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The Culdotomy Two U Procedure for Vaginal Ovarian Cystectomy

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21 Abstract

22 When transvaginal removal of ovarian cysts is performed successfully, the procedure
23 compares favorably with laparoscopy in terms of invasiveness. However, the approach
24 into peritoneal cavity has been laborious. The objective was to evaluate feasibility of
25 an ultrasound-guided culdotomy using a newly-developed umbrella needle. New
26 culdotomy was performed on 36 patients with ovarian cysts. Each cyst was directly
27 punctured by the needle from vagina under ultrasound guidance. The vaginal walls on
28 both sides of the needle were incised with an electric scalpel. Through wound, cyst
29 was exteriorized and enucleated. Preoperative characteristics of patients, outcome,
30 operating time, blood loss, complications, and cyst histology were analyzed.
31 Culdotomy was performed successfully in all cases. Operating time was less than 10
32 minutes and blood loss was less than 10 ml. There were no culdotomy-associated
33 complications. Culdotomy assisted by ultrasound imaging and an umbrella needle is a
34 simple, safe, and reliable method for vaginal ovarian cystectomy.

35 Introduction

36 Since the establishment of minimally invasive surgery with the introduction of
37 laparoscopy, new procedures following this concept have been developed. Natural
38 orifice transluminal endoscopic surgery (NOTES) has become an area of great
39 interest.^{1,2} In NOTES, natural orifices such as the mouth, anus, urethra, and vagina are
40 used as ports of entry into the peritoneal cavity through which the flexible endoscopic
41 devices are passed. Although NOTES currently has unresolved issues, the elimination
42 of an abdominal incision is expected to result in the less invasive surgery. Among
43 natural orifices, the transvaginal route is considered to be the most promising for the
44 peritoneal cavity access.³

45 In the gynecological arena, the use of the vaginal route for the removal of ovarian
46 cysts is currently being reevaluated.⁴⁻⁷ In laparoscopically assisted vaginal ovarian
47 cystectomy, following laparoscopic inspection, the ovarian cyst is enucleated via the
48 vaginal route. Alternatively, the enucleation is done laparoscopically and the excised
49 mass extracted vaginally. The merits of this procedure compared to a laparoscopic
50 cystectomy are that it permits removal of larger ovarian cysts, has a shorter operating
51 time, and results in less cyst spillage. In laparoscopically supported vaginal ovarian

cystectomy, the cystectomy is initially approached transvaginally, and in the cases in which a transvaginal extraction is impossible, laparoscopy is used to complete the operation.⁸ The merits of this system are that an abdominal incision can be avoided in most patients treated and the remaining patients can be salvaged by laparoscopy; thus, a laparotomy is avoided in all cases. In both NOTES and an ovarian cystectomy, the use of a vaginal route may greatly contribute to the progress in the minimally invasive surgery.

In an ovarian cystectomy using a transvaginal route, a culdotomy is one of the most important steps.⁹⁻¹⁰ Especially in the laparoscopically supported system beginning with a vaginal approach, a successful culdotomy is an essential step.¹¹ The peritoneal cavity cannot be entered without an accurate vaginal wall incision, and a blind incision may occasionally injure the rectum.¹² We previously presented the new culdotomy technique using an ultrasonographic guidance and a renal balloon dilator catheter; this procedure facilitates the flawless performance of a culdotomy.¹¹ Visualization by ultrasound ensured safe entry into the cul-de-sac without complications. The drawback of this method, however, was that this multi-step procedure using a balloon dilator, took longer to perform than a traditional culdotomy; therefore, it was not

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69 practical. Simplification of the technique was our next objective.

70 In this report, we present a novel, simplified culdotomy technique using a newly

71 developed needle. The purpose of the present study was to evaluate the feasibility and

72 effectiveness of this method, which we termed “Culdotomy Two U.”

