Revista Colombiana de Obstetricia y Ginecología Vol. 70 No. 3 •Julio-Septiembre 2019 • (165-173)

ORIGINAL RESEARCH

DOI: https://doi.org/10.18597/rcog.3177

SAFETY AND EFFICACY OF VECCHIETTI VAGINOPLASTY IN VAGINAL AGENESIS: COHORT STUDY. MEDELLÍN, COLOMBIA 2007-2012

Seguridad y eficacia de la vaginoplastia de Vecchietti en agenesia vaginal: estudio de cohorte, en Medellín, Colombia, 2007 a 2012

Segurança e eficácia da vaginoplastia de Vecchietti na agenesia vaginal: coorte de 2007 a 2012

***Jorge Enrique Aristizábal-Duque, MD, MSc*[*1]*; Joan Camilo Piedrahíta-Mejía, MD, MSc*[2]**

Received: June 14/18 - Accepted: September 16/19

ABSTRACT

Objective: To describe the Vecchietti vaginoplasty technique (VVT) in patients diagnosed with secondary vaginal agenesis, and to analyze the safety and efficacy of this technique.

Materials and Methods: Historical cohort of patients with vaginal agenesis secondary to Mayer-Rokitansky-Kuster-Hauser and androgen insensitivity syndromes, subjected to vaginoplasty using the Vecchietti technique at San Vicente Fundación University Hospital, a high complexity referral institution located in the city of Medellín, during the time period between 2007 and 2012. Patients with a functional vagina for intercourse were excluded. Sampling was consecutive. Sociodemographic, clinical, safety and efficacy variables were measured. Descriptive statistics were used.

Results: The chief complaint was primary amenorrhea (69.2%). Associated malformations included right renal agenesis (15.4%) and skeletal malformations (15.4%). There was one intra-operative bladder perforation and, postoperatively, there were three (23.1%) minor complications. At 1-year follow-up, a functional vagina had been obtained in 84.6% of cases.

Conclusion: Vecchietti vaginoplasty is a simple surgical technique resulting in satisfactory functional outcomes with only minor complications. Further studies with control groups are required in order to better assess the efficacy of the various techniques used for neovagina creation.

Key words: Reconstructive surgical procedures; vaginal diseases; androgen resistance syndrome.

RESUMEN

Objetivo: describir la técnica de vaginoplastia de Vecchietti (TVV) en pacientes diagnosticadas con

* Correspondence: Jorge Enrique Aristizábal Duque (Principal Investigator), carrera 51 D N° 62-69/HUSVF, bloque 12 (maternidad). Medellín, Colombia. jead1@une.net.co
Physician and Surgeon; specialist in Obstetrics and Gynecology; en Ginecología y Obstetricia; specialist in Reproductive Medicine. Faculty, Obstetrics and Gynecology Department, Universidad de Antioquia, Medellín, Colombia. jead1@une.net.co

2 Physician and Surgeon; specialist in Epidemiology; specialist in Publication Editing. Faculty, Obstetrics and Gynecology Department, Universidad de Antioquia, Medellín, Colombia.

agenesia vaginal secundaria y hacer una aproximación a la seguridad y eficacia de esta técnica.
Materiales y métodos: cohorte histórica de pacientes con agenesia vaginal secundaria al síndrome de Mayer-Rokitansky-Kuster-Hauser y al síndrome de insensibilidad androgénica, a quienes se les realizó vaginoplastia por técnica de Vecchietti en el Hospital Universitario San Vicente Fundación, institución de referencia, de alta complejidad, en el periodo 2007 a 2012. Se excluyeron quienes tenían una vagina funcional para relaciones coitales. Muestreo consecutivo. Se midieron variables sociodemográficas, clínicas, de seguridad y de eficacia. Se utilizó estadística descriptiva.
Resultados: el principal motivo de consulta fue la amenorrea primaria (69,2 %). Las malformaciones asociadas fueron agenesia renal derecha (15,4 %) y malformaciones esqueléticas (15,4 %). Se presentó una perforación intraoperatoria de la vejiga y tres complicaciones menores (23,1%) en el posoperatorio. En el 84,6% de ellas se obtuvo una vagina funcional a un año de seguimiento.
Conclusiones: la TVV es una técnica quirúrgica simple que ha permitido obtener resultados funcionales satisfactorios con complicaciones menores. Se requieren estudios con grupo control para tener una mejor evaluación de la eficacia de las diferentes técnicas de construcción de la neovagina.
Palabras clave: procedimientos quirúrgicos reconstructivos; enfermedades vaginales; síndrome de resistencia androgénica.

