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► **To cite this version:**

Isabelle Enderle, Ludivine Dion, Estelle Bauville, Pierre-Yves Moquet, Jean Leveque, et al.. Surgical management of isthmocele symptom relief and fertility. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, 2020, 247, pp.232-237. 10.1016/j.ejogrb.2020.01.028 . hal-02498464

HAL Id: hal-02498464

<https://hal-univ-rennes1.archives-ouvertes.fr/hal-02498464>

Submitted on 2 Apr 2020

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1 Surgical management of isthmocele: symptom relief and fertility.

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30 Key words: isthmocele, surgery, fertility

31 Disclosure statements:

32 The authors declare that they have no competing interests.

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35 Précis: Isthmocele surgery is effective for relieving abnormal uterine bleeding and pain
36 regardless of the surgical route.

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Accepted manuscript

39 ABSTRACT:

40 Objective: To describe the effect of isthmocele surgery by hysteroscopy, the vaginal approach
41 and laparotomy on symptoms, fertility and quality of life.

42 Study design: We conducted a retrospective study of all patients who underwent surgery for
43 symptomatic isthmocele from January 2012 to December 2017 in two tertiary referral centers
44 in Rennes (France). The following data were collected: surgical procedure, symptoms and
45 fertility before and after surgery, patient satisfaction about the surgery, and quality of life after
46 surgery.

47 Results: Eighteen patients were included. The mean duration of follow-up was 15 months.
48 Surgical procedures consisted of hysteroscopy (n=5/18, 27.8%), vaginal surgery (n=8/18,
49 44.4%) and laparotomy (n=5/18, 27.8%). Surgical indications were: secondary infertility
50 (n=10/18, 55 %), pelvic pain (n=5/18, 28%) and abnormal uterine bleeding (n=3/18, 17%).
51 Among patients with abnormal uterine bleeding, improvement was obtained after
52 hysteroscopy, laparotomy and vaginal surgery for 83.3%, 75% and 50%, respectively. Among
53 those with pelvic pain, improvement was obtained after hysteroscopy, laparotomy and vaginal
54 surgery for 80%, 81% and 66%, respectively. One patient (1/18, 5.5%) experienced a post-
55 operative complication. Of the 12 patients who wished to conceive 11 pregnancies were
56 obtained (91.7%). Of the 10 patients with secondary infertility, six became pregnant (60%).
57 Five pregnancies (5/11 ,45.4%) were carried to full term, including four in patients whose
58 surgical indication was infertility. Among these, one patient had a vaginal delivery (after vaginal
59 surgery) without obstetric complication. All patients who underwent hysteroscopy would
60 recommend this surgery versus 75% of patients with vaginal surgery and 60% of patients with
61 laparotomy. Pain and quality-of-life scores were comparable between the three groups.

62 Conclusion: Isthmocele surgery is effective for abnormal uterine bleeding and pain regardless
63 of the surgical route.

64

65 Introduction

66 The rate of cesareans has been gradually increasing in western countries over the
67 last 30 years and has resulted in an increased prevalence of caesarean scar defect (or
68 isthmocele) and cesarean scar pregnancy. Isthmocele was first described by Morris in 1995
69 [1]. On ultrasound, it is defined as a triangular anechoic structure of 2mm at the site of a
70 previous cesarean section [2]. It may be responsible for symptoms such as pelvic pain,
71 abnormal uterine bleeding and infertility and have an impact of quality of life. The reported
72 prevalence of isthmocele varies from 19.4% to 88% depending on the study [3–5].

73 Surgical procedures for isthmocele include hysteroscopy, vaginal surgery,
74 laparoscopy and laparotomy. In the absence of recommendations, the choice of the optimal
75 surgery route depends mainly on the measurement of the isthmocele and future desire of
76 pregnancy. Overall though, to date, few studies have reported objective outcomes of
77 isthmocele surgery, especially concerning fertility and quality of life.

78 Here, we report a series of patients who underwent surgical isthmocele
79 management. The aim of the study was to assess symptoms, post-surgical fertility outcome
80 and quality of life.