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Materials and Methods

We performed vaginal ovarian cystectomies via ultrasound-guided culdotomy with an umbrella Hakko needle on 35 patients with presumed benign unilateral ovarian cysts and one with bilateral cysts; the procedures were performed between June 2006 and March 2010 at Kanazawa University Hospital or Sagawa Clinic.

The patients were required to be non-virginal for employment of the transvaginal route. The inclusion criteria for patients with an ovarian cyst were: presumed to be benign; located in the cul-de-sac; and presumed absence of extensive adhesions. The presence of one or more of the following sonographic criteria was considered to increase the index of suspicion for a malignancy: multilocular appearance; irregular border; intracystic papillary vegetation; or the presence of ascites.¹³⁻¹⁵ In some cases magnetic resonance imaging (MRI) was used to distinguish mature cystic teratomas or endometriomas from other ovarian tumors (including malignancies). Teratomas with serum squamous cell carcinoma antigen (SCC) levels outside of the normal range (> 1.5 ng/ml) were excluded, because of the possibility that teratomas with a SCC beyond the normal value may have a malignant transformation.¹⁶⁻¹⁸ Teratomas with alpha-fetoprotein levels outside of the normal range were also excluded because of the

possibility of an immature cystic teratoma.¹⁹ Cyst location was determined by preoperative transvaginal sonography and patients with at least one ovarian cyst located in the cul-de-sac were included. The adhesion is examined on bimanual examination or pre-operative ultrasound examination. The cases of endometriomas in which the women without infertility and dysmenorrhea desires no scar and the cyst is deemed not to be adherent, were included.

For each patient, the following parameters were included in the analysis: age, body mass index, parity, the diameters of ovarian cysts, outcome of culdotomy, operating time for culdotomy, blood loss during culdotomy, complications of culdotomy, C-reactive protein (CRP) level on postoperative day 3, and histology. Some data were reported as mean $\pm$ standard deviation or n (%).

The following procedure was used for each culdotomy. Patients were administered enemas on both the day prior to and the day of surgery. The culdotomy was performed with the patient in the dorsal lithotomy position on the operating table, under general or spinal anesthesia. A speculum was placed in the vagina and the cervix was visualized and grasped with forceps. A vaginal ultrasound probe with a needle guide was then inserted into the vagina. The ovarian cyst was directly punctured under ultrasound

guidance with an umbrella Hakko needle via the center of the posterior vaginal fornix.

Following ultrasonographic confirmation of the placement of the top of the umbrella

needle into the cyst, the umbrella portion of the needle was opened and stabilized by

forceps and an inner needle was inserted. Following the extraction of the ultrasound

probe with a needle guide from the vagina, the needle remained, penetrating the center

of the posterior vaginal fornix. While the needle was gently retracted towards the

operator's side, the vaginal walls on both sides of the needle were incised with an

electric scalpel. Following an adequate incision of the vaginal wall, the ovarian cyst

wall was visible in the cul-de-sac through the vaginal defect. By bluntly enlarging the

defect in the vaginal wall with forceps, the culdotomy was completed.

The ovarian cyst was then partially exteriorized through the vaginal wall defect with

gentle traction on the umbrella Hakko needle towards the operator's side. The cyst

contents were aspirated with another needle to reduce its volume and permit complete

exteriorization. After the descent of the cyst into the vagina, a transvaginal ovarian

cystectomy was performed in a manner similar to that of a laparotomy. The culdotomy

was then closed with a suture.

The umbrella Hakko needle consists of a 19-gauge, 30-cm-long, metal needle with

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124 an overcoat. The metal needle and the overcoat are fixed at the top of the needle.
125 The needle has four 10-mm, longitudinal slits beginning 2 mm below the overcoat tip.
126 By moving the overcoat, these slits enable this portion of the needle to open in an
127 umbrella-like fashion. The umbrella can then be held open by stabilizing the needle
128 and the overcoat with forceps. This needle has two attachments. One is an inner
129 needle and the other is a screw. The tip of the inner needle is dull to prevent injury to
130 the bowel or other tissues in the cul-de-sac when it is inserted into the metal needle.
131 The screw is used to fix the metal needle to the overcoat prior to removal of the forceps.
132 The umbrella Hakko needle is a newly-developed device that is not yet approved for
133 medical use. The Kanazawa University Hospital ethics committee authorized the
134 experimental use of this device in our patients. A full explanation of the device was
135 provided to the patients and all gave informed consent prior to participating in the study.