RESUMO

Objetivo: descrever a técnica da vaginoplastia de Vecchietti (TVV) em pacientes diagnosticadas com agenesia vaginal secundária e fazer uma abordagem a respeito da segurança e eficácia desta técnica.
Materiais e métodos: coorte histórica de pacientes com agenesia vaginal secundária à síndrome de Mayer-Rokitansky-Kuster-Hauser e à síndrome de insensibilidade androgênica, que foram submetidas a uma vaginoplastia pela técnica de Vecchietti no Hospital Universitário San Vicente Fundación, es--tabelecimento de referência, de alta complexidade, no período 2007-2012. Foram excluídas aquelas pacientes que tinham uma vagina funcional para relações coitais. Amostragem consecutiva. Foram mensuradas diversas variáveis sociodemográficas, clínicas, de segurança e de eficácia, utilizando o método de estatística descritiva.
Resultados: o principal motivo de consulta foi a amenorreia primária (69,2%). As malformações correlatas foram agenesia renal direita (15,4%) e malformações esqueléticas (15,4 %). Verificou-se uma perfuração intraoperatória da bexiga e três complicações menores (23,1%) no pós-operatório. Em 84,6% delas conseguiu-se uma vagina funcional durante o primeiro ano de acompanhamento.
Conclusão: a TVV é uma técnica cirúrgica simples que permitiu obter resultados funcionais satisfatórios com complicações menores. É preciso levantar estudos com grupo-controle para fazer uma melhor avaliação da eficácia das diferentes técnicas de construção da neovagina.
Palavras chave: procedimentos cirúrgicos reconstrutivos; doenças vaginais; síndrome de resistência androgênica.

INTRODUCTION

Vaginal agenesis is the congenital partial or total absence of the vagina, resulting from two main disorders: uterovaginal agenesis or Mayer-Rokitansky-Kuster-Hauser (MRKH) syndrome, with a prevalence of 1/5,000 live births, and the androgen insensitivity syndrome (AIS), with an estimated prevalence of 1/50,000 live births. Uterine absence or structural abnormality are present in both disorders, affecting sexual and reproductive function in all cases (1).

Different strategies for creating a neovagina have been developed, falling in two categories, namely, surgical and mechanical dilation techniques. Surgical techniques may offer an immediate definitive result or require the use of some form

of vaginal mold for a variable period of time after surgery. These techniques include various intestinal flaps, William's technique and its variants, the Davydov technique, and the use of full thickness skin flaps (2). William's technique is used to create a vestibular sac by means of vulvoplasty, with no dissection of the rectovesical pouch. It does not require the use of dilators, but it has anatomical limitations (3). Ileal and rectosigmoid flaps are the preferred techniques of many surgeons but are also the most complex and most frequently associated with serious complications (4). When the Davydov technique is used, the rectovesical pouch, expanded with peritoneum, is lined through a laparoscopic approach (5).

As far as progressive manual dilation is concerned, although it is a simple strategy, it is more time consuming and requires the availability of trained support staff, and patient commitment to the daily use of the dilator (6). This option includes McIndoe's technique and its variants, Shears' method and Vechietti's technique (7). Shears' method is based on progressive surgical dilation of both Müllerian canals that converge on the vaginal plate through the rectovesical pouch. It does not require tissue coverage of the formed space, but it does require the use of dilators during a variable period of time (8). McIndoe's technique is also a complex modality in which a synthetic mold lined with a free skin flap from the thigh or the gluteal area is introduced into the rectovesical space (9).

En 1979, Vecchietti published a 14-year experience using a dilation technique based on a relatively simple surgical approach in 307 cases of vaginal agenesis of various origins (10). In 1992, Gauwerky introduced the laparoscopic approach (11). Since that time, growing experience and excellent long-term results have led to wide acceptance of this technique in Europe (12). In our case, the knowledge of the technique and the appropriate instruments, similar to the original, was built on the work done in collaboration with professors Bernard Hedon and François Laffargue from the Obstetrics and Gynecology Service of Montpellier I Arnaud de Villeneuve University Hospital in Montpellier.

