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Training design and improvement of technical skills in the transvaginal cholecystectomy (NOTES)

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A B S T R A C T

Introduction: The current surgical scenario of the surgery through natural orifices or "no-scar surgery" requires acquiring new technical skills by the surgeon. We introduce the initial experience of the Minimally Invasive Surgery Centre Jesús Usón (MISCJU) in the design and setting-up of a surgical training programme using the the natural orifices approach for the acquisition of surgical skills and abilities, based on the preliminary trials in simulators and a pig model.

Material and methods: After initial training, using a laparoscopic pelvic-trainer, 7 female pigs, with weights between 35–40 kg, were operated on. The transvaginal approach was completed using a one-channel gastroscope in all the animals. After accessing the abdomen, the abdominal cavity was explored, and the surgery was concluded with the endoscopic cholecystectomy.

Results: Endoscopic cholecystectomy was successfully completed in 6 cases. In one of the animals, the procedure was stopped because of technical problems regarding the endoscope leaning to one end. The average surgical time was 107.14 min (range, 80–150 min). The transvaginal approach enabled the abdominal to be explored and the dissection, ligature and section of the cystic duct and the cystic artery. After cholecystectomy, the gallbladder was extracted through the vagina. After the procedure necropsy did not reveal intra-abdominal lesions or intraoperative complications.

Conclusions: The pure transvaginal cholecystectomy is a feasible and reproducible procedure in the animal model. A systematized training model, which includes physiopathology knowledge as well as technical knowledge, in order to translate these procedures to the clinical practice in a safe way, is needed.

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Diseño del entrenamiento y la adquisición de habilidades técnicas en la colecistectomía transvaginal (NOTES)

Palabras clave:
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R E S U M E N

Introducción: El reciente escenario quirúrgico de la cirugía a través de orificios naturales o «cirugía sin cicatrices» requiere que el cirujano adquiera nuevas habilidades técnicas. Presentamos la experiencia inicial del Centro de Cirugía de Mínima Invasión Jesús Usón (CCMIJU), en la fase de diseño y desarrollo de un programa de formación quirúrgica con abordaje por orificios naturales para la adquisición de habilidades y destrezas quirúrgicas, basado en las pruebas preliminares realizadas en simuladores y en modelo porcino.

Material y métodos: Tras un entrenamiento inicial en simulador laparoscópico, fueron intervenidos 7 animales hembras de la especie porcina con pesos de 35–40 kg. En todos los animales se completó el abordaje transvaginal mediante un gastroscopio con un solo canal. Tras el acceso al abdomen, se procedió a la exploración de la cavidad abdominal y se concluyó con la realización de la colecistectomía endoscópica.

Resultados: En 6 de los casos se completó con éxito la colecistectomía endoscópica. En un animal el procedimiento se detuvo por problemas técnicos relacionados con la orientación del extremo del endoscopio. El tiempo quirúrgico medio fue 107,14 (intervalo, 80–150) min. El abordaje transvaginal permitió la exploración abdominal y la disección, la ligadura y la sección del conducto cístico y la arteria cística. Tras la colecistectomía la vesícula fue extraída a través de la vagina. Tras el procedimiento la necropsia no reveló lesiones en los órganos abdominales ni complicaciones intraoperatorias.

Conclusiones: La colecistectomía transvaginal pura es un procedimiento factible y reproducible en modelo animal. Es necesario un modelo de formación sistematizado, que incluya tanto conocimientos fisiopatológicos como técnicos, para trasladar de forma segura estos procedimientos a la práctica clínica.

Introduction

Since it became popular in the eighties, laparoscopic surgery was adopted as the chosen procedure instead of conventional surgery to treat numerous illnesses. It has been widely reported that laparoscopy, compared with conventional surgery, provides a series of benefits, such as less surgical stress,[1,2] reduced post-operative pain,[3] less serious parietal problems,[4] faster reincorporation into the work force[3,5-7] and better aesthetic results.[8]

Continuing with this focus on trying to reduce surgical aggression, a series of new surgical techniques have recently been described which imply operating through natural orifices[9-18] and that, theoretically, would avoid having to cut the abdominal wall with the hypothesis of causing less surgical stress[19] and, therefore, would imply a great advantage for the patient aside from the aesthetic benefits.