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84 Material and Methods

85 *Study design*

86 We performed a retrospective study at two tertiary referral centers in Rennes (France):
87 the University Hospital of Rennes and La Sagesse Medical Centre. All included patients gave
88 their consent. The Ethics Committee of the National College of the French Gynecologists and
89 Obstetricians approved the study (reference number: CEROG 2018-OBS-0801).

90 *Patients*

91 All patients aged over 18 years who underwent surgical management for isthmocele
92 between 1st January 2012 to 31st December 2017 were included and asked to complete a
93 written questionnaire.

94 *Diagnosis*

95 Symptoms related to isthmocele were: chronic pelvic pain, dyspareunia, abnormal
96 uterine bleeding and secondary infertility. All clinical diagnoses were confirmed by ultrasound
97 imaging. The following measurements of the isthmocele were reported: depth, width and
98 residual myometrial thickness.

99 *Surgery*

100 All the surgical procedures were performed by one of three surgical routes –
101 hysteroscopy, vaginal surgery or laparotomy – according to the surgeon's choice. The surgical
102 procedures are summarized below.

103 *Hysteroscopy:* The uterine cavity is distended using NaCl solution. Positive pressure is
104 ensured with an automatic pressure infusor. The inferior and superior edges of the defect are
105 resected using a cutting loop and coagulation is performed on the thinnest part of the scar [6].

106 *Vaginal surgery:* After sterile preparation and bladder catheterization, a vaginal retractor is
107 inserted to visualize the cervix uteri, and the anterior lip of the cervix held with grasping forceps.

108 At a distance of 0.5cm below the reflexed vesico-cervical area, an anterior incision is made
109 from the 3 to 9 o'clock position. The bladder is then dissected away from the uterus. After
110 entering the abdominal cavity and completely exposing the cervical and lower uterine
111 segments, a uterine probe is placed into the uterine cavity through the cervix and slid down
112 from the bottom of the uterus to the cervix. The surgeon then evaluates the thickness of the
113 lower uterine segment of the isthmocele with the index finger. The isthmocele tissue is cut to
114 the normal healthy muscle using a knife and dissecting scissors. The probe remains in place
115 as a marker, and the incision closed with a double layer of 1-0 absorbable interrupted sutures.
116 The peritoneum is sutured followed by the incision in the cervical vaginal area [7,8].

117 *Laparotomy:* Laparotomy surgery is performed by a low transverse Pfannenstiel incision. The
118 first step consists of dissecting the isthmocele below the site of the reflexed vesico-cervical
119 area. The fibrous fascia is then opened to access the scar defect. All the pathological tissue is
120 cut to the normal healthy muscle and the incision closed in two layers [9].

121 *Data collection*

122 The following patient characteristics were retrospectively collected from medical
123 records: age, body mass index (BMI), history of pelvic surgery and cesarean section, number
124 of pregnancies and deliveries, cesarean defect size and residual myometrial thickness on
125 imaging, details of the surgical procedure performed, pre-operative pain (chronic pelvic pain,
126 dyspareunia) by means of a validated visual analogue scale (VAS), abnormal uterine bleeding
127 and desire to conceive after surgery. At the beginning of the study, the patients were asked to
128 complete a questionnaire including information about obstetric history, post-operative pain
129 (chronic pelvic pain, dyspareunia) by means of a validated visual analogue scale (VAS),
130 abnormal uterine bleeding and desire to conceive after surgery.

131 The Clavien-Dindo classification system was used to classify post-operative
132 complications.

133 All the women had at least 6 months of post-surgical follow-up. We used World Health
134 Organization criteria to define infertility: absence of a pregnancy for at least 12 months among
135 the women wishing to conceive.

136 Patient satisfaction about their surgery was evaluated by the questions: "Are you
137 satisfied with your surgery?" "Would you recommend this surgery to your friend?" Patient
138 quality of life and general health status was evaluated by two questionnaires: the EQ-5D-5L
139 and EQ-VAS (EuroQol Visual Analogue Scales).

