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MANOS: transvaginal cholecystectomies: preliminary report

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A B S T R A C T

Objective: To present the first transvaginal cholecystectomies performed in Cuba.

Methods: This is a study involving 7 female patients. The ages of the patients varied from 33 to 62 years of age, with an average age of 47.7. All of them had symptomatic cholelithiasis performed between March 11, 2008 and May 7, 2008. The operation performed in each case was a transvaginal cholecystectomy assisted with minilaparoscopy. Inclusion criteria: females between 18 and 65 years old; diagnosis of disease which requires cholecystectomy. The exclusion criteria included ASA III and IV, morbidly obese patients (BMI >35), venereal diseases, acute and chronic pelvic inflammatory diseases, virgins, and pregnant patients. The operations were performed by general surgeons using rigid laparoscopic instruments. Studied: operating room time, analgesia required, and post-operative complications. **Results:** The operating room time was between 61 and 86 min, with an average of 72.4 min. Patients required no analgesia during the post-operative period. They were discharged in less than 24 h following surgery. We found no complications in follow-up visits for up to one month after surgery.

Conclusions: Minilaparoscopic-assisted transvaginal cholecystectomy is a feasible and safe method for expert laparoscopic surgeons. This technique was, and could be, performed using rigid, currently available laparoscopic instruments. Minilaparoscopic-assisted natural orifice surgery (MANOS) could be an intermediate step between laparoscopic surgery and NOTES.

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MANOS: colecistectomías transvaginales. Reporte preliminar**R E S U M E N****Palabras clave:**

Colecistectomía transvaginal

MANOS

Minilaparoscopia

Culdolaparoscopia

Objetivo: Comunicar las primeras colecistectomías transvaginales realizadas en humanos en Cuba.

Métodos: Se realizó un estudio prospectivo, longitudinal y de intervención que incluyó a 7 pacientes portadoras de litiasis vesicular sintomática, desde el 11 de marzo al 7 de mayo de 2008, a las que se realizaron colecistectomías transvaginales asistidas por minilaparoscopia. Criterios de inclusión: mujeres con edades entre 18 y 65 años y diagnóstico de enfermedades que requieran colecistectomías. Los criterios de exclusión fueron Asa III y IV; obesidad mórbida (IMC > 35); portadoras de enfermedades venéreas; infecciones inecológicas asociadas agudas o crónicas; pacientes con procesos malignos; pacientes vírgenes y pacientes gestantes. Las intervenciones quirúrgicas fueron realizadas por cirujanos generales utilizando los mismos instrumentos rígidos empleados en la cirugía laparoscópica. Se estudiaron el tiempo quirúrgico, la necesidad de analgésicos en el postoperatorio y las complicaciones postoperatorias.

Resultados: Las edades de las pacientes fluctuaron entre 33 y 62 años, con una media de 47,7 años. El tiempo quirúrgico medio fue de 72,4 (61-86) min, y disminuyó con la práctica de la técnica. En el postoperatorio no hubo que administrar a ninguna de las pacientes analgésicos parenterales ni orales. El alta hospitalaria se dio antes de las 24 h del procedimiento y no se presentaron complicaciones postoperatorias luego de un seguimiento mínimo de 30 días.

Conclusiones: La colecistectomía transvaginal asistida por minilaparoscopia es un método factible y seguro que puede ser realizada por cirujanos generales con experiencia en la cirugía de mínima invasión, empleando los mismos instrumentos rígidos que se utilizan en la cirugía laparoscópica. La cirugía a través de orificios naturales asistida por minilaparoscopia (MANOS) puede ser un paso intermedio entre la cirugía laparoscópica y NOTES.

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Introduction

Experience from minimally invasive surgery induced surgeons to keep reducing the surgical aggression patients are subject to. One of the aspects was the progressive miniaturization of the work instruments reaching the diameter of needles, incorporating new technology: needlescopic surgery.¹

The other, even more innovative one is NOTES (natural orifice transluminal endoscopic surgery),² which is currently under clinical-technological study and evaluation. However, a hybrid between laparoscopic surgery and NOTES, through minilaparoscopy-assisted natural orifice surgery (MANOS), is starting to take its first steps.³

Of all the natural orifices, the vaginal route is currently the most promising; gynaecologists started using this technique via abdominal entry for diagnostic procedures in the 1940s.^{4,5} Despite the disadvantages of it being limited to women, it is well-known and offers the guarantee of fast closing, safety and with a very low incidence rate of complications.⁶ This route had already been used successfully during laparoscopic surgery for the removal of larger surgical pieces,⁷ and Daniel Tsin started to use it for endoscopic procedures in 1998, known as culdolaparoscopy.⁶

The aim of our study is to present our experience with transvaginal cholecystectomy using the MANOS technique in our first seven patients.

