

# The First Report on Hybrid NOTES Adjustable Gastric Banding in Human

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Published online: 31 March 2010  
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## Abstract

**Background** Despite their current limitations, metabolic surgery and natural orifice transluminal endoscopic surgery (NOTES), set new horizons. In this article, the first three cases of adjustable gastric banding (AGB) through transvaginal access in obese women are described.

**Methods** In the General and Vascular Surgery Department, Ceynowa Hospital, Poland, three cases of AGB through the transvaginal access in hybrid, laparoscopically assisted NOTES technique were performed. All patients were female with BMI range 35–37. A dual-channel endoscope and regular laparoscopic instruments were used.

**Results** The mean operating time was 110 min. Indometacin was given intravenously PRN for postoperative pain. None of the patients required more than 3 g of indometacin and for longer than 24 h postoperatively. None required opioids either. There was one major complication of iatrogenic damage to the ureter, which required subsequent hospitalisation and laparoscopic repair. Hospitalisation time was 2 days. During 2 months follow up, the mean weight loss was 15 kg. There were no malpositions of the band. There was no early mortality in the study group.

**Conclusion** Feasibility of the proposed hybrid laparoscopically assisted NOTES adjustable gastric banding was proved. It is a technically demanding procedure, requiring appropriate endoscopic and laparoscopic skills. To avoid ureteric damage one should acquire safe colpotomy skills before commencing transvaginal NOTES operations.

**Keywords** Transvaginal adjustable gastric banding · Obesity surgery · Natural orifice transluminal endoscopic surgery · NOTES · Adjustable gastric banding · AGB · Transvaginal NOTES · Minimally invasive surgery

## Introduction

Since Kallo described the idea of natural orifice transluminal endoscopic surgery (NOTES) in 2004, it yields new proponents [1]. One of the main benefits is minimisation of operative trauma. Despite technical difficulties, NOTES starts to be perceived by surgeons and patients as a logical next step in the evolution of minimal invasive surgery and probably, as a beginning of a post-laparoscopic era. There have been several hundred NOTES operations performed worldwide till June 2009, and this number increases rapidly. Our knowledge and experience in NOTES surgery grow even faster.

The very first article regarding bariatric NOTES operation in human was published in October 2008 [2]. Ramos et al. from San Paulo, Brazil, presented experience with transvaginal sleeve gastrectomy [2]. He was followed by S. Horgan (San Diego, USA) [3], J. Marescaux (Strasbourg, France) [4] and A. Lacy (Barcelona, Spain) [5].

In this article, the first published experience with transvaginal placement of an adjustable gastric band in three female patients is described.

## Materials and Methods

In the General and Vascular Surgery Department, Ceynowa Hospital, Wejherowo, Poland, three operations of placement of an adjustable gastric band through the transvaginal

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access were performed in April 2009. There were strict patients' selection criteria. Age ranged between 29 and 52 years. All patients were relatively 'slim' regarding bariatric surgery with a mean BMI of 36 kg/m<sup>2</sup> (range of 35–37 kg/m<sup>2</sup>). Two patients had a minor comorbidity of arterial hypertension. None had previous abdominal operations. One underwent thyroidectomy for nontoxic goitre. Patients' characteristics are summarized in Table 1.

## Technique

Operations were performed with patients in a gynaecological position. On the induction to general anaesthesia, all patients received 1.2 g Amoxicillin with Clavulonic Acid i.v., as per local protocol for preoperative antibiotic prophylaxis. Pneumoperitoneum of 12–14 mm Hg was achieved with Veress needle, inserted in the left hypochondriac area. The Veress needle insertion spot was later used to place a 15-mm trocar and at the end of procedure as a location for the gastric band's port. An additional 5-mm trocar was inserted in the umbilicus. Through the umbilical trocar, a laparoscopic camera was inserted for better control of colpotomy. The incision was made in the posterior vaginal fornix, and the flexible, dual-channel endoscope GIF-Q 165, Olympus, was inserted directly through the incision, without trocars' use.