Results

The mean age was 32.3 years with a standard deviation of 5.7 years. The mean body mass index was 20.7 with a standard deviation of 3.1. Twenty-three patients (64%) were nulliparas. The mean maximum cyst diameter was 6.9 cm with a standard deviation of 2.1 cm.

In all cases, culdotomy was successfully performed; the operating time was less than 10 minutes and the blood loss was less than 10 ml. There were no culdotomy-associated complications, including rectal injury. The mean CRP value on postoperative day 3 was 1.47 mg/dl with a standard deviation of 1.25 mg/dl.

Histological examination of the resected specimens demonstrated eighteen teratomas, eleven serous cystadenomas, three endometriomas, and four mucinous cystadenoma.

There were no cases of malignancy.

148 Discussion

149 Culdotomy for transvaginal removal of ovarian cysts is sometimes laborious. In a
150 vaginal hysterectomy, the other operative steps can replace the unsuccessful culdotomy,
151 and culdotomy can be re-challenged after several successful steps. Unlike a
152 culdotomy for a vaginal hysterectomy, that step for an ovarian cystectomy must be
153 successfully accomplished at the beginning of the operation; this is because the other
154 operative steps cannot be started without the entering the cul-de-sac. A
155 poorly-executed culdotomy should be avoided because the cicatrices in the cul-de-sac
156 may cause subsequent dyspareunia. Needless to say, rectal injury must be avoided.
157 A reliable and safe culdotomy technique is needed for a vaginal ovarian cystectomy.

158 Direct centesis of the ovarian cyst under ultrasound guidance is a marked
159 characteristic of our culdotomy technique. We positively utilize the fact that most
160 ovarian cysts are located in the cul-de-sac. In such cases, transvaginal ultrasound can
161 easily visualize the safe vaginal area for the entry into the cul-de-sac; this area is
162 between the cyst and the ultrasound probe. The needle penetrating from the vaginal
163 side toward the cyst is a useful guide for the accurate incision of the vaginal wall.

164 Visualization by ultrasound and direct centesis prevent intestinal and rectal injuries and

165 always lead to successful culdotomy.

166 The culdotomy technique described in this report employed a newly-developed
167 device, the umbrella Hakko needle. This method simplifies our previously-developed
168 method that uses a balloon dilator.¹¹ The mean operating time was shortened from 23
169 minutes to less than 10 minutes. This is because culdotomy with the umbrella Hakko
170 needle eliminates several steps required when the balloon dilator is used. Ultrasound
171 guidance and centesis using the umbrella needle are key to this practical culdotomy
172 procedure. Thus, we named this procedure “Culdotomy Two U,” for ultrasound and
173 umbrella.

174 The umbrella Hakko needle has some noteworthy features. The most important
175 feature is the guidance for cul-de-sac entry. If only we incise the vaginal wall on both
176 sides of the needle, the intraperitoneal cavity can be opened without exception. In this
177 technique, we do not have to possess any excellent skills in regard to experience and
178 intuition. After the centesis of the cyst, the needle is fixed in an umbrella-like fashion
179 and the top of the needle is maintained within the cyst. This prevents the cyst from
180 withdrawing into the pelvic cavity and eliminates the difficulty of locating the cyst after
181 culdotomy. The needle is gently pulled towards the operator’s side to incise the

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182 vaginal wall. The opened umbrella is useful to prevent the needle from escaping.

183 Moreover, the traction of the opened needle is expected to fill in a tiny hole caused by

184 the centesis and to diminish the spillage of the cyst contents.

