. Appropriate lead implantation sites are diagrammed in Fig. 2.

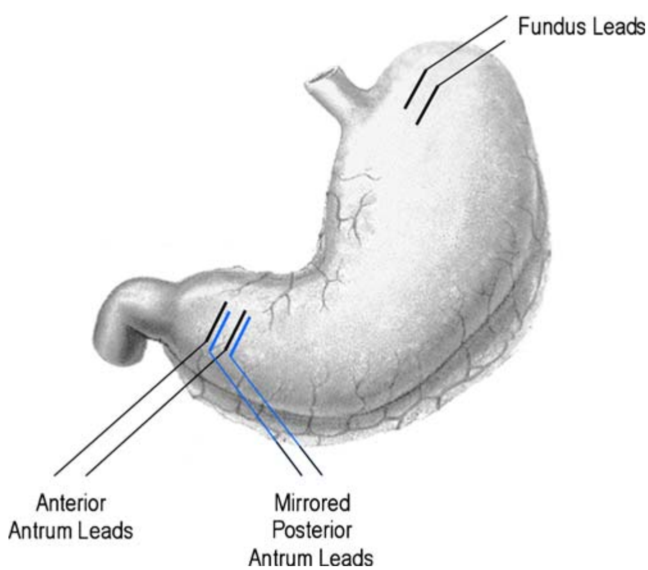

Fig. 2 Lead implantation sites

IPG and Charge Coil Implantation

After some trials, it was elected to tunnel from the midline incision subcutaneously toward the left rib cage and construct, by blunt and sharp dissections, a superior pocket for the charge coil over the lower left anterior rib cage and an inferior pocket for the IPG. The charge coil was telescoped into place via two fascial anchoring sutures. The IPG was not suture-secured but snugly fitted into its pocket location.

Anesthesia

General Anesthesia

In two animals, general anesthesia was induced by spontaneous breathing with isoflurane by facemask, subsequent to which the animals were intubated orally with a #6.5 mm endotracheal tube after the larynx, and trachea were sprayed with 4 ml of 4% xylocaine. Anesthesia in these pigs was maintained with isoflurane 1.5% to 2%, using controlled ventilation to an $ETCO_2$ of between 35 and 38 mmHg. In the one general anesthesia animal maintained for follow-up, the animal was weaned off from the isoflurane, awakened, and extubated when cough reflexes returned. All animals received maintenance crystalloid infusion in the form of normal saline throughout the operation. Once the surgery was completed, the drug infusions were stopped, and the animals were allowed to become alert. The animals received ketoprofen (2 mg/kg intramuscularly) for post-operative analgesia.

IV Sedation/Local Anesthesia

In four animals, total intravenous anesthesia was employed. The animals received glycopyrrolate 0.2 mg IV for the control of secretions and droperidol 5 mg IV for prophylaxis against nausea and vomiting. Sedation was assured by the continuous infusion of a mixture of ketamine plus propofol (800 mg ketamine added to 100 ml propofol) infusion at a rate of 14 to 20 ml/h, adjusted to ensure the presence of spontaneous breathing with minimal movement. The pigs also received dexmedetomidine in a loading dose of 1 μg/kg given over 10 min followed by an infusion of 0.5 μg/kg/h. This combination of drugs, without the use of narcotics, assured the presence of analgesia, spontaneous breathing, and no nausea. In addition, 2% lidocaine with epinephrine along with 0.5% bupivacaine solution was used for local anesthesia, subcutaneously and in the fascia, prior to the start of the procedure, and throughout the procedure as indicated; in particular, local anesthesia was used in the construction of the separate pockets for the IPG and the charge coil. All animals received maintenance crystalloid infusion in the form of normal saline throughout the operation. Once the surgery was completed, the drug infusions were stopped, and the animals were allowed to become alert. These pigs also received ketoprofen (2 mg/kg intramuscularly) for postoperative analgesia.

Results

Ex Vivo

Accurate implantation of electrodes by the three surgeons was achieved in the five porcine stomachs with no mucosal penetration, confirmed by examination of the open porcine stomachs. The learning curve was extremely brief.

Cadavers

Accurate implantation of electrodes by the three surgeons was achieved with no mucosal penetration, confirmed by excision and opening of the porcine stomachs. There were no failures in the four porcine stomachs.

In Vivo

The 31-kg animal having an implantation of leads under general anesthesia and subsequently sacrificed was also used to study IPG and charge coil implantation sites. On necropsy, the leads showed accurate subserosal placement with no mucosal penetration.

The five large animals all demonstrated successful abdominal entry and performance of the Tantalus™ System implantation via a single, 6.0 to 7.5 cm, midline incision, approximately 6 cm below the xiphoid. Successful surgery was performed in each animal with standard open surgery instruments, exposure, and lighting. Operating time in this learning setting was a mean of 1 h 43 min in the last three animals operated upon (Table 1).

Except for the single episode of a loss of IV infusion (see below), all animals which underwent IV sedation/local anesthesia, maintained comfortable analgesia and normal physiologic parameters as demonstrated by continuous pulse rate, electrocardiogram, and pulse oximetry monitoring, intermittent noninvasive blood pressure determinations, and respiratory rate observations with IV sedation anesthesia flow rate adjusted to maintain an $ETCO_2$ between 35 and 38 mmHg.