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140 Results

141 *Population (Table 1)*

142 Among the 23 patients who underwent surgical treatment for an isthmocele during the
143 study period, three declined to participate and two were lost to follow-up. The study population
144 was thus composed of 18 patients (Figure 1). Five (27.8%) patients were operated on by
145 hysteroscopy, eight (44.4%) by vaginal surgery, and five (27.8%) by laparotomy.

146 The median duration of follow up was 15 months (8-85 months).

147 Table 1 summarized the characteristics of the study population. Four patients had a
148 history of primary infertility. The median number of cesarean sections was two (1-3).

149 The main indications for surgery were infertility (n=10, 55%), pelvic pain (n=5, 28%)
150 and abnormal uterine bleeding (n=3, 17%).

151 Chronic pelvic pain was the most frequent symptom (11 patients, 61.1%), followed by
152 metrorrhagia (9 patients, 50%), menorrhagia (8 patients, 44.4%), dysmenorrhea (8 patients,
153 44.4%) and dyspareunia (6 patients, 33.3%). Pain intensity was evaluated as 3.5 for chronic
154 pelvic pain, 2.9 for dysmenorrhea, and 2.9 for dyspareunia by VAS. The median depth of the
155 isthmocele was 13mm, the median width was 11mm, and the median residual myometrial
156 thickness was 2mm.

157 *Surgery (Table 2)*

158 Isthmocele size and residual myometrial thickness were comparable regardless of the
159 surgical procedure.

160 The median hospital stay was 3 days for both laparotomy and vaginal surgery. All the
161 hysteroscopies were outpatient procedures.

162 One intraoperative complication occurred: a bladder injury during vaginal surgery,
163 which was immediately sutured and required bladder catheterization for 15 days.

164 One Clavien-Dindo Grade I complication occurred: a scar hematoma that resolved
165 spontaneously after laparotomy.

166 Among the patients who presented with abnormal uterine bleeding, improvement was
167 obtained after hysteroscopy, laparotomy and vaginal surgery for 83.3%, 75% and 50%,
168 respectively. Among those with pelvic pain, improvement was obtained after hysteroscopy,
169 laparotomy and vaginal surgery for 80%, 81% and 66%, respectively. There was no difference
170 in total improvement after surgery according to the surgical route.

171 Surgery was unsuccessful for three patients who required additional surgery (two after
172 vaginal surgery and one after laparotomy).

173 *Fertility (Table 3)*

174 Twelve patients (12/18, 66.7%) wished to conceive: four underwent hysteroscopy,
175 five vaginal surgery and three laparotomy. Among the patients operated on for infertility (n=10),
176 six conceived (6/10, 60%) resulting in five miscarriages and three live births. Overall, 11 (11/12,
177 92%) pregnancies were obtained without any difference between surgery procedures. The
178 average time to conception was 14 months.

179 All the patients who underwent hysteroscopy and who wished to conceive were
180 successful with an average time to conception of 13.3 months (three pregnancies after *in vitro*
181 fertilization and one spontaneous pregnancy).

182 After vaginal surgery, four of the five patients who wished to conceive were successful
183 (two spontaneous pregnancies and two after fertility treatment).

184 After laparotomy, two of the three patients who wished to conceive were successful
185 (one spontaneous pregnancy and one after fertility treatment).

186 *Obstetric outcomes*

187 Among the 11 pregnancies obtained after surgery, six terminated in a miscarriage and
188 the remaining five (5/11, 45.5%) were carried to full term. Four patients (4/5, 80%) delivered

189 by cesarean section and one (1/5, 20%) by vaginal delivery (spontaneous pregnancy after
190 vaginal surgery). There appeared to be no difference in time to conception, type of conception
191 (spontaneous or fertility treatment), or mode of delivery between the three surgical procedures.

