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ORIGINAL ARTICLE

Combining NovaSure® endometrial ablation and Essure® hysteroscopic sterilization: a feasibility study to evaluate the confirmation tests

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Abstract Since NovaSure® endometrial ablation (GEA) is not reliable as contraception, a reliable permanent contraceptive method which can be offered during the same operative session is often preferred by patients. We present a series of 24 patients treated by NovaSure® GEA followed by Essure® hysteroscopic sterilization at the same session. Bilateral placement of the micro-inserts after GEA was successful in all 24 patients. Confirmation by ultrasound and plain X-ray of the pelvis indicated a correct position in all 48 tubes. Routine follow-up by hysterosalpingography (HSG) to document bilateral tubal occlusion was only possible in 17/23 (74%) patients; these 34 tubes were blocked. In 6/23 (26%) patients, tubal occlusion could not be determined by HSG because of minimal filling of the uterine cavity with contrast medium. The latter was caused by severe uterine synechiae. All patients were satisfied with the result of GEA at 3 months; 19 women (83%) reported amenorrhea and the others, a strong reduction in menstrual blood loss. The combination of Essure® hysteroscopic sterilization and NovaSure® GEA is feasible and safe. However, after this combined approach the HSG as confirmation test is not always useful because of severe synechiae.

Keywords Endometrial ablation · NovaSure® · Hysteroscopic sterilization · Essure® · Hysterosalpingography

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Introduction

NovaSure® bipolar impedance-controlled GEA (Cytyc/Hologic, Palo Alto, CA, USA) is a safe and effective method to resolve heavy menstrual bleeding [1]. Radiofrequency energy destroys the regenerative ability of the endometrium and creates an iatrogenic Asherman's syndrome [2]. Patients treated with GEA tend to develop an amenorrheic state in 48–75%, which is persistent even 5 years after the operation [3, 4].

Though risk of pregnancy is low, endometrial ablation cannot be regarded as an anticonceptive method [5]. In case of pregnancy after GEA, the risk of miscarriage, preterm delivery, and abnormal placental attachment is increased [6, 7]. Because contraception after GEA is necessary, patients may prefer a permanent form of birth control.

Essure® sterilization (Conceptus, Inc, San Carlos, CA, USA) is a minimally invasive hysteroscopic technique for permanent tubal occlusion. This procedure can be performed without anesthesia [8]. The inserts in the fallopian tubes induce an inflammatory response, causing occlusion of the intramural part of the fallopian tubes 3 months after placement. Advantages of this method compared to laparoscopic sterilization are obvious because it is less invasive with lower cost and shorter recovery time and hospitalization [9–11].

Recently, two studies presenting data of the combined approach of Essure® hysteroscopic sterilization and NovaSure® endometrial ablation were published [12, 13]. It was recommended to perform the hysteroscopic sterilization after GEA because the Essure® micro-inserts could potentially conduct the radiofrequency energy thereby damaging the surrounding tissue. Although GEA is known for its capacity to create Asherman's syndrome follow-up by HSG showed only mild synechiae in 24% of the patients

and subtle filling defects in 33% of the cases [12]. The HSG as confirmation test was not impaired by the adhesions. Follow-up by 3D ultrasound was also described and considered to be reliable [13].

After an uneventful Essure®-only procedure, it is common in the Netherlands to confirm correct placement by transvaginal ultrasound 3 months after the procedure under the strict condition that a validated protocol is followed to recognize improper placements [14]. In this Dutch protocol follow-up by HSG after 3 months is only required in case of unsatisfactory placement.

The objective of this study was to evaluate the feasibility and results of Essure® hysteroscopic sterilization combined with NovaSure® endometrial ablation as well as to determine the effectiveness of transvaginal 2D ultrasound and hysterosalpingography in documenting proper localization of the micro-inserts and tubal occlusion.

