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.

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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 translumenal 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

52	cystectomy, the cystectomy is initially approached transvaginally, and in the cases in
53	which a transvaginal extraction is impossible, laparoscopy is used to complete the
54	operation. ⁸ The merits of this system are that an abdominal incision can be avoided in
55	most patients treated and the remaining patients can be salvaged by laparoscopy; thus, a
56	laparotomy is avoided in all cases. In both NOTES and an ovarian cystectomy, the use
57	of a vaginal route may greatly contribute to the progress in the minimally invasive
58	surgery.
59	In an ovarian cystectomy using a transvaginal route, a culdotomy is one of the most
60	important steps. ⁹⁻¹⁰ Especially in the laparoscopically supported system beginning
61	with a vaginal approach, a successful culdotomy is an essential step. ¹¹ The peritoneal
62	cavity cannot be entered without an accurate vaginal wall incision, and a blind incision
63	may occasionally injure the rectum. ¹² We previously presented the new culdotomy
64	technique using an ultrasonographic guidance and a renal balloon dilator catheter; this
65	procedure facilitates the flawless performance of a culdotomy. ¹¹ Visualization by
66	ultrasound ensured safe entry into the cul-de-sac without complications. The
67	drawback of this method, however, was that this multi-step procedure using a balloon
68	dilator, took longer to perform than a traditional culdotomy; therefore, it was not

- Simplification of the technique was our next objective. 69 practical.
- 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
- effectiveness of this method, which we termed "Culdotomy Two U." 72

n

73 Materials and Methods

74	We performed vaginal ovarian cystectomies via ultrasound-guided culdotomy with
75	an umbrella Hakko needle on 35 patients with presumed benign unilateral ovarian cysts
76	and one with bilateral cysts; the procedures were performed between June 2006 and
77	March 2010 at Kanazawa University Hospital or Sagawa Clinic.
78	The patients were required to be non-virginal for employment of the transvaginal
79	route. The inclusion criteria for patients with an ovarian cyst were: presumed to be
80	benign; located in the cul-de-sac; and presumed absence of extensive adhesions. The
81	presence of one or more of the following sonographic criteria was considered to
82	increase the index of suspicion for a malignancy: multilocular appearance; irregular
83	border; intracystic papillary vegetation; or the presence of ascites. ¹³⁻¹⁵ In some cases
84	magnetic resonance imaging (MRI) was used to distinguish mature cystic teratomas or
85	endometriomas from other ovarian tumors (including malignancies). Teratomas with
86	serum squamous cell carcinoma antigen (SCC) levels outside of the normal range (> 1.5
87	ng/ml) were excluded, because of the possibility that teratomas with a SCC beyond the
88	normal value may have a malignant transformation. ¹⁶⁻¹⁸ Teratomas with
89	alpha-fetoprotein levels outside of the normal range were also excluded because of the

90	possibility of an immature cystic teratoma. ¹⁹ Cyst location was determined by
91	preoperative transvaginal sonography and patients with at least one ovarian cyst located
92	in the cul-de-sac were included. The adhesion is examined on bimanual examination
93	or pre-operative ultrasound examination. The cases of endometriomas in which the
94	women without infertility and dysmenorrhea desires no scar and the cyst is deemed not
95	to be adherent, were included.
96	For each patient, the following parameters were included in the analysis: age, body
97	mass index, parity, the diameters of ovarian cysts, outcome of culdotomy, operating
98	time for culdotomy, blood loss during culdotomy, complications of culdotomy,
99	C-reactive protein (CRP) level on postoperative day 3, and histology. Some data were
100	reported as mean \pm standard deviation or n (%).
101	The following procedure was used for each culdotomy. Patients were administered
102	enemas on both the day prior to and the day of surgery. The culdotomy was performed
103	with the patient in the dorsal lithotomy position on the operating table, under general or
104	spinal anesthesia. A speculum was placed in the vagina and the cervix was visualized
105	and grasped with forceps. A vaginal ultrasound probe with a needle guide was then
106	inserted into the vagina. The ovarian cyst was directly punctured under ultrasound