192 *Patient satisfaction*

193 All the patients who underwent hysteroscopy (n=5) reported they would recommend
194 this surgery versus 75% operated on by vaginal surgery (n=6) and 60% by laparotomy (n=3).
195 The average EQ-VAS score was 87 after hysteroscopy, and 84 after vaginal surgery and
196 laparotomy. No mobility, autonomy deficit or dependence in carrying out activities of daily living
197 were noted with the EQ5D-5L score.

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199 Discussion

200 This retrospective study suggests that isthmocele repair surgery is effective for
201 treating pelvic pain and abnormal uterine bleeding regardless of the surgical route –
202 hysteroscopy, vaginal surgery or laparotomy – but obstetric outcomes are poor with over 50%
203 of miscarriages.

204 It is somewhat difficult to compare our results with those reported in the literature
205 because of differences in inclusion criteria between studies and the lack of a consensual
206 threshold to define isthmocele and classification of its severity. For some authors isthmocele
207 was considered to be severe when residual myometrial thickness was 2.2 mm [10]. In our
208 study, the median residual myometrium thickness was 2 mm.

209 In our series, 94% of the patients suffered from abnormal uterine bleeding, and
210 improvement was reported for 70% of them. This result is in agreement with the findings by
211 Zhang et al. [11] .

212 Three-quarters of the patients who suffered from pelvic pain in the present study
213 reported an improvement. Only three patients require additional surgery. In the literature,
214 authors report that as many as 97% of the patients obtain pain relief [12]. The seemingly
215 poorer result in our study could be because we used an objective VAS to quantify pain, or
216 because of differences in the definition of isthmocele.

217 Overall, we observed a 92% pregnancy rate among our patients wishing to conceive,
218 and a 60% pregnancy rate for patients with secondary infertility. Nevertheless, we report a
219 miscarriage rate of around 55%, with particularly poor results after hysteroscopy (3/4 patients
220 miscarried). This last result is surprising and deserves to be confirmed by an additional study.
221 Donnez et al. noted a pregnancy rate of 44% among patients with infertility [13], all of which
222 were carried to full term. In Jeremy et al.'s study [9], 14 symptomatic patients with a pregnancy
223 project were operated on by laparotomy, laparoscopy or vaginal surgery. Among them, 10
224 became pregnant, representing a pregnancy rate of 71% (six spontaneous pregnancies and

225 four after medical treatment), of whom one aborted and nine delivered: eight cesarean sections
226 and one vaginal delivery. No cases of placenta accreta or uterine rupture were described.
227 Other studies support the high pregnancy rate with few complications after laparotomy [14],
228 hysteroscopy and laparoscopy [15].

229 Although there is no consensus about surgical management of isthmocele, most
230 studies suggest laparoscopy for symptomatic patients who wish to conceive and who have a
231 median residual myometrium thickness of less than 3 mm [13]. After laparoscopic treatment,
232 Donnez et al. observed an improvement for 91% of patients [13]. Moreover, this study
233 demonstrated that repair via laparoscopy could increase the residual myometrial wall even
234 when the preoperative thickness was less than 2.5 mm. Furthermore, the pregnancy rate was
235 44% among infertile patients. Zhang et al. conducted a retrospective study with 124 patients
236 to assess the impact of the surgical route (vaginal surgery compared with laparoscopy) on
237 post-operative results [11]. They concluded that the surgical results were similar but that the
238 operation time and duration of hospital stay were shorter with vaginal surgery. They also
239 observed that hospital stay was shorter after hysteroscopy than after laparoscopy and vaginal
240 surgery. Xie et al. found that surgical duration and blood loss were greater after vaginal surgery
241 than hysteroscopy [8]. In our study, surgical outcomes were similar for the three surgical
242 routes. However, hospital stay was longer after laparotomy and vaginal surgery than after
243 hysteroscopy which is an outpatient procedure. In Van der Voet et al.'s review, the surgical
244 results were also comparable regardless of the surgical procedure [16].