Patients and methods

On approval from the ethics commission for the centre's research and patient informed consent, a prospective, longitudinal and intervention study was performed from March 11, to May 7, 2008. Inclusion criteria: women aged 18 to 65 and diagnosed with illnesses requiring cholecystectomies. The exclusion criteria was Asa III and IV, morbid obesity (BMI>35), carriers of venereal diseases, associated acute or chronic gynaecological infections, patients with malignant processes, virgins and pregnant patients. Surgical duration, the need for analgesics in the postoperative period and postoperative complications were studied.

Preoperative assessment

All of the patients underwent gynaecological screening and an ultrasound of their internal gynaecological organs.

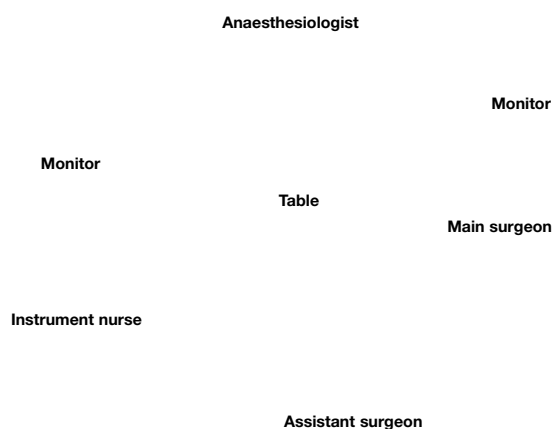


Figure 1 – Position of the surgical equipment: main surgeon on the right, assistant surgeon between the patient's legs, instrument nurse on the left of the assistant and the anaesthesiologist in his/her usual place.

Prophylactic antibiotic therapy was used according to the service protocol: single dose of 2 g intravenous cephazolin during the anaesthetic induction, and for those allergic to beta-lactam, 500 mg of metronidazole diluted in saline and administered before the procedure.

Surgery

By means of general endotracheal anaesthesia and the patient in gynaecological position with both legs on the feet supports, the abdomen, top of thighs, vagina and perineum were sterilized with a 10% solution of povidone-iodine; then a vesical probe, vaginal speculum and uterine manipulator were inserted.

The operating table was placed in the Trendelenburg position. The position of the surgical team is shown in Figure 1.

A pneumoperitoneum with a Veress needle at a pressure of 15 mm Hg was performed, a 5 mm trocar was inserted in the lower internal edge of the navel and through this port site, a 5 mm in diameter laparoscope 45° (Olympus) attached to a video camera was inserted. The entire abdomen was explored and finally the laparoscope was placed visualising the anterior wall of the base of the rectouterine pouch.

With direct vision through the video camera placed in the umbilical port, an incision of 1 cm in length was performed through the vaginal route on the back vaginal wall and a 10 mm in diameter and 45 cm long blunt metal guidewire was introduced through it to the abdominal cavity, traditionally used as a Gotz-Pier (Karl Storz) guide. A 5-12 mm trocar (Auto Suture, Versaport) was placed on the metal guide and introduced as far as the abdominal cavity then the blunt metal guidewire removed.

The 5-12 mm trocar placed in the vagina was used to pass an extra long 30° and 10 mm in diameter telescope (Olympus); basket punches and extraction bag. In one of the patients

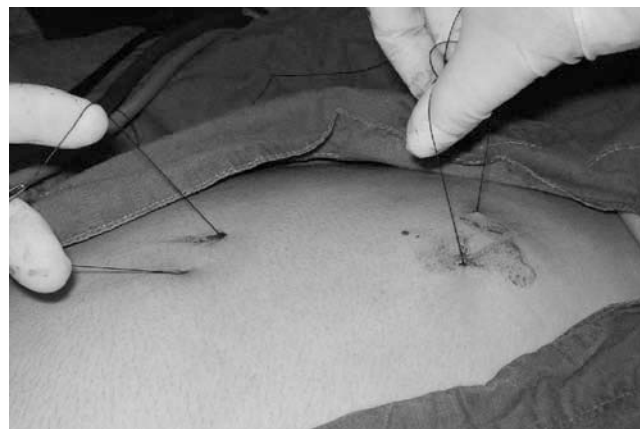


Figure 2 – External view of the sutures in rein shape which is percutaneously introduced into the abdominal cavity using straight needles, and which are employed to traction the gallbladder.

Table 1 – Different techniques used for the cholecystectomies

Patient	Working ports	Percutaneous sutures
1	2 (vaginal-umbilical)	
2	2 (vaginal-umbilical)	
3	2 (vaginal-umbilical)	
4	3 (vaginal-umbilical-right hypochondrium)	
5	1 (umbilical)	2 (renal pelvis-vesicular base)
6	2 (vaginal-umbilical)	1 (vesicular base)
7	2 (vaginal-umbilical)	1 (vesicular base)

measuring less than 160 cm, a standard 10 mm diameter and 30° telescope (Karl Storz) was used.