107	guidance with an umbrella Hakko needle via the center of the posterior vaginal fornix.
108	Following ultrasonographic confirmation of the placement of the top of the umbrella
109	needle into the cyst, the umbrella portion of the needle was opened and stabilized by
110	forceps and an inner needle was inserted. Following the extraction of the ultrasound
111	probe with a needle guide from the vagina, the needle remained, penetrating the center
112	of the posterior vaginal fornix. While the needle was gently retracted towards the
113	operator's side, the vaginal walls on both sides of the needle were incised with an
114	electric scalpel. Following an adequate incision of the vaginal wall, the ovarian cyst
115	wall was visible in the cul-de-sac through the vaginal defect. By bluntly enlarging the
116	defect in the vaginal wall with forceps, the culdotomy was completed.
117	The ovarian cyst was then partially exteriorized through the vaginal wall defect with
118	gentle traction on the umbrella Hakko needle towards the operator's side. The cyst
119	contents were aspirated with another needle to reduce its volume and permit complete
120	exteriorization. After the descent of the cyst into the vagina, a transvaginal ovarian
121	cystectomy was performed in a manner similar to that of a laparotomy. The culdotomy
122	was then closed with a suture.

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

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.

136 **Results**

- 137 The mean age was 32.3 years with a standard deviation of 5.7 years. The mean
- 138 body mass index was 20.7 with a standard deviation of 3.1. Twenty-three patients
- 139 (64%) were nulliparas. The mean maximum cyst diameter was 6.9 cm with a standard
- 140 deviation of 2.1 cm.
- 141 In all cases, culdotomy was successfully performed; the operating time was less than
- 142 10 minutes and the blood loss was less than 10 ml. There were no
- 143 culdotomy-associated complications, including rectal injury. The mean CRP value on
- 144 postoperative day 3 was 1.47 mg/dl with a standard deviation of 1.25 mg/dl.
- 145 Histological examination of the resected specimens demonstrated eighteen teratomas,
- 146 eleven serous cystadenomas, three endometriomas, and four mucinous cystadenoma.
- 147 There were no cases of malignancy.

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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

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 Ic 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

199	intraperitoneal observation with a flexible culdoendoscope during a vaginal ovarian
200	cystectomy. Using this scope, it is possible not only to observe but also to irrigate the
201	pelvic cavity; thus, this method may become useful as a routine procedure for vaginal
202	ovarian cystectomy.
203	We cannot adopt the Culdotomy Two U procedure in all benign ovarian cysts. In
204	cases in which the ovarian cyst is out of cul-de-sac, we adopt either of the following two
205	methods. When the cyst is only a short distance from the cul-de-sac, the Culdotomy
206	FourS Two U procedure is selected; in this procedure, an artificially-developed, saline
207	solution space in the cul-de-sac is punctured by the umbrella needle. ³ When the cyst is
208	located on the anterior surface of the uterus, we employ an anterior colpotomy, using the
209	traditional method of incising the anterior vaginal fornix. ⁸
210	When an ovarian cystectomy is successfully completed vaginally, it compares
211	favorably to laparoscopic surgery in terms of its invasiveness. Vaginal surgery has the
212	additional benefit of no visible scarring. The culdotomy is one of the most important
213	steps in completing the transvaginal removal of ovarian cysts; thus, we focused on
214	optimizing the culdotomy procedure. The Culdotomy Two U procedure provides a
215	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.

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Jb.

272 Figure Legends

273

- Figure 1. Sagittal view of the pelvis illustrating the Culdotomy Two U procedure.
- 275 The ovarian cyst is directly punctured transvaginally with an umbrella Hakko needle
- 276 under ultrasound guidance and the umbrella portion of the needle is opened.
- 277 c: ovarian cyst; us: ultrasound probe; um: umbrella Hakko needle
- 278
- Figure 2. The Culdotomy Two U procedure.
- A. With the patient in the dorsal lithotomy position, the ovarian cyst is punctured under
- 281 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
- 284 umbrella Hakko needle and the umbrella portion of the needle is opened within the
- 285 cyst.
- 286 C. The umbrella Hakko needle penetrates the center of the posterior vaginal fornix.
- 287 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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- 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.
- A. The body and attachments; an inner needle with a screw.
- 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

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