Material and methods

In the period of April 2007 to July 2009 24 patients with menorraghia and the desire for permanent contraception underwent GEA followed by hysteroscopic Essure® sterilization. Pre-operatively, all patients underwent transvaginal ultrasound and endometrial sampling when indicated. Patients were excluded for the following conditions: suspected endometrial carcinoma, submucous myomas, polyps larger than 2 cm, abnormal uterine sounding length, and active pelvic inflammatory disease or hydrosalpinx. All procedures were performed under general anesthesia. To decrease the amount of post-ablation debris, they were timed in the early follicular phase of the menstrual cycle. The endometrium was not routinely pretreated with progesterone. The combination of any GEA and placement of a foreign body can increase the risk of chronic infection [15]. Therefore all patients received a prophylactic dose of antibiotics (Cefazolin/Metronidazole). Before GEA, a standard hysteroscopy, using a 4.3- or 4.9-mm CF hysteroscope (Karl Storz, Germany), was performed to identify the tubal ostia and to confirm the absence of intracavitary abnormalities. After GEA, the hysteroscope was reinserted and the tubal ostia were visualized. The Essure® micro-inserts were placed according to manufacturer's instructions. Procedure time (minutes) was registered as the time between the insertion of the hysteroscope before the GEA till the moment that the scope was withdrawn from the vagina after the sterilization. All procedures in our hospital were performed by the same gynecologist who was experienced and skilled to perform GEA, hysteroscopic Essure® sterilization, and transvaginal ultrasound detection of the micro-inserts. He also reviewed the HSG images together with a member of the radiology department. Until Essure® sterilization was proven to be successful, all patients were advised to use alternative contraception.

The choice of the confirmation test was based on the standard protocol used in the Netherlands for the Essure®-only procedure. In this protocol the confirmation test is limited to ultrasound after 3 months in uncomplicated procedures. Whether or not placement of the Essure® micro-inserts is considered as complicated depends on the number of coils in the uterine cavity, procedure time, and resistance during the insertion. In case of unsatisfactory placement ultrasound is performed after 1 month and HSG after 3 months. This protocol is validated [14] and the choice for ultrasound after 1 month inspired by the idea that it is not rational to wait for 3 months when ultrasound already demonstrates abnormal placement. For safety reasons, we considered the combined GEA and Essure procedure as "complicated" and performed a transvaginal ultrasound after 1 month. Placement was considered to be successful in case the reflections of the micro-insert crossed the outer line of the uterine wall and the proximal ends of both devices were visualized inside the outer line or in the region of the endometrial cavity [14]. The HSG after 3 months was done in an outpatient setting by the same gynecologist who performed the operative procedure. We started the HSG with a plain pelvic X-ray and used lipiodol as contrast medium. Most important objective of a HSG is to evaluate the relationship of the proximal end of the inner coil of the micro-insert to the uterine cornua. Only when maximal distension of the cornua is achieved and contrast meets or obscures the proximal portions of the Essure® micro-insert, a HSG can be used to evaluate tubal occlusion [16]. HSG was thought to be satisfactory when (1) both micro-inserts were visible with <50% of the length of the inner coil trailing into the cavity, (2) the proximal ends of the inner coils appear to be <30 mm into the tube from where the contrast fills the uterine cornua, and (3) no contrast visible in the tubes beyond micro-inserts or in the peritoneal cavity [16]. At the follow-up visit after 3 months rate of satisfaction with the outcome of the procedure was evaluated using a three point scale: very satisfied, satisfied, and unsatisfied. Monthly blood loss was recorded as: amenorrhea, bleeding less than before treatment, bleeding same as before treatment, and bleeding more than before treatment. Amenorrhoea was defined as cessation of bleeding immediately after ablation until the control visit at least 3 months after the procedure.

Results

The mean age of the 24 patients was 39 years (32–46) and mean parity 2.1 (range 0–5). Eighteen women had previously received medical therapy for their bleeding disorder: oral

contraceptives (22%) or a levonorgestrel IUD (72%). The procedure time ranged between 5 min and 25 min (mean 10.6 min±5), including hysteroscopy before GEA. Bilateral placement of the micro-inserts after GEA was successful on the initial attempt in all 24 patients. All tubal ostia could be identified with one to six expanded Essure® coils visible trailing in the uterine cavity after placement. No complications occurred per- or postoperatively and all patients were discharged the same day (Fig. 1).

