

# Endometrial Thermoablation with Novasure® for the Treatment of Abnormal Uterine Bleeding in the Obstetrics and Gynecology Department of the Hospital Center of Nevers, France from 2019 to 2022

# Eléonore Gbary-Lagaud<sup>1,2\*</sup>, Carine Houphouet-Mwandji<sup>1</sup>, José Loba<sup>1</sup>, Denis Effoh<sup>1</sup>, Roland Adjoby<sup>1</sup>, Rémi Kosi-Tuavawa<sup>2</sup>

<sup>1</sup>Department of Mother and Child, University of Félix Houphouët Boigny, Abidjan, Côte d'Ivoire <sup>2</sup>Hospital Center of Nevers, Nevers, France Email: \*eleonoregbarylag@gmail.com

How to cite this paper: Gbary-Lagaud, E., Houphouet-Mwandji, C., Loba, J., Effoh, D., Adjoby, R. and Kosi-Tuavawa, R. (2025) Endometrial Thermoablation with Novasure<sup>\*</sup> for the Treatment of Abnormal Uterine Bleeding in the Obstetrics and Gynecology Department of the Hospital Center of Nevers, France from 2019 to 2022. *Open Journal of Obstetrics and Gynecology*, **15**, 444-451. https://doi.org/10.4236/ojog.2025.153039

**Received:** February 1, 2025 **Accepted:** March 21, 2025 **Published:** March 24, 2025

Copyright © 2025 by author(s) and Scientific Research Publishing Inc. This work is licensed under the Creative Commons Attribution International License (CC BY 4.0).

http://creativecommons.org/licenses/by/4.0/

## Abstract

Introduction: Anormal uterine bleeding is a situation that disrupts genital life. Extreme cases can be life-threatening. Several treatments are available, including thermoablation of the endometrium using the Novasure<sup>®</sup> procedure. Objective: This paper aims to describe the results of treatment of anormal uterine bleeding with Novasure® thermoablation. Method: This was a descriptive and analytical study which took place from November 1, 2019 to December 31, 2022 at the Centre Hospitalier de l'Agglomération de Nevers, France. All patients diagnosed with anormal uterine bleeding after ruling out an organic cause with a Higham score > 150 constituted the study population. Patients included in the study were those treated by endometrial thermoablation. Incomplete files and patients who continued postoperative follow-up in another health facility were not included in the study. A Novak cannula endometrial biopsy was performed each time. We were interested in the following variables: qualitative (profession, medical treatment received, favouring factors, endometrial histology, postoperative evolution), and quantitative (age, parity, intraoperative uterine cavity measurements). It should be noted that all patients no longer wished to have children. Results: During the study period, we selected 156 patients with HUF, including 17 (10.90%) treated by Novasure® thermoablation. The patients were over 40 years of age in 64.7% of cases. Contributing factors were dysthyroidism, dysovulation and anticoagulant use (11.8%). Failure of medical treatment was the indication for thermoablation in 81.82% of cases. Patients were fully satisfied, with complete reversal of signs in 82.36% of cases. Simple glandular hyperplasia without atypia was present in 52.94% of cases. **Conclusion:** Endometrial thermoablation is an effective way of overcoming abnormal uterine bledding with very few complications. Anormal uterine bleeding can be stopped immediately, often with a marked improvement in quality of life. A large uterine cavity is a major factor limiting its effectiveness. The high cost of the device is the main factor limiting its widespread use.

## **Keywords**

Anormal Uterine Bleeding, Endometrial Thermoablation, Quality of Life

## **1. Introduction**

The menstrual cycle disorders have been classified as abnormal uterine bleeding (AUB) in the PALM-COEIN classification according to FIGO [1] [2]. They affect 15% of women [3]. It is a diagnosis of elimination in the absence of any organic cause [4]. In some cases, AUB can seriously disrupt a woman's daily routine and even impair her quality of life [5]. In extreme cases, anemia or one of its complications can be life-threatening. Several treatments exist for the management of AUB: hormones (estrogens, progestins, LH-RH agonists, levonorgestrel intrauterine device), haemostatics (tranexamic acid) [6]. These therapies often fail, and more aggressive means such as surgery are used [5] [6]. In this case, a hysterectomy may be performed to be excessive, or the endometrium may be ablated: endometrectomy. Another conservative treatment option is thermoablation of the endometrium using the Novasure<sup>®</sup> procedure.

