

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 ablator 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-

put from the drains was recorded. Subsequently, 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 multiple follow-up visits over a three-month period, and there was full recovery with no issues.

3. Discussion

Second generation or non-hysteroscopic endometrial ablation (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 introduced into clinical practice. All balloons consist of a catheter (4–10 mm diameter), a silicone balloon, and a control unit. Liquids used to inflate the balloons include internally heated dextrose in water (ThermaChoice, 87 °C), externally 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 conventional hysteroscopic ablation [8], they are not entirely free of complications, especially uterine perforation [9]. According 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 complications in NHEA systems including TBEA is that the procedure is not performed under direct visualization to ensure that the device is fully inside the uterine cavity before the intended thermal energy is delivered. Thus, if uterine perforation 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 operative 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 injury following endometrial ablation, as the denominator is not known despite several reports on such adverse events. The FDA developed a reporting system for NHEA complications, and bowel injury was the most common complication reported to its Manufacturer and User Facility Device Experience (MAUDE) database [13]. In 2012, Brown and Blank [14] analyzed adverse events associated with endometrial 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 devices, 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 diagnosed postoperatively after the patient presented with significant 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 endometrial 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 cycle. Uterine perforation can occur with any of the instruments used (sound, hysteroscope, curette) prior to the insertion of the thermal balloon catheter. Although the intraballoon 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 possible perforation; they depend mainly on the steps recommended in their instructions for use (IFU) pamphlets. Even though other NHEA ablation devices have incorporated perforation detection features, such as the NovaSure endometrial ablation device, thermal bowel injuries have nonetheless occurred. Thus, their perforation detection systems are not 100% reliable.

Della Badia and colleagues, in their evaluation of complications in the MAUDE database [18], suggested that some complications were due to physician error and out of protocol use. This might be the result of excellent safety record of NHEA which make physicians underestimate the risk of serious adverse events and becoming complacent and less diligent over time in following all necessary safety measures, including 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 addition, some experts have recommended performing the procedure under ultrasound guidance and followed by repeat hysteroscopy 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 repeating diagnostic hysteroscopy after curettage and before inserting 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 essential.

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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Conflict of interest

The authors declare no conflict of interest.

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