



Original article

Non-randomised, comparative, prospective study of transvaginal endoscopic cholecystectomy versus transparietal laparoscopic cholecystectomy

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A B S T R A C T

Introduction: We present a non-randomised comparative study of 2 patients series followed up prospectively, in which convention laparoscopic cholecystectomy is compared with transvaginal cholecystectomy, a hybrid transluminal endoscopic procedure, with the objective of assessing the clinical safety of the procedures and its efficacy in the resolution of cholelithiasis.

Patients and method: A non-randomised prospective clinical series of 40 female patients, operated on for cholelithiasis using endoscopic surgery, 20 with a conventional laparoscopic approach and 20 using a transvaginal endoscopic approach. Surgical wound infection, urinary infection, evisceration, eventration, mortality, and other complications.

Results: Scheduled operations were performed on the 40 patients as indicated. There were no complications during the operations. There was no mortality associated with the procedures and there was only 1 post-surgical complication, a urinary tract infection in 1 patient operated on by the transvaginal approach. The mean follow up was the same in both groups (9 months). The mean hospital stay was less than 0.8 days in both groups. The duration of the surgery was longer in the transvaginal approach group, with a mean of 69.5 min, compared to 46.2 min in the laparoscopy group.

Conclusions: Although the cosmetic benefit is obvious, no differences were found as regards parietal problems in this series. The duration of the transvaginal surgery is higher than that of the transparietal, but the times of both are acceptable. In this study, the non-inferiority in the safety and efficacy of the transvaginal approach is able to be assessed.

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Estudio comparativo, prospectivo y no aleatorizado de la colecistectomía endoscópica transvaginal frente a la colecistectomía laparoscópica transparietal

R E S U M E N

Palabras clave:

Colecistectomía transvaginal

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Colecistectomía laparoscópica

Introducción: Presentamos un estudio comparativo no aleatorizado de 2 series seguidas de manera prospectiva en las que se compara la colecistectomía laparoscópica convencional con la colecistectomía transvaginal, procedimiento endoscópico transluminal híbrido, con el objetivo de valorar la seguridad clínica del procedimiento y su eficacia en la resolución de la coledolitiasis.

Pacientes y método: Serie clínica prospectiva no aleatorizada de 40 mujeres intervenidas por coledolitiasis mediante cirugía endoscópica, 20 con abordaje laparoscópico convencional y 20 mediante abordaje endoscópico transvaginal. Se analizaron como variables la infección de herida quirúrgica, la infección urinaria, la evisceración, la eventración, la mortalidad y otras complicaciones.

Resultados: Se realizó la intervención prevista en las 40 pacientes a quienes se indicó. No hubo complicaciones intraoperatorias. No hubo ningún caso de mortalidad relacionada con los procedimientos y sólo se produjo una complicación postoperatoria, infección del tracto urinario, en una paciente operada por vía transvaginal. El seguimiento medio ha sido el mismo en ambos grupos (9 meses). La estancia media fue en ambos grupos < 0,8 días. La duración de la cirugía fue mayor en el grupo con abordaje transvaginal, con 69,5 min de media frente a 46,2 min en el grupo laparoscópico.

Conclusiones: Si bien la ventaja estética es patente, en esta serie no se han encontrado diferencias en relación con problemas parietales. La duración de la cirugía transvaginal es mayor que la de la transparietal, pero los tiempos medios de ambas son aceptables. En este estudio se puede valorar la no inferioridad en eficacia y seguridad del abordaje transvaginal.

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Introduction

Transluminal endoscopic surgery through natural orifices (Natural Orifice Transluminal Endoscopic Surgery [NOTES]) includes an array of endoscopic-surgical procedures that aim to be less invasive than laparoscopic surgery. This surgical technique enables a surgeon to perform abdominal surgery without making any incisions in the abdominal wall. The history of the use of this technique in humans is very recent, and it will take some time before any prospective series that include many patients that show the safety of these procedures and that carry out long term follow-up exist. Our group has performed the first transvaginal hybrid endoscopic cholecystectomy in our country and we have also carried out a non-randomised prospective clinical series over the span of 1 year. The results of the series compare the transvaginal laparoscopiccholecystectomy(hybridendoscopic-laparoscopic procedure) with the conventional (transparietal) laparoscopic cholecystectomy.