This device is often used at the *Centre Hospitalier de l'Agglomération de Nevers* (CHAN), France. It therefore seemed appropriate to describe the results of treatment of AUB with Novasure<sup>®</sup> thermoablation.

## 2. Method

The study took place at CHAN, *France*. It was a descriptive and analytical study that ran from November 1, 2019 to December 31, 2022 (38 months). All patients diagnosed with AUB after ruling out an organic cause with a Higham score > 150 constituted the study population. Patients included in the study were those with AUB treated by endometrial thermoablation at CHAN. Incomplete files and patients who continued postoperative follow-up in another health facility were not included in the study. Prior to the Novasure<sup>®</sup> procedure itself, a diagnostic hysteroscopy was performed to visualize the uterine cavity and walls. Endometrial biopsy was then performed using a Novak cannula.

We were interested in the following variables: qualitative (profession, medical treatment received for AUB, favouring factors, endometrial histology, postoperative evolution), quantitative (age, parity, intraoperative uterine cavity measurements). It should be noted that all patients no longer wished to have children. We used the chi-square test to compare certain numbers at the = 5% threshold.

#### Description of the Novasure®

The Novasure® device is an endometrial vaporization system that emits radiofrequency waves. Treatment takes place in the outpatient operating room, with the patient anesthetized in the gynecological position, after sterile drapes have been applied in compliance with aseptic rules. A diagnostic hysteroscopy and endometrial biopsy are performed. Application of the deployed probe in the uterine cavity lasts an average of 90 seconds, with a maximum of 120 seconds. The ablation procedure terminates automatically when tissue impedance reaches 50 ohms, or after 2 minutes. A diagnostic hysteroscopy is then carried out again to verify the effective destruction of the endometrial surface layer. The endometrium appears charred. The procedure can be performed at any time during the menstrual cycle. No uterine distension is required. The main indications for Novasure® thermoablation are AUB, absence of desire for maternity and Highman score > 150. Contraindications are pregnancy or a patient wishing to become pregnant, endometrial carcinoma, history of Caesarean section or transmural myomectomy, active genital or urinary tract infections, intrauterine device, uterine cavity measuring less than 4 cm long or more than 6.5 cm, uterine cavity measuring less than 2.5 cm wide and more than 5 cm.

## **3. Results**

During the study period, we retained 156 patients with AUB, 17 of whom were treated with Novasure<sup>®</sup> thermoablation. This represents a frequency of 10.90% of patients with AUB requiring physical treatment by thermoablation.

#### 3.1. Socio-Demographic Characteristics

Sixty four per seven per cent of patients were over 40 years of age. The minimum age was 35 and the maximum 49. Patients with 2 or 3 parities accounted for 73.5% of cases. Multiparous women accounted for 17.6% of patients. The most common occupations were in the tertiary sector (administration, education, police, health) in 35.3% of cases, followed by the secondary sector in 17.6% of cases, with agriculture and animal husbandry at the top of the list (**Table 1**).

Variables	Workforce (n)	Percentage (%)
Age (Years)		
35 years - 40 years	6	35.3
> 40 years	11	64.7
Profession		
Tertiary sector (administration, education, police, health)	6	35.3

 Table 1. Distribution of patients by socio-demographic characteristics.

Continued		
Without profession	6	35.3
Secondary sector (industry, catering)	3	17.6
Primary sector (agriculture and livestock)	2	11.8
Parity		
Primiparous	1	5.9
Pauciparous	13	76.5
Multiparous	3	17.6

## **3.2. Clinical Features**

#### **3.2.1. Contributing Factors**

Dysthyroidism, dysovulation and the use of anticoagulants were the most common factors, with a respective frequency of 11.8%. Nephropathy was present in 5.9% of patients. In 58.83% of cases, no factors were identified (Table 2).

Table 2. Distribution of patients according to factors favouring AUB.

Contributing factors, causes	Workforce (n)	Percentage (%)
No	10	58.83
Dysthyroidia	2	11.76
Anti-coagulant	2	11.76
Dysovulation	2	11.76
Nephropathy	1	5.89
Total	17	100

## 3.2.2. Indications

Meno-metrorrhagia was initially treated with medical therapy. This was done when the Higham score exceeded 150 points. Persistent menometrorrhagia of the same intensity was considered a therapeutic failure. Failure of medical treatment was the indication for Novasure<sup>®</sup> in 81.82% of cases. This was followed by deterioration in quality of life (13.64%). It should be noted that some patients may have had two indications, resulting in a total of 22 (**Table 3**).

