Available online at http://www.journalcra.com

International Journal of Current Research
Vol. 9, Issue, 03, pp.48111-48115, March, 2017

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

ISSN: 0975-833X

RESEARCH ARTICLE

ENDOMETRIAL ABLATION USING SILICON FOLEY CATHETER: AN ALTERNATIVE MODALITY OF TREATMENT IN A RESOURCE-POOR SETTING

***,[1]Priyanka Suhag, [2]Charu Srivastava, [3]Sriram Gopal, [4]Abhishek Chandavarkar and [5]Shreyas Arun Chawathey**

[1]Senior Resident, OBGYN Department, Dr DY Patil Medical College, India
[2]Junior resident, OBGYN Department, Dr DY Patil Medical College, India
[3]Professor and head of Department, OBGYN Department, Dr DY Patil Medical College, India
[4]Assistant Professor, OBGYN Department, Dr DY Patil Medical College, India
[5]Dr DY Patil Medical College, India

ARTICLE INFO

Article History:
Received 07th December, 2016
Received in revised form
14th January, 2017
Accepted 24th February, 2017
Published online 31st March, 2017

Key words:
Hydroablation Foley AUB.

ABSTRACT

Endometrial ablation is the procedure in which we remove or destroy the endometrium and superficial myometrium to destroy the basal layer of endometrium and inhibit its regeneration, hence preventing blood loss during menses. Based on the Principles used for the development of the second generation techniques for endometrial ablation, we have utilised a technique in which a silicone Foley's catheter with Hot Normal Saline is used to ablate the endometrium.

Materials and Methods: This prospective study was carried out in the outpatient Gynaecology clinic and the department of Obstetrics and Gynaecology in Dr DY Patil Medical College, Nerul, Navi Mumbai with recruitment of subjects from March 2016 to September 2016 and follow up till date. The study included 50 patients aged from 35 to 55 years complaining of menorrhagia not responding to treatment (medical treatment) for 3 to 12 months. Foleys cathetar inserted in endometrial cavity inflated with boiling saline was used to ablate endometrium.

Results: 92% satisfaction rate with the procedure at 6 months was observed. Complete cessation of menses was reported in 26% patients and 18% patients had eumenorhea. 48% Patients had reported Hypomenorrhoea at 6 months post procedure.

Conclusion: Foley's thermal balloon endometrial ablation is a safe, cost effective, simple and effective procedure.

Citation: Priyanka Suhag, Charu Srivastava, Sriram Gopal, Abhishek Chandavarkar and Shreyas Arun Chawathey, 2017. "Endometrial ablation using silicon foley catheter: An alternative modality of treatment in a resource-poor setting", *International Journal of Curent Research*, 9, (03), 48111-48115.

INTRODUCTION

Abnormal Uterine Bleeding (AUB) is defined subjectively as excessive blood loss per vaginum as loss of >80 ml/ day (Fraser, 2011). Previously, Hysterectomy was considered as the most appropriate management for abnormal uterine bleeding not controlled by medication (Maresh, 2002 and Andersson, 2007). With the advent of conservative surgeries and potent hormonal preparations, hysterectomy can be averted in many cases. Endometrial ablation has been explored and many devices and techniques have been developed which have been found to be effective. Many products are available in the market which have a costly set-up and many others require anaesthesia and an operation theatre setup for their application. Nearly 30% of women will seek medical assistance for their gynaecological complaints during their reproductive age, of which menstrual complaints are a distress to a lot (Laberge, 2015). In India, many women continue to suffer in silence and avoid discussing the distressing symptoms of heavy bleeding per vaginum. Often, at the end of their obstetric career, the only option they consider is to remove the uterus. Endometrial ablation is the procedure in which we remove or destroy the endometrium and superficial myometrium to destroy the basal layer of endometrium and inhibit its regeneration, hence preventing blood loss during menses. First generation techniques such as transcervical resection of endometrium, rollerball ablation of endometrium came as a boon to conservative surgery but had their own set of shortcomings such as requirement of anaesthesia, hysteroscopic complications, long learning curve and guarded safety (Overton, 1997).