Although the use of flexible endoscopic equipment to explore the abdominal cavity and carry out simple interventions in experimental models was described by Usón et al[20] in 1992, with a single laparoscope trocar, currently, the use of endoscope equipment through natural orifices is very attractive for patients and surgeons; however, it does require great efforts from the surgeons that, before using these techniques in a generalised manner, must take the weak points of this new approach into consideration.

To do so they must resolve certain delicate aspects such as the contaminating effect of the peritoneal cavity when perforating an organ such as the stomach, the vagina, the colon or the bladder. And not less important, to develop an efficient and trustworthy system to close those orifices created from the endoscope. In this respect, numerous research projects have been started on the effects of different approaches through natural orifices and the development of novel closure systems is trying to be developed.[21-29]

Another challenge presented by surgical techniques performed with the NOTES approach (natural orifice transluminal endoscopic surgery) is the adequate handling of the endoscope, unknown by the majority of surgeons in our country, and its use within the peritoneal cavity and not inside of a tubular structure such as the gastrointestinal tract.

We present the initial experience of the Minimally Invasive Surgery Centre Jesús Usón (CCMIJU in Spanish) in the design of an experimental learning program to acquire the surgical skills and abilities with approaches carried out through natural orifices, based on the initial experience and the analysis of the feasibility and safety of the pure transvaginal cholecystectomy, without laparoscopic aid, in a porcine animal model.

Figure 1 – Initial training to acquire skills in endoscopic manoeuvres in a laparoscopic simulator (SIMULAPIC 05®, CCMIJU, Caceres, Spain).

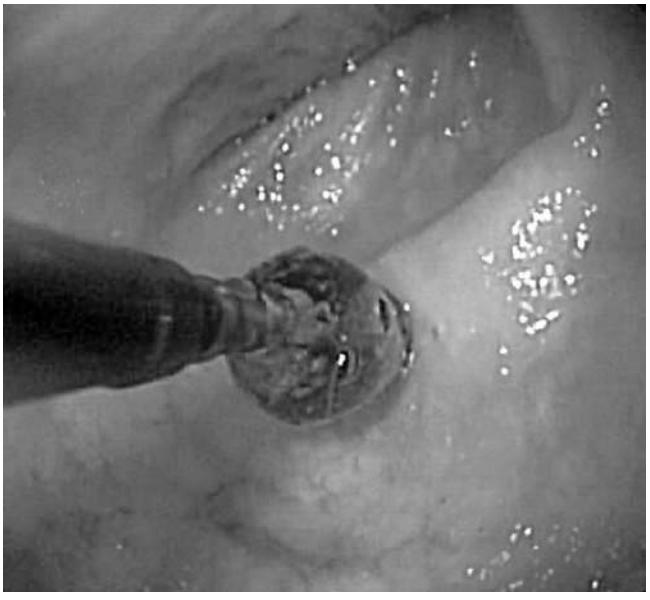

Figure 2 – Practice of the transgastric approach in a physical simulator.

Material and methods

Experimental training

The use of a laparoscopic simulator developed in our centre (SIMULAPIC 05®, CCMIJU, Caceres, Spain) has allowed us to practice the basic skills and learn the knowledge needed for those techniques required in NOTES surgery (Figure 1). Experimental tissues were used including porcine stomachs, livers and uteruses to simulate transgastric (Figure 2) and transvaginal approaches and to practice the endoscopic dissection manoeuvres. The laparoscopic simulator was placed on the surgical table with the tissues and organs used for the training session. Special attention was paid during this phase to acquiring skills related with the handling and orientation of the endoscope, approach through organs and the dissection and endoscopic cutting manoeuvres.

The learning sequence in the simulator begins with inorganic tissues to practice the handling and orientation of the endoscope. Organic tissues are used to practice the approach (transgastric and transvaginal), dissection, cutting, and placement of endoscopic and laparoscopic clips, alternating the hybrid and endoscopic approaches until being able to perform the cholecystectomy in the simulator with guarantees before beginning to use the single endoscopic approach in the experimental model.