245 In our study, the only hysteroscopy performed on a patient for pelvic pain, failed to
246 provide relief. However, Raimondo et al. noted an improvement in pelvic pain in 80% of cases
247 after hysteroscopy (8). In contrast, all the patients in our study who had hysteroscopy because
248 of menorrhagia (n=3) had normal menses after surgery versus 80% in Raimondo et al.'s study
249 [6]. However, in Raimondo et al.'s population, the severity of the isthmocele and the residual
250 myometrial thickness were not reported. In our study, median residual myometrial thickness
251 was 2 mm which corresponds to severe isthmocele. Literature reports that 80% to 89% of

252 patients had normal menses after vaginal surgery [7,11] in contrast to only 50% in our study.
253 These surgical differences may be explained by our small sample size (five patients had
254 hysteroscopy and eight vaginal surgery). Finally, no differences are reported in literature about
255 fertility results according to the surgical route. Xie et al. noted a 25% pregnancy rate (2/8
256 patients) after vaginal surgery versus 33% (2/6) after hysteroscopy. Reported pregnancy rates
257 after laparotomy are also high [9,14].

258 The only intra-operative complication observed in our series was one bladder injury
259 during vaginal surgery. Similar low rates of complications are found in the literature. In 2014,
260 Xie et al. described one case of sepsis in 46 women who underwent vaginal surgery [8]. Zhang
261 et al. found no complications among 65 patients [17] and Zhou et al. [7] observed three
262 hematomas in the vesicouterine flexion among 121 women undergoing vaginal surgery. No
263 peroperative complications have been described during hysteroscopy surgery for isthmocele
264 [8,18]. However, Aas-eng et al. reported a rate of complications after hysteroscopy between
265 1% and 2.7% with uterine perforation, bleeding, infection, fluid overload and intrauterine
266 adhesions with pregnancy loss risk [19]. In our study, one patient had a subcutaneous
267 hematoma after laparotomy and did not require further surgery. The vaginal route would seem
268 to be an interesting option to treat isthmocele in terms of fertility outcome and due to its
269 minimally invasive nature.

270 In the present study, post-operative patient quality of life as evaluated by the EQ-VAS
271 and EQ-5D-5L scores was satisfactory supporting the management of isthmocele by surgery.

272 The study we report here suggests that the three surgical routes – hysteroscopy,
273 vaginal surgery and laparotomy – are equally effective for the repair of symptomatic
274 isthmocele. Hysteroscopy and vaginal surgery may be preferred options for most women as
275 they are minimally invasive. Laparotomy should be reserved for patients with severe
276 isthmocele and a desire for pregnancy as the procedure can strengthen the myometrial wall
277 [20]. Nevertheless, women should be advised of the risk of miscarriage for future pregnancies

278 regardless the procedure. Larger, randomized studies reporting post-operative thickness of
279 the myometrium are required to further assist the surgeon in his/her choice of route.

280 Nevertheless, some limitations to our study deserve to be mentioned. The first is due
281 to the retrospective nature of the design which cannot rule out the risk of bias. However, out
282 of the 23 patients eligible for inclusion, we captured data for 18. Furthermore, although the
283 sample size was small, as is the case for most publications to date [3,9,14,21–23]. We assume
284 that the power of our study is poor. However, we included all patients who underwent
285 isthmocele surgery in two surgical centers over a 6-year period. Second, none of the patients
286 underwent laparoscopic management which could be interesting to compare with the three
287 routes we report here. Finally, our results would have been enhanced with post-operative
288 imaging including post-operative thickness of the myometrium. Nevertheless, we provide
289 quantitative evaluation of post-operative chronic pelvic pain, dysmenorrhea, and dyspareunia
290 with VAS scores and patient satisfaction, which has been lacking to date. Furthermore, our
291 study is one of the few to describe post-operative fertility analysis.

292

293 Conclusion

294 This study supports the interest of surgery for symptomatic women with isthmocele
295 and shows that the three surgical routes are safe and effective in relieving symptoms leading
296 to an improvement in quality of life. Larger, randomized studies reporting post-operative
297 thickness of the myometrium are required to further assist the surgeon in his/her choice of
298 route.

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