Patients and method

A prospective series of 40 women operated on for non-complicated cholelithiasis by choice, divided in 2 groups of 20

patients each: the group of the transparietal cholecystectomy, done by conventional laparoscopic cholecystectomy, and the transvaginal group, done by transvaginal endoscopic cholecystectomy, a hybrid procedure combined with a mini-laparoscopic transparietal approach. The interventions were performed by a multidisciplinary team of surgeons and endoscopists.

Specific informed consent and approval from the Ethics Committee of Clinical Research of the Autonomous Community were obtained for the transvaginal procedures. The recruitment period lasted 6 months, from December 2007 to May 2008, and follow-up was carried out until the results were analysed in December 2008. Inclusion criteria were as follows: symptomatic cholelithiasis with surgical indication by laparoscopy, absence of gynaecological diseases that could make the procedure more difficult (inflammatory pelvic disease or endometriosis), non-intact hymen and the patient acceptance to not using the vaginal route for 2 weeks after the intervention and signing the specific informed consent after receiving specific information about the new type of treatment.

General anaesthesia in the modified Lloyd Davies surgical position was used in all of the patients during the intervention. Antibiotic and antiemetic prophylaxis was used. The surgical intervention was started by forming a pneumoperitoneum

using a Veress needle placed in the posterior portion of the belly button in the group undergoing endoscopic surgery, and in the supra-umbilical region in the group undergoing conventional surgery. Three trocars were used in the transparietal or conventional cholecystectomy: two 10 mm trocars at the supra-umbilical level and one in the left mammillary line, respectively, and one of 5 mm in the right mammillary line. Gall bladder removal was performed through the supra-umbilical route with an extraction bag. Three trocars were also used for the transvaginal cholecystectomy: one of 5 mm in the floor of the umbilical sack, another one of 3 mm in the right mammillary line and another one of 15 mm through the floor of the posterior fornix of the vagina. Gall bladder removal was performed through the vaginal entry, also with a protective extraction bag.

For the transvaginal access, the patients were placed in the forced Trendelenburg position and 2 valves were inserted to better the vision of the vaginal fornix. Once the area was determined by vaginal touch, the vaginal trocar was introduced to enter in the peritoneal cavity through the Douglas fornix. A double channel video-endoscope was introduced through this trocar.

After correctly placing the endoscope, the patients were placed in the anti-Trendelenburg and smooth left lateral position to facilitate the exposure of the hepatic pedicle. After dissecting the cystic duct and the cystic artery, they were sealed with surgical (proximal) clips and endoscopic (distal) clips and later sectioned. The cholecystectomy was performed from the hilum to the floor with endoscopic and laparoscopic electro-coagulation and the piece removed was introduced into the extraction bag. Gall bladder removal was performed through the vaginal route in the forced Trendelenburg position. Using a "mouse teeth" type forceps that passed through the operating channel of the endoscope, the plastic bag was closed and—controlling the process with laparoscopic vision—the video-endoscope, the forceps that held the bag and the vaginal trocar were removed once they were clearly visible in the vagina.

Once the intervention was finished, the parietal entries from the transvaginal surgery were not sutured while the supra-umbilical incision from the laparoscopic cholecystectomy was closed with an absorbable suture. The patients were in the post-anaesthesia recuperation unit for a normal amount of time and they were evaluated to be discharged to an ambulatory surgery regime when they met the inclusion criteria of said program for early discharge. The same post-operative treatment protocol was prescribed in both groups regarding when to start eating, walking and the administration of analgesics.

To obtain an image in the laparoscopic approach, a high definition system was used, while in the endoscopic approach, standard definition endoscopic equipment was used (Full HD Platform IMAGE1™ and the Gastro-pack, by Karl Storz). The laparoscopic vision was obtained with a 5 mm 0° and 30° optic, and the endoscopic image was obtained with double channel video-gastroscope (Video-gastroscope 13806 PKS, Karl Storz, Tuttlingen), sterilised together with the irrigation bottle and its connector tube with ethyl oxide.

The trocars used for the surgery were 10-11 mm wide and 15 mm (Ethicon Endo-Surgery) and of 3 and of 5 mm in the

abdominal entries, occasionally with expandable sleeves (STEP™ Radially Expandable Sleeve), both from Autosuture (Tyco Healthcare).