Animal model

The protocol to perform a transvaginal cholecystectomy was approved by the Animal Ethics and Wellbeing Committee (CEBA in Spanish) of the CCMIJU and it was carried out according to the European Directive 86/609/EEC. In this study, 7 healthy female pigs of the Large-white breed were used, that weighed between 35 and 40 kg. The animals were left fasting for 24 hours before each surgical procedure. After general anaesthesia, gastroscopes with a single channel (Fujinon, Japan) were used to make a 2 cm incision in the posterior vaginal fornix, using an endoscopic needle connected to electrocoagulation equipment. Wall dilating systems were not used, direct access was used through the vaginal itself until reaching the retroperitoneal area that was opened sectioning with the endoscopic needle until reaching the abdominal cavity. Urinary catheters were not used in any of the animals.

Access to the peritoneal cavity was done forcing the Trendelenburg position. The pneumoperitoneum manoeuvre was done with Veress needle introduced in the infra-umbilical position. Using an electronic CO_2 inflator (Storz, Tuttlingen), gas was introduced into the abdomen until reaching a pressure of 8-10 mm Hg, finding the correct orientation of the end of the endoscope, the exploration of the peritoneal cavity was completed using the transillumination technique and by changing the position of the animal. Ambient air was never used in the endoscope to create the pneumoperitoneum and the CO_2 pressure was kept stable with the electronic inflator.

Once the gall bladder was located, the fundus of the gall bladder was clamped with endoscopic graspers until it was in contact with the abdominal wall of the right hypochondrium. Subsequently, the gall bladder was fixed to the wall using a transparietal suture, applied from the outside of the animal and that penetrated the abdominal wall and the fundus of the gall bladder and that suspended and exposed the gall bladder. Next, the Calot's triangle was dissected separating the cystic artery and the cystic duct (Figure 3). Endoscopic

Figure 3 – Endoscopic dissection manoeuvres in the cystic duct and the cystic artery.

Figure 5 – Endoscopic liberation of the gall bladder.

Figure 4 – Placement of endoscopic clips in the cystic duct and the cystic artery of the porcine model.

clips (QuickClip2®, Olympus) were used for the ligature of the cystic duct and the cystic artery (Figure 4); sectioning was done using endoscopic scissors.

Using posture changes and different levels of tension in the traction point, the liberation of the gall bladder was completed, from the neck to the fundus, with an electrically charged loop or an endoscopic needle connected to the electrocoagulation source (Figure 5). The changes in the supine position and the inclinations of the position of the animal together with the different levels of tension in the transparietal point allow for us to achieve a correct exposure of the surgical field and displace the hepatic lobes within the abdomen. Finally, the hepatic floor was reviewed and the gall bladder was removed through the vagina using endoscopic graspers. All of the animals used in this study were sacrificed immediately after completing the surgical procedures and the abdominal cavity and the area that was intervened on were explored through necropsy to determine the level of safety of the procedure.

Results

The simulator training enabled for, before using animals, practicing the exercises of handling the endoscope and refining the dissection, cutting, and endoscopic clip placement manoeuvres. It also enabled the surgeons to improve their skills and evaluate the different equipment and endoscopic instruments. Different working sessions were carried out in this first training period until successfully performing the dissection and placement of endoscopic clips, initially with endoscopic images and laparoscopic assistance, before practicing the single endoscopic approach in the experimental model.

The transvaginal approach in the porcine experimental model was performed without any complications in all of the cases. The exploration of the abdominal cavity was complete and satisfactory in 6 of the 7 animals. The average intervention time was 107.14 (range, 80-150) min. The gastroscope provided an excellent view of all of the phases of the intervention. The distance from the end of the endoscope to the work area was approximately 5 cm, however, the double channel endoscopes allow for the magnification of the image during the intervention. The procedure was detained in one animal as it could not be continued in safe conditions, due, essentially, to problems of the orientation of the endoscope inside of the abdominal cavity and the interference of the intestinal loops for its movement. The maximum intra-abdominal pressure was 10 mm Hg, and no haemodynamic or cardio-respiratory problems were reported during the anaesthetic monitoring of the animals. No intra-operatory complications or injured adjacent organs were observed in the necropsy of 6 animals where the endoscopic cholecystectomy technique was completed successfully. A perforation of the gall bladder was produced in one case.

Discussion

This study presents certain training guidelines to put into practice surgery through natural orifices, while simultaneously presenting our results regarding the feasibility of the pure transvaginal cholecystectomy in a porcine animal model. In future animal survival studies, we will try to evaluate the safety of this technique. However, we believe that this just the starting point in the development of surgery through natural orifices. We consider, thus, that learning these skills and the benefits of the technique should be backed up by well designed future studies.[9]

In our institution, we undertake the experience with a transvaginal approach[30] as it presents certain advantages over the transgastric and transcolonic approach related with a lower number of infections and leakage by avoiding gastric closure methods, that may be related to fistulae or peritonitis.[9-11,15,31-35] Therefore, our group continues to analyse other approaches, such as the transgastric[12,21,36,37] or transvesical[38,39] routes.