The 5 mm umbilical port gave way to the dissector entry, electro-coagulation hook, metallic irrigation-aspiration cannula and 5 mm diameter clip applicator (Ethicon). After introducing the instruments through the vaginal port, they were placed on the anterior wall of the abdomen near the umbilical region and the surgical table's position changed to reverse Trendelenburg with left lateralisation.

To facilitate holding, traction, and mobilisation of the gallbladder, an extra long atraumatic basket punch introduced in the adjacent abdominal cavity to the 5-12 mm trocar was used. In some surgical interventions, this punch was aided by 1 or replaced by two 00 sutures with straight, piercing tip, atraumatic needles to facilitate dissection. They were percutaneously introduced into the abdominal cavity (following an aspirating puncture of all the bile in the gallbladder) and through a needle driver into the 5 mm umbilical port, the vesicular wall was crossed at the back and then exteriorised in the point close to the initial entry point, giving the suture a rein function (Figure 2).

Table 2 – Duration of the intervention

Patient	Colpotomy opening and closing	Pneumoperitoneum and cholecystectomy	Total duration
1	13	73	86
2	15	70	85
3	12	61	73
4	9	63	72
5	10	56	66
6	9	55	64
7	8	53	61

The vesicles were extracted through the vaginal port with direct vision using the video camera placed once again on the umbilical port.

The colpotomy closing was performed with 2 chromed catgut stitches.

Results

Seven transvaginal endoscopic cholecystectomies assisted by minilaparoscopy were performed in patients diagnosed with symptomatic vesicular lithiasis. The patients ages ranged from 33 to 62 (average, 47.7) years. The cholecystectomies were performed using different techniques (Table 1). The average duration of surgery was 72.4 (61-86) minutes and progressively decreased as the technique became more familiar (Table 2).

Despite a short term analgesic (fentanyl) being used during the whole procedure, neither oral nor parenteral analgesics were necessary in any of the patients in the recovery room or in the rest of the postoperative stage; with discomfort only from the pneumoperitoneum. They were all discharged within 24 h of the intervention, after which they were examined as outpatients weekly for the first 30 postoperative days.

None experienced complications related to the procedure.

Discussion

In theory, NOTES promises to open new possibilities in the field of endoscopic surgery, but to obtain this, a number of clinical and technological barriers must be overcome.⁸ The most outstanding is the design of flexible or multi-channel transporting endoscopic instruments that allow easy undertaking of not only complex surgical procedures, but also unforeseen events such as the control of haemorrhages and repair of possible iatrogenic lesions. In addition, it should solve the problem of potential risk of contamination that could occur during the intervention.

Current multi-channel flexible endoscopes do not guarantee a fast and safe closure of the opening which must be performed on the hollow organs used as a transit route to the peritoneal cavity.^{9,10}

Currently, only the vaginal route, due to its approachability, offers guarantees to be used as a natural entry orifice to the

abdomen. The ten year experience contributed by the working group at the Queens Mount Sinai Hospital⁶ in transvaginal endoscopic interventions has proven its feasibility.

The first transvaginal cholecystectomy (NOTES) performed on humans was carried out in Brazil by Zorrón et al¹¹ using a 2 port colonoscope. Similarly, other authors^{12,13} have resorted to flexible endoscopes; nevertheless, these have generally needed assistance via one or more miniports in the abdominal wall with the aim of tractioning or elevating the gallbladder to facilitate its dissection, performing a surgical intervention with the participation of a multidisciplinary team including surgeons, gastroenterologists, and gynaecologists. This proves the incompetence of the currently available flexible endoscopes to undertake it only with these and assumes greater complexity in the participation of the different specialities in the operation where a greater coordination of all parts is needed to carry it out efficiently.

In addition, Zornig et al,¹⁴ aided by a gynaecologist, showed that the transvaginal cholecystectomy could be performed using the same rigid instruments as for the laparoscopic cholecystectomy, with which general surgeons are more familiarised, as we have seen in our patients, the difference being that in our surgical interventions, the medical team had always been trained by general surgeons.

The use of traditional rigid instruments makes the participation of the gastroenterologist and the need for a colpotomy unnecessary. Its closing is not difficult for a general surgeon, familiarised with more complex procedures, even more so when performed using direct vision. This allows for greater coordination and facilitates the procedure. In addition, although it was not an objective of our study, it is obvious to state that these factors also have a repercussion on intervention costs.