Table 3. Distribution of patients according to AUB indications.

Indications	Workforce (n)	Percentage (%)
Failure of medical treatment	18	81.82
Impaired quality of life	3	13.64
Medical contraindication to treatment	1	4.54
Total	22	100

### 3.3. Intraoperative Data

Intraoperative uterine cavity characteristics, in particular uterine cavity width,

were cross-referenced with Novasure<sup> $\circ$ </sup> procedure time. The procedure time was 2 minutes for uterine cavities wider than 5 cm (p = 0.01) (**Table 4**).

Uterine cavity width/Procedure time	< 2 minutes	2 minutes	Total
≤ 5 cm	+0	-6	16
> 5 cm	-6	+89	1
Total	16	1	17

 Table 4. Distribution of patients according to uterine cavity width and procedure time.

 $chi^2 = 17.00 ddl = 1, p = 0.01.$ 

Three cells (75.0%) have a theoretical size of less than 5, so the chi<sup>2</sup> rules don't really apply. Chi<sup>2</sup> is calculated on the quotation table (marginal numbers equal to the sum of row/column numbers). The values in the table are the partial chi<sup>2</sup>/total chi<sup>2</sup> percentages. The sign represents the deviation from independence.

#### 3.4. Post-Operative Follow-Up

Patients were seen up to 3 months postoperatively. Patients were fully satisfied, with a complete reversal of signs in 82.36% of cases (14 patients). In these cases, metrorrhagia and menorrhagia stopped, sexual intercourse was resumed, and quality of life improved. There was 1 case of failure (5.88%) (Figure 1).



Post operative patient satisfaction

Figure 1. Postoperative patient satisfaction.

#### **3.5. Histological Features**

Simple glandular hyperplasia without atypia was present in 52.94% of cases. Pure follicular proliferative endometrium accounted for 23.52% of histological diagnoses (Table 5).

Table 5. Distribution of patients according to histological data.

Histology	Workforce (n)	Percentage (%)
Simple glandular hyperplasia without atypia	9	52.94
Proliferative endometrium in the pure follicular stage	4	23.52

Continued		
Glandular cystic endometrial hypertrophy	2	11.76
Adenomyosis	1	5.89
Secretory endometrium	1	5.89
Total	17	100

## 4. Discussion

AUB represent a pathology of hormonal imbalance. They are most frequently observed in premenopausal women, affecting 15% of patients over the age of 40 [3] [7]. AUBs can occur as a result of ovulatory dysfunction or coagulation disorders. In fact, the hormonal imbalance induced by pre-menopause favours an increase in pituitary hormones FSH and LH and a decrease in ovarian hormones. Histologically, this leads to simple glandular hyperplasia without atypia, induced by high FSH levels. These hormonal imbalances are not related to parity or occupation. In most cases of AUB, no favourable factors are found. However, in some cases, haemostasis disorders, ovarian dysfunction and dysthyroidism are risk factors [8].

Gallinat's study of 107 patients found failure of medical treatment to be the major indication for endometrial thermoablation using the Novasure<sup>®</sup> procedure [9].

Procedure time was 2 minutes for uterine cavities wider than 5 cm (p = 0.01). In a study carried out on a cohort of 2,152 patients, Hui Xie et al showed that uterine cavity length (>10 cm) was significantly associated with lower efficacy of the Novasure<sup>®</sup> procedure for AUB management (p = 0.003) [10]. However, for normal uterine cavities that are neither too long nor too wide, treatment with Novasure<sup>®</sup> thermoablation is stable over the medium and long term [10].

Comparison of endometrial thermoablation with the levonorgestrel intrauterine device showed that in 27% of cases, surgical treatment would be required to achieve the same result, *i.e.* reduction or cessation of AUB, compared with 10% for endometrial ablation (Relative risk 2.64; 95% confidence interval 1.49 - 4.68 [5]. Novasure\* thermoablation is a minimally invasive technique with several advantages: it avoids hysterectomy, has a high success rate, no skin scarring, is fast, ambulatory, requires little or no interruption of professional activity, and causes little postoperative pain [11]. It is a procedure with a low incidence of serious complications compared with hysterectomy [12]-[15].

