Should diagnostic hysteroscopy be performed routinely following thermal balloon endometrial ablation? A case report of thermal bowel injury and literature review

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Although thermal balloon endometrial ablation (TBEA) is an effective and easy technique, it can cause serious complications, including bowel injury, if perforation occurs. In this paper, a case of thermal bowel injury caused by the Thermablate Endometrial Ablation System is presented with a review of previous literature on such complications. Based on this case and expert recommendations, users are advised to follow established protocols, including hysteroscopy just prior to the insertion of the TBEA catheter to exclude prior uterine perforation from the uterine sound or curettage, and an additional hysteroscopy after completion of the ablation as the final step to ensure that a perforation has not occurred.

Keywords
Menorrhagia; Heavy menstrual bleeding; Endometrial ablation; Thermal balloon ablation; Bowel burn; Bowel injury

1. Introduction

Thermal balloon endometrial ablation (TBEA) was introduced by Neuwirth et al. [1] in 1994 as a new ablation instrument. Many studies have shown that TBEA is an equally effective and possibly safer procedure than hysteroscopic endometrial ablation (HEA), introduced in the 1980s as an alternative to hysterectomy in women with heavy menstrual bleeding from benign causes [2]. However, uterine perforation and associated risks were reported with all types of endometrial ablation devices including TBEA. Thus, strict vigilance should be followed to minimize such perioperative complications associated with TBEA, which have been reported in approximately 4% of cases [2].

Below, we present a case report of thermal bowel injury associated with uterine perforation during TBEA to elucidate the patient characteristics, circumstances, presentation, intervention, clinical outcome, and a review of relevant literature to provide recommendations regarding prevention, early diagnosis, and intervention of uterine perforation with subsequent bowel injury to avoid associated life-threatening consequences.

2. Case report

The case involves a 50-year-old mother of six children, all born vaginally, with no prior surgical history. She had been suffering from heavy and prolonged menstrual bleeding for more than two years. She had tried multiple medical therapies, including a levonorgestrel intrauterine system (LNG-IUS), with no improvement. Pelvic ultrasound and office endometrial biopsy were unremarkable. Endometrial ablation was recommended, and after explaining the procedure and related risks, the patient agreed.

Intraoperatively, the uterus was sounded to 10 cm size with anteversion orientation followed by diagnostic hysteroscopy, which was optimal with no significant findings. This was followed by sharp curettage without the need for cervical dilatation, to remove what appeared to be a thickened endometrium. The Thermablate Endometrial Ablation System (by Idoman Teoranta, Ireland) was inserted into the cavity up to the 10 cm mark. The device was activated, and after a system check by the device, a full treatment cycle of 2:35 min was completed. The device was then removed safely, and a post-ablation diagnostic hysteroscopy was performed. It was suboptimal due to inadequate distention and poor visualization of the uterine cavity. Despite poor visualization, the endometrial lining did not appear to be ablated and a bleeding perforation was noted in the right fundal area. Diagnostic laparoscopy was carried out immediately, which confirmed a right fundal perforation of the uterus and a large blanched area of about 6 cm in length over a loop of small bowel. The general surgery team was called in and a laparotomy was done using a Pfannenstiel incision.

A full exploration of abdominal and pelvic contents revealed a large blanched area (approximately 8 cm²) over the distal ileum, appendix, right tube, and lower side of the sigmoid colon with the appearance of thermal injury to all those organs. The general surgery team performed a right hemicolectomy with ileo-colic anastomosis. To assess the sigmoid colon thermal injury, a sigmoidoscopy was performed; the mucosa appeared healthy with no discoloration or evidence of thermal injury. Thus, no resection was carried out on the sigmoid colon, and it was treated conservatively. The right tube was removed and the uterine perforation was sutured. Following an abdominal drain and rectal tube left in situ, the patient was kept NPO and provided intravenous fluids for seven days. During this time, she remained asymptomatic with normal vital signs and white blood count. No fluid out-
Experience (MAUDE) database 

Reported to its Manufacturer and User Facility Device 
calls, and bowel injury was the most common complica-
tion reported postoperatively, the patient’s diet was started in a step-wise fashion, and she tolerated it 

well with continuous improvement in her condition. Ten days postoperatively, CT scans with oral contrast indicated 
an intact bowel with no signs of leakage of the contrast or pelvic collection, and the patient was discharged to home in 
good condition with no dietary restrictions. She had multi-
ple follow-up visits over a three-month period, and there was 

full recovery with no issues.

3. Discussion 

Second generation or non-hysteroscopic endometrial ab-
lation (NHEA) techniques are common and have become an 
effective alternative to hysteroscopic endometrial ablation 
(HEA) and/or hysterectomy for treatment of women with 
heavy menstrual bleeding, with success rates up to 94% and 
patient satisfaction ranging from 57% to 94% [3–6]. Among 
a variety of NHEA devices, four hot liquid balloons have been 
troduced into clinical practice. All balloons consist of a 
catheter (4–10 mm diameter), a silicone balloon, and a con-
trol unit. Liquids used to inflate the balloons include inter-

nally heated dextrose in water (ThermaChoice, 87 °C), ex-
ternally heated glycine (Cavaterm, 78 °C), saline (Menotreat, 
85 °C), and glycerin (Thermablate, 173 °C) [7].

Although TBEA devices are effective, thought to be safe, 
and easy to use with a short learning curve compared to con-
ventional hysteroscopic ablation [8], they are not entirely free 
of complications, especially uterine perforation [9]. Accord-
ing to Baggish and Savells study [10], serious complications 
have occurred with every NHEA system despite the poor 
reporting of complications associated with NHEA, particularly 
the serious ones. They described the reason for serious com-

plications in NHEA systems including TBEA is that the pro-

cedure is not performed under direct visualization to ensure 
that the device is fully inside the uterine cavity before the in-
tended thermal energy is delivered. Thus, if uterine perfor-

ation occurs, the TBEA can cause thermal injuries to any 
unintended organ, including the bowel, which can be life-

threatening if undiagnosed.