The dissection was performed with electro-coagulation and in some cases, with a harmonic scalpel. The surgical clip used in the transvaginal approach was of 5 mm and of 10 mm in the conventional approach (Ethicon Endo-Surgery) as was the endoscopic clip, QuickClip2™ (Olympus EndoTherapy). The sample extraction bags (Unimax 5"×7", Unimax Medical Systems Inc, Taipei, Taiwan) were anchored for their transvaginal endoscopic extraction with mouse tooth type pincers (Medi Globe GmbH, Achenmühle, Germany).

The vaginal closure was performed with 2/0 calibre polyglycolic acid (Vicryl, Ethicon Inc.). No closure was performed for the trans-umbilical access, only a local instillation of Iodine. Skin was approximated with a 3 mm adhesive strip in the access of the right flank.

The following variables were analysed in the follow-up: infectious, mechanical and of other non-specified characteristics. Surgery wound infection (parietal and vaginal), pelvic infection and urinary tract infection were collected among the infections found. Regarding the mechanical parietal complications, eviscerations and eventrations (parietal and vaginal) were collected. In the section of other complications, any other adverse events related with the intervention were collected. Patients were examined 1 week after and 1, 6, and 12 months after surgery.

Results

The interventions were successfully completed in all 40 patients who had been indicated for said procedure. The average age of the series was similar, 45.2 years old for the conventional laparoscopic cholecystectomy and 42.7 years old for the transvaginal cholecystectomy. The average hospital stay for patients that underwent surgery did not vary regarding the standard presented in the health centre: conventional group, 0.8 (interval, 0-3) days; transvaginal approach, 0.75 (0-2) days. The out-patient rates were also similar between the different series and to that offered by the health centre, with 35% (7/20) of patients that underwent laparoscopic surgery discharged before 12 hours after surgery without spending the night in the hospital, while 30% (6/20) of those that underwent the transvaginal approach were also discharged with the same

Table 1 – Data on hospitalisation, surgery time, and follow-up in both series of patients that underwent surgery

	Transparietal	Transvaginal
Patients, n	20	20
Age, y	45.25	42.7
Hospital stay	0.8	0.75
Out-patient surgery, n (%)	7 (35)	6 (30)
Surgery time, min	46.25	69.55
Follow-up, mo	9.1	9.1

Table 2 – Post-operative complications in both series of patients

	Transparietal	Transvaginal
Patients, n	20	20
SWI	0	0
UTI	0	1
Pelvic infection	0	0
Evisceration	0	0
Evisceration	0	0
Other complications	0	0

criteria Surgery took longer with the transvaginal approach than with the conventional laparoscopy, with an average of 69.5 (40-120) min compared to 46.25 (30-85) min; this surgical time accounts for all of the procedures performed from the moment that the surgical team put their gloves on to the moment when they take them off, after finishing the intervention (Table 1).

The average follow-up of both series is of 9.1 (6-14) months. Only one complication has been found in the follow-up period that took place in the transvaginal approach group: a urinary infection by *Gardnerella vaginalis*, which was resolved with outpatient antibiotic treatment. The rate of complications was null in the conventional approach group, and 5% for the transvaginal approach group (1/20, urinary infection). No deaths or serious complications took place in any of the series (Table 2).

Discussion

Transvaginal access currently seems to be safer and more feasible for the clinical practice of transluminal endoscopic surgery through natural orifices. Since March 2007 Zorron et al performed the first series of transvaginal NOTES cholecystectomies in 4 patients, based on the anterior experimental studies,^{1,2} and different groups have continued to report their experiences with this technique. In the same month, Bessler successfully performed a hybrid transvaginal cholecystectomy with 3 laparoscopic abdominal entries.³ Marescaux performed the purest NOTES cholecystectomy in a patient in the beginning of April 2007, using only 1 abdominal entry where the Veress needle was introduced to control the pneumoperitoneum and a clamp for vesicular traction.⁴ The Branco group has reported their experience with the hybrid cholecystectomy, intervening in a case with only 1 abdominal access trocar,⁵ and later with a transvaginal nephrectomy with two 5 mm abdominal trocars.⁶ The first hybrid transvaginal NOTES cholecystectomy carried out in Spain was performed in the Hospital Son Llàtzer in Palma de Mallorca, in October 2007.⁷ In January 2009, this same group published their results with a prospective series of 11 patients operated on using this new approach.⁸