Considering safety parameters and operation theatre requirement, second generation techniques were developed which were minimally invasive but their widespread use has been limited due to their high cost (Micheal, 2005). Based on the Principles used for the development of the second generation techniques for endometrial ablation, we have utilised a technique in which a silicone Foley's catheter with Hot Normal Saline is used to ablate the endometrium. Certain workers have carried out studies in which they have used

Corresponding author: Priyanka Suhag,
Senior Resident, OBGYN Department, Dr DY Patil Medical College, India.

similar methods with favourable outcomes (Azza, 2012; Singer, 1994 and Kishor 2000). We have tried to examine its efficacy in relation to clinical and menstrual outcomes.

MATERIALS AND METHODS

This prospective study was carried out in the outpatient Gynaecology clinic and the department of Obstetrics and Gynaecology in Dr DY Patil Medical College, Nerul, Navi Mumbai with recruitment of subjects from March 2016 to September 2016 and follow up till date. The study included 50 patients aged from 35 to 55 years complaining of menorrhagia not responding to treatment (medical treatment) for 3 to 12 months. Exclusion criteria were as follows: (1) patient needs further pregnancy, (2) uterine depth more than 10 cm, (3) the presence of uterine scars (previous Cesarean section, myomectomy etc.), (4) any pathology distorting the uterine cavity as sub mucous fibroids, intrauterine polyps or adhesions, (5) suspicion of malignancy or pelvic inflammatory disease. Endometrial biopsy within the last 6 months is needed to exclude malignant or a typical lesion in the endometrium. Informed written consent was obtained from all cases. All cases were subjected to full history taking of mainly menstrual pattern and severity of bleeding by recording the number of pads per day, duration of bleeding, presence of blood clots and manifestation of iron deficiency anemia. Clinical examination (general, abdominal and gynecological) and laboratory investigations (CBC, kidney function, liver function tests, and coagulation profile) were done for all patients. Transvaginal ultrasound (TVS) was done for all cases to rule out any pathology in uterus or adnexa and to measure endometrial thickness and to exclude uterine cavity abnormalities and endometrial lesions.

Technique

- Counselling of patients regarding the procedure.
- The patient was draped in the lithotomy position.
- Pre ablation endometrial biopsy was done for 50 cases.
- A Foley's catheter number10 Fr/CH (latex silicon coated),with a capacity of 10 ml was tested for possible leak and risk of rupture by inflation of about 10 ml boiling saline then deflation and the tip of the catheter was cut just above the balloon to allow the inflated balloon to fit well close to the uterine fundus.
- The Foley's catheter was inserted gently into the uterine cavity and inflated by 10 ml of boiling saline (0.9%) Vaginal gauze pack was placed around the catheter to protect against accidental balloon leak or rupture. Maintenance of temperature was done by frequentchanging of the boiled saline every 5 minutes for 3 consecutive cycles and the procedure took a total of15 minutes after which the balloon was deflated and removed.
- Prophylactic antibiotic was given at the start of the procedure and analgesic non steroidal anti inflammatory agent (Diclofenac sodium 75 mg intramuscular) was given to all patients at the end of the procedure. Follow up of the patient was done for few hours and the patient was discharged on the same day. Follow up of all patients in the outpatient clinic was done for 6 months with a subjective assessment of clinical outcome including patients' satisfaction, menstrual outcome and occurrence of amenorrhea, hypomenorrhea, eumenorrhea and persistent or increasing menorrhagia. Diagnostic hysteroscopic evaluation was performed by another physician who was blinded to the technique 3

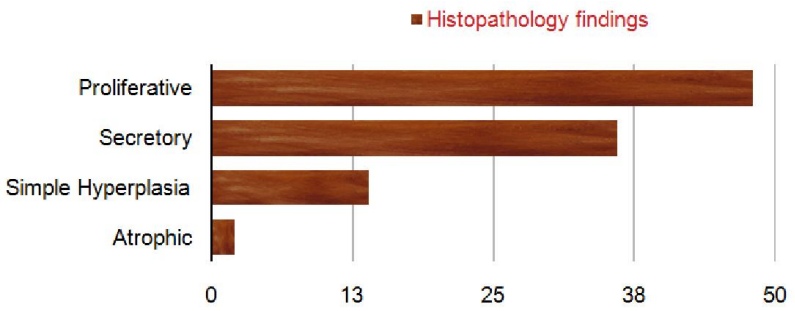
I. Demographic characteristics

Mean age (yrs.)	Parity	Duration of Menorrhagia (months)	Pre procedure Hb (mg/dL)	Post Procedure Hb (mg/dL)	Endometrial Thickness (mm)
44.2	2.46	10.2	9.662	10.462	8.826