185 We must take into consideration the influences of intraperitoneal spillage of cyst

186 contents. When we perform an ovarian cystectomy, either laparoscopically or

187 transvaginally, it is theoretically impossible to avoid intraperitoneal spillage in all

188 cases.²⁰ Thus, it is imperative to preoperatively minimize the possibility of an ovarian

189 malignancy. Meticulous preoperative studies, including ultrasound, MRI, and tumor

190 markers are essential; all cases of possible malignancy should be excluded.¹³⁻¹⁹ In

191 some cases in which preoperative examinations don't perfectly deny the possibility of

192 malignancy, laparoscopy should be selected because laparoscopic inspection may be

193 useful to find low ovarian malignancy. Chemical inflammation after intraperitoneal

194 spillage also must be avoided. The mean CRP value on postoperative day 3 was 1.47

195 mg/dl and statistically equal to that of laparoscopic ovarian cystectomy cases (data not

196 shown). These results suggest that intraperitoneal spillage is minimal and chemical

197 inflammation does not occur. However, the degree of intraperitoneal spillage should

198 be estimated using a different method. Currently, in some cases, we perform the

intraperitoneal observation with a flexible culdoendoscope during a vaginal ovarian cystectomy. Using this scope, it is possible not only to observe but also to irrigate the pelvic cavity; thus, this method may become useful as a routine procedure for vaginal ovarian cystectomy.

We cannot adopt the Culdotomy Two U procedure in all benign ovarian cysts. In cases in which the ovarian cyst is out of cul-de-sac, we adopt either of the following two methods. When the cyst is only a short distance from the cul-de-sac, the Culdotomy FourS Two U procedure is selected; in this procedure, an artificially-developed, saline solution space in the cul-de-sac is punctured by the umbrella needle.³ When the cyst is located on the anterior surface of the uterus, we employ an anterior colpotomy, using the traditional method of incising the anterior vaginal fornix.⁸

When an ovarian cystectomy is successfully completed vaginally, it compares favorably to laparoscopic surgery in terms of its invasiveness. Vaginal surgery has the additional benefit of no visible scarring. The culdotomy is one of the most important steps in completing the transvaginal removal of ovarian cysts; thus, we focused on optimizing the culdotomy procedure. The Culdotomy Two U procedure provides a simple, safe, and reliable method and we expect that a vaginal ovarian cystectomy will

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216 become more accessible to both patients and gynecologists desiring minimally invasive
217 surgery.

For Peer Review

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Figure Legends

Figure 1. Sagittal view of the pelvis illustrating the Culdotomy Two U procedure.

The ovarian cyst is directly punctured transvaginally with an umbrella Hakko needle under ultrasound guidance and the umbrella portion of the needle is opened.

c: ovarian cyst; us: ultrasound probe; um: umbrella Hakko needle

Figure 2. The Culdotomy Two U procedure.

A. With the patient in the dorsal lithotomy position, the ovarian cyst is punctured under ultrasound guidance through a needle guide; an umbrella Hakko needle is inserted at the center of the posterior vaginal fornix.

B. The ovarian cyst is punctured transvaginally under ultrasound guidance with an umbrella Hakko needle and the umbrella portion of the needle is opened within the cyst.

C. The umbrella Hakko needle penetrates the center of the posterior vaginal fornix.

D. With gentle traction on the needle towards the operator's side, the vaginal walls on both sides of the needle are incised with an electric scalpel.

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289 E. Following an adequate incision, the ovarian cyst wall is visible, punctured by an
290 umbrella needle.

291 F. The cyst wall is enucleated transvaginally.

292

293 **Figure 3.** The umbrella Hakko needle.

294 A. The body and attachments; an inner needle with a screw.

295 B. The umbrella portion is closed.

296 C. The umbrella portion is opened.

297 D. An inner needle is inserted into the opened umbrella needle.

Fig.1

Review

Fig.2

Review

Fig3 **A** **B****C****D**

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