In all five animals, successful subserosal insertion of electrodes was achieved with no mucosal penetration ascertained on necropsy at the end of the follow-up period. In all animals, the anterior and posterior antral leads were accurately placed with respect to the paired electrodes being parallel, about 2 cm apart, and the appropriate distance from the pylorus (Fig. 3). For the fundic implantations, the paired electrodes were accurately placed with respect to each other, parallel and about 2 cm apart, and in three of the five animals they were placed at the appropriate distance from the esophagus and at the designated body–fundus junction of the stomach (Fig. 2). In two of the pigs, the fundic electrodes were somewhat more cranial than the body–fundus junction. At follow-up necropsy, there was no lead migration, the clips on the lead thread were in place, and the securing sutures, at the proximal end of the electrodes, were firmly in place.

Feasibility and preferability was established for using the single midline incision to tunnel to the left of the midline to perform the reverse L-shaped (⌋) extension for the separate IPG and charge coil pockets.

The pigs that received IV sedation recovered faster from anesthesia when compared to the animals that received general anesthesia.

No major operative or postoperative complication occurred. There were no deaths prior to scheduled animal sacrifice and necropsy. During the first IV sedation/local anesthesia procedure, the single IV line was inadvertently kinked over a short time interval, resulting in a temporary and momentary loss of sedation levels and animal movement. Two pigs developed significant seroma formations in their IPG or charge coil pockets despite the compression wrapping; reabsorption occurred without intervention.

Discussion

Metabolic/bariatric surgery is gaining a prominent therapeutic role in meeting the global challenge of obesity and certain metabolic diseases demonstrably associated with obesity (e.g., type 2 diabetes, hypertension, and hyperlipidemia), as well as the functional and mechanical diseases associated with obesity (e.g., obstructive sleep apnea, GERD, and back and lower extremities joint pathology). As the volume of metabolic/bariatric surgery increases, there is a definite trend toward the development and utilization of simpler and safer procedures.

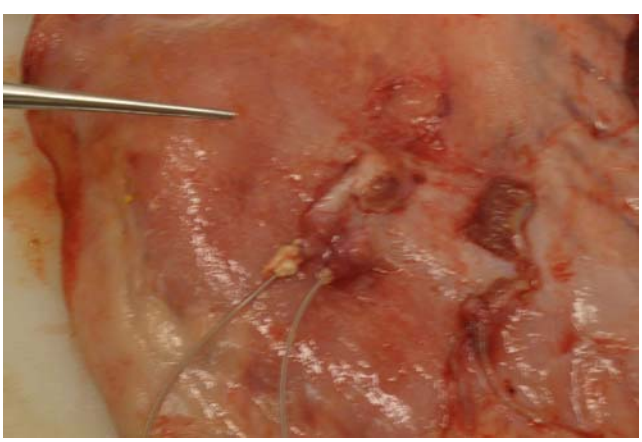

Fig. 3 Anterior antral lead placement

This porcine feasibility was not a study of the efficacy of the TANTALUS™ System; the system was not activated during the follow-up period in the five animals observed post-operatively for 17 to 18 days. The electrode implantation system was used as a prototype for assessing the concept of micro-orifice metabolic bariatric surgery under IV sedation/local anesthesia, without general anesthesia, insufflation, and intubation.

Though laparoscopic surgical feasibility is readily available in the USA and in many other nations, in vast areas of the globe (e.g., rural India and rural Brazil) where metabolic/bariatric surgery is needed, it is being practiced by open technique. At this time, it is highly unlikely that laparoscopic technology will penetrate this expanse of metabolic/bariatric surgery practice. On the other hand, if metabolic/bariatric surgery becomes feasible via a micro-orifice, open, approach under IV sedation/local ("twilight") anesthesia, without general anesthesia, abdominal insufflation, and intubation, it is readily more conceivable that this micro-orifice approach will become a valuable access for many metabolic/bariatric operations, even where general anesthesia laparoscopy is available.

Standard laparoscopic bariatric surgery in addition to its many advantages also has certain disadvantages: carbon dioxide absorption with hypercarbia, hypercapnea, and the potential for respiratory acidosis; increased intra-abdominal pressure effects on body organs, e.g., heart, lungs, and kidneys; and a greater incidence of leaks, anastomotic ulcers, and internal hernias than experienced via open surgery [10].

The micro-orifice approach, under IV sedation/local anesthesia, has the following advantages: elimination of the risks of general anesthesia, absence of the above cited potential complications of abdominal cavity insufflation, and the tissue damage associated with endotracheal intubation, as well as the minimal physiologic trauma of a small single incision, minimal postoperative pain and discomfort, cosmetic appeal in comparison to five to six port sites, and the psychologic appeal for the patient of not having to undergo general anesthesia but still experiencing freedom from pain during surgery and amnesia of the procedure thereafter.

Further, this postulated technique may decrease operative risk, facilitate 1-day, outpatient surgery, enhance the utilization of free-standing bariatric surgery clinics, decrease costs (making surgery affordable for those individuals with minimal or no obtainable insurance coverage), possibly increase insurance company coverage due to simplicity and safety, increase public acceptance, increase government acceptance, increase patient access, increase the number of bariatric surgeons, and optimize care for the bariatric patient. By virtue of the advantages listed, this approach may facilitate the ability of physician/surgeons to more successfully keep their compact to care for the metabolic/bariatric patient during this global obesity crisis.

This feasibility study has demonstrated that implantation of the TANTALUS™ System, as a prototype model, can be accomplished in the porcine model via a single, open surgery, micro-orifice incision, and that this surgery can be performed with IV sedation/local anesthesia, without general anesthesia, abdominal insufflation, and endotracheal intubation. The human trials to follow this study may offer an alternative option for the performance of metabolic/bariatric surgery.

Disclosure Dr. Buchwald is a consultant for MetaCure, Ltd., Ethicon Endo-Surgery (Johnson & Johnson), and Fulfillium, Inc.

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