It was possible to identify all micro-inserts with transvaginal ultrasound in all women 4 weeks after the procedure. All micro-inserts appeared to be in good position. After this initial ultrasound examination at 4 weeks, one patient was lost for follow-up, so 23 patients received a pelvic X-ray and HSG 3 months after the procedure. The plain pelvic X-ray documented appropriate placement of both micro-inserts in all 23 patients. The HSG could be done properly in 17 patients (74%) and documented bilateral tubal occlusion in all these 17 patients (Fig. 2a). In these patients, no patent tubes or spill of contrast in the peritoneal cavity was found. In the other six patients (26%), HSG demonstrated minimal contrast medium in the uterine cavity probably caused by severe uterine synechiae. Tubal occlusion could not be determined by HSG in these patients (Fig. 2b, c).

No pregnancies were reported during follow-up. All patients were satisfied with the result of the GEA 3 months after procedure; 83% of the women reported amenorrhea, while 17% had a strong reduction in menstrual blood loss (bleeding less than before treatment). One patient returned after 10 months because of dysmenorrhea, which already existed before the procedure. Although she had significantly reduced loss of blood each month, this patient underwent a vaginal hysterectomy. Histological examination of the uterus revealed the presence of severe adenomyosis. In a second patient, a diagnostic hysteroscopy was performed 14 months after the combined procedure for reason of pain. The uterine cavity was not accessible due to an Asherman's syndrome. This finding was compatible with her amenorrhea and her complaints resolved spontaneously after a while. The third patient came back after 7 months with complaints of cyclic abdominal pain. In this patient the 3-month follow-up HSG failed because of synechiae. Transvaginal ultrasound showed hematometra due to Asherman's syndrome. The uterus was drained of 200 ml blood after which treatment the complaints resolved completely.

Discussion

NovaSure® endometrial ablation is a safe and effective alternative to hysterectomy for women with menorraghia when treatment with oral medication or levonorgestrel IUD fails [3, 4]. Because pregnancy is still possible after GEA, with higher risk of complications, supplementary contraception is necessary. Advantage of Essure® hysteroscopic sterilization is the transcervical approach with its minimal invasive properties.

This study demonstrates that combination of Essure® hysteroscopic sterilization and NovaSure® GEA is easy to perform and safe for women with persistent menorraghia and