We performed transvaginal cholecystectomy on patients 1, 2, and 3 because of the ease of the dissection with only 2 working ports (vaginal and umbilical). However, just as occurs in traditional laparoscopic cholecystectomy, this is not always possible due to different local conditions of the hilum of the liver which makes dissection difficult as well as the particular anatomy of the liver.

In patient number 4, it was necessary to insert a miniport in the right hypochondrium aimed at elevating the vesicular bottom. An additional miniport was used only with this patient (umbilical-vaginal-right hypochondrium).

In patient number 5 we did not use the transvaginal basket punch, substituting it by 2 suture threads with straight needles introduced percutaneously which worked as reins, one holding the renal pelvis and the other in the vesicular base, this technique is described by Davila et al¹⁵ and the cholecystectomy in just one working port (umbilical) was performed. However, it should be pointed out that the suture thread placed on the renal pelvis does not allow for traction in all of the angles which the surgeon sometimes needs.

In patients 6 and 7 the basket punch was applied on the vaginal port and the intervention undertaken with two working ports (vaginal and umbilical) with the aid of a suture thread given traction to the vesicular base, which eased the manoeuvre and facilitating surgery. Therefore, the third working port can be replaced, which has an almost

static function and is generally used to elevate the vesicular base, by a suture thread with a straight needle inserted percutaneously and held in a rein form to the vesicular base (or to its peritoneal fold in the union with the hepatic parenchyma) and achieve the same aim.

Our patients did not require parenteral or oral analgesics in the postoperative, Zornig et al¹⁴ also registered an absence of postoperative pain in their patient. The reduction of the number of ports on the abdominal wall, the smaller diameter of these and the knowledge that the vaginal wall is almost painless seem to explain this; nevertheless, our case incidence is still very limited and randomised testing is needed to prove this.

Postoperative complications in the vaginal routes are minimal¹⁶; these have not manifested in any of our patients, who have been followed up for at least 30 days.

The position of the instruments in traditional laparoscopic cholecystectomy achieves excellent triangulation; although, in transvaginal cholecystectomy, as the dissector is placed in the umbilical port and the basket punch in the vaginal port, the angle made with respect to the dissection plane is in this position slightly more acute and requires greater depression when the renal pelvis is in traction, while moving away from the main bile duct and obtaining a more perpendicular angle to the dissection plane.

When large stones which are impacted in the vesicular neck and intervene and make dissection of the hepatobiliary triangle difficult, substituting the traditional dissector for a reticular one facilitates the technique. We experienced this in one of our cases (patient 7) with a stone measuring 2.1 cm in diameter.

In all of our patients, it was possible to block the cystic ducts with the small clips of a 5 mm clip applicator introduced through the umbilical port. In the event of duct with larger diameters, the ligature can be performed with a surgeon's end loop using this same port.

If we exclude these last observations, from a technical point of view we have not found any differences with respect to traditional laparoscopic cholecystectomy, since an excellent vision of the hilum of the liver is achieved and allows for adequate dissection. It is obvious that the opening and closing of the colpotomy increased the surgical duration 8 to 15 minutes in the intervention, but the benefits of the reduction of ports in the abdominal wall and the smaller diameter of these seem to compensate the final results, the postoperative pain is diminished and a better aesthetic result is achieved, although future studies are needed to prove this. On the other hand, if the local anatomical conditions make the cholecystectomy very difficult, there is always the possibility of converting to traditional laparoscopic surgery increasing the number of ports on the abdominal wall or performing the conversion to open surgery.

In our opinion, mini-laparoscopic assisted transvaginal cholecystectomy undertaken by general surgeons using the same rigid instruments as for laparoscopic surgery has obvious advantages over the cholecystectomies performed with flexible endoscopes, without considering the route used (trans-gastric, purely transvaginal, assisted transvaginal, or

trans-umbilical), due to the surgical limitations that flexible instruments current pose and to other factors which were expressed at the beginning of the discussion referring to NOTES. We also believe that it is more appropriate than the trans-umbilical cholecystectomy performed with rigid instruments,¹⁷ given that with this the instruments do not allow triangulation, as when they are all placed in the umbilical region they take on an almost parallel direction, which does not allow for and adequate dissection. We must then assume that it must be very uncomfortable for the surgeon and dangerous to the bile ducts, creating greater risk of iatrogenic lesions. It should be added that the length of the incision needed on the navel to introduce various trocars is larger than the ones performed on our patients, which was of only 5 mm.

Conclusions

Mini-laparoscopic assisted transvaginal cholecystectomy can be performed on patients selected by a team composed of general surgeons in a safe manner, with appropriate surgical durations and better aesthetic results than for traditional laparoscopic cholecystectomy. The use of the same instruments as for laparoscopic surgery makes it more efficient. MANOS can be an intermediate stage between laparoscopic surgery and NOTES.

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