Patient satisfaction has been demonstrated by the cessation of bleeding or at least a considerable reduction in menstrual flow [9] [16]. The isolated case of failure of the Novasure<sup>®</sup> procedure in our series was linked to a uterine cavity larger than 5 cm (p = 0.01). Our results show a high level of patient satisfaction (82.36%). A high satisfaction rate of 80% - 96% has been reported by other authors in cases of endometrial ablation [14] [17]-[19]. Some authors note adenomyosis as a factor in failure of Novasure<sup>®</sup> treatment [20].

Despite its unquestionable efficacy, Novasure<sup>\*</sup> thermoablation has its drawbacks, notably pelvialgia and postoperative leucorrhoea. The main factor limiting its widespread use is its high cost [21]. The generator is electronic, and the cannula with the electrode at its tip is a single-use device.

## **5.** Conclusion

The Novasure<sup>®</sup> procedure is an effective way of overcoming AUB with very few complications. Thermoablation of the endometrium ensures immediate cessation of AUB, often with a marked improvement in quality of life. A large uterine cavity is a major factor limiting the effectiveness of Novasure<sup>®</sup> thermoablation. However, it is indicated for women over the age of 40 who no longer wish to procreate, in premenopause and without any organic cause. It is a second-line treatment after failure of medical therapy for AUB. The high cost of the device is the main factor limiting its widespread use.

## **Conflicts of Interest**

The authors declare no conflicts of interest regarding the publication of this paper.

### References

- Munro, M.G., Critchley, H.O.D., Broder, M.S. and Fraser, I.S. (2011) FIGO Classification System (PALM-COEIN) for Causes of Abnormal Uterine Bleeding in Nongravid Women of Reproductive Age. *International Journal of Gynecology & Obstetrics*, 113, 3-13. <u>https://doi.org/10.1016/j.ijgo.2010.11.011</u>
- [2] Munro, M.G., Critchley, H.O.D. and Fraser, I.S. (2011) The FIGO Classification of Causes of Abnormal Uterine Bleeding in the Reproductive Years. *Fertility and Sterility*, 95, 2204-2208.e3. <u>https://doi.org/10.1016/j.fertnstert.2011.03.079</u>
- [3] Pourcelot, A.G. and Fernandez, H. (2023) Hémorragies utérines fonctionnelles. Elsevier.
- [4] Fernandez, H., Gervaise, A., Faivre, E. and Deffieux, X. (2008) Les hémorragies utérines fonction-nelles ou idiopathiques. *Gynécologie et Obstétrique*, XXXII, 261-274.
- [5] Beelen, P., van den Brink, M.J., Herman, M.C., Geomini, P.M.A.J., Dekker, J.H., Duijnhoven, R.G., *et al.* (2021) Levonorgestrel-Releasing Intrauterine System versus Endometrial Ablation for Heavy Menstrual Bleeding. *American Journal of Obstetrics and Gynecology*, **224**, 187.e1-187.e10. <u>https://doi.org/10.1016/j.ajog.2020.08.016</u>
- [6] Marjoribanks, J., Lethaby, A. and Farquhar, C. (2016) Surgery versus Medical Therapy for Heavy Menstrual Bleeding. *Cochrane Database of Systematic Reviews*, No. 1, CD003855. <u>https://doi.org/10.1002/14651858.cd003855.pub3</u>
- [7] Bradley, L.D. and Gueye, N. (2016) The Medical Management of Abnormal Uterine Bleeding in Reproductive-Aged Women. *American Journal of Obstetrics and Gynecol*ogy, 214, 31-44. <u>https://doi.org/10.1016/j.ajog.2015.07.044</u>
- [8] Critchley, H.O.D., Maybin, J.A., Armstrong, G.M. and Williams, A.R.W. (2020) Physiology of the Endometrium and Regulation of Menstruation. *Physiological Reviews*, **100**, 1149-1179. <u>https://doi.org/10.1152/physrev.00031.2019</u>
- [9] Gallinat, A. (2007) An Impedance-Controlled System for Endometrial Ablation: Five-Year Follow-Up of 107 Patients. *Journal of Reproductive Medicine*, 52, 467-472.
- [10] Xie, H., Wan, Y., Yi, S., Zeng, F., Sun, X., Yang, Y., et al. (2021) Clinical Analysis of