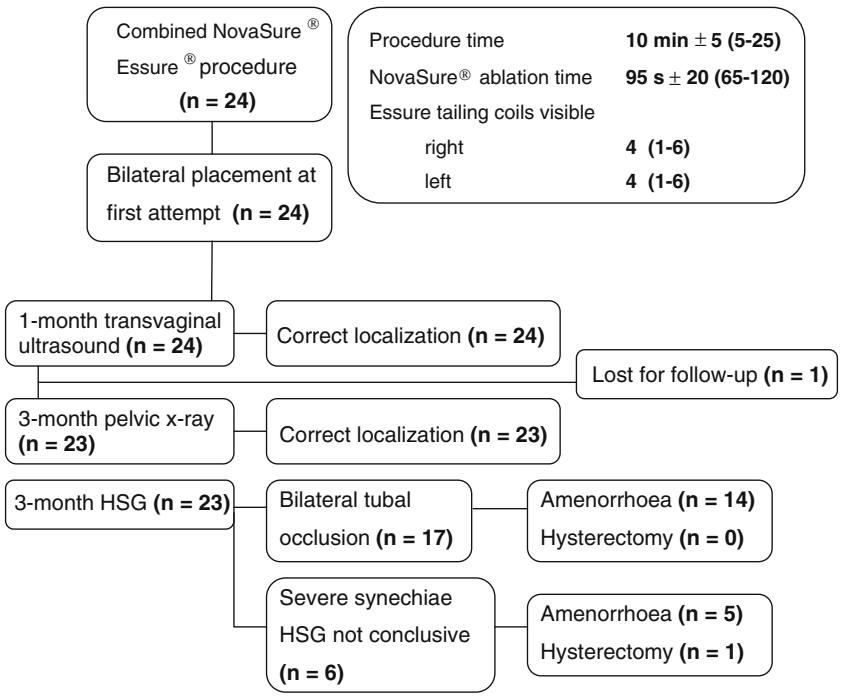

Fig. 1 Study design

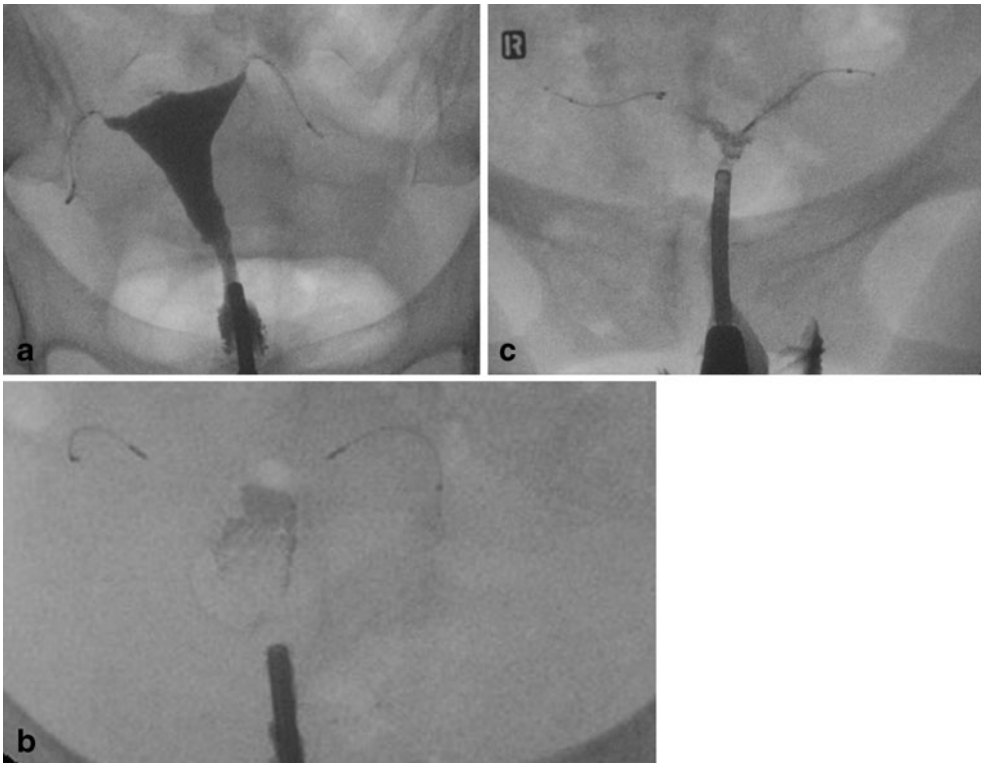

Fig. 2 HSG image after combined NovaSure® / Essure® procedure. **a** HSG showing proper localization of both micro-inserts, good filling of the uterine cavity, and no contrast visible in the tubes beyond micro-inserts or in the peritoneal cavity. **b** HSG performed at 3 months follow-up after an uncomplicated combined procedure. Normal visualization and location of Essure® inserts. Almost no distension of the uterine cavity by the contrast medium. **c** HSG 3 months after the combined procedure with almost no filling of the uterine cavity

wish for permanent contraception. No complications occurred and mean procedure time was short. All patients were (very) satisfied at 3 months follow-up and a high amenorrhea rate was reported. In our study, one adverse event (hematometra) was reported. A recent Cochrane review concluded that women undergoing newer ablative procedures are less likely to have fluid overload, uterine perforation, cervical lacerations and hematometra than women undergoing the more traditional procedures [17]. Although the risk for an adverse outcome is low for NovaSure® GEA, it is possible that a combined procedure may increase the risk for hematometra and eventually hysterectomy.