At this stage, patient was moved to reverse Trendelenburg's position. This manoeuvre's additional benefit was perfect sealing of air leaks by viscera dislocated to the pelvis minor. A 10-mm laparoscopic liver retractor was introduced through the 15-mm abdominal trocar and was used to visualise pars flaccida. The standard pars flaccida technique of adjustable gastric banding was used (Fig. 1a–c). Dissection of pars flaccida (Fig. 1a) was performed using endoscopic HookKnife KD-620LR (Olympus) and endoscopic grasping forceps FG-47L-L (Olympus) introduced through the endoscope's working channels. When the left diaphragmatic crus was identified, preparation of the space behind the stomach's cardia towards the angle of Hiss was performed. At this stage, Swedish Adjustable Gastric Band™ was inserted through the 15-mm abdominal port

into the abdominal cavity. In two cases, the endoscope has been passed behind the stomach, through pars flaccida to angle of Hiss to enable catching the band with endoscopic grasping forceps FG-47L-L (Olympus) and positioning it in the right place (Fig. 1b). In one case this manoeuvre was not possible, therefore the 5-mm laparoscopic manipulator Goldfinger®, Ethicon Endo-Surgery, was introduced through the 15-mm abdominal port and was used as in standard laparoscopic procedure. This stage of operation required a laparoscopic camera to provide better visualisation and control of instruments at least in the first performed cases. The band was closed with its 'quick-close' system by using endoscope's grasping forceps and one laparoscopic grasper (Fig. 1c). The band was not secured with stitches. The procedure was followed by band's placement control, abdominal cavity inspection performed with the endoscope, CO<sub>2</sub> desufflation and trocars retraction. The defect of the posterior vaginal fornix was fixed with interrupted sutures under visual control. The SAGB subcutaneous port was implanted in the left upper quadrant through the extended 15-mm trocar skin incision.

## Results

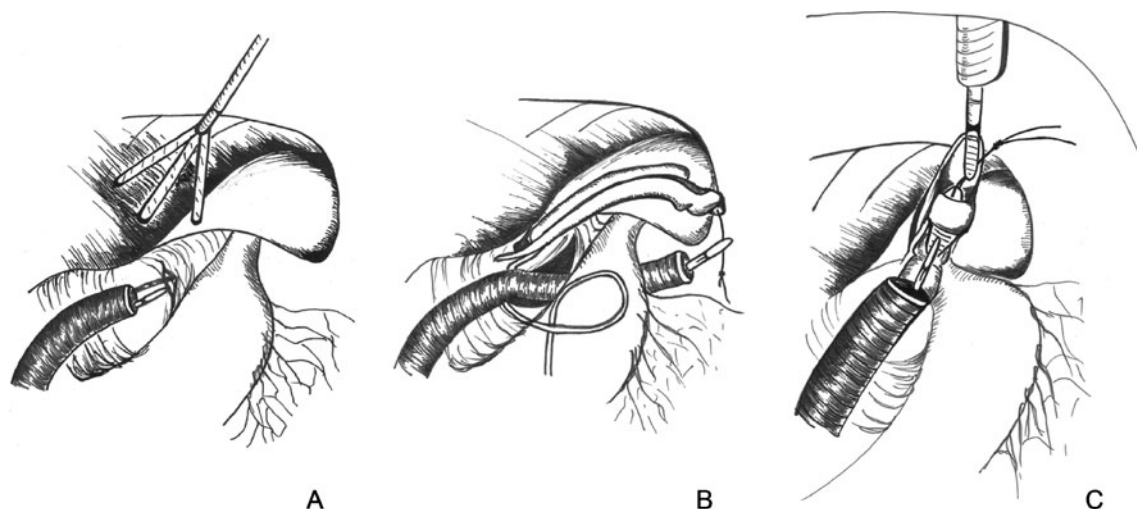
Mean operating time was 110 min. Indometacin was given intravenously PRN for postoperative pain. None of the patients required more than 3 g of indometacin and for longer than 24 h postoperatively. None required opioids either. All patients underwent gynaecological evaluation the day after the procedure. All patients were discharged home on the second postoperative day with standard recommendations as for laparoscopic SAGB implantation.

During 2 months follow up, the mean weight loss was 15 kg (14–16 kg). There were no malpositions of the band. On average, 3 ml of fluid was injected into each SAGB port for the best restrictive effect. There were no dysphagic symptoms.

One of the patients reported urinary incontinence on the discharge day. Gynaecology opinion was sought, and on gynaecology advice, patient was discharged home with ambulatory follow up. Right ureteric damage with uretero-vaginal fistula was diagnosed on the tenth postoperative day. Right ureter was damaged about 4 cm from its vesical ostium. Operation's video documentation was analysed to identify the ureteric damage that occurred during trans-vaginal insertion of the endoscope. Uretero-vaginal fistula was provisionally decompressed through the right nephrostomy. After the fistula healed, patient was readmitted, and the distal end of the ureter was laparoscopically implanted into the bladder by the urology team. Apart from this one, postoperative period till now was not complicated.