Uterine perforation is a common complication of oper-

ative hysteroscopy with an incidence ranging from 0.12–

3% [10, 11] occurring more frequently in HEA compared 
to NHEA procedures (1.3% and 0.3%, respectively) [11, 12]. 
There is no clear estimate of the incidence of bowel in-

jury following endometrial ablation, as the denominator is 
not known despite several reports on such adverse events. 
The FDA developed a reporting system for NHEA compli-
cations, and bowel injury was the most common complica-
tion reported to its Manufacturer and User Facility Device 
Experience (MAUDE) database [13]. In 2012, Brown and 
Blank [14] analyzed adverse events associated with endome-
trial ablation procedures that were reported to the MAUDE 
database. Of the 128 reports of bowel injuries (93 noted as 
thermal injuries), 86 were associated with the radiofrequency 
endometrial ablation device, 27 with microwave ablation, 9 
with hydrothermal ablation, 5 with thermal balloon ablation, 

and one case with cryoablation [14]. Despite the fact that 
TBEA devices have a lower number of reported bowel injury 
cases compared with other global endometrial ablation de-

vices, these cases all ended with bowel resection [13–15]. In 
addition, it is noted in the literature that most reported cases 
of bowel injuries associated with NHEA procedures were di-
agnosed postoperatively after the patient presented with sig-
nificant consequences of undetected bowel injury leading to 
sepsis and resulting in death in rare cases. For instance, the 
ThermaChoice device was associated with five thermal bowel 

injuries of which one ended in death due to sepsis [16].

Downes and Manoharan [17] summarized the factors 
contributing to the development of complications during en-
dometrial ablative procedures. A key concern in delivering 
heat to destroy the endometrium is to ensure that the device 
is actually in the uterine cavity before activating the heat cy-

cle. Uterine perforation can occur with any of the instru-
ments used (sound, hysteroscope, curette) prior to the in-
sertion of the thermal balloon catheter. Although the intra-
hysteroneal catheter tip has been designed to be soft and unlikely 
to perforate the uterine wall, as with the Thermablate EAS, 
it may still cause uterine perforation. Not all TBEA devices, 
including the Thermablate EAS, have a feature to detect pos-
sible perforation; they depend mainly on the steps recom-

mended in their instructions for use (IFU) pamphlets. Even 
though other NHEA ablation devices have incorporated per-

foration detection features, such as the NovaSure endome-
trial ablation device, thermal bowel injuries have nonetheless 
ocurred. Thus, their perforation detection systems are not 
100% reliable.

Della Badia and colleagues, in their evaluation of compli-
cations in the MAUDE database [18], suggested that some 
complications were due to physician error and out of proto-

col use. This might be the result of excellent safety record of 
NHEA which make physicians underestimate the risk of se-
rious adverse events and becoming complacent and less dili-
gent over time in following all necessary safety measures, in-
cluding the manufacturer’s IFU protocol [14]. For example, 
the IFU for Thermablate EAS outlines the following steps: 
sound the uterus, dilate the cervix to 7 mm, sound the uterus 
again, perform a diagnostic hysteroscopy, curettage if needed, 
repeat diagnostic hysteroscopy, insert the thermal balloon 
catheter, activate and treat the patient, remove/discard the 
balloon catheter, and perform hysteroscopy again. In addi-
tion, some experts have recommended performing the proce-
dure under ultrasound guidance and followed by repeat hys-
teroscopy after completion of the treatment to minimize the 
risk of uterine perforation and subsequent thermal injuries 
associated with TBEA. In the present case, we skipped re-
peating diagnostic hysteroscopy after curettage and before in-
serting the device, which could be the step that permitted the 
perforation. It must be emphasized that the last step just prior 
to the insertion of the balloon catheter should be a diagnostic 
hysteroscopy. Thus, awareness among gynecologists of the 
potential harm that may be caused by these devices is essen-
tial.
Uterine perforation and subsequent thermal bowel injury can be avoided or diagnosed immediately by following the IFU protocol for the use of TBEA or by using ultrasound guidance during insertion of the device. Ultrasound guided insertion should be more considered in women with specific risk factors, such as retroverted uterus, previous cesarean sections, a fixed uterus due to endometriosis, and previous endometrial ablation procedure. A study to assess the use of ultrasound guidance vs. other safety measures for NHEA would be useful.

Finally, if uterine perforation is suspected, especially after heat treatment was deployed with possible thermal injury outside the uterine cavity, explorative laparoscopy or laparotomy is warranted [19]. If a complication is identified, remedial surgery should be initiated in a timely fashion and documented in detail.

4. Conclusions
Thermal bowel injuries associated with thermal balloon endometrial ablation are rare but can be a serious complication resulting in significant morbidity and even mortality. To prevent such complications, users are advised to follow the established protocols outlined in the manufacturer’s IFU, including performing a hysteroscopy just prior to insertion of the TBEA catheter (to exclude uterine perforation from the uterine sound, cervical dilatation, or curettage), or to perform TBEA procedure under ultrasound guidance. It is also recommended that after completion of any NHEA treatment, a hysteroscopy should be performed as the final step to ensure that a perforation has not occurred even in devices with proposed incorporated safety features to detect perforation. If a perforation is detected or suspected, exploration of the abdomen is warranted to identify and treat in a timely fashion any possible thermal injuries that may have happened.

Author contributions
HA performed the research all of it including treating the patient, writing the paper and submitting the paper with all corrections.

Ethics approval and consent to participate
The patient provided signed informed consent.

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