II. Histopathology Findings

Proliferative (%)	Secretory (%)	Simple Hyperplasia (%)	Atrophic (%)
24 (48 %)	18 (36%)	7 (14%)	1 (2%)

III. Clinical Outcome = 46 (92%) Satisfaction



IV. Menstrual Outcome

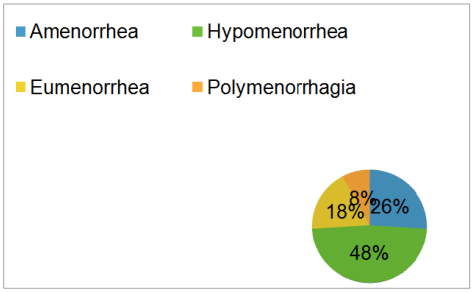
Amenorrhea	Hypomenorrhea	Eumenorrhea	Polymenorrhagia
13 (26%)	24 (48%)	9 (18%)	4(8%)

months after the procedure to detect the presence of endometrial scarring as a sign of successful endometrial ablation.

V. Hysteroscopic Follow up

RESULTS

In the study conducted by our department of OBGYN, Fifty patients were enrolled.



Scarred Endometrium	Unscarred Endometrium
15 (30%)	35 (70%)

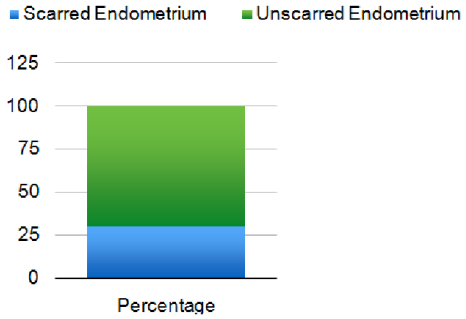


Table 1. Characteristics of the Studies

Author	Year of Publication	Country	Procedure	No. of Patients
Alakananda et al	2016	India	Thermachoice	35
Azza et al	2012	Egypt	Foley's catheter thermal ablation	48
Glasser et al	2004	USA	Hydrotherm ablation system	33
Goyal et al	2015	India	Uterine Balloon system	30
Kapur et al	2005	India	Thermachoice	50
Kopeica et al	2011	USA	Hydrothermal ablation	376
Patel et al	2012	India	Foley's catheter thermal ablation	50
Sood et al	2014	India	Thermachoice	24
Swarnima et al	2011	India	Uterine Balloon system	75

Table 2. Characteristics of the included studies with Outcomes

Author	Mean Age (yrs.)	Histopathology Findings	Clinical Outcome (Satisfaction Rate)	Menstrual Outcome	Pre procedure Endometrial Thickness (mm)
Alakananda et al	40	25.71% Pro 51.42% Sec 14.25% S. Hyp 5% Atr		21.2% Ame 37.5% Hypo 12.1% Eum	
Azza et al	46.16	52.83% Pro 8.30% Sec 27.09% S. Hyp 12.50% Atr	83.3% S	35.4% Ame 25.0% Hypo 18.8% Eum	7.34
Glasser et al	46.7		91.00% S	54% Ame 23% Hypo 14% Eum	
Goyal et al				39.28% Ame 10.7% Hypo 32.14% Eum	6-11
Kapur et al			94.00% S	14.00% Ame 80.00% Eum	
Kopeica et al	43		77.00% S	38% Ame 37% Hypo	
Patel et al	36-40	40% Pro 34% Sec 12% S.Hyp		14.58% Ame 14.58% Hypo 64.58% Eum	4-18
Sood et al	21-50	53.57% Pro 28.57% Sec 03.57% S.Hyp	90.67% S	20.83% Ame 37.50% Hypo 33.33% Eum	6-11
Swarnima et al				17.33% Ame 21.33% Hypo 03.22% Eum	5-8
Our Study	44.2	48% Pro 36% Sec 14% S . Hyp	92%	26% Ame 48%Hypo 18%Eum 8% polymen	8.826