This technique is seldom used in Colombia and in the Latin-American region, hence the paucity of literature regarding its complications or effectiveness. Therefore, the objective of this study is to describe the Vecchietti vaginoplasty technique (VVT) in patients with vaginal agenesis secondary to MRKH and AIS, and to approach the efficacy and safety of the procedure.

MATERIALS AND METHODS

Design and population. Historical cohort study that included women with a diagnosis of MKRH or AIS who underwent VVT between 2007 and 2012 at San Vicente Fundación University Hospital in the city of Medellín, located in central-western Colombia. This institution serves patients of the contributive regime in the Colombian social security system. Patients with functional vaginal for intercourse were excluded. Consecutive sampling was used.

Procedure. Women in whom this technique was used were identified using the registry of cases intervened in this institution since the technique was introduced in 2007. The principal investigator retrieved the information directly from the institutional electronic clinical record (SAP), using a form especially designed for the study.

Preoperative workup: in patients with MKRH, renal and vertebral malformations were ruled out using ultrasound or magnetic resonance imaging (MRI). In AIS cases, images for assessing gonadal condition and total testosterone measurements were required. Karyotyping was not requested when gonadal pathology testing was available. All the patients underwent a standardized procedure performed by the same senior surgeon.

Description of the surgical technique: the patients are admitted on the same day of the procedure and taken to the operating room. Cleaning, asepsis and antisepsis of the perineal region are

performed in the anesthetized patient. In gynecological position, conventional laparoscopy is carried out using the 11 mm umbilical port and the lateral 6 mm pelvic ports. The next step is the perineal approach. With the index finger of the non-dominant hand placed in the rectal canal, a 14-gauge mandrill needle is introduced into the rectovesical pouch pointing towards the abdomen. Laparoscopy is used to check that the needle comes out exactly on the fibrous cord replacing the uterus, without compromising the bladder or the rectum. The needle in the abdominal cavity is fixed with a strong locked clamp, introduced through any of the laparoscopy pelvic ports (Figure 1).

Cystoscopy is then performed to rule out bladder perforation. If bladder perforation is evidenced, the needle is removed and the procedure is repeated until correct positioning is documented. The mandrill needle is then removed and two 1-0 polyglactin sutures are passed through the needle into de abdominal cavity. Maryland forceps are used for fixation of the sutures and the needle is retired at that point. In the perineal end, a 22 mm high-density teflon sphere is tied to the two sutures, taking care to allow sufficient length for removal days later (Figure 2).

The sutures are pulled through each of the pelvic ports, one on each side. Given the risk of gastrointestinal complications, the sutures must be pulled out on an extraperitoneal plane. To do this, a long steel "fishing" instrument with a modified tip is introduced to retrieve the sutures. An extraperitoneal dissection is performed in order to avoid entering the cavity, going beyond the ovarian plane, to where the sutures are, in the center of the pelvis. The "fishing" device pierces the peritoneum as close to the sutures as possible and the assistant uses the Maryland forceps to grasp one of the sutures in order to introduce it through the hole in the distal end of the "fishing" device. The thread is brought to the hole in the skin for fixation, pulling it along the extraperitoneal plane. The procedure is repeated on the other side (Figure 3).

The Vecchietti retractor is placed in the suprapubic position between the two pelvic ports. Next, the sutures are mounted on the retractor mechanism on each side of the device and well tightened, making as many turns as needed on both sides. The device is supported on the abdominal wall only as a result of the tension of the sutures on both sides. The sphere is no longer visible (Figure 4).

A half-turn must be applied every day on each of the fixators during the first seven days after the surgery, which is equal to approximately 1 centimeter in length. No additional analgesia is needed. The urinary catheter is left in place until discharge due to the risk of urinary retention from the pressure exercised by the sphere on the urethra and trigone.