The closure of the orifices where the abdominal cavity was accessed is one of the critical points regarding the safety of NOTES. There are no safe and effective systems in the transgastric and transcolonic approaches, despite the fact that

different systems have been described based on anchoring points, the combination of forceps with suturing needles, endostaplers and multiple clips systems.⁹⁻¹² However, the transvaginal route offers fast access and allows for a simple and safe closure. The colpotomy is a procedure of proven safety from the extensive use by gynaecologists over the past several decades. The vagina is an elastic tube that allows for large samples, such as ovarian cysts or uterine myomas, to be removed through its orifice.¹³ Occasionally, the transvaginal route has also been described as a non-gynaecological organ extracting route, for pieces removed from nephrectomies or hemicolectomies.¹⁴ The posterior colpotomy is practically painless and its complications are very infrequent; pointing out lesions in the urinary bladder, pelvic hematomas, urinary tract infection, and the infection of vaginal sutures as possible complications. Regarding the dyspareunia, the risk that a relevant and persistent case is produced after a posterior colpotomy is very slight.¹³

Laparoscopic exploration with mini-optics through the umbilical access is a necessary gesture to ensure the feasibility and safety of the transvaginal entryway. Unlike other authors,^{3,4} the introduction of the video-endoscope through the colpotomy was carried out using a rigid trocar with a 15 mm diameter, that presents various advantages: it makes it possible to maintain the pneumoperitoneum thanks to its contention valve and its longitude stabilises that endoscope, makes navigating in the peritoneal cavity easier, allows for endoscope orientation towards the gall bladder, avoids the risk of peritoneal contamination with the entry and exit manoeuvres of the endoscope and it reduces the risk of lesions during the extraction of the gall bladder.

Clamping of the cystic artery and duct was done with a proximal laparoscopic double clip and an endoscopic clip in the vesicular portion. In many cases, the endoscopic clip has showed to be inefficient, which is the reason why we do not usually leave endoscopic clips in the proximal portion. The separation of the gall bladder from the hepatic floor is usually performed with laparoscopic and endoscopic instruments. After liberating the gall bladder and inserting it in the extraction bag, both were removed together with the endoscope using the vaginal route, and afterwards, the colpotomy was closed from its external region.

In the series that we present, the transvaginal access has proven to be as safe as the conventional laparoscopic cholecystectomy. It has proven to be efficient in all of the cases in the resolution of cholelithiasis, completing the cholecystectomy without any problems, and with no differences in intra-operative nor entryway problems in a 9 month follow-up period. The transvaginal approach presented a longer surgical time, with an average duration of 23 min longer than the conventional approach. The average hospital stay and the percentage of out-patient cases with the vaginal approach were kept at the same levels as those offered by the laparoscopic cholecystectomy; however, the parameters regarding the post-operative stay could not be improved. From a commercial point of view, the transvaginal cholecystectomy has caused a discrete increase in the price of the procedure, as the hours of dedication of the endoscopist and the increase of the cost of endoscopic clips and the sterilisation of the

endoscopic material all has to be added to the habitual costs of the intervention. Other economic aspects such as the days of work leave have not been evaluated in this study.

This study has important limitations concerning the results of the infection of the surgical wound and post-operative eventration, as the study includes few patients and the follow-up period is still short. Taking into account the previously published parameters, results of infection of the surgical wound greater than 5%¹⁵ (local infection especially in peri-umbilical access) can be expected from the laparoscopic technique. Regarding the mechanical complications of the entryways, according to authors like Nassar and Tonouchi, rates of hernia in long term follow-up from laparoscopic approaches in the cholecystectomy that oscillate between 0.65% and 2.8% can be expected.^{16,17} These rates are those that should be improved with the new transluminal approaches in long series with prolonged follow-up periods. The aesthetic benefits of the transvaginal approach is noticeable, however, as indicated in a recent study carried out in women asked about their preferences regarding the transvaginal approach, only 39% preferred said approach because of its aesthetic benefit, while decreased pain and possible post-operative hernias were the chosen causes in the majority of the patients.¹⁸

The hybrid cholecystectomy is becoming the only feasible and safe clinical application in these moments. The performance of the hybrid transvaginal cholecystectomy allows us to be able to continue advancing in this field. As Shih¹⁹ says, the hybrid approaches are like a bridge between the laparoscope and NOTES which, at the moment, must be crossed if we want to reach a point where we can perform pure transluminal endoscopic procedures.

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