Mean age of patients were 44.2 yrs which was comparable to study by (Kopeika, 2011). Based on the endometrial biopsy report, the distribution of patients on histopathology was similar to study by Patel *et al*. (2012). We had a 92% satisfaction rate with the procedure at 6 months, however various studies report a satisfaction rate of as high as 94% with lowest being 77%. Complete cessation of menses was reported in 26% patients and 18% patients had eumenorhea. 48% Patients had reported Hypomenorrhoea at 6 months post procedure. This was comparable to study by (Sood *et al*., 2016; Alakananda *et al*., 2014). Successful outcome was achieved at a mean endometrial thickness of 8.826 mm which was comparable to (Sood *et al*., 2015 and Goyal *et al*., 2014).

DISCUSSION

Second Generation techniques for Endometrial ablation have proved to be efficacious in several studies in the past. Development of a technique that utilises easily available resources which are not too costly can help a gynaecologist at the low resource setting to offer endometrial ablation as an alternative before hysterectomy. Hence obviating unnecessary Hysterectomy. In cases of abnormal uterine bleeding where the cause has been endometrium, ablating it with Hot saline causes amennorhea in nearly 50% females. This technique is a principle of various uterine balloon ablation systems. Histopathology examination of the endometrium obtained post ablation showed necrosis and acute inflammation due to thermal injury which would last for 3 months. Also subjecting a endometrium to temperature of 91 degree celsius would raise the serosal temperature to 34-35.9 degree celsius, and no visceral injury occurs at such temperature (Kishor, 2000; Mishra, 2003 and Anderson 2007). Greater depth of ablation can be achieved with temperature above 87 degree C. Systems used for thermoablation utilise a temperature of 87-93 degree C with depth of ablation ranging from 3.41-4.39 mm. Similarly Temperature employed by such devices have raised the endometrial surface temperature to 84.31-90.15 degree F, (Malcolm, 2005 and Ashraf, 2012). In our patients no endometrial preparation was given and they were subjected to the procedure on day 2-5 of menses. First generation techniques reported successful menstrual results in 61-90% cases (Overton, 1977 and O'Connor, 1996), whereas thermoablation had success rates of 80-97% (24) Our study had a 92% satisfaction rate and 30% scarred endometrium on hysteroscopies which was less than a study conducted by Ahonkallio *et al* who demonstrated a scarring of 75% (25) The disadvantage of this model for procedure is that the temperature can not be regulated. We calculated the rate of decrease in temperature of boiling normal saline at room temperature in silicon cathetar using Newton law of cooling (vlab.amrita.edu) which showed that the rate of temperature fall is directly proportional to the difference in temperature. So it was decided that 3 cycles each of 5 min will be done and hot saline will be replaced with new hot saline at 5 minutes interval. Another deficiency is the short follow up of 6 months with small number of patients. So a large series of patients with longer follow up is required. All said and done, this appears to be of some value in treating patients at low resource settings.

Conclusion

Foley's thermal balloon endometrial ablation is a safe, cost effective, simple and effective procedure for treatment of abnormal uterine bleeding in selected cases with good clinical and menstrual outcome.

REFERENCES

Ahonkallio, S., Martikainen, H. *et al*. 2008. Endometrial thermal balloon ablation has a beneficial long - term effect on menorrhagia; *Acta Obstet Gynaecol Scan,* 63:36-9

Alakananda, *et al*. 2016. Thermal balloon endometrial ablation in dysfunctional uterine bleeding. The New Indian Journal Of OBGYN, 2(2):115-8

Andersson, S., Mints, M. 2007. Thermal balloon ablation for the treatment of menorrhagia in an outpatient setting *Acta Obstet Gynecol,* 86, pp. 480–483

Ashraf, S. 2012. Heat Transfer Model for Menorrhagia (Doctoral dissertation, National Institute of Technology Rourkela).