Postoperative management: the protocol requires postoperative hospital care for seven days. During that time, the retractor is tightened every day and the patient receives education on the use of the silicone vaginal mold. In seven days, a 7-10 cm long vaginal canal is obtained as a result of sustained expansion of the introital mucosa. A marking may be left in the sutures that stick out in order to estimate the depth being gradually achieved. On the seventh day, the urinary catheter is removed, the sutures are cut at the retractor and the sphere is removed by pulling on the sutures exiting through the vagina. Next, the silicone mold is introduced as needed, until the patient can do it on her own. At that point, she is discharged and is instructed to use it permanently and remove it only for physiological functions. The mold is washable and a hydrophilic lubricant is prescribed to help with the introduction. The patient is seen every few days, as many times as needed, in order to ensure adequate use of the mold, and is instructed to return in case she has difficulty introducing it. The mold must be used continuously for three months and then only

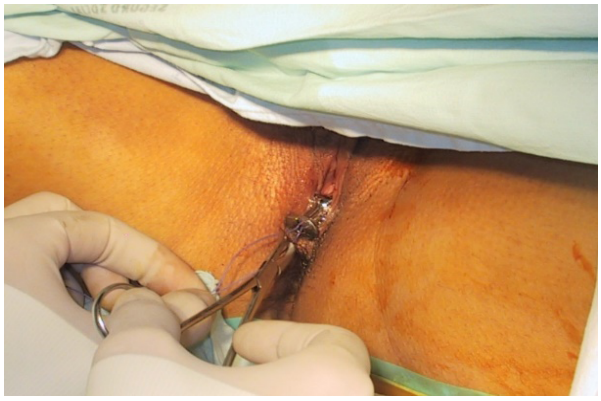


Figure 1. The mandrill needle is passed from the introitus into the abdominal cavity.
Source: Courtesy of the author.

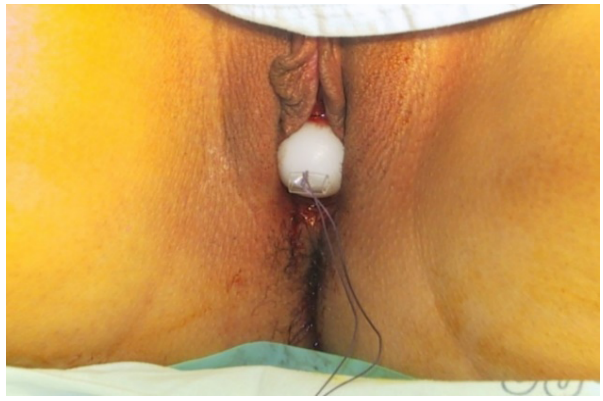


Figure 2. Polyglactin sutures retrieved extra-peritoneally from the pelvis.
Source: Courtesy of the author.

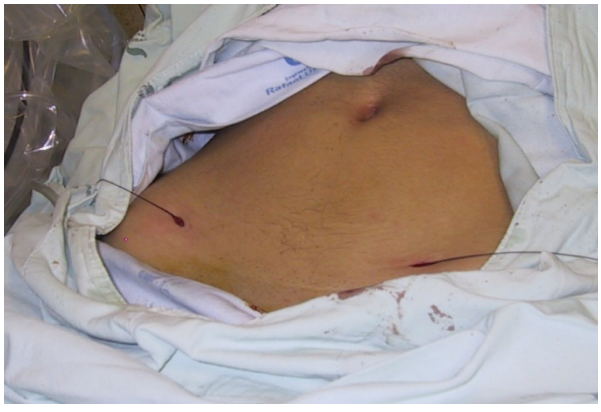


Figure 3. Polyurethane sphere tied to the sutures, in the process of pulling upwards
Source: Courtesy of the author.

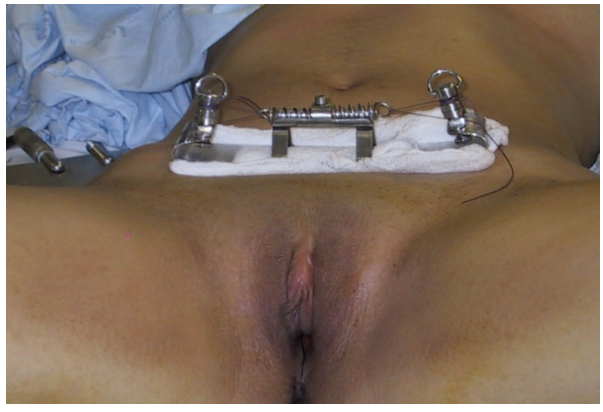


Figure 4. Final appearence of the retractor on the abdomen, with the sutures under tension. The sphere is no longer visible.
Source: Courtesy of the author.

at night during a year. Straight cylindrical silicone molds 3 cm in diameter are currently used.

Follow-up consists of monthly appointments for the first three months, followed by quarterly visits for at least one year. The length of the vagina is determined at the time of discharge and then every three months up to the first year of follow-up based on a measurement in centimeters of penetration of the lower blade of the speculum in the neovagina.