Transvaginal ultrasound and pelvic X-ray revealed a proper placement of all micro-inserts. However, these techniques are not yet validated as confirmation test for the combined procedure. On the other hand, the HSG as confirmation test was not conclusive in 26% of the women. Severe uterine synechiae hampered a sufficient filling with contrast medium of the uterine cavity. It was therefore impossible to determine both the proper placement of the micro-inserts and the occlusion of the fallopian tubes.

Only one other study has been published with a comparable number of patients with the GEA followed by Essure® sterilization [12]. In that study successful Essure® sterilization after GEA was achieved in all 25 patients. In contrast to our data, the authors reported only mild synechiae not interfering with the ability to document proper placement of the micro-inserts. They were able to assess tubal blockage by HSG in 90% of cases and tubal patency in 10%.

The advantages of the transvaginal ultrasound compared to pelvic X-ray and HSG are no radiation exposure, more comfortable examination, and lower costs. Ultrasound has the ability to locate the device and visualize its relationship with surrounding tissue. Contrast infusion sonography (CIS) is another technique to assess micro-insert placement in the post-Essure® setting. In a pilot study with a small sample, the authors concluded that CIS has comparable accuracy to HSG [18]. Although pelvic X-ray and transvaginal ultrasound can demonstrate proper placement of the micro-inserts, tubal occlusion can only be determined by HSG.

In the Dutch protocol follow-up by HSG after 3 months is only required in case of unsatisfactory placement [14]. Follow-up according to this protocol after a combined procedure will reduce the number of useless HSG's by synechiae as confirmation test. However, in case of unsatisfactory placement HSG remains the gold standard for determination of tubal occlusion. In this perspective, we have to consider a different sequence of procedures. That is to say, to start with the hysteroscopic sterilization and in case of an uneventful placement as defined in this protocol, continue immediately with the GEA, followed by ultrasound after 3 months. In case an HSG is needed according to the criteria of the Dutch protocol, GEA could be postponed until after the 3-month HSG. Performing GEA after Essure® sterilization implicates a theoretical risk of thermal injury of the tubes or intraperitoneal organs by the energy conductance over the micro-inserts. However, there is growing evidence that this risk is negligible. In a series of 77 patients GEA after hysteroscopic Essure®

sterilization turned out to be safe and well tolerated [19]. In a perihysterectomy safety study, GEA after Essure® sterilization was found to cause no thermal serosal injury. The rise in serosal temperature during GEA was similar in the tubes with and without an Essure micro-insert [20].

Whether the above-mentioned Dutch protocol is applicable for the group of patients described in this feasibility study has to be evaluated. In this evaluation study, the Essure® sterilization is done first after which the type of confirmation test needed according the Dutch protocol decides whether the GEA is performed in the same session or after the 3-month HSG.

Today, all combined procedures in our hospital are performed under general anesthesia thereby adding costs and risks to the treatment. Recent studies demonstrated that Essure® hysteroscopic sterilization was feasible and safe in the outpatient setting [8, 9, 21, 22]. NovaSure® GEA can also be performed without problems in an office setting [23]. Therefore, it is interesting to conduct a randomized controlled trial comparing pain and acceptance of the combined approach in the inpatient and outpatient setting.

In conclusion, NovaSure® endometrial ablation followed by Essure hysteroscopic sterilization is feasible and safe. Transvaginal ultrasound and pelvic radiography are effective methods to confirm proper localization of bilateral micro-inserts after combined procedure. Proper follow-up by HSG is not always possible because of impairment by synechiae. Whether or not the sequence of both treatments can be changed to bypass the difficulty in performing and evaluating the HSG remains to be validated.

Declaration of interest R.J. Detollenaere reports no conflicts of interest. M.P.H. Vleugels is a trainer for Essure sterilization method. With regard to H.W.F. van Eijndhoven, the institution received payments for training courses in Essure sterilization for Dutch Gynecologists (entity: Sigma Medical Netherlands). The authors alone are responsible for the content and writing of the paper.

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