In the existing literature related to NOTES techniques, various articles have surfaced that describe hybrid techniques in animals and humans[9-13,15-18,22,28,33-35,40-47] in which, in the case of a cholecystectomy, the dissection is either performed by laparoscope and the portion removed is extracted by the transvaginal route, or it is completed using the technique in combination with laparoscopic help.

We consider that during initial surgical learning hybrid techniques should be used that combine endoscopic approach with laparoscopic assistance, before trying pure endoscopic approaches, as we believe that laparoscopic assistance seems to be reasonable as a safety measure when putting this technique into practice,[48,49] as the application of true NOTES technique, to reach the abdomen and carry out surgical procedures, remains quite unclear.

We consider that the optimal learning sequence should include initial training with simulators, similar to laparoscopic or thoracoscopic surgery,[50] and practicing of endoscope handling and of dissection and clip placement manoeuvres. Furthermore, training with hybrid techniques using the simulator will later enable the practice of said techniques in experimental models and to combine the endoscopic and laparoscopic dissection manoeuvres with the placement of clips in vascular structures and the biliary system before undertaking the single endoscope approach.

We have found certain limitations during the course of surgery in the first 2 animals of the series, essentially related with orienting the end of the endoscope inside of the abdominal cavity, which makes the inclusion of practice of endoscope handling necessary during the training phase.[30,51] We have progressively reduced surgical times, related with the optimisation of the transvaginal access in the animal model, the systematisation of endoscope handling in the abdominal cavity and the exposure of the gall bladder after fixing it to the abdomen wall. Similarly, the lack of initial experience may cause iatrogenic lesions and make decision making for the surgeon regarding surgical aspects or the treatment of said complications difficult,[51] as we have yet to have suturing instruments or adapted devices for this type of techniques

This experience demonstrates in experimental conditions that the use of simple gastroscopy equipment enables the successful completion of the endoscopic cholecystectomy without laparoscopic assistance. The traction and surgical exposure manoeuvres, necessary for safe dissection, are achieved through posture changes, traction from a fixed point and with the endoscope itself.

The average time used in our initial experience considerably surpasses the standard time required for a laparoscopic cholecystectomy. However, the progression of surgical times of this series has progressively decreased, from 150 min in the first animals to 80-90 min in the last ones. The procedure was stopped only in the second animal of the series because of problems with the orientation of the endoscope inside the abdominal cavity. The intestinal loops interfered in the endoscopic vision and the difficulties to move the endoscope safely in the abdominal cavity made us stop the procedure. In the following animals, the entry to the abdomen was done in the anti-Trendelenburg position, and we therefore avoided this type of problems.

Circumstances such as the difficulty in endoscope handling inside the peritoneal cavity, the loss of triangulation capacity and the complexity of the traction manoeuvres of the organic structures must be improved with these new techniques or safer surgical manoeuvres must be developed. Similarly, problems that had already been resolved in laparoscopic surgery, such as intra-corporal suturing or surgical dissection, continue to present too much risk with this new technique, for which adaptations should be made or new surgical material[52] should be specifically developed to allow for the incorporation of these essential manoeuvres during surgery.

This makes us think that this type of techniques may be very dependent on the future technological development that would allow for an adequate triangulation of the material[32,33] and improvements in spatial orientation and exposure of the surgical field. Similarly, possible applications are yet to appear using robotics that allow for the further development of these types of techniques.[53-55]

In our experience, the importance of establishing surgical training programs to acquire surgical skills and abilities for surgery through natural orifices has been demonstrated. The preliminary tests carried out in simulators and in porcine models show the feasibility of the transvaginal endoscopic cholecystectomy without laparoscopic assistance. New studies in experimental models and training protocols will be evaluated by our multidisciplinary team in order to try to determine the safety and efficiency of new approaches and this type of surgical techniques.

This study has been presented as a presentation in the First Iberian International Conference of Laparoscopic and Thoracoscopic Surgery. Caceres, Spain. October 17-18, 2008.

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