Measured variables: age, initial complaint, diagnosis of renal agenesis or bone malformations seen on diagnostic imaging studies, length of the procedure in minutes according to the anesthesia record, from the start of surgical scrubbing until the end of scrub nurse activities. In terms of intra-operative complications, variables were bladder perforation and bleeding, based on the volume of blood quantified in the suction canister and sponge impregnation. Postoperative complications considered were infections and neovagina stenosis. Efficacy outcome variables were intercourse activity and satisfaction with coital intercourse.

Statistical analysis. For qualitative variables, absolute and relative values were calculated using the total number of women taken to surgery, and means with their respective ranges were calculated

for the quantitative variables. The calculations were done using Microsoft Excel.

Ethical considerations. The informed consent for the procedure was signed by the women or their legal guardians, depending on their age. The study was approved by the Research Ethics Committee of San Vicente Fundación University Hospital. Confidentiality of the information and patient privacy were ensured.

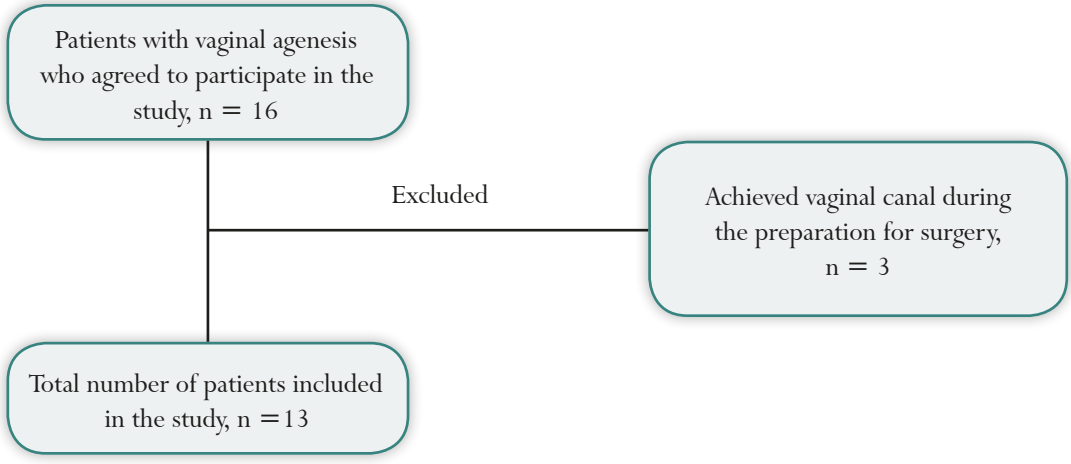
RESULTS

During the study period, care was provided to 16 patients with vaginal agenesis. Of them, 13 met the clinical criteria for VVT, and they were all included in the research study. Three patients were excluded because of their ability to have satisfactory intercourse while waiting for the surgery. Of the 13 patients included, 11 had a diagnosis of MRKH and 2 had a diagnosis of AIS. Follow-up every three months was possible in 11 patients (84%) during at least one year. One patient was lost to follow-up after discharge and a second patient did not return to follow-up after treatment for hematometra (Figure 5).

Mean age was 20.8 years (range: 14- 32). Patient complaints included primary amenorrhea in 9 (69.2 %), apareunia in 3 (23%) and abdominal pain in 1 (7.7%). Four patients had associated malformations: 2 (15.4 %) right renal agenesis, 1 (7.7%) right fibular agenesis, and 1 (7.7%) congenital dislocation of the right hip. Three of the women (23.0%) had undergone laparoscopy in a different institution.

All of the procedures were performed through laparoscopy, with a mean time of 100 minutes (range: 60-180). Mean blood loss during the procedure was 28.4 mL (range: 10-50). There were no laparoscopy-associated complications. There was one case (7.7%) of bladder perforation with the needle. There were no cases of rectal passage of the needle. Mean vaginal length at the time of discharge was 7.2 cm (range: 7-12) in all the patients. In terms of postoperative complications during observation, there were three events (23.1%). In one case (7.7%), the sphere ruptured the expanded tissue and was retained in the peritoneum but did not give rise to negative consequences after it was removed, except pain at the time of removal. There was suture dehiscence in one of the pelvic incisions supporting the retractor in one case. There was one (7.7%) late complication related to persistent bleeding resulting

Figure 5.
Flow diagram showing the patients included in the study on the Vecchietti technique at San Vicente Fundación University Hospital in Medellín, between 2007 and 2012



from granuloma formation due to contact with the acrylic mold used at the time, which required several curettage procedures under anesthesia. In one case of a pediatric patient, there was definitive occlusion of the neovagina due to unmanageable rejection of the vaginal mold, in the context of urgency treatment for hematometra.