**Table 1** Patients' characteristics

	Mean value	1	2	3
Age (years)	39	52	35	29
Initial weight (kg)	106	89	112	117
Height (m)	1.71	1.60	1.74	1.78
BMI (kg/m <sup>2</sup> )	36	35	37	37
Time of operation (min)	110	145	105	80



**Fig. 1** a–c. Operative technique. **a** Dissection of pars flaccida of gastrohepatic ligament. **b** Endoscope passing behind the stomach, through pars flaccida to angle of Hiss to catch the band with endoscopic forceps. **c** Closing the band with endoscopic forceps and laparoscopic grasper

## Discussion

Natural orifice transluminal endoscopic surgery seems to be the logical next step in the minimal invasive surgery evolution. In most of the cases, it eliminates skin incision, which results in minimalisation of the body trauma and stress response. It does reduce the risk of infective wound complications as well as postoperative hernias. Finally the use of analgesics is reduced. NOTES shortens the postoperative recovery time and enables earlier return to occupational activity. Decarli et al. proved that the greatest beneficiaries of the advantage of NOTES are obese patients [6]. This group of patients has the highest risk of immunological deficiencies with comorbid diabetes, therefore with defected wound healing predisposing to wound infections and postoperative hernias. Decarli et al. noted a decreased number of complications with reduced analgesics' use in his transvaginal NOTES cholecystectomies group when compared to the laparoscopic group [6].

In this paper, authors prove the feasibility of the adjustable gastric band implantation procedure through the transvaginal access in NOTES technique. There has to be appropriate patients selection to make sure the procedure is safe. Operation can be done with a standard flexible dual-channel endoscope introduced through the vaginal fornix incision and long (bariatric) laparoscopic instruments. In these three cases, transvaginal access was used along two abdominal access points, one in the left epigastric region and one in the periumbilical area. Left epigastric region was chosen deliberately for the 15-mm incision and trocar. This incision was utilized for the 15-mm port for the liver retractor use and as the SAGB port implantation site later in the procedure. A 5-mm port in the periumbilical area was used to provide safety for the patient with initial experience

with the new operative technique through adding an extra source of intraoperative imaging. With greater experience, this additional port could well be excluded. The band was not secured with stitches as our experience shows that there are very few slippages when the appropriate technique is used. Initially, the average operating time of 110 min was above the average for laparoscopic SAGB implantation, nevertheless comparable with the first laparoscopic SAGB cases performed by the team, it shortened significantly with consecutive operations. The procedure itself was straightforward, although the insertion of flexible endoscope had the greatest burden of complications. Hence, an operating surgeon should acquire appropriate colpotomy and safe abdominal cavity entry skills [7].

The pain control was very good with no patients requiring more than 3 g of indometacin, for longer than 24 h postoperatively. None required opioids as in other published studies [8]. There were no wound complications noted. The average weight loss of 15 kg was satisfactory for a 2-month follow-up period.

Lack of the skin incision does not mean lack of complications. Experience with NOTES operations in our department proves that despite broad experience with laparoscopic surgery and operative endoscopy, each new technique brings new challenges and possible complications. Described cases were preceded by five transvaginal cholecystectomies and still the transvaginal access was associated with major complications of right ureteric damage that occurred in one in eight patients operated through this access. Most probably, when the learning curve comes to the plateau for the team, the complication rate would decidedly decrease as what happened in all previous laparoscopic procedures with improved outcomes compared to open surgery.

To our knowledge there were only few obesity operations performed through the transvaginal access in NOTES technique. All published papers describe transvaginal sleeve resection or gastric by-pass operations and proved the feasibility and safety of this operation [2–5, 9]. This is the first published report of three cases of transvaginal adjustable gastric banding in NOTES technique proving its feasibility, safety and benefits compared with laparoscopic procedure. Based on published reports and from personal experience, the authors believe that NOTES could play a crucial role in the future of bariatric surgery.

Finally, it is important to note that the search for the least invasive bariatric operation led surgeons not only towards NOTES, but also towards the laparoendoscopic single site surgery (LESS). Publications on those very promising techniques started to appear in 2008 [10–12]. Published LESS techniques are relatively straightforward and the cosmetic effect is very good. Nevertheless, both NOTES and LESS bariatric operations are at their development stage regarding the operative technique itself, as well as the required instruments. Proper evaluation and comparison of the end results of NOTES and LESS bariatric operations require further studies on a larger group of patients.

## Conclusions

Transvaginal adjustable gastric banding is technically feasible with several benefits when compared to laparoscopic banding. To avoid the most common access complications, the operating team should acquire appropriate colpotomy and safe abdominal cavity entry skills.

**Authors disclosure** All authors have no conflicts of interest or financial ties to disclose.

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