Azza, A. Abd El Hameed. 2012. Endometrial thermal balloon ablation by a simple technique using Foley's catheter with or without pre ablation endometrial curettage to treat cases with intractable menorrhagia. *Middle East Fertility Society Journal,* 17, 116–121.

Feitoza, S.S. *et al*. 2003. Efficacy of thermal balloon ablation in patients with abnormal uterine bleeding. *Am J Obstet Gynecol*, 189:453-7.

Fraser, I.S. *et al*. 2011. The FIGO Recommendations on Terminologies and Definitions for Normal and Abnormal Uterine Bleeding. *Semin Reprod Med.,* 29(5): 383–390

Glasser, M.H. *et al*. 2003. The HydroThermAblator system for management of menorrhagia in women with sub mucous myxomas:12 to 20 month follow-up. *The Journal of the American Association of Gynecologic Laparoscopists.* Nov 30;10(4):521-7

Goyal Shweta *et al* , Sch . J. App. Med. Sci., August 2015;3(5B):1922-1925

Kapur, K. *et al*. 2007. Uterine balloon therapy:An alternative therapy for menorrhagia. *Medical Journal Armed Forces India.* Jan 31;63(1):36-9

Kishor, C., Singh, I., Sengupta, R., Agarwal, N., Misra, K. 2000. Thermal endometrial ablation: a simple technique. *Acta Obstet Gynecol Scand*, 79:54–9.

Kopeika, J. *et al*. 2011. Does hydrothermal ablation avoid hysterectomy? Long- term follow- up. *Am J Obstet Gynecol*, 204:207.e1-8.

Laberge, P. *et al.*, 2015. Endometrial Ablation in the Management of Abnormal Uterine Bleeding. *J Obstet Gynaecol Can,* 37(4):362–376

Lethaby, A., Cohepperd, S., Cooke, I., *et al*. 2000. Endometrial resection and ablation versus hysterectomy for heavy menstrual bleeding. *Cochran Database Syst Rev,* CD000392

Malcolm, G. M. 2005. Abnormal Uterine Bleeding; Cambridge University Press 978-0521-72183-7.

Maresh, J.M., Metcalfe, M.A., McPherson, K., Overton, C., Hall, V., Hargreaves, J., *et al*. 2002. The VALUE national hysterectomy study: description of the patients and their surgery. BJOG, 109:302–12.

Micheal j, O' Donova, J.B. 2005. Update on endometrial ablation. In Recent advances in Obstet and Gynecol, 23.

Mishra, K. *et al*. 2003. Cytomorphology and histomorphology after thermal endometrial ablation. Early changes. *Acta Cytol* 47(6): 1001-1007)

O'Connor, H. and Magos, A. 1996. Endometrial resection for the treatment of menorrhagia. *N Engl J Med,* 335:151-6

Overton, C., Hargreaves, J., Maresh, M. 1997. A national survey of the complications of endometrial destruction for menstrual disorders: the MISTLETOE study Minimally Invasive Surgical Techniques– Laser, Endo Thermal or Endoresection. *Br J Obstet Gynaecol,* 104:1351–539.

Patel Tejal, *et al*. 2012. Uterine thermal ablation by a simple technique using foley's catheter. *Gynaecol Perinatol* 21(1):8-13

Singer, A., Almanza, A., Gutierrez, A., Haber, G., Bolduc, L.R., Neuwirth, R. 1994. Preliminary clinical experience with a thermal balloon endometrial ablation method to treat menorrhagia. *Obstet Gynecol,* 83:732–4.

Sood, I.V. *et al*. 2014. Experience with uterine Balloon Therapy For Dysfunctional Uterine Bleeding.www. jkscience.org, 16(4).

Swarnima, A. *et al*. 2011. Uterine balloon therapy for treatment of menorrhagia. *J Obstet Gynaecol India.* 61(1):67-71

vlab.amrita.edu,. 2011. Newton's Law of Cooling. Retrieved 14 March 2016, from slab.amrita.edu/?sub=1&brch= 194&sim=354&cnt=6

****