A total of 11 patients reported minor issues with intercourse during the first six months (n = 11). At 1-year follow-up, 11 women achieved a mean vaginal length of 9.5 cm (range: 7-12) and were able to use the mold without any significant discomfort. At the 1-year follow-up visit, 11 women reported having intercourse, and 10 (76.9%) reported satisfaction with sexual intercourse. One patient (7.7%) reported that her partner complained constantly during intercourse but, on examination, introduction and opening of the standard disposable speculum was found to be easy and wide. None of the women reported lubrication issues. The two patients with a diagnosis of AIS had undergone bilateral gonadectomy and were receiving hormonal therapy in the form of oral estrogens (Table 1).

DISCUSSION

This study found the technique to be safe, associated with a low frequency of intra- and postoperative complications and no serious complications, and effective in terms of functionality and patient satisfaction. Considering that the only proven vaginal occlusion occurred in a 14-year-old patient, it is worth thinking about postponing this procedure, whenever possible, until the woman has the need to initiate her sexual life.

There are some variations in the technique used in our service when compared with the original description. We have found it easier to pass the sutures through a needle from the perineum, instead of the abdominal cavity. This variant has been described in other publications (13). Daily tightening and discomfort with the retractor required prolonged length of stay, which could be reduced with home hospitalization. Although there was no follow-up of the histological quality of the neovaginal tissue, the appearance on examination with the speculum showed no difference from a normal vagina. Not surprisingly, sexual response was described as satisfactory, given that it depends mostly on clitoris and surrounding areas stimulation.

As far as patient safety is concerned, there were no complications as described in a systematic review (14) which included 162 studies comparing the different techniques for neovagina creation in 4326 patients, including 939 cases of VVT. Among the cases treated with VVT, the authors identified 4 intestinal injuries, 20 urologic injuries and 2 cases of bleeding requiring transfusion of blood products. In terms of immediate postoperative complications, the reports included 24 infections, 5 hematomas and 2 cases of vaginal vault necrosis. In the long-term, they report 5 cases of stenosis and 3 granulomas, complications which were also found in our study. In 62 cases, Cetin, in Turkey, does not report serious complications with this technique (13).

In terms of functionality, our results are similar to those reported by Pastor *et al.* in 42 cases intervened with VVT, with adequate sexual function according to the Female Sexual Function Index (15).

CONCLUSIONS

VVT is a safe procedure resulting in a functional neovagina. Controlled studies are required in order to better assess the effectiveness of the various neovagina creation techniques.

REFERENCES

1. Capraro VJ, Gallego MB (1976) Vaginal agenesis. Am J Obstet Gynecol. 1976;124(1):98-107. https://doi.org/10.1016/0002-9378(76)90020-X
2. Michala L, Cutner A, Creighton SM. Surgical approaches to treating vaginal agenesis. BJOG. 2007;114(12):1455-9. https://doi.org/10.1111/j.1471-0528.2007.01547.x
3. Creatsas G, Deligeoroglou E. Vaginal aplasia and

Table 1.
Summary of the results of women with vaginal agenesis who underwent Vecchietti vaginoplasty at San Vicente Fundación University Hospital in Medellín, Colombia, between 2007 and 2012