2152 Cases of Abnormal Uterine Bleeding Treated by Novasure Endometrial Ablation. *International Journal of Gynecology & Obstetrics*, **158**, 301-307. https://doi.org/10.1002/ijgo.13983

- [11] Cooper, J., Gimpelson, R., Laberge, P., Galen, D., Garza-Leal, J.G., Scott, J., et al. (2002) A Randomized, Multicenter Trial of Safety and Efficacy of the Novasure System in the Treatment of Menorrhagia. *The Journal of the American Association of Gynecologic Laparoscopists*, 9, 418-428. https://doi.org/10.1016/s1074-3804(05)60513-0
- [12] de Léotoing, L., Chaize, G., Fernandes, J., Toth, D., Descamps, P., Dubernard, G., et al. (2019) The Surgical Treatment of Idiopathic Abnormal Uterine Bleeding: An Analysis of 88 000 Patients from the French Exhaustive National Hospital Discharge Database from 2009 to 2015. PLOS ONE, 14, e0217579. https://doi.org/10.1371/journal.pone.0217579
- [13] Kroft, J. and Liu, G. (2013) First- versus Second-Generation Endometrial Ablation Devices for Treatment of Menorrhagia: A Systematic Review, Meta-Analysis and Appraisal of Economic Evaluations. *Journal of Obstetrics and Gynaecology Canada*, 35, 1010-1019. <u>https://doi.org/10.1016/s1701-2163(15)30789-1</u>
- Bongers, M.Y. (2015) Hysteroscopy and Heavy Menstrual Bleeding (to Cover TCRE and Second-Generation Endometrial Ablation). *Best Practice & Research Clinical Obstetrics & Gynaecology*, 29, 930-939. https://doi.org/10.1016/j.bpobgyn.2015.03.011
- [15] Fergusson, R.J., Bofill Rodriguez, M., Lethaby, A. and Farquhar, C. (2019) Endometrial Resection and Ablation versus Hysterectomy for Heavy Menstrual Bleeding. *Cochrane Database of Systematic Reviews*, No. 11, CD000329. https://doi.org/10.1002/14651858.cd000329.pub3
- [16] Gallinat, A. (2004) Novasure Impedance Controlled System for Endometrial Ablation: Three-Year Follow-Up on 107 Patients. *American Journal of Obstetrics and Gynecology*, **191**, 1585-1589. <u>https://doi.org/10.1016/j.ajog.2004.05.020</u>
- [17] Smith, P.P., Malick, S. and Clark, T.J. (2014) Bipolar Radiofrequency Compared with Thermal Balloon Ablation in the Office. *Obstetrics & Gynecology*, **124**, 219-225. <u>https://doi.org/10.1097/aog.00000000000395</u>
- [18] Penninx, J.P.M., Herman, M.C., Mol, B.W. and Bongers, M.Y. (2011) Five-Year Follow-Up after Comparing Bipolar Endometrial Ablation with Hydrothermablation for Menorrhagia. *Obstetrics & Gynecology*, **118**, 1287-1292. <u>https://doi.org/10.1097/aog.0b013e318236f7ed</u>
- [19] Bofill Rodriguez, M., Lethaby, A., Grigore, M., Brown, J., Hickey, M. and Farquhar, C. (2019) Endometrial Resection and Ablation Techniques for Heavy Menstrual Bleeding. *Cochrane Database of Systematic Reviews*, 1, CD001501. <u>https://doi.org/10.1002/14651858.cd001501.pub5</u>
- [20] Mengerink, B.B., van der Wurff, A.A.M., ter Haar, J.F., van Rooij, I.A. and Pijnenborg, J.M.A. (2015) Effect of Undiagnosed Deep Adenomyosis after Failed Novasure Endometrial Ablation. *Journal of Minimally Invasive Gynecology*, 22, 239-244. https://doi.org/10.1016/j.jmig.2014.10.006
- [21] van den Brink, M., Beelen, P., Herman, M., Geomini, P., Dekker, J., Vermeulen, K., et al. (2021) The Levonorgestrel Intrauterine System versus Endometrial Ablation for Heavy Menstrual Bleeding: A Cost-Effectiveness Analysis. *BJOG: An International Journal of Obstetrics & Gynaecology*, **128**, 2003-2011. https://doi.org/10.1111/1471-0528.16836