Personal history of other malformations	Number of patients, n = 13 (%)
None	9 (69.2)
Right renal agenesis	2 (15.4)
Right fibular agenesis	1 (7.7)
Congenital dislocation of the right hip	1 (7.7)
Complaint	
Primary amenorrhea	9 (69.2)
Abdominal pain	1 (7.7)
Apareunia	3 (23)
Diagnostic tests	
Magnetic resonance imaging (MRI)	5 (38.4)
Ultrasound	3 (23.0)
MRI + Ultrasound	2 (15.4)
Laparoscopy + ultrasound	1 (7.7)
Laparoscopy + MRI	1 (7.7)
Laparoscopy + ultrasound + MRI	1 (7.7)
Complications	
None	9 (69.2)
– Early	
Accidental bladder injury (intra-operative)	1 (7.7)
Vaginal tear (postoperative)	1 (7.7)
Suture dehiscence (postoperative)	1 (7.7)
– Late	
Canal narrowing after treatment for hematometra (follow-up)	1 (7.7)
Final length at one-year follow-up	
12 cm	2 (15.4)
10 cm	5 (38.4)
8.0 cm	3 (23.0)
7.0 cm	1 (7.7)
Unknown	2 (7.7)
Sexual satisfaction	
Satisfied	10 (76.9)
Unsatisfied	1 (7.7)
Unknown (failed to return for follow-up)	2 (15.4)

reconstruction. Best Pract Res Clin Obstet Gynaecol. 2010;24(2):185-91. https://doi.org/10.1016/j. bpobgyn.2009.11.002

4. Bouman M, van Zeijl MC, Buncamper ME, et al. Intestinal vaginoplasty revisited: A review of surgical techniques, complications, and sexual function. J Sex Med. 2014;11: 1835-47. https://doi.org/10.1111/jsm.12538
5. Pravin M, Jyoti M, Rakhi S. New laparoscopic peritoneal pull-through vaginoplasty technique. Reprod Sci. 2014;24(6):181-6.
6. Edmons DK, Rose GL, Lipton MG, Quek J. Mayer-Rokitansky-Küster-Hauser Syndrome: A review of 245 consecutive cases managed by a multidisciplinary approach with vaginal dilators. Fertil Steril. 2012;97(3):686-90. https://doi.org/10.1016/j.fertnstert.2011.12.038
7. ACOG Committee on Adolescent Health Care. ACOG Committee Opinion. Nonsurgical diagnosis and management of vaginal agenesis. Obstet Gynecol. 2002;100(1):213-6. https://doi.org/10.1097/00006250-200207000-00034
8. Kuhn A, Neukomm C, Dreher EF, Imobersteg J, Mueller MD. Prolapse and sexual function 8 years after neovagina according to Shears: A study of 43 cases with Mayer-von Rokitansky-Küster-Hauser syndrome. Int Urogynecol J. 2013;24(6): 1047-52. https://doi.org/10.1007/s00192-012-1980-z
9. Templeman CL, Lam AM, Hertweek SP. Surgical management of vaginal agenesis. Obstet Gynecol Sur v. 1999;54(9):583-91. https://doi.org/10.1097/00006254-199909000-00023
10. Vecchietti G. Le neo-vagin dans le syndrome de Rokitansky-Küster-Hauser. Rev Med Suisse Romande. 1979;99(9):593-601.
11. Brucker SY, Gegusch M, Zubke W, Rall K, Gauwerky JF, Wallwiener D. Neovagina creation in vaginal agenesis: Development of a new laparoscopic Vecchietti-based procedure and optimized instruments in a prospective comparative interventional study in 101 patients. Fertil Steril. 2008;90(5):1940-52. https://doi.org/10.1016/j.fertnstert.2007.08.070
12. Fedele L, Busacca M, Candiani M, Vignali M. Laparo- scopic creation of a neovagina in Mayer-Rokitansky- Küster syndrome by modification of Vecchietti's operation. Am J Obstet Gynecol. 1994;171(1):268-9. https://doi.org/10.1016/0002-9378(94)90482-0
13. Cihan C, Cenk S, Ibrahim F, Murat A, Turan C. Long-term outcomes of laparoscopic bean vaginoplasty (modified Vecchietti procedure) for Mayer-Rokitansky-Kuster-Hauser Syndrome. J Laparoendosc Adv Surg Tech. 2016;26(8): 591-5. https://doi.org/10.1089/lap.2016.0031
14. McQuillan SK, Grover SR. Dilation and surgical management in vaginal agenesis: A systematic review. Int Urogynecol J. 2014;(25):299-311. https://doi.org/10.1007/s00192-013-2221-9
15. Pastor Z, Fronek J, Nováčková M, Chmel R. Sexual life of women with Mayer-Rokitansky-Küster-Hauser Syndrome after laparoscopic Vecchietti vaginoplasty. Sex Med. 2017;5(2):e106-e113. https://doi. org/10.1016/j.esxm.2016.12.003

Conflicto de